The dementia research involvement study: Exploring and explaining the involvement of people living with dementia and family carers through patient and public involvement activities

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Abstract

Background. The last two decades have seen increased recognition of the centrality of patient and public involvement (PPI) in the conduct of relevant and impactful research. In the dementia field, evidence suggests that the lack of PPI opportunities is associated with methodological challenges for people living with dementia (PLWD) and family carers. As part of a broader programme designing a new model of care post-dementia diagnosis, this study aims to identify contexts and mechanisms promoting the involvement of PLWD and family carers in research through PPI activities. The ultimate purpose is to provide guidance on how best to involve PLWD and family carers, ensuring they contribute to shaping future research and care.

Methods. Drawing on realist methodological principles, the study consisted of an iterative research process characterised by three phases. Phase I entailed a case study including the collection of documents, observations, and fieldwork notes to formulate programme theories. Phase II focused on consulting relevant stakeholders to question the context-mechanism-outcome configurations underpinning those theories and refine them if appropriate. Phase III included the collection of fifteen interviews to test and further refine the programme theories.

Findings. Eleven programme theories resulted from the three-phase realist evaluation. These theories informed the development of a conceptual framework that explains how PPI operates theoretically and details core processes leading to good practice.

Conclusions. The involvement of PLWD and family carers in PPI activities is fundamental to advance dementia care research and practice. To that end, findings from this study provide theoretical and practical guidance for the design, implementation, and evaluation of PPI in dementia studies. While future research could build upon these findings through further testing and refinement processes, recommendations included in this thesis have potential application in other research fields where inclusive and sustainable involvement is a goal.

COVID-19 Impact statement

Although changes in study design are not uncommon, the restrictions and disruptions caused by the COVID-19 pandemic have resulted in some significant adjustments to the original proposal of the research discussed in this thesis.

Initially, the research design entailed an ethnographic study aiming to inform a realist synthesis by identifying the initial programme theories to test against secondary data. Focus groups and interviews would have contributed to the refinement and consolidation of programme theories. However, due to the COVID-19 pandemic outbreak and subsequent lockdowns, fieldwork and patient and public involvement (PPI) activities, until then observed and documented, were interrupted, and there was no clarity as to when, how and with whom they would have restarted.

When the first lockdown was announced in March 2020, the PhD programme was eighteen months in, and much progress had been made. Following discussions with the supervisory team and academic assessors responsible for the study's annual review, methodological adjustments were made in favour of a realist evaluation. Funders and research team members of the programme this study is embedded in were informed and given the opportunity to share any concerns.

A new ethics application detailing changes made to the study design was submitted to and approved by the Newcastle University Faculty of Medical Sciences Research Ethics Committee. Research participants of the study involved until then were notified about changes and kept informed about the research progress, whether they decided to continue being involved or not.

While the COVID-19 pandemic has affected the research process in different ways, the ultimate purpose of the study has remained aligned to its original proposal, contributing to the current PPI literature in dementia research with novel and transferable findings.

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List of abbreviations

3NDWG	3 Nations Dementia Working Group
ADI	Alzheimer’s Disease International
CMOc	Context-Mechanism-Outcome configuration
CPTs	Candidate Programme Theories
DCC	Dementia Care Community
DEEP	Dementia Engagement and Empowerment Project
DemRI	Dementia Research Involvement
DH	Department of Health
DHSC	Department of Health and Social Care
FMS	Faculty of Medical Sciences
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NU	Newcastle University
PE	Public Engagement
PhD	Doctor of Philosophy
PI	Public Involvement
PLWD	People Living With Dementia
PPI	Patient and Public Involvement
PriDem	Primary care-led post diagnostic Dementia care
PTs	Programme Theories
R&D	Research & Development
REC	Research Ethics Committee
SDWG	Scottish Dementia Working Group
UK	United Kingdom
VCSE	Voluntary Community and Social Enterprise
WHO	World Health Organisation
WSs	Workstreams

Preface

The starting point

The study discussed in this thesis is the result of a Doctor of Philosophy (PhD) programme at Newcastle University funded by the Alzheimer's Society as part of the PriDem[1] programme. The research study was advertised as a full-time PhD studentship aimed at exploring the collaboration between PriDem programme research team members and people living with dementia (PLWD) and their families for developing a primary care-led model of post-dementia diagnosis support through qualitative methods of research. With a background in nursing in dementia care and a passion for qualitative research, I decided to undertake this challenge. This was initially facilitated by the privileges that came with being included in the PriDem programme's research team which entailed: the early access to key documents informing about the design of, and expectations on, the involvement of PLWD and their family carers in the PriDem programme through patient and public involvement (PPI); and the ability to discuss research ideas with research team members, who acted as advisors and a sounding board to its focus and methods before taking part in this study.

The beginning of my PhD programme comprised an initial review of the literature discussing the origin and benefits of PPI, along with its evolution and gaps in dementia research to narrow down the focus of the study and develop clear research questions. This happened while surrounded by a research team who invested considerable resources to recruiting PLWD and their family carers in the community to invite them to join the PriDem programme. Within this context, I found myself asking the following questions: Why is the extent of PPI opportunities in dementia research minimal in comparison to other health research fields? Why there is not a shared understanding and practice of PPI? Why does the PriDem programme team prioritise PPI? Why is the PriDem programme team's approach to PPI different, if at all? These initial queries informed the conduct of this study.

The conduct of this study

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[1] Acronym for 'Primary care-led post diagnostic Dementia care'

Before embarking on my PhD programme, I had no experience or formal training in realist methodology; initial exposure was gained from attending a three-day workshop whilst developing the research protocol for this study. Following this early training, and deepening of my understanding of the realist methodology initiated by Pawson and Tilley (1997), three reasons prompted me to pursue it, thus influencing the development of my research questions and the subsequent design of my study. Firstly, one of the foundations of realist methodology is the generation and testing of theories to understand why a programme does or does not work and how it can be made to work more effectively. The opportunity to ensure conceptual clarity and obtain theoretical guidance to address the issues of PPI in dementia studies in a field of practice often lacking both was appealing. Secondly, realist research is usually encouraged when there is a need to evaluate an innovative initiative, or an initiative implemented in different settings. Both these aspects resonated with the PPI context within the scope of this study. Indeed, the PriDem programme team's PPI strategy appeared innovative for several reasons: the involvement of PLWD and family carers in PPI activities alongside dementia care providers; the presence of an involvement coordinator responsible for initiating the relationship between researchers and PLWD and family carers and maintaining it throughout the PriDem programme; and the decision to hold PPI activities in different settings, given the involvement of PLWD and family carers included in local pre-established support groups. Thirdly, realist methodology recognises the uniqueness of individual differences and reasoning, considering it a crucial aspect of any programme's success. The possibility of explaining how the resources offered by a certain PPI strategy led to the outcomes of interest by deepening into the experiences of all involved was attractive to me.

The structure of this thesis

This thesis provides a series of chapters documenting the process of theorising about PPI in dementia research. Chapter 1 defines the broader context underpinning this study, documenting the current scenario of dementia care, the policy response to the extent of its impact, and the challenges experienced by PLWD and their family carers. It then discusses the theoretical models informing the different, and at times contrasting, understandings of dementia, reporting the implications for the research involvement practice. Finally, it outlines the knowledge gap of interest, indicating the research questions, aims and objectives of this study.

Chapter 2 places its emphasis on the concept of PPI in health research. The chapter begins by exploring the benefits of PPI, along with the most common methods of involvement at different steps of the research cycle and the current gaps in the field of PPI practice. It then informs about the key learnings obtained from a review of the literature on the nature of PPI, documenting the evolution of its understanding conceptually and theoretically. Finally, it explains how all this information was relevant to the design and conduct of a research study focusing on PPI in the context of dementia research.

Chapter 3 details the methodology and methods employed, clarifying differences in context, purpose and process among the three phases characterising the conduct of this study. The chapter also discusses the involvement of public members in the research process, reporting an evaluation of my PPI practice. Finally, it explains how the funders (i.e., Alzheimer’s Society) and host organisation (i.e., Newcastle University) contributed to the research progress.

Chapters 4, 5, and 6 report the overall findings of this study. Chapter 4 describes the architecture of the PPI strategy under the scope, which was obtained from the primary analysis of the data collected during Phase I. Chapter 5 reports the theories developed as a result of an iterative process of analysis that progressively informed the formulation of eleven theoretical statements. Finally, Chapter 6 illustrates and narratively describes the conceptual framework encompassing these statements.

Chapter 7 concludes this thesis. The chapter begins by revisiting the aims and objectives of this study, summarising its key findings and discussing them in relation to existing literature to reflect on their innovative account and value. It then reports the validity of this study and reveals the most significant challenges I experienced during its conduct. Finally, it provides the strengths and limitations of this study, along with recommendations for future research.

Chapter 1. Introduction

1.1 Overview of the chapter

Chapter 1 includes relevant information about the context within which the dementia research involvement (DemRI) study is embedded. The chapter begins by examining the nature of dementia, the policy response to the extent of its impact and the challenges experienced by people living with dementia (PLWD) and their family carers. Next, it explores the evolution of the theoretical models informing the different, and at times contrasting, perspectives about dementia, reporting key concepts that have informed dementia care practice and research as well as the social perception of PLWD. Then, it discusses the implications of these models for research practice, with particular attention to the trends influencing the development of new knowledge in the dementia field. Finally, it introduces the research questions, aims and objectives of this study.

1.2 Dementia

1.2.1 What is dementia?

Dementia is a broad term that indicates a set of associated symptoms caused by diseases and injuries that affect the brain and result in progressive cognitive decline (World Health Organisation [WHO], 2020). Whilst its prevalence is most common as people grow older, dementia is not a part of normative cognitive ageing, and it includes problems associated with committing ideas and thoughts to memory, thinking, understanding, using language, exhibiting behaviours and emotions, engaging in relationships, and undertaking day-to-day activities (National Health Service [NHS], 2020). Although these problems are common among PLWD, certain signs and symptoms may be more specific to the type of dementia diagnosed or its stage of progression – early, medium, or advanced (NHS, 2020). There are over 200 subtypes of dementia; the most common is Alzheimer’s disease, which accounts for between 50-75% of all cases. Other types of dementia include vascular dementia (20%), Lewy body dementia (10-15%) and frontotemporal dementia (2%) (Alzheimer’s Society, 2020a). Sometimes, different types of dementia occur together – usually, Alzheimer’s disease and vascular dementia – determining a mixed dementia diagnosis (NHS, 2020).

1.2.2 Prevalence and costs

Dementia is the leading cause of disability amongst older people and constitutes one of the most significant challenges faced by health and social care services (WHO, 2017). Around 50 million people worldwide live with dementia, and this number is expected to triple by 2050 (WHO, 2020). In 2015, the global societal costs of dementia, including formal and informal care, were estimated to be approximately $818 billion, with the risk of reaching two trillion dollars by 2030 (Alzheimer's Disease International [ADI], 2015). In the United Kingdom (UK), around 885,000 people live with dementia, and the amount is predicted to reach 1.6 million by 2040 if public health interventions and changes are only driven by an ageing population (Wittenberg et al., 2019). Considering all four UK countries, in 2019, the costs associated with dementia amounted to £29.5 billion[2], including the funds invested in policing, advocacy and research (1%) and the support provided by health care professionals (14%), social care professionals (45%) and unpaid carers (40%) (Wittenberg et al., 2019). According to these estimates, PLWD are cared for by a combination of health and social care professionals, with a substantial amount of support provided by the unpaid carers; this is also seen internationally (ADI and Karolinska Institutet, 2018). Adding to the direct costs associated with dementia, the money spent to address the health care needs that PLWD aged over 65 years may have, brings the total amount to around £34.7 billion of UK costs (Wittenberg et al., 2019)

1.2.3 Government policies

Dementia was declared a public health priority a decade ago due to global concerns associated with dementia and its impact on PLWD and their family carers, as well as society and the economy (WHO, 2012). Since then, this argument has been reinforced by the documentation of rising trends (ADI, 2015) and the discovery of twelve modifiable risk factors[3] that could prevent or delay dementia (Livingston et al., 2017; Livingston et al., 2020), encouraging major reflections on how to tackle what the WHO (2020) has recently defined the twenty-first century's most serious public health challenge. As a result, organisations such as the WHO and ADI have joined forces to provide policymakers and

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[2] 2015 rate costs.

[3] Less education, hypertension, hearing impairment, smoking, obesity, depression, physical inactivity, diabetes, infrequent social contact, excessive alcohol consumption, head injury and air pollution.

partners with guidance on how to address various challenges – from raising awareness and promoting dementia-friendly campaigns to investing in risk reduction, early diagnosis, better care and support and research innovation (WHO, 2017). Guidelines to support and assess national strategies' development, implementation and progress have also been continuously updated, with the WHO (2018) asking countries to monitor and share information on an international surveillance platform named the Global Dementia Observatory. The WHO's (2017) current vision is to create *'a world in which dementia is prevented and people with dementia and their carers live well and receive the care and support they need to fulfil their potential with dignity, respect autonomy and equality'* (p.6). However, the slow progress documented in several countries, coupled with the disruptions caused by the COVID-19 pandemic globally, appears to be on the way to making this vision reality soon (ADI, 2021).

The UK is amongst 34 countries that have committed to the WHO 's 2017 Global Action Plan on dementia (ADI, 2021). Nationally, the government's specific dementia policy started in 2009 with England's first dementia strategy: *Living well with dementia* (Department of Health [DH], 2009). This strategy targeted the following key actions: raising awareness of dementia, removing the stigma surrounding the condition, improving diagnosis rates, and increasing the range of services provided to PLWD (DH, 2009). In 2012, a report published by the Alzheimer's Society suggested that PLWD and their family carers were not experiencing the required level of care and support. They were also affected by struggles extended to their social life caused by the lack of understanding of dementia among communities (Lackey et al., 2012). That same year, Prime Minister David Cameron launched a new national strategy – *Dementia 2012: a national challenge* (DH, 2012a) – aiming to deliver change in three key areas: awareness of dementia, quality of care, and dementia research. Key recommendations for positive change included: creating dementia-friendly communities that understand how to help, driving improvements in health and care, and increasing research funding to promote better and more dementia research (DH, 2012a). In 2015, the UK Government confirmed its commitment to support the population affected by dementia by launching the *Challenge on Dementia 2020,* which strove to make England a worldwide leader in the fight against dementia (DH, 2015). An implementation plan was also developed to address actions in four areas: risk reduction, health and care, awareness and social action, and dementia research (DH, 2016). According to the phase 1 review of the implementation plan, in 2019, the UK appeared to be on the way to achieve the 2020 targets (Department of

Health and Social Care [DHSC], 2019). However, circumstances may have changed due to the disruptions caused by the COVID-19 pandemic (Alzheimer's Society, 2020b).

1.2.4 Research funding and priorities

In the last decade, an unprecedented global response to the challenges posed by dementia has been documented. World leaders participating at the 2013 G8 Dementia Summit launched the Global Action Against Dementia initiative to address current and future challenges together (DHSC, 2014a), following the WHO's (2012) call for dementia to be treated as a public health priority. Identifying dementia research priorities was one of the topics about which the summit debated; attending countries committed to make a coordinated effort to find a cure or a disease-modifying treatment by 2025 (DHSC, 2014a). After undertaking this commitment, the UK Government allocated a significant amount of funds to dementia research (DHSC, 2014b), documenting an increase in funding equal to 93.1% between 2011 and 2016 (Pickett and Barayne, 2019). However, most UK Government funds have been invested in basic and medical biosciences research studies, leaving only 5% to research on dementia care (Pickett and Barayne, 2019). Considering the complexities of dementia care and the need for better post-diagnostic care both nationally (Alzheimer's Society, 2021) and internationally (Alzheimer Europe, 2020), there has been a call for greater focus on care-related research. Increased concerns have also been raised following the COVID-19 pandemic and its potential impact on future decisions about the research agenda of different countries (ADI, 2020; Alzheimer's Society, 2020b).

The impact of the COVID-19 pandemic in the UK has also been documented in relation to dementia care research. After the announcement of the first lockdown in March 2020, numerous dementia care studies funded by the National Institute for Health and Care Research (NIHR) were paused, with many clinical researchers being asked to increase their NHS clinical commitments (Kulakiewicz et al., 2020). Although the NIHR (2020a) published a roadmap to address the restart of research activities later that year, the consequences of this pause are expected to increase the burden on the dementia care sector, whose crisis has affected PLWD and their families for a long time now (Alzheimer's Society, 2020b). Recently, the All-Party Parliamentary Group on Dementia[4] and the Alzheimer's Society have partnered to conduct an inquiry about the government's spending on dementia care research. Indeed, considering the lack of commitment to increase significantly the funds invested in this field of research – the so-called *Dementia Moonshot*[5] – this inquiry aims to compare the research targets of the UK with other countries to understand differences and quantify the extent of the impact of the COVID-19 pandemic on dementia research (Alzheimer's Society, 2021).

1.3 Dementia support

1.3.1 Diagnosis

As dementia is progressive, and to date incurable, living with this condition, or caring for a family member affected by it, is a unique experience characterised by personal, ever-changing needs. In low- and middle-income countries, it is estimated that 10% of PLWD receive a formal diagnosis (ADI, 2017). In contrast, in high-income countries, about half of the population affected by dementia receives it (ADI, 2017). Several benefits are associated with obtaining a formal diagnosis of dementia. Firstly, it allows PLWD, and their family carers, to access relevant information, evidence-based therapies and local care and support services (ADI, 2018). Additionally, it gives them an opportunity to participate in research on future treatments, care practices and support services (WHO, 2017) while also helping promote awareness and overcome stigma by making dementia visible (ADI, 2017). Consequently, across the last few years, the scope of the global dementia campaign has included raising awareness about the early signs and symptoms of dementia to improve the diagnostic rates worldwide (WHO, 2017). In 2017, the WHO's (2017) Global Action Plan encouraged countries to adhere to the plan to reach a diagnostic rate target of 50% by 2025. However, the data currently available on the Global Dementia Observatory knowledge exchange platform[6] suggests that it may be challenging to reach such a target, especially after the disruptions caused by the COVID-19 pandemic (ADI, 2021).

In the UK, diagnosis rates have improved over the years, with a national commitment for 66.7% of the estimated PLWD to receive a formal diagnosis (Parkin and Baker, 2021).

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[4] https://www.alzheimers.org.uk/about-us/policy-and-influencing/all-party-parliamentary-group-dementia

[5] https://assets-global.website-files.com/5da42e2cae7ebd3f8bde353c/5dda924905da587992a064ba_Conservative%202019%20Manifesto.pdf

[6] https://www.who.int/data/gho/data/indicators/indicator-details/GHO/availability-of-dementia-diagnostic-rate

Unfortunately, a significant decline in diagnosis, from 67.6% in February 2020 to 61.6% in January 2022, has been documented since the start of the pandemic (NHS Digital, 2022), reflecting the cessation of diagnostic services like memory clinics during the COVID-19 pandemic. Such change raises concerns about the current situation of people who have not been diagnosed yet and their families (Alzheimer's Society, 2020b). It can be difficult to diagnose dementia, as no single test provides an immediate answer, and some of the symptoms may resonate with other neurological conditions common in older age (Robinson, Tang and Taylor, 2015). Although considered a fearful and distressing moment (Alzheimer's Society, 2017), receiving a formal diagnosis entails different benefits for PLWD and family carers living in the UK. For instance, it allows people to decide on current and future care possibilities, provides access to research and pharmacological and non-pharmacological interventions, and gives the opportunity to receive emotional, practical, financial and legal advice when or if needed (NHS, 2020). Recently, evidence has revealed unequal access to diagnostic services and long waiting times for diagnostic assessments, with variations affective Black, Asian and minority ethnic communities the most (DH, 2015). According to more recent data, the disruptions caused by the COVID-19 have worsened the situation, with serious concerns about the shift towards remote ways of assessment, whose validity and suitability is still unknown (Alzheimer's Society, 2020c).

1.3.2 Post-diagnostic support

Currently, no treatment is available to cure dementia or slow its progressive nature. The key recommendations for PLWD include providing continuous and holistic post-diagnostic support, managing neuropsychiatric symptoms, and developing effective interventions to respond to the needs of their family carers (Livingston et al., 2020). All care services, starting from diagnosis until end of life, comprise post-diagnostic support (ADI, 2016). Ideally, such support should be holistic, continuous and integrated between providers, levels of care and health and social care systems (ADI, 2016). However, in practice, it is fragmented, uncoordinated and unresponsive to the needs of PLWD and their family carers, with inequalities concerning the level or quality of care across countries or within the same country (ADI, 2016). Several factors contribute to the issue, such as social and health inequalities and inequities, lack of awareness about dementia or services available, absence of continuity of care, language barriers and stigma (Giebel, 2020). In the UK, around half of the people affected by dementia feel they get insufficient support or face difficulties accessing care services after receiving a diagnosis (Alzheimer's Society, 2015). Additionally, as those services are provided by various sectors (i.e., primary and secondary health care, social care and voluntary organisations) and different professional figures, the support received is shaped by different structures, priorities, funds and capacity (Piercy et al., 2018). As a result, the post-diagnostic support system in the UK presents variable service provision among different localities (Alzheimer's Society, 2020c; Frost et al., 2020; Wheatley et al., 2021), with increased concerns now that local authorities' duties have been reduced under the *Coronavirus Act 2020*.

In 2018, the National Institute for Health and Care Excellence (NICE, 2018) published national guidelines for assessing and managing dementia, following which a new version of standards for high-quality care was developed for commissioners and providers (NICE, 2019). These guidelines, along with the Prime Minister's *Challenge on Dementia 2020* (DH, 2015) and the DHSC's (2016) *Joint declaration on post-diagnostic dementia care and support,* established the benchmark that defined the care and support required to improve or maintain the quality of life of PLWD and their family carers. However, despite the progress documented, inconsistencies in accessibility, provision and evaluations of post-diagnostic services confirm even wider geographical inequalities in care nationally and thus the need to standardise a national core dementia care pathway (Frost et al., 2020; NICE, 2020). Additionally, recent data on post-diagnostic support has revealed how the disjointed nature of services and the lack of coordination and leadership on dementia have worsened the pandemic's impact on PLWD and their families (Alzheimer's Society, 2020c; Wheatley et al., 2022). In the context of a change towards a more comprehensive, personalised care (NHS England, 2019), there has been an increased interest in facilitating the integration amongst post-diagnostic services (NHS England, 2020a; 2020b). However, several barriers might prevent the successful integration of services and the development of a new model of care, including different conceptual understandings of dementia amongst the parties involved in providing post-diagnostic support (Wheatley et al., 2020).

1.4 Conceptual understandings of dementia

1.4.1 How do we know what we know?

The nature of dementia and the extent of its challenges has attracted the interest of different disciplines and professions across time, thus broadening the understanding of dementia and public awareness of this condition. However, since the discovery of Alzheimer's disease – approximately one hundred years ago – different theoretical models have contributed to the development of new knowledge in the dementia field, with implications for changes in policy and professional approaches to care (Innes and Manthorpe, 2012). This, in turn, has had ramifications not only in terms of the experience of PLWD or their carers but also with respect to public members' perception of dementia and their attitude towards those living with it (Manthorpe and Iliffe, 2016). By exploring the origins, assumptions and implications of the various theoretical models of dementia, it is possible to recognise the social context of dementia and identify the different perceptions that research team members, care professionals, family carers and PLWD may hold on to dementia (Innes, 2009). In the next sections, I will review these models (see section 1.4.2) and explore more in detail their implications for research practice (see section 1.4.3).

1.4.2 Explanatory models of dementia

The biomedical model of disease has historically dominated the conceptualisation of dementia (Downs, 1997), which was initially largely accepted as a progressive mental disorder caused by damage to the brain that occurs as a part of normal ageing (Holstein, 1997). However, the discovery of Alzheimer's disease marked a turning point whereby dementia ceased being defined as part of the normal ageing process, and scientists began to investigate this condition (Holstein, 2000). In 1907, the focus on pathological and psychological signs of brain disorder was crucial for Alois Alzheimer's description of a middle-aged woman who presented symptoms of senile dementia and signs of presenile dementia (Holstein, 1997). Three years later, a neuropathologist, Emil Kraepelin, coined the term 'Alzheimer's disease' to refer to the form of middle-age-onset dementia first discussed by Alzheimer. Since then, the patient's age became a way to differentiate between Alzheimer's disease and senile dementia, with the latter still considered as an inevitable part of ageing (Holstein, 2000), with little to negligible expectation regarding the treatments, type of care or specialist skills required by PLWD (Downs, Clare and Mackenzie, 2005). As more symptoms became known, the term 'disease' was replaced with 'syndrome' (Gubrium, 1986), and the classification of dementia in progressive stages started being used in diagnosis, prognosis and intervention development (Crisp et al., 2000). In the late 1970s, research studies reporting clinical and pathological commonalities between presenile and senile dementia (Holstein, 2000), together with the advancement in diagnostic practices (Katzman, 2004), encouraged a clear distinction between Alzheimer's disease and age-related changes in cognitive functioning. Subsequently, Alzheimer's disease was renamed 'Dementia of the Alzheimer Type' and was defined as a distinction from the normal ageing process, even though age was still considered a risk factor (Holstein, 2000).

As age was removed from being a criterion for diagnosis of Alzheimer's disease, a significant increase in the number of older people with this condition was documented in the United States of America (Ballenger, 2006). This moment provided the opportunity for the development of social movements campaigning for the allocation of health and social services to PLWD and their family carers and the increase in research funding to find a cure (Fox, 1989). However, while funds were invested in studies looking for a cure, little attention was given to the care of PLWD and their families. Reasons were attributed to the negative sociocultural perceptions of the older age population (Fox, 2000), which were developed around old age myths (Innes, 2009). Common assumptions shared by those myths included the perception of older people as a 'burden' because of the increased dependency, which significantly impacted society and the economy (Innes, 2009). According to Estes and Binney (1989), the biomedical model of dementia fostered the development of such perception, defining ageing as an inevitable and irreversible health decline process that requires medical interventions (Kaufman, Shim and Russ, 2004). The consequences of old age myths projected onto dementia led people diagnosed with this condition to experience fear of ageing, disease and death (Harding and Palfrey, 1997), along with marginalisation and social exclusion (Innes, 2009).

Notwithstanding the value of the biomedical model, the resulting medicalisation of dementia culminated in some unintended, negative consequences for PLWD (Holstein, 1997). According to Lyman (1989), this model was used to explain behaviour difficult to comprehend and to legitimise medical authorities' control over PLWD through physical and chemical restraints. Bond (1992) added three other negative consequences of this theoretical perspective, namely social control, individualisation of behaviour and depoliticisation of behaviour. Social control is enacted through the label given to the person after diagnosis, which results in the institution of boundaries to contain the progress of dementia within the person. Individualisation of behaviour consists of the sole association of the person's behaviour with the condition, ignoring the possibility of finding explanations in the social context. Depoliticisation of behaviour generally occurs as the person's perspective on their behaviour is neglected in favour of its medical explanation (Bond, 1992). Dillman (2000) also argued that the medical commitment to using symptoms to classify PLWD was underpinned by the assumption of homogeneity amongst them all, when, according to him, heterogeneity is the rule. Background characteristics such as class, race, ethnicity and gender and their impact on the experience of dementia were not relevant within a framework that considers neuropsychiatric treatments to be the only form of care (Hulko, 2004).

With its sole focus on the biological and pathological aspects of dementia, the biomedical model considers PLWD as passive subjects – or patients – who are affected by a condition they cannot control. Hence, labels such as 'victims' or 'sufferers' were used to refer to them (Downs, Clare and Mackenzie, 2005). Aquilina and Hughes (2005) discussed the terrifying public perception of PLWD using the analogy of 'zombies', as they were perceived to be in a limbo status between life and dead, where the sensations of the body may not have been completely lost, but the sense of self would be lost eventually, thus making them the 'living dead'. Cohen and Eisdorfer (1986) described the disembodiment and disfranchisement experienced by PLWD to be worse than that experienced by the empowered and politicised mental health patients. Indeed, unlike them, they did not reflect the notion of *'proactive, rational consumer of services'* (Smith et al., 2012, p.1466). As a result, the diagnosis was not always disclosed, as it was feared that it would cause distress to the person and their family members, who were perceived on the way to face the inevitable 'burdens' of care (Downs, Clare and Mackenzie, 2005). However, ignoring the diagnosis may have further fostered stigmatisation (Innes, 2009), as recognised in the attitudes of care professionals who communicated with PLWD and labelled patients as 'demented' (Golander and Raz, 1996). At this point, the care of a person living with dementia was mainly the responsibility of geriatric and neuropsychiatric specialists accountable for diagnosis, prescription of cognitive enhancers and management of behavioural symptoms (Downs, Clare and Mackenzie, 2005).

The biomedical perspective of dementia remained dominant for a long time, driving empirical research and theorisation about dementia (Downs, 1997) and limiting the focus of inquiry to the biological or pathological aspects of this condition (Cotrell and Schultz, 1993). However, a critical response to this model came in the mid-1970s with the case made for a biopsychosocial model of health by the psychiatrist George Engel, who argued that health was better viewed through interconnected systems including biological, psychological and sociological components and that 'disruptive effects of (psychiatric) illness' resulted from their interplay (Engel, 1977). A key contributor to the advancement of this perspective in the dementia field was the social psychologist Thomas Kitwood (1990), who defined dementia as a dynamic, dialectical process involving the neurological, psychological and social dimensions of this condition. After criticising the biomedical model for the limits of neuropathological research, the medicalisation of dementia, and the imprecisions of diagnostic results, Kitwood argued the need to change the focus of inquiry from the ill-being of PLWD to their well-being, thereby proposing a reconsideration of dementia within a more personal framework (George and Whitehouse, 2010). According to Kitwood (1993), dementia was best perceived as a process characterised by individual, personal and social aspects, thus making its course unique to the people affected by dementia and their context. As a result, he promoted a shift of focus from dementia to the person living with dementia (Bruens, 2013).

After discussing his ideas in different articles, Kitwood (1997) collated them in a book – *Dementia Reconsidered: The Person Comes First* – which discusses his perspective on dementia and dementia care. A central concept of his theory is personhood, which he defined as *'a standing or status that is bestowed upon one human being by others in the context of relationship and social being; it implies recognition, respect and trust'* (Kitwood, 1997, p. 8). Kitwood (1997) argued that even though the self of a person with dementia can change over time, it persists. Thus, PLWD can experience relative ill-being and well-being, with both statuses being dependent upon the cognitive decline caused by dementia, the interactions in which PLWD engage and their contextual circumstances (Kitwood, 1997). A central assumption of his explanatory model of dementia – *Enriched Model* – is that behaviour has meaning because it is affected by the environment as much as it is by the brain. Therefore, ill-being cannot be merely reduced to a sign of random occurrence (Kitwood, 1997). This premise contributed to the development of a person-centred approach to dementia care, which emphasises the importance of acknowledging the person's life history and experience of dementia to know more about the condition and the care needed (Brooker, 2007).

Kitwood (1997) claimed that PLWD primarily lose personhood due to the actions of others rather than their own cognitive decline – a concept he termed as ‘malignant social psychology’. Examples of malignant social psychology include 17 types of interactions, namely ‘*treachery, disempowerment, infantilization, intimidation, labelling, stigmatization, outpacing, invalidation, banishment, objectification, ignoring, imposition, withholding, accusation, disruption, mockery, and disparagement’* (Kitwood, 1997, pp.46-47). Even if unintended or culturally inherited, these interactions are responsible for people’s negative experience of unwarranted and avoidable disability, which Sabat (2001) named ‘excess disability’ as not caused by dementia itself. By bringing together ideas about ways of working with PLWD, Kitwood (1997) provided carers with the ‘positive person work framework’ to improve the well-being of people diagnosed with this condition. This framework includes 12 ways to maintain personhood that are *‘recognition, negotiation, collaboration, play, timalation, celebration, realization, validation, holding, facilitation, creating, giving’* (Kitwood, 1997, pp.119-120). According to Kitwood (1997), malignant social psychology is present and often condoned at the level of organisational structures. Therefore, he believed that promoting a shift from an ill-centred to a person-centred approach for PLWD within organisations and in the culture of care was crucial for sociocultural change (Kitwood, 1997).

Compared to the deterministic vision of the biomedical model, Kitwood offers a socially constructed understanding of dementia, in which the condition is shaped by PLWD’s inner self and their interaction with the environment (Baldwin and Capstick, 2007). When adopting this perspective, people’s behaviour is not perceived as ‘challenging’ anymore but rather an attempt to communicate physical or psychological needs or personal will (Kitwood, 1997). The reason can be traced back to Kitwood’s belief in the dialectical process underpinning dementia, which accounts for a weak correlation between symptoms and pathology and attributes the manifestation of dementia to interactions between several other factors (e.g., life history, personality, agency, past experiences and social context) (Downs, Clare and Mackenzie, 2005). Following this line of reasoning, PLWD have unique expertise, which is warranted by care professionals, service providers and researchers to provide appropriate and effective care (Cotrell and Schulz, 1993). Additionally, family carers are encouraged not to perceive and treat their loved ones as ‘zombies’, as the loss of self is not contemplated (Aquilina and Hughes, 2005). Furthermore, family carers are not perceived as overwhelmed by their caring responsibilities but as individuals requiring adequate information and support to negotiate an ever-changing relationship that has the potential to be fulfilling (Downs, Clare and Mackenzie, 2005). Thus, a person-centred approach to care focuses on maintaining and enhancing the quality of life for PLWD and their loved ones. As a result, implications for care management include three key domains: support for active coping, promotion of rehabilitation and facilitation of enriched environments (Downs, Clare and Mackenzie, 2005).

Despite being recognised as ground-breaking at the time (Bruens, 2013), Kitwood’s *Enriched Model* has been, just like the biomedical model, critiqued by those who considered his work incomplete for several reasons. These reasons include the absence of recommendations for identifying care needs and resources required to meet them due to theoretical development lacking empirical support and tested methodologies (Baldwin and Capstick, 2007). Moreover, the neglect of sociocultural and sociopolitical factors influencing people’s perception of dementia, which suggests the adoption of an essentialist and individualist approach to personhood (Bartlett and O’Connor, 2007; Nolan et al., 2002). Furthermore, the inconsistency arising from valuing caring relations that promote personhood and person-centred care but ignoring the relational aspect characterising these relations, whether they are dyadic (i.e., PLWD-family carers) or triadic (i.e., PLWD-family carers-professionals) in nature (Nolan et al., 2002). Finally, the discussion of personhood mainly in relation to others, which seems to attribute a passive role to PLWD, thereby neglecting their agency (Bartlett and O’Connor, 2007; Nolan et al., 2002).

Building on Kitwood’s theory, and aiming to empower PLWD, Bartlett and O’Connor (2010) developed the social citizenship model, arguing in favour of the importance of adding a political dimension to personhood. For a very long time, PLWD were denied their citizenship status because considered lacking rational capacity (Graham, 2004) and unable to make a valuable public contribution (Minkler and Holstein, 2008). To broaden the scope of citizenship and encourage the involvement of PLWD in society, Bartlett and O’Connor (2010) drew on the notions of ‘social practice’ (Prior, Stewart and Walsh, 1995) and ‘everyday talk and actions’ (Barnes, Auburn and Lea, 2004). As such, the relation of PLWD and society, communities or the state should be intended as co-constructed through usual practices taking place every day around them. In making social practice relevant to the dementia context, Bartlett and O'Connor (2010) coined the term 'social citizenship', defining it as *'a relationship, practice or status, in which a person with dementia is entitled to experience freedom from discrimination, and to have opportunities to grow and participate in life to the fullest extent possible. It involves justice, recognition of social positions and the upholding of personhood, rights and a fluid degree of responsibility for shaping events at a personal and societal level'* (p.37).

By adopting citizenships lenses, the focus shifted towards redressing the social and structural challenges experienced by PLWD, which highlighted the *'extremely stigmatizing and discriminatory'* (Kitwood, 1997, p.98) attitudes of society still present ten years after Kitwood's claim that stigmatisation was fading. Consequently, PLWD were perceived as gradually losing their citizenship status and agency, in addition to their sense of self (Boyle, 2008). Drawing on a wide range of theories and disciplines – critical gerontology, disability studies, feminist theories, and critical psychiatry – Bartlett and O'Connor (2010) extended the traditional notion of citizenship to the degree to which rights are recognised and upheld for PLWD through care practices, policies and institutions (Bruens, 2013). More recently, the social citizenship model of dementia has expanded to incorporate the concept of 'everyday citizenship' (Nedlund, Bartlett and Clarke, 2019). Within this model, the person with dementia, alias citizen, is believed to interact with others in an ever-changing context, including actors such as family members, friends, neighbours, social workers and strangers. Therefore, the idea of promoting citizenship is intended to be executed as a continuous and dynamic practice (Nedlund and Bartlett, 2017). Applying the everyday citizenship perspective means shifting the focus to ordinary aspects of the lives of PLWD to gain a greater understanding of their ability to participate in daily activities and the extent to which the environment and any adaptations are required as their dementia progresses (Neal and Murji, 2015).

The implications of a social model of citizenship for practice are mainly related to the advancement of a relationship-centred approach to care, which recognises the importance of the active participation of PLWD in decisions about their care (Nolan et al., 2002). A relationship-centred model of care then proposed to redress the focus on PLWD as social agents who are embedded in a context that includes those who provide care and support either formally or informally (Adams and Gardiner, 2005). However, Kontos, Miller and Kontos (2017) argued that this new model of care was mainly used to conceptualise the person with dementia in a ‘in-need-of-care’ context, thereby focusing on care-centred relationships and neglecting the social context discussed by Bartlett and O’Connor (2010). By drawing on the social model of citizenship and insights of a new theoretical subfield of critical gerontology named embodied selfhood (Kontos and Martin, 2013), Kontos, Miller and Kontos (2017) developed the concept of ‘relational citizenship’, according to which agency can be expressed through the body in daily habits, actions, or gestures. As such, the citizenship status, and related implications, are extended to people with an advanced stage of dementia or living in long-term care settings (Kontos, Miller and Kontos, 2017).

Recently, a new model of dementia is taking shape by building on the current trends guiding dementia-related policies and some of the limitations of the social citizenship model. In a critique of the views of Bartlett and O’Connor (2010) on dementia, Cahill (2020a) argued that the richness of the subjective experience of dementia and the understanding of the relation between the inner self and society would be lost by focusing solely on sociopolitical factors affecting PLWD. Additionally, supporting the case made by Kontos, Miller and Kontos (2017), Cahill (2020a) believed that Bartlett and O’Connor’s (2010) interpretation of citizenship excluded the possibility of including people at an advanced stage of dementia. Finally, a model of dementia only rooted in the right of equality and participation in public life would neglect other types of rights that respond to the social, economic and cultural needs of PLWD (Cahill, 2018). Against this backdrop, following reflection on the WHO’s (2017) Global Action Plan principles[7] oriented on human rights (Cahill, 2020b), Cahill (2020a) proposes a human rights model of dementia. According to Cahill (2020a), who drew on Degener’s (2014) work on the social model of disability, adopting a human rights lens implies a more comprehensive perception of PLWD’s needs, thereby providing clearer guidance on how to address political and social changes. Additionally, it helps to overcome the limitations of the social citizenship model, considering a broad spectrum of rights rather than limiting them to the civil and political kind. Moreover, it emphasises the need for policies that encourage the development and support of prevention programmes without necessarily

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[7] *‘(a)Human rights of people with dementia, (b)empowerment and engagement of people with dementia and their carers, (c)evidence-based practice for dementia risk reduction and care, (d)multisectoral collaboration on the public health response to dementia, (e)universal health and social care coverage for dementia, (f)equity, (g)appropriate attention to dementia prevention, cure and care’* (WHO, 2017, p.5).

considering the matter discriminatory. Finally, at the care practice level, it entails recognising several rights (e.g., timely diagnosis, equitable and accessible post-diagnostic support and increased inclusion in care decisions) and considering the assessment of mental capacity as a decision-specific rather than a one-time assessment (Cahill, 2020a).

In the last few years, an increased number of international policies have considered dementia a human rights issue (WHO, 2017; ADI, 2018). Many have already explored the possibility of learning from innovations in disability studies and the assumptions of the social model of disability to advance dementia care practice (Alzheimer Europe, 2017; Mental Health Foundation, 2015; Shakespeare, Zeilig and Mittler, 2019). Unfortunately, there is growing evidence of the lack of human rights in the care provided to PLWD. Examples include the exclusion from decision-making (Robinson et al., 2007), use of physical restraints (Hughes, 2010) or disregard of intention to refuse treatment (Haskins and Wick, 2017). A human rights model of dementia could address such issues by encouraging care providers to make decisions on values such as dignity, respect, equality, and independence (Hughes, 2014). However, there is still little evidence that explains how to translate the human rights model of dementia into care strategies supported by legislation and ethical principles (Kinderman, 2014). More recently, Cohen-Mansfield (2021) has developed a framework to address the identification of human rights in the care needs of PLWD. To do so, first, she reviewed the dementia literature using an analysis framework that comprises the list of rights included in the Declaration of Children Rights[8], which refers to children, another so-called ‘vulnerable’ population. Then, she grouped the findings using the ethical principles of Beneficence, Autonomy, and Justice (Cohen-Mansfield, 2021). According to Cohen-Mansfield (2021), a human-rights based approach to dementia can prioritise dementia care research, promote quality of care and well-being, and positively affect the social perception of PLWD (Cohen-Mansfield, 2021). However, to date, the adoption of a human rights model in the dementia field has not been discussed or used extensively (Cahill, 2020a).

1.4.3 Implications for research practice

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[8] https://cyc-net.org/cyc-online/cycol-0504-korczak.html

In the literature, it is possible to identify trends characterising research practice and influencing the development of new knowledge about dementia. The first trend originated from the biomedical model of dementia, which emphasised the need to find a cure or treatment for PLWD and encouraged research 'on' them, thus neglecting the value of investigating their experiences or feelings (Cotrell and Schultz, 1993). Following the case made for a biopsychosocial model of dementia, the second trend emerged, which promoted the investigation of the social context of dementia and its lived experiences (Innes, 2009). However, PLWD continued to be *'a silent and excluded voice'* (Wilkinson, 2002, p.9) when compared to family carers, who had been participated in research in their own rights or as proxies for PLWD since the early 1980s (Keady, 1996). According to Downs (1997), three main themes challenged researchers and consequently limited the participation of PLWD in research: (1) believing that personhood and sense of self existed in some forms, even if dementia progressed; (2) acknowledging the rights of PLWD to be informed about their diagnosis and availing their consent for treatments and participation in research; (3) and recognising the value of hearing the authentic voices of PLWD to identify indicators of quality of life to improve care practice and services. As a result, the accounts of family carers or care professionals were preferred to the insights of PLWD, who were largely perceived as incapable of contributing meaningfully or credibly to research (Downs, 1997; Cotrell and Schultz, 1993).

Although Kitwood's (1997) theoretical approach to care encouraged the exploration of the subjective experience, at a time where increased evidence underlined its value concerning the identification of dementia-specific quality of life measurement tools (Brod et al., 1999), the shift towards greater participation of PLWD in research was not so straightforward. Indeed, in addition to the discriminatory perception of PLWD as fuelled by the overmedicalisation of dementia (O'Connor et al., 2007), ethical challenges discouraged their involvement even further (Hubbard, Downs and Tester, 2003). Having been targeted by the legislation as a 'vulnerable' population, the participation of PLWD in research was rendered to be an object of heightened scrutiny by ethics bodies, leading to the introduction of time-consuming legislative requirements to access PLWD and gain their consent (Dewing and Pritchard, 2004). According to Innes (2009), different conceptual understandings of dementia may have contributed to the development of such a trend, resulting in the polarisation of approaches to research conduct. On the one hand, researchers who interpreted dementia as a disease viewed people affected by it as ‘vulnerable and incompetent’ and ‘subject’ of research that it is conducted ‘on’ them, if consent was granted by their proxies (i.e., family or formal carers) (Berghmans and Ter Meulen, 1995). On the other hand, researchers who believed that PLWD retained their sense of self and could communicate their views valued their participation in research, gaining consent directly from them as a result of a reflective and continuous evaluation process (Dewing, 2007).

Methodological challenges, alongside practical issues arising from the progressive nature of dementia and proxies’ interpretation of risks, were also documented as reasons for the exclusion of subjective experience, especially if the person was at an advanced stage (Hellström et al., 2007; Innes, 2009). Consequently, most of the knowledge about the experience of dementia and perception of quality of life was constructed from analysing family carers’ account of the condition and their perspectives of associated needs (Hubbard, Downs and Tester, 2003). Notwithstanding the value of carers’ insights, further literature highlighted the discrepancies between their views on priorities and the account provided by PLWD themselves (Dröes et al., 2006). Differences were noted in the ratings of the quality of life for PLWD, which, if provided by family carers, were significantly under-estimated (Logsdon et al., 2002). Contrasting opinions on the value of support provided at day centres were also documented, and it was occasionally observed that PLWD experienced the exertion of control by family carers if they believed their loved ones were at risk (Bamford and Bruce, 2003). This was also consistent with findings that reported how, at times, PLWD felt they had lost autonomy and control on their life decisions, even though they recognised the good intentions of their family carers (Aggarwal et al., 2003).

With growing evidence about similar concerns (Clarke and Keady, 2002; Moore and Hollett, 2003; Sands et al., 2004), it became clear that the experience of PLWD was unique, and their participation in research began to increase as a means to identify tools to evaluate their quality of life (Brod et al., 1999; Hubbard, Downs and Tester, 2003) and understand the specifics of living with this condition (Cotrell and Schultz, 1993; Wilkinson, 2002). The great emphasis placed on the need to explore the subjective experience of dementia challenged researchers to seek ways in which those experiences could be heard (Downs, 1997; Keady, 1996). Consequently, dementia researchers started documenting lessons learnt from conducting empirical studies to promote methodological advancement (Hubbard, Downs and Tester, 2003). Whilst it became apparent that family carers' insights could not replace the subjective experience of dementia, their role in the participation of the person they cared for was reconsidered. Indeed, they were increasingly perceived as enablers because of their ability to give and maintain access to PLWD while also providing critical information for the ongoing capacity assessment (Dewing, 2007). Additionally, if willing to participate alongside their loved ones, they could promote a sense of familiarity and safety, thus possibly enhancing the communication between PLWD and the researcher (Cantley, Woodhouse and Smith, 2005; Hellström et al., 2007).

Within this context, the participation of PLWD in research increased; however, concerns were raised about the little progress made in their inclusion as partners in the research process (Tanner, 2012). This collaborative approach to research conduct, which originates from the research tradition recognising the rights and value of service user involvement in research (Beresford and Croft, 2001), started being acknowledged in the dementia field during the 1990s. At that time, the growing interest in the rights of marginalised groups encouraged the activism of the disability rights movements campaigning for greater inclusion in policy decision-making – 'Nothing about us without us' (Charlton, 1998) – and the rise of the emancipatory disability research advocating for the empowerment of disabled people (Barnes and Mercer, 1997). Researchers adopting an emancipatory paradigm of inquiry challenged the conventional approach of research by conducting research 'with' disabled people rather than 'on' them (Wilkinson, 2002). However, the dominance of the biomedical perspective of dementia and its impact on related research culture and practice represented a barrier to normalising this approach to knowledge production in the dementia field (Harrison and Johnson, 2015).

A real shift towards a more inclusive dementia research agenda arose about a decade ago with the claims for the rights of autonomy, equality, and respect to be afforded to PLWD, as supported by the social model of dementia (Bartlett and O'Connor, 2010). Indeed, increased concerns about the experience of social exclusion and stigma of PLWD (Bartlett, 2014a), and the negative correlations between their quality of life and socioeconomic status (Cahill, 2020a), caught the attention of policymakers, international organisations and dementia rights movements (Bartlett, 2014b). The WHO (2012) asked researchers to collaborate with PLWD, considering their contribution crucial for the development of evidence-based practice. On the other hand, the ADI (2012) encouraged PLWD to become spokespersons of key organisations to increase awareness and reduce stigma, while the Alzheimer Europe (2012) reported the advantages of conducting research 'with' or 'alongside' PLWD who were by then included in the organisation's working groups. This change in direction was first implemented in the UK with the 2012 National Dementia Strategy (DH, 2012a), and it was further endorsed by one of the NICE's (2013) dementia quality standards, which highlighted the importance of allowing PLWD and family carers to contribute to the design and implementation of care services. Around the same time, it was also documented an increase in campaigning for better support of existing service users' groups (Williamson, 2012).

Building on these foundations, 14 members of the Scottish Dementia Working Group (SDWG) developed a list of core principles to encourage a more dementia-friendly research community, clearly stating their interest in and capability of contributing to research meaningfully (SDWG Research SubGroup UK, 2014). Since then, there has been a growing emphasis on fostering an inclusive dementia research agenda (Alzheimer's Research UK, 2016; Alzheimer's Society, 2017; DH, 2015; DHSC, 2014b), with many highlighting the extent of the benefits associated with the employment of patient and public involvement (PPI) in dementia studies (Alzheimer's Society, 2018; Pickett and Murray, 2018). PPI differs from participation in research as it entails the direct contribution of PLWD and their family carers to the research process through activities that enable them to advise researchers on research questions, support them in the collection and analysis of data, and engage in the dissemination of findings (INVOLVE, 2012). Although core principles for the inclusion of PLWD in the research process have been established (SDWG Research SubGroup UK, 2014), and some ways of promoting it co-developed (Swarbrick et al., 2016), PLWD still face several barriers compared to family carers, even though the lack of adequate methods of involvement in PPI activities affect both (Bethell et al., 2018; Gove et al., 2017; Marjanovic et al., 2015). Adding to the methodological challenges, the tendency towards a conventional approach to research conduct (i.e., research 'on' rather than 'with') or paternalistic behaviour towards PLWD in particular, PPI in dementia research is often reduced to a box-ticking exercise that lacks meaningful involvement (Gove et al., 2017).

1.5 Outline of the DemRI study

1.5.1 Research background

PPI in dementia research is the focus of the DemRI study, which the Alzheimer's Society funded as part of the Newcastle University's Primary care-led post diagnostic Dementia care (PriDem) programme[9]. The PriDem programme aims to develop guidance on how to successfully implement a primary care-based approach to equitable and sustainable post-diagnostic support, which maintains the quality of life of PLWD and their family carers (Wheatley et al., 2020). To achieve this aim, in 2018, the PriDem programme team founded the Dementia Care Community (DCC) to promote PPI in all stages of the research process (Wheatley et al., 2020). In what is considered an 'innovative approach to PPI' (Brunskill et al., 2018), the DCC includes dementia care service users (i.e., PLWD and family carers) and providers (i.e., health and social care professionals and representatives of the voluntary community and social enterprise sector), thus bringing together different stakeholders whose knowledge and experience of dementia and care services may differ from one another. The PriDem programme team's approach to PPI is the object of interest of the research conducted as part of the DemRI study, which aims to contribute to the current lack of guidance on how best to involve PLWD and their family carers in dementia research through PPI activities (Bethell et al., 2018; Gove et al., 2017; Marjanovic et al., 2015).

1.5.2 Research questions, aims and objectives

The DemRI study aims to promote advancement in the field of PPI in dementia research by answering the following questions:

1. What are the key concepts characterising PPI in research, and how do these fit with what we know or need to know about involving PLWD and family carers through PPI activities?
2. What are the facilitators and barriers to the involvement of PLWD and family carers through PPI activities?
3. What are the outcomes of the involvement of PLWD and family carers through PPI activities?

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[9] https://research.ncl.ac.uk/pridem/

4. What are the mechanisms and contextual factors leading to the attainment of those outcomes?
5. In involving PLWD and family carers through PPI activities: what works, for whom, in what circumstances, in what respects and why?

The primary aims of this study are:

- To develop programme theories (PTs) explaining what works, for whom, in what circumstances, in what respects and why when aiming to involve PLWD and family carers in research through PPI activities
- To design a conceptual framework that promotes good practice in the field of PPI activity in dementia research.

Specific objectives of this study include:

- To conceptualise PPI
- To identify the gaps and shortcomings of the conceptualisation of PPI
- To explore the facilitators and barriers to the involvement of PLWD and family carers in research trough PPI activities
- To develop candidate programme theories (CPTs) for the involvement of PLWD and family carers in research through PPI activities
- To test and refine these CPTs consulting relevant stakeholders
- To develop, test and refine PTs for the involvement of PLWD and family carers in research through PPI activities
- To design a conceptual framework that supports the explanation of the PTs developed.

1.6 Summary of the chapter

Chapter 1 has provided key information about the context of the DemRI study, which requires particular attention to understand the need for the research and the challenges it entails. The chapter began by defining the term dementia and reporting the extent of its impact, thus explaining the reasoning behind the unprecedented global response to it. Then, it documented the challenges experienced by PLWD and family carers and targeted by the broader programme that includes this study (i.e., the PriDem programme). Next, it reviewed the construction of knowledge about dementia, highlighting how different theoretical models have influenced research and care practice as well as the social perception of PLWD and their family carers. Finally, it provided an outline of the DemRI study, clarifying its research questions, aims and objectives.

Chapter 2. Patient and public involvement

2.1 Overview of the chapter

Chapter 2 discusses patient and public involvement (PPI) in more detail, aiming to clarify its nature and current operationalisation in practice. The chapter begins by defining PPI in health research and outlining the PPI activities that researchers may include at different stages of the research cycle, along with the most common methods and possible benefits. Next, it informs about the current gaps in the field of practice, highlighting consequences. Then, it discusses findings obtained from a review of the literature that explores the evolution of PPI in health research, examining the underpinnings of its conceptual understandings and drawing key lessons for future research. Finally, it explains how findings from the literature are relevant in the context of the dementia research involvement (DemRI) study.

2.2 Background

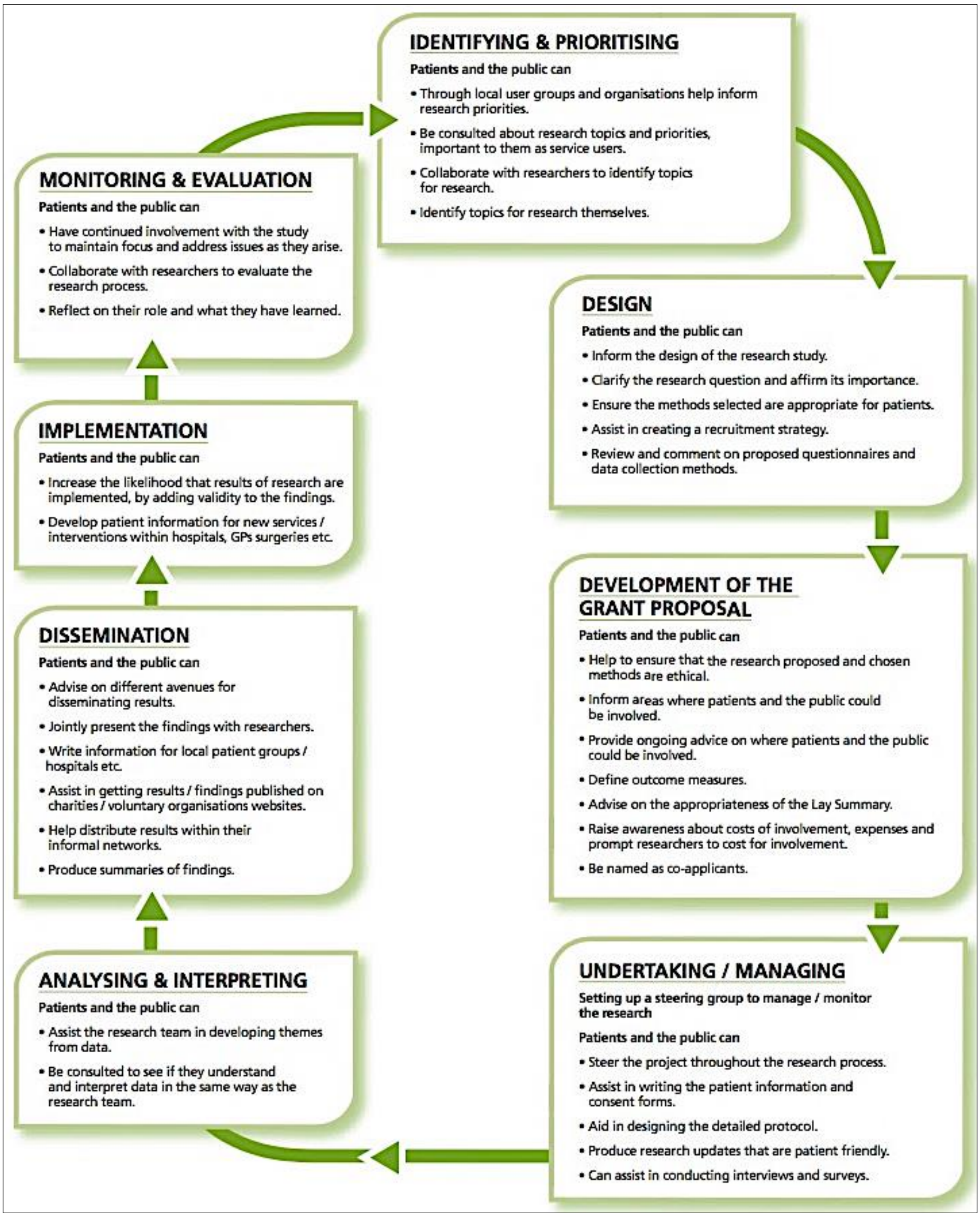
2.2.1 PPI in health research

PPI in health research, also known as 'public involvement' since 2018 (National Institute for Health and Care Research [NIHR], 2018a), has determined substantial changes in the patterns of research planning and conduct in the United Kingdom (UK) (NIHR, 2015a). INVOLVE (2012) defines PPI as *'research being carried out "with" or "by" members of the public rather than "to", "about" or "for" them'* (p. 6). In these terms, 'involvement' refers to *'an active partnership'* (NIHR, 2018b, p.6) between researchers and the public, whereby 'public' includes *'patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services'* (Hickey, 2020). This partnership implies that public members join research teams or reference groups where they can engage in debates and decisions by sharing their perspectives, knowledge and experiences. They may also contribute to the prioritisation of research, development of research questions, choice of outcomes measures or data collection tools, analysis of data, and communication of findings to a wider audience (INVOLVE, 2018). As such, 'involvement' differs from 'participation' in research, where public members become subjects of clinical research with minimal inputs into recognising the needs of the design and conduct of trial studies. It also varies from ‘engagement’, which aims to raise awareness about research and disseminate new knowledge to the wider community (INVOLVE, 2018).

In the UK, PPI is a policy imperative and an integral part of the main health research funding stream, being supported by a system of infrastructures that facilitate the collaboration between research funders, researchers, patients and the public, local organisations – charitable and non – and industry (NIHR, 2021a). The strengthening of such collaboration is one of the objectives of the Centre for Dissemination and Engagement (ex-INVOLVE) (NIHR, 2020b), and it is also highly encouraged in the context of a shift toward integrated care as a future model of the healthcare system (Department of Health and Social Care, 2021; National Health Service [NHS] England, 2021). More recently, PPI was included among the six core workstreams of the NIHR (2021b), which is committed to strengthening the partnership with members of the public to improve the relevance, quality and impact of research by fostering a more inclusive and diverse research environment. As such, finding ways to overcome concerns over the shortcomings of PPI and barriers to involvement, such as negative attitudes and lack of support, has become a priority (NIHR, 2015a). Meanwhile, key recommendations for researchers employing PPI include adopting the NIHR’s (2019a) UK Standards of Public Involvement, which were recently introduced to support the delivery of more consistent and meaningful PPI.

2.2.2 PPI activities and potential benefits

PPI in practice can be imagined as a set of activities organised throughout the conduct of research to promote the inclusion of ‘patients and the public’ – hereafter referred to as ‘PPI contributors’ – in different ways for several purposes. By adapting the INVOLVE’s (2014) cycle of research in Figure 1 to the research phases proposed by Shippee et al. (2015), the benefits of PPI activities for the research can be framed in three phases: preparatory phase (i.e., identifying and prioritising, design and development of the grant proposal); execution phase (i.e., undertaking or managing, analysing and interpreting); and translational phase (i.e., dissemination, implementation, monitoring and evaluation).



IDENTIFYING & PRIORITISING

Patients and the public can

- Through local user groups and organisations help inform research priorities.
- Be consulted about research topics and priorities, important to them as service users.
- Collaborate with researchers to identify topics for research.
- Identify topics for research themselves.

DESIGN

Patients and the public can

- Inform the design of the research study.
- Clarify the research question and affirm its importance.
- Ensure the methods selected are appropriate for patients.
- Assist in creating a recruitment strategy.
- Review and comment on proposed questionnaires and data collection methods.

DEVELOPMENT OF THE GRANT PROPOSAL

Patients and the public can

- Help to ensure that the research proposed and chosen methods are ethical.
- Inform areas where patients and the public could be involved.
- Provide ongoing advice on where patients and the public could be involved.
- Define outcome measures.
- Advise on the appropriateness of the Lay Summary.
- Raise awareness about costs of involvement, expenses and prompt researchers to cost for involvement.
- Be named as co-applicants.

UNDERTAKING / MANAGING

Setting up a steering group to manage / monitor the research

Patients and the public can

- Steer the project throughout the research process.
- Assist in writing the patient information and consent forms.
- Aid in designing the detailed protocol.
- Produce research updates that are patient friendly.
- Can assist in conducting interviews and surveys.

ANALYSING & INTERPRETING

Patients and the public can

- Assist the research team in developing themes from data.
- Be consulted to see if they understand and interpret data in the same way as the research team.

DISSEMINATION

Patients and the public can

- Advise on different avenues for disseminating results.
- Jointly present the findings with researchers.
- Write information for local patient groups / hospitals etc.
- Assist in getting results / findings published on charities / voluntary organisations websites.
- Help distribute results within their informal networks.
- Produce summaries of findings.

IMPLEMENTATION

Patients and the public can

- Increase the likelihood that results of research are implemented, by adding validity to the findings.
- Develop patient information for new services / interventions within hospitals, GPs surgeries etc.

MONITORING & EVALUATION

Patients and the public can

- Have continued involvement with the study to maintain focus and address issues as they arise.
- Collaborate with researchers to evaluate the research process.
- Reflect on their role and what they have learned.

Figure 1. Research cycle, reproduced with permission from the NIHR Research Design Service

At the preparatory phase, PPI activities have been shown to enhance the value, quality and ethical conduct of research by helping identify or prioritise topics and research questions relevant from the perspective of patients and the public (Brett et al., 2014a; 2014b; Mockford et al., 2012), thereby avoiding research waste (Chalmers and Glasziou, 2009). For these purposes, methods of involvement may entail consultation through surveys, group discussions, or workshops. However, there may be more engaging structured processes, such as the one designed by the James Lind Alliance Priority Setting Partnership, which enables patients, carers and health professionals to come together and discuss priorities identified following the completion of several rounds of surveys (Green, 2016). Once research priorities and questions are set, PPI contributors may be invited to work with researchers in developing research proposals, reviewing funding applications, and providing feedback on design and methods (Green, 2016; Wilson et al., 2015). This can allow researchers to ensure ad-hoc search strategies for reviews (Brett et al., 2014b), solve ethical dilemmas and improve the clarity, acceptability and appropriateness of the study by enhancing the information included in research-related websites (Green, 2016) or lay summaries (Brett et al., 2014b; Dudley et al., 2015), anticipating cultural issues (Brett et al., 2014b), and advising on variables and outcomes that matter to patients and the public (Brett et al., 2014b; Green, 2016).

At the execution phase, PPI contributors may assist researchers by reviewing recruitment material or actively participating in the recruitment process, providing access to the population of interest, raising awareness and understanding of research purpose and value, and enhancing the likelihood of success of recruitment and retention strategies (Brett et al., 2014a; Crocker et al., 2017; Dudley et al., 2015; Wilson et al., 2015). The data collection and analysis process can also benefit from PPI. For instance, PPI contributors conducting peer-to-peer interviews or co-facilitating focus groups can help obtain high-quality data (Brett et al., 2014b; Wilson et al, 2015). This is consistent with PPI contributors who felt the beneficial role of PPI in terms of both quality of findings and their relevance to the real world (Gordon, Franklin and Eltringham, 2018; Gradinger et al., 2015). It is also aligned to evidence reporting the enhancement of quality and safety of care (Brett et al., 2014b; Crocker et al., 2017; Shippee et al., 2015). Regarding the data analysis process, through group discussions or workshops, PPI contributors can ensure that user perspectives are reflected in the way data are interpreted and support researchers in the identification of themes, whether the research entails a review of evidence or a qualitative study (Brett et al., 2014a; 2014b; Crocker et al., 2017). They can also provide crucial insights for developing more relevant practice recommendations (Shippee et al., 2015) by encouraging them to reflect more on real-world scenarios (Staley, 2015).

At the research translation phase, PPI contributors have either collaborated with researchers to develop reports and publications (Wilson et al., 2015) or provide feedback to drafted versions (Dudley et al., 2015), thereby creating a more understandable and accessible version for patients and the public. Additionally, by engaging in dissemination events and delivering presentations (Brett et al., 2014b; Wilson et al., 2015), PPI contributors may improve the communication of research to a wider audience and increase the likelihood that findings are translated and implemented in practice (Staniszewska, Thomas and Seers, 2013). Finally, accepting to fill in surveys about their experience of involvement or participating in interviews, patients, and the public alike can promote the monitoring and evaluation of PPI for a specific research study (Crocker et al., 2017; Dudley et al., 2015; Wilson et al., 2015).

2.2.3 Gaps in the field of PPI practice

Considering the wide range of research benefits reported above, and adding to them the positive impact that PPI activities may have on public members (e.g., peer support, increased self-worth and broadened knowledge on health services or research) and communities involved (e.g., increased capacity of organisations) (Wilson et al., 2015), PPI has increasingly attracted the interest of policymakers, research funders, researchers, local authorities and patient and lay organisations. However, despite this generalised interest towards PPI and the availability of numerous tools for its design and evaluation (Greenhalgh et al., 2019a; NIHR, 2019b), there is still little understanding of 'how to do it well'. One explanation for this discrepancy is the lack of shared language and purpose across the fields using PPI (Tritter, 2009). As a result, PPI is not universal in its label or definition (Hoddinott et al., 2018). Moreover, the lack of conceptual and theoretical clarity (Evans et al., 2018; Madden and Speed, 2017), along with published studies including a little assessment of the involvement process and related outcomes (Brett et al., 2010; 2014b; Mockford et al., 2012; Wilson et al., 2015), have raised additional questions regarding the focus and purpose of its evaluation (Crocker et al., 2017; Staley, 2015). Indeed, whilst there is consensus around its intrinsic value, there is less agreement on the rationale for conducting PPI, thus leaving researchers wondering if or what part of involvement should be evaluated, and which methods are fit for purpose (Edelman and Barron, 2016). Furthermore, the variations of contexts of, and approaches to, PPI (Evans et al., 2014; Wilson et al., 2015) coupled with poor-quality reports (Brett et al., 2010; 2014b; Staniszewska et al., 2017) pose both practical and methodological challenges, as it is difficult to understand how to evaluate PPI and what good practice should entail (Staley, 2015). All these issues appear to foster a tokenistic and exclusive approach to PPI, confirming the enduring dominance of a technocratic and individualistic practice in the health research field (Green, 2016; Madden and Speed, 2017; NIHR, 2015a; Paylor and McKevitt, 2019). Given this context, it is challenging to imagine the possibility of promoting advancement in the field of PPI practice without bringing clarity first to its conceptualisation.

2.3 Seeking conceptual understanding of PPI

2.3.1 Chain of reasoning

In the UK, PPI, also known in the literature as a ‘service user’ or ‘consumer’ or ‘lay’ involvement, finds its roots in the notion of ‘public participation’, which entered the context of health service policy and provision in the 1960s. Since then, a series of events shaped its evolution, from the activism of social movements campaigning for personal and political change to the emergence of consumerism in the healthcare system and empowering practice in health care. These events, along with the numerous structural changes of the NHS informed by broader ideologies or clinical failings, led to the institutionalisation of PPI in health care first and health research afterwards. Whilst a detailed account of the historical evolution of PPI from its origins is discussed as an appendix (see appendix A), the key learnings obtained from its critical assessment highly contributed to my understanding of the ‘contested’ nature of PPI and its conceptualisation in research, which I discuss in the next section.

2.4 Conceptual understandings of PPI

2.4.1 Brief historical outline

The introduction of PPI in health research can be traced back to the early 1990s when the Department of Health (DH, 1991) published the first research and development (R&D) policy for the NHS. This policy document preceded an official government commitment to support the inclusion of ‘consumer involvement’ in research within the NHS (DH, 1993). To align with the new government mandate, the then Director of the NHS R&D founded the Consumers in NHS Research group – formally known as Standing Advisory Group on Consumer Involvement – to ensure the inclusion of consumers in decisions about how research was prioritised, commissioned, undertaken and disseminated (Hanley et al., 2000). One of the first actions of the consumers included in this advisory groups was to commission a report of lay involvement in the R&D programmes to understand its benefits and challenges (Oliver and Buchanan, 1997). Whilst bringing clarity to several barriers, many perceived as questionable the lack of discussion concerning the impact of lay involvement, reflecting wider debates about the evidence of its benefits and the methodologies applied to conduct it or evaluate it (Evans, 2014), thus making it challenging for the advisory group to define clear objectives, provide recommendations or make plans of action (Consumers in NHS Research, 2000). The years following this review were characterised by an increased interest in gaining a greater understanding of consumer involvement to identify facilitators and barriers as well as clarify purpose and methods of practice.

In 2000, Hanley et al. (2000) published the first guidance to support researchers in the involvement of consumers in the research process. In the guide, the term ‘consumer’, which is used interchangeably with ‘lay people’ and ‘service users’, was defined as *‘patients, carers, long-term users of services, organisations representing consumers’ interests, members of the public who are the potential recipients of health promotion programmes and groups asking for research because they believe they have been exposed to potentially harmful circumstances, products or services’* (p.1). Meanwhile, involvement was presented as a hierarchical model entailing three levels: consultation, collaboration and user-control. Advantages and disadvantages of each level were provided, along with clarifications about user-control, which was discussed as dominant in the field of social care and usually funded by charitable organisations (Hanley et al., 2000). According to Evans (2014), Hanley et al.’s (2000) guidance on the use of consumer involvement in health research was the first official document conceptualising PPI and explaining the rationale for its use in research (see Text box 1), which was rooted in several benefits, whose evidence though was documented only about a decade later (Staley, 2009, cited in Evans, 2014).

Text box 1. Why involve consumers in research and development? Adapted from Hanley et al., 2000, pp.5-6

1. Consumers can help to ensure that issues which are important to consumers and therefore to the NHS as a whole are identified and prioritised.
2. The involvement of consumers can help to ensure that money and resources aren't wasted on research that has little or no relevance to the NHS.
3. Consumers can help to ensure that research doesn't just measure outcomes that are identified and considered important by professionals.
4. Consumers can help with the recruitment of their peers.
5. Consumers can access people who are often marginalised, such as people from black and minority ethnic communities.
6. Consumers can disseminate the results of research and work to ensure that changes are implemented.
7. The involvement of consumers is also becoming an increasing political priority.

However, around that time, more evidence on the value of PPI came with a review commissioned by the Consumers in NHS Research advisory group to learn from the involvement of service users in other contexts. The literature for the review – *Small Voices Big Noises* (Baxter, Thorne and Mitchell, 2001) – included eight case studies in the fields of community development and social care. The population included in these studies encompassed groups of people often underrepresented in health research, such as young people, older people, and people experiencing poverty, disabilities, learning difficulties and mental health problems. Findings from this review brought significant recognition of the role played by involvement in achieving relevant research and of quality. However, they also revealed potential barriers to the promotion of involvement within organisational contexts, including negative attitudes of professionals, inflexibility, power imbalances, lack of adequate resources, and dominance of the ethical protection principle amongst the values influencing involvement practice (Baxter, Thorne and Mitchell, 2001). The key recommendations to improve practice included the evaluation of the process of involvement by focusing on context, people, process and resources, and the use of qualitative methods and participatory approaches rather than quantitative methods and consultative approaches (Baxter, Thorne and Mitchell, 2001).

In 2001, the Consumers in NHS Research advisory group was expanded to include public health and social care research (Evans, 2014). The role of this advisory group, which was renamed INVOLVE in 2003, became pivotal to support the advancement of consumer involvement in health research, especially after PPI became a statutory part of the *Research Governance Framework for Health and Social Care* (DH, 2005). In 2006, with the *Best Research for Best Health* (DH, 2006) policy document, the role of patients and the public became mandatory in all stages of the research process as a means to increase the authenticity and credibility of research. INVOLVE was given the responsibility to support the inclusion of PPI in health research in coordination with the NIHR, which was founded to improve the health and wealth of the nation through research (DH, 2006). The *2012 Health and Social Care Act* consolidated the legislation around PPI in health service but also health research. Since then, PPI became embedded within the UK main health research funding streams, encouraging other funders to do the same. In 2012, the DH (2012b) issued the first statutory legislative requirement to consult carers, patients, family members and community members in health services planning. Conformingly, the NIHR started including PPI in their research development strategy (NIHR, 2015b). In 2014, the DH commissioned a review of PPI in the NIHR work to analyse its progress since its inception in 2006. The findings from this review informed on the progress and challenges encountered, underlying the importance of promoting good practice in the field of PPI activity (NIHR, 2015a).

2.4.2 The rationale for PPI

In addition to the policy argument, it is possible to identify two major set of justifications for PPI in the literature, namely, the consequentialist and the deontological rationale. The consequentialist rationale – also known as methodological (Ward et al., 2010), pragmatic (Wright et al., 2010), substantive (Gradinger et al., 2015), managerial and instrumental rationale (Carter et al., 2013) – justifies PPI based on its contribution to relevant and quality research, thus owning to the knowledge that patients and the public add to professionals' work (Thompson et al., 2009). As such, PPI is instrumental because it provides evidence of the validity and credibility of the research (Carter et al., 2013). The deontological rationale – also called ideological (Wright et al., 2010), normative (Gradinger et al., 2015), and the moral and ethical perspective (Ward et al., 2010) – is rooted in the democratic rights that patients and the public hold to be involved in decisions about health services and publicly funded research as citizens and taxpayers (Thompson et al., 2009). In the literature, this rationale is often associated with arguments describing PPI as a way of addressing the democratic deficit in policy and research contexts, or as a means of *'shedding light on previously esoteric research practices'* (Thompson et al., 2009, p.47) by increasing transparency and accountability.

2.4.3 Underpinning ideological drivers of PPI

The organisation of rationales for PPI in two distinct sets of justification – that is consequentialist and deontological – has dominated conceptual debates surrounding its nature, which is considered 'contested' on the account of being underpinned by two distinct political ideologies: consumerism and democracy. These two ideologies have informed the conceptual understanding of public participation in social policy and practice first, and service user involvement in research and evaluation afterwards (Beresford, 2002; 2003).

In social policy and practice, the notion of 'public participation' is defined as *'the ways in which ordinary citizens can or do take part in the formulation or implementation of policy decisions'* (Richardson, 1983, p.8) that refer to statutory services such as health, housing, education, social security and the personal social services. Origins of public participation can be traced back to the 1960s, when community development initiatives were implemented to tackle inequalities and land planning regulations were created to guarantee the sustainability of an environment which meets the needs and demands of people (Beresford and Croft, 1992). The challenges related to the conceptualisation of 'participation' were already a contentious matter in the 1980s, creating a division between scholars arguing for its value in improving the responsiveness and efficiency of services and those considering it a tokenistic tool in the hands of powerholders (Richardson, 1983). This division reflected the two developments that encouraged the rise of public participation in healthcare matters: the ascension of consumerism and the pressure of social movements including service users in the fields of women's health, learning disabilities and mental health (Rowe and Shephard, 2002). In the literature, the competitive political ideologies that underpin these two developments (i.e., consumerism and democracy) are often used to distinguish between the two different models of participation discussed below.

The consumerist model of participation draws upon the private sector notion of market and thus, it is primarily concerned with improving health services by involving the public in service planning and implementation. From a consumerist perspective, the public is identified as a group of 'consumers' who have rights that ensure they are given the opportunity to choose the 'best buy', thus treating health services as a commodity and giving consumers the power to affect the organisations' competitiveness in the NHS internal market (Lupton, 1997). Additionally, as entitled to redress health services, upon request, they can provide feedback based on personal preference and experience. However, this feedback may or may not be valued, as the purposes of this approach reflect values that encompass finance and managerial disciplines (e.g., consumer responsiveness and values for money) (Rowe and Shephard, 2002). Whilst the consumerist model is driven by economic and managerial forces, the democratic model is grounded on broader political and social philosophies (Beresford, 2002; 2003) and is perceived as both a form of legitimisation of decisions and a tool capable of promulgating 'democratic renewal' (Rowe and Shepherd, 2002). Within this model, participation is conceived as a means of empowering 'citizens users' by including them in decision-making, broadening their experiences and perspectives, and ensuring their active contribution, thus addressing power imbalances. This may explain why this approach is often considered 'developmental' in nature (Rowe and Shephard, 2002).

2.4.4 Implications for PPI practice

In the literature, the origin of the commitment to PPI is usually associated with the establishment of the Consumers in NHS Research advisory group in 1996. This group was founded to ensure the presence of consumer involvement in the NHS research and development programmes, whereby 'consumers' are those who *'do not have professional roles (such as doctors, nurse, researchers, etc.)'* and 'involvement' is an *'active partnership between consumers and researchers in the research process'* (Hanley et al., 2000, p.1). This call for an 'active partnership' between researchers and consumers was soon perceived challenging, as accompanied by methodological and epistemological concerns (Boote, Telford and Cooper, 2002). Indeed, including consumer involvement in research would entail a shift from research 'on' to research 'with' consumers, which is not supported by the traditional model of health research underpinned by a positivist paradigm of research (Boote, Telford and Cooper, 2002). Additionally, if consumers are not to be viewed as research participants, the recognition of their lay knowledge as a form of expertise, and its inclusion in the research process, requires the development of a new framework of involvement (Boote, Telford and Cooper, 2002) and the desertion of values such as 'objectivity', 'neutrality', and 'scientific rigour' (Beresford, 2003). Although deemed 'unscientific' from a positivist perspective, action research and participatory research methodologies were proposed as an alternative to the traditional model of health research (Boote, Telford and Cooper, 2002). However, the possibility of employing them in the health research context raised additional concerns.

Common to action research and participatory research is the interest in addressing power imbalances to facilitate the integration of different types of knowledge and achieve changes that are relevant to people’s lives (Boote, Telford and Cooper, 2002). These aims reflect a model of empowerment that is democratic in nature and as such, different from the consumerist, managerial model of empowerment that is focused on consumers’ rights (Beresford, 2002; 2003). Against this backdrop, some thinking is required in relation to the role of empowerment throughout the research process, as it has been influential in developing a distinction between strategies of involvement. When adopting a consumerist, managerial approach, the way of involvement responds to market research terms and, consequently, it entails mainly consultative methods employed to improve care services (i.e., the product) (Beresford, 2002). A consumer is then empowered in the way which is given ‘choice’ within pre-existent frames and the possibility of ‘exit’ from a provider, thereby impacting the healthcare system’s internal market (Taylor et al., 1992). On the contrary, a democratic approach to involvement empowers services users by giving them ‘voice’ in decisions about services and providing them with the opportunity to achieve change (Taylor et al., 1992). Therefore, adopting a democratic perspective entails more direct ways of involvement, being primarily concerned with the (re)distribution of power, whether those involved are service users or service users’ groups and organisations (Beresford, 2002; 2003).

Reflecting on the differences between the two forms of empowerment discussed, a consumerist model of involvement with its instrumentalist method-based approach and its neglect for service users’ perceptions of changes needed is less likely to impact their lives. By contrast, the use of a democratic approach has the potential to do so, whether in the context of action, participatory (Boote, Telford and Cooper, 2002), or emancipatory research (Beresford, 2002). The origin of emancipatory research can be traced back to the activism of disabled people who, alongside other disfranchised groups of people, challenged the status quo, promoting the development of a social model of disability (Campbell and Oliver, 1996). According to this model, a person is considered ‘disabled’ due to the barriers imposed by social structures rather than impairments, as per the individualised, pathological definition under the biomedical model of health and illness (Barnes and Mercer, 1997). Therefore, the emancipatory paradigm originated as an alternative to the positivist paradigm, aiming to uncover the structures affecting the social perception of disability and achieve the emancipation of the oppressed (Oliver, 1996). For this reason, this paradigm is considered democratic and 'liberational' (Campbell and Oliver, 1996). The central purpose of emancipatory research is not necessarily the 'emancipation' but the empowerment of service users through personal and contextual change (Beresford, 2002). As such, key priorities of researchers entail *'reciprocity, gain, and empowerment'* (Oliver, 1992, p.111).

Whilst questions such as 'who is the research for?' and 'where does the control lie?' are concerns shared among researchers adopting methodologies rooted in democratic principles, there are differences in the understanding of empowerment among them all (Beresford, 2002). Indeed, action and participatory research focus on the experiences of those researched within the social realities they are embedded in. As such, it gives researchers the possibility to shift away from the positivist paradigm by getting closer to the people involved and focusing more on their experiences (Boote, Telford and Cooper, 2002). Even though emancipatory research shares the same experiential focus, its underlying paradigm is 'emancipatory' in the way which encourages an exploration of people's experiences in relation to the micro and the macro-context wherein they are embedded (Beresford, 2002). Therefore, an emancipatory approach requires researchers to explore the micro social processes, which include the power relations between researchers and people involved, but also the macro social processes, which provides insights of the power relations between the individual and the organisations and institutions (Starkey, 2003). By implication, the evaluation of involvement cannot be merely reduced to an investigation of the research process to understand where the control lies, but requires an approach that reflects on the personal, cultural and structural levels at which oppression operates (Starkey, 2003). It is argued that only by doing so the research can 'liberate' groups of people from the systemic type of oppression inflicted on them (Campbell and Oliver, 1996) and support their inclusion where their voice has been silenced and their presence excluded (Oliver, 1996).

2.4.5 Conceptual frameworks of PPI

The different ideological perspectives on involvement and the understanding of its operationalisation in practice have influenced how PPI has been conceptualised over time. Earliest understandings of PPI were built upon Arnstein's (1969) model of public participation, namely the *Ladder of Citizen Participation.* By being upfront with readers, before discussing her model, Arnstein (1969) clarifies her use of the ladder metaphor to encourage reflection on the struggles she had witnessed between institutions or organisations (i.e., powerholders) and citizens (i.e., powerless) while working at the Department of Housing and Urban Development in the United States of America. Arnstein's conceptualisation of citizen participation consisted of different degrees of power, which are figuratively represented as a continuum in the form of a ladder with eight rungs. Reviewing these rungs from the bottom-up perspective (see Figure 2, retrieved from Arnstein, 2019, p.26), there are eight steps: (1) *manipulation* and (2) *therapy,* which are considered equivalent to 'non-participation' as the aim is not to seek advice or feedback, but to educate and cure, so that public support can be achieved through public relations; (3) *informing,* (4) *consultation* and (5) *placation* encompass methods through which the citizens involved are given the opportunity to contribute, even though they do not have control over whether or not this contribution will have any significant impact on final decisions; and finally, (6) *partnership,* (7) *delegated power* and (8) *citizen control*, which refer to the degree of decision-making power that citizens can be granted.

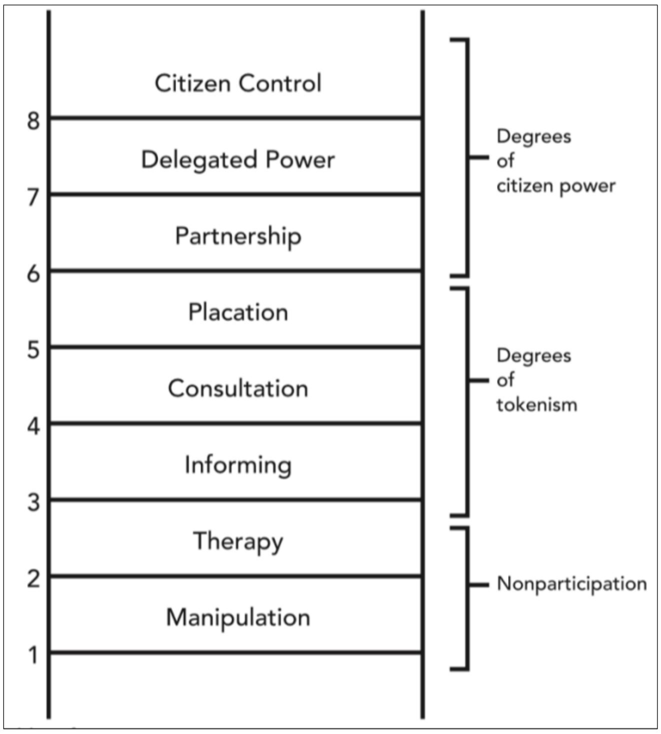


Figure 2. Ladder of Citizen Participation, reproduced with permission from Taylor & Francis Ltd on behalf of American Planning Association

Arnstein's model of citizen participation entered the health research context in the late 1990s, becoming a 'benchmark' to evaluate involvement in health research priority settings and service evaluation. Boote, Telford and Cooper (2002) were amongst the firsts who discussed involvement as organised in three hierarchical levels: *consultation*, *collaboration*, and *consumer control*. According to their model (see Figure 3, retrieved from Boote, Telford and Cooper, 2002, p.24), *consultation* represents the lower level of power and entails involvement activities that are finalised to obtain consumers' insights without any guarantee of influence over researchers' decisions. In other words, consultation is underpinned by the assumptions of a consumerist model of participation, whereby the consumer plays a passive role in the research process. Meanwhile, *collaboration* is considered as an on-going partnership between researchers and consumers throughout the research cycle. Examples of collaboration may be the inclusion of consumers in steering groups of a programme or their participation in dissemination activities. Finally, *consumer control* provides the involved consumers complete control over the research, with researchers being brought in as facilitators and experts in research skills.

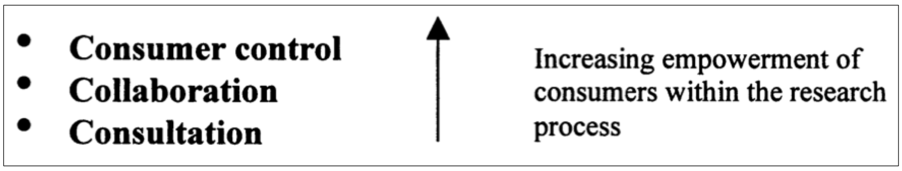


Figure 3. Levels of consumer involvement in health research, reproduced with permission from the corresponding author

Although widely applied, the model illustrated in Figure 3 has been criticised for not addressing the limitations of Arnstein's theorisation of public participation. According to Tritter and McCallum (2006), the *Ladder of Citizen Participation* (Arnstein, 1969) was built on the assumption that participation is hierarchical and that assigning power to citizens should be the ultimate goal of public participation. As such, any absence of citizens complete control represents a failure of participation or a form of delegitimisation, ignoring the value of a collaboration between people with different knowledge and levels of power (Tritter and McCallum, 2006). Moreover, the linear understanding of participation organised in rungs undermines the process of involvement and the impact of time upon it (Collins and Raymond, 2006; Tritter and McCallum, 2006). Furthermore, Arnstein's explanation of roles and responsibilities of citizens, communities and authorities only in relation to power does not recognise individual agency, thereby denying the possibility that users may want to be involved in certain occasions and specific ways or not at all (Tritter and McCallum, 2006). Finally, *'ladders do not exist in free space'* (Collins and Raimonds, 2006, p.6). By neglecting the circumstances characterising the context and the diversity of citizens, Arnstein's model fails to capture the complexity of involvement, which is shaped by interactions and conflicts of interests or opinions that may better explain how decision-making occurs (Tritter and McCallum, 2006).

On the wave of the limited conceptualisation of involvement, Oliver et al. (2008) published the multidimensional conceptual framework used to conduct a systematic review (Oliver et al., 2004) commissioned by the NHS R&D Health Technology Assessment Programme to explore the impact of consumer involvement on the national and regional R&D programmes. Oliver et al.'s (2008) multidimensional framework was built on concepts drawn from different resources: Arnstein's (1969) hierarchical conceptualisation of public participation; Mullen, Murray-Sykes and Kearns's (1984) distinction between reactive and proactive involvement[10]; theories about learning organisations, with particular focus on inclusion, reflection and diversity (Blackemore and Drake, 1996; Cheung and Henley, 1994); and finally, insights from participatory approach to research (Macaulay et al., 1999), which had already been recognised as an enabler of involvement but were considered challenging to employ within organisational settings (Boote, Telford and Cooper, 2002; Hanley et al., 2000). Drawing on these resources, the framework includes the following three critical dimensions: who are the people involved (i.e., lay people or members of organised groups), who initiated the involvement (i.e., lay public or researchers), and the degree of involvement (i.e., consultation, collaboration, or lay control).

Oliver et al. (2008) explained the relationship between the dimensions mentioned above in a matrix (see Figure 4, retrieved from Oliver et al., 2008, p.76), which was developed to support the systematic review they had been commissioned. This matrix enabled them to assess involvement in terms of researchers' approach, level of people engagement and chosen methods of involvement. Being interested in the dynamics resulting from the interactions of these three domains, they retained crucial to document details such as the context of the programme (e.g., historical, geographical, or institutional circumstances), the

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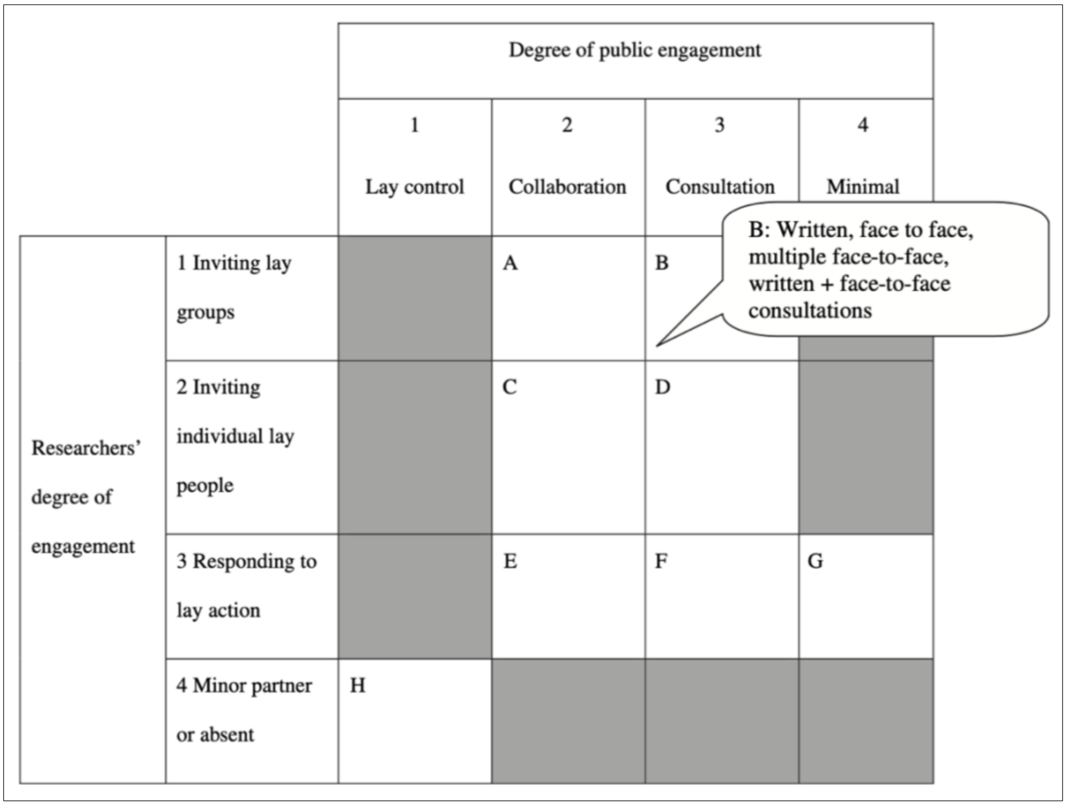
[10] 'Reactive' involvement aims to gain a reaction from citizens and users involved in activities, services, plans and priorities, whereas 'proactive' involvement encourages citizens and users to initiate an activity and formulate a proposal.

underpinning theories of involvement with related outputs and positive or negatives outcomes, and the nature of people involved. However, these aspects were not included in the matrix. In reflecting on the strengths of the framework developed, Oliver et al.’s (2008) argued in favour of its heterogeneous nature and capacity to discern between collaborative and tokenistic involvement by translating the concept of empowerment in practical terms. According to Oliver et al. (2008) empowerment is defined by *‘the numbers of people involved, whether they were individuals or networked group members; within one-off or repeated opportunities for involvement; whether the forum allowed two-way communication; whether members of the public had leading roles or played a part in decision making; and whether there was any training or other resources to support their involvement’* (p.80).



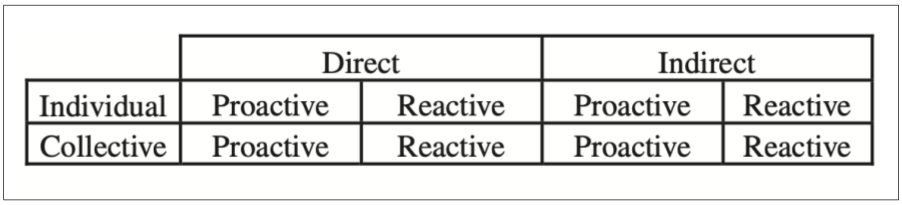
		Degree of public engagement			
		1 Lay control	2 Collaboration	3 Consultation	4 Minimal
Researchers’ degree of engagement	1 Inviting lay groups	▨	A	B	▨
	2 Inviting individual lay people	▨	C	D	▨
	3 Responding to lay action	▨	E	F	G
	4 Minor partner or absent	H	▨	▨	▨

B: Written, face to face, multiple face-to-face, written + face-to-face consultations

Figure 4. Framework for describing consumer involvement in research agenda setting, reproduced with permission from the corresponding author

In 2009, Tritter (2009) developed a framework for the conceptualisation of PPI by reflecting on its nature as a *‘continuum between democratic and consumerist models’* (p.279). In building his framework, Tritter began highlighting the limitations of previous power-orientated theoretical models (Arnstein, 1969; Burns, Hamilton and Hogget, 1994; Wilcox, 1994). In particular, (a) the identification of citizen control as the ideal involvement, which he believed was difficult to imagine in a consumerist world and regulatory-based UK's forms of governance; and (b) the denial of key involvement aspects, such as process and outcomes, power differentials between institutional and non-institutional actors, and the values associated with the integration of different forms of power and types of knowledge. After discussing the possible reasons for employing PPI (i.e., individual participation in treatment decisions, service development, evaluation of services, education and training of health professionals, and research cycle), before explaining the development of its model, Tritter's (2009) clarifies his own definition of PPI, that is *'ways in which patients can draw on their experience and members of the public can apply their priorities to the evaluation, development, organization and delivery of health services'* (p.274). As such, he argued, PPI incorporates different rationales, thereby overcoming confusion arising from terminology issues.

Tritter's model (see Figure 5, retrieved from Tritter, 2009, p.277) focuses on the power-dynamics between professionals or managers and patients and the public as organised in possible degree of influence on decision-making. The model is characterised by three dimensions, namely (1) *direct* or *indirect* involvement, which distinguishes between service users who influence decisions (direct) and those who are invited to share their views with the control on decisions lying on professionals or managers (indirect); (2) *individual* or *collective* involvement, which depends on whether service users involved act individually (individual) (e.g. deciding on a particular procedure) or as a part of a group (collective) (e.g. cancer support group deciding on a new clinic); and finally, (3) *proactive* or *reactive* involvement, which clarifies whether people involved shape the agenda (proactive) or work on something pre-existing (reactive). According to Tritter (2009), in reality, power always lies in 'dominant groups of people', as they can confer legitimacy to involvement and limit the degree of inclusion in decision-making.



	Direct		Indirect	
Individual	Proactive	Reactive	Proactive	Reactive
Collective	Proactive	Reactive	Proactive	Reactive

Figure 5. A model of involvement, reproduced with permission from the author

By drawing on a framework of power, that is Clegg’s (1989) *Circuits of Power*, Morrow et al. (2010) created a model of involvement (see Figure 6, retrieved from Morrow et al., 2010, p.20) that encompasses service users and research context factors. Clegg’s (1989) framework is underpinned by a theory of social organisation that discusses the concept of power as relational and organised in three circuits, which are agency, social integration, and system integration. These circuits need to be considered as open systems because they can be influenced by environmental contingencies, resulting in changing dynamics. Therefore, by drawing on Clegg’s (1989) theorisation of power, the model of service user involvement proposed by Morrow et al. (2010) is presented as a means to reflect on how power is manifested in different, ever-changing ways through people and the social structures they inhabit.

Compared to previous models, which focused on where the control lies and how it manifests, the model developed by Morrow et al. (2010) (see Figure 6) broadened the understanding of service user involvement by defining the concept of ‘quality involvement’. According to Morrow et al. (2010), quality involvement should be considered as an accumulation of practices that empower service users rather than being a value-based notion (Boote, Telford and Cooper, 2002; Telford, Boote and Cooper, 2004). By empowering service users, they argued, it is possible to achieve research structures and outcomes of quality. To define empowerment in the context of service user involvement, Morrow et al. (2010) drew on concepts characterising social theories of power, which have been applied in research about health care practice (Porter, 1998). Their definition of empowerment in practical terms differs from Oliver et al.’s (2008) interpretation of it, as it recognises individual agency in the form of ‘ability to’, ‘potentiality to’ and ‘sense of being’ expressed by service users in relation to specific domains: logic of research structures, involvement methods and involvement roles and expectations (see Figure 6). As such, the focus of the model is the individual, as opposite to the whole, along with micro social processes characterising the practice of involvement.

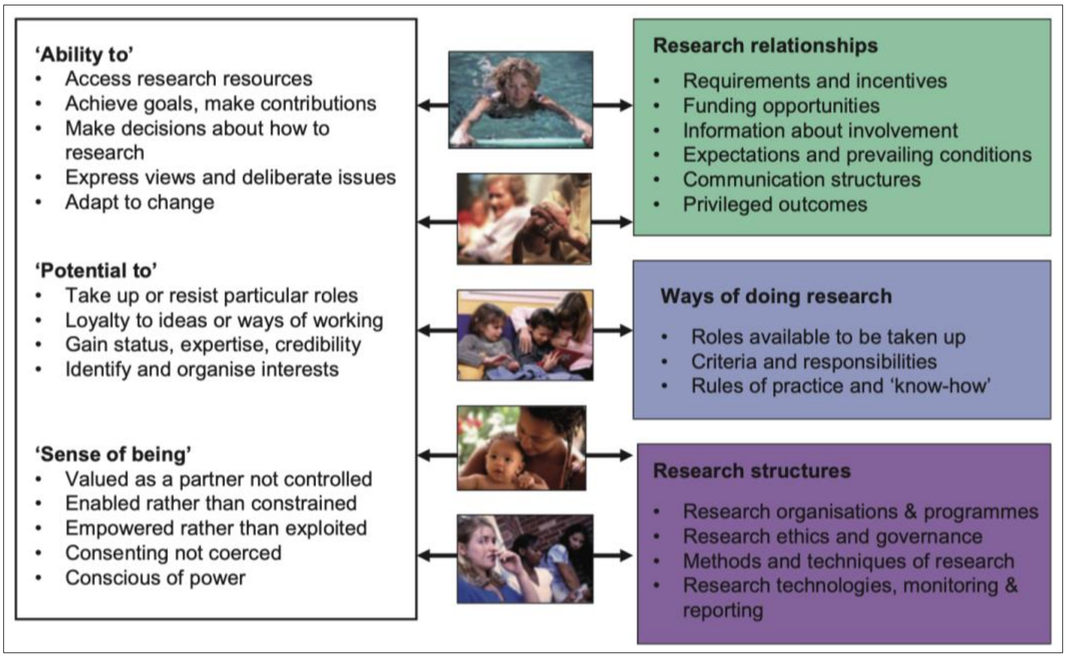


Figure 6. Quality Involvement Framework, reproduced with permission from the corresponding author

Alike Morrow et al. (2010), Gibson, Britten and Lynch (2012) theorised the involvement of patients and the public by drawing on social theories discussing the role of power within social structures. However, they were more interested in how knowledge is linked to power within these structures to facilitate and support the integration of lay and professional knowledge. Gibson, Britten and Lynch's (2012) conceptualisation of PPI include the understanding of lay knowledge by social scientists (Elliott and Williams, 2008; Popay and Williams, 1996), who argued that it is a form of legitimate expertise worthy of consideration because it can help to gain a greater and holistic understanding of health problems while also promoting the democratisation of the research process. For this to happen, though, there needs to be adequate 'knowledge spaces' (Elliott and Williams, 2008) where people act as co-contributors of 'civic epistemology' (Janoff, 2005). Gibson, Britten and Lynch (2012) were able to theoretically map and define these knowledge spaces building upon the conceptualisation of PPI as a *'complex social phenomenon'* (p.535).

In order to explain the complexity characterising PPI, Gibson, Britten and Lynch (2012) used the theoretical and empirical work of Habermas (1987), who discussed society as being characterised by two social spheres: the 'lifeworld', which represents the background of social action (i.e., public opinion, norms, values, experiences, and behaviours); and the 'system', which refers to bureaucracies and markets that are characterised by instrumental action. Additionally, they employed Fraser's (1997) work on the 'public' sphere of society intended as private individuals coming together to discuss issues publicly and provide a counterweight to the power of the state and the capitalist logic of the market. Moreover, they applied Bourdieu's (1990) social theory, according to which social structures of society are built upon the distribution of different forms of capital (e.g., economic, social, and cultural capital), thus explaining how knowledge takes different forms and why these forms may not be judged the same. On a continuum from *conservation* to *change* – that is the ability of an organisation or programme team to resist or welcome the change arising from PPI – Gibson, Britten and Lynch's (2012) model (see Figure 7, retrieved from Gibson, Britten and Lynch, 2012, p.543) includes the following dimensions: *instrumental* to *expressive*, drawing on Habermas' (1987) distinction between system and lifeworld social spheres; *weak* to *strong*, which refers to Fraser's (1997) levels of influence of groups in the public sphere; and *monism* to *pluralism,* following Bourdieu's (1990) organisation of resources in the forms of capital. In 2017, a more accessible version of this model (see Figure 8, retrieved from Gibson, Welsman and Britten, 2017, p.829) was published as a result of an empirical study that explored the possibility of using it as a tool to map the ongoing experience of PPI contributors and support the design and evaluation of the involvement practice.

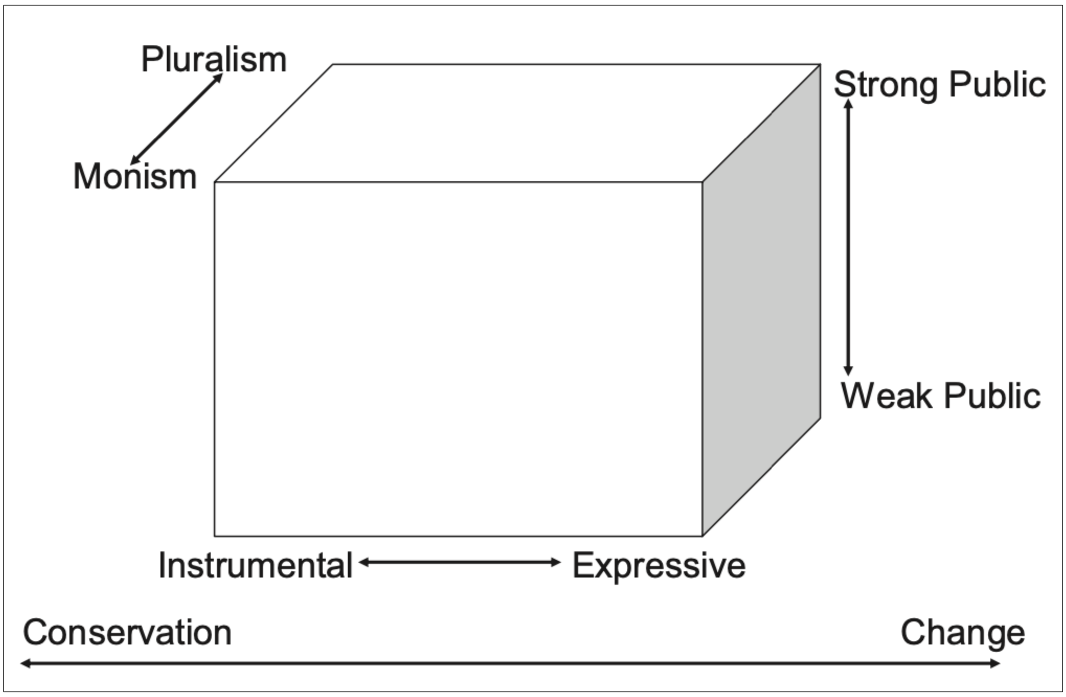


Figure 7. A four-dimensional view of knowledge spaces, reproduced with permission from the corresponding author

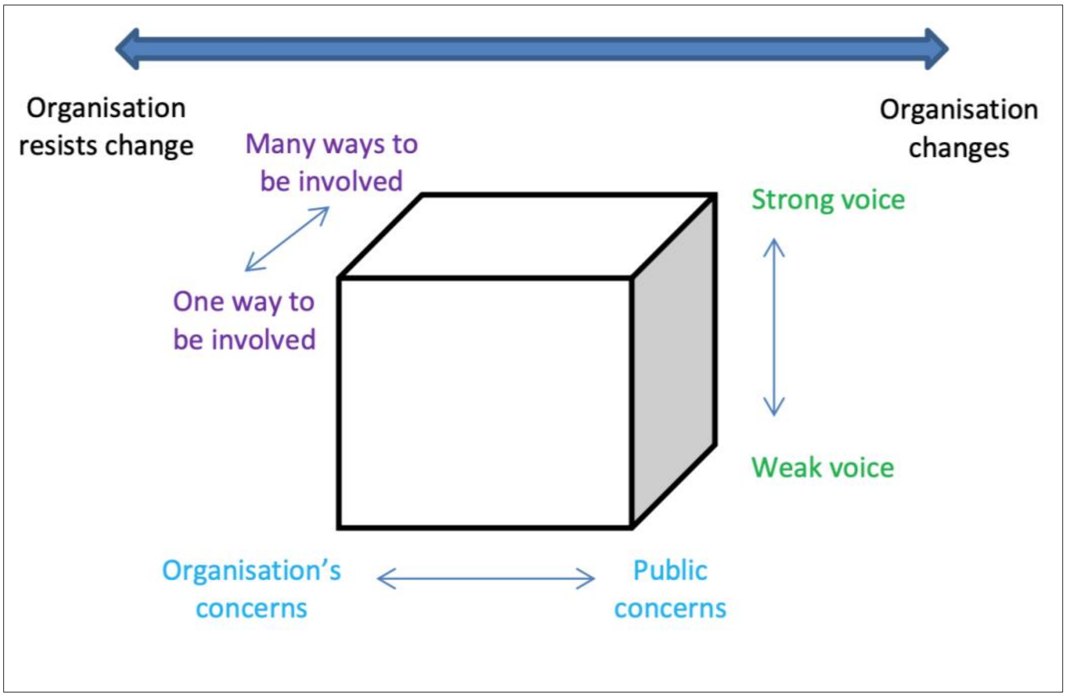


Figure 8. The revised 'cube' with alternative terminology, reproduced with permission from the corresponding author

2.4.6 *What can we learn from the past?*

What can we learn from the past? First of all, the introduction of PPI in health research is strictly related to the government's plan to normalise public participation in health service decision-making processes (DH, 1991; 1993). However, several shortcomings already identified in the health service policy and provision contexts (see appendix A) were soon visible in health research too. For instance, the under conceptualisation of consumers and the consequent absence of clarity around their roles and responsibilities resulted in a confusing field of practice (Consumers in NHS Research, 2000), which was initially justified by a consequentialist rationale (Hanley et al., 2000), although the lack of evidence about the benefits claimed (Evans, 2014). Moreover, the documentation of differences between implementation contexts (i.e., community versus organisational contexts) and power dynamics among the actors included (Baxter, Thorne and Mitchell, 2001; Hanley et al., 2000) revealed the tendency towards a paternalistic and exclusive approach to involvement within organisational contexts. Finally, the support for PPI stated in policy documents and demonstrated by structural changes during the ten years after its statutory inception in research (DH, 2005) did not necessarily lead to greater inclusion of patients and the public in the research process. This can be attributed to both the inconsistencies arising from the aforementioned shortcomings of PPI and the researchers' paternalistic and sceptical attitude towards it (NIHR, 2015a).

Second, there are two major set of justifications associated with PPI in health research: the consequentialist rationale, which is rooted in the consumerist, managerial model of public participation; and the deontological rationale, which draws upon the democratic model of public participation. Within the context of health research, the consumerist, managerial approach to PPI has dominated, creating a field of practice mainly characterised by consultation (Beresford, 2002). The tendency towards this level of involvement has been explained by two reasons: the influence of the organisational context wherein research is embedded, and the alignment to the tenets of the positivist paradigm of research which privileges instrumentalist method-based approaches to involvement and scientific knowledge over lay knowledge (Beresford, 2003; Boote, Telford and Cooper, 2002). In other words, PPI is considered tokenistic and exclusive to the extent that serves the interests of the health system and researchers whilst maintaining power imbalances (Beresford, 2002; 2003). Action and participatory research methodologies have been suggested as an alternative to the traditional (i.e., positivist) model of research because they are rooted in democratic ideological principles and can promote a more inclusive framework of involvement (Boote, Telford and Cooper, 2002). However, the concerns associated with using these methodologies involve the possibility of abstraction from the political context and the absence of individual empowerment as an objective of the involvement process (Beresford, 2002).

Third, conceptual frameworks of PPI in health research have been drawn upon three different perspectives on power: the power to influence, which entails varying degrees of power reflecting a stratified social system based upon hierarchical levels (Boote, Telford and Cooper, 2002; Oliver et al., 2008; Tritter, 2009); the relationship between structures and power, which highlights how power can manifest in different, ever-changing ways through people and the structures they inhabit (Morrow et al., 2010); and the relationship between power and knowledge, which explains how different types of resources and knowledge carry a certain level of power to influence (Gibson, Britten and Lynch, 2012). The most influential conceptualisation of PPI in health research is built upon Arnstein's (1969) theorisation of public participation; however, there are several limitations associated with this model. Indeed, it denies the possibility that people with different levels of power and types of knowledge can collaborate to achieve the common good. Additionally, it neglects the dynamic, relational and developmental nature of PPI by viewing it as a linear, a-contextual, a-transactional and a-temporal process. Finally, it denies individual agency, considering all users interested in being involved, without reservation on individual favourable conditions for making that happen (Collins and Raymond, 2006; Tritter, 2009; Tritter and McCallum, 2006). Even though these limitations were initially identified in relation to Arnstein's (1969) model, they are shared with other frameworks (Gibson, Britten and Lynch, 2012; Morrow et al., 2010; Tritter, 2009), which neglect the heterogeneity of contexts, factors and changing circumstances impacting PPI.

2.4.7 Concluding remarks

1. The interplay between policy and research has influenced the evolution of PPI, including its rationale and operationalisation in practice.
2. PPI has been characterised by the dominance of a consumerist, managerial approach, which, coupled with the traditional (i.e., positivist) model of research, has failed to address power imbalances and recognise the heterogeneity of people involved.
3. The increased interest in action and participatory research methodologies is justified by their value in promoting greater involvement. However, given the possibility of abstraction from the political dimension of PPI, both methodologies may not be sufficient to tackle current issues.
4. Conceptual frameworks of PPI have used different theoretical perspectives of power to identify dimensions worth assessing in the evaluation of PPI in practice. However, they all underline the role of the structures characterising the process of involvement.
5. Except for one (Morrow et al., 2010), all frameworks consider power as 'power over' someone, thus conceiving empowerment as a static, unidimensional concept translated in 'power to' act. Consequently, they focus on the level of control shared when PPI occurs. Meanwhile, the framework developed by Morrow et al. (2010) builds upon social theories of power that encourage an exploration of personal experiences in social contexts, considering power as diffuse in nature and empowerment as the capacity or ability to transform oneself and others.
6. All frameworks have been developed upon a critical account of the historical, sociopolitical and socioeconomic aspects of the context, along with theories deriving from different fields and research traditions.

2.5 Delineating the path forward

2.5.1 How does it work with what we know or need to know?

Whilst there has been increasing interest and commitment to PPI, the literature reveals that its progress in practice has been variable and certainly slow in dementia research (see section 1.4.3). PPI still meets several challenges in practice, which have little chance to be resolved without bringing clarity to the shortcomings of its conceptualisation. Historically, the practice of PPI in health research has been dominated by a consumerist, managerial approach to involvement, which has failed to address power imbalances and has fostered the exclusion of the public or some members of it. While it is now more apparent to me why certain tendencies in practice persist within health-related research organisations and among researchers, the imminent shift towards an integrated system of health care, including dementia care (see section 1.3.2), encourage a major rethinking about PPI. Indeed, such tasks require a collaborative effort that goes beyond the walls of a research institution or health organisation and entails an enduring interaction among diverse people. Therefore, I believe that a lot could be learnt from democratic approaches to involvement, which have a history of collaboration between various stakeholders and, without denying hierarchical levels of power, tend to conceptualise involvement as a process that entails different purposes and phases (see Wilcox, 1994, cited in Tritter, 2009, p.12). However, additional thought must be given to the characteristics of the stakeholders and how they relate to each other. For instance, considering the history of oppressive and discriminatory social structures excluding PLWD (see section 1.4.2), it becomes crucial to acknowledge certain aspects of the context of involvement. These include: the characteristics of the stakeholders involved and how they relate to each other; the nature of the relationships among them all and how they change over time; and the interplay of actions and social contexts at a certain moment and over time. The value of these aspects is missed from the power-focused conceptual frameworks discussed. Moreover, whilst the framework of power used by Morrow et al. (2010) to conceptualise 'quality involvement' (see Clegg's, 1989) can help discern the power dynamics at an individual and organisational level, Starkey's (2003) understanding of empowerment can explain how to enable the inclusion of those who have been so far excluded.

2.6 Summary of the chapter

Chapter 2 has given key information about the concepts used to examine PPI in health research. The chapter began by defining PPI and providing an outline of its benefits and gaps in the field of practice. Then, it explored the origin and evolution of PPI in health research, revealing the underpinnings informing its conceptualisation and highlighting relevant contradictions and limitations. Finally, it explained how findings from the literature reviewed were relevant in the context of the DemRI study.

Chapter 3. Methodology and methods

3.1 Overview of the chapter

Chapter 3 discusses the realist analysis framework used in the dementia research involvement (DemRI) study and explains how it informed the research design and conduct. The chapter begins by delineating the philosophical underpinnings of my approach to research inquiry and their relevance to the context of this study. Next, it outlines the operationalisation of the methodological approach chosen, detailing the context, purpose, and process of each of its three phases. Then, it describes the patient and public involvement (PPI) activities that I designed and carried out throughout the research cycle, reporting the evaluation of my involvement practice according to the United Kingdom (UK)'s Standards of Public Involvement (PI) in research (National Institute for Health and Care Research [NIHR], 2019a). Finally, it clarifies how the study funders (i.e., Alzheimer's Society) and the host organisation (i.e., Newcastle University [NU]) have contributed to the study's progress.

3.2 Philosophical underpinnings of the study

3.2.1 What is meant by paradigm?

The philosophical underpinnings of any research study rest in the paradigm chosen for its design and conduct (Denzin and Lincoln, 2013). The term paradigm in this context denotes a set of beliefs and values that influence how the inquiry of interest is understood, investigated, and addressed (Guba and Lincoln, 1994). According to Guba and Lincoln (1994), the foundations of a paradigm are defined by ontology, epistemology, and methodology. Ontology refers to the branch of philosophy focused on the nature of reality and its features; it answers questions such as *'What is the nature of knowable?'* or *'What is the nature of reality?'* (Guba, 1990, p.18). Epistemology is concerned with the nature of knowledge and how the researcher can learn about the research topic. As such, it answers the question: *'What is the nature of the relationship between the knower (the inquirer) and the known (or knowable)?'* (Guba, 1990, p.18). The methodological approach chosen to conduct research is informed by a certain ontological and epistemological perspective, thus addressing the question *'How should the inquirer go about finding out knowledge?'* (Guba, 1990, p.18).

Clarifications regarding the researcher's ontological, epistemological, and methodological position reveal the overarching rationale informing decision-making throughout the research process (Denzin and Lincoln, 2013). There are different paradigms of inquiry that researchers can decide to employ; however, three of them are particularly relevant to understand the philosophical underpinnings of the DemRI study: the positivist, the post-positivist, and the constructivist paradigms. Table 1 (adapted from Guba, 1990, pp.17-30) illustrates the related key defining characteristics of the ontological, epistemological, and methodological assumptions, while the following sections discuss the paradigm of inquiry adopted for this study.

Table 1. Positivist, post-positivist and constructivist paradigms of inquiry

Paradigm	Ontology	Epistemology	Methodology
Positivist	*Realist:* Reality exists 'out there' and is driven by immutable, natural laws, thus allowing for predictive generalisation.	*Objectivist:* Researchers can and must adopt a distant approach to reality, encountering personal bias and other confounding factors that can affect the understanding of *'how things really are/work'*.	*Experimental, manipulative:* Conducting research entails the empirical testing of preestablished hypotheses under controlled conditions and through quantitative methods.
Post-positivist	*Critical realist:* Reality exists 'out there' and is driven by immutable, natural laws. However, it can never be fully understood for limitations that are proper of human perception of it.	*Modified objectivist:* Researchers cannot be entirely objective, as findings result from the interaction between them and the researched. However, researchers can get closer to objectivity by 'coming clean' and relying on 'critical tradition' and 'critical community'.	*Modified experimental, manipulative:* Conducting research includes a theory-building and refining process rooted in local, specific circumstances. Research is carried out in natural settings and values both qualitative methods and creative discovery.
Constructivist	*Relativist:* There are multiple realities, which depend on the constructions made by the person's mind, as this holds them.	*Subjectivist:* Researchers believe that subjective interaction is the only way to access the reality held in people's minds.	*Hermeneutic, dialectic:* Conducting research consists of eliciting and refining individuals' constructions of reality, then, comparing them to generate a construction of reality that has substantial consensus.

3.3 A scientific realist paradigm of inquiry

3.3.1 Background

Realism is rooted in the logic of inquiry that characterises the philosophy of science and social science (Bhaskar, 1975). It has been labelled the principal post-positivistic perspective due to its ability to provide an explanatory account of phenomena underpinned by beliefs in between the positivist and constructivist paradigms of inquiry (Pawson, 2006a) (see Table 1). There are two strains of realism in social science: scientific realism and critical realism. Scientific realism – also known as emergent realism, analytical realism, middle-range realism (Pawson, 2006a) – recalls the blueprint originally developed by Pawson and Tilley (1997) to explain the potentials of realist inquiry in evaluation research. On the other hand, critical realism is generally associated with the work of Bhaskar (1979) and includes several schools of thought (e.g., experiential realism, constructive realism, natural realism) (Maxwell, 2012). Scientific realism and critical realism share several similarities but also some significant differences; I briefly mention them in the following paragraph.

Scientific and critical realism agree on the nature of social systems, which they believe are 'complex' and characterised by an infinite number of ever-changing events that require the employment of theory to be explained (Pawson, 2006a). Theory can indeed guide realists to identify the critical components of social systems whilst elucidating what gives rise to them and the relationships they form (Pawson, 2013). This theory-driven approach draws upon a generative model of causation, which places emphasis on explaining events with reference to the underlying mechanisms that shape structures, agency, social relations and occurring practices (Pawson and Tilley, 1997). Social systems are also 'open' (Bhaskar, 1979) and in a permanent state of 'self-transformation' (Archer, 1995) because they are shaped by human volition (Pawson, 2013). Against this backdrop, it is denied by both instances the possibility of theorising by creating closed systems under controlled conditions (Pawson, 2013); however, there are differences related to their standpoints on social explanation. Critical realism argues that there will always be an excess of explanatory possibilities, some of which will be mistaken (Pawson, 2006a). Therefore, the primary task of realist inquirers is to develop *a priori* reasoning and then critically evaluate human actions (Pawson, 2006a). As such, the complexity of social systems is conceptually assumed rather than explored (Pawson, 2013). On the other hand, whilst acknowledging the need to adjudicate between alternate explanations, scientific realism recognises that plausible theories can be obtained through a great deal of conceptual, critical and empirical work (Pawson, 2006a).

For the purpose of the DemRI study, I adopted scientific realism, which has already been used to assess PPI in health research (Evans et al., 2014; Wilson et al., 2015) and is currently suggested among the possible approaches to its evaluation (Kok, 2018). The advantages of employing scientific realism rely on the possibility it gives to explore the complexity characterising PPI, providing evidence that can better inform PPI practice due to its explanatory power (Staley et al., 2014). The ontological, epistemological and methodological assumptions discussed in the next section can help understand why that is the case.

3.3.2 Ontology and epistemology

According to realists, reality includes three different ontological domains: the ‘empirical’, the ‘actual’ and the ‘real’ (Pawson, 2013). The ‘empirical’ is what can be observed and experienced, either directly or indirectly. The ‘actual’ includes the events that manifest in the world, irrespective of whether they are observed and experienced or not. The ‘real’ is the main object of interest of realists, as it refers to where it rests the generative power (i.e., mechanisms) that is responsible for the manifested world (Jagosh, 2019). The relationship among the three domains can be described as follows: the ‘real’ includes the ‘actual’, which in turn encompasses the ‘empirical’ (see Figure 9, retrieved from Mukumbang et al., 2020, p.489). A practical example provided by Pawson (2013) can help in discerning differences: the explosion of gunpowder. Moving from the deepest domain of reality to the most superficial, it is possible to claim that the chemical composition of gunpowder (i.e., the ‘real’), when triggered by a flame (i.e., the ‘actual’), can cause an explosion of fireworks (i.e., the ‘empirical’) (Pawson, 2013). According to realists, anything that can have effects in the world is real, including social constructs and institutions (Westhorp, 2018).

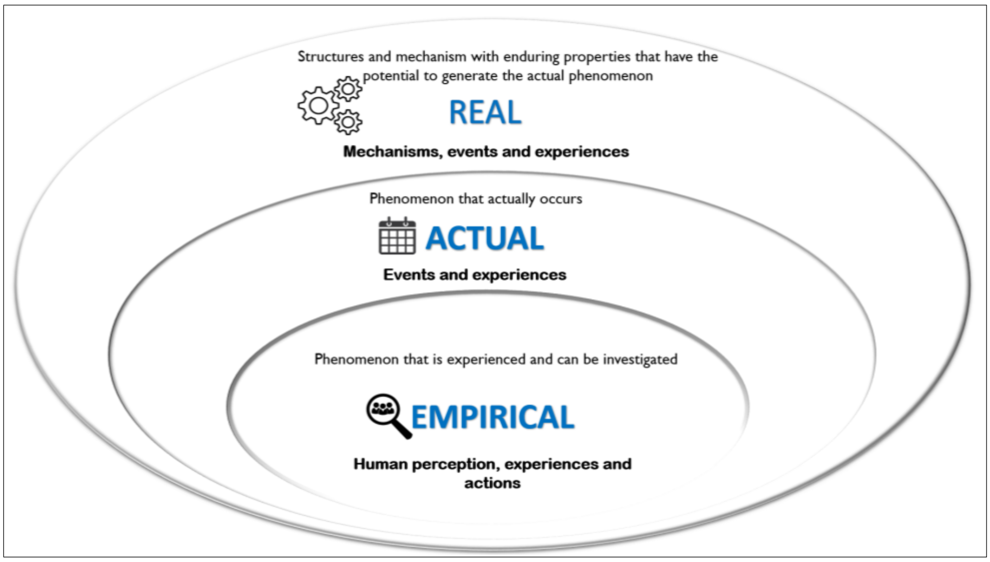


Figure 9. Ontological positions of realist philosophy, reproduced with permission from the corresponding author

‘Ontological depth’ is one of the key messages of scientific realism, along with ‘approximation’ and ‘accumulation’ of knowledge (Pawson and Tilley, 1997). Realists argue that knowledge of the ‘real’ will always be partial due to the numerous changes and anomalies characterising the social world, which make absolute and definitive truth about reality impossible to achieve (Williams, 2018). Researchers are also part of why this is the case since they cannot provide an objective account of their own thinking and, at times, remain unaware or mistaken about how they see reality (Maxwell, 2012). Consequently, realist research aims not to produce definitive facts but to develop a 'family of answers' that covers several contexts and is open to reinterpretation (Pawson and Tilley, 1997). Although true knowledge of reality is impossible to obtain, empirical evidence plays a significant role, as it enables researchers to falsify or limit their scope of inquiry to a certain understanding of reality. As a result, it becomes easier to access the 'actual' domain of reality, where the observation of regularities and their organisation in a sequence of events can inform the development of hypotheses about what is real (Pawson, 2013).

Given these premises, realists believe in the value of approaching reality with 'criticality', thus consistently asking themselves the 'why' question rather than limiting their search for individual instances within the empirical domain of reality (Neuman, 2014). Indeed, the realists' understanding of causality is 'generative' rather than 'successionist' (Pawson, 2006a). According to a successionist model of causality, the focus of the inquiry is 'Does *x* cause *y*?' (Robson, 2011). A certain number of observations revealing the presence of uniformities could be enough for researchers adopting philosophies underpinning this model of causation (e.g., positivism and empiricism) to associate variables and develop causal inferences, as they believe in a 'flat ontology' (Sayer, 2000). On the contrary, a generative model of causation implies the question, 'What is it about *x* that causes *y*?' (Robson, 2011). To answer this type of question, assuming the ontological depth of reality, realists seek to explore the context and explain the underlying mechanisms that generate the patterns of outcomes observed (Pawson and Tilley, 1997). It is by using theories that researchers explain the observed regularities, whose generative causation rests in underlying processes, namely 'generative mechanisms' (Pawson, 2006a).

3.3.3 Methodology

The methodological values and beliefs of scientific realism build upon the ontological and epistemological perspectives discussed above. Whether the mode of realist inquiry consists of primary or secondary research – in other words, realist evaluation or realist synthesis – realists seek to discover and explain the mechanisms that generate the patterns of outcomes observed (Pawson, 2013). In doing so, they value the use of qualitative and quantitative methods (Pawson and Tilley, 1997), as long as they are employed to understand not just whether a social programme works, but what works or does not, for whom, under what circumstances, and why (Pawson, 2013). Social programmes represent the exploratory territory of realist research; they can be described as open social systems subject to continuous change and characterised by *'the interplays of individual and institution, of agency and structure, and of micro and macro social processes'* (Pawson and Tilley, 1997, p.63). According to realists, social programmes represent the solution to a specific issue, which 'works' by enabling participants to make different choices (Pawson and Tilley, 2004). Therefore, they are shaped by a vision of change that manifests through the introduction of new resources into the system in the hope of disturbing or re-balancing it (Pawson and Tilley, 2004). Programme theories (PTs) outline this vision of change (Pawson and Tilley, 1997).

Programme theories

PTs are central to realist research because they provide plausible explanations of why or why not certain resources under specific circumstances work (Pawson, 2013). There are differences in the way PTs have been conceptualised. For instance, Pawson (2010; 2013) uses the term PTs interchangeably with middle-range theories, which are considered by other realists at a higher level of abstraction, as not attached to any specific programme or setting (Davidoff et al., 2015; Jagosh et al., 2014). In this thesis, I refer to PTs in the narrower sense, that is, as theoretical statements explaining how certain resources introduced in a specific context produce the agents' responses that lead to the outcomes (Davidoff et al., 2015; Funnell and Rogers, 2011). However, these PTs should not be considered in a vacuum; there are relationships between them and the more abstract theories that can guide the development of theoretical statements by highlighting key concepts or relationships that are likely to affect them (Westhorp, 2012). Indeed, some aspects of the PTs may not be unique to one programme but may be commonly applied across a wide range of contexts. The task of the researcher is then to identify how, when, and why these abstract theories apply to a particular context, if at all (Jagosh et al., 2014). At the development stage of PTs, it may be also worthwhile seeking 'folk theories', as the assumptions held by those implementing the programme or targeted by it may contribute to gaining a clearer understanding of circumstances under which the programme works (Pawson, 2013). Similarly, the experience and insights of the researcher are also to be considered an integral part of theory development, as causation cannot be understood only based on empirical evidence because mechanisms are invisible (Williams, 2018).

Outcome patterns

PTs can be detected following an iterative process of theory testing and refinement that starts with developing hypotheses by assessing the outcome patterns observed (Pawson and Tilley, 1997). According to realists, outcomes alone are not sufficient to explain causality, whose evidence lies in 'outcome patterns' (Pawson, 2006a). Outcome patterns comprise the intended and unintended consequences of a programme (Pawson and Tilley, 2004). Consequently, they can provide evidence for a range of explanations about the circumstances under which a programme works and why that is not the case (Westhorp, 2018), thus resulting in knowledge that is more informative in directing implementation (Pawson and Tilley, 1997). By exploring plausible reasons for the emergence of the outcome patterns observed, researchers can discern the context responsible for the activation of mechanisms that lead to them (Pawson and Tilley, 2004).

Context

Scientific realists believe that the context is a key contributing factor to the success or failure of the programme, thus contrasting the positivists' belief that context is a set of static variables that should be controlled during experiments (Pawson, 2013). Despite the central role given, the operationalisation of the context in realist studies is often problematic or neglected (Greenhalgh et al., 2017), stemming from the different ontological and epistemological beliefs that inform research designs and related methods (Greenhalgh and Manzano, 2021). According to Pawson (2013), the context should be imagined '*as a large set of concentric ovals surrounding the programme mechanism'* (p.36). Against this backdrop, it comes with little surprise why the nature of the context is considered by realists to be analytical rather than descriptive (Greenhalgh et al., 2017). There are different 'types' of context (e.g., material, psychological, cultural, organisational and economic), and they all operate and interact at different levels of the programme, thus making it challenging for researchers to understand how they interact and what the results of this interaction are (Greenhalgh and Manzano, 2021). An 'aide memoir' has been developed to support researchers in discovering what the context entails (Pawson, 2013). This aide includes four layers – individual, interpersonal relationships, institutional settings and infrastructure (see Table 2, adapted from Pawson, 2013, p.37) – which, although useful, should not be considered a complete visual of the context (Pawson, 2013). Indeed, the context is also *'dynamic, historically located, relational and agentic'* (Greenhalgh and Manzano, 2021, p.10).

Table 2. Context aide memoire: The four I's

Contextual layer	Contextual circumstances
i. Individual	The characteristics and capacities of the various stakeholders in the programme
ii. Interpersonal relationships	The stakeholder relationships that carry the programme
iii. Institutional settings	The rules, norms and customs local to the programme
iv. Infrastructure	The wider social, economic and cultural setting of the programme

Mechanisms

By exploring the context, the researcher can identify relevant mechanisms (Maxwell, 2012). Mechanisms are the main focus of any realist investigation, as they can explain the outcome patterns discovered (Pawson and Tilley, 1997). Mechanisms rest within the 'real' domain of reality, which, as discussed earlier (see section 3.3.2), is not directly observable (Pawson and Tilley, 1997). Generally, they are activated by specific contexts that make them move from the 'real' to the 'actual' and 'empirical' domain of reality (Pawson and Tilley, 2004). This explains why a deeper understanding of the programme's context can facilitate the identification of mechanisms and the understanding of how their interaction work or what it leads to (Wong et al., 2013). In addition to their latency and contingency to the context, mechanisms owe two additional features which are particularly significant for the conduct of realist inquiry. Firstly, mechanisms generate outcomes by introducing resources affecting agents who are considered capable of making choices that, even if limited, can directly affect the social conditions surrounding them (Pawson and Tilley, 1997). Consequently, it is the agents' response to new resources that can lead to a change in the system. As such, mechanisms comprise the resources and responses that generate the observed outcome patterns (Pawson, 2013). Secondly, mechanisms operate within 'open' social systems (Bhaskar, 1979), which are in a status of continuous 'self-transformation' (Archer, 1995). Therefore, they interact not only with the context but also with the effects they generate within the system, possibly becoming a different theoretical component of the realist explanation. For instance, a mechanism in one theory can be the context activating the mechanism of another theory (Jagosh et al., 2015; Shaw et al., 2018).

Realists advocate for the use of retroduction to identify and verify mechanisms that can provide causal explanations (Fletcher, 2017; Jagosh, 2020). They believe that induction (i.e., process of creating general claims from specific cases) and deduction (i.e., process of deriving logical conclusions from known premises) as stand-alone methods are implied by a 'flat ontology' (Sayer, 2000). In other words, they can provide an understanding of the 'empirical' level of reality only without going deeper through the 'actual' and until the 'real' (see Figure 9). On the other hand, retroduction enables access to a deeper level of reality and helps identify the contextual conditions necessary for a certain mechanism to manifest at the actual and empirical levels (Fletcher, 2017). Retroductive thinking requires the application of deductive and inductive logic to discover regularities in the empirical world and offer explanatory accounts of the mechanisms detected (Jagosh, 2020). However, retroduction works in association with abduction. If retroduction is to consider a mode of inference to theorise and test mechanisms, abduction is the 'hunch' that leads researchers to reframe the object of interest in a new conceptual framework that makes them explore the empirical world in an innovative way (Jagosh, 2020; Tavory and Timmermans, 2014).

Context-Mechanism-Outcome configuration

The Context-Mechanism–Outcome configuration (CMOc) is the heuristic proposed by Pawson and Tilley (1997) to help researchers think in realist causal terms and develop theoretical statements for testing purposes. Although some alternative heuristics have been advanced (Marchal, Kegels and Van Belle, 2018; Punton, Vogel and Lloyd, 2016), with some realists arguing the value of including other explanatory factors to the original CMOc (see examples in Table 3, adapted from De Weger et al., 2020, p.3), they all must serve the purpose of assembling data to indicate generative causation. The term 'configuration' was added to the CMO realist explanatory formula to remind researchers that it should not be a 'labelling exercise' whereby contexts, mechanisms and outcomes are listed in a disconnected way (Pawson, 2013). Instead, these theoretical elements depend on one another and assume their meaning at a specific time, as programmes never offer a single theory but many contexts, mechanisms and outcomes (Pawson and Manzano-Santaella, 2012). The researcher should then identify which combination of these elements would work best in the process of theoretical proposition-building (Pawson, 2013).

Table 3. Variations in CMOc types

Type of configuration	Heuristic
Context-Mechanism-Outcome	CMO
Context-Intervention-Mechanism-Outcome	CIMO
Intervention-Context-Mechanism-Agency-Outcome	ICMAO
Strategy/Intervention-Context-Mechanism-Outcome	S/ICMO
Intervention-Context-Actor-Mechanism-Outcome	ICAMO

3.4 Outline of the research study

3.4.1 Realist evaluation

Realist evaluation is the mode of realist inquiry chosen for conducting the DemRI study. Compared to other forms of evaluation, realist evaluation is underpinned by a particular ontological and epistemological understanding of the real world, and it is guided by theory to seek and refine explanations of the social programmes of interest (Pawson, 2013). Realists believe that programmes are designed and implemented to create change (Pawson and Tilley, 1997) and, as such, they are ‘theories incarnate’ (Wong et al., 2016). Therefore, in a realist evaluation, the unit of analysis is not the programme per se, but the underlying PTs explaining the possible cause of change (Wong et al., 2016). Undertaking a realist evaluation comprises making these PTs explicit, developing hypotheses that explain how the programme works, and testing and refining these hypotheses to attain its ‘specification’, that is what works, for whom and in what circumstances (Pawson and Tilley, 1997).

3.4.2 Research design

There is no standard formula to conduct a realist evaluation (Wong et al., 2016). Instead, researchers are encouraged to develop strategies based on the realist logic of evaluation, which considers any programme as an ‘open system’ as opposed to a closed ‘black box’. Therefore, the purpose of a realist evaluation lies in ensuring a greater understanding of the contextual factors that trigger the mechanisms through which change is accomplished and eventually achieving clarity about the predictions of related outcome patterns (Pawson and

Tilley, 1997). This logic implies that the chosen research strategies must enable the following: obtaining in-depth knowledge about the programme and its concomitant implementation process; discerning amongst contextual circumstances that may be directly involved in the emergence of certain outcomes; and finally, describing the mechanisms triggered by the underlying circumstances that ultimately lead to the outcomes (Wong et al., 2016). Following this line of reasoning, the realist evaluation discussed in this thesis entails a combination of qualitative research methods and a continuous engagement with relevant literature and stakeholders. For clarity purposes, I organised the realist evaluation in three phases, whose key differences are presented in Table 4. In the following sections, I discuss the details of the design and conduct of each phase separately, although the data analysis for developing, testing and refining PTs was iterative. Table 5 displays an overview of the data sources informing the analysis process throughout the evaluation.

Table 4. Overview of the three-phase realist evaluation

Phases	Objectives	Data sources	Outputs
Phase I	• To develop candidate programme theories (CPTs) about the involvement of people living with dementia (PLWD) and family carers in research through patient and public involvement (PPI) activities	• Document analysis • Observations • Fieldwork • Stakeholders' views	• Architecture of the programme • Potential facilitators & barriers • Identification of relevant cases • CPTs statements
Phase II	• To test and refine CPTs	• Stakeholder consultations	• Additional facilitators & barriers • Additional CPTs • Refined CPTs
Phase III	• To develop, test and refine programme theories (PTs) about the involvement of PLWD and family carers in research through PPI activities • To design a framework supporting the explanation of these PTs, addressing future PPI practice	• Realist interviews	• PTs • Conceptual framework

Table 5. Overview of data used for theory development and refinement processes

Phases	Data sources	Amount	Type of data included	Data excluded	Timeline
Phase I	Documents	n.200	PriDem[1] programme application PriDem programme protocol PriDem programme report PriDem team monthly meeting minutes DCC[2] strategy & recruitment documents DCC meetings impact summaries DCC-related communication plan DCC-related dissemination documents DCC meetings-related material DCC meetings summaries for members Public members' contribution to DCC DCC members' registration forms DCC members' feedback cards	Info repeated Drafts Duplicates	Feb-Dec 2019
	Observations	12 hrs	Typed notes[3] collected during: - DCC meetings at the university venue - DCC meetings at the memory café - DCC meetings at the dementia hub	None	Mar-Oct 2019
	Fieldwork	13 pp.	Typed notes collected during: - Monthly team meetings - Pre- and post-DCC meetings	Info repeated	Feb 2019-Mar 2020
	Stakeholders' views	14 pp.	Typed notes collected during: - Meetings with DCC members - Meeting with AS[4] network group - One-to-one conversations Additional comments received via email	None	Nov 2018-Nov 2019
Phase II	Consultations	37 pp.	Typed notes collected during: - One-to-one conversations - Group discussions Additional comments received via email	None	Nov-Dec 2020
Phase III	Interviews	n.15	Interview transcripts	None	Feb & Apr2021

[1]PriDem = Primary care-led post diagnostic Dementia care
[2]DCC = Dementia Care Community
[3]Format = Font: Calibri; Size: 12; Margins: Top 1.92 cm, Bottom 1.42 cm, Left 2.54 cm, Right 1.96 cm
[4]AS = Alzheimer's Society

3.4.3 Ethical approval

The DemRI study has undergone the review of the NU Faculty of Medical Sciences (FMS) Research Ethics Committee (REC) on three occasions. In early 2019, I applied for ethics on the first version of the research protocol, which included a realist synthesis of evidence alongside the case study and stakeholder consultations. At that time, I received approval from the NU FMS REC on 29th January 2019 (reference:10397/2018) (see Appendix B). A few weeks after gaining this approval, a member of the supervisory team was replaced. Following discussion of the study with the new supervisor, the possibility of making some changes to the approved version of the protocol was explored. These changes included the formulation of a research question with its related objectives and the content of the recruitment material. For this reason, I submitted a new application form, explaining the details and rationale for the protocol amendments requested. A second ethical approval from the NU FMS REC was received on 9th July 2019 (reference:14045/2018) (see Appendix C). Finally, constrained by the need to overcome the challenges posed by the outbreak of

COVID-19, it became necessary to adapt the study to the purposes of a realist evaluation and the restrictions imposed by the pandemic. Therefore, I submitted a third application form to the NU FMS REC in October 2020, clarifying what aspects of the study would change and why. On this occasion, I was notified about the approval on 19th November 2020 (reference: 2021/5888/2020) (see Appendix D).

3.5 Phase I: Case study

Phase I aimed at developing ideas on the aspects that could support the involvement of people living with dementia (PLWD) and family carers in PPI activities. This phase entailed the collection of qualitative data conducted alongside the continuous consultation with relevant stakeholders and empirical and theoretical literature. Given that this phase was embedded in the Primary care-led post diagnostic Dementia care (PriDem) programme[11] and focused on the team's PPI practice, the methods chosen for collecting data were influenced by the context of research, in addition to the methodological principles of scientific realism. Compared to other phases, the data collection process during Phase I (see Table 5) was not affected by the COVID-19 pandemic, thus remaining faithful to the original research protocol.

3.5.1 Recruitment

The participants included in Phase I were recruited among members of the Dementia Care Community (DCC). The PriDem programme team founded the DCC to guarantee a close research collaboration with local dementia care service users (i.e., PLWD and family carers) and providers (i.e., health and social care professionals and representatives of the voluntary community and social enterprise sector). Service users were included in the DCC either as individuals who gathered at a local university venue or as members of the local community attending a memory café or dementia hub. For this reason, in this chapter, I often refer to the DCC as a unit organised in three groups, making a distinction between the PLWD and family carers attending the meetings organised by the PriDem programme team at the university venue and those participating in PPI activities held at a local memory café or

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[11] https://research.ncl.ac.uk/pridem/

dementia hub. Each of these groups had a different facilitator, who became a gatekeeper for me as the research unfolded. Any member of the DCC was eligible for being included in the DemRI study, with the exclusion of people lacking the capacity to give consent. Considering the presence of PLWD in the targeted population, the recruitment process demanded additional precautions. By adopting McKeown et al.'s (2010) suggestions, I followed Dewing's (2007) five stages of consent gathering – (1) background study and preparation, (2) establishing the basis for capacity and other abilities, (3) initial consent seeking, (4) ongoing consent monitoring, and (5) feedback and support – alongside the UK's Mental Capacity Act guideline[12], which explains how to enable PLWD to make their own decision.

All DCC members were provided with a brief introduction to the DemRI study and an explanation of the recruitment material (i.e., letter of invitation, participation information sheet and consent form) (see Appendix E) during the meetings organised by the PriDem programme team across settings (i.e., university venue, memory café and dementia hub). DCC members participating in this study were expected to provide oral consent for my observation of the meetings during which they engaged in PPI activities. Additionally, they were required to fill in a consent form if they allowed me (a) to access their contact details from their group facilitators and (b) to use this data as their contributions to the PriDem programme in a PPI capacity (see Appendix E). A printed copy of the recruitment material was given to DCC members together with a stamped envelope in case they preferred to take some extra time to decide whether to get involved. I personally collected most of the consent forms signed, receiving 3 via post and 5 through the DCC groups' facilitators. A total of 35 people accepted to become research participants, of which 6 were members of the PriDem programme team, and 29 were members of the DCC. I have provided an overview of all Phase I participants in Table 6, where they are organised in relation to their role in the programme, which in realist terms is either practitioners (i.e., people implementing the programme) or subjects of the programme (i.e., people targeted by the programme) (Pawson and Tilley, 1997). As the recruitment process was ongoing in different settings and included a diverse population, I kept a reflective diary to document details and make sure that I adhered to ethical principles. The notes included in this diary played a significant role in adapting this study to the circumstances induced by the COVID-19 pandemic in 2020.

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[12] https://www.nhs.uk/conditions/social-care-and-support-guide/making-decisions-for-someone-else/mental-capacity-act/

Table 6. Phase I: Research participants

Role in the programme	Category	Subcategory	n.
Practitioners	PriDem programme team	PriDem programme PPI lead	1
		DCC coordinator	1
		Group facilitators	2
		Research administrators	2
Subjects of the programme	DCC members	PLWD	12
		Family carers	11
		Health care professionals	3
		Social care professionals	2
		VCSE sector representatives	1

3.5.2 Data collection

Phase I entailed different qualitative methods of data collection, such as document analysis, observations and fieldwork. Document analysis necessitates identifying and organising existing, essential information related to the topic under investigation (Bowen, 2009). Recently, this method has been increasingly used in evaluative studies, owing to the perceived value in broadening the understanding of the topic of inquiry in addition to generating new knowledge about it (O'Leary, 2014). Usually, it is regarded as an additional data gathering method that allows for the convergence and corroboration of information to guarantee quality research (Yin, 1994). In realist studies, the use of document analysis is often justified by the need to gain a greater understanding of how programmes are perceived, delivered and received in order to develop PTs (Manzano, 2016; Mukumbang et al., 2016). Observations and fieldwork are also considered suitable methods for studies aiming at building theories (DeWalt and DeWalt, 2011), including realist studies (Maxwell, 2012; Pawson and Tilley, 1997). Indeed, conducting observations and engaging in fieldwork can help researchers acknowledge the context and detail the phenomenon under the scope (Emerson, Fretz and Shaw, 2011; DeWalt and DeWalt, 2011). In particular, observations allow accessing the *'backstage culture'* and describe the '*behaviours, intentions, situations, and events as understood by one's informants'* (deMunck and Sobo, 1998, p.43, cited in Kawulich, 2005) while also giving the possibility of documenting unscheduled events (Emerson, Fretz and Shaw, 2011). On the other hand, field notes guarantee a good ongoing record of the researcher's observational experience, which enhances the study's validity when combined with documents (DeWalt and DeWalt, 2011).

As part of the realist evaluation, document analysis aimed at reporting the PPI strategy designed and implemented by the PriDem programme team and the DCC members' perception of it. Though unconsciously, the collection of documents started very early in advance. Indeed, as soon as I began my Doctor of Philosophy (PhD) programme, it became necessary first, to acknowledge the purpose, aims and timelines of the PriDem programme; then, to discern among team members and their different roles; and finally, to capture their understanding and expectation on both PPI and my evaluation of the same. As the scope and the aim of the DemRI study became clearer, I began a more purposive and rigorous selection of documents by questioning their relevance (i.e., is the information included in this document relevant and appropriate to the purpose of the study?) and utility (i.e., are the knowledge claims useful and appropriate to the purpose of the study?) (Porter, 2007). The relevant and useful documents were uploaded on my NU Outlook OneDrive, where I could store and organise data, as per the data management plan (see Appendix F) approved by the NU FMS REC (Reference:10397/2018). This data collection process continued throughout 2019 (see Text box 2). An overview of all documents collected is provided in Table 5.

Text box 2. Document collection step-by-step

1. I secured myself access to the hard drive shared by members of the PriDem programme team
2. I started reading documents randomly, asking the team for clarifications on purpose and targeted audience
3. I created a list of hypothetical relevant documents based on the information required to define the architecture of the programme
4. I searched for documents discussing the involvement of the DCC in the PriDem programme and uploaded them on my OneDrive
5. I edited the hypothetical list of documents a couple of times as the study progressed
6. I organised the documents collected in a table, reporting details on content and development (i.e., when, why, and by whom the document was created)
7. I asked PriDem programme team members to confirm the update of the shared drive when close to the end of the data collection in Phase I
8. I reviewed the list of documents several times and updated the table developed in line with the changes applied

The documents meeting the criteria of relevance and appropriateness were also evaluated about attributes known for enhancing the quality and rigour of the research conducted (Bowen, 2009; Hodder, 2000). These attributes include *clarity* and *completeness,* so that team members could be promptly asked for clarifications while I was in the field. Moreover, *purpose*, *targeted audience*, and *solicitation* to provide additional details to the circumstances affecting the development of a document and the reasoning behind choices of factors such as format and language. Finally, the *author(s)* of the document to better discern among the PriDem programme team members responsible for the involvement of the DCC and the organisation of PPI activities. Evaluating documents by applying these attributes was not always a straightforward process and required a continuous update. Nevertheless, it broadened my understanding of the dynamic context within which the involvement of the DCC unfolded, making it possible for me to start the 'informed guesswork' that is deemed necessary for the development of hypotheses (Pawson, 2013) – referred to as candidate programme theories (CPTs) in this thesis. Following the completion of the data collection (i.e., December 2019), I screened all documents once again. At this stage, documents were excluded in case of duplication of the information multiple times. Additionally, some were further discussed with PriDem programme team members or the supervisory team as they elicited doubts or contrasted field notes. All the documents excluded were listed in a table explaining the reasoning behind their rejection to allow for continuous revision.

Alongside documents, the collection of observational data and field notes was crucial for the development of CPTs. These types of data enabled me to uncover aspects of the programme that were not reported via the documentation collected or, at least, not in a complete manner. Moreover, they made me identify discrepancies between peoples' intentions and behaviours, thus providing relevant information requiring further exploration. Furthermore, they helped me reflect on the unpredictability characterising the programme of interest and the diversity of how it was perceived among the people involved. I collected observational data throughout 2019 during DCC meetings that differed for several reasons (e.g., setting, format and attendees). Prior to all meetings, DCC members were informed about my presence on the day, and, as part of the meeting agenda, I always introduced myself to the attendees, reminding people about the purpose of my note-taking task and gaining oral consent before doing that. As such, my role as an observer was always 'uncovered' (DeWalt and DeWalt, 2011). However, my level of participation was 'moderate' (Spradley, 1980), as I tried to maintain a balance between being an insider and an outsider.

Observations were documented in a notepad that included 'jotted field notes', which helped me record information to include in the 'full-field notes' (Bryman, 2012) that were completed later the same day. The collection of field notes was informed by an observation chart (see Table 7, adapted from Spradley's, 1980, pp.37-80) that allowed me to identify key factors affecting the involvement dynamics at a particular time and place and differences and changes over time. The items included in this chart played a significant role in summarising the full-field notes written and identifying cases relevant to the development of CPTs. To enhance clarity and guarantee rigour, I documented reflective notes alongside the notes describing the meeting (DeWalt and DeWalt, 2011), thus writing down personal feelings, impressions, moments of discomfort, revelations, connections, and any other idea or query related to the programme of interest. This written record supported the analysis process, providing a framework to better understand the descriptive notes and encouraging reflection about my influence on them (Emerson, Fretz and Shaw, 2011).

Table 7. Observation chart

Item	Description
Place	Physical layout of the place
Actor	Range of people involved
Activity	Activities that people carry out
Object	The physical things that are present
Act	Single actions people undertake
Event	A set of related activities
Time	The sequencing of events that occur
Goal	Things that people are trying to accomplish
Feeling	Emotions felt and expressed

3.5.3 Stakeholders' views

Realist approaches are known for using different types of data to develop, support, refute, and refine PTs, as 'nuggets of information' can come from any source (Pawson, 2006b). A frequently employed non-documentary source of data is the consultation of stakeholders (Wong, 2018). In the literature, the term stakeholder has been defined differently, with further arguments around the purpose of their inclusion in the research process and the most adequate methods to do so (Abrams et al., 2020). In realist studies, the term 'stakeholder' generally refers to policy makers, commissioners, professionals and the public (Booth, Wright and Briscoe, 2018). Although the nature and level of involvement may vary, stakeholders are all considered 'content experts', as they are recognised to possess a certain degree of expertise about the content of the topic of inquiry (Wong, 2018). The advantages of including these experts in realist approaches to research lie in the possibility of gaining some additional interpretative lenses through which unearthing assumptions about the programme, finding relevant sources of information at a faster pace, and identifying or prioritising PTs (Booth, Wright and Briscoe, 2018; Wong, 2018). During Phase I, I engaged with several stakeholders to collect their views on the involvement of PLWD and family carers in PPI activities. The ultimate purpose of this involvement was to draw theoretical ideas from their insider knowledge, with particular focus on the contextual circumstances known for leading to the success or failure of PPI in dementia research. Among the stakeholders consulted, some were experienced in designing, implementing and evaluating PPI in dementia research (i.e., practitioners), while others were usually involved in related PPI activities (i.e., subjects of the programme), such as PLWD and family carers.

The consultations conducted at this stage of the DemRI study took place face-to-face in the context of research-related events, which I was able to attend with funds received by the Alzheimer's Society and NU (i.e., the funders and the host organisation of my PhD programme) (see section 3.9). On these occasions, a total of 14 stakeholders were consulted; among them, 8 were practitioners and 6 were subjects of the programme. With the exception of some introduced to me on the event day, I identified relevant stakeholders through their published work or their public engagement activities taking place locally or online. To gain their views on PPI in dementia research, I contacted stakeholders in advance, introducing myself and the study before inviting them to discuss my topic of inquiry at a day and time of preference during the event. The information gathered from these stakeholders was documented in a notepad and then transcribed on different Microsoft Word documents. The content of these documents was organised in a table (see Figure 10), which also included the inputs received by the public members contributing to this study during the preparatory and execution phases of the research cycle (see section 3.8.1). On some occasions, I also received additional contributions via email, with some stakeholders – 2 PLWD and 1 family carer – deciding to get involved in different ways in other phases of the realist evaluation. The notes taken from the conversations with stakeholders supported the data analysis process by allowing me to create the conditions for comparing contexts, identifying patterns of behaviour and changes, and developing and iteratively questioning CPTs.

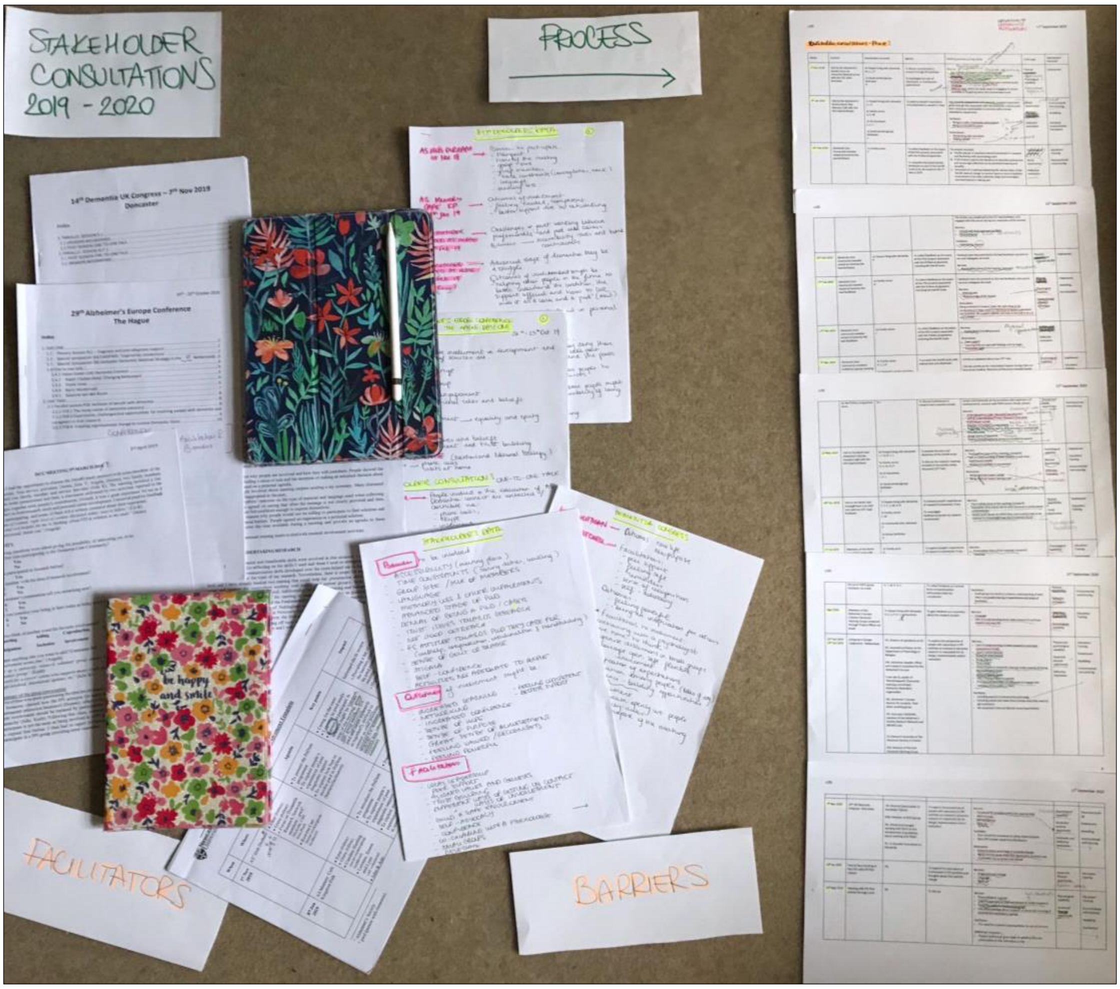

Figure 10. Phase I: Organising stakeholders' views for analysis

3.5.4 Data analysis

Initially, all the information collected from the different data sources (see Table 5) was organised and coded separately on paper (see Figure 11) to gain a clear understanding of the architecture of the programme (see Chapter 4). Once all the data was organised, and related narratives were developed, I was expected to upload this data on the NVivo software to proceed with the analysis using a realist coding framework. However, following discussion with supervisors and approval from the NU FMS Graduate School, this step was postponed until Phase II (see Appendix G), coinciding with the beginning of the first COVID-19-induced lockdown. At that time, there was little understanding about how long the lockdown would last and when or how I would have had access to the software outside university premises.

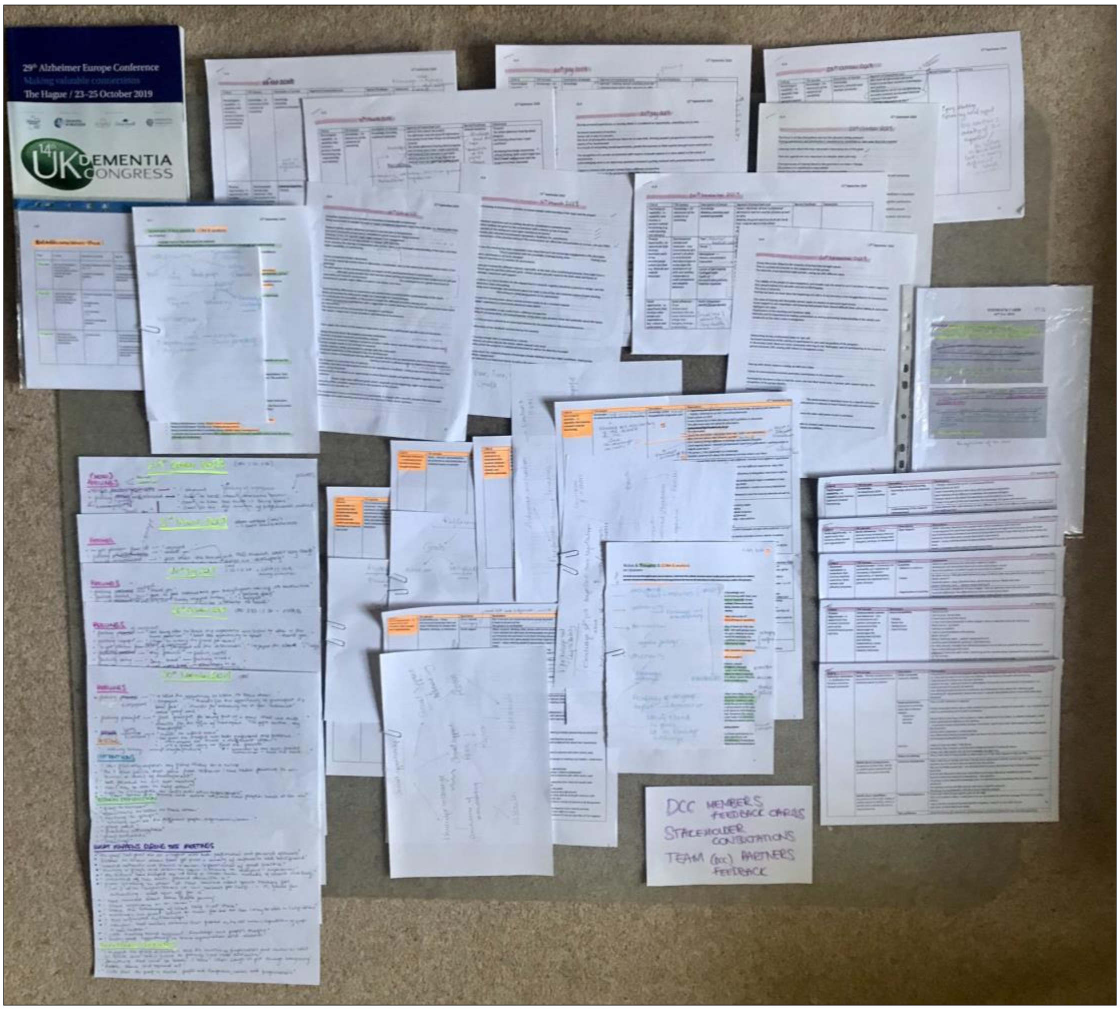

Figure 11. Phase I: Preliminary data analysis

After delineating the key characteristics of the programme’s architecture (see Chapter 4), I coded the feedback cards (n.80) filled in by DCC members in the aftermath of PPI activities, as they included information about the facilitators and barriers experienced during their involvement in the PriDem programme and the changes observed over time. Then, I reviewed them in relation to the field notes documenting the implementation of PPI activities across different settings (i.e., university venue, memory café and dementia hub) to identify cases that could reveal patterns or changes in patterns. Finally, I consulted the information obtained after exploring the experience of stakeholders consulted during Phase I, who shared with me the challenges experienced when using PPI in dementia research or participating in related PPI activities. After coding and schematically organise all this evidence in tables (see Figure 11), I started the CMOc mapping exercise. However, this came with two challenges: distinguishing between contexts, mechanisms and outcomes; and guessing the causal link connecting them all underneath. Indeed, as Pawson (2013) claims, *'programmes do not come with pre-determined ingredients called context, mechanisms and outcomes. Rather these terms take their meaning from their function in explanation'* (p.27).

The context of the programme, including the circumstances under which is implemented, is crucial to unpack the complexity characterising it (Greenhalgh and Manzano, 2021). Indeed, a fundamental assumption of realist evaluation is that *'programmes are complex interventions introduced into complex social systems'* (Pawson, 2013, p.33). Therefore, it is critical to uncover these systems and their related dynamics to understand how the programme works. The review of the literature exploring the conceptual understandings of PPI and its value within the context of dementia research prompted me to consider the advantages of exploring theoretical models of involvement rooted in democratic ideological principles (see section 2.5.1). Among these models, one, in particular, influenced the initial conceptualisation of PPI in this study, namely Wilcox's (1994) theoretical model of public participation. Wilcox (1994) argued that participation is a process wherein lay people, or lay groups, collaborate with other stakeholders for the achievement of the common good. Considering Arnstein's (1969) theorisation of public participation only in terms of hierarchical levels of power limited, Wilcox (1994) added another two dimensions: the phases of participation (i.e., initiation, preparation, participation and continuation), which define the stages experienced by its initiators; and the nature of stakeholders involved, which helps in discerning the differences in motivations and power interplays. According to Wilcox (1994), all these three dimensions are crucial to uncovering the dynamics characterising the context of participation and effectively addressing issues in practice.

By drawing on Wilcox's (1994) model of participation and Pawson's (2013) definition of the multi-layered context of a programme (see Table 2), I developed a diagram that organised all actors included in the programme of interest (i.e., research team members, PLWD, family carers and dementia care professionals) according to stages of involvement and circumstances possibly affecting their behaviour (see Appendix H). This diagram helped me question the data collected, in addition to the conceptual understandings of dementia and PPI discussed in chapters 1 and 2. Indeed, if on the one hand, the theoretical models of dementia explored (see section 1.4.2) warned me of the possibility that interactions among all actors involved could result from sharing divergent perspectives on dementia and their impact on people's lives, on the other hand, Clegg's (1989) and Starkey's (2003) theorisation of power and empowerment encouraged me to conceptualise these two causal forces as dynamic and affecting involvement at different and interconnected levels (e.g., individual and organisational system levels). This implies that there are implications for the interpersonal relations between the research team members and PLWD and family carers involved. Therefore, the focus of the context was narrowed down to the interactions characterising the process of involvement at different stages.

When the context of the programme became more apparent, I started looking for mechanisms that could represent a possible explanatory link between the contexts and the outcome of interest (i.e., the involvement of PLWD and their family carers in research through PPI activities). Mechanisms are known for being ‘hidden causal forces’ (Wong et al., 2016) that operate at a different ontological level than the outcome they generate (Mukumbang et al., 2020) (see Figure 9). Usually, they become more evident by investigating the ‘best prediction possible’ from observed behavioural patterns (Jagosh, 2020). Therefore, it was beneficial to have used qualitative methods of data collection, which promoted a deeper understanding of the programme in its own context and its due course. Nevertheless, the search for mechanisms came with the challenge of discerning between the contexts and resources responsible for activating the response desired from stakeholders (Jagosh et al., 2014; Marchal et al., 2012). By adopting Dalkin’s et al. (2015) CMOc analytical framework (see Figure 12, retrieved from Dalkin et al., 2015, p.4), I was able to better reflect on the mode of action of mechanisms, making a clear distinction between the context under which the research team members and the PLWD/family carers involved acted and the resources possibly impacting their reasoning.

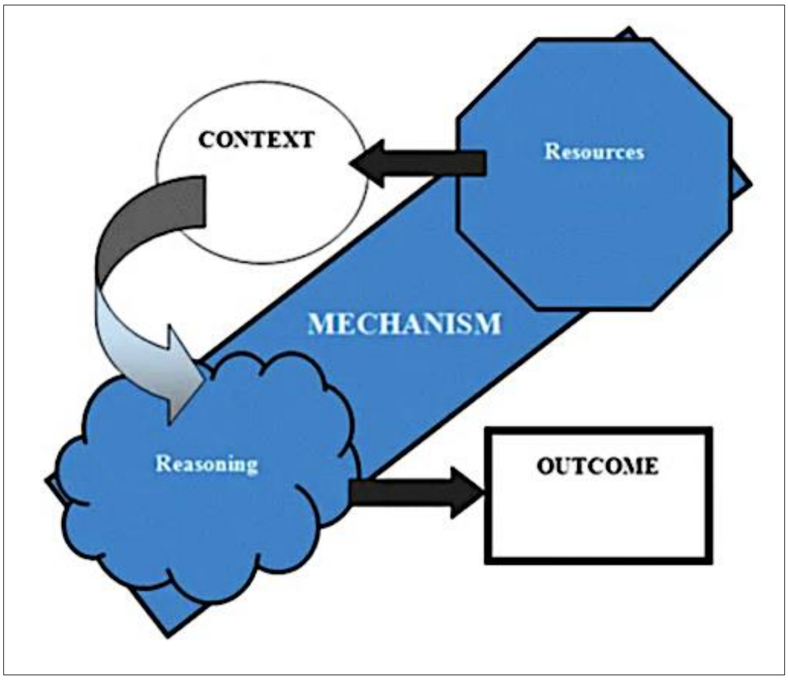

Figure 12. A CMOc framework, reproduced with permission from the corresponding author

Several mechanism-resources were identified from the data collected during Phase I. For instance, the programme's architecture revealed several strategies, which, as per the research team members, could lead to the sustainable involvement of PLWD and their family carers in the PriDem programme (e.g., flexible involvement and reflective approach to its implementation). Meanwhile, the feedback cards completed by DCC members attending PPI activities revealed some of the facilitators and barriers experienced, underscoring the changes over time and their impact on the level of engagement (e.g., relationship building linked to increased openness of fellow DCC members in PPI activities). However, these data on their own could not provide a complete view of the mechanisms leading to a successful implementation of PPI, which was supposed to be further explored by interviewing the participants of Phase I before the outbreak of the COVID-19 pandemic. To fill in gaps and fine-tune concepts, apart from the above-mentioned theoretical resources, I consulted some realist experts and used additional literature to question patterns identified in the data. For instance, I drew upon realist studies explaining the role of trust in participatory research (Jagosh et al., 2012; Jagosh et al., 2015) to understand under what circumstances and how it may affect the involvement of PLWD and family carers.

Finally, given the focus of the DemRI study and my understanding of involvement as a process characterised by different phases, the outcome of interest (i.e., the involvement of PLWD and their family carers in research through PPI activities) was intended as threefold:

the involvement of PLWD and family carers in the research process, their engagement in associated PPI activities, and their continuous involvement in the research process. However, conscious of the context being dynamic and open to change, I decided to explore the impact of the programme in a wider sense (i.e., on the research progress, on researchers and on DCC members), thus documenting the multiple outcomes resulting from the implementation of the PriDem programme's PPI strategy. The value of this additional step depended on the contribution it could provide in explaining how and why the context changed over time. Indeed, outcomes can become embedded in the context, triggering a specific mechanism, or becoming mechanisms themselves (Jagosh et al., 2015; Shaw et al., 2018).

The identification of contexts, mechanisms and outcomes and their organisation in CMOc took weeks while undergoing an iterative refinement process documented in a table continuously updated (see Table 8, adapted from Pawson and Manzano-Santaella, 2012, p.185). This process was supported by the organisation of CMOc within the 'open system' that researchers are expected to assume when evaluating a social programme (Pawson, 2013). Indeed, realists believe that programmes are characterised by causal properties that cannot just be reduced to the decision-making of the individuals targeted by the programme but lie in the interplay between individuals and institutions, agency and structure, and micro and macro-social processes (Westhorp, 2018). To draw conclusions without losing focus on this interplay, I followed Westhorp's (2012) suggestion on theory development, according to which the evaluation process can be facilitated by organising CMOc at different system levels: macro (i.e., infrastructure, institutional settings), meso (i.e., interpersonal), and micro (i.e., individual) levels. Doing so helped me overcome the overwhelming feeling caused by the volume of data collected, ensuring a certain level of coherence between contexts and relevant mechanisms when making theoretical claims. Moreover, it enabled me to move between system levels, recognising how CPTs, or their theoretical aspects (i.e., contexts, mechanisms and outcomes), could affect the dynamics and causal properties of different system levels (see Figure 13).

Table 8. CMO mapping table

Context (C)	+	Mechanism (M)		=	Outcome (O)
		Resources	*Reasoning*		
C_1	+	M_1	M_2	=	O_1
C_2	+	M_3	M_4	=	O_2
C_3	+	M_5	M_6	=	O_3

Figure 13. CMO pattern configurations

At the end of this analysis process, I had developed several CPTs, which were later discussed with my supervisors. To document the analytical thinking applied to the data and ensure transparency in decision-making, I organised all the CPTs in a table that included the CMOc and the 'if ... then' statement for each of them (see format in Table 9). The CPTs developed, and the contexts, mechanisms and outcomes defining them were numbered to maintain a temporal order so that I would be continuously encouraged to reflect on the changes to the system over time. Additionally, for each CPT, I included a column outlining the barriers that could have negatively affected the success of the programme if resources mentioned in that specific theory were absent or not enacted by the context. The content of the CPTs resulting from Phase I were then further refined during Phase II.

Table 9. Format of the table organising findings

Context (C)	+	Mechanism (M)		=	Outcome (O)	Candidate Programme Theory n.1	Potential Barriers
		Resources	*Reasoning*				
C_1 C_2		M_1	M_2		O_1 O_2	If … ($C_{1,2}$), then … (M_1) encourage … (M_2), leading to … ($O_{1,2}$).	List of barriers related to the contextual circumstances and relevant actors (i.e., PLWD, family carers, or research team).

3.6 Phase II: Stakeholder consultations

During Phase I, consultations with stakeholders were significantly explorative, as I particularly focused on understanding the nature of PPI and identifying the facilitators and barriers to the involvement of PLWD and family carers in PPI activities. During Phase II, I engaged with stakeholders to question the validity of the primary data collected and evaluate the relevance and appropriateness of the theoretical elements (i.e., contexts, mechanisms and outcomes) characterising the CPTs developed. To do so, I first created a framework describing the stakeholders' characteristics that were relevant for the achievement of Phase's II objectives (see Table 4). This framework included stakeholders identified among those having a role in the programme (i.e., DCC and PriDem programme team members) and public members agreeing to contribute to the DemRI study by sharing their PPI experience. The public members referred to here include the PhD PPI advisor, who joined the supervisory team in 2020 (see section 3.8.1), and members of well-established groups contributing to research: the NU VOICE[13] Research Support Group, the 3 Nations Dementia Working Group[14] (3NDWG), the Dementia Engagement and Empowerment Project[15] (DEEP) Group, and the Dementia Voice[16] Local Groups.

3.6.1 Stakeholders involved

Throughout November 2020, I consulted 23 stakeholders, 7 of which contributed to the DemRI study as part of a group discussion (see Table 10). The stakeholders involved had varying experiences of PPI, with some – primarily researchers or DEEP group members – often being at the driving seat of research and others having ideas about how to deal with the challenges they had faced when contributing to the research process alongside researchers. Additional differences were related to individual contextual circumstances. For

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[13] https://www.voice-global.org
[14] https://www.3ndementiawg.org
[15] https://www.dementiavoices.org.uk/about-deep/
[16] https://www.alzheimers.org.uk/get-involved/dementia-voice/local-groups

instance, among the Phase I research participants, some were responsible for organising PPI activities and coordinating the involvement of PLWD and family carers across settings and over time (i.e., PriDem programme PPI lead and DCC coordinator), while others facilitated group discussions held at the university venue (i.e., facilitators of PPI activities) or participated in them (i.e., dementia care professional). Consequently, they had different knowledge and understanding of the needs of the PLWD and the family carers included in the DCC. On the other hand, many similarities were found among stakeholders involved due to their background, that is, their lived experience of PPI. This was especially true concerning the practical challenges of getting involved, which, for PLWD and family carers, also entailed those related to the impact of dementia on their daily lives.

Table 10. Phase II: Sampling framework and number of stakeholders consulted

Characteristic	Rationale	Category	n.
Participants Phase I	- To question the validity of primary data collected - To test the appropriateness of the CMOc and related PTs - To inform the development of new CMOc if necessary	PriDem programme PPI lead[1] DCC coordinator[1] Facilitators of PPI activities[1] Family carers[2] Dementia care professional[2]	1 1 2 3 1
Background knowledge	- To investigate different contexts - To provide opportunities for comparing contexts - To reflect on interaction dynamics and relevant barriers - To clarify uncertainties about the CMOc developed	PLWD Family carers VOICE members PhD PPI advisor	4 3 7 1

[1]PriDem programme team members
[2]DCC members

3.6.2 *Process of consultation*

The consultation process began with an invitation email, which I personally sent only to the PriDem programme team members of interest. The DCC and other groups' members were reached via an email forwarded by their group facilitators (see example in Appendix I). With the exception of VOICE members, stakeholders interested in getting involved communicated directly to me their preferences about when (i.e., date and time within a three-week window) and how (i.e., phone call, zoom call, or email exchange) to proceed with the consultation. In addition to DCC and PriDem programme team members, I was familiar with a few other stakeholders interested in contributing to the DemRI study. In particular, 2 members of VOICE who were included in a group consultation I organised in July 2019 to obtain feedback on the recruitment material developed for the data collection during Phase I. Additionally, 1 member of the 3NDWG who contributed to creating a lay summary for the progress report submitted to the study funders (i.e., Alzheimer's Society) in September 2019 (see Appendix J). Finally, 3 members of the 3NDWG and 2 members of the DEEP group who were among the stakeholders consulted in Phase I.

Once arrangements about when and how were made, I would send stakeholders a PowerPoint presentation, which included various statements and associated questions informed by the CPTs developed at the end of Phase I. The consultation aimed at exploring stakeholders' personal relevance to the statements and encouraging them to reflect on how and why the key aspects of involvement identified were relevant, if at all. The formulation of the statements and the language used changed slightly, depending on the type of stakeholder and their characteristics (i.e., role in the programme and background) (see PowerPoint samples in Appendix K). Before using the material for consultation purposes, I sought feedback on relevance and clarity from both supervisors and the PhD PPI advisor. I also incorporated a few alterations as the consultations unfolded, considering stakeholders' insights on the language used. Within two days from the consultation, I sent an email including a summary of the conversation for review. This allowed stakeholders to edit my notes, expand any point, or add comments if they wanted. All stakeholders were consulted on a one-to-one basis, except for 7 VOICE group members who participated in a group discussion and a couple (i.e., a person living with dementia and their wife and full-time carer) who asked to participate together. Whilst most stakeholders chose to be consulted via Zoom video call, 2 opted for a phone call owing to limited mobile data and fatigue associated with overusing virtual communication platforms as a consequence of the COVID-19-induced restrictions.

3.6.3 Data analysis

After engaging with stakeholders, I reviewed all the summaries created and the additional comments received via email to identify similarities and differences. I then began to analyse data from Phase I again, adding or editing some of the initial theoretical elements and highlighting changes by using a colour-coding system. This enabled me to organise the inputs received by stakeholders based on the relevant CMOc and reflect further on the CPT it informed. Throughout the refinement process, my supervisors encouraged me to explore the tensions arising among experiences documented, reflecting on whether to include them into the theoretical model developed and how best to do so. Experts in scientific realist methodology advised me to continue reviewing relevant theoretical literature to provide a robust conceptual ground for theoretical claims and avoid drawing conclusions lacking novelty or plausibility and coherence, which are two key principles defining rigorous realist research (Wong, 2018). At the end of this refinement process, I developed 10 CPTs, which informed the list of questions for collecting additional primary data in Phase III and the coding system initially employed to analyse them. At the end of Phase ll, I sent a summary to all stakeholders consulted, detailing the process they had participated in and explaining the cumulative impact of the contribution given to the study. In addition to informing them about the next steps of the research study, I asked them to provide feedback on their experience of involvement in the DemRI study by contacting me or clicking on a link that allowed them to provide anonymous comments (see Appendix L). All members of the DCC were also provided a separate update via its inclusion in the bi-monthly newsletter so that those involved in Phase I had not ambiguity on the progress of the study (see Appendix M).

3.7 Phase III: Realist interviews

The CPTs developed at the end of Phase II represented a set of ideas about what could potentially work, for whom, how, under what circumstances and why, when involving PLWD and family carers in PPI activities. In Phase III, I drew on realist interviews and a re-assessment of all information collected till then to confirm, refute, or further refine these ideas. This phase of the DemRI study was conducted while the UK was under the restrictions of the COVID-19-induced third lockdown, which the UK Government announced on 4th January 2021. Therefore, data collection took place at a distance, giving those interested the possibility to participate safely.

3.7.1 Recruitment

Realist interviews entail a qualitative approach to data collection, as people's experiences are explored through conversations (Manzano, 2016); however, they are different in terms of purpose because the data obtained are not considered constructions of reality but *'evidence for real phenomena and processes'* (Maxwell, 2012, p.103). It is for this reason that the sampling strategy employed for the recruitment of research participants requires a purposeful approach that identifies information-rich participants (Manzano, 2016). Against this backdrop, I developed a sampling framework that considered both the PPI experience required to test the CPTs developed and the roles of participants in the programme (i.e., practitioners and subjects of the programme). As such, the initial sample included PPI leads (i.e., practitioners) identified through their professional role or published works and PLWD and family carers (i.e., subjects of the programme) chosen amongst stakeholders during Phase I and Phase III or recruited via the facilitators of pre-established groups, such as the NU VOICE Research Support Group and the 3NDWG.

When it comes to realist evaluation, there is no ideal number of participants that can be assumed beforehand (Pawson, 2013). The sample size is usually defined by the criteria shared with qualitative research – completeness and saturation (Corbin and Strauss, 2008) – and those proper of realist research, such as relevance and rigour built upon a multi-method approach to theory development and refinement (Emmel, 2013; Pawson, 2013). With this in mind, I considered a range of 12 to 15 participants before commencing recruitment, trying to balance between the possibility of gaining richer findings in theory-based interview studies (Francis et al., 2010) and my capacity to conduct interviews within the timeframe and resources of a PhD programme conducted during a pandemic. The recruitment process began on 28th January 2021 with a standard invitation email, including the participation information sheet and the consent form as an attachment (see Appendix N). Those evincing their interest in participating in the study were provided with the interview schedule (see Appendix O) and invited to choose how to be interviewed (i.e., via phone call or Zoom/Microsoft Teams call/videocall) and when. Once these arrangements were made, I would ask them to familiarise themselves with the material shared and get in contact if they had any queries about its content or the interview process in general.

The participants recruited for Phase III were 15: 7 PPI leads, 3 PLWD and 5 family carers. 12 of these participants were interviewed during the first round of interviews (i.e., February 2021); 3 additional participants were recruited when the initial analysis on the transcripts obtained till then had been conducted (i.e., April 2021). As such, the recruitment strategy adopted in Phase III was not only ‘theory laden’ (Emmel, 2013) but ‘progressively purposeful’ (Patton, 2015). Table 11 lists all participants in order of interview, organising them per role in the programme (i.e., subject of the programme and practitioner) and participant categories (i.e., PPI leads, PLWD and family carers). The names mentioned in the table are pseudonyms, except for the PLWD (i.e., Eric, Jim and Kevin) and 2 family carers (i.e., Alan and David) who insisted I use their real name, arguing about the value of maintaining confidentiality in the context of the DemRI study. Some of these participants had contributed to previous phases as well. In particular, 3 family carers and 1 person living with dementia were stakeholders in Phase II; 2 family carers were participants in Phase I; 1 family carer and 1 person living with dementia were recruited through the gatekeepers of two of the pre-established groups included in Phase II (i.e., the NU VOICE Research Support Group and the 3NDWG); and finally, 2 PPI leads were identified by Phase III participants.

Table 11. Phase III: Sampling framework and participants interviewed

Interviewee	Role in the programme	Category
Round I: February 2021		
Grace	Subject of the programme	Family carers
Sophie	Practitioner	PPI leads
John	Practitioner	PPI leads
Eric	Subject of the programme	PLWD
Olivia	Practitioner	PPI leads
Lisa	Practitioner	PPI leads
Jim	Subject of the programme	PLWD
Patrick	Subject of the programme	Family carers
Emma	Subject of the programme	Family carers
Emily	Practitioner	PPI leads
Alan	Subject of the programme	Family carers
Barbara	Practitioner	PPI leads
Round II: April 2021		
Kevin	Subject of the programme	PLWD
David	Subject of the programme	Family carers
Hannah	Practitioner	PPI leads

3.7.2 Data collection

Realist interviews are different from qualitative interviews in the way they aim to test theoretical ideas by assisting participants in making sense of them through their own experience (Mark, Henry and Julnes, 1999). Therefore, the researcher's objective is not to elicit participants' narratives but to unearth PTs by capturing their stories (Patton, 2015). To do so, the researcher should engage with participants in a conversation that adopts a 'teacher-learner' approach, which entails an exchange of roles throughout the interview (Manzano, 2016). Conducting this type of interview necessitates a good understanding of realist methodology and clarity on theoretical elements and CMOc to test (Manzano, 2016).

For this reason, I developed an interview schedule, wherein questions were informed by the realist evaluation 'starter set' of questions (Greenhalgh et al., 2019b) though made more specific to the theories to test and the participants to interview (see Appendix O). Additional contributions were also made by supervisors and realist researchers participating with me in an online, three-day course led by Dr Justin Jagosh on behalf of the Centre for Advancement in Realist Evaluation and Synthesis[17] in December 2020. All the questions formulated were semi-structured to facilitate further exploration of participants' views, if necessary, as the emergence of unanticipated contexts, mechanisms and outcomes could not be excluded (Pawson, 2013). Prior to data collection, minor changes to the questions' wording and flow were also incorporated after discussing the interview schedule with a person living with dementia and their family carer who had contributed to the DemRI study by becoming stakeholders in Phase II.

Despite the presence of alternatives, all research participants preferred a Zoom videocall, and most of them were comfortable with receiving an e-form of the interview schedule. I was asked to send the material via both email and post only on one occasion. The day before the interview, research participants were notified by an automatic email that reminded them about the upcoming Zoom meeting. On the day of the interview, the conversation would begin with an introduction of myself, the study's aims and progress, and the interview purpose and process. After clarifying doubts, if any, I would start recording the conversation with participants' consent. Before moving ahead with the interview schedule, I would read the consent form and record their oral consent. As done in Phase II, a PowerPoint presentation was created to facilitate the exchange of information remotely and to maintain the focus on the questions, limiting the possibility of going off-topic. The type of approach adopted to questioning participants was 'progressively purposeful' within and across interviews, thus making the refinement and consolidation functions of realist interviews explicit (see example in Table 12, adapted from Manzano, 2016, pp.353-354). The average duration of a videocall was 66 minutes, including introductory questions to gain consent and debrief post-interview.

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[17] https://realistmethodology-cares.org

Table 12. Example of progressive purposeful questioning

Interviewee	Interviewer's transcript fragments	Logic
John (PPI lead)	1. How, if at all, do you think that an early engagement with members of the public, or people living with dementia and their family carers in this specific case, influences decision-making about ways of involvement?	Exploring mechanism Testing mechanism
	2. You just said if possible. What do you think are the circumstances under which it is possible, or it is not?	Exploring context
	3. You mentioned that it might have an impact in the long run in terms of relationship with them and [the] type of partnership that is going to be built. Do you think that it might also have an impact on how, from a researcher perspective, decisions are made about the involvement approach? Why?	Testing outcome Exploring mechanism
Eric (Person living with dementia)	1. How would you feel about being involved in a way that is adaptable to your preferences and changing needs or priorities? Would that affect your involvement? How?	Exploring mechanism Testing outcome
	2. You mentioned time as one of the key factors. Could you be a bit more specific about what the team asked you [in that involvement occasion]? I mean, what [does] time stands for?	Exploring context
	3. I liked the example that you gave about the hearing loop. So, the team replied saying they were able to make that happen. And how did you feel about that? Did that have an impact on your decision to be involved? How?	Exploring mechanism Testing outcome
Emma (Family carer)	1. When you're invited to participate in a group meeting, do you prepare for it? Does the research team help you prepare, for example, by sending some material in advance? How does being prepared affect you and your participation in group meetings?	Exploring mechanism Exploring outcome
	2. In the example that you just gave seems like if you don't receive anything, you won't be able to contribute as perhaps you would have otherwise. Am I right? Why is that?	Testing outcome Exploring mechanism
	3. I understand now. Thanks. And I wonder whether in similar situations people might also be discouraged from going to the meeting in the first place. What do you think? Has it ever happened to you?	Testing outcome

3.7.3 Data analysis

All the recordings obtained were transcribed verbatim and then compared to the automatic transcription provided by the Zoom and Otterai software, which supported the verification of the content. All the transcripts, along with related recordings, were uploaded and stored on the NVivo 12 software (version 11.4). The interviews transcribed were then analysed using a theory-driven thematic approach (Gilmore et al., 2019), with an evolving coding system, which was initially based on the CPTs resulting from Phase II and subsequently, on refined or emerging themes as the analysis progressed. The coding process started on paper and was conducted alongside the collection of data to reflect upon my approach to questioning and identify aspects of theories necessitating further exploration. A colour coding system was developed to identify relevant data units for extraction (see Figure 14). Each colour would correspond to a theme (i.e., CPT) and distinctions among codes (i.e., contexts, mechanism-resources, mechanism-reasoning and outcomes) were noted on the text, along with comments for further reflection within and across transcripts.

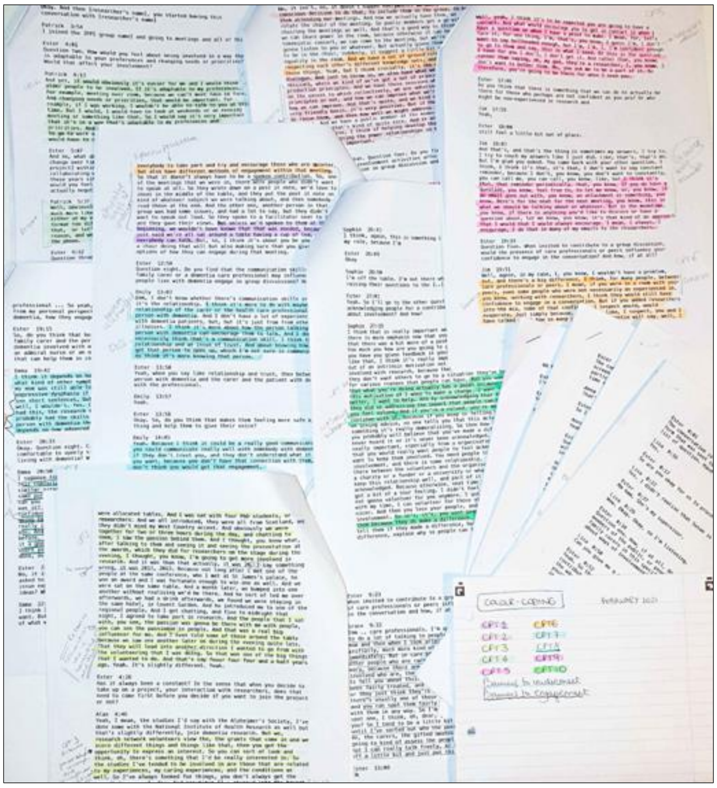
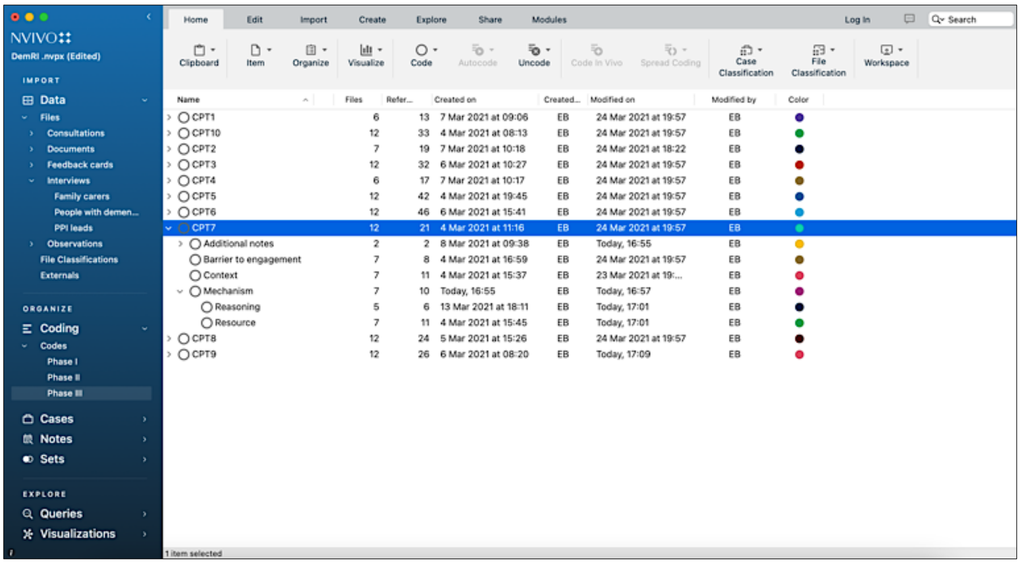


Figure 14. Preliminary analysis of interview transcripts

When the first round of interviews was concluded, I started coding on NVivo (see Figure 15), whose use in realist research has been increasingly encouraged, because it can help guarantee rigour and transparency (Dalkin et al., 2021). As the analysis progressed, I uploaded all the data stored till then on the NVivo 12 software, thus making it easier for me to proceed with an iterative process of theory refinement that included all the data collected during the DemRI study. The PTs resulting from this analysis process were discussed with supervisors, who were provided beforehand with a report that included the content of the NVivo memos created to document theoretical changes and rationale for decision-making (see Table 13, adapted from Gilmore et al., 2019, p.7). Finally, I tested PTs against the entire dataset, including in the analysis all the data previously collected and assessing them by using the latest version of the coding system. As a result of this additional round of analysis, I made several changes to the theories, all of which were documented on the NVivo memos initially created by using two font colours: red and purple (see Figure 16). The red indicated the introduction of a new theoretical element, while the purple highlighted changes finalised to enhance clarity.

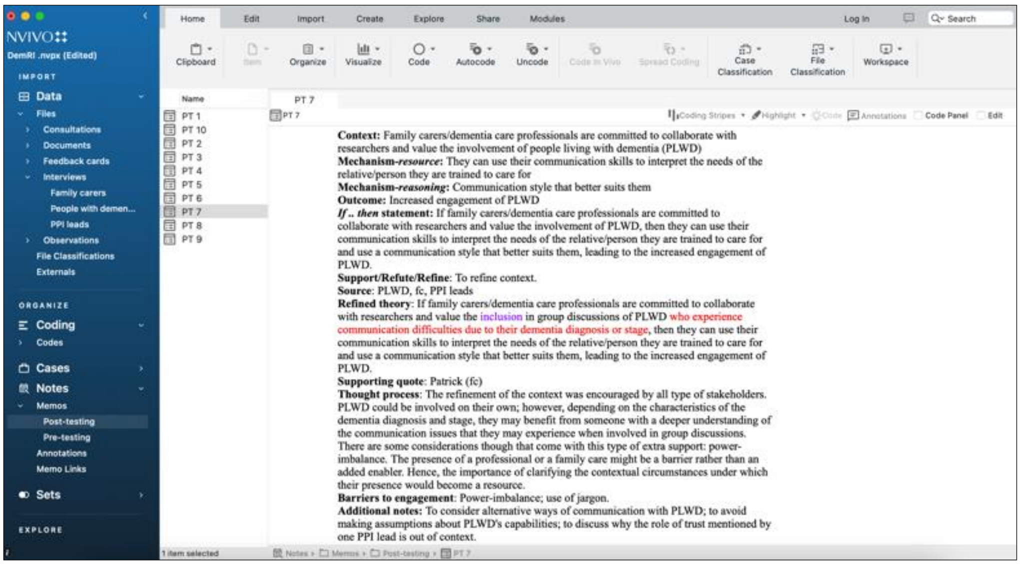


Name	Files	Refer...	Created on	Created...	Modified on	Modified by	Color
CPT1	6	13	7 Mar 2021 at 09:06	EB	24 Mar 2021 at 19:57	EB	●
CPT10	12	33	4 Mar 2021 at 08:13	EB	24 Mar 2021 at 19:57	EB	●
CPT2	7	19	7 Mar 2021 at 10:18	EB	24 Mar 2021 at 18:22	EB	●
CPT3	12	32	6 Mar 2021 at 10:27	EB	24 Mar 2021 at 19:57	EB	●
CPT4	6	17	7 Mar 2021 at 10:17	EB	24 Mar 2021 at 19:57	EB	●
CPT5	12	42	4 Mar 2021 at 19:45	EB	24 Mar 2021 at 19:57	EB	●
CPT6	12	46	6 Mar 2021 at 15:41	EB	24 Mar 2021 at 19:57	EB	●
CPT7	12	21	4 Mar 2021 at 11:16	EB	24 Mar 2021 at 19:57	EB	●
Additional notes	2	2	8 Mar 2021 at 09:38	EB	Today, 16:55	EB	●
Barrier to engagement	7	8	4 Mar 2021 at 16:59	EB	24 Mar 2021 at 19:57	EB	●
Context	7	11	4 Mar 2021 at 15:37	EB	23 Mar 2021 at 19:...	EB	●
Mechanism	7	10	Today, 16:55	EB	Today, 16:57	EB	●
Reasoning	5	6	13 Mar 2021 at 18:11	EB	Today, 17:01	EB	●
Resource	7	11	4 Mar 2021 at 15:45	EB	Today, 17:01	EB	●
CPT8	12	24	5 Mar 2021 at 15:26	EB	24 Mar 2021 at 19:57	EB	●
CPT9	12	26	6 Mar 2021 at 08:20	EB	Today, 17:09	EB	●

Figure 15. Preliminary coding on NVivo

Table 13. NVivo memo content

Memo element	Content
CMOc	Formula used to link theoretical elements
CPT statement	Theory at a pre-testing stage
Support/Refute/Refine	Decision made following analysis of interviews
Source	Category that has encouraged the refinement
Refined theory	Theory post-refinement
Thought process	Reasoning behind refinement
Supporting quote(s)	Quotes explaining the theory
Barriers	Related to involvement and engagement
Additional notes	Queries or links to phases I and II



Context: Family carers/dementia care professionals are committed to collaborate with researchers and value the involvement of people living with dementia (PLWD)
Mechanism-*resource*: They can use their communication skills to interpret the needs of the relative/person they are trained to care for
Mechanism-*reasoning*: Communication style that better suits them
Outcome: Increased engagement of PLWD
***If .. then* statement:** If family carers/dementia care professionals are committed to collaborate with researchers and value the involvement of PLWD, then they can use their communication skills to interpret the needs of the relative/person they are trained to care for and use a communication style that better suits them, leading to the increased engagement of PLWD.
Support/Refute/Refine: To refine context.
Source: PLWD, fc, PPI leads
Refined theory: If family carers/dementia care professionals are committed to collaborate with researchers and value the inclusion in group discussions of PLWD who experience communication difficulties due to their dementia diagnosis or stage, then they can use their communication skills to interpret the needs of the relative/person they are trained to care for and use a communication style that better suits them, leading to the increased engagement of PLWD.
Supporting quote: Patrick (fc)
Thought process: The refinement of the context was encouraged by all type of stakeholders. PLWD could be involved on their own; however, depending on the characteristics of the dementia diagnosis and stage, they may benefit from someone with a deeper understanding of the communication issues that they may experience when involved in group discussions. There are some considerations though that come with this type of extra support: power-imbalance. The presence of a professional or a family care might be a barrier rather than an added enabler. Hence, the importance of clarifying the contextual circumstances under which their presence would become a resource.
Barriers to engagement: Power-imbalance; use of jargon.
Additional notes: To consider alternative ways of communication with PLWD; to avoid making assumptions about PLWD's capabilities; to discuss why the role of trust mentioned by one PPI lead is out of context.

Figure 16. NVivo memo post-testing phase

After the second round of interviews (i.e., April 2021), I reviewed the analysis carried out thus far once again. On this occasion, I made additional changes documented by using the aforementioned colour-coded system but adding a different font colour – green – to indicate the editing resulting from a synthesis of the entire dataset, thus leading to the consolidated version of the PTs. The changes affecting the formulation of theories throughout the three phases of the DemRI study (see overview in Appendix P) were documented in a report, which was updated and discussed with supervisors continuously. Once completed the data analysis of Phase III, I informed the stakeholders consulted in Phase II and the participants of Phase III about the study's progress and the plan for the following months (see Appendix Q). I also contacted the facilitators of the groups whose members had contributed to this study either in Phase I or II, inquiring about the best ways to give an update. The DCC coordinator and the dementia hub facilitator requested the content for a newsletter to upload online or send via post to those preferring a printed copy (see Appendix R and Appendix S). The facilitator of the memory café communicated to me the preference of group members to be called on their mobile phone for an update. Finally, the facilitator of the NU VOICE Research Support Group asked me to fill in an online form that would be made available to group members.

3.8 Patient and public involvement in the DemRI study

PPI was not merely the focus of the DemRI study, as I employed it throughout the realist evaluation conducted, documenting the design and implementation strategies as an ongoing process. This process involved regularly reflecting on the purpose and value of PPI at a particular stage of the study, organising PPI activities in advance and reporting related outputs, key lessons learnt and impact as the research progressed. The entire process was underpinned by Gibbs' (1988) reflective cycle, which became very valuable, aligning with the UK's 'Support and Learning' Standard for PI in research (NIHR, 2019a). Considering the aforementioned INVOLVE's (2014) research cycle (see Figure 1), I can confirm that, PPI activities were carried out at each stage of the cycle, except for 'implementation'. In the following paragraphs, I detail the background, design and conduct of PPI adopting Shippee's et al. (2015) framework, which organises research in three phases: the preparatory phase (see Figure 17), the execution phase (see Figure 18), and the translation phase (see Figure 19). The GRIPP2 checklist (Staniszewska et al., 2017) informed the content of this section, which does not include the narrative about the consultations with PLWD and family carers had in phases I and II, as already discussed in sections 3.5.3 and 3.6.

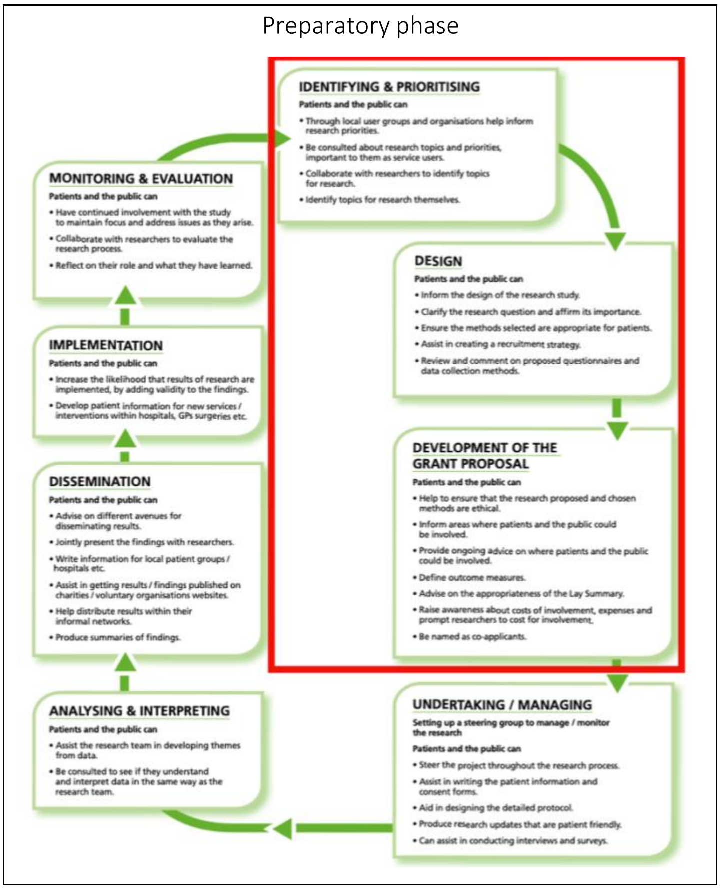


Figure 17. Preparatory phase of the research cycle

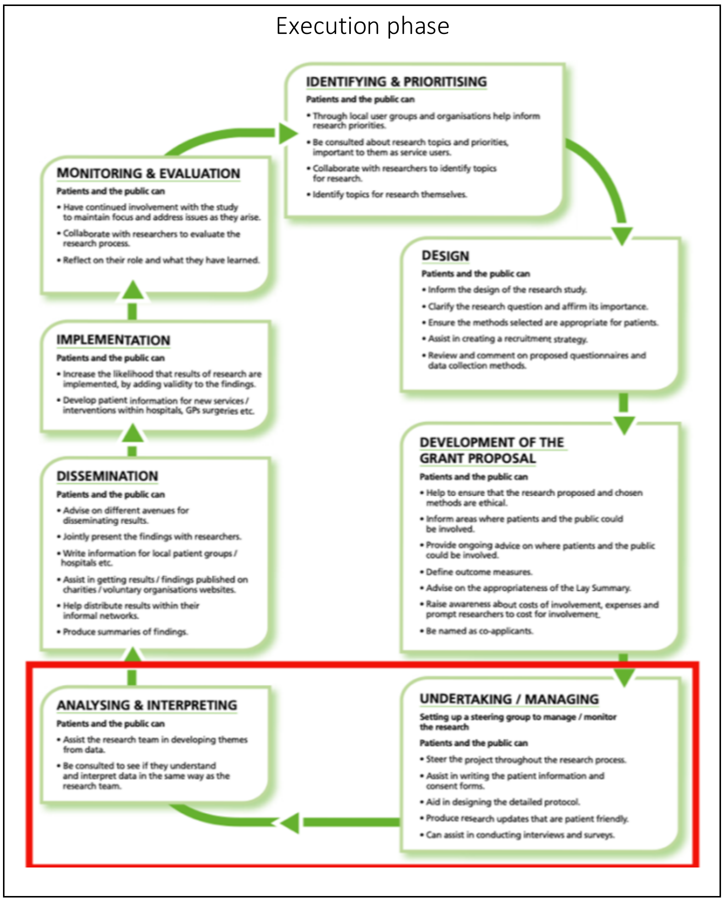
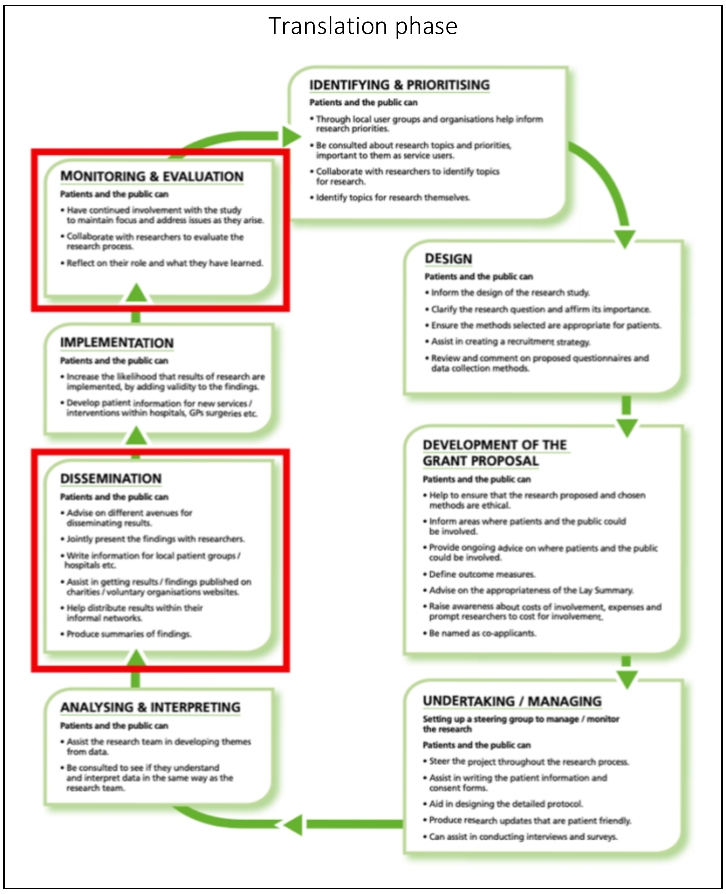


Figure 18. Execution phase of the research cycle


Translation phase

IDENTIFYING & PRIORITISING

Patients and the public can

- Through local user groups and organisations help inform research priorities.
- Be consulted about research topics and priorities, important to them as service users.
- Collaborate with researchers to identify topics for research.
- Identify topics for research themselves.

DESIGN

Patients and the public can

- Inform the design of the research study.
- Clarify the research question and affirm its importance.
- Ensure the methods selected are appropriate for patients.
- Assist in creating a recruitment strategy.
- Review and comment on proposed questionnaires and data collection methods.

DEVELOPMENT OF THE GRANT PROPOSAL

Patients and the public can

- Help to ensure that the research proposed and chosen methods are ethical.
- Inform areas where patients and the public could be involved.
- Provide ongoing advice on where patients and the public could be involved.
- Define outcome measures.
- Advise on the appropriateness of the Lay Summary.
- Raise awareness about costs of involvement, expenses and prompt researchers to cost for involvement.
- Be named as co-applicants.

UNDERTAKING / MANAGING

Setting up a steering group to manage / monitor the research

Patients and the public can

- Steer the project throughout the research process.
- Assist in writing the patient information and consent forms.
- Aid in designing the detailed protocol.
- Produce research updates that are patient friendly.
- Can assist in conducting interviews and surveys.

ANALYSING & INTERPRETING

Patients and the public can

- Assist the research team in developing themes from data.
- Be consulted to see if they understand and interpret data in the same way as the research team.

DISSEMINATION

Patients and the public can

- Advise on different avenues for disseminating results.
- Jointly present the findings with researchers.
- Write information for local patient groups / hospitals etc.
- Assist in getting results / findings published on charities / voluntary organisations websites.
- Help distribute results within their informal networks.
- Produce summaries of findings.

IMPLEMENTATION

Patients and the public can

- Increase the likelihood that results of research are implemented, by adding validity to the findings.
- Develop patient information for new services / interventions within hospitals, GPs surgeries etc.

MONITORING & EVALUATION

Patients and the public can

- Have continued involvement with the study to maintain focus and address issues as they arise.
- Collaborate with researchers to evaluate the research process.
- Reflect on their role and what they have learned.

Figure 19. Translation phase of the research cycle

3.8.1 *PPI in practice*

At the preparatory phase of the DemRI study (see Figure 17), while working on the protocol, I discussed the focus of the research and its aims with 5 PLWD members of the Durham-based Alzheimer's Society Focus on Dementia Network. At the time, this group's members would meet monthly to explore research involvement initiatives and contribute to studies funded by the Alzheimer's Society in the capacity of PPI contributors. On 1st November 2018, I participated in one of their meetings to discuss with the PLWD attending their experiences of participation in PPI activities. While experiences did vary, with someone being new to the role of PPI contributor, all the PLWD present recognised the need for more inclusivity in research, thereby supporting the purpose of my study. However, they encouraged me to reflect on the different needs that PLWD and family carers may have, thus prompting me to consider alternative methods of involvement to prevent challenging the participation of peers in the DemRI study. They also advised me about ways of accessing local PLWD in the future, giving some tips based on their past experiences. As part of the preparatory phase, on 8th January 2019, I also interacted with PLWD and family carers gathering monthly at a memory café operated by Alzheimer’s Society’s staff and volunteers. This meeting, which was held in the community room of a local store, included 3 PLWD and 3 family carers with whom I discussed recruitment and data collection strategies included in the first draft of the research protocol. Most people attending that meeting had little experience of PPI, thus giving me an opportunity to overcome assumptions, explore personal perceptions and needs, and identify ways of increasing accessibility and inclusivity.

As the study had already received funds because it was embedded in the PriDem programme, no PPI activity was aimed at securing support on the grant proposal, which is one of the other steps included in the INVOLVE’s (2014) research cycle. However, I found it useful to reach out to public members to develop a lay summary of the study. In September 2019, one year after commencing my PhD programme, I was expected to submit the first research progress report to the funders of this study (i.e., Alzheimer’s Society) to detail its design and aims whilst also informing about the progress achieved thus far. To develop the lay summary for its inclusion in the report, I sought help from members of the 3NDWG, which I discovered during the Alzheimer’s Society Annual Conference hosted in London in May 2019. After contacting the group’s facilitator via email, I was asked to submit my contact details along with a summary for review, with the possibility of receiving answers within three weeks. People willing to contribute were allowed to do so by sending an email or filling in an anonymous blank text box they could access by clicking on a link sent to them. On that occasion, I received 6 anonymous comments and 2 emails with suggestions for improvement. I then discussed the ultimate version of the lay summary (see Appendix J) with supervisors for further refinement and provided it to the 3NDWG’s members with an overview of the comments received and the list of changes applied subsequently.

At the execution phase of the DemRI study (see Figure 18), I involved different public members at different stages of the research cycle. For instance, on 5th March 2019, the PriDem programme team allowed me to discuss with DCC members the details of the research strategy before starting data collection. The meeting, which was held at the NU Biomedical Research Building based at the Campus for Ageing and Vitality, included 5 family carers, 2 of which were new to PPI. After delivering a succinct presentation introducing myself and the study, I provided group members with some materials to reflect on the research journey ahead of me and explore ways of ensuring the participation of the population of interest. Before its use, the material had been reviewed by supervisors who had contributed towards making it more accessible and feasible for the time allocated – 20 minutes. As some PLWD and family carers members of the DCC were unable to participate, a copy of the activity was sent to them by the DCC coordinator, along with some instructions I had written to explain how to complete it. I also provided my contact details to give further assistance or clarification, if required. Following that meeting, I developed a summary of the contribution received, along with a reflective piece of writing, which I discussed with supervisors and the PriDem programme team members during a monthly meeting.

Another PPI activity included at the execution phase of the DemRI study is the face-to-face meeting I had with 7 members of the NU VOICE Research Support Group on 3rd July 2019. The meeting aimed at gaining feedback on the Phase I recruitment material, which was sent to them a couple of weeks before for the purpose of review. On the day of the meeting, some attendees handed me a printed copy of the documentation sent to them, including notes written at the margin of the text; others decided to share their thoughts and suggestions for improvement orally. Following the contribution received on that occasion, several format and content-related changes were made to the participation information sheet and the consent form. Additionally, a letter of invitation was added to the recruitment material and included in the ethics amendment submitted in late July 2019 to the NU FMS REC. A couple of weeks later, I provided VOICE members who had contributed to this stage with a document summarising the inputs received and explaining their impact on the recruitment material ultimately developed. I adopted a similar approach with VOICE members who accepted my invitation to participate in a remote group discussion during Phase III. On 3rd March 2021, I was given the opportunity of discussing with some public members the doubts arising from the analysis conducted on the Round I interviews (i.e., February 2021). As done during Phase II, before the day of the meeting, I sent attendees a one-page document providing key information about the study and its progress to then, along with a PowerPoint presentation that included questions for discussion. On the day of the meeting, a total of 7 public members participated in the Zoom video call, 4 of which had an experience of involvement in dementia studies. On this occasion as well, people participating in the PPI activity were sent a report summarising process, outputs and impact of their involvement, along with information about future research steps.

About a year into the execution phase, after receiving suggestions from one of my supervisors – Dr Susan Moloney – I adopted an innovative approach to PPI by including a member of the public in the PhD supervisory team: Dave Green[18]. I was introduced to Dave via email and met face-to-face for the first time on 12th January 2020 to discuss the details of the project and his role as PhD PPI advisor. However, given the COVID-19 pandemic outbreak and its impact on this study and our lives, we had little opportunity to work closely for the first half of 2020, even though I kept him informed via email about the research progress. In August 2020, we began meeting remotely to discuss whether and how he could contribute to the research tasks planned for the following phases. Overall, throughout the realist evaluation, Dave has contributed in several ways. For instance, at the end of Phase I, during a remote meeting where I presented the analysis of the primary data already collected, he made me reflect further on the differences among the significant cases identified. In particular, he encouraged me to explore additional factors he believed were particularly significant for the analysis at that stage. In Phase II, before holding stakeholder consultations, he reviewed the PowerPoint including the material for discussion to enhance clarity and improve accessibility. Finally, during Phase III, he gave feedback on the draft of the progress report developed for Phase II stakeholders and Phase III participants, underscoring my improvements over the years.

At the translation phase of the DemRI study (see Figure 19), the PPI activities organised were limited to the 'dissemination' and 'monitoring and evaluation' domains of the research cycle. In particular, I asked for, and received advice on, how and where to disseminate findings, also collecting availability for future participation in academic/non-academic dissemination and engagement activities. The PhD PPI advisor played a significant role in the monitoring and evaluation of the research process. However, I began to gather the experience of PPI contributors included throughout the study way earlier, making changes on how to do so as the study progressed. For instance, DCC members attending the meeting held in March 2019 were asked to fill in a blank space in the document including the activity they had participated in to share their experience and provide suggestions for improvement. In July 2019, VOICE members contributing to the study were given a feedback form, which they completed at the end of the session. The members of the same group involved in March

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[18] https://research.ncl.ac.uk/behscipru/people/davegreen.html

2021 were invited to provide feedback via email or phone call or by clicking on a link that would have redirected them to an anonymous survey.

3.8.2 Reflecting on my PPI practice

The PPI approach employed to conduct PPI activities throughout the realist evaluation was different, albeit predominantly qualitative. The methodological approach chosen was participatory, but the nature and level of involvement varied from one phase to another, having been highly affected by several factors. Among them all, my increasing knowledge about PPI over time; the presence of a member of the public in the supervisory team; the amount and type of resources available while conducting research as part of a PhD programme; and the ongoing COVID-19 pandemic, which required continuous adaptations challenging to anticipate. Even though incredible effort was put into guaranteeing that PPI was meaningful and aligned with the NIHR's (2019a) UK Standards for PI in Research (see Table 14), I must concede that PPI contributors did not limit their contribution to the activity organised, supporting the study and my progress in ways I did not anticipate. For instance, my PhD PPI advisor would now and then share with me publications relevant to my literature, information about PPI events and examples of good practice. Moreover, several public members included in phases II and III contacted me after the one-to-one or group meetings to share additional thoughts or to introduce me to peers with knowledge and experience they believed were relevant to my study. Furthermore, many PPI contributors supported my access to internal networks that have kept me informed about interesting local community events or webinars. Finally, I was invited to share my PPI knowledge and learning experience at some events, such as the 90 minutes workshop I delivered remotely for the NIHR Applied Research Collaboration North East and North Cumbria Public Advisory Network members and the 30 minutes talk I gave remotely to the NU NIHR Policy Research Unit Behavioural Science members.

Table 14. Applying the NIHR's (2019) UK Standards for PI in Research

Standards	How I met this standard
1. Inclusive opportunities: 'Offer public involvement opportunities that are accessible and that reach people and groups according to research needs'	Public members affected by and interested in the research were included since the early stages of the study. They were reached in different ways and included members of local and national academic and community networks. Significant efforts were put in to guarantee accessibility to the material of PPI activities and flexibility in methods of involvement. A continuous evaluation of the involvement practice from the perspective of PPI contributors made it possible to gain a better understanding of 'inclusivity' in the context of this study, thus promoting continuous improvement.
2. Working together: 'Work together in a way that values all contributions, and that builds and sustains mutually respectful and productive relationships'	Public members invited to participate in PPI activities were provided with a succinct, accessible summary, including key information about this study and its progress along with clarifications on expectations from them. Practical requirements and arrangements for collaborations were discussed on a person-to-person basis, unless public members involved were invited to participate in a group discussion as part of a pre-established group (e.g., NU VOICE Research Support Group). Public members who were unable to continue being involved but interested in the study were kept informed about its progress. Public members' ideas and contributions have been acknowledged and discussed in academic and non-academic documentation.
3. Support and learning: 'Offer and promote support and learning opportunities that build confidence and skills for public involvement in research'	Adopting Gibbs' reflective cycle (1988) helped reinforce my tendency in 'learning by doing' and improve my PPI practice over time. Insights related to my learning process were shared with members of the PriDem programme, supervisory team, as well as public members included in this study. Online blogs[19] and engagement events made it possible to extend the communication of my journey to peers, researchers and the wider public.
4. Communications: 'Use plain language for well-timed and relevant communications, as part of involvement plans and activities'	To ensure clarity and accessibility, the invitation to participate in PPI activities, along with the material used to encourage engagement in those and inform on related outputs and impact, was provided to public members following consultations with all the three members of the supervisory team. Material for activities was also made available in advance and in different ways (e.g., via email, post and phone call) or format, depending on personal preferences or needs.
5. Impact: 'Seek improvement by identifying and sharing the difference that public involvement makes to research'	A scrupulous documentation of PPI strategies employed throughout this study facilitated reflections on the impact made by public members at different stages of the research cycle. Gibbs' reflective cycle (1988) supported the improvement of my PPI practice over time. Regular communication with public members made sure that changes, benefits and learning resulting from their contribution to the study were acted upon.
6. Governance: 'Involve the public in research management, regulation, leadership and decision making'	The contribution received by public members and its impact on this study was documented and fed back to them to guarantee transparency in decision-making and allow for additional discussions, if necessary. Since their invitation, public members were informed about the context of PPI, which was undoubtedly affected by my learning journey and the limited resources at my disposal. Public members were encouraged to regularly share their experience of involvement for monitoring purposes. Personal information and contributions given were stored on a password-protected drive shared only with supervisors.

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[19] https://www.dementiaresearcher.nihr.ac.uk/author/e-bellavia/

3.9 Role of funders and host organisation

The Alzheimer's Society played an important role in the design, implementation, and progress of the realist evaluation. Besides supporting my PhD programme at NU, it facilitated my initial engagement with PLWD and family carers, who then decided to get involved in the DemRI study as PPI contributors, stakeholders, or research participants. The initial engagement referred here transpired in various ways and through different means. For instance, by funding my participation in dementia-related events, such as the Alzheimer's Society Annual Conference[20] in London on 22nd-23rd May 2019, and the 14th UK Dementia Congress [21] in Doncaster on 7th November 2019, the Alzheimer's Society allowed me to attend sessions discussing the challenges experienced by PLWD and family carers interested in contributing to research. These sessions were led by researchers and PLWD and family carers with experience of involvement, participation and engagement in health research (see differences in section 2.2.1). These events represented an important learning experience and a crucial building block of this study. Indeed, they gave me the opportunity to establish long-lasting relationships with people who have contributed to the research process in different ways, such as providing suggestions on the involvement practice to employ, giving me access to pre-established groups of PLWD and family carers, and taking on one role (e.g., that of a stakeholder in Phase II), or more than one role (e.g., that of a stakeholder in Phase II and of a participant in Phase III) throughout this study.

Even though more at a local level, I received similar support by being a member of the NU postgraduate research community. Indeed, besides giving me access to resources offered to all research students, NU contributed to this study in additional ways. For instance, the NU VOICE Research Support Group[22] provided me with incredible support by enabling my interaction with several public members on different occasions, whether as part of Phase II or PPI activities characterising the entire research cycle. Moreover, by accepting my application for the 2019 Institute for Health and Research Ageing Theme Budget Funding Call, NU allowed me to participate in the 29th Alzheimer's Europe Conference[23] in The Hague on 23rd-25th October 2019. On that occasion, several sessions were dedicated to the

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[20] https://www.alzheimer-europe.org/News/Members-news/Tuesday-21-May-2019-Alzheimer-s-Society-holds-Annual-Conference-2019

[21] https://careinfo.org/wp-content/uploads/2019/10/UKDC-2019-12pp-Brochure-v5-online.pdf

[22] https://www.voice-global.org

[23] https://www.alzheimer-europe.org/conferences/past-conferences/2019-hague/programme-and-abstracts

advancement of PPI in the dementia field. Additionally, different UK-based studies were presented to discuss benefits and lessons learnt from conducting PPI activities involving PLWD and family carers who were there to share their experience. By interacting with members of such a diverse research community, I was able to establish connections with many people during the three days of the 2019 Alzheimer's Europe Conference. These people went on to become PPI contributors in the DemRI study and kept me informed on resources and learning opportunities about PPI in dementia research. Finally, events organised by the NU Engagement FMS[24] team, such as the 'Human Library' initiative promoted as part of the event 'Unequal Ageing: Responding to Health Inequalities in Later Life', enabled me to engage with members of the local community. During that event, 7 members of the public expressed their interest in spending some time discussing my study and providing inputs for reflection. Among them all, there was a family carer who decided to join the NU VOICE Research Support Group on that day, becoming a stakeholder in Phase II.

3.10 Summary of the chapter

Chapter 3 discussed the realist analysis framework informing the design and conduct of the DemRI study, providing insights into the various methods employed throughout my research journey. The chapter started by discussing the philosophical underpinnings informing the reasoning behind the chosen research strategies. Next, it presented the realist methodological approach employed to conduct this study, detailing the contextual circumstances, methods and outputs characterising each of its three phases. Then, it reported the PPI activities carried out throughout the research cycle, including an evaluation of my involvement practice in compliance with the NIHR's (2019a) UK Standards of PI in research. Finally, it informed about the benefits of eliciting the support of organisations such as the Alzheimer's Society (i.e., the funders of the study) and NU (i.e., the host organisation).

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[24] https://www.ncl.ac.uk/medical-sciences/engage-with-us/engage-fms/

Chapter 4. The architecture of the programme

4.1 Overview of the chapter

Chapter 4 provides a descriptive account of the architecture of the programme evaluated, which was obtained from a primary analysis of relevant documents alongside descriptions drawn upon observational data and fieldwork. The chapter begins by introducing the context surrounding the programme of interest, that is, patient and public involvement (PPI) intended as a set of involvement practices designed to support the collaboration between the Primary care-led post diagnostic Dementia care (PriDem) programme team and people living with dementia (PLWD) and family carers included in the Dementia Care Community (DCC). Next, it discusses the characteristics of the DCC, informing about its developmental process and membership terms. Then, after detailing the roles and responsibilities of research team members towards the DCC, the chapter reports the involvement strategy they designed and implemented across settings. Finally, it outlines the programme's architecture, including the key components informing the chain of inferences reported in Chapter 5.

4.2 PriDem programme

4.2.1 Background context

The PriDem programme was developed after the emergence of evidence of the United Kingdom (UK)'s need for better care after a diagnosis of dementia. The key evidence reported by the research team to support the need for and design of the PriDem programme included: national audits indicating a fragmentation of the care system at the post-diagnostic stage (National Audit Office, 2007; 2010); the 2015 Alzheimer's Society's (2015) report on dementia care raising concerns about the quality and equality of support services available to PLWD and their family carers; and the 2016 World Alzheimer Report encouraging a shift towards a more holistic, integrated approach to post-diagnostic care across the world (Alzheimer's Disease International, 2016). All the aforementioned factors contributed to the development of a well-defined aim for the study: to develop a new model of care in collaboration with dementia care professionals, PLWD and their family carers as encouraged by policymakers (Department of Health, 2016). This new model of care was expected to be evidence-based, person-centred and primary care coordinated.

> ‘[The aim is] To develop and evaluate acceptable, feasible and hopefully sustainable model(s) of evidence based, person-centred, primary care coordinated post diagnostic dementia care to maintain and improve quality of life for people with dementia and their families.’ (PriDem programme funding application 2016)

However, the PriDem programme’s design was premised not solely on a well-informed response to a local and global call for better post-diagnostic care. Indeed, several public members had worked with the team in a PPI capacity during its developmental stage. For instance, the ideas informing the programme and its objectives were influenced by the feedback received from public members included in two well-established PPI groups, one of which was familiar to the team for previous collaboration.

> ‘The idea for this research, a primary care-led LTC [Long Term Care] model for post diagnostic care, originated in the NIHR [National Institute for Health and Care Research] DeNDRoN Primary Care Clinical Studies Group, a joint researcher/PPI forum [..] Specific objectives were refined after consultation of the Alzheimer’s Society/James Lind Alliance partnership research priority exercise recommendations.’ (PriDem programme funding application 2016)

Moreover, additional inputs were sought on two occasions during the developmental stage of the PriDem programme protocol. On both these occasions, the research team received inputs affecting the study’s design. More specifically, after reviewing the PriDem programme’s objectives, a Newcastle University’s (NU) PPI reference group warned on potential challenges and provided options to overcome them at a community level.

> ‘Our Stage 1 application was reviewed by members of AS North East and Years Ahead (North East University PPI network); key points included: looking at costs of different models i.e. a core good practice model with a menu of ‘optional extras’; ensuring co-ordination between primary and community care and getting ‘sufficient secondary care buy in’ to ensure change.’ (PriDem programme funding application 2016)

From a group of professionals and public members participating in a local workshop, including a discussion related to the DCC in the PriDem programme, the research team received comments focused on ensuring that researchers valued the role played by the voluntary community and social enterprise (VCSE) sector in dementia care. Accordingly, they suggested a different approach to PPI, which was documented by the team as being more open and inclusive than the one discussed on that day. This approach entailed the foundation of a dementia care community that included representatives of the VCSE sector supporting PLWD and family carers locally alongside health and social care professionals.

> 'Our Stage 2 application was reviewed in a 'sharing innovative practice' workshop co-hosted by DAA North East & Comic Relief and attended by local charities and leads of local DAA/Comic Relief-funded dementia care projects. Key feedback included: danger of over-medicalising dementia by focusing on a medical model and wider, more inclusive stakeholder involvement in the conduct of the programme needed over and above our planned PPI. They suggested a Dementia Care Community, involving a wider range of voluntary organisations and also dementia-friendly community initiatives.' (PriDem programme funding application 2016)

The PriDem programme research team members valued these experiences and discussed their impact on the final version of the protocol submitted alongside the application for funds to the Alzheimer's Society. The connections established with local PPI networks and support services on both occasions played a key role in the development of the DCC (see section 4.3).

4.2.2 PPI in the PriDem programme

In official documentation such as the PriDem programme funding application and yearly versions of the protocol and progress reports, the research team did not mention only the DCC when discussing PPI. Indeed, the PriDem programme's PPI strategy entailed the organisation of public members in two different monitoring groups defined as 'external' or 'internal', depending on their role and their level of involvement. The 'external' contribution was made by public members included in the Patient Programme Advisory Board who were responsible for overseeing the management and outputs of the research throughout each of the six PriDem programme's workstreams (WSs). On the other hand, the 'internal' contribution referred to the close collaboration of the research team with (a) public members with PPI experience, who had been co-applicants of the PriDem programme and were on-going members of the Programme Management Board, and (b) several members of the public included in the DCC, whose characteristics are detailed in section 4.3.

> 'PPI during the programme: internally this will be via our PriDem DCC. In addition co-applicants [names] will be members of the PriDem Programme Management [Board] team; they have had i) personal experience of caring for relatives with dementia and ii) active participation in the development and conduct of research via the Alzheimer's Society PPI network. External PPI programme monitoring will be via a separate Patient/public Programme Advisory Board (PPAB); this will: i) oversee progress in terms of milestones/deliverables and act as critical 'friends' to the DCC'. (PriDem programme funding application 2016)

Figure 20 (retrieved from the PriDem programme funding application, p.82) shows a visual representation of the relationship between external and internal PPI contributions. In this figure, adaptations to the original image were made to maintain the anonymity of the PriDem programme team members cited.

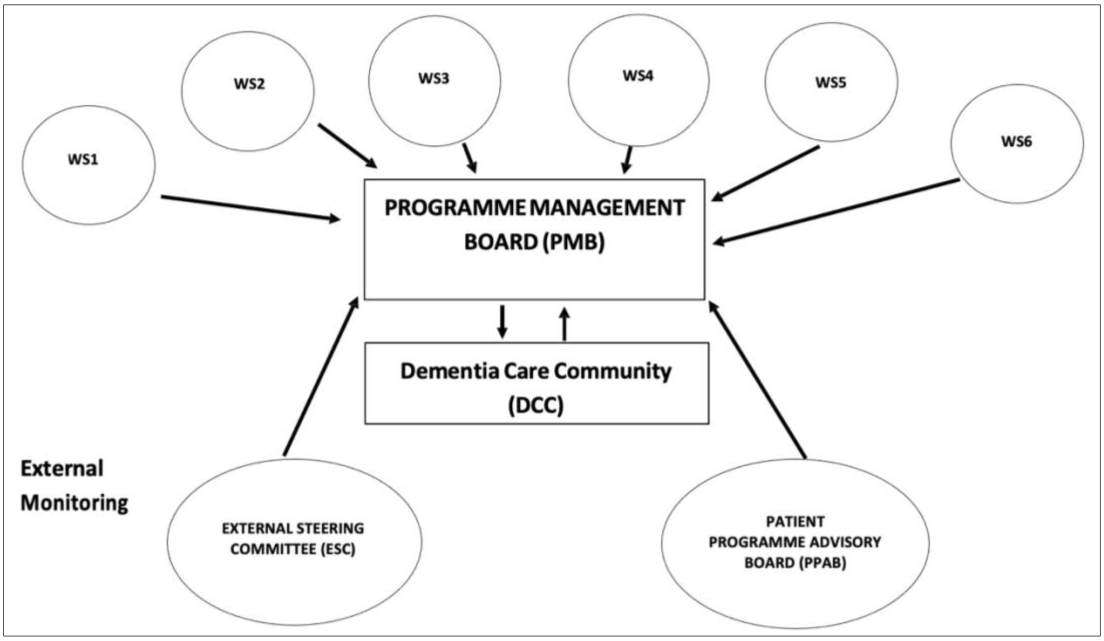

Figure 20. PriDem programme: Internal management and monitoring, reproduced with permission from the principal investigator

4.3 Dementia Care Community

4.3.1 Purpose and value

The public members involved in the second stage review of the PriDem programme protocol (see section 4.2.1) informed the research team's idea of moving away from the usual PPI practice, which entails a few public members reunited in an advisory board, thus confirming the interest for a broader PPI approach.

> 'The importance of actively involving patients and public in research is now well-established. Commonly this takes the form of a patient and public involvement (PPI) panel or advisory group. The DCC represents an innovative approach to involvement by engaging a wider range of stakeholders in the same group, including those who use dementia services and those involved in their delivery, to inform and shape the work of PriDem.' (UK Dementia Congress and IPPE poster 2018)

The first graphical representation of the DCC is illustrated in Figure 21 (retrieved from PriDem programme funding application, p.79), where the DCC is represented by its members organised in four different categories (i.e., people with dementia, their families, service providers and service commissioners) within red rectangles. These rectangles are included as the background of all WSs, underscoring the intention of including DCC members throughout the PriDem programme.

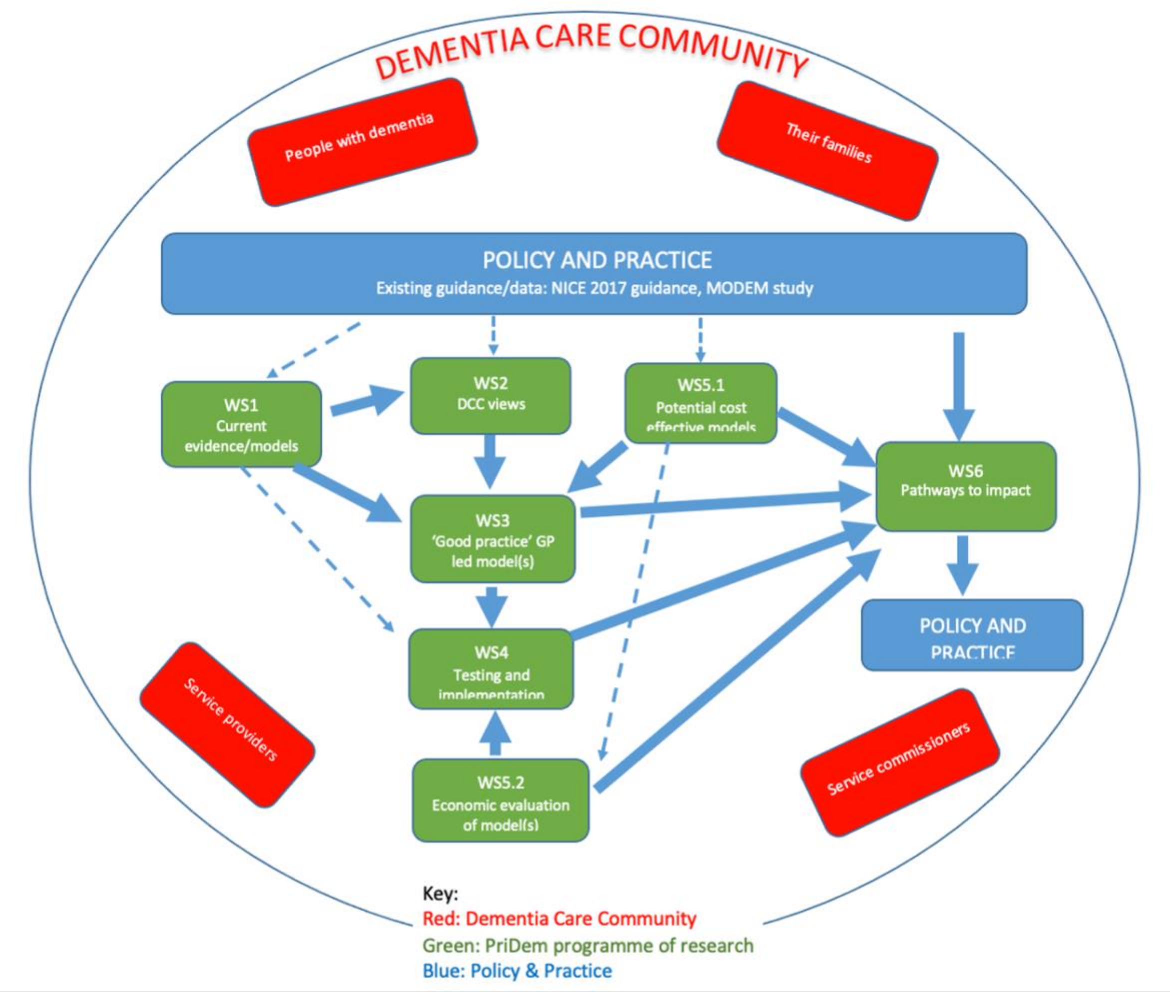

Figure 21. Initial representation of the DCC, reproduced with permission from the principal investigator

The centrality of the role given to the DCC was highlighted in several documents discussing the research's objectives and the developmental plan for the new model of care. Subsequently, it was also confirmed by the monthly team meeting minutes, which conveyed a story about the resources and efforts invested in recruiting PLWD and family carers to include in the DCC. The reasons why the team decided to establish a collaboration with public members early and over a period of time was attributable to several reasons, such as being aligned to health care policies' demands for PPI in the development of dementia care interventions, funders' (i.e., Alzheimer's Society) requirements, the host organisation's (i.e., NU) recommendations, and the principles of good research practice. Additionally, the information included in the documentation analysed denotes a reason that is reiterated in various ways but made clear in the following statement:

> 'By drawing on this individual and collective experience, we hope to ensure that the programme of work is embedded in real life experiences and is tailored to local contexts.' (PriDem programme protocol 2018)

The centrality given to ‘real life experiences’ in the PriDem programme was strictly related to the awareness of the possible challenges coming with a view to developing a new model of care post-dementia diagnosis. For this reason, designing a type of involvement that united service providers and users was argued to be the solution to overcome these challenges and develop a coordinated, agreed upon response for testing purposes.

> ‘Such involvement will help ensure acceptable, pragmatic and adaptable models for implementation testing.’ (PriDem programme protocol 2018)

4.3.2 Process of development

The development of the DCC started at the beginning of the PriDem programme. The research team meetings’ minutes underscore how the DCC was developed by a collaborative effort among the team members. The enrolment of DCC members in the PriDem programme was ascribed to a series of steps and actions described as a ‘process’ characterised by one research team member – the DCC coordinator – participating in dementia events, visiting local support groups (e.g., dementia hubs), and attempting to reach the targeted population through alternative, engaging ways (e.g., radio interview).

> ‘A range of approaches have been used to engage people in the DCC, including joining meetings of provider organisations and local dementia networks, presenting at a local carer event, and visiting dementia support groups and cafes. […] We have recently been invited to take part in a short interview with a Radio. [..] We hope that this will reach more people with dementia and carers who may wish to join our DCC. [..]’ (PriDem programme progress report 2019)

In recruiting PLWD and family carers for the DCC, the research team received significant support from the PriDem programme’s funders, namely the Alzheimer’s Society. Indeed, through officers working for this charity organisation, an invite to join the DCC was sent via email to the PLWD and family carers included in the Alzheimer’s Society’s PPI Research Network and distributed in the form of a brief advert (see Appendix T) to local PPI forums and memory cafés.

4.3.3 DCC membership

All people invited to become DCC members were provided with flyers (see Appendix T), which informed them about the PriDem programme’ background and rationale, as well as the purpose of the DCC involvement in it. Other details included were related to the possible ways of involvement, the expected frequency, and the type of support offered to those deciding to participate, such as reimbursement for travel expenses, vouchers of participation if attending in-person meetings, and a unique point of contact accessible via email or phone call. Initially, the DCC was perceived as a group of people including two subgroups, which would have been involved throughout the PriDem programme with varying frequencies. However, in practice, it was founded only one DCC, thus giving members the opportunity of participating in as many meetings as possible.

In addition to flyers, people invited to join the DCC were provided with two documents: a 'letter of invitation' and a 'contact and involvement preference form'. The letter of invitation outlined the terms and conditions of involvement, explaining the treatment of personal data according to the ethical requirements of good practice. The contact and involvement form, which was different between public members (i.e., PLWD and family carers) and dementia care professionals (i.e., health and social care professionals and representatives of the VCSE sector), asked personal details, category of belonging, and preferences about the ways of communication (i.e., email, post and phone calls) and involvement (i.e., in-person or remote meetings, home visits from a researcher, phone calls or email exchanges). A blank text box was also included to let people document further information about what could help them participate in PPI activities, such as the days of the week to avoid or audio-visual aids required. People interested in receiving more clarifications about the programme were directed to the Alzheimer's Society's webpage[25], as the PriDem programme's website was not developed at that time. Those having difficulties in completing the documentation provided or wanting to discuss their involvement further were given the possibility of contacting the DCC coordinator or the research administrator via email or phone call.

4.3.4 DCC members

The DCC was a 'mixed' group of people defined as representative of the post-dementia diagnosis care path present locally. It included users of dementia care services (i.e., PLWD

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[25] www.alzheimers.org.uk/research/our-research/research-projects/dem-project

and family carers) and providers (i.e., health and social care professionals and VCSE sector representatives) with experience of developing, managing and or delivering services.

> ‘The DCC aims to bring together people with dementia and their family carers, and a wide range of professionals involved in support throughout the illness, including those employed by health and social care and key voluntary organisations.’ (ICCPE conference oral and poster abstract 2019)

Given the mix of service users and providers, the DCC was also often referred to as a ‘group of stakeholders’, whereby the overlapping characteristic of them was the knowledge of local dementia care services, whether due to professional or personal reasons.

> ‘To ensure that this research is embedded in real life experiences and contexts, a wide, inclusive stakeholder group is being established; the Dementia Care Community.’ (UK Dementia Congress and IPPE conference poster abstract 2018)

This group of stakeholders was defined as ‘inclusive’ not only in relation to the variety of categories included but also for the opportunity given to participate in different ways. For instance, some PLWD and family carers had expressed their willingness to get involved in the DCC in an individual capacity and participate in PPI activities organised at a NU’s venue, along with peers and professionals. Others preferred to join as part of a well-established group meeting monthly at a local memory café or dementia hub. Moreover, a limited number of PLWD and family carers were visited at home, thus contributing to the PriDem programme by a one-to-one discussion on a specific topic or completing individually the activity organised for the group meetings.

The number of DCC members changed over time, as the opportunity of joining the group was ongoing throughout the PriDem programme to guarantee a certain level of representativeness in all its WSs.

> ‘Continue to maintain membership by taking research project flyer/DCC advert to events/networking opportunities for professionals and pwd/carers who may be interested.’ (PriDem DCC strategy 2018-2020)

Table 15 provides an overview of the DCC from before its involvement in the PriDem programme (i.e., August 2018), which started in October 2018, to the end of my data collection in the field (i.e., December 2019).

Table 15. Overview of DCC members 2018-2019

Categories	16.8.2018	6.12.2019
PLWD	1	23
Family carers	3	22
Health care professionals	16	16
Social care professionals	3	6
VCSE sector representatives	4	8
Total	27	75

4.4 PriDem programme team

4.4.1 Research team members

The PriDem programme team included several researchers and research administrators working for different universities and owing a specific role in each of the six programmes' WSs. However, all research team members included in the dementia research involvement (DemRI) study were based at NU and entailed the following: 2 research administrators; 3 research associates; and 1 postgraduate research student who, at that time, was also undertaking a Doctoral of Philosophy (PhD) programme embedded in the PriDem programme. These team members worked on coordinated research tasks and were based in the same office. Through monthly meetings, they were able to discuss the research progress and any information about the DCC or the PPI activities its members were involved in.

All research team members were endorsed with responsibilities towards the DCC, with a list of duties that insisted on guaranteeing clarity of communication, continuous updates on the research progress, and commitment to valuing the contribution made by DCC members.

> 'The research team will ensure the following: Research questions, methodology, analysis and findings are explained and summarised in a clear, jargon-free and concise manner; Information will be written in an accessible format; Members of the group will be kept up to date with progress of the research and provided with summary documents; Members' views and suggestions will be valued.' (DCC terms of reference)

In addition, each of them was assigned specific tasks concerning the involvement of the DCC in the PriDem programme (see Table 16). In particular, the 'DCC coordinator' was the research team member responsible for maintaining contact with the PLWD and family carers included in the DCC and guaranteeing their continuous involvement in different ways.

> 'We provide a single point of contact, the DCC facilitator [DCC coordinator], who keeps in touch regularly with people with dementia and carers. The facilitator also visit people with dementia and

> carers who expressed an interest in the DCC as part of the recruitment to provide an opportunity to meet with them in a safe and familiar environment' (Entry for NIHR award–DCC description)

The DCC coordinator worked closely with the 'PriDem programme PPI lead', who contributed to the design of the PPI strategy included in the funding application (see section 4.2.2) and collaborated with other research team members to develop the DCC. The DCC coordinator and the PriDem programme PPI lead were accountable for organising DCC meetings and associated PPI activities. The other research team members supported the DCC by ascribing different tasks. For instance, if available on the day, the PhD student and the remaining researcher would become 'group facilitators' of the PPI activities held at the university venue. Meanwhile, research administrators would be responsible for providing administrative assistance for the DCC meetings, such as booking the rooms for the activities, ordering the catering for the day, providing attendees free parking space tags and travel expenses refunds, arranging taxi journeys and distributing vouchers for participation.

Table 16. Research team members' roles

Role in relation to the PriDem programme	Role in relation to the DCC
1. Research associate	DCC coordinator
2. Research associate	PriDem programme PPI lead
3. Research associate	Group facilitator
4. PhD student	Group facilitator
5. Research administrator	Administrative assistant
6. Research administrator	Administrative assistant

4.5 Patient and public involvement in practice

4.5.1 DCC in the PriDem programme

The writing used to elucidate the relationship between the research team and DCC members denotes the 'collaborative working' unfolding when they all met and worked together. According to the design, the DCC was expected to (a) 'inform processes' characterising WSs 1, 2, and 3 of the PriDem programme; (b) 'provide members' for a panel responsible for prioritising core and desirable components of the new model of care and commenting on the prototype developed by researchers during WS 3; and (c) 'directly influence' the various steps of WS 3, that is from the discussion of ideas about the new model of care to the final version of the model before testing (see Figure 22, retrieved from DCC overview document, p.1). The involvement of the DCC was also intended to be maintained throughout WSs 4, 5, and 6 (see Figure 21). However, these WSs were beyond what was feasible within the scope of my PhD programme timeline.

The involvement of the DCC in each of the three WSs included in this study was defined by specific objectives at a very early stage. In particular, during WS 1, DCC members were expected to contribute to the review of the literature mapping existing ‘good practice’ models of post-diagnostic support in the UK by commenting on their ‘appeal’ and ‘acceptability’.

> ‘DCC WS1 working group. As part of a review of post-diagnostic support for people with dementia and their families to understand current support, the DCC will help by reviewing existing ‘good practice’ models and making comments on their appeal and acceptability. This DCC will be facilitated by researchers [..] who are leading workstream 1.’ (PriDem programme funding application 2016)

Meanwhile, during WS 2, DCC members were meant to share personal and professional experiences of post-diagnostic support while also advising on research methods for primary data collection, such as recruitment strategy and topic guide.

> ‘[To] Provide alternative experience-based perspectives to the project team and posed research, either as a person living with dementia, a family member or a professional delivering services to people with dementia; [To] Offer feedback on proposed recruitment approaches and materials; [To] Provide feedback on data collection tools, such as topic guide.’ (PriDem programme protocol 2018)

Finally, during WS 3, DCC members were supposed to contribute to developing the ideal model of post-diagnostic support by identifying potential outcomes of interest and related issues, thereby ascribing to the varying needs and their possible interpretations from the perspective of both service providers and users.

> ‘Contribute to the development of new model(s) of post diagnostic care through activities such as: identifying key outcomes; identifying key components of the intervention; considering practical aspects of intervention delivery-when, how, who, where, how often.’ (PriDem programme protocol 2018)

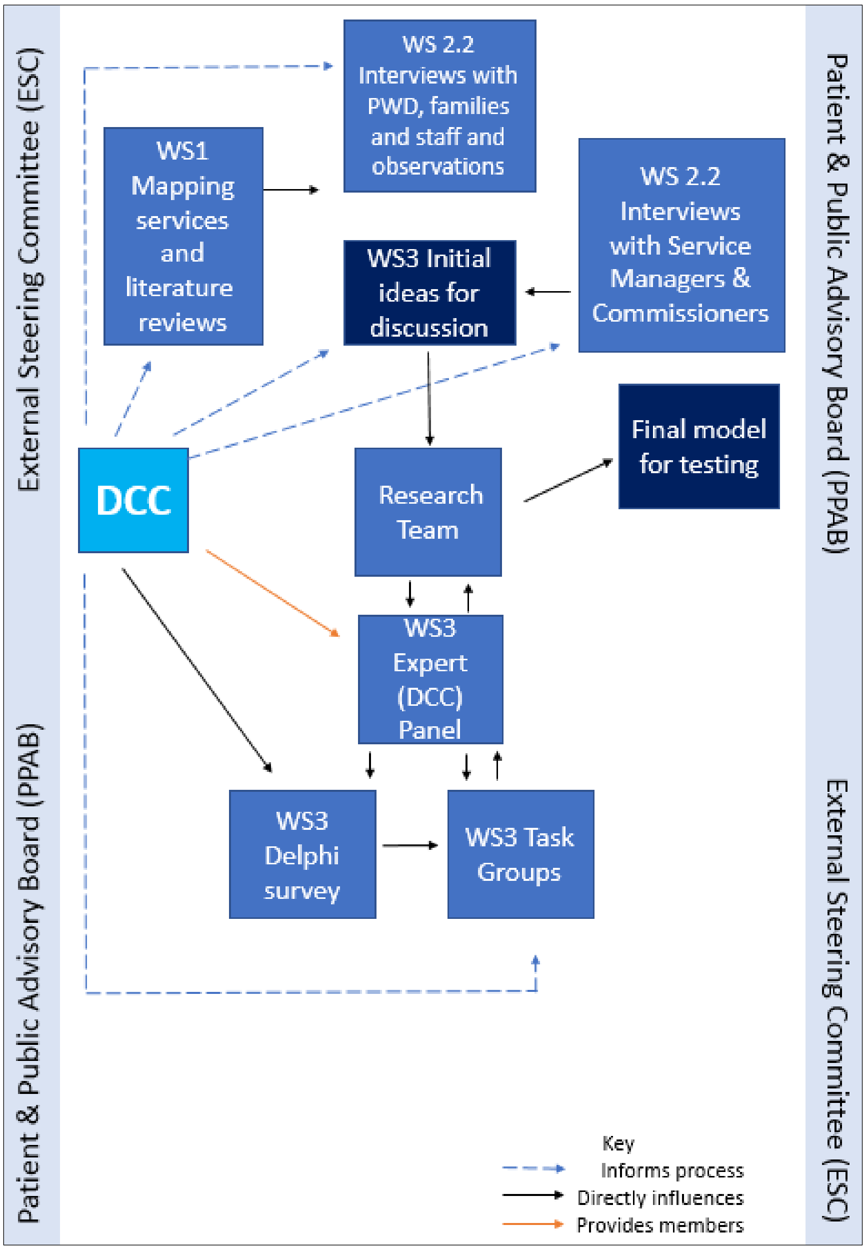

Figure 22. DCC overview, reproduced with permission from the principal investigator

4.5.2 *Key characteristics of the involvement strategy*

A variety of options were provided to those interested in becoming DCC members, such as visits at home by the DCC coordinator, informal chats over the phone or Skype, in-person meetings and email exchanges. Additionally, the possibility of further arrangements based on personal commitments or individual needs was not excluded.

> ‘[Write down] Anything we need to know to help you take part. e.g. days of the week you have other commitments, aids that may help.’ (DCC contact and involvement preference form)

Despite the differences among the full range of involvement possibilities, the research team was committed to guaranteeing equality among members’ contributions.

> 'All options will give you the opportunity to make a valuable contribution to our research.' (PriDem programme flyer and DCC advert)

After joining the DCC, members were afforded the opportunity to contribute to the PriDem programme individually or as members of well-established local groups. To be included, they were not expected to be knowledgeable in research or have experience of PPI, leaving the inclusion criteria as open as possible. Research training, however, was offered upon request. Although early official documentation about the PriDem programme entailed a detailed plan about the frequency, type of group tasks, and organisation of the DCC in each of these tasks, a new architecture of involvement was defined when DCC meetings began. Indeed, following discussion with DCC members participating individually, some new terms of reference were agreed among the parts involved, with some changes affecting frequency, timing, venue and meetings content.

> 'This structure was co-produced with the DCC and included: Frequency – 3 – 4 meetings per year of the programme; Timing – to date meetings have been held in the afternoon, for approximately two hours; Venue – to meet at a university and other relevant community spaces, with visitor parking a key consideration; Content – to add an information session on topics related to dementia to some meetings for people to join if they wish to.' (DCC strategy)

A different approach was chosen for PLWD and family carers included in the DCC as part of well-established local groups. In that case, the research team was required to adapt to the organisation of these groups' monthly meetings, making arrangements with their facilitators who guaranteed regular access to the DCC coordinator.

The involvement of DCC members in the PriDem programme was set to be continuous as the research progressed from one WS to another. Consequently, the communication between the research team and the DCC members was regular and occurred in many ways, including social media (i.e., Twitter[26]) and PriDem programme website[27], where material relevant to PPI was uploaded in the form of PowerPoint presentations and newsletters.

The PPI strategy implemented by the research team was continuously evaluated, giving the decision of adopting an ongoing reflective approach which was considered valuable since the early stages of the PriDem programme.

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[26] https://twitter.com/PriDemProject

[27] https://research.ncl.ac.uk/pridem/patientpublicinvolvement/

> ‘We will explore the experiences of members of the DCC via an ongoing reflective process, where feedback is sought on ways of enhancing the experience and value of the DCC, and adaptations made in a timely manner.’ (PriDem programme funding application)

The evidence required for this approach to positively affect the research team’s decision-making about terms of the DCC members’ involvement was gathered in various ways: by encouraging the DCC members to fill in feedback cards or contact the DCC coordinator via email or phone call to share their experiences; documenting DCC meetings and discussing related summaries during research team meetings; and recording and transcribing the PPI activities conducted to reflect collectively on issues as and when they arise.

> ‘At each meeting we provide participants with a blank postcard and invite them to write any comments or feedback on the content, structure or any other aspect of the DCC. This feedback is used to inform activities-e.g. to use small group work to facilitate involvement. […] We record and evaluate the impact of engagement through the summaries of meetings, reflecting and discussing meetings within the team and with a DCC member who as extensive experience of research and PPI and recording and transcribing meetings to ensure that we capture key points.’ (Entry for NIHR award – DCC description)

A couple of public members contributed to the involvement strategy adopted by the PriDem programme team. After supporting the research team as co-applicants in the funding application, these public members were included in the Programme Management Board (see Figure 20) and were consulted about the material created to recruit PLWD and family carers for the DCC. Additionally, having both PPI and caring experience, they were invited to provide inputs on the PPI activities plan and comment on the feasibility and clarity of related material. If available on the day, they would also attend DCC meetings to observe the unfolding of the activities and evaluate the facilitation of group discussions and the level of attendees’ engagement. Besides them, some professionals supporting local PLWD and family carers aided the research team in many ways. Examples include the following: giving and maintaining access to the targeted population (i.e., PLWD and family carers); offering opportunities for research engagement activities; providing inputs on DCC recruitment material or PPI activities plan; supporting the organisation and unfolding of PPI activities taking place in the community; and facilitating the communication with PLWD and family carers included in the DCC as members of well-established local groups.

4.5.3 PPI activities

The PPI activities undertaken by the PriDem programme research team during the DCC meetings were developed upon the pre-established objectives of the WSs (see section 4.5.1). There was no standard formula informing the design of these activities, with materials and approaches changing as the involvement unfolded over time and across settings (see Appendix U). Usually, DCC members would participate in group discussions facilitated by a research team member and encouraged by prompts provided in various ways, such as questions projected on a screen or posters developed to collectively reflect on research findings. On each occasion, DCC members would be encouraged to engage in the discussion by commenting orally or writing on post-it notes. After seeking DCC members' consent, the PPI activities were audio-recorded to capture everyone's contribution. The DCC coordinator would document the impact of this contribution on the PriDem programme as an ongoing activity (see Table 17) feeding that back to DCC members regularly.

Table 17. Impact of PPI activities on the PriDem programme

Workstream N.	Impact
WS 1	There is no documentation of impact related to WS 1 since the DCC was not involved, contrary to the plan. The reasons behind this decision are not entirely clear, since referring to DCC members that should have collaborated with researchers working for the PriDem programme but based away from the field explored.
WS 2	DCC members were reported informing the topic guide created for data collection by prioritising pre-defined questions and developing new ones. Additionally, they were seen to be responsible for including PLWD and family carers in the population targeted for interviews that consisted of service providers thus far. 'Informed WS2.2 data collection – key areas to look for. Informed WS2.2 topic guide for pwd and carers. Informed methods – i) widened scope of recruitment to include pwd and carers' (DCC meetings summary, July 2019)
WS 3	DCC members' inputs contributed by validating the key outcome areas identified by researchers, informing the identification of resources that could facilitate the implementation of a new model of care, and highlighting the advantages and disadvantages of different professional approaches. 'No additional specific outcomes were identified – supporting the 7 outcome areas identified from the literature review.' (DCC meetings summary, October 2019) 'Informed WS3 intervention development through: Identifying key things a named professional should be equipped with; Highlighting the relative pros and cons of an individual and a team approach; Identifying key considerations and ideas around access to a named professional.' (DCC meetings summary, November 2019)
	After having engaged in discussions about the components of the ideal model of care, DCC members were also deemed capable of encouraging reflection on the different perspectives that service providers and users may hold onto the results of its implementation, addressing further research. 'Made the team aware of areas of similarity and difference in how professionals and PWD & carers rate different outcomes.' (DCC meetings summary, October 2019) 'Refined understanding of 'carer well-being' as an outcome area – 'supporting carer well-being' should encompass a range of more specific outcomes.' (DCC meetings summary, November 2019)

4.6 Dementia Care Community meetings

4.6.1 Overview

The involvement of the DCC in the WSs 2 and 3 of the PriDem programme commenced in October 2018 and continued throughout 2019, entailing a total of 11 meetings held in three different settings (i.e., university venue, memory café and dementia hub) (see Table 18). While a detailed description of these meetings across settings is provided as an appendix (see Appendix U), the following sections report relevant similarities and differences.

Table 18. Overview of DCC meetings

University venue	Memory café	Dementia hub
16th October 2018	8th January 2019	
5th March 2019	12th March 2019	16th April 2019
10th July 2019	9th July 2019	6th August 2019
28th October 2019		1st October 2019
20th November 2019		

4.6.2 Similarities and differences across settings

The PPI activities designed by the PriDem programme team were conducted as part of DCC meetings held in different settings. These meetings were characterised by similarities and differences related to the following aspects:

- the range of people attending
- the format of the meetings
- the organisation and facilitation of PPI activities

I will briefly explore all the above in the following paragraphs.

The range of DCC members attending the meetings was different across settings. For instance, the members of the DCC participating in PPI activities held at the university venue included service users (i.e., PLWD and family carers) and providers (i.e., health and social care professionals and representatives of the VCSE sector). When the DCC began to get directly involved in the PriDem programme (i.e., WS 2), this mixed group of people did not know the venue, the research team, or each other, except for some DCC members who were colleagues or had a past/present service provider-user relationship. A total of five meetings were organised at the university venue, with DCC members being mostly represented by family carers and care professionals each time (see Table 19).

Table 19. Attendees of DCC meetings at the university venue

	DCC meetings				
Attendees	October 2018	March 2019	July 2019	October 2019	November 2019
PLWD	1	2	1	1	1
Family carers	7	10	9	10	7
Health care professionals	4	6	2	4	4
Social care professionals	3	3	4	4	2
VCSE sector representatives	2	1	1	2	2
PriDem programme PPI lead	1	1	1	1	1
DCC coordinator	1	1	1	1	1
Group facilitators	2	2	1	1	1
Administrative assistants	2	2	1	2	1
Total	23	28	21	26	19

Meanwhile, the DCC members attending meetings at the memory café included only service users (i.e., PLWD and family carers) who knew each other, as they had been regular visitors of the café for a long time. However, on two occasions, a couple of people (i.e., one person living with dementia and their family carer) visited the café for the first time, deciding then and there to hear more about the PriDem programme and participate in the PPI activity planned for the day. A total of three meetings were hosted at the memory café during WSs 2 and 3; on each of them, PLWD outnumbered family carers by one (see Table 20).

Table 20. Attendees of DCC meetings at the memory café

	DCC meetings		
Attendees	January 2019	March 2019	July 2019
PLWD	4	6	5
Family carers	3	5	4
Memory café facilitators	1	1	1
Memory café volunteers	2	3	2
DCC coordinator	1	1	1
Total	11	16	13

Finally, the DCC members attending the dementia hub primarily consisted of PLWD who lived locally and visited the hub with their family carers monthly. Therefore, like the memory café, they held the same perspective (i.e., service users) and were familiar with each other and the place. Considering all the DCC meetings organised at the hub – three in total – the number of PLWD participating in the meetings ranged from 7 to 15, with a couple of family carers participating each time (see Table 21).

Table 21. Attendees of DCC meetings at the dementia hub

	DCC meetings		
Attendees	April 2019	August 2019	October 2019
PLWD	7	11	15
Family carers	2	2	2
Dementia hub facilitator	1	1	1
Dementia hub volunteers	2	3	2
PriDem programme PPI lead	0	0	1
DCC coordinator	1	1	1
Total	13	18	22

The format of the meetings in which the DCC members participated was different across settings, with similarities mainly observed in those held at the memory café and the dementia hub. In particular, the meetings at the university venue were well-structured and included time slots allocated to specific agenda items (i.e., introduction, first PPI activity, break, second PPI activity and conclusion) and related material, which was provided to attendees beforehand. These meetings were research-orientated, with little time given to attendees to converse other than when the two PPI activities planned for the day took place. On the contrary, the DCC meetings at the memory café or dementia hub were shaped by the specific circumstances of where they took place. These meetings were shorter because they were included in the monthly gathering of local PLWD and family carers coming together to socialise and look for dementia support and advice. These two were indeed the reasons why the café and the hub were founded. Therefore, the DCC coordinator would conduct only one PPI activity, using some of its time to inform the attendees about the impact of their contribution to the research progress. Also, no exchange of agenda or material would take place with attendees before the visit of the DCC coordinator.

While the topic of the PPI activities was the same across settings, their organisation and facilitation were different. For example, the PPI activities conducted at the university venue were organised as parallel group discussions unfolding in separate rooms and facilitated by different members of the PriDem programme team. Before the meeting, DCC members would receive the agenda and a summary of the PPI activities planned, with the opportunity to discuss any doubts or concerns with the DCC coordinator beforehand. On the day of the meeting, DCC members would be divided into groups, including a fair balance of service providers (i.e., health and social care professionals and VCSE sector representatives) and users (i.e., PLWD and family carers). Meanwhile, DCC members attending meetings at the memory café or dementia hub included only service users (i.e., PLWD and family carers) who would participate collectively in the activity, remaining in the same room for the entire meeting. The same research team member – the DCC coordinator – would facilitate the PPI activities carried out at the café or hub, being supported by the related group facilitators and volunteers present on the day.

4.7 Concluding remarks

The primary analysis of the data collected during Phase I led to the identification of the key components of the programme's architecture, which are summarised in the following remarks:

1. The PPI strategy of the PriDem programme was clearly defined in the funding application, which included a representation of the DCC and a clear instrumental purpose for its involvement throughout its six WSs.
2. A range of approaches was used to engage PLWD, family carers and dementia care professionals (i.e., health and social care professionals and representatives of the VCSE sector) in the DCC: connecting with funders' PPI networks and organisations providing care services; participating in local events and radio interviews; and visiting dementia support groups (e.g., memory cafés and hubs).
3. DCC members were offered flexible ways of involvement (e.g., in-person or remote meetings, home visits from a researcher, phone calls or email exchanges) and adaptations according to personal circumstances and needs.
4. The DCC included PLWD and family carers who participated in PPI activities alongside dementia care professionals or peers they regularly met at the local memory café or dementia hub.
5. PriDem programme team members worked on coordinated tasks for the successful involvement of the DCC, maintaining continuous contact with group members and collaborating for the design, facilitation and ongoing evaluation of PPI activities.
6. In implementing their PPI strategy, research team members were supported by the presence of the DCC coordinator, the availability of funds covering the costs associated with the involvement strategy, and the access to university and local organisations' premises and networks.

7. PPI activities were designed upon the PriDem programme's WSs' objectives and entailed a research team member facilitating discussions in groups including a mixed population (i.e., service providers and users) or not (i.e., only service users).
8. PPI activities were carried out using supporting material, which varied over time. The DCC members attending meetings at the university venue would receive information about the activities beforehand, being given the possibility of discussing any doubt or concern with the DCC coordinator.
9. All DCC members were provided with information about the impact of their contribution to the PriDem programme's progress.

4.8 Summary of the chapter

Chapter 4 presented the findings obtained from the primary analysis of data collected during the first phase of the realist evaluation discussed in this thesis. The chapter started by delineating the background context informing the design and purpose of PPI in the PriDem programme, reporting aspects relevant to the inclusion of PLWD and family carers in the programme as members of the DCC. Then, it explained the role and responsibilities of the PriDem programme team members towards the DCC and discussed the PPI strategy they implemented. After that, it provided an overview of the DCC meetings carried out in different settings, reporting relevant similarities and differences. Finally, it outlined the programme's architecture, including the key components informing the chain of inferences reported in Chapter 5.

Chapter 5. Programme theories

5.1 Overview of the chapter

Chapter 5 presents the programme theories (PTs) consolidated from a synthesis of the data collected throughout the realist evaluation conducted as part of the dementia research involvement (DemRI) study. The chapter begins by providing an overview of the eleven PTs obtained by the end of Phase III, detailing their underlying Context–Mechanism–Outcome configurations (CMOc). It then goes on to discuss each PT singularly, including the evidence informing their development and refinement. Finally, it summarises the facilitators and barriers to patient and public involvement (PPI) identified.

5.2 Introduction

This chapter presents the eleven PTs developed following an iterative process of analysis characterised by several theoretical changes, which are detailed in Appendix P and summarised in Figure 23. In line with the RAMESES II reporting standards for realist evaluations (Wong et al., 2016), this chapter includes the chains of inference based on the data available from Phase I and the evidence used to test and gradually refine the theoretical statements explaining 'what works, for whom, in what circumstances, in what respects and why' when involving people living with dementia (PLWD) and their family carers through PPI activities. A comprehensive view of the PTs and the related CMOc is provided in Table 22.

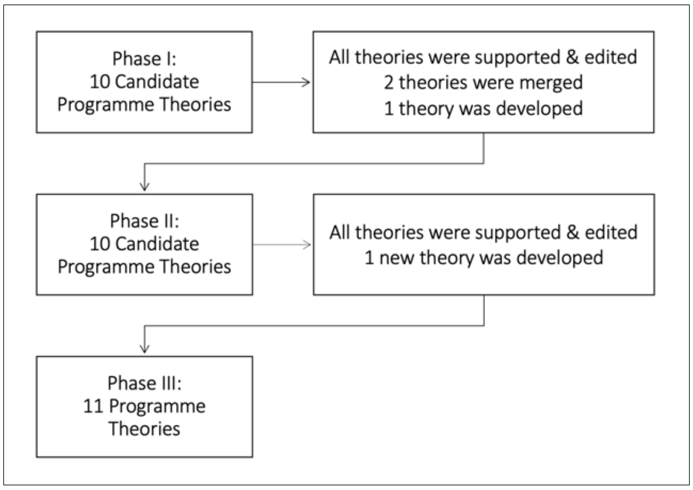

Figure 23. Programme theories trail

Table 22. Overview of PTs and related CMOc

Contexts	Mechanism-resources	Mechanism-reasonings	Outcomes
1. If the research team develops a well-established plan of involvement which is supported by funders and host organisation, in the context of accessible dementia-related local support services	then the early engagement with the community of an involvement coordinator responsible for facilitating the inclusion of PLWD and family carers in the research programme	encourages the research team to adopt a reflective approach to decision-making,	leading to the involvement of PLWD and family carers because of the tailored involvement strategy resulting from the increased researchers' understanding of this population's concerns and needs.
2. If the involvement coordinator conducts early engagement activities with PLWD and family carers who are included in existing local support groups and are new to research,	then the relationship among group members and the ongoing positive interaction between group members and involvement coordinator	encourage PLWD and family carers to feel comfortable and safe,	leading to their involvement because they overcome research-related fear and apprehension and discuss openly involvement-related concerns or needs.
3. If PLWD and family carers are invited for the first time to collaborate with unknown researchers on a research programme that aims to improve dementia care,	then the perceived value of the research based on their lived experience and the endorsement from peers, community workers and volunteers	encourage them to feel comfortable and safe,	leading to their involvement because they overcome research-related fear and apprehension.
4. If PLWD and family carers are invited for the first time to collaborate with researchers throughout a research programme,	then the opportunity to choose how to get involved and the option to change their decision as the involvement unfolds and personal preferences or needs change	encourage PLWD and family carers to feel confident and valued,	leading to their involvement and continuous involvement because of the support perceived and the acknowledgement of their role in the research programme.
5. If PLWD and family carers are invited to participate in group activities about dementia care throughout a research programme,	then a jargon-free summary about the subject of discussion provided beforehand together with an accessible and approachable point of contact should they need clarification	encourages them to feel confident and valued,	leading to their engagement in the activities because they are better prepared to meet the activities demands and to their continuous involvement in the research programme as they are acknowledged for their role in it.
6. If PLWD and family carers are invited to discuss care issues in groups including dementia care professionals with whom they have no experience of collaboration,	then a group facilitator with good facilitation skills along with the presence of peers	encourages PLWD and family carers to feel confident, comfortable and safe,	leading to their engagement in the discussion because they feel well-equipped and overcome involvement-related fear and apprehension.
7. If the research team is well-supported, values the contribution of PLWD and family carers, and aims to promote their involvement throughout the research programme,	then an ongoing collective assessment of the involvement practice as experienced by team members and people involved	encourages the research team to apply learning to future decision-making,	leading to the continuous involvement of PLWD and family carers because of the responsive involvement practice implemented.
8. If family carers or dementia care professionals are committed to collaborate with researchers and value the inclusion in group activities of PLWD who may experience involvement challenges due to their dementia diagnosis or stage,	then they can use their knowledge to anticipate or interpret the needs of the relative they care for/person they are trained to care for and employ their communication skills to	encourage PLWD to feel comfortable and safe,	leading to their engagement in the activity because they overcome involvement-related fear and apprehension as well as adverse involvement circumstances.
9. If PLWD and family carers are involved with dementia care professionals in group activities focused on the care they receive as part of an ongoing collaborative relationship,	then the trusting relationship developed with the research team and other group members	encourages them to feel comfortable and safe,	leading to their engagement in the activities being open about personal challenges and needs because they overcome involvement-related fear and apprehension.
10. If PLWD and family carers engage in group conversations about dementia support planning with dementia care professionals as part of an ongoing collaborative relationship built on trust,	then the effective communication among group members conveyed with accessible narrative	encourages them to feel confident, comfortable and safe	leading to their engagement in the conversation with new and informed perspectives because they feel well-equipped and overcome involvement-related fear and apprehension.
11. If there is an established collaborative relationship between PLWD, family carers and the research team,	then keeping PLWD and family carers updated on the research progress and explaining their contribution to it	encourage them to feel confident and valued,	leading to their continuous involvement in the research programme because they feel well-equipped and are acknowledged for their role in it.

5.3 Programme Theory 1

PT 1 explains the impact of an early engagement with PLWD and family carers, reporting when and how it leads to their involvement. The consolidated version of this theory is stated in the text box below (see Text box 3), while evidence supporting its development and refinement is reported in the following subsections.

Text box 3. Programme Theory 1

If the research team develops a well-established plan of involvement (C) which is supported by funders and host organisation (C), in the context of accessible dementia-related local support services (C), then the early engagement with the community ($M_{resource}$) of an involvement coordinator responsible for facilitating the inclusion of PLWD and family carers in the research programme ($M_{resource}$) encourages the research team to adopt a reflective approach to decision-making ($M_{reasoning}$), leading to the involvement of PLWD and family carers (O) because of the tailored involvement strategy (O) resulting from the increased researchers' understanding of this population's concerns and needs (O).

5.3.1 Chain of inference

The chain of inference illustrated in Figure 24 links a well-supported PPI strategy to the early engagement of an involvement coordinator with PLWD and family carers and their involvement resulting from adaptations to the pre-established PPI strategy.

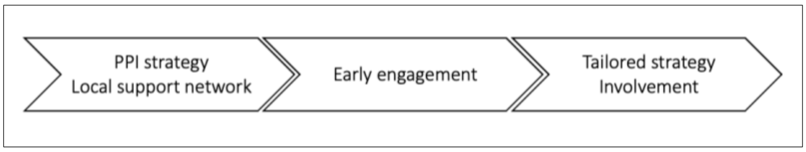

Figure 24. Chain of inference 1

The involvement plan described in the Primary care-led post diagnostic Dementia care (PriDem) programme funding application was drawn upon the PPI expertise of some researchers and the inputs they had received from public members (see section 4.2.1). The initial details of this plan, including the economic resources that were assumed to be necessary for its implementation, were made clear to all research team members as early as the developmental stage of the programme. After obtaining the funds, the team benefitted from the additional support received by different local organisations. For instance, in addition to the economic resources to cover the costs associated with the PPI strategy discussed in the application, the PriDem programme's team received from funders (i.e., Alzheimer's Society) the access to PLWD and family carers included in their PPI Research

Network or regularly meeting at a local memory café, thus contributing to the development of the Dementia Care Community (DCC) and its 'inclusive' aspect. In addition, the early and continuous involvement of PLWD and family carers in the PriDem programme was also facilitated by other organisations, either by providing cost-free accessible premises for DCC meetings (i.e., university venue, including parking) or encouraging the involvement of PLWD and family carers included in pre-established groups (e.g., dementia hub group).

The early engagement with the local community and the development of the DCC or its inclusion in the PriDem programme over time was responsibility of the DCC coordinator, who represented 'the single point of contact' for PLWD and family carers included. If on the one side, the presence of a DCC coordinator in the research team was expected to promote involvement by guaranteeing an ongoing flexible and inclusive approach to PPI (see section 4.5.2), on the other side, it supported the research team's understanding of the possible challenges. The meetings minutes dating back to early 2019 document the research team's acknowledgement of the different dynamics characterising the DCC meetings across settings (i.e., university venue, memory café and dementia hub), with specific reflection on the diversity of DCC members participating in PPI activities and the subsequent need to tailor both the format of the meetings and the design of the activities (see section 4.6.2).

5.3.2 Stakeholders' insights

All PriDem programme team members consulted in Phase II underscored the value of having a key individual – the DCC coordinator – spending a substantial amount of time and energy in establishing networks with local dementia support groups early in advance. Through monthly meetings, all research team members were kept informed about the ongoing engagement with these groups, thus being able to contribute to the design of PPI activities. Although resource-intensive, this approach towards the establishment of a PPI reference group for the contribution of PLWD and family carers to the research process was deemed crucial for the DCC to be inclusive and involved for the long-term. Additionally, according to the PriDem programme PPI lead, the presence of a PPI strategy with clear terms of reference, involvement objectives and associated costs ensured that the DCC was founded and its involvement guaranteed from a workstream to another.

5.3.3 Consolidation

When questioned about the value of early engagement in decision-making about the involvement strategy, the emphasis of all PPI leads interviewed was placed mainly on the resulting quality and relevance of research.

> ‘I think it's absolutely crucial. I think that the earlier you involve members of the public, people with dementia and family members in identifying a research subject, designing a research proposal, obtaining the research funding, and identifying the methodology that you want to use, advising about ethical issues, the better. The earlier you have people involved, the better your research will be because it will be research on a subject that is really important and that potentially has the possibility of impact, the possibility of implementation. [..] So, the earlier you can get people involved, the better your research, and the better the outcomes for the research.’ (Olivia, PPI lead)

> ‘I think it's obviously important in helping shape the research question and the research approach and making sure that you're doing research on an issue that is of relevance and important to that group. And of course, they can help influence the recruitment procedures for your, for those participating your study and make sure that they are the most appropriate, make sure that your research instruments are appropriate, you know, and that your interview schedule, for example, when using interviews, the questions are legible, understandable to that group. I think it's very important.’ (John, PPI lead)

It was only when they were probed further that they shared experiences about their early engagement with community members and the resulting improved understanding of circumstances that could be conducive to involvement (e.g., appropriate time and place of a meeting or type of ongoing support needed).

> ‘So, if you're looking about supporting people to take part in it, then you might want to know, what are the best times? Is it best to be with somebody else? Where's the best location? So, actually, early engagement is really quite ... yeah, it is probably best practice to make sure that you're actually planning your research with the people who are likely to be the beneficiaries in mind from the outset.’ (Hannah, PPI lead)

> ‘I think if you can engage them early you will know what works with them and what doesn't because, you know, obviously, you’ve asked them what it is that they need, what support do they need, what training do they need, and all those things, and what ongoing support would they need, especially in the case of people with dementia and their family carers. I mean, their life will change down the line, and you should take that into account.’ (Emily, PPI lead)

Among the challenges that could prevent researchers from early engagement, the one recurrently mentioned was the lack of funds necessary for that to be carried out, which was reported often to be the case at the stage of research development.

> ‘Well, money, of course, always rears its ugly head. Because if you're developing a research proposal at that stage, you're unlikely to have any money. So, involving people at that stage, I always appreciate, can be very, very difficult. You know, we don't live in a perfect world. And sometimes it's just not possible. And I really, I really understand that. If you can, if your university has some money, if your local research design service can give you some money because they have a public involvement fund

> [..] NIHR [National Institute for Health and Care Research]-funded research generally offers a public involvement fund so that they can help you to involve members of the public by providing you with funds and advice about how you may do that as you develop your research proposal. But sometimes I appreciate it's just not possible, and it's a real challenge for people.' (John, PPI lead)

Aside from the scarcity of funds, the circumstances challenging the possibility of an early engagement, or the opportunity of that early engagement to be meaningful, included the absence of PPI training among researchers and their limited awareness of good practice.

> 'In any case, researchers should reflect on what's feasible for the work that I'm doing. How much time can I invest in this as well because it does take time. And if you know that you don't have the time, think of what the question is that you can ask or what it is that you can offer. [..] here is also where funders come in. So, you're funded by Alzheimer's Society. They pay your mentors, that's being reimbursed by the society. But if you're funded by the NIHR [National Institute for Health and Care Research], you need to have an involvement budget and then, how big is your budget? [..] So, I think it's not just about engaging with people early. It's really about training and raising awareness amongst researchers on how to start these conversations and what should you also ask yourself when thinking or planning or implementing. I think that has maybe even a bigger impact because if they don't know how to do it, they also don't know how to ask the questions or how to have these early conversations.' (Sophie, PPI lead)

5.4 Programme Theory 2

PT 2 explains the ramifications of an early engagement with PLWD and family carers included in local dementia support groups. This is inclusive of the development of a relationship with the research team and its concomitant effect on their decision about participating in PPI activities. The consolidated version of this theory is stated in the text box below (see Text box 4), while evidence supporting its development and refinement is reported in the following subsections.

Text box 4. Programme Theory 2

If the involvement coordinator conducts early engagement activities with PLWD and family carers (C) who are included in existing local support groups (C) and are new to research (C), then the relationship among group members ($M_{resource}$) and the ongoing positive interaction between group members and involvement coordinator ($M_{resource}$) encourage PLWD and family carers to feel comfortable and safe ($M_{reasoning}$), leading to their involvement (O) because they overcome research-related fear and apprehension (O) and discuss openly involvement-related concerns or needs (O).

5.4.1 Chain of inference

The chain of inference illustrated in Figure 25 links the early engagement of the research team with PLWD and family carers included in pre-established support groups to their familiarity with the context of involvement and the resulting increased willingness to get involved.

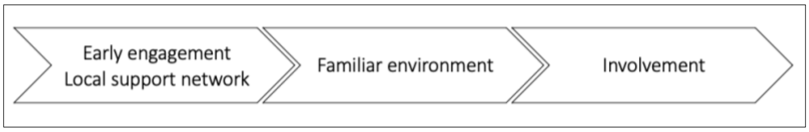

Figure 25. Chain of inference 2

The field notes documenting the implementation of PPI activities across settings helped identify the differences between the DCC meeting at the memory café or the dementia hub and those at the university venue (see section 4.6.2). These differences included details about ‘where’ and ‘with whom’ the PPI activities took place; both these aspects were initially considered among the factors possibly affecting the PLWD and family carers’ willingness to get involved in the PriDem programme. For instance, PLWD and family carers included in the DCC as members of pre-established groups met regularly at a local memory café or dementia hub, each time surrounded by peers with whom they had built a relationship over time. During their monthly meetings, they would engage in social activities (e.g., quizzes and music bingo) and share personal struggles to find some practical or moral support, as these were the reasons for funding these local initiatives. According to the insights shared by PLWD and family carers, some would also spend additional time together outside the context of the café or the hub. They would do so by participating in other social initiatives organised locally by the Alzheimer’s Society (e.g., singing for the brain sessions and memory walks events), checking on each other weekly via phone calls or text messages, or sharing a meal in a café close to where their meetings took place. Moreover, both these pre-established support groups had received several visits by the DCC coordinator before their involvement in the PriDem programme. By the time they joined the DCC – nearly a year after the beginning of the DCC developmental process (see section 4.3.2) – they had already established a connection with the DCC coordinator, which transpired in the positive interactions characterising the meetings, the conversations entertained during the break, and the level of detail they were willing to share in both instances.

5.4.2 Stakeholders’ insights

The contribution given by PriDem programme team members to this theory is mainly related to their discussion of the significant role played by the DCC coordinator in engaging with local dementia support groups early in advance, all of which was reported earlier (see section 5.3.2). When sharing the personal experience of engaging early with pre-established groups, the DCC coordinator underlined the benefits of having spent some time interacting with them before inviting them to contribute to the PriDem programme, as this encouraged them to get involved. Meanwhile, the insights of PLWD and family carers relevant to this theory were similar to those collected from the other public members consulted during Phase II. The presence of a key person willing to engage with PPI contributors before their actual involvement was perceived as a facilitator.

5.4.3 Consolidation

In explaining why the early engagement would lead to a successful involvement practice, PPI leads mentioned how a pre-established relationship with public members before their invitation to PPI activities may impact their willingness to get involved. According to them, this relationship helps public members overcome the fear and apprehension caused by what research involvement may entail, encouraging them to be open about doubts or concerns.

> ‘If you've got the early engagement, you've got a relationship, if you like, and you build a relationship. And I think that's very important because there are power differentials between yourself as a researcher and a member of the public who isn't maybe research aware or perhaps not used to dealing with universities and big institutions like National Institute for Health [and Care] Research. And I think overcoming those fears, perhaps, that kind of apprehension, I think it's really, I think it helps, shall we say if you've got a relationship already. And I'm increasingly … now going back to my research, encouraging people to develop a relationship with the community first and then involvement after [..] I think it aids the involvement because you've already got that relationship. And you've already kind of addressed a lot of those fears and the apprehensions that people have. Because otherwise, I think we often parachute people into being involved in research. And suddenly, we expect them to perform. Now of course they may not be used to express themselves in formal meetings and they may not be aware of all the research jargon and etc. we use. So having that early engagement, I think, is really important. [..] Because I think if you've developed that relationship with them, they can be honest about how best you can approach people and how best you can work with them.’ (John, PPI lead)

When exploring experiences relating to early engagement, PPI leads highlighted the historical lack of involvement of PLWD and family carers in PPI activities compared to other populations. They were of the view that if on the one hand, this lack of involvement impacted researchers’ understanding of this population’s needs, on the other hand, it caused little awareness among PLWD and family carers about research and related options of involvement. This can negatively affect their decision about PPI opportunities, along with experiences of tokenism. As such, early engagement can become handy for both the research team, as discussed in PT 1 (see section 5.3), and the PLWD and family carers targeted by the involvement strategy.

> ‘It goes both ways. Like the person living with dementia or their carer will have a better understanding of research, but then through that rapport, the person like me or other researchers will have a better understanding of people will respond positively to this, they won't interact with this, this is offensive, I know personally, they will not, people will not like this.’ (Lisa, PPI leads)

> ‘I think people are still a bit uncertain, not everybody, but I think a lot of people are still uncertain about what research is, what it means. And then sometimes those people who have a bit of an idea are a little cynical because they’ve been involved like a tick box exercise. So, I think, if you're looking and explaining while you're involving them, when you're involving them, and that is a really early stage, I think it will have, hopefully, an impact on how they perceive the whole of the research process, and you as a researcher, and then their willingness to engage.’ (Hannah, PPI leads)

Some of the PPI leads interviewed were experienced in regularly engaging with PLWD and their family carers included in local support groups to encourage their involvement in research by building a relationship with them. However, they also underscored the value of PLWD and their family carers being surrounded by peers in this process, as the resulting sense of safety leads to greater openness about their concerns.

> ‘So, I think the earlier the engagement, the better, the more likely, at some point, that there'll be a positive response. Not always, but it's worth trying. [..] Because there is the opportunity there to build rapport with the people that you're inviting to get involved. And it might be that people are coming to this completely fresh and you've encountered them through an event somewhere, or they might have just heard about something happening through social media and they're coming along for the first time, or it might be that they are part of a group, and you want them to join you. [..] If you visit them in Alzheimer’s cafés or community centres for example, and you build a relationship with them, they may tell you what they think about research, if they had any negative experience or any experience at all. [..] I believe it is much easier to get them on board if you go to them and they are in this kind of safe environment, if you like, with people that, you know, understand their needs and difficulties.’ (Barbara, PPI lead)

5.5 Programme theory 3

PT 3 explains the importance of building connections with PLWD and family carers for the purpose of their involvement. The consolidated version of this theory is stated in the text box below (see Text box 5), while evidence supporting its development and refinement is reported in the following subsections.

Text box 5. Programme Theory 3
If PLWD and family carers are invited for the first time (C) to collaborate with unknown researchers (C) on a research programme that aims to improve dementia care (C), then the perceived value of the research based on their lived experience ($M_{resource}$) and the endorsement from peers, community workers and volunteers ($M_{resource}$) encourage them to feel comfortable and safe ($M_{reasoning}$), leading to their involvement (O) because they overcome research-related fear and apprehension (O).

5.5.1 Chain of inference

The chain of inference illustrated in Figure 26 links PLWD and family carers' experience of PPI and the research topic and aim to the personal motivation that results in involvement, in addition to the endorsement of a familiar person.

Figure 26. Chain of inference 3

When compared with PLWD and family carers involved in the PriDem programme as members of pre-established support groups, PLWD and family carers attending meetings at the university venue were accessed through links within local general practices and organisations (see section 4.3.2). All of them were new to PPI, except for three family carers recruited from the Alzheimer's Society's PPI Research Network.

> 'An advert was also circulated to the Alzheimer's Society Research Network volunteers, and three volunteers have joined the DCC' (PriDem programme progress report 2019)

The value of the PriDem programme's aim appeared to motivate PLWD and family carers since the very early stage of DCC involvement in it.

> 'Thank you for inviting me. [..] This research is so important for me [family carer], my dad [person living with dementia] and everyone else out there dealing with dementia' (Feedback card, DCC meeting October 2018)

> 'A very interesting afternoon. Just to know that someone is out there thinking about all the things that we go through every day, and it is going to change because of this' (Feedback card, DCC meeting March 2019)

However, this enthusiasm seemed to be accompanied by a certain level of nervousness, which was not considered a valuable reason for not attending the meetings or dropping out.

> 'I was a little nervous but [I] feel good about how it went, and I look forward to how this goes forward. I hope to help out more in the future' (Feedback card, DCC meeting October 2018)

> 'I was scared at first. It's good to be able to see it all through now. I learned so much. I hope to be here again in November' (Feedback card, DCC meeting October 2019)

5.5.2 Stakeholders' insights

Stakeholders consulted in Phase II acknowledged the importance of building connections between the research team and the local organisations providing care services to PLWD and family carers. PriDem programme team members underscored the role played by some community workers in developing an inclusive DCC and guaranteeing its ongoing involvement. In particular, they joined the DCC recruitment effort, worked closely with the DCC coordinator, and attended group meetings at the university venue. Many PLWD and family carers shared the experience of being drawn to research by service providers or peers after receiving clarification on what it entailed and how they could contribute. Trust issues or ideas of how complicated, invasive or time-consuming research is were among the reasons cited by people for refusing to get involved. All public members included in Phase II discussed their interest in joining research that is aligned to personal interests and motivations, with PLWD and family carers considering studies centred on improving local services more attractive.

5.5.3 Consolidation

Upon being asked about the reasons that encouraged them to join research, PLWD and family carers first discussed the importance of the topic and its relationship with the lived experience of dementia. With the exception of one family carer, all PLWD and family carers interviewed had joined research due to their dementia-related journey. While revisiting their personal experience of struggles, they explained to have consciously chosen to do so out of altruism.

> 'I think the first study that that I was involved in advising was back in [..] 2010, actually. And it was about self-management for people with dementia. And so it was, yeah, if I have something to contribute to, to get more people like me being able to self-manage with dementia, more people able to gain confidence to self-advocate, then I'm really happy to work with researchers to ensure the best outcomes of the research.' (Jim, person living with dementia)

> 'Well, [relative with dementia] developed Alzheimer's disease, lived at home for about three years after diagnosis, she lived near me, and I helped look after her. But eventually, she deteriorated and had to go into a care home. And I visited her as often as I could. But then she died. And obviously, her

> illness had a major impact on me, and I wanted to do something to improve things for others.' (Patrick, family carer)

From their description of involvement over the years, it became clear that, compared to family carers, PLWD were more sceptical about getting involved in research, with PPI leads also being aware of how doubtful some of them may be. As such, the endorsement of trustworthy people (e.g., community workers or volunteers) was deemed to be a facilitator, as it could encourage PLWD to overcome doubts about personal capabilities and tackle research-related fear and apprehension.

> 'When I was first asked to collaborate, actually, believe it or not, I was afraid. Because I said, quite often ... and it was because of a volunteer for the Alzheimer's Society called [volunteer's name]. [volunteer's name] said, no, she said, you're going to be of more help to this than you think. And it was because I got the reassurance from [her] that I said, yes. I trust her. I trust her with my life. [..] And if she said that I could be of help, then I knew I was going to be of help [..] She just seemed to fit you into the right things. So, I knew that she would ... she wasn't trying, I mean, to deep me into the swimming pool.' (Kevin, person living with dementia)

> 'I work with all these different patient groups living with dementia. So, I have all these friends and connections among people living with dementia. It's then easier for them to know me based on my advocacy work. We have a repertoire of different experiences, and they know that their best interest is at the heart of what I do, and I'm not going to dig around and hurt anybody. [..] But because I'd already built rapport with all these people through different ways it was, they [a research team interested in getting PLWD involved] were able to access them. It wasn't just a random stranger knocking on their door saying, hey, help me. I've already vouched for them [..] I think that if trust is involved there, I think it makes them, it'll make people be more comfortable, more engaged, more committed to work with you. [..] They'll be more committed and saying, okay, I'll do this because X said this was okay, and I trust her.' (Lisa, PPI lead)

Meanwhile, many family carers shared the experience of having been drawn to PPI by peers. By listening to someone who was believed of equal standing, it was deemed possible to dismantle assumptions about health research and considering the possibility of contributing to it with experiential knowledge.

> 'There's a perception of research being only about laboratories and things like that. But it's not; they can be involved in so many ways. They can be involved in PPI, they can be involved in recommendations, they can share experiences [..] it's expressing the different ways in which you can by making awareness and talking to people. And if you've been there, and you've worn the hat, that way, you can encourage people to sign up [..] I've encouraged people to take part in research that probably wouldn't have thought they could. I've said, look, I'm an ordinary person whose life has changed, I became a carer. My life changed overnight, and now, 10 years on, 12 years on, I'm still sharing experiences [..] And the fact that I brought things down to earth to say to people, the ordinary people, we all want good things for people [..] if you share a little bit about your journey, you say, I never realised, the same as you, I never realised how I could be involved and what ways I could be involved [..] It's about encouraging other people saying you could do it as well. It breaks the barriers; it breaks the ice.' (Alan, family carer)

> 'Okay, so obviously, it was because I was looking after my mom who had dementia. I had also looked after my dad when he had Parkinson's disease and Lewy body dementia. So, that was a factor [..] But I think [name of a family carer] was the person who got me interested in participating. If it hadn't been

> for [name of a family carer], I probably would have never thought that I could be of help, maybe not even heard about the research going on at [name of a university in the UK]. And I wasn't sure whether they would have contacted me anyway, so, that was primarily the reason, that I looked after mom with dementia and helped with dad [..] And [name of a family carer] was another factor.' (Emma, family carer)

Some PPI leads recognised the positive influence that peers could have on PLWD and family carers' decision about whether to get involved, considering it among the possible benefits of conducting early engagement activities.

> 'So, if you talk really early with in your case people who've just been diagnosed with dementia, or who are living with dementia, or their family carers, [and say] I've got an idea for some research, these are the things I'm thinking, help me to shape it, help me to design it. Then they will know other people, I've met this person in the clinic, or I've been to a support group with this person, she'd like to come and join us, you'll get other people joining in that ongoing conversation, because they know each other, they talk the same language, and that can only benefit your research.' (Olivia, PPI lead)

5.6 Programme Theory 4

PT 4 explains the impact of a flexible and responsive approach to PPI on PLWD and family carers' decisions about getting involved. The consolidated version of this theory is stated in the text box below (see Text box 6), while evidence supporting its development and refinement is reported in the following subsections.

Text box 6. Programme Theory 4

If PLWD and family carers are invited for the first time (C) to collaborate with researchers throughout a research programme (C), then the opportunity to choose how to get involved ($M_{resource}$) and the option to change their decision as the involvement unfolds and personal preferences or needs change ($M_{resource}$) encourage PLWD and family carers to feel confident ($M_{reasoning}$) and valued ($M_{reasoning}$), leading to their involvement and continuous involvement (O) because of the support perceived (O) and the acknowledgement of their role in the programme (O).

5.6.1 Chain of inference

The chain of inference illustrated in Figure 27 links PLWD and family carers' PPI experience and the terms of reference for their involvement to the researchers' flexible approach to PPI and the resulting effects on PLWD and family carers' involvement.

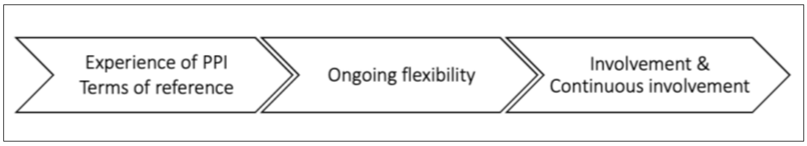

Figure 27. Chain of inference 4

The terms of reference for the involvement of PLWD and family carers in the PriDem programme as part of the DCC were made explicit in the flyers used for their recruitment (see Appendix T). PLWD and family carers invited to join the DCC could get involved in the PriDem programme as members of pre-established groups or as individuals choosing among the options cited in the registration form (i.e., in-person or remote meetings, home visits from a researcher and email exchanges), which also included a blank text box to document personal circumstances that could represent a barrier (see section 4.3.3). Among the possible barriers, the most often mentioned were family carers' caring and working responsibilities and the commitments they shared with the person they cared for.

> 'Currently I spend alternate weeks caring for my mother' (DCC Registration form 2018)
>
> 'I work full time 8-4 pm and spend time with mum 3 times a week after work' (DCC Registration form 2018)
>
> 'Giving us [family carer and person living with dementia] some notice as we have a busy week at times with health appointments, social activities, group etc in the Newcastle area' (DCC Registration form 2018)

The PriDem programme research team demonstrated flexibility in how DCC members could contribute to the research progress throughout 2019. For instance, DCC members who had initially chosen to attend in-person meetings at the university venue were invited to send an email or arrange a phone call with the DCC coordinator if they changed their mind or were unavailable to attend. At the same time, if they had decided to receive a visit at home because of caring responsibilities, they were given the option to attend in-person meetings if circumstances changed or some additional adaptations could enable their participation (e.g., participating in one PPI activity only and having a taxi journey arranged). The same approach was adopted towards the DCC members who initially chose to get involved as members of pre-established groups and then decided to contribute differently to the PriDem programme (e.g., via phone call or by receiving a visit at home).

5.6.2 Stakeholders' insights

Stakeholders consulted in Phase II considered that a flexible approach towards involvement was crucial for including PLWD and family carers in PPI activities. In exploring the matter, PriDem programme team members focused on the context enabling them to guarantee flexibility (see PT 1, section 5.3.2) and how they could ensure responsiveness to arising needs (see PT 7, section 5.9.2). Meanwhile, PLWD and family carers shared details of personal struggles. While some were dementia-specific, others were common with those experienced by other public members consulted, such as visual and hearing impairments, limited mobility, transport issues and working and life commitments. Conscious of the fact that ‘one size does not fit all’, stakeholders advised on communicating clearly the possibility of adaptations to personal needs, as this aspect of involvement can affect decision-making, especially if public members have not contributed to research before or are affected by a neurodegenerative condition that presumes changes further down the line.

5.6.3 Consolidation

PPI leads interviewed agreed on the need to guarantee some flexibility to enable the involvement of PLWD and their family carers in dementia research. If some impediments to involvement may be common among public members, others may be more personal or explicitly related to the progressive nature of dementia, which comes with ever-changing needs for both the person living with dementia and their family carer.

> ‘It's all about people making decisions about what is possible for them, what they can manage [..] and also what their work or life commitments are. And people are very busy. There are a very few people, even in a pandemic, where you know, the media would have us believe that there are people sitting around really bored. And I don't know anybody that's sitting around bored. And people, particularly when they're living with ongoing health conditions, or they're caring for somebody with an ongoing health condition, they're busy people. They've got lots of commitments and that sort of comes and goes.’ (Olivia, PPI lead)

When examining the reasoning for their decision of guaranteeing flexibility, some PPI leads explained how providing multiple options can lead to the involvement of PLWD and their family carers, even though they may have some reservations. This can be explained by the increased level of confidence resulting from the reassurance that they can change their minds or seek adaptations to the already agreed way of involvement.

> ‘I think, flexibility in acknowledging that if you want to include people living with dementia, even in other aspects of life, you know, you've got to meet them where they are. [..] So, I think it's good practice to acknowledge that people have different requirements. So, it could be time of the day, it could be that they might need to go to the loo periodically or, you know, quickly, or just the whole setup. And I think acknowledging that you recognise that as a researcher might well put people more at ease, making them more confident to sign up for it and express their preferred options for meetings.’ (Hannah, PPI lead)

Indeed, especially if involved for the first time, public members may be unaware of what they can handle in terms of commitment and how they prefer to contribute to research. As such, giving them options and leaving open the possibility of negotiations can encourage them to overcome feelings of inadequacy and discuss alternatives rather than refuse to get involved or withdraw along the way.

> ‘With something like this, there can be quite a difference between an experienced or a non-experienced contributor. So, if it's someone who is quite new, it's really easy to kind of put the words into someone's mouth, like, where do you want to be involved in? Would you want to do this and that? While someone who has done it before might actually be able to identify opportunities that the researcher couldn't foresee beforehand or didn't think of before. So, I think, here, it's almost more depending on, yeah, on the experience of the public contributor in this case and how confident and knowledgeable they are with it. If it’s their first time, they may not tell you what’s troubling them, and you lose them, because they think it’s their problem, they simply can’t make it. Especially, if they have dementia. I mean, environments may not be as dementia-friendly as we think.’ (Sophie, PPI lead)

However, while openness to a negotiable involvement practice was deemed a good strategy, PPI leads shared the pressure of that being part of an already demanding research process. Therefore, they advised on offering options of involvement based upon the terms of reference agreed and available resources, which, as already mentioned (see PT 1, section 5.3), help create the condition for a tailored approach that can be pursued by the research team.

> ‘Clearly, that [flexibility] has to be balanced against your resources, and, you know, your commitments, and all the rest of it. And I think giving them that [flexibility], is difficult, isn't it? Because, often when I think of when I'm involving people in research, I am looking for some kind of an ongoing commitment on their behalf as well. [..] And obviously, if someone really can't meet it, then sometimes you have to say, well, this is not right then for you or for me, because I do need X number of hours, roughly, and all the rest of it. But obviously, we all try to be as flexible as we can.’ (John, PPI lead)

> ‘You can have a chat with someone and say okay, so where would you want to be involved? Let's do the lay summary and a dissemination meeting at the end and whatever. But in any case, researchers should reflect on what's feasible for the work that I'm doing, how much time can I invest as well in this because it does take time.’ (Sophie, PPI lead)

When discussing the matter, PLWD and family carers agreed on the importance of researchers adopting an involvement strategy that is adaptable to personal circumstances. If, on the one hand, PLWD explained the value of this approach in relation to the progressive nature of dementia, on the other hand, family carers considered it a necessary condition for their involvement, given their caring and working responsibilities.

> ‘I guess, my belief would be that they [researchers] will learn from me and will adapt to my needs as we go along. But I guess part of it is a wish and a hope, you know? If they don’t, I could never get involved.’ (Jim, person living with dementia)

> ‘Well for me, it's essential. I have caring responsibilities. I cannot go swanning off down to London for meetings and spending a day down there [..] So, I think that that has been a big thing in dictating who I decided to work with … the fact that they would take me remotely [..] that they would accept my working remotely. And if they didn't, well, then I just didn't work for them.’ (Grace, family carer)

> ‘And yes, it would obviously be easier for me, and I would think other people too to be involved. [..] For example, if I was working at this time, I wouldn't be able to talk to you. I would have to look at weekends or evening meetings or something like that. So, I would say it's very important that it's in a way that's adaptable to my preferences but also priorities. And obviously, if they couldn't adapt, and let's say I had to go to work at that time, well then I would have to consider whether to be involved.’ (Patrick, family carer)

The possibility of being involved in a way that is responsive to a change of needs or circumstances was also considered a motive for involvement, given that ad-hoc adaptions of the involvement strategy demonstrate the research team’s commitment to PPI, and subsequently, to the inclusion of PLWD and family carers in the research process.

> ‘I think when I express an interest in something, I would now say, however, please note that I'm hard of hearing. And therefore, if you're going to have a lot of meetings in noisy rooms like in the past, that would be very difficult for me. And they say oh, don't worry, we'll get a hearing loop, so that you can join in properly with that. And that's adaptable to my preferences or changing needs or priorities, I suppose [..] So, how would I feel about it? I would expect I think that if there were certain preferences and changing needs or priorities that could affect how a person is involved in a study, then, as involvement in some sort of partnership, you'd expect that the research team would try to adapt and would understand that it is important to adapt as they would if one of their research colleagues was in a difficult situation.’ (Eric, Person living with dementia)

> ‘It certainly makes you feel you've got a seat at the table when you're discussing, for example, when a meeting is going to take place, whether that's in-person or online, feeling you're from the start included in the team. You're being asked when is it convenient for you and would you prefer for us to meet in a group or on your own? Giving people options is always great. [..] And, I mean, who knows if I [family carer] can be there at that time or if the person with dementia is ok to do the same thing over and over again. [..] So, it is always preferable to be asked. And I mean, to a certain extent, with the work you do, you've got to take into account what people say because otherwise they won’t come.’ (David, family carer)

5.7 Programme Theory 5

PT 5 explains how to encourage the engagement of PLWD and family carers in PPI activities. The consolidated version of this theory is stated in the text box below (see Text box 7), while evidence supporting its development and refinement is reported in the following subsections.

Text box 7. Programme Theory 5
If PLWD and family carers are invited to participate in group activities about dementia care (C) throughout a research programme (C), then a jargon-free summary about the subject of discussion provided beforehand ($M_{resource}$) together with an accessible and approachable point of contact should they need clarification ($M_{resource}$), encourages them to feel confident ($M_{reasoning}$) and valued ($M_{reasoning}$), leading to their engagement in the activities (O) because they are better prepared to meet the activities demands (O) and to their continuous involvement in the research programme (O) as they are acknowledged for their role in it (O).

5.7.1 *Chain of inference*

The chain of inference illustrated in Figure 28 links a certain organisation of the PPI activity to the related information and support provided to PLWD and family carers beforehand and the resulting engagement on the day of the activity.

Figure 28. Chain of inference 5

As already mentioned, the organisation of DCC meetings was observed to be varied across settings (see section 4.6.2). PLWD and family carers attending DCC meetings at the university venue were sent via email or post the agenda of the meeting and a summary of the topic of discussion beforehand, following explicit request at a very early stage of their involvement in the PriDem programme.

> ‘Advance agenda/topics for discussion might be helpful.’ (Feedback card, DCC meeting October 2018)
>
> ‘Can we have an agenda before next time?’ (Feedback card, DCC meeting October 2018)

Along with this information, they would also receive the contact details of the DCC coordinator to ask for clarifications on the topic of discussion or arrangements for participation if needed. On one occasion, one of the two public members collaborating with the research team for the involvement of the DCC in the PriDem programme (see section 4.5.2) was explicitly asked to document the level of engagement observed during the activities held at the university venue. According to the notes taken that day by this public member, the information provided beforehand may have affected attendees’ contribution to the PPI activity.

> ‘The activities certainly engaged people. They all seemed to understand what was being asked of them, so I felt that they had been given enough background/preparatory information.’ ([Name], DCC meeting October 2019)

Meanwhile, PLWD and family carers attending meetings at the memory café, or the dementia hub, were solely informed about the upcoming visit of the DCC coordinator by their group facilitators, who were not given details of the PPI activity. This lack of prior information may have reduced the engagement of PLWD and family carers in activities unfolding in these other two settings, especially at the beginning of their involvement, when group members appeared to take longer to ‘warm-up’, despite being surrounded by peers in a familiar environment.

5.7.2 Stakeholders’ insights

All stakeholders consulted during Phase II acknowledged the importance of having some material explaining key details of the activity before this takes place. PLWD, family carers and other public members expressed how they find it challenging to navigate meetings without spending the necessary time reflecting on the topic of discussion, whether the expected contribution entails lived experience or inputs on research domains. Some of them also explained the value of making some notes to take to the meeting to ensure they could contribute within the time given without forgetting or getting distracted. The majority of public members consulted were experienced in having one consistent research team member available to be contacted for further information or support, considering it a valuable resource regardless of the level of PPI experience.

5.7.3 Consolidation

Upon being questioned about the preparation before group meetings, PLWD and family carers explored their experiences of research involvement, associating the information received beforehand with their level of confidence on the day of the meeting.

> ‘I think for any meeting, whether it's a group meeting or not, I do prepare for it in different ways. You sent me the list of the questions and so, I read them. I didn't write anything down about them or I didn't write anything as far as a response is concerned. But I guess, I read them just to say, okay, you know, I will answer to them on the fly, but I'm confident about answering them.’ (Jim, person living with dementia)

> ‘Okay, so I would always try to prepare, especially if it's a group meeting. And yeah, normally, researchers are more than happy to share materials, information questions, what is expected of you. And obviously being prepared, I think it gives you confidence.’ (David, family carer)

Many family carers reported increased engagement in the conversation owing to some alone time for reflection on the topic of discussion and its linkage with lived experience. Moreover, they discussed the negative consequences of not receiving material beforehand, such as forgetting details, remaining silent or being unable to contribute as they could otherwise.

> ‘Generally, yes [I prepare for meetings] because I like to try and get my thoughts together. Because otherwise, if I'm just talking off the top of my head, I might forget things [..] I think it makes me more willing to contribute. I've had a chance to think about the material in advance, you see. [..] If I wasn't told the questions in advance, I probably would still participate but I just think having the questions in advance makes it easier to get your thoughts in order and not forget something. [..] It enables you to, well, certainly for me, enables you to focus your thoughts and associate your own experience with the question that they are trying to get an answer to.’ (Patrick, family carer)

> ‘If they give me any kind of information or documentation, I always look at it, comment on it, scribble in the margins, that sort of thing. [..] And if they haven’t sent anything, for instance, I’m a co-applicant on a research project and they don't always send it out [..]. So, on those situations, I just sit and smile in a mysterious kind of a way and then I shake my head and just, oh, yes, very interesting. Then, if he actually asks me a question, I'd say, I don't know what you are talking about [..] I'm sorry, but you’ve lost me about five minutes ago. I'm just hanging on, like grim death, hoping something will become plain.’ (Grace, family carer)

PLWD shared similar experiences; however, additional reflections were made in relation to their diagnosis of dementia. According to them, a certain level of nervousness can be triggered by uncertainty and forgetfulness, which can add further pressure to get it right then and there.

> ‘I find it difficult going into meetings of any sort without preparation. Any sort of meeting, lots of other sorts of meeting. So, agendas are important for me, and those like me.’ (Eric, person living with dementia)

> ‘Sometimes, depending on the research, like, if you send me an email, a Zoom meeting with Ester, Monday at 10 o'clock. Who's Ester? Where is she from? Did I know her? What's going on? So, I like to know some little bit about what's happening, so that I can remember and I’m ready at any time.’ (Kevin, person living with dementia)

When discussing the matter, all PPI leads appeared aware of the potential negative impact of the lack of information beforehand on the engagement of PLWD and family carers in PPI activities. According to their experiences, providing material in advance would enable PLWD and family carers to contribute meaningfully to the activity, increasing their confidence and encouraging them to overcome the pressure they may experience.

> 'I feel it's not fair to make that a complete surprise, because people are trying to take in that information. And then it'd be much harder for them to reflect on it and come up with some answers because they're still trying to grip the initial information.' (Barbara, PPI lead)

> 'But what I've seen is that people have found it very helpful if they knew in advance what was going to be asked or what are the things that we need to review, what's going to be discussed so that they can prepare and be there also more confident that they can contribute because they've written down their answers, and then there is still the opportunity for them to give more answers there. But at least there isn't a pressure on them, especially people with dementia, that they have to be quick on the spot, because you never know at what kind of stage your brain is and you never know how quick you can be on the specific date.' (Sophie, PPI lead)

However, while PLWD and family carers focused on exploring the differences in their engagement when with or without receiving material beforehand, PPI leads also explained its potential impact on peoples' decisions about whether getting involved. This is attributed to the fact that the complete absence of material could be associated with the lack of genuine interest from the research team in hearing the voice of public members.

> 'I think making material available in advance is a really good idea. Even if people don't have time, or they choose not to read it. I think it demonstrates that you're thinking about what's best for them, what can help them making a real contribution to the project rather than being a number.' (Olivia, PPI lead)

> 'Having something in advance can be quite useful. Because otherwise, you might say, for example, you want someone's views on your questionnaire. If you only send it, if you only give them the questionnaire when you're actually at the meeting, then they haven't really had time to reflect and think. And therefore, they might regard their involvements a little bit tokenistic because they'll say, well, you showed me a questionnaire, but I have not had time to reflect on this and I might need it.' (John, PPI lead)

> 'I think this sort of shows how you value people coming into an activity or a meeting, or whatever it is. [..] So, I think, you know, it's just good practice to let people know what they're letting themselves in for. It encourages them to come and shows that you respect them, you're interested in knowing what they have to say'. (Hannah, PPI lead)

Despite being conscious of the potential negative consequences, three PPI leads admitted their reluctancy in providing information beforehand on certain occasions. The reasoning behind this decision included the belief that it could be misleading, the interest in capturing people's immediate response, and the lack of resources necessary to develop concise, jargon-free material.

> 'It's hard, isn't it? Because sometimes if you give the material before, and they have a long time to think about it, they can overthink it. [..] I have done it [sending the material in advance], and then they've gone off down the wrong track. So, I try to give as minimal amount of information about the project as possible beforehand just to avoid that kind of overthinking.' (Emily, PPI lead)

> 'It can it's also a bit about what is your aim. Do you want people quick and honest opinion, or do you want a more reflective answer? Because that is not always the same of course. So, I think it comes down to what is it really that you're looking for in a meeting. Do you want a more in-depth discussion? And I think for that, it's always better for people if you give them an option to prepare. Or do you want

> them to just come and give you their initial responses and their initial feelings and thoughts? Both can be valid, but both require a different approach.' (Sophie, PPI lead)

> 'I guess it is getting that balance of what it is that they want and also your capacity to give it as well. Because this is one of my other issues. [..] The more stuff you send, the more you have to think about, is it in plain language? Are they going to understand it? Is it going to cause more problems than if I explain things face to face? So, there's all of those things.' (John, PPI lead)

In relation to the organisation of PPI activities, all interviewees underscored the value of having a dedicated member of the research team available for clarifications before the actual involvement. Among the positive aspects, they can reassure attendees about their understanding of the topic of discussion while also clarifying any doubt about their participation in it.

> 'But again, that simple thing, if you need, contact me, if you're unsure or if you have any questions, please feel free to contact me, it puts my mind at ease. It's a simple thing but it means so much for me.' (Kevin, person living with dementia)

> 'They are always provided with a team members' contact details [..] I have had that a couple of times with people wanting to just have a little chat before the meeting. And just either wanting to be sure that they know what the meeting is about or wanting to be clear that, that they're not expected to have particular expertise before they come to the meeting. So, it's mainly a kind of reassurance that this is something that they can come along to and not feel that they don't have something to contribute.' (Barbara, PPI lead)

When questioned about what would encourage PLWD and family carers to get in contact before the activity, PPI leads underlined the importance of choosing a member of the research team who is approachable and reachable in different ways (e.g., phone call or email) and at different times of the day or the week.

> 'I think in any research project, it's always useful to have one member of the team, who is the go-to person for the public members if they have any concerns. I think that can be quite reassuring for them. [..] What would encourage them to get in contact, if in doubt? Well, again, it's just the vibe, the message that you send out, isn't it, that making sure that the individual chosen is approachable. And so, it's important, I guess, to have the right person in place to do that. [..] You want someone, don't you, that people feel comfortable approaching.' (John, PPI lead)

> 'That'd be something I'd automatically do in a nice, friendly way. Whether it's an email or a letter or however you're contacting people, you know. Sometimes it's quite nice that you even put a photo in so, this is me, you know, this is what it's about, you know, please don't hesitate. And so, it's hopefully … use a welcoming tone in the any correspondence that you have. And sometimes it might be, I mean, some people like to have a letter and a phone call. So, you know, look, I'm going to bring you, or would you like me to bring you and discuss any issues you have? That that sort of thing. I think that might encourage people. It's the welcoming tone, the fact that you do sound as you're keen to be contacted, and they can do that in different days of the week or maybe different times on the same day [..] Sure, because you are busy, but they are busy too.' (Hannah, PPI lead)

Being approachable and accessible appeared to be also the attributes valued by PLWD and family carers, who shared the experience of communicating with different research team members before participating in PPI activities.

> ‘And I suppose if I didn't understand what was being asked, I would get in contact with them [research team members]. And they're very approachable. They don’t make me feel embarrassed about asking silly questions, you know, things that I think are irrelevant. They might be irrelevant to me, but they are not necessarily silly to them. [..] No, it depends really, sometimes I get back to them with an email or I just give them a call. They give us choice, which getting back to your question [what would encourage you to get in contact?], I think it helps.’ (Emma, family carer)

> ‘I think it's that reminder periodically that, you know, if you do have a question, feel free to let me know or if an email goes out with an attachment or something, you know, here is the material for the next meeting, this is what we should be talking about or whatever. But in the meantime, you know, if there is anything you'd like to discuss or have a question about, let me know. Give me a call or send me an email on these days or times, so that they can pick. [..] It's that kind of approach that I would always encourage researchers to have. [..] No, it’s never one [researcher], but it doesn’t really matter, does it, as long as they use the approach that I just told you about.’ (Jim, person living with dementia)

5.8 Programme Theory 6

PT 6 explains the impact of the presence of a good facilitator and some peers on PLWD and family carers participating in group activities that include dementia care professionals with whom they have no experience of collaboration. The consolidated version of this theory is stated in the text box below (see Text box 8), while evidence supporting its development and refinement is reported in the following subsections.

Text box 8. Programme Theory 6

If PLWD and family carers are invited to discuss dementia care issues (C) in groups including dementia care professionals (C) with whom they have no experience of collaboration (C), then a group facilitator with good facilitation skills ($M_{resource}$) along with the presence of peers ($M_{resources}$) encourages PLWD and family carers to feel confident ($M_{reasoning}$), comfortable and safe ($M_{reasoning}$), leading to their engagement in the discussion (O) because they feel well-equipped (O) and overcome involvement-related fear and apprehension (O).

5.8.1 Chain of inference

The chain of inference illustrated in Figure 29 links the topic and organisation of PPI activities to the facilitator’s approach to the involvement dynamic and the presence of peers to the engagement of PLWD and family carers.

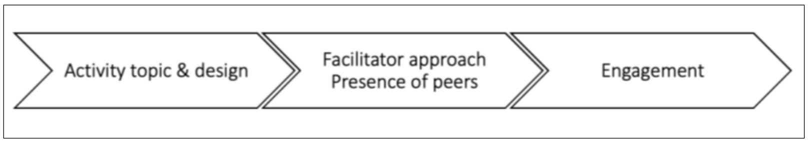

Figure 29. Chain of inference 6

While the content of the activities carried out by PriDem programme team members was similar across settings, the organisation and facilitation were different (see section 4.6.2). For instance, attendees of DCC meetings at the memory café or dementia hub included only PLWD and family carers. Meanwhile, meetings organised at the university venue required the cohesive engagement of PLWD, family carers and dementia care professionals, thus offering different perspectives on dementia care (i.e., service users and providers). On these occasions, the ability of some group facilitators to chair discussions characterised by different perspectives was deemed to be particularly significant so that everyone could contribute.

> 'Good liaising with all different people, professionals, carers, etc.' (Feedback card, DCC meeting November 2019)
>
> 'Well facilitated, everyone got a chance to talk' (Feedback card, DCC meeting July 2019)

The active listening of group facilitators during the PPI activities was also documented as a considerable element of positive feedback, along with the genuine interest showed by them in hearing the voice of DCC members.

> 'Coordinators/facilitators all very receptive, do not seem to the be trying to pull out pre-decided answers.' (Feedback card, DCC meeting October 2019)
>
> 'Good facilitation today. I like that people are consulted and have a voice' (Feedback card, DCC meeting July 2019)

Some DCC members also highlighted the support provided by group facilitators in circumstances where PLWD would get emotional after recalling upsetting personal experiences to contribute to the group activity.

> 'Dementia is a very emotional subject. I felt [that] the person with dementia involved was well supported by the group + leader.' (Feedback card, DCC meeting October 2019)

Group facilitators were also deemed capable of establishing a relaxed atmosphere where people felt comfortable to share intimate details of lived experiences or controversial opinions about the matter of discussion without fearing consequences.

> ‘People seemed relaxed, comfortable and very open and honest, and in some cases even disclosing things that they knew would be controversial. They all clearly felt they were in a safe environment which is down to yourself as facilitators doing a good, effective job.’ ([Name], DCC meeting October 2019)

Despite all the above, group facilitators’ lack of exposure may have sporadically compromised the engagement of PLWD and family carers in PPI activities, allowing professionals to dominate the conversation.

> ‘In each group that I observed everyone got a chance to speak. I only observed one group where one individual, a professional, appeared to dominate the conversation.’ ([Name], DCC meeting October 2019)

5.8.2 Stakeholder’s insights

All stakeholders consulted during Phase II concurred on the importance of guaranteeing an equal status among people involved in group activities. Each of them highlighted the value of a good facilitator and a balance of professionals and public members in the composition of groups. In particular, the PriDem programme PPI lead and the DCC coordinator admitted how in the organisation of groups for the activities at the university venue particular effort was put in guaranteeing a balance of perspectives (i.e., service users and providers). Meanwhile, the group facilitators consulted shared the challenges experienced while facilitating group activities that included a mixed population, discussing the tendency of professionals to be more vocal than PLWD and family carers and recognising personal limitations in facilitation skills. They were of the view that achieving a good balance in this type of contexts requires both training and co-facilitation. According to the experience of PLWD and family carers, the presence of professionals is intimidating, especially at the beginning of a PPI journey when there is limited awareness of the value of personal knowledge about dementia. There was no difference with the insights shared by other public members consulted, who agreed with PLWD and family carers on the need for the group facilitator to be aware of unspoken tensions and skilful enough to deal with the potential challenging group dynamics.

5.8.3 Consolidation

When questioned about group activities, all PPI leads underscored the importance of thinking about the composition of the group, which they considered partly responsible for the level of public members' engagement in PPI activities. According to the examples reported by PPI leads, people tend to be influenced by whom they are surrounded by, and while certain power dynamics can be easily anticipated, others may require time to reveal.

> 'I think that people monitor what they say based on who's in the room, and that could be a Zoom room or a chat room or a real room. And so, having different populations involved together can be … there are hierarchies, power imbalances and dynamics that are not always apparent to a researcher or to a PPI lead and that they need to be sensitive to, and that they could learn over time.' (Lisa, PPI lead)

PPI leads explained their view on the impact of power imbalance among group members, reflecting on the possible advantages and disadvantages. On the one hand, they believed that there is value in creating a mixed group of public members and professionals; on the other hand, they knew public members could feel intimidated by the expertise of professionals, thus avoiding contributing or limiting their contribution due to their fears concerning future ramifications.

> 'If there is a mixed audience that you're asking for mixed input from, and there are health care professionals and patients who you are kind of getting that information from, then yes, that does affect the dynamic. Because the patients don't want to say anything that they think that the health care professionals would think is wrong, even though there's no right or wrong answer. So, I think it does affect what they say. [..] Because, you know, we're still in that kind of paternalistic model of the doctor or the healthcare professional knows best. And they ought to be saying, it's a great idea, doctor, and it's getting them kind of moved onto that.' (Emily, PPI lead)

> 'It has happened in the past that people might not be happy to speak within certain, you know, yeah, they might feel a bit discouraged by other people who are present. [..] If it was somebody who's directly involved in their care, you might, you know, you're not going to turn around, or it would be more difficult to turn around and discuss anything that you felt there were problems or issues with. And even if they were just a professional representing somebody who delivered that sort of service that people are accepting, you know, in a similar sort of way they might feel … well, at least I'm getting something, and I don't want to create any problems in that respect. And regardless of how you might say, well, this doesn't get back to you I mean, you know, and that we're trying to say, look, you know, this is not personal, whatever. But, yeah, these things may be problematic. And so, it may be better not to have mixed groups.' (Hannah, PPI lead)

PLWD reported several examples of involvement with care professionals. Under these circumstances, they all communicated the possibility of experiencing lack of confidence, which was described as a natural consequence of comparing themselves with someone having technical knowledge about dementia.

> 'There is a big difference, I think, for many people, between care professionals and peers. I mean, if you were in a room with your peers, even some people who were not necessarily as experienced in, you know, working with researchers, I think they would still have the confidence to engage in a conversation. But if you added care professionals into the mix, some of that confidence, I suspect,

> would evaporate. Just simply because, you know, like, I suspect, you and I have talked about how so many people with dementia will say, well, I couldn't do anything with researchers, because I don't know anything about research, period. And, you know, really, that's not the point. And in many cases, that's not the point. The point is providing your lived experience voice to that research [..] But many would be inhibited, whether slightly, or more than slightly, with the presence of care professionals.' (Jim, person living with dementia)

While some PLWD considered this type of response to mixed group activities common among public members, others shared how PLWD may experience additional inhibition caused by the lack of credibility it could be associated with dementia.

> 'I suppose in the early days I would have felt a little bit intimidated by a person's title. And by me talking about my own experience and what I'm going through there was just that thought in me that maybe they wouldn't believe me or that they'd say no that's wrong. And I was little, I was a little afraid of that. But that is long gone now. But for people who are newly diagnosed, I know that's there.' (Kevin, person living with dementia)

Family carers appeared to share the same experience as PLWD, with many of them explaining how their continuous involvement in PPI activities had taught them what they were bringing to the table and why their contribution to the research process was valuable as much as the one given by professionals having technical knowledge.

> 'I might be a bit wary because I would think that they've got a lot more specialist knowledge than I have [..] I think as being a non-specialist, it's better if you have another, at least one other non-specialist there. So, you're not the only non-specialist. [..] And some people might take a very different view. And some people might want to be in a group with only non-specialists before being happy [..] but I've realised over the years that it's important to have both points of view. And just because I don't know the technical difference between different types of dementia, that's no, I realise now, it's not a barrier for me, just say, well, can you explain this or the other? [..]I would say that from experience, I am much more positive now about going into discussion with care professionals, or doctors, or other people with a lot of technical knowledge that I don't have.' (Patrick, family carer)

PLWD and family carers concurred with PPI leads on the importance of having a fair balance between public members and professionals if they are required to be involved together for the purpose of the PPI activities.

> 'I think you have to be very careful with the numbers, so that people don't feel outnumbered and intimidated by professionals.' (Barbara, PPI lead)
>
> 'If you were in a room with your peers, even some people who are not necessarily as experienced in, you know, working with researchers, I think they would still have the confidence to engage in a conversation.' (Jim, person living with dementia)
>
> 'I really feel there should always be at least two public members to any committee or whatever. Because one does suffer from that.' (Alan, family carer)

When questioned about the organisation of PPI activities, the presence of professionals in group activities was not the only aspect explored by PLWD and family carers. According to their experiences, the use of technical language was the most frequently reported barrier, with PPI leads aware of the negative impact that jargon can have, regardless of whether it is adopted by professionals involved or group facilitators.

> ‘And sometimes it depends on the jargon that's used. If I think that's way over my head, I don't know what that is, I will probably not speak up straight away and say, well, I really don't understand what they're asking. I would hold back and maybe ask later.’ (Emma, family carer)
>
> ‘There's something about having plain language in any of the interactions they (professionals) have. [..] There's nothing more off putting, I think, than the jargon that we use in health and social care.’ (John, PPI lead)
>
> ‘I’d say make sure that you [facilitator] are using accessible language and try to avoid jargon and all of these things that make it more difficult to engage in a meeting.’ (Sophie, PPI lead)

Particular attention was also devolved to the dominance of certain group members over others. While the majority of PLWD and family carers reported how that scenario was mainly recurrent in contexts where they were involved with professionals, PPI leads mentioned how among peers there could also be who is more vocal than others due to considerable PPI experience or personality reasons.

> ‘If you’ve got some very experienced contributors, and they tend to dominate, so I think if you’ve got some experienced and non-experienced contributors that affect the composition and what said within that group as well [..] So, if you’ve got that mix of people, sometimes the more experienced can then dominate.’ (Emily, PPI lead)
>
> ‘That’s really hard, isn’t it, because you know, in groups, there’s always somebody who likes the sound of their own voice and has got a lot to say for themselves and other people who are less confident or shy or more anxious.’ (Olivia, PPI lead)

The presence of a ‘good’ facilitator was deemed crucial to enable everyone involved in group activities to contribute. The profile of the ‘good’ facilitator drawn by PPI leads entailed the following skills: advanced preparation, active listening, clear communication, and focus on involvement dynamic and goal of the activity.

> ‘So, there are several things that you [facilitator] can do. In the beginning, you can, people use different words for it, but it kind of comes down to some terms of reference so that you set up ground rules. What’s the language that we use, every voice is equal, everyone’s being heard, we don’t judge each other, talala. So, those kinds of things set the scene for the discussion. That’s something you can do to make people feel at ease. I think, at the end of the day, the facilitators’ role is to make sure that partly no one will overtake the discussion because people can get really passionate or might come with their own agenda. So, as a facilitator, you wanna drag them back to the point that you actually wanna discuss. [..] It's about active listening, and things like that show you have an interest in people show that you are there to listen to them. [..] Make sure that you ask further when someone tells

> something, that you're inviting them to speak as well. Make sure that you are using accessible language and avoid jargon and all of these things that make it more difficult to engage in a meeting.' (Sophie, PPI lead)

Moreover, PLWD and family carers opined that a good facilitator knows how to create a relaxed atmosphere so that public members feel comfortable to open up despite being challenged by being unfamiliar with PPI or working with professionals. Additionally, they are capable of encouraging everyone to contribute without pressuring them to do so.

> 'I think they're good listeners. They pay attention. They obviously ask you, as you asked me at the beginning, you know, do I consent to various things and explain things. They know how to let a conversation and a discussion flow by asking the right sort of questions and standing back when the conversation in a group gets going. Because a group facilitator has got a very important role in the sense that they've got to trigger the discussion, but once the discussion gets going, it's very important that they allow different people within the group to have their say. [..] So, they know when to speak and when not to speak. They know how to put people at ease by saying, how are you? How's your morning going? Or stuff like that.' (Patrick, family carer)

> 'It's a matter of the facilitator being patient, being aware of group dynamics and ensuring that someone who has not necessarily been the most vocal is given that opportunity to talk. But yet, at the same time, without putting that person on the spot or making that person feel awkward by forcing them to say something. Being sensitive to the group that you're dealing with. That is vital.' (Jim, person living with dementia)

While some people may need encouragement to open up, others may choose not to verbally interact with other group members during the activity. By valuing non-verbal communication, group facilitators can become aware of these circumstances and propose alternative ways of contributing, such as writing personal contributions on paper or sharing their thoughts only with them.

> 'Sometimes, people aren't necessarily saying a lot in the group, but they are absolutely engaged in the conversation. So nonverbal participation is really important. There might be a really vocal member of the group, who's saying, you know, who's dominating, but other people will be nodding or shaking their heads. So, I think allowing people to participate non-verbally is okay, people can choose to do that, you don't have to speak in a group to contribute if you do not want to.' (Olivia, PPI lead)

> 'Also have different methods of engagement within the meeting so that it doesn't always have to be a spoken contribution. In one of the meetings that we were in, there were people who didn't want to speak at all. So, they wrote down on a post-it note and we left a sheet in the middle of the table for them to put the post-it notes on whatever subject we were talking about. Then somebody read those at the end. And the other one, another person in that group had some issues and had a lot to say, but they didn't want to speak out loud. So, they spoke to one the facilitators who was next to them, and they gave their views that way.' (Emily, PPI lead)

5.9 Programme Theory 7

PT 7 explains under what circumstances an ongoing collective assessment of the PPI strategy implemented by research team members leads to an involvement approach that is responsive to the unanticipated needs of PLWD and family carers involved. The consolidated version of this theory is stated in the text box below (see Text box 9), while evidence supporting its development and refinement is reported in the following subsections.

Text box 9. Programme Theory 7

If the research team is well-supported (C), values the contribution of PLWD and family carers (C), and aims to promote their involvement throughout the research programme (C), then an ongoing collective assessment of the involvement as experienced by team members and people involved ($M_{resource}$) encourages the research team to apply learning to future decision-making ($M_{reasoning}$), leading to the continuous involvement of PLWD and family carers (O) because of the responsive involvement practice implemented (O).

5.9.1 Chain of inference

The chain of inference illustrated in Figure 30 links the organisational culture characterising the research team and the support they receive for the implementation of PPI to the ongoing assessment of the involvement practice and the resulting responsive strategy of involvement.

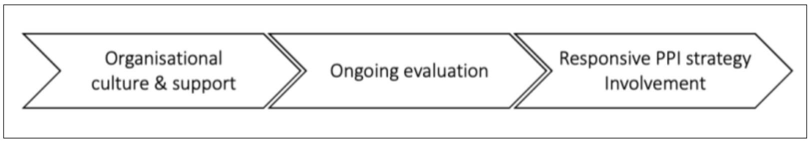

Figure 30. Chain of inference 7

The value of the support that the PriDem programme team received from funders and the host and local organisations towards the development of the DCC and its involvement in the programme has already been mentioned in this chapter (see sections 5.3.1 and 5.4.1). The research team's expectations about the DCC's contribution to the PriDem programme were stated in the funding application (see section 4.5.1) and met as a result of the PPI activities implemented across settings (see section 4.5.3), demonstrating the alignment of research team members to the PPI strategy initially developed. However, for the DCC's contribution to persist throughout 2019, several adaptations to the initial involvement design were made. These adaptations resulted from the research team's reflective approach to PPI (see section 4.5.2), which was made possible by the continuous assessment of the feedback received in different ways (i.e., via feedback cards, email exchanges and phone calls) from the various actors included in the involvement process (i.e., DCC members, memory café and dementia hub groups' facilitators, and public members contributing to the involvement of the DCC in the PriDem programme). The research team would discuss this feedback during their monthly meetings, along with the DCC coordinator's documentation of 'personal reflections' and 'group reflections', which reported the insights of the short debrief meetings held just after the PPI activities had taken place. These reflections, in conjunction with a summary of the inputs received from attendees, would eventually result in the documentation of some ideas for improvement.

> 'Thoughts for next visit [to the dementia hub]: Get everyone to introduce themselves; Visuals/scenarios to get people talking; Avoid abstract/complex concepts.' (DCC meeting notes, April 2019)
>
> 'How can we make it easier for PWD [coming to the university venue] to contribute: Smaller group discussions as dominant format; Minimising large groups, noise; Prep visit to talk through their views/home visit instead; Need more time to 'warm up'; Road testing slides/update slides – just enough information.' (DCC meeting notes, March 2019)

5.9.2 Stakeholders' insights

All PriDem programme team members consulted during Phase II underscored the benefits of involving the DCC in the research process, revealing how a continuous negotiation between resources, research progress and DCC members' needs had been crucial to guarantee the successful implementation of PPI throughout 2019. This negotiation was discussed by the PriDem programme PPI lead as something rarely experienced in the past and probably explained by the availability of funds exclusively allocated to PPI and the collaboration of local organisations, which guaranteed continuous access to the DCC coordinator. Furthermore, according to the DCC coordinator, the documentation of DCC members' experiences in feedback cards and the follow-up conversations with many of them helped the team further reflect on the impact of certain involvement decisions on PLWD and family carers' engagement.

5.9.3 Consolidation

All PPI leads interviewed had experience of PPI as an ongoing collaboration with public members throughout the research process, thereby understanding the nuances of the differences with one-off PPI opportunities. In addition, they were all aware of the existing national standards of good practice, which they discussed in relation to the resources promoting long-term involvement, such as the accessibility and familiarity of places where PPI activities are held, the possibility of reaching these places by pre-paid taxis or reimbursable public/private transport, and the remuneration for the time offered.

> ‘There are some really basic things like making sure that you make it possible for people to travel there. Obviously not at the moment [as in lockdown], but you know, pay their travel expenses, or if they're not able to travel on public transport, make sure they can get taxis that you pay for. Make sure it's in an accessible building that is somewhere that they know. Don't invite them into the university, [choose] a community centre, a parish hall or youth club, somewhere that they're familiar with, that's accessible and familiar to them. And I personally pay for people's time and their knowledge and expertise. You can do that in lots of different ways. And most people would prefer to have cash. And if you follow the NIHR [National Institute for Health and Care Research] national guidance, you should be paying for people's time. Lots of universities, lots of NHS [National Health Service] organisations really struggle with that. But you just have to keep going back to the guidance. Pay for people's time.’ (Olivia, PPI lead)

When exploring personal strategies to guarantee long-term involvement, PPI leads underscored the importance of considering the specific circumstances of the involvement under the scope. Indeed, while some facilitators may be common among public members, others are more specific to PLWD and family carers or the characteristics of the involvement practice designed (e.g., the collective participation of public members and professionals in PPI activities). Therefore, all PPI leads agreed on the importance of an ongoing evaluation of practice that includes inputs from the public members involved in the process.

> ‘It's about, you know, checking that they were okay with the first one, that things worked for them at that meeting. And you know, I think it's constantly checking with people that what you've done is working and what you might wanna do in the future to improve. So, it is constantly evaluating your activities, really, to make sure that they are, you know, meeting people's needs rather than merely checking a box given by guidelines.’ (Hannah, PPI lead)

According to PPI leads, the information for this evaluation can be collected in different ways, such as by having an in-person conversation with people involved post-activity or following it up with an email or a phone call. Alternatively, it may be worthwhile to invite some of them to participate in the meetings organised by the research team to discuss the involvement plan.

> ‘So, discussing with them at the prior meeting and what we think is going to be happening next with the project and asking them, would that be okay? Would you like to come back together again for a follow-up meeting? [..] Or if you like, after the meeting, you're very welcome to send any comments by email. And I've certainly had that happen that people have followed up by email afterwards. And we've heard more of their thoughts.’ (Barbara, PPI lead)

> ‘It could also be coming back with a phone call. [..] Do you want to follow this up with a phone call in a private way?’ (Lisa, PPI lead)

> 'So, one of my roles is to take care of the research design service in [place] and we have public members like lay reviewers who now attend our team meetings, and we work with them, and we plan our activities with them.' (John, PPI leads)

Once this information is obtained, its assessment can lead to a greater understanding of how to improve current practice, thus making informed decisions that are likely to result in continuous involvement.

> 'In all the PPI projects, it's a team of people who makes the decision, even if one person is the person who's putting forward the final decision making it happen. It's a conversation, a collaborative conversation between X amount of people who hold in mind the stakeholders' interests in the outcome of the decision. [..] So maybe it's just the collaborative nature of PPI. [..] If the opportunity is there to get these stakeholders involved and get their voices, then that's taken into account. We learn from what they say, so that we can take decisions that keep them involved' (Lisa, PPI lead)

> 'And just to throw in, we also have what we call reflective sessions, where we kind of reflect on the extent to which we're doing well and how we can improve what we're doing. And that's quite ... we kind of keep it on a very friendly basis. It's very positive. But if there are issues, we do raise them, and then discuss how well we might address it. And we do that together [..] No, nothing is definitive, it's a learning process for them and for us.' (John, PPI lead)

However, gaining insights into the public members' experiences of involvement does not necessarily impact PPI leads' decision-making about practice, which is triggered by the availability of necessary resources and support, as well as the alignment of team members to the value of PPI. It is under these circumstances that research team members may express their willingness to negotiate the terms of involvement as part of the research process.

> 'The only thing is that you need to be sure is that you've got a level of flexibility in place or an option of additional support that you budget in as well. So, they can be enforced throughout because you never know how fast or slow a condition like dementia might progress. People might be really good in their early days but who knows. If it's a five-year research project and they might need more support towards the end. So, you need to be able to build in that flexibility [..] So, of course with the carer you never know how peoples' life change and how it does the intensity of their caring duties which in a way would change as well.' (Sophie, PPI lead)

> 'I think, for me, that's been easy because we [research team] have made those plans at the very beginning of the research so that whenever we've had kind of concurrent, sorry, subsequent involvement events, we always knew there was going to be some feedback to the public members. And then they would decide how the next event would go based on that.' (Emily, PPI lead)

> 'It doesn't happen everywhere. We made a conscious decision to do that, to include them [public members] in the group [research team], to have them attending our meetings and inform the future strategy.' (John, PPI lead)

5.10 Programme Theory 8

PT 8 explains under what circumstances, how and why the presence of a family carer or dementia care professional can positively affect PLWD’s engagement in PPI activities. The consolidated version of this theory is stated in the text box below (see Text box 10), while evidence supporting its development and refinement is reported in the following subsections.

Text box 10. Programme Theory 8

If family carers or dementia care professionals are committed to collaborate with researchers (C) and value the inclusion in group activities of PLWD (C) who may experience involvement challenges due to their dementia diagnosis or stage (C), then they can use their knowledge to anticipate or interpret the needs of the relative they care for/person they are trained to care for ($M_{resource}$) and employ their communication skills to ($M_{resource}$) encourage PLWD to feel comfortable and safe ($M_{reasoning}$), leading to their engagement in the activity (O) because they overcome involvement-related fear and apprehension (O) as well as adverse involvement circumstances (O).

5.10.1 Chain of inference

The chain of inference illustrated in Figure 31 links the regular participation of family carers and dementia care professionals in PPI activities to the employment of their dementia expertise to promote PLWD’s engagement.

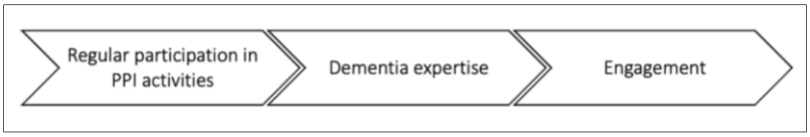

Figure 31. Chain of inference 8

The organisation of DCC meetings was varied across settings (see section 4.6.2), with possible implications for the dynamic characterising them. For instance, the DCC members attending the meetings at the memory café included a limited number of PLWD participating alongside their family carers in each meeting (see Table 20). Except for two PLWD who regularly engaged in the PPI activities facilitated by the DCC coordinator, all PLWD would be quiet, limiting their contribution to confirming the insights shared by their family carers. On the contrary, the attendees of the dementia hub were mainly PLWD (see Table 21), with a couple of family carers each time. These family carers had expressed their interest in contributing to the PriDem programme with their experience and supporting the participation of the person with dementia they cared for, as they were worried over the possibility of them being in need or unable to fully express themselves. Finally, only a few PLWD were present at the DCC meetings held at the university venue (see Table 19). Each time, they would be included in group discussions alongside their family carers, following their explicit request to the research team. The role played by these family carers during the DCC meetings transpired in the way they encouraged the participation of their loved ones in activities unfolding under challenging circumstances (e.g., use of jargon or people talking over each other). On these occasions, family carers helped PLWD contribute rather than replace their voice.

5.10.2 Stakeholders' insights

When asked about the organisation of groups for the PPI activities held at the university venue, the PriDem programme PPI lead and the DCC coordinator underscored the support received by some family carers for the engagement of PLWD. According to them, these family carers could keep PLWD involved in the activity for its entire duration, along with one dementia care professional, who, compared to others, was considered to have strong communication skills. While comparing the PPI activities facilitated in different settings, the DCC coordinator also underlined the value of the support received by the memory café and dementia hub groups' facilitators, who could anticipate PLWD's needs and provide meaningful suggestions to enhance the clarity of the language used. The insights of the PriDem programme PPI lead and the DCC coordinator resonated with the experience of some of the PLWD consulted, who shared their tendency to participate in PPI activities alongside their family carers to ensure their contribution despite some potential barriers (e.g., the format of the material provided, the language used in its content, the type or duration of the activity and the dynamic characterising it).

5.10.3 Consolidation

When questioned about the impact of a family carer or a dementia care professional on the engagement of PLWD, all interviewees initially focused on explaining its negative consequences because of the accompanying power imbalance. However, when reflecting on the progressive nature of dementia and its possible symptoms, they agreed on the supportive role that could be played by a family carer or trained care professional.

> 'This is about what stage in dementia someone is in. If we're talking about a bit more early, mid-stages, in my experience, people can very well express how they think. But if it's someone in the late stage, or

> when, for instance, they're not able to speak as well anymore, maybe that is a good point.' (Sophie, PPI lead)

> 'Clearly, when you're dealing with people with dementia, it is often the case that they would need that extra support at some point, wouldn't they? [..] Generally, I find that carers are welcomed [..] To get to someone in need their carer or a professional is actually very valuable, especially if the person has communication difficulties.' (Eric, person living with dementia)

> 'I think it depends on how advanced the dementia is, and what kind of other symptoms they've got. So, for example, my mom was still able to communicate a little bit, but she had an expressive dysphasia, if you like. She could listen to you and maybe say short sentences, but I don't think she would have been able … well, I wouldn't have helped this. The research team members and the specialists would have probably the skills to maybe draw out from that person with dementia the information that they needed. But again, it depends on how advanced it is.' (Emma, family carers)

When discussing the engagement of PLWD, PPI leads explained how the advantages of involving them alongside family carers are in terms of improved facilitation of group discussions and increased awareness of PLWD's needs under certain circumstances (e.g., whether they are uncomfortable or need a break).

> 'I've seen the difference it can make., and especially for researchers who are not always used to working with groups of people who are not other researchers, where there's a formal agenda in a very particular way of speaking, and everyone using jargon. If you have to step away from that and talk about your research in more everyday terms plus go with a much looser agenda, some researchers can feel quite uncomfortable with that because it's different. It's not what they are used to. [..] I think a lot of carers are actually quite familiar with being in that role because they have to do a lot of joint appointments, for example, with GPs and other care professionals. So, they have actually developed, I'd say a lot of confidence about being that person that has to speak up on behalf of the other person, because they know that person best, I mean, the one that they're caring for. They are the ones who know that person best and they can actually guide the professional or the researcher as to when they've said enough, or you know, whether the person is happy or not comfortable. And you can get an awful lot of support from the carer and have the involvement of a person with dementia.' (Barbara, PPI lead)

When exploring personal experiences of involvement, a person living with dementia shared how participating in PPI activities with their family carer had enabled him to place emphasis on the subject matter of discussion and contribute, rather than withdrawing due to the challenging way in which these activities were designed or facilitated.

> 'I have to think about ... what I think about is my wife in this. My wife is my full-time carer. And yeah, she will, she can influence a conversation big time. [..] There's a lot of meetings like this I do on my own. But [wife name] would be asking me would you like me to be there? [And I'd say] No, I'm ok. And it's good that [wife name] trust me enough and that she knows my capabilities as well. But sometimes, if there are a lot of people or we are on Skype or Zoom, I can get lost and spend most of the meeting wondering whether I know what they are talking about. So, I'd be in silent. But if she is there, she would check on me and tell me what about this and this? Do you want to say something? And then I think, and I click the button, the raise hand thing [to talk].' (Kevin, person living with dementia)

Whilst recognised valuable, family carers opined that additional support should be offered to PLWD after assessing the PPI activities based on the specific needs of the person involved. This is because the uniqueness of individuals with dementia can make it difficult for research team members to fully predict the evolution of certain dynamics. Meanwhile, a family carer or a dementia care professional can easily anticipate or promptly respond to adverse circumstances by creating a comfortable atmosphere for the engagement of PLWD to happen.

> 'A family carer member or dementia care professional can influence how well people with dementia engage in group discussions because you've got to remember that they've got the problem of dementia, which may affect people in different ways. Some people with dementia depending on how severe it is may have relatively little problem in talking to others. On the other hand, there might be others who have been affected in a way that gives them mood swings. They might have difficulty following the thread of a conversation etc. So, it would be really important in that type of situation to have a family carer or a professional who's aware of that. And let's say the family carer is able to prompt the other person or perhaps suggest, you know, it's time for a break if they could see that the person with dementia was getting a bit unsettled. And similarly, with a dementia care professional, that's very important that he or she is able to gauge how the person is responding. Listening is a very important communication skill, as well as showing empathy and body language, because the person may have difficulty in understanding the word spoken. Dementia care professionals are good at that' (Patrick, family carer)

Nevertheless, some interviewees felt it is necessary to remain cautious about circumstances where the presence of a family carer or a care professional can turn into a rather negative outcome, namely the non-engagement of PLWD. These circumstances included the presence of a family carer attending group meetings with a personal agenda or professionals speaking on behalf of PLWD rather than supporting their inclusion in the conversation.

> 'If there's somebody with an agenda, they can override everybody, including the person they're caring for, because they have a belief that there's something that's not being addressed and that I want to bring it into the open. And the person with the dementia, may be just, you know, along for the ride while this person goes off on their mission to get this point put across. Having said that, if you've got somebody who has a good relationship and no obvious agenda, then yes, of course, because they know the person with dementia.' (Grace, family carer)
>
> 'If somebody is overbearing, the person with dementia won't talk or won't be able to get something in because the other person is constantly overcompensating for them and trying to speak for the person so, taking their voice. But again, that goes back to the power thing, right? If the person with dementia has the least power, the care professional has the most. And they think they're speaking as a proxy for that individual. But really, the proxy is being overbearing and taking away the voice of that person.' (Lisa, PPI lead)

5.11 Programme Theory 9

PT 9 explains the impact of trust developed among group members on the level of engagement of PLWD and family carers in activities that include dementia care professionals. The consolidated version of this theory is stated in the text box below (see Text box 11), while evidence supporting its development and refinement is reported in the following subsections.

Text box 11. Programme Theory 9

If PLWD and family carers are involved with dementia care professionals (C) in group activities focused on the care they receive (C) as part of an ongoing collaborative relationship (C), then the trusting relationship developed with the research team ($M_{resource}$) and other group members ($M_{resource}$) encourages them to feel comfortable and safe ($M_{reasoning}$), leading to their engagement in the activities being open about personal challenges and needs (O) because they overcome involvement-related fear and apprehension (O).

5.11.1 *Chain of inference*

The chain of inference illustrated in Figure 32 links a certain organisation of the PPI activity to the relationship developed among actors involved in the research process and the resulting engagement of PLWD and family carers.

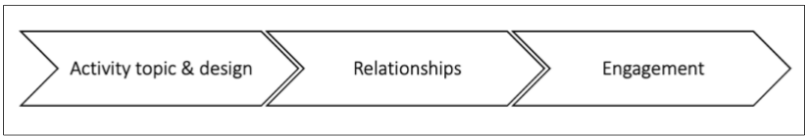

Figure 32. Chain of inference 9

The relationships characterising the DCC members included in the PriDem programme were already mentioned when reporting the similarities and differences of the DCC meetings taking place in three different settings (i.e., university venue, memory café and dementia hub) (see section 4.6.2). When compared with the pre-established groups embedded in the DCC (i.e., memory café and dementia hub groups), PLWD and family carers participating in PPI activities at the university venue were not familiar with each other before their involvement in the PriDem programme. Additionally, they were involved alongside dementia care professionals, possibly facing the power imbalance challenges referred to in PT 6 (see section 5.8). However, over time, a change in interactions was noticed among these DCC members. According to one of the two public members involved in the evaluation of PPI activities (see section 4.5.2), they began supporting each other during the activities, regardless of their perspective towards the development of the ‘ideal’ model of care (i.e., service provider or user).

> ‘Looking at the mix of people who attended the DCC and reflecting on their combined knowledge and experience, I found [it] was quite amazing. The group is made up of so many different people all coming with their own individual perspective, which means so much can be gained in one session. [..] Everyone had lots of really valuable contributions to make there were lots of shared experiences, people acknowledging each other’s contributions and being very supportive of each another.’ (PriDem PPI representative, DCC meeting October 2019)

Additionally, they shared contact details to find solutions to the personal issues socialised during the activity.

> ‘Networking very useful! (got a contact @Alzheimer Society which might help dad).’ (Feedback card, DCC meeting October 2019)
>
> ‘From speaking to others we have learned about a speech therapist for [name of person living with dementia] & other organisations we can contact for help i.e. its good for networking – good spin off for us.’ (Feedback card, DCC meeting November 2019)

The impact of the relationship developed among DCC members on the level of engagement of PLWD and family carers was documented in many of the feedback cards filled in at the end of 2019, which is one year since the first DCC meeting. In particular, some DCC members stated how the relationships developed by then had positively influenced the level of engagement of group members, enabling PLWD and family carers to honestly share their experiences.

> ‘I am enjoying the developing relationships; I have found it has led to more open discussion within the group. I feel as today session could have run for a whole day and we would still not have said everything.’ (Feedback card, DCC meeting October 2019)
>
> ‘A really great mix of people around the table – people living with and caring for someone with dementia and also people in the health and research sector too. The group is really relaxed & people really seem able to talk openly and honestly about their experiences.’ (Feedback card, DCC Meeting November 2019)

5.11.2 Stakeholders’ insights

All stakeholders underscored the value of being involved with consistency throughout a research programme. The increased familiarity with the environment, the format of DCC meetings, and the various members of the DCC participating in PPI activities were all considered by the PriDem programme team reasons for the increased engagement in group discussions in late 2019. However, under certain circumstances, something else was deemed necessary for public members to feel they could openly talk about personal matters. For instance, PLWD and family carers consulted articulated how they often felt embarrassed to discuss personal struggles in front of service providers or unknown researchers due to the fear of being judged because of what they shared or the level of contribution given compared to those with technical knowledge. According to them, building a relationship with all involved would help overcome this fear. Other public members consulted agreed on the value of a well-established relationship, adding that researchers should not underestimate the challenges people may face if asked to contribute alongside unknown peers.

5.11.3 Consolidation

While PLWD and family carers interviewed appeared enthusiastic about PPI, they all shared the struggles of being open about the challenges caused by dementia, despite the years of PPI experience. For instance, some family carers shared how, in the absence of relationships among group members, they felt reluctant to speak the truth about the difficulties characterising their caring journey, as they feared being judged. Others discussed the possible ramifications of sharing the issues experienced with a care provider, thus considering confidentiality a crucial aspect of involvement.

> ‘And I think that's the important thing is that if you're a layperson, you want people to know that the other people on the team, so to speak, aren't going to be judgmental. People can have experience of caring and still be very judgmental. I did have one meeting where I went to, and this woman was a living saint. And she, you know, she said, oh, this was wonderful, it was fantastic, I love being with my mother. And this, you know, and I was having a lot of trouble with my mother at that point in time. And I just felt it was very difficult. And I didn't think I could talk because I thought I would be judged. So, I think it’s very important that that kind of relationship exist in the team at the group meeting.’ (Grace, Family carer)

> ‘I suppose I need to know that people around ... that it's gonna be a confidential type of meeting. I mean, imagine you complain about a service that you use and then they know you said so and so to a researcher or someone else. [..] I mean, you gotta trust whoever is there listening or recording. [..] Confidentiality is really important.’ (Emma, family carer)

Meanwhile, some PLWD expressed how they feared facing discrimination if they admitted they had dementia, thus sharing personal experiences only if they were certain that people present would not question their capabilities to contribute to research.

> ‘I would share it if I felt comfortable to do so [..] There is, there's a stigma attached to dementia. And I don't, not many people know that I have been diagnosed with it. I don't share that normally. But if it's relevant, if I think it's relevant, then I will share it. And once or twice, I've shocked the whole meeting

> [..]. There is a stigma, and therefore in me, there's a certain sense of, well, I don't want this getting out because people will say, blah, blah, blah, whatever, you know. People might think, well, I don't want to work with him, he's got dementia, you know. So, I need to be sure about them first.' (Eric, Person living with dementia)

From PPI lead's insights into the matter, it became apparent that they were aware of the challenges faced by PLWD and family carers if they were asked to contribute to the research by sharing personal experiences. The fear of being judged by other people involved and the risk of confidentiality breach were among the most cited barriers to engagement that PPI leads identified during their career. Establishing trust was the most common response when they were questioned about potential solutions to enable engagement.

> 'If you're more into maybe personal experience and personal reflections, I think you wanna create as safe, open environment as you can. And therefore, in certain ways, you want it to be quite homogeneous or at least that people feel like they're talking amongst people that they can trust, and that won't judge them in any way.' (Sophie, PPI lead)
>
> 'I think if she'd have had any doubt that that would have been kind of used elsewhere or used against her or spoke about outside, she [family carer struggling taking care of her mom] would have never shared that. [..] She knew them, you know, she trusted them, that's why.' (Emily, PPI lead)

A trustworthy relationship was deemed necessary not only with other people involved but also with research team members because they are the ones responsible for facilitating the activities and documenting the experiences shared during the activities. According to PPI leads, it takes time to develop trust, which is usually a culmination of several positive interactions.

> 'And then when you've got to talk to them about really sensitive issues, like the recent diagnosis of their partner with dementia [..] they will open up to you about those sensitive issues because you've demonstrated that you listened. And you're trustworthy [..] And I think it's trust in the people running the group more than anything. You've got to know them, you've listened to them, you've been accessible. You've demonstrated you're trustworthy, you know. They've told you things and said, I don't want you to tell experts, and you haven't. And so, people are much more likely to open up if they've developed a good trusting relationship with you as the researcher or you as the link person'. (Olivia, PPI lead)

5.12 Programme Theory 10

PT 10 explains how PLWD and family carers can contribute to PPI activities by providing new insights into the topic of discussion in the context of trustworthy relationships. The consolidated version of this theory is stated in the text box below (see Text box 12), while evidence supporting its development and refinement is reported in the following subsections.

Text box 12. Programme Theory 10

If PLWD and family carers engage in group conversations (C) about dementia support planning (C) with dementia care professionals (C) as part of an ongoing collaborative relationship (C) built on trust (C), then the effective communication among group members ($M_{resource}$) conveyed with accessible narrative ($M_{resource}$) encourages them to feel confident ($M_{reasoning}$), comfortable and safe ($M_{reasoning}$), leading to their engagement in the conversation with new and informed perspectives (O) because they feel well-equipped (O) and overcome involvement-related fear and apprehension (O).

5.12.1 Chain of inference

The chain of inference illustrated in Figure 33 links the type of activity organised within a familiar environment to the information received about the activity, the interaction among group members, and the resulting engagement of PLWD and family carers.

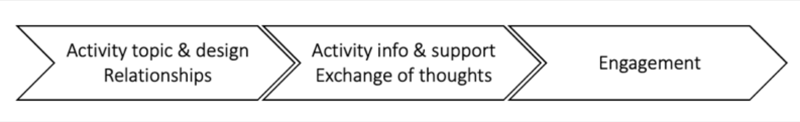

Figure 33. Chain of inference 10

The development of relationships discussed in PT 8 (see section 5.10.1) was not the only change documented among DCC members in late 2019. At that time, the research team aimed to continue exploring the diverse attendees' experiences of dementia care services to better understand current issues; however, the emphasis was more on encouraging a deeper reflection on potential solutions to inform the development of a new model of care. Consequently, rather than slides with open questions for discussion, the research team created a different type of material for the PPI activities. This material included a narrative explanation and or illustration of key findings obtained from primary and secondary research, along with prompts to encourage attendees' contributions. Some DCC members noticed the changes in the organisation of PPI activities, explaining how they may have contributed to better focus on the task, affecting their engagement as much as the exchange of people's views.

> 'Something good or bad? Good format + structure [of the activity]. It was clear what participants had to focus on + why; various input of key issues identified.' (Feedback card, DCC meeting October 2019)

> 'The input from the group activities: Everyone had various answers that fitted into all areas illustrated, regardless of how it was written. Activity 2 gave food for thought as in a professional role care plans in the home could maybe be designed to support the type of care and support plan that was discussed. Impact: is giving a lot of ideas of how to try and support family or friends involved with

> living with dementia. Each meeting brings different knowledge and peoples' thoughts.' (Feedback card, DCC meeting November 2019)

5.12.2 Stakeholders' insights

When questioned about possible changes of PPI over time, stakeholders explored different aspects of involvement by sharing details of their past or current experiences. In particular, by comparing the group meetings organised and facilitated throughout 2019, PriDem programme team members confirmed the increased engagement of PLWD and family carers noted in the field. They explained this change by recalling the above-mentioned differences in the material developed for PPI activities and the familiarity among DCC members resulting from the continuity of involvement in the research process. Meanwhile, PLWD, family carers, and other public members consulted explained the evolution of their contribution over time with the increased confidence they gained by being regularly involved in PPI activities. This confidence would allow them to be more outspoken if within a context where they felt their opinion was valued and respected by other people present.

5.12.3 Consolidation

Several PPI leads reported their experience of designing and or facilitating group activities that required PLWD and family carers to do more than merely sharing their lived experiences. For instance, that is the case of PPI activities organised to interpret some data or discuss their implementation into practice. On such occasions, PPI leads found that providing some material during the activity can positively affect peoples' engagement. However, in such cases, it was made clear that particular attention had been devolved to the content and design of the material, which required to be clear and accessible to everyone involved.

> 'So, the research was looking at how we prevent avoidable admissions to hospital, which are generally a factor of inequality. In lower socio-economic areas, you're more likely to get a high percentage of avoidable admissions that could have been treated at home. And we got the public members to talk about it with some clinicians. But because it was quite an abstract thing or because it's public health and it was kind of at a population level, they needed concrete examples beyond their lived experience. So, we created some vignettes [..]. And they use those as almost like a social story [..]. So, we had to give them an idea of what the situation might look like. And then they used those vignettes to help the discussion, and that got the discussion going. And they were then able to use their own experience. But to begin with, they didn't think they had an experience that was kind of connected. So, the social vignettes helped.' (Emily, PPI lead)

> 'So, we asked them to think about their own experience, but then we gave them descriptions of what X components were prior to the PPI call. Alongside every description, we put an image beside the description. And then, when we had the Zoom, we organised the little components so that people could have an infograph, not an infograph, but a logo to say this is, you know, this is tailoring. And so then, people would have their lived experience of what tailoring is, the little blurb about this is how we're defining tailoring and then the infographic. So, all these different parts in your brain are being ticked off to be like, now we can have a really complex, rich conversation about what are these things. How will this affect this outcome we want for research and the intervention that's been developed? [..] But yeah, that would help provide ideas in addition to lived experience, have different modes of way to get at the question, or the conversation topic [..] Yeah, so, the material was provided to encourage that way of thinking, but the material was also in a number of different modalities [..] I think having a variety of different ways, again, because we're all diverse learners and with cognitive diversity [..] If somebody really doesn't learn with language, then that's not going to hit home with them. If somebody doesn't learn with pictures, we have to find a different way. So, be respectful and aware of all that.' (Lisa, PPI lead)

In addition to the activities' practicalities, PPI leads discussed the circumstances necessary to successfully engage PLWD and family carers in them. In particular, they highlighted the value of having already a well-established relationship that encourages the development of a relaxed atmosphere. This is attributed to the fact that a non-threatening environment can allow them to overcome barriers such as fearing judgement or feeling inadequate for the task.

> 'It's somewhat about setting that scene which doesn't happen overnight. And it goes back to that idea of having that ongoing relationship that enables people not to be scared to speak up because they think they might be judged or saying something foolish. And giving them that confidence, that encouragement to actually do it.' (John, PPI lead)

> 'I think it was just about the atmosphere, the group dynamics about feeling part of the group where their ideas were valuable to us as researchers and whether they were making a useful contribution. I think, if that kind of trust is there, well, they feel they can do it. I think the confidence is what help people do it.' (Barbara, PPI lead)

According to PLWD and family carers, the relaxed atmosphere stemming from the trust embedded in the context of involvement is also conducive for exchanges that facilitate group work and lead to new ideas.

> 'How do you come up with ideas? Well, if there is trust, I think there's a lot of ... what's the word? Well, collaboration, I suppose. There's a lot of people encouraging each other passively, informally, subconsciously, even to think laterally and say, oh, yeah, that's good or what about such and such or on the other hand, you know? And so, how did I come up with ideas? I think being relaxed, not feeling threatened, including by one or two people, that perhaps feel they know everything about everything, you know, and feeling that my ideas are relevant to others. [..] There's like a catalysis, isn't there? Catalysis can happen in that sort of meeting. The whole is greater than the sum of the parts.' (Eric, person living with dementia)

> 'So, there is this comfortable thing of being in a room with people you've spent a lot of time with during meetings and you sort of know them, you can almost predict what they're going to say or how they're going to react. [..] And so, it's about what do I bring to it? Or do I remember a meeting where this issue came up before? And these were the answers, you know, these were the answers I came up with. I'll start with that, and then someone else's say something, and it stems in your mind an idea that

> you hadn't thought of before. So, what I'm thinking about is having people who can spark off each other because they know they need each other to find a solution.' (David, family carer)

5.13 Programme Theory 11

PT 11 explains the impact of research feedback on PLWD and family carers' enduring involvement in a research programme. The consolidated version of this theory is stated in the text box below (see Text box 13), while evidence supporting its development and refinement is reported in the following paragraphs.

Text box 13. Programme Theory 11

If there is an established collaborative relationship between PLWD, family carers and the research team (C), then keeping PLWD and family carers updated on the research progress ($M_{resource}$) and explaining their contribution to it ($M_{resource}$) encourage them to feel confident and valued ($M_{reasoning}$), leading to their continuous involvement in the research programme (O) because they feel well-equipped (O) and are acknowledged for their role in it (O).

5.13.1 Chain of inference

The chain of inference illustrated in Figure 34 links the ongoing participation in PPI activities to the feedback provided to PLWD and family carers who have contributed to the research process and their resulting continuous involvement.

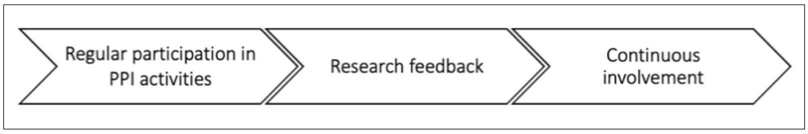

Figure 34. Chain of inference 11

While the format of the DCC meetings was different across settings, with similarities mainly involving the memory café and the dementia hub (see section 4.6.2), the PriDem programme team would usually update all DCC members on the research progress, providing details of their contribution to it. The documentation of this contribution was a very early concern of a family carer with experience of research involvement, who warned about the possible negative impact of the lack of feedback on people taking part in the research process.

> 'May be useful to consider how info is recorded–e.g. I assume the notes will be written up, but in my experience, participants can feel that info is disappearing into a black hole.' (Feedback card, DCC meeting October 2018)

Over time, the research team's effort in keeping DCC members informed became apparent in the feedback provided by those who attended the DCC meetings. This feedback confirmed awareness of the research team's work and personal contribution to it while also communicating the intention of continuing to get involved in the PriDem programme.

> 'Overall, [I] enjoyed hearing update with PRIDem. I look forward to the next meeting.' (Feedback card, DCC meeting March 2019)
>
> 'Enjoyed: The whole afternoon hearing about progress and thinking about how I might contribute next'. (Feedback card, DCC meeting July 2019)
>
> 'I'm going to take away the knowledge that I am contributing to something that will make a difference in the future. It is nice to be part of something like that. [..] I think [there was] good balance between group activities and repeat back on what you are doing.' (Feedback card, DCC meeting October 2019)
>
> 'Well done to all – I can see the progress we've made.' (Feedback card, DCC meeting November 2019)

5.13.2 Stakeholders' insights

Stakeholders included in Phase II agreed on the value of providing research feedback to PPI contributors to ensure their continuous involvement. In particular, among the PriDem programme research team members, the DCC coordinator and one group facilitator were able to recall the positive reaction of DCC members receiving information about the progress made by the research team. Meanwhile, the PriDem programme PPI lead and the other group facilitator discussed the matter more in general, reflecting on the rarity of keeping public members informed given the limited resources usually allocated to PPI. The scarcity of research feedback referred to by these two research team members was amply discussed by the public members consulted, who shared similar PPI experiences, whether or not they had been involved exclusively in dementia research. According to their insights, the lack of feedback is indicative of a tokenistic attitude of researchers towards PPI. Meanwhile, receiving feedback confirms researchers' interest in hearing the voice of the 'experts by experience' and being committed to publicly acknowledging it. Additionally, some PLWD with experience of discrimination explained how even a brief written summary or a phone call could signify a validation of their abilities to contribute to research, which then results in them feeling valued in the team like any other member.

5.13.3 Consolidation

All PPI leads interviewed confirmed the impact of providing research feedback on PPI contributors, which is likely to result in their willingness to continue being involved, whether in the same research programme or in the future. There are various ways in which PPI lead operated to ensure that people felt acknowledged for their contribution throughout the research process. Examples included mentioning public members in research reports, academic articles or dissemination events; thanking people for their contribution in person or via email or phone call; offering to participate in dissemination events; and reimbursing people for their time.

> ‘Whether that's a monetary token of appreciation, or it's an acknowledgement in the output that's developed ... either a paper or a presentation, or a thank you from the group or a verbal, you know, thank you so much, this was really important, which I know with the [PPI group], we do a lot of ... we did a lot of emails and phone calls, you know, I just want to circle back what you said was really important, it's going to influence the project in this way. And we wouldn't have got here without you, and the outcomes only going to be stronger because of this. I think it does, I think it just adds value.’ (Lisa, PPI lead)

With the exception of two family carers who shared their positive experience of being kept informed during their collaboration with researchers, receiving research feedback was deemed rare by the PLWD and family carers interviewed. However, many of them discussed the change they had noticed over the past few years due to the top-down pressure exercised by research funders, who are demanding evidence of PPI practice and inclusion of public members in regular or final research reports.

> ‘It's very rare or fairly rare. It's much better than it used to be. Nowadays, researchers have to report on the public involvement they've had in their research and its impact. And more and more the public involvement people are supposed to assess their impact. [..] Now that's getting on quite good now. The NIHR [National Institute for Health and Care Research] published some standards for public involvement a few years ago, you might remember. And one of them was about impact of the public involvement to try to assess the impact of the public, I think they say to evaluate and assess it. [..] As public involvement persons then nowadays we contribute to the final reports and so on like everybody else.’ (Eric, person living with dementia)

> ‘I think that's one of the big things on this *what is health research?* [National Institute for Health and Research] course … Some people used to say, and it sounds like quite a few years ago, people wouldn't have feedback. So, they’d say what's the point if nobody's telling me anything? Now, with regards to the monitoring that the Alzheimer's Society does, we [members of the PPI network] have a monitor report to submit. Researchers have to write that report with us, you see? So, now we know.’ (Alan, family carer)

The top-down pressure discussed by PLWD and family carers was confirmed by PPI leads, who spoke about funders increasingly checking on their PPI practice and seeking clarity on the content and frequency of feedback to public members, considering it a means for guaranteeing continuous involvement.

> ‘I think that is really important and you see it more happening now. Like there is more emphasis now that you should be giving feedback and there is a bit more of a push from funders. They’d say how much you are you going to give feedback, or they’d ask have you given feedback in your report? [..] So, I think that's really important, especially from an organisation's point of view. You really want people to feel acknowledged because you want to keep them involved. You need people to be involved to have involvement [..]. So, whether it is a charity or a funder or a university or whatever, you want to keep the involvement going, and part of it is by making people feel acknowledged.’ (Sophie, PPI lead)

According to PPI leads, this continuous involvement is explained by what research feedback represents: the confirmation of public members being partners in the research process and, as such, valued members of the team.

> ‘By acknowledging that they did or how they did so, addressing the impact that people have, will make you feel valued. And if you're valued, you're more likely to continue with it. Because if you keep telling your story and keep giving advice and no one tells you that this actually has led to something, it's really demoralising [..] You really want people to feel acknowledged because you want to keep them involved.’ (Sophie, PPI lead)

> 'I think it encourages people to be involved. If there is some acknowledgement, either and what that acknowledgement is it could differ. It could be financial, it could be, you know, inclusion in a paper, but I do think it encourages people to get involved. [..] I think it does influence their feelings about taking part because they then become a partner if there's some acknowledgement of that involvement, rather than somebody you're just taking from. They become a partner in the research [..], but it also gives them an indication of how important it is that they're there, that their opinion and their involvement is valued.’ (Emily, PPI lead)

PLWD and family carers confirmed the link between receiving feedback and increased chance of their participation in PPI activities due to their resulting feeling of being valued. They opined that the lack of feedback might suggest a tokenistic attitude of the research team towards PPI or a paternalistic behaviour towards PLWD in particular. As a result, they may question their collaboration with the research team and eventually decide to leave.

> ‘I mean, I think I'd always be committed to it after what happened to [name of the relative living with dementia], but I'd be more likely involved if I felt I could see how my contribution was making a difference, even if it was a very small difference. […] Why? Well, it would prove that I’m not a number to them.’ (Patrick, family carer)

> ‘Not knowing that I've made a difference is not a bearing on my future involvement, because I'll just plough ahead hoping and feeling that there is a contribution being made. […] It would influence my involvement with that particular researcher or that group, because I would question their commitment to hearing the lived experience voice or their commitment to research within the field of dementia or their commitment to looking at me or others with dementia as a partner compared to, you know, just being there to answer a question and pat you all on the head and be paternalistic’. (Jim, person living with dementia)

While PPI leads associated feedback with continuous involvement due to public members feeling valued, several PLWD and family carers also underscored the increased confidence it results from it, which, in turn, affects their willingness to contribute further to research.

> ‘I think it it's always quite flattering when you're sort of referenced as you go through the research. [..] It sort of makes you feel, oh well, I was on the right track, that's a job well done. [..] And so, it gives you confidence in what you have to offer, it encourages you to come along and get involved in the future in further bits of the research.’ (David, family carer)

> ‘It makes me feel good. [..] Well, I always feel that when there's research being done about any type of dementia, if the person with dementia, and in my case with Lewy body [dementia], if we're listened to and that’s being held, then it makes such difference. [..] Because as a person with dementia you wouldn’t think you could do research, would you? So, people with dementia need to know they can [..] and if you give them feedback explaining what they did, how they helped, well, they’ll believe they can, you know, and they will do it again in the future.’ (Kevin, person living with dementia)

5.14 Conclusion

A total of eleven PTs was obtained from the three-phase realist evaluation conducted. Each theory highlighted specific circumstances (i.e., contexts) and resources (i.e., mechanism-resources) leading to the outcomes of interest by triggering a specific response (i.e., mechanism-reasoning) from research team members (i.e., the practitioners) or PLWD and family carers (i.e., the subjects of the programme). The facilitators and barriers to PPI identified were reported as an integral part of these theories. However, the following subsections will explicitly mention them.

5.14.1 Overview of facilitators

The key facilitators that can promote the involvement of PLWD and family carers in research through PPI activities include:

- a well-established PPI strategy that is supported by funders, the host organisation and the local dementia support services (see PT 1) and that is implemented by a committed team of researchers (see PT 7)
- the presence in the research team of an involvement coordinator who is responsible for enabling the inclusion of PLWD and family carers in the research process and who engages early with the community (see PT 1), building connections that can directly (see PT 2) or indirectly (see PT 3) contribute to their involvement
- a flexible and responsive approach to involvement (see PT 4)
- the provision of jargon-free material before PPI activities, along with an accessible and approachable point of contact for clarifications (see PT 5)

- the organisation of balanced groups in the context of multi-stakeholder PPI activities, along with the presence of a skilled facilitator (see PT 6)
- an ongoing collective evaluation of the involvement strategy from the perspective of both research team members and PLWD and family carers involved (see PT 7)
- the support received by research team members from family carers or dementia care professionals in the facilitation of PPI activities that include PLWD who may experience unanticipated or unnoticed barriers (see PT 8)
- the development of trust among all people included in the involvement process, which encourages PLWD and family carers' engagement in PPI activities (see PT 9) and promotes effective communication, along with the provision of accessible narrative (see PT 10)
- a regular research feedback that informs PLWD and family carers about the research progress and their contribution to it (see PT 11).

5.14.2 Overview of barriers

The identified barriers that can hinder the success of PPI in dementia research include:
- the researchers' lack of training or awareness of good PPI practice (see PT 1)
- the little understanding of PLWD and family carers' needs and challenges in joining a research team and commit to PPI for the entire duration of a research programme (see PTs 1 and 2)
- the absence of financial resources, support networks or local initiatives that can contribute to accessing PLWD and family carers and building a relationship with them (see PTs 1 and 2)
- the lack of PLWD and family carers' experience of PPI, which can trigger research or involvement-related fear and apprehension (see PTs 2, 3 and 4)
- the lack of support that PLWD and family carers may experience in relation to ways of involvement (see PT 4) or engagement (see PT 5)
- the lack of balanced groups in the context of multi-stakeholder PPI activities, along with the absence of a skilled facilitator (see PT 6)
- the absence of an ongoing involvement evaluation, which can hinder issues that are not apparent to researchers (see PT 7)
- the paternalistic attitude of family carers or dementia care professionals towards PLWD when involved alongside them (see PTs 6 and 8)

- the lack of PLWD and family carers' trust towards researchers and other people involved – whether they are peers or dementia care professionals – which can challenge their willingness to participate in PPI activities (see PTs 9 and 10)
- the absence of research feedback, which appears to be associated with a tokenistic attitude of researchers towards PPI or PLWD in particular (see PT 11).

5.15 Summary of the chapter

Chapter 5 presented the PTs obtained from an iterative process of analysis informed by the data collected throughout the three phases characterising the DemRI study. The chapter started by providing an overview of the PTs, organising the theoretical statements according to their underlying CMOc (see Table 22). Then, it focused on each theory, reporting the evidence progressively contributing to their development and consolidation. Finally, it summarised the facilitators and barriers to PPI identified.

Chapter 6. Conceptual framework

6.1 Overview of the chapter

Chapter 6 presents the conceptual framework encapsulating the eleven programme theories (PTs) derived from the three-phase realist evaluation discussed in this thesis. The chapter provides an illustrative and narrative account of the framework, detailing the configurations underpinning the PTs developed. It also documents the core set of processes explaining how patient and public involvement (PPI) in dementia research is proposed to facilitate the involvement of people living with dementia (PLWD) and family carers in the research process and their engagement in related PPI activities.

6.2 Introduction

Chapter 6 summarises the eleven PTs presented in Chapter 5 in the form of a conceptual framework, as illustrated in Figure 35. The focal point of the conceptual framework is premised on several interactions: first, between research team members (RTM) and the PLWD and family carers (FC) invited to join the research programme; then, among the actors involved in PPI activities (i.e., PLWD, FC and dementia care professionals [DCP]); and finally, among all the actors carrying PPI, whether in the role of implementers (i.e., RTM) or people involved in related activities (i.e., PLWD, FC and DCP). These interactions are affected by time and other contextual factors, as indicated by the presence of an arrow and the use of dashed lines (see Figure 35). The following sections provide a narrative account of this framework, which encompasses the four interconnected categories of contextual factors – environmental, organisational, involvement, individual – that derive from the explanatory insights of the PTs developed (see Table 23). These categories are detailed below, together with the associated contexts (C) that were identified as conducive to the most desired outcomes (O) by activating mechanisms (M) that enable PLWD and family carers to overcome the barriers identified.

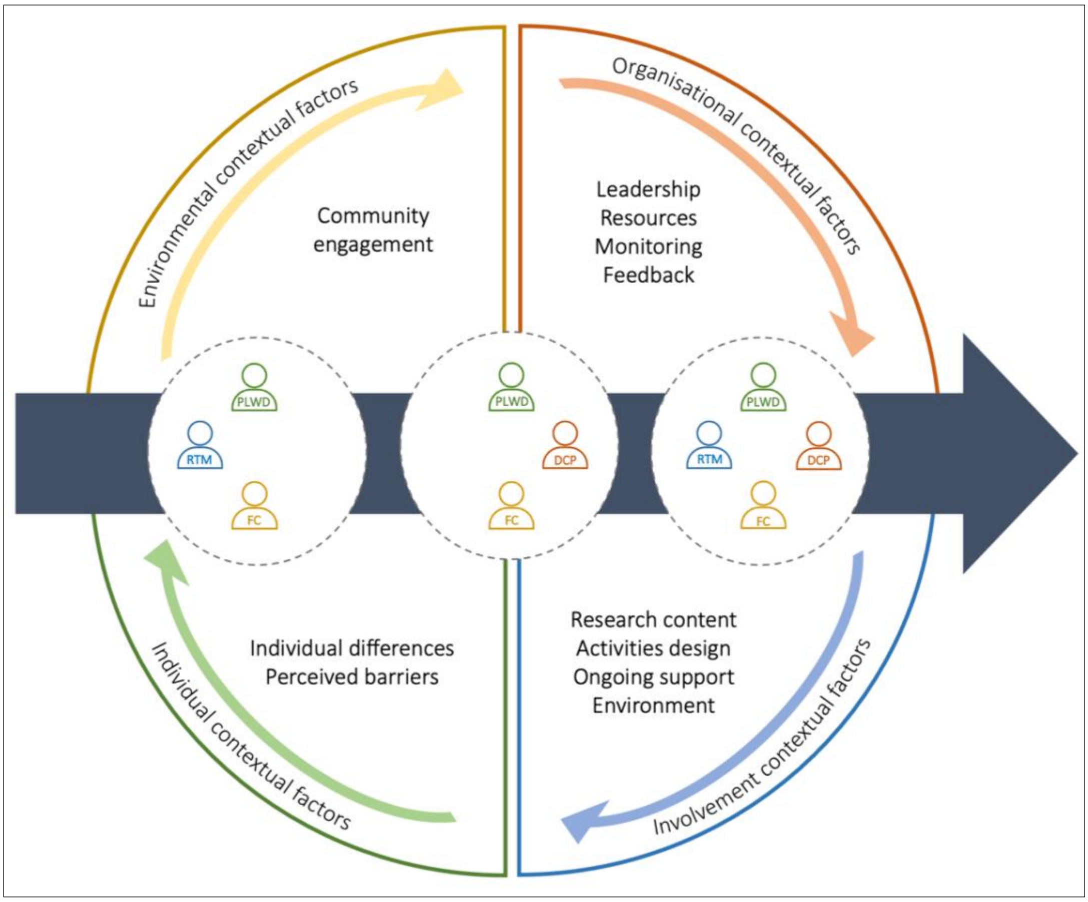

Figure 35. Conceptual framework

Table 23. Linking contextual factors to PTs

Contextual factor		Programme Theory N.
Environmental	Community engagement	PT 1, PT 2, PT 3
Organisational	Leadership	PT 1, PT 2
	Resources	PT 1, PT 4
	Monitoring	PT 7
	Feedback	PT 11
Involvement	Research content	PT 2
	Activities design	PT 6
	Ongoing support	PT 4, PT 5, PT 7
	Environment	PT 9, PT 10
Individual	Individual differences	PT 8
	Perceived barriers	PT 4, PT 6

6.3 Environmental contextual factors

6.3.1 Community engagement

Various initiatives are taking place locally to mitigate the challenges experienced by PLWD and family carers. Examples of these initiatives include memory cafés or dementia hubs where people can receive the support they need while entertaining relations with peers, community workers and volunteers. If researchers are given access to these local initiatives (C), they can encourage the involvement of PLWD and family carers (O) by engaging with them at an early stage (M) and gaining a greater understanding of this population's needs (O). By reflecting on these needs further (M), the research team can tailor the planned involvement strategy (O) according to available resources and support (C). When early engagement activities occur (C) with PLWD and family carers included in existing local support groups (C), the already established relationship among group members (M) and their ongoing positive interaction with researchers (M) denote the resources that are likely to promote involvement (O). This pattern is explained by these resources making PLWD and family carers feel comfortable and safe (M) to overcome reservations related to their understanding of research and their involvement in it (O). The endorsement from peers, community workers and volunteers embedded in these local support groups (M) can also encourage the involvement of PLWD and family carers (O), especially if they are new to both this type of involvement and researchers leading it (C).

6.4 Organisational contextual factors

6.4.1 Leadership

A key individual who thoroughly understands the needs of PLWD and family carers (M) can encourage the research team to further reflect (M) on the pre-established involvement plan (C). The support of funders, the host organisation and local dementia-related services towards the research team's implementation of the PPI strategy is crucial (C) for the key individual to engage early with PLWD and family carers (M) and, if deemed necessary by the rest of the team (M), leading to the change of the involvement plan (O). If at a strategic level the role played by this key individual can positively affect the involvement strategy, at an operational level, it can directly influence PLWD and family carers' decision on whether to get involved (O) if a positive interaction has been entertained with them (M) during the early engagement activities (C).

6.4.2 Resources

The lack of resources such as funds, access to the funders and host organisation's networks and facilities, and support of local dementia-related services can discourage the research team from pursuing the inclusion of PLWD and family carers in the research cycle. However, merely their presence is insufficient to successfully implement an involvement strategy, which also requires agreements on roles and responsibilities, information sharing, and evaluation tools. The research team members' agreement on a well-established plan of involvement (C) and the support received from funders, host organisation, and local dementia-related services to implement it (C) affects the characteristics of the involvement strategy. Indeed, under these circumstances, PLWD and family carers can be offered financial and practical aids (e.g., refunds for transport, free parking space and taxi arrangements), options of involvement (e.g., via email, phone calls and visits at home), and adaptations to individual, everchanging circumstances (M) that can encourage them to get involved (O) and overcome uncertainty triggered by life/caring commitments or dementia diagnosis. This flexible and responsive strategy of involvement (M) can also provide a sense of validation (M) that is necessary for some PLWD and family carers to overcome concerns around tokenism (O), which represent a barrier.

6.4.3 Monitoring

Monitoring the implementation of the involvement strategy can address unanticipated challenges that may impel PLWD and family carers to stop contributing to the research programme (e.g., time and place of meetings, members included in a group activity, and design of activities or their topic of discussion). In particular, an ongoing collective assessment of involvement from the perspective of research team members carrying the PPI activities and PLWD and family carers participating in those (M) can help ensure that these challenges are recognised and addressed in a timely manner (O). However, for that to occur, there must be in place resources (see section 6.4.2) that enable the research team to respond to the needs identified or communicated, along with the researchers' commitment to the involvement of PLWD and family carers throughout the research programme. Under these circumstances (C), the aforementioned assessment of involvement (M) is likely to encourage research team members to apply learning to future decision-making (M), resulting in the enduring involvement of PLWD and family carers (O) owning to the continuous adaptations of the involvement strategy (O).

6.4.4 Feedback

Providing feedback to PLWD and family carers who have contributed to research affects their decision about whether to continue collaborating with researchers. If PLWD and family carers have participated in PPI activities (C), being informed about the research objectives achieved and the challenges faced along the way (M) can make them feel valued members of the team (M), resulting in their enduring involvement in the research programme (O). The same can be said about researchers' acknowledgement of the contribution provided by PLWD and family carers for the progress of the research. Although there is more than one way to do it (e.g., vouchers, thank you cards or emails and citation in dissemination papers or events), acknowledging PLWD and family carers for their contribution to the research progress (M) helps them feel valued and enhances their confidence (M). As a result, they are likely to continue getting involved in PPI activities (O), overcoming concerns around tokenism as well as insecurities about personal capabilities (O).

6.5 Involvement contextual factors

6.5.1 Research content

The research content must be relevant to PLWD and family carers for them to consider working with researchers. For example, when invited to join a research team for the first time, PLWD and family carers may experience barriers such as apprehension caused by self-doubt or fear of consequences. In such instances (C), a research programme that reflects issues of concern to them (M) is likely to make them feel at ease and safe (M), encouraging their involvement (O).

6.5.2 Activities design

The design of PPI activities has a major impact on the engagement of PLWD and family carers when the involvement takes place. For instance, if PLWD and family carers are invited to discuss their experiences of dementia care services (C) in front of professionals who generally deliver these services to them (C), they may feel anxious and be reluctant to contribute. This is particularly true if PLWD and family carers have not collaborated with these professionals in the past (C). Under these circumstances, the presence of a group facilitator fostering the development of a relaxed and egalitarian atmosphere through their facilitation skills (M) can make PLWD and family carers feel comfortable and safe (M), leading to their engagement in the discussion (O). Equally, it may be necessary the presence of peers (M) for PWLD and family carers to feel confident enough (M) to share personal thoughts (O), given the insecurity may be caused by the comparison with those having technical knowledge.

6.5.3 Ongoing support

Ongoing support is central for PLWD and family carers' participation in PPI activities, helping them to address their queries and adjust to the role of PPI contributor. For example, upon being invited to discuss dementia care services as part of a series of activities embedded in a research programme (C), providing PLWD and family carers with a jargon-free summary beforehand (M) may increase their engagement on the day of the activity (O). This pattern can be explained by the need or preference of some PLWD and family carers to gather their thoughts and feel confident enough (M) to participate in the activity. Part of this confidence (M) may also stem from the possibility of contacting an approachable research team member (M) who can address concerns and queries, if any. If on the one hand, such a supportive approach beforehand affects the level of engagement of PLWD and family carers (O), on the other hand, it can lead to their enduring involvement (O) by making them feel valued members of the team (M). Meanwhile, other forms of support can also be offered to encourage the engagement of PLWD and family carers in PPI activities (O) and their retainment throughout the programme as PPI contributors (O). They can be identified by adopting a flexible and responsive approach to involvement (M) and continuously monitoring the involvement strategy's implementation (M).

6.5.4 Environment

A relaxed atmosphere encourages PLWD and family carers to openly contribute to PPI activities without fearing negative ramifications and judgements. For instance, PLWD and family carers who have established a collaborative relationship with dementia care professionals included in the activities (C) are likely to honestly share personal experiences and thoughts (O) if they trust them (M) and then, feel comfortable and safe (M) to do so. Over time, trust can become embedded in the context of involvement (C) and positively affect the unfolding of activities that aim to find shared solutions to care service issues (C). Indeed, under these circumstances, effective communication among all involved in the activity can take place (M), promoting greater engagement of PLWD and family carers (O), along with an accessible narrative about the task at hand (M).

6.6 Individual contextual factors

6.6.1 Individual differences

There may well be differences in individual circumstances that play a role in the success of a PPI strategy. Depending on the dementia diagnosis and its stage, some PLWD may benefit from the presence of a family carer or dementia care professional who is willing to collaborate with researchers (C) and value the inclusion of PLWD in the research programme (C). In these instances (C), a family carer or dementia care professional can promote the engagement of PLWD in group activities (O) by using their knowledge and understanding of dementia in the context of involvement (M) and employing their communication skills (M) to make PLWD feel at ease and safe (M). Conducting an individual assessment of needs beforehand and monitoring the involvement practice as it unfolds (M) can help identify the situations where this additional support is necessary.

6.6.2 Perceived barriers

PLWD and family carers may not consider the possibility of working with researchers, especially if challenged by barriers that make their contribution difficult. Personal factors related to life, working, and caring commitments may all affect PLWD or family carers' decision to become PPI contributors. Indeed, PPI requires a level of commitment that can be difficult to guarantee. Against this backdrop, when invited to get involved in a research programme alongside researchers (C), PLWD and family carers may accept to do so (O) if encouraged by a flexible and responsive strategy of involvement (M) that make them believe they can meet researchers' expectations (M). Meanwhile, PLWD and family carers who are asked to contribute to the research by sharing experiences and thoughts about the care and support they receive (C) may experience fear caused by the potential ramifications of their contribution. They can also be anxious about the presence of dementia care professionals having technical knowledge. Under these circumstances (C), the presence of a facilitator who employs active listening, uses jargon-free language, and is prepared to manage a multi-stakeholder group activity (M) is likely to result in the engagement of PLWD and family carers (O), along with the presence of peers (M).

6.7 Summary of the conceptual framework

The conceptual framework discussed to date can be summarised in the form of transferable ‘core processes’, which explain how the programme of interest is proposed to lead to the most desired outcomes (Pawson, 2013). Based on the above-mentioned contextual factors (i.e., environmental, organisational, involvement and individual factors) and the associated explanatory accounts (i.e., PTs), PPI in dementia research is proposed to work best by:

- Gaining the support of different systems, including funders, host and local organisations
- Investing time, human and economic resources in building connections
- Assessing the implementation of PPI as an ongoing task
- Providing evidence of the research progress and individual contribution to it
- Giving options of involvement and being responsive to a change of mind or needs
- Addressing power imbalances in the organisation and facilitation of PPI activities
- Offering support beforehand and throughout
- Creating opportunities for relationships to develop
- Cultivating a safe and trusting environment
- Providing additional support if necessary.

Table 24 reveals the link between the core processes, the PTs and the contextual factors they are included in. Some of these processes are mentioned multiple times in the table but referred to only once in the list above.

Table 24. From conceptual and theoretical explanation to practical guidance

Contextual factor		Programme Theory N.	Core process
Environmental	Community engagement	PT 1, PT 2, PT 3	• Gaining the support of different systems • Investing time, human and economic resources in building connections
Organisational	Leadership	PT 1, PT 2	• Gaining the support of different systems • Investing time, human and economic resources in building connections
	Resources	PT 1, PT 4	• Gaining the support of different systems • Investing time, human and economic resources in building connections • Giving options of involvement and being responsive to a change of mind or needs
	Monitoring	PT 7	• Assessing the implementation of PPI as an ongoing task
	Feedback	PT 11	• Providing evidence of the research progress and individual contribution to it
Involvement	Research content	PT 2	• Investing time, human and economic resources in building connections
	Activities design	PT 6	• Addressing power imbalances in the organisation and facilitation of PPI activities
	Ongoing support	PT 4, PT 5, PT 7	• Giving options of involvement and being responsive to a change of mind or needs • Offering support beforehand and throughout • Assessing the implementation of PPI as an ongoing task • Gaining the support of different systems
	Environment	PT 9, PT 10	• Creating opportunities for relationships to develop • Cultivating a safe and trusting environment
Individual	Individual differences	PT 8, PT 7	• Providing additional support if necessary • Assessing the implementation of PPI as an ongoing task
	Perceived barriers	PT 4, PT 6	• Giving options of involvement and being responsive to a change of mind or needs • Addressing power imbalances in the organisation and facilitation of involvement activities

6.8 Summary of the chapter

Chapter 6 provided a figurative and narrative account of the conceptual framework created upon the PTs deriving from the three-phase realist evaluation detailed in Chapter 3. In addition, the chapter reported the core set of processes summarising how to successfully promote the involvement of PLWD and family carers in research through PPI activities. These processes will be discussed in relation to the broader literature in the following chapter (see section 7.4).

Chapter 7. Discussion

7.1 Overview of the chapter

Chapter 7 concludes this thesis. The chapter begins by reviewing the dementia research involvement (DemRI) study's aims and objectives and explaining how they were met. Next, it summarises the main findings and discusses them in relation to existing literature. It then critically reflects on the validity of the new knowledge obtained and the personal challenges experienced throughout the conduct of this study. Finally, it reports the study's strengths and limitations, along with the recommendations for future research.

7.2 Revisiting research aims and objectives

The Alzheimer's Society funded the DemRI study as part of the Primary care-led post diagnostic Dementia care (PriDem) programme to promote advancement in the field of patient and public involvement (PPI) activity in dementia research. The study's aims were (a) to develop explanatory theories addressing the involvement of people living with dementia (PLWD) and family carers in PPI activities, and (b) to design a conceptual framework to promote good practice. This thesis discussed the attainment of these aims. Chapter 5 presented the eleven programme theories (PTs) resulting from the synthesis of data collected during the three-phase realist evaluation. Chapter 6 focused on the conceptual framework resulting from further reflection on the theoretical components of the PTs consolidated due to an iterative process of analysis. Meanwhile, the study's objectives included the following:

- To conceptualise PPI
- To identify the gaps and shortcomings of the conceptualisation of PPI
- To explore the facilitators and barriers to the involvement of PLWD and family carers in research trough PPI activities
- To develop candidate programme theories (CPTs) for the involvement of PLWD and family carers in research through PPI activities
- To test and refine these CPTs consulting relevant stakeholders

- To develop, test and refine PTs for the involvement of PLWD and family carers in research through PPI activities
- To design a conceptual framework that supports the explanation of the PTs developed.

I briefly describe how all the above were achieved in the following paragraph.

The learning obtained from the review of the literature with particular focus on the nature of PPI and its understanding in health research helped identify the key concepts of PPI, underscoring gaps and shortcomings that explain current tendencies in practice (see Chapter 2). The understanding of 'how PPI works' in this study was supported by the realist methodological approach chosen (see Chapter 3), which provided a framework of evaluation that adequately responded to the needs of a field of practice lacking conceptual clarity and theoretical direction. Facilitators and barriers to the involvement of PLWD and family carers in PPI activities were initially identified while examining cases among the data documenting the implementation of the programme presented in Chapter 4. They were then further explored through consultations and interviews, being integrated within the contexts and mechanisms, leading to the most desired outcomes (see overview of facilitators and barriers in section 5.14). The PTs resulting from the conduct of the DemRI study can be found in Chapter 5, wherein each PT was discussed in relation to the evidence informing its development (i.e., chain of inference), refinement (i.e., stakeholders' insights) and testing (i.e., consolidation). The changes characterising the theoretical statements throughout the realist evaluation – that is, from CPTs to PTs – are detailed in Appendix P. Finally, the conceptual framework illustrated in Figure 35 and narratively described in Chapter 6 explains how PPI in dementia research operates according to the PTs developed.

7.3 Summary of key findings

The DemRI study has evaluated a PPI strategy designed to promote the inclusion of PLWD and family carers in the research cycle, looking at facilitators and barriers to PPI and exploring them to identify contextual circumstances conducive to mechanisms that are likely to promote PPI in dementia research. A PPI strategy appears to be successful if flexible and responsive to individual circumstances, which are subject to change over time. The researchers' engagement with the chain of support offered locally to PLWD and family carers can encourage PLWD and family carers to explore possibilities and discuss doubts and concerns, whether these relate to their understanding of research or the terms of involvement. However, this approach to PPI alone cannot guarantee contribution to PPI activities, which seems to be affected by preparation, group composition and dynamics of interactions. Ongoing monitoring of the PPI strategy's implementation can help identify related issues in a timely manner. The implementation of PPI will be more successful if the PLWD and family carers involved are informed about its progress, and positively acknowledged for their impact, as this seems to promote their transition from a person of interest to a PPI contributor.

Findings were organised in contextual factors to guide those designing, implementing and evaluating PPI in dementia research (see Chapter 6). Each contextual factor includes aspects of a PPI strategy that merits consideration when planning this type of involvement. These aspects are interconnected and subject to change as the involvement unfolds, as explained by the theoretical insights of the PTs developed (see Table 22). At an organisational level, PPI appears to demand the presence of a dedicated member of the team, adequate economic resources, and research team's commitment to ongoing monitoring and communication. Valuable support can be found in the community, where local services can collaborate with the research team by hosting early engagement activities or vouching for PPI, thus helping bridge differences between researchers and PLWD/family carers and address potential fear and apprehension. Certain incentives can facilitate PLWD and family carers' engagement in PPI activities. For example, the provision of briefing material and contact details beforehand and the presence of peers and skilled facilitators during multi-stakeholders group work. Over time, the development of a trustworthy environment can contribute to creating the atmosphere necessary for some PLWD and family carers to openly share personal experiences or provide new insights. There are individual differences among PLWD and family carers in perceived barriers and needs that may require specific involvement adaptations.

As illustrated in Figure 35, time represents a key component of the conceptual framework, affecting the interactions of the actors involved in the research process and cross-cutting all contextual factors influencing the successful implementation of a long-term PPI strategy. Although resources at the organisational level are crucial to guarantee PPI throughout a research cycle, these are not the only concerns for researchers when planning PPI. The complexity of issues at all PPI system levels must be understood to ensure the enduring involvement and engagement of PLWD and family carers throughout the research programme. Researchers conducting dementia studies should be encouraged to develop a PPI plan and evaluate it, considering the recommendations given in the form of core processes (see section 6.7). While it is not certain that by following these recommendations PLWD and family carers will get and remain involved throughout the research cycle as PPI contributors, they are likely to encourage reflections upon the contextual circumstances conducive to the successful implementation of PPI.

7.4 Comparing findings with existing literature

When considering the findings according to their organisation in contextual factors and in relation to the related *core processes* of PPI identified (see Table 25), it is possible to better reflect on their account within existing literature.

Table 25. Contextual factors and related core processes of PPI

Contextual factors		Core processes
Environmental	Community engagement	• Gaining the support of different systems • Investing time, human and economic resources in building connections
Organisational	Leadership Resources Monitoring Feedback	• Gaining the support of different systems • Investing time, human and economic resources in building connections • Giving options of involvement and being responsive to a change of mind or needs • Assessing the implementation of PPI as an ongoing task • Providing evidence of the research progress and individual contribution to it
Involvement	Research content Activities design Ongoing support Environment	• Investing time, human and economic resources in building connections • Addressing power imbalances in the organisation and facilitation of PPI activities • Offering support beforehand and throughout • Assessing the implementation of PPI as an ongoing task • Creating opportunities for relationships to develop • Cultivating a safe and trusting environment
Individual	Individual differences Perceived barriers	• Assessing the implementation of PPI as an ongoing task • Providing additional support if necessary

Findings from the DemRI study reveal how the early engagement of researchers with the local community represents one of the environmental factors that can affect the successful implementation of PPI in dementia research (see Table 25). Based on the theories detailing the preparatory phase leading up to the actual involvement, research engagement activities can enable researchers to develop connections that can directly (i.e., through positive interactions in a safe environment) or indirectly (i.e., through the endorsement of peers, community workers and volunteers) affect PLWD and family carers' decision on whether to work with researchers, encouraging them to overcome research-related fear and apprehension while also discussing involvement concerns and needs. Consequently, researchers would be able to develop a better understanding of potential barriers, developing PPI strategies that are likely to be successful. As explained, the chain of benefits resulting from *building connections* with the community through research engagement activities can be situated within the broader literature of participatory research for health. According to this methodological approach to research inquiry, the co-construction of knowledge with people affected by the issues under study requires ways to strengthen relations between the community and academia to identify systemic and personal barriers to involvement, tackle natural scepticism resulting from historical research patterns, and address power imbalances (Jagosh et al., 2012; Minkler and Wallerstein, 2008). The current study suggests that establishing partnerships with organisations that offer local support to PLWD and family carers can allow dementia researchers to strengthen these relationships.

The value of the collaborative endeavours between dementia researchers and charities and volunteer groups supporting PLWD and their family carers locally has already been identified as a facilitator of PPI (Bethell et al., 2018). However, the theoretical insights derived from the realist evaluation discussed in this thesis encourage major reflection on the significant role they could play if embedded in the 'engagement' – also known as public engagement (PE) – and 'involvement' – also known as PPI – processes. While sharing the same democratic ideological underpinnings, PE and PPI have been traditionally considered two distinct components of health-related research activity in the United Kingdom (UK). PE refers to the provision of knowledge about research and dissemination of findings; on the other hand, PPI is research being carried out 'with' or 'by' members of the public (INVOLVE, 2018). Even though they may be considered distinctive in practice, findings from this study help reflect upon their combined value which can potentially fortify the collaboration between research organisations and society and promote a more inclusive PPI, thus fulfilling some of the current ambitions in the broader domain of PPI (National Institute for Health and Care Research [NIHR], 2015a; 2021b). Nonetheless, specific circumstances do appear to be conducive to the conduct of PE activities before the recruitment of public members for PPI purposes. These circumstances entail *gaining the support of different systems* and *investing time, human and economic resources* in the preparatory phase to PPI, thus leading to the discussion of the organisational factors affecting involvement (i.e., leadership, resources, monitoring and feedback) (see Table 25).

This study regarded the presence of a person with designed responsibility for initiating the interaction with the local community, and facilitating the development of relationships with PLWD and family carers, as a mechanism for the PPI's success; they worked as a *'boundary spanner'* (Williams, 2002, cited in Wilson et al., 2015, p.110) between the worlds of academia and the public. The value of this role was also discussed with respect to the implementation of an effective PPI strategy, affecting PLWD and family carers' involvement directly (e.g., by providing support before PPI activities) or indirectly (e.g., by guaranteeing flexible ways of involvement), thus executing a *'bridging role'* (Wilson et al., 2015, p.124) between researchers and PPI contributors. The benefits resulting from a named researcher whose main role was to lead on PPI – also known as 'PPI lead' – resonate with previous findings which consider leadership a factor affecting the embeddedness of involvement in a research study (Evans et al., 2014) and its sustainability (Wilson et al., 2015). Even though nowadays PPI leads are recognised as an integral part of the UK health and care research workforce (Crowe, Lodemore and Wray, 2017) with a clear definition of role and responsibilities (NIHR, 2019c), their presence in a research team is not the norm according to the current study, thus making it challenging for researchers to fulfil the expectations of good practice due to barriers such as lack of time or PPI expertise. Moreover, their presence does not imply positive outcomes, as PPI requires the contribution of a variety of systems to be successfully implemented. For instance, organisations delivering dementia support locally can become gatekeepers for PPI leads conducting PE and PPI activities; on the other hand, funders and host research organisations can supply PE and PPI funds, training and advice, in addition to access to their PPI networks and facilities or other necessary equipment for the conduct of the activities. Furthermore, these systems' contributions are shown effective if they are coupled with the commitment to PPI of other research team members, who can enable the PPI leads to exert their role by contributing to the administrative aspects of PPI, the development of PPI material, and the organisation, facilitation and evaluation of PPI activities. In summary, ‘leadership’ is a key factor of PPI, but its value for implementation purposes is dependent on the ‘resources’ supporting it.

The current study explains how a well-supported leadership in the conduct of involvement throughout a research programme promotes the inclusive and sustainable aspects of PPI by *giving options of involvement and being responsive to a change of mind or needs.* Based on the relevant theoretical insights, a flexible approach to involvement increases PLWD and family carers’ confidence in meeting the research team’s demands, encouraging involvement despite reservations related to the progressive nature of dementia or personal commitments. Moreover, to some PLWD and family carers, the possibility of choosing among options of involvement and the responsiveness to their preferences or needs may also signify the research team’s acknowledgement of the value of their inclusion in the research process, leading to their continuous involvement. The importance of adopting a flexible approach to PPI to promote inclusiveness confirms previous findings in health and dementia research (Bethell et al., 2018; Wilson et al., 2015) and is in line with the NIHR’s (2019a) UK Standards for Public Involvement (PI). However, this study reveals the possible underlying mechanism of action from the perspective of public members for the first time, documenting the contextual circumstances conducive to not only inclusive but also sustainable PPI.

In order to guarantee flexibility over time, *assessing the implementation of PPI as an ongoing task* is crucial, as it enables researchers to promptly address the issues experienced by PLWD and their family carers. PPI leads experienced different ways of collecting the information necessary for this assessment (e.g., feedback cards, follow-up chats via email or phone calls, and meetings including public members). However, they agreed on the importance of dedicating some time to reflect on the things that worked well and those that did not with all the researchers involved in the PPI process, so that they could learn from their experiences. Researchers’ learning attributable to retrospective reflection on the process of involvement has already been regarded as a mechanism for the improvement of PPI practice (Staley, 2017; Staley, Abbey-Vital and Nolan, 2017), becoming integrated into current guidance for reporting PPI (Staniszewska et al., 2017) as well as the NIHR’s (2019a) UK Standards for PI. However, findings from this study underscore the importance of the contextual circumstances that are likely to translate that learning into practice, which, in turn, entail a certain organisational culture and support, whether at the preparatory or implementation phase of PPI.

Finally, at the organisational level of PPI, the conceptual framework developed (see Table 25) includes ‘feedback’, which relates to the core process: *providing evidence of the research progress and individual contribution to it.* PLWD, family carers and PPI leads contributing to this study, either as stakeholders or participants, concurred on the importance of feedback, confirming previous findings (Bethell et al., 2018). According to the relevant theoretical insights, providing feedback to PLWD and their family carers encourages them to feel valued members of the team, whilst enhancing their confidence in the ability to conduct research, leading to their continuous contribution to research. As elucidated, the impact of feedback on PLWD and family carers involved in research as PPI contributors is shared with the documented experience of the general public (Mathie et al., 2018). However, findings from this study encourage further reflection on the content of this feedback. Current UK research guidance considers feedback among the relevant communications between researchers and public members contributing to research through PPI activities (NIHR, 2019a), with the only available definition of feedback being in terms of ‘communication of findings’ (INVOLVE, 2018). The feedback alluded to in this study, as well as in previous research (Mathie et al., 2018), entails an ongoing exchange of information about the research progress and the impact of PPI contributors to it, thus necessitating more than one-off communication of findings.

At the involvement level, PPI, as it has been conceptualised in this study, is characterised by factors affecting PLWD and family carers’ willingness to get involved in the research process and contribute to it by engaging in PPI activities (see Table 25). For a long time, health researchers have disregarded the possibility of conducting research ‘with’ public members, giving the dominance of a positivist model of involvement which encourages research ‘on’ them (see section 2.4.4). A parallel can be drawn with PLWD and their family carers who do not have a history of conducting research and may not immediately consider the possibility of becoming PPI contributors. According to the experiences of PLWD and family carers collected during the conduct of this study, several reasons can influence the decision to join a research team, some of which may change or arise with time. However, when sharing their very first experience of involvement, all of them seemed to have given a lot of significance to the research content and its relevance to their current or past life, finding in this aspect the comfort needed to overcome research-related apprehension. Therefore, a clear communication of the research and how it relates to PLWD and family carers' lives before being invited to join a research team can positively impact PPI, reinforcing the importance of *investing time, human and economic resources in building connections* at the preparatory phase of PPI (i.e., community engagement) to promote inclusiveness.

Apart from the value of 'research content', findings referring to the involvement level of PPI encourage reflection on the 'activities design' and how it may affect PLWD and family carers' contribution to research. To illustrate, the involvement of dementia care professionals alongside PLWD and family carers who are invited to discuss personal experiences of care can represent a barrier to engagement. Indeed, PLWD and family carers may experience self-doubt caused by people having technical knowledge and fear and apprehension triggered by the possible consequences of what is shared in front of professionals providing them with the care they should discuss. Under these circumstances, a balance of perspectives (i.e., care providers and recipients) in the composition of groups for PPI activities can promote the engagement of PLWD and family carers in the discussion, along with a skilled group facilitator who can help them by creating a relaxed and egalitarian atmosphere where they feel confident to contribute. Thus, especially in the context of a multi-stakeholder approach to PPI, particular attention should be devolved to how it is possible to *address power imbalances in the organisation and facilitation of PPI activities,* as already recommended to researchers (INVOLVE, 2012; Wilson et al., 2015). However, this study also motivates researchers to consider the power imbalances that may exist among public members. Examples entail the involvement of PLWD and family carers with varied levels of experience in PPI, which can then lead to the dominance of those with more experience; the involvement of PLWD alongside their family carers, which can affect PLWD's confidence and openness; and the involvement of PLWD with other members of the public, which could evoke experiences of stigma and discrimination that challenge willingness into contributing. In these contexts, researchers should identify the resources necessary for PLWD or family carers to feel at ease and confident to engage in PPI activities.

Concerning the engagement of PLWD and their family carers in PPI activities, particular attention should be devolved to the 'ongoing support' they require to contribute meaningfully to research. In this study, the engagement of PLWD and family carers in PPI activities was strictly linked to their level of confidence, which was affected by several factors, including the provision of sufficient, jargon-free information beforehand as well as an accessible and approachable point of contact. The possibility of reflecting on the topic of discussion and perhaps writing some notes or asking for further clarifications before the actual involvement was considered valuable by PLWD and family carers despite the level of PPI experience. The importance of providing public members with the necessary support for their contribution is encouraged in any field of health research (INVOLVE, 2018), including dementia research (Gove et al., 2017; Scottish Dementia Working Group [SDWG] Research SubGroup UK, 2014). However, this study's findings suggest that *offering support beforehand and throughout* not only has an impact on the level of PLWD and family carers' engagement in PPI but also on the sustainability of PPI. Indeed, a parallel can be drawn with the mechanism of action explaining why an ongoing flexible approach to PPI results in PLWD and family carers' continuous involvement. By ensuring that PLWD and family carers are prepared to meet the activities demands, researchers demonstrate their commitment to their inclusion in the research programme, thus encouraging them to continue their involvement. Moreover, by *assessing the implementation of PPI activities as an ongoing task*, researchers can understand whether or not the level or type of support is adequate, thus guaranteeing that practical requirements for working together are rightly addressed (NIHR, 2019a).

Valuing and strengthening the relationship between the research team and PPI contributors is a facilitator of PPI in health research, including dementia research (Bethell et al., 2018; Wilson et al., 2015). In this context, measures such as redressing unequal power relationships and building trust in the process have long been identified as key drivers of PPI (Brett et al., 2010; Brett et al., 2014a; 2014b). While findings from this study support the extant literature, they reveal their implications for the quality of PPI in dementia research by building on a realist study explaining the long-term effects of trust in participatory research (Jagosh et al., 2015). As a case in point, participating in a PPI activity that requires PLWD and family carers to share personal experiences of care in front of dementia care professionals could be an underlying cause of distress, resulting in their limited or nil engagement. The current study's findings suggest that this distress can be overcome through the trust developed as a result of an ongoing collaborative relationship, which will likely lead to open and honest contributions to the activity. Moreover, against the backdrop of long-term involvement, trust will eventually become embedded in the context, fostering proactive communication among all parts involved and subsequently, leading to valuable contributions to PPI activities such as data analysis or implementation of findings. Hence, the core processes *creating opportunities for relationship to develop* and *cultivating a safe and trusting environment* deserve deeper consideration as they promote PPI while also affecting its quality.

The remaining contextual factors to reflect upon are those referring to the individual aspect of PPI (see Table 25). These entail the ‘perceived barriers’ experienced by PLWD and their family carers, which have already been discussed about the factors affecting the organisational and involvement aspects of PPI; and the ‘individual differences’ among PLWD, which encourage more profound considerations on the nature of dementia and its impact on people’s lives. This study’s findings reveal how PLWD share several barriers to PPI with family carers and other members of the public. However, some barriers are unique to PLWD, being strictly linked to the diagnosis and stage of dementia or their experience of living with it. These barriers must be encountered by researchers embarking on a collaboration with PLWD (Gove et al., 2017; SDWG Research SubGroup UK, 2014). To illustrate, when invited to engage in PPI activities, some PLWD may have communication difficulties or be uncomfortable discussing certain topics. An assessment of PLWD’s needs before their actual involvement can help anticipate and promptly address possible challenges. However, there may be situations where the knowledge and expertise of family carers and dementia care professionals can better help promote their well-being, thus encouraging their contribution. Therefore, is spite of the possible power imbalance arising from the involvement of family carers and dementia care professionals alongside PLWD, their collaboration with researchers can yield positive outcomes, especially if the facilitators of PPI activities have little knowledge of dementia or limited experience of PLWD’s involvement in research.

The extant literature has already discussed the role of family carers as an enabler of PLWD’s interaction with researchers who are interested in exploring the experience of living with dementia. Family carers can provide critical information for the ongoing capacity assessment of PLWD (Dewing, 2007) and promote a sense of familiarity and safety that is likely to improve their communication with researchers (Cantley, Woodhouse and Smith, 2005;

Hellström et al., 2007). While both these aspects were explored in the context of PLWD's participation in research, they are also relevant to their involvement as PPI contributors, as contented by Gove et al. (2017). However, specific contextual circumstances do exist under which the presence of family carers is conducive to mechanisms that lead to positive outcomes, which are shared with dementia care professionals. The literature often discusses the interactions between dementia care professionals and PLWD in relation to the type of care provided, which, in turn, is informed by the conceptual understanding of dementia held (see section 1.4.2). Based on this study's findings, dementia care professionals can become enablers of PLWD's involvement if, as much as family carers, interpret dementia through the lens of the social citizenship model (Bartlett and O'Connor, 2010), thereby respecting PLWD's right to contribute to shaping research affecting them and empowering them to do so by upholding their personhood and well-being. To summarise, dementia researchers should carefully consider the kind of measure that might be required for the engagement of PLWD in PPI activities, promoting their autonomy in any given circumstance but *assessing the implementation of PPI activities as an ongoing task* and *providing additional support if necessary*.

7.5 Reflecting on findings and their value

Findings from the DemRI study confirm and contribute to the current literature on facilitators and barriers to PPI in dementia research. Upon comparing the facilitators and barriers obtained from the three-phase realist evaluation (see overview in section 5.14) with the conclusions outlined by Bethell et al.'s (2018) review on PPI in dementia research, several common facilitators have been observed, including early planning by the research team; support of funders, research institutions, health charities and volunteer groups; a flexible approach to involvement, accounting for individual preferences and everchanging needs; relationship building; jargon-free communication; regular updates on the research progress; and acknowledgement of contributions. Meanwhile, the shared barriers entail the following: limited funds and time, perceived complexity of the research or involvement in the research process, potential for distress when discussing certain topics, challenges associated with symptoms of dementia, and lack of evidence demonstrating the impact of personal contribution to the research progress. While many of the facilitators and barriers identified confirm existing literature (Bethell et al., 2018), findings from this study explain when, how and why they affect the involvement of PLWD and family carers in PPI activities, thus providing information that can better inform future practice.

The PTs (see Table 22) encompassing the facilitators and barriers mentioned above contribute to the PPI field of practice in dementia research by providing researchers with a conceptual and instrumental tool for evaluation. The DemRI study is the first study that theorises about how PPI in dementia research operates and examines the resources that appear to prompt PLWD and family carers to join a research programme as PPI contributors. The core processes obtained from a further assessment of PTs (see Table 25), and the conceptual framework they informed (see Figure 35), can be used to shape future evaluation of PPI strategies, operating at a level of abstraction that can apply to a variety of dementia research studies. Moreover, as the programme evaluated on this occasion includes dementia care professionals, these core processes consider PPI from multiple key perspectives and can be used to better inform the practice of researchers adopting a multi-stakeholder approach (i.e., service providers and users) to research inquiry. While this approach is rare in the dementia field (Burton, Ogden and Cooper, 2019), it has been deemed particularly significant in promoting the advancement of dementia care (Brunskill et al., 2022).

The DemRI study focused on the involvement of PLWD and family carers in PPI activities, aiming to develop guidance for future involvement practice in dementia research. However, given the realist and participatory approaches employed, some of the core processes obtained from the PTs developed can apply to PPI in general. Indeed, by comparing findings with existing literature (see section 7.4), it becomes apparent that there are several similarities between the facilitators identified in the context of dementia research and those characterising involvement in other research fields. In particular, this is the case of the core processes related to the ‘environmental’, ‘organisational’ and ‘involvement’ factors of involvement reported in Table 25. Meanwhile, the core processes associated with the ‘individual’ factors of involvement – i.e., ‘perceived barriers’ and ‘individual differences’ – are specific to PLWD and family carers, being particularly affected by the nature of dementia and its impact on people’s lives and their involvement in research. The specificity of these factors was also highlighted by members of the public included in Phase II, who, although often sharing similar experiences of involvement with PLWD and family carers, could not fully relate to them.

In addition to the conceptual and instrumental use of findings presented in the form of PTs and core processes, there is a deeper value in the knowledge obtained from the DemRI study, given that it can prompt rethinking about the theorisation of PPI. Findings from this study support the thesis of many arguing that a linear, a-contextual, a-transactional and a-temporal representation of involvement, such as the one provided by Arnstein's (1989) model of public participation, is reductionist (Collins and Raymond, 2006; Tritter and McCallum, 2006). It also confirms the value of assessing the purpose, process and outcomes of involvement when evaluating PPI (Oliver et al., 2008; Tritter, 2009), in addition to the power of structures affecting it (Gibson, Britten and Lynch, 2012; Morrow et al., 2010). A further strength of this study is the representation of the dynamic, relational and developmental nature of PPI (see Figure 35), which is premised on deeper reflection about the political dimension of PPI and the theorisations it has encouraged (see section 2.5.1). This dimension has particular significance in the context of dementia research, which has seen the prevalence of professionals' expertise over lived experience in the production of knowledge for a long time (Bartlett and O'Connor, 2010; Dewing, 2019).

Scrutiny of the key concepts of PPI within the context of dementia research resonated closely with Clegg's (1989) circuits of power and Starkey's (2003) liberational model of empowerment (see section 2.5). These two theoretical perspectives considering *power* and *empowerment* informed the development of the framework illustrated in Figure 35; I will explain how in the following paragraphs.

According to Clegg (1989), *power* can be reduced to a discursive process that follows the functioning of an electric board comprising interacting circuits. These circuits operate at three levels: one at the micro level and two at the macro level. The micro level is characterised by agents exercising power by addressing feelings, conflicts and communication in daily interactions. The macro levels entail, on the one hand, the rules of practice and socially constructed meanings that inform relations and legitimate authority, and on the other hand, the environmental resources, job design and networks that become channels for empowerment or disempowerment. Building on these premises and the framework developed (see Figure 35), it can be concluded that, at the macro level, power operates through the environmental and organisational contingencies that affect the involvement strategy implemented. Whereas, at the micro level, it operates through the agents' response to specific circumstances, including the interaction between research team members and PLWD/family carers or between dementia care professionals and PLWD/family carers.

In line with Clegg's (1989) theorisation, the framework developed does not encourage the analysis of power in relation to the level of control owned or shared in decision-making, as power is assumed not to be something that someone can hold. Instead, power is a causal force generated at the point of connection between individuals and influenced by *'the apparent order of taken-for-granted categories of existence as they are fixed and represented in a myriad of discursive forms and practices'* (Clegg, 1989, p.184). Therefore, achieving greater involvement of PLWD and family carers in PPI activities requires a deeper understanding of the existing rules, practices and social actions that may have led to their disempowerment in a specific context. The evolution of the conceptual understandings of dementia and their implications for research practice (see section 1.4) could support this process by revealing barriers to involvement and identifying ways to dismantle them. This is particularly relevant to the contribution of PLWD to the research process. As a point in case, by interpreting dementia from the *social citizenship* (Bartlett and O'Connor, 2010) and *human rights* (Cahill, 2020a) perspectives, involvement can be reframed according to civil and human rights. This implies ensuring that PLWD are involved, have a say, and are acknowledged for their contribution as much as family carers. It also encourages the promotion of PPI practice that is underpinned by values of respect, dignity and autonomy. A clear understanding of the 'contexts' and the 'mechanism-resources' characterising the PTs developed can help researchers align with the perspectives mentioned above. However, this brings forth a crucial issue: How do we know if PLWD and family carers are empowered or if PPI practices empower them?

The concept of *empowerment* in this study was interpreted through the lens of the liberational model designed by Starkey (2003) concerning the empowerment of groups of people with experience of oppression and discrimination. Starkey (2003) defines empowerment as a reflexive activity initiated by the power seeker, likely resulting in personal development first and collective action and participation afterwards. According to this model, empowerment cannot be reduced to a measurable outcome. Instead, it should be considered a dynamic process that can be encouraged at the micro level – through positive interactions – or at the macro level – through the facilitative strategies promoted by professionals, organisations, and other social systems. The effects of this process should be visible at the personal and structural levels, confirming the impact of power at both these levels (Starkey, 2003). The empowering process experienced by the PLWD and family carers can be grasped by reviewing the explanatory account of the framework developed, with particular attention to the context-mechanism-outcome configurations (CMOc) underpinning the PTs resulting from the three-phase realist evaluation (see Table 22). In particular, the detailed description of the 'context' provides hunches about the barriers responsible for the lack of involvement or engagement of PLWD and family carers. The 'mechanism-resources' represent the strategies facilitative of the reflexive process of empowerment, which is explained through personal or collective 'mechanism-reasoning'. The 'outcomes' of this process reveal the changes obtained at the personal level and their effect on the involvement level, confirming whether empowerment has taken place.

According to this study's findings, *trust* represents a key source of empowerment, impacting the micro and macro levels of involvement. Trust was initially identified as a potential 'mechanism-resource' following the CMOc mapping exercise on the data collected during Phase I (see section 3.5.4). This appeared in line with Wilcox's (1994) model of participation, which informed the initial understanding of the involvement dynamic (see section 2.5.1) alongside the methodological principles of realism (see Appendix H). According to Wilcox (1994), the diversity of actors and perspectives characterising a participatory process rooted in democratic practices can be overcome by building trusting relationships. However, as the research progressed, this understanding of trust appeared limited. Hence, the discussion with some realist experts and the identification of studies theorising the role of trust in the involvement of individuals and communities, including disempowered and marginalised groups (Jagosh et al., 2012; Jagosh et al., 2015). Aligned with these studies, the PTs obtained from this three-phase realist evaluation consider trust the outcome of an ongoing collaborative relationship, which then becomes a 'resource-mechanism' and a 'context' that leads to greater engagement (see PTs 9 and 10 in Table 22). Therefore, the importance of core processes such as *'investing time, human and economic resources in building connections'*, *'creating opportunities for relationships to develop'*, and *'cultivating a safe and* *trusting environment'* for the development and implementation of a successful involvement strategy (see section 7.4).

In summary, in the DemRI study, *power* and *empowerment* are dynamic forces affecting PPI at the micro (i.e., individual) and macro (i.e., environmental, organisational, and involvement) levels of the system, being influenced by *social citizenship* and *human rights*-informed decisions, as well as *trust*, which develops as a result of interactions over time. Figure 36 illustrates the relationships between all these concepts, which underpin the framework shown in Figure 35 and described in Chapter 6.

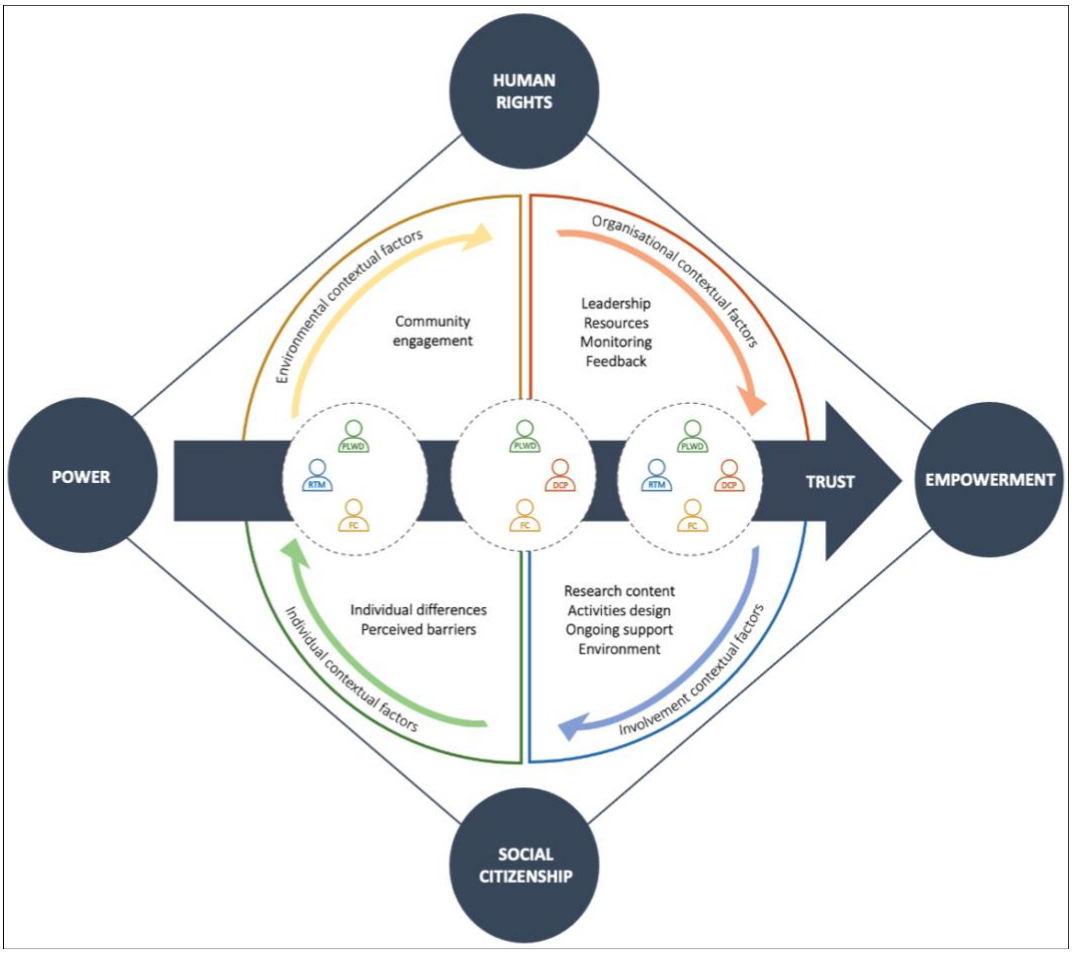

Figure 36. Conceptual underpinnings

Given the aforementioned conceptual underpinnings, findings from this study arguably challenge exclusion and power imbalance characterising PPI, shedding light on existing concerns (NIHR, 2015a) and emphasising ways to overcome them in practice. Moreover, the PTs developed promote the understanding of contextual circumstances affecting how PLWD and family carers experience involvement in the research process over time by triggering specific resources. As such, it acknowledges the context as a potential source of support in implementing PPI and positions it at the centre of evaluation. This, too, is congruent with recommendations in the broader field of PPI, which consider involvement dependent on the context under which it unfolds, thus encouraging its assessment (Kok, 2018). Meanwhile, at a global policy level, documents such as the World Health Organisation's (2017) Global Action Plan advocate the empowerment and engagement of PLWD and their family carers in dementia research. The explanatory insights of this study can contribute to achieving these aims by providing researchers with possible solutions to challenges that are limitedly addressed in the literature, such as how to involve, support and maximise the involvement of PLWD and family carers through PPI activities (Gove et al., 2017).

7.6 Validity of the study

In the literature, there are several methodological arguments over the criteria used to evaluate the validity of new knowledge claims, with some believing that perhaps a universal agreement will never be reached (Porter, 2007). When adopting realist methodology, the focus of validity lies in the extent to which the researcher integrates the perspectives that different stakeholders hold on the programme and the rigour applied in developing related explanatory accounts that should inform change in practice (Pawson and Tilley, 1997). Given this premise, Pawson et al. (2003) developed a framework for assessing the quality of research based on both validity and rigour concerns, such as ethics and accessibility. The term coined for this framework is 'TAPUPAS', following the acronym formed with the initial letters of the criteria included for the research assessment: Transparency, Accuracy, Purposivity, Utility, Propriety, Accessibility and Specificity. Table 26 provides a brief description of the criteria included in this framework along with an explanation of how I met them.

Table 26. Applying the TAPUPAS framework of quality assessment

Criterion retrieved from Pawson et al., 2003	How I met this criterion
1. **T**ransparency: 'The process of knowledge generation should be open to outside scrutiny. For knowledge to meet this standard, it should make plain how it was generated, clarifying aims, objectives and all the steps of the subsequent argument, so giving readers access to a common understanding of the underlying reasoning.' (p.38)	The thesis began by informing about the background and rationale leading to the development of this study's research questions, aims and objectives. The methodological underpinnings affecting decision-making about the design and conduct of the research were detailed, together with the process of data collection characterising each of the three phases of the realist evaluation.
2. **A**ccuracy: 'All knowledge claims should be supported by and faithful to the events, experiences, informants and sources used in their production. For knowledge to meet this standard, it should demonstrate that all assertions, conclusions and recommendations are based upon relevant and appropriate information.' (p.38)	Documents' citations, stakeholders' insights and interviewees' quotations were all used to report the different perspectives collected. The organisation of findings clarified which data were used during the analysis process whilst describing how they progressively informed the development, refinement and testing of theories.
3. **P**urposivity: 'The approaches and methods used to gain knowledge should be appropriate to the task in hand, or 'fit for purpose'. For knowledge to meet this standard, it should demonstrate that the inquiry has followed the opposite approach to meet the stated objectives of the exercise.' (p.38)	A realist evaluation of different stakeholders' experience of the programme of interest was identified as an enabler of theoretical development. The use of multiple cases across different contexts enabled an in-depth exploration of CMOc, which through an iterative process of synthesis led to the PTs resulting from this study.
4. **U**tility: 'Knowledge should be appropriate to the decision setting in which it is intended to be used, and to the information need expressed by the seeker after knowledge. For knowledge to meet this standard, it should be 'fit for use', providing answers that are as closely matched as possible to the question.' (p.39)	Findings from this study answered the pre-established research questions, explaining what works, for whom, under what circumstances and why when involving PLWD and family carers in PPI activities. However, some limitations were found in relation to data collection and other sources of knowledge that could have added to utility in this study (see section 7.8.2).
5. **P**ropriety: 'Knowledge should be created and managed legally, ethically and with due care to all relevant stakeholders. For knowledge to meet this standard, it should present adequate evidence, appropriate to each point of contact, the informed consent of relevant stakeholders. The release (or withholding) of information should also be subject to agreement.' (p.39)	A data management plan was created to guarantee compliance with the relevant institutional policies and ongoing monitoring of data storage and management (see Appendix F and Appendix G). Each research participant was provided with a participation information sheet and a consent form to sign or verbally consent to while on the record. Guidelines of the Newcastle University (NU) Faculty Medical Sciences (FMS) Research Ethics Committee granting ethical approval were followed. All data collected were stored, audio-recorded and anonymised following the agreement with participants.
6. **A**ccessibility: 'Knowledge should be presented in a way that meets the needs of the knowledge seeker. To meet this standard, no potential user should be excluded because of the presentational style employed.' (p.40)	Following the NU FMS Graduate School guidelines for the format of theses, academic language was used in this document. Accessible language and format will be used in reporting findings back to funders and disseminate them where appropriate.
7. **S**pecificity: 'The knowledge must pass muster within its own source domain, as perceived by its participants and proponents.' (p.40)	The RAMESES II reporting standards for realist evaluations (Wong et al., 2016) were followed when deciding about the organisation and content of this thesis's chapters (see Appendix V).

7.7 Personal challenges

Upon starting my Doctor of Philosophy (PhD) programme (2018), my experience of PPI was limited to the collaboration with family carers included in the Dementia and Frail Older Person PPI group at The University of Nottingham, where I conducted a qualitative research project as part of my master's programme in research methods (2016-2017). During this research, some members of this PPI group participated in meetings organised to discuss the topic and design of my research study and its related recruitment process and material. Consequently, my understanding of PPI was limited to its value for the research process, ignoring critical aspects such as its contested nature and the heterogeneity of definitions and practices. These aspects became more apparent while working with a librarian on a literature search strategy for the original design of the study (i.e., realist synthesis) as well as when engaging with various debates characterising the PPI arena at conferences (see section 3.9) and other events (e.g., in-person/online workshops or symposiums). These experiences suggested that the empirical literature about PPI is extensive but often ambiguous about what this type of involvement entails and why. Consequently, at the start of my PhD programme, I had two main concerns: to gain an in-depth understanding of the origins of PPI to clarify its meaning in this study; and to network with experts by experience to gain insights from a broader perspective.

The realist approach chosen was a rewarding yet demanding process. Gaining a clear understanding of the contexts, mechanisms and outcomes was a time-consuming process characterised by challenges in its relevance and validity every step of the way. Managing and learning to be comfortable with an iterative, ever-changing analysis process was difficult, and there were times when my focus on the study did waiver. However, these difficulties seem to be common among realists; they are considered 'the swamp' through which evaluators must wade in search of evidence (Greenhalgh, 2004). While these impediments were unavoidable, I attempted to address them in the best manner possible. For instance, I found relevant resources and learned how to apply methodological principles using the research methods chosen for this study by attending realist research-related events, online workshops and reading group sessions. Moreover, I was able to document relevant changes at different system levels and over time by developing a broad conceptual framework at a very early stage (see section 3.5.4). Doing that helped me overcome the overwhelming feeling experienced with discerning which context, mechanism, or outcomes was relevant to the study's focus. Finally, I ensured that the research conducted was relevant and reflected the PPI experience of other PLWD and family carers by engaging with stakeholders outside the context of the PriDem programme.

My role as evaluator embedded in the field during Phase I was pivotal in comprehending the dynamics characterising the development and implementation of a PPI strategy in dementia research. However, this was accompanied by the challenge of negotiating access and relationships with a broad range of people involved across different settings and over time. While being a member of the PriDem team guaranteed my continuous access to the field and facilitated my interaction with research participants, a certain level of personal skills and reflection was required to build and maintain a rapport with them. The documentation of my experience in the field in a diary allowed me to identify the different stages characterising my interaction with research participants and assess whether this interaction had any effect on the data collection and analysis processes. To this end, I also found it beneficial to have an ongoing dialogue with a supervisory team which included one academic supervisor embedded in the programme evaluated and another one who was an outsider. Their diverse perspectives helped me further discern my judgements on more than one occasion. I undoubtedly questioned my research practice more in phases II and III owing to increased self and methodological awareness and ongoing collaboration with public members (see section 3.8).

The unprecedented disruptions caused by the COVID-19 represented a unique opportunity for rethinking the study's design. When socially distancing measures restricted the possibility of in-person data collection, several questions arose about inclusivity, logistical requirements for participation and ethics. Although uncertainty was prevalent in the real and research worlds, I attempted to address these queries effectively to guarantee the study's progress. To ensure inclusivity, I gave research participants recruited in Phase III the possibility of receiving a phone call or joining a Zoom or Microsoft Teams meeting. I also sent them the recruitment and interview material via email and post upon request. Moreover, I kept informed all Dementia Care Community (DCC) members about the study's progress throughout the pandemic, offering PLWD and family carers who had not participated in Phase I or had recently joined the DCC the option of getting involved. Despite being given other options, all interviewees chose Zoom. Anticipating the limited control over an interview taking place remotely, I provided them with clear instructions about the interview process beforehand and utilised a PowerPoint to support the flow of our conversation, minimising interruptions and distractions. Regarding ethics, the ongoing update of a data management plan helped me ensure that privacy, confidentiality and data collection policies of the online platforms used were in alignment with the ethical principles of good practice.

7.8 Strengths and limitations of the study

The DemRI study presents a balance of strengths and limitations, which I discuss in the next sections.

7.8.1 Strengths

Firstly, this study contributes to a long-standing gap of knowledge in the dementia research field, shedding light on existing concerns about the dominance of an exclusive and tokenistic tendency towards PPI in practice and providing a conceptual and instrumental tool to overcome current challenges. By adopting a realist approach to research inquiry, several theories were developed and tested (see Chapter 5), culminating in a conceptual framework explaining how PPI works and detailing a set of core processes promoting the involvement of PLWD and family carers in research through PPI activities (see Chapter 6). Given the explanatory focus of the theories obtained (i.e., what works, for whom, in what circumstances, in what respects and why?), findings from this study can be useful beyond the context of this research, having implications on future directions about the conceptualisation, design and evaluation of PPI in dementia research.

Secondly, the context of PPI activities evaluated during the course of this study included the presence of dementia care professionals alongside PLWD and family carers. Although the collaboration between service users and providers is deemed important to advance dementia care (Pickett et al., 2018), the presence of a multi-stakeholder approach to producing new knowledge is scarce in the dementia research field (Burton, Ogden and Cooper, 2019). By focusing on the interactions between dementia care professionals and PLWD and family carers as part of the PPI activities evaluated, this study encourages reflection on the circumstances that may affect this type of collaboration and the mechanisms that could lead to positive outcomes. As such, the conceptual framework developed could find applicability in the service development area.

Thirdly, this study contributes to research methodologically for two key reasons. First, it describes the process of conducting PPI as part of a doctoral research programme, explaining its contribution to the progress and quality of research, while also evaluating its implementation (see Chapter 3). In the literature, the process and impact of PPI on doctoral research programmes are seldom reported, with little understanding on how to evaluate it (Tomlinson et al., 2019). Second, it discusses the contribution of stakeholders in the development and refinement of theories, making a clear distinction between the insights of professionals (i.e., research team members) and those of public members (i.e., PLWD, family carers and the general public). Currently, there are not many published examples of realist research studies discussing PPI and reporting how stakeholders' insights can be integrated into the theoretical process (Abrams et al., 2020). The study discussed in this thesis represents a worked example of how it can be done and what are the advantages of doing it.

7.8.2 Limitations

Despite the strengths discussed above, there are some limitations. Firstly, the conduct of the case study informing the development of theories was influenced by the PriDem programme timeline and aims. To minimise the impact of my research in the field, some aspects of the involvement could not be directly addressed by the researchers or DCC members then and there. The study's original design entailed follow-up interviews to discuss any aspect requiring further clarification. Unfortunately, the surge of the COVID-19 pandemic hindered this possibility, with many DCC members dropping out from the PriDem programme or choosing to be exclusively involved in that. Therefore, it is possible that the diversity of experiences characterising the involvement observed was not fully captured. However, given the participatory approach employed to conduct this study these experiences were discussed extensively, and several experts were consulted when facing doubts.

Secondly, while there were tangible benefits in using the online Zoom platform for the purpose of data collection Phase III (e.g., participation in research safely and from different geographical areas), this approach may have hindered physical cues (e.g., tone of voice, body language) that could have helped identify triggers meriting further exploration. Moreover, interruptions were occasionally caused by setup issues (i.e., software or audio-related) or unreliable internet connection, resulting in lost call connection or dropped calls. Although these interruptions signified a distraction from the momentum of the conversation, they did not seem to discourage participation, creating the possibility of bonding with participants while working together to overcome the issue.

Thirdly, the findings presented in this thesis are built upon an understanding of PPI from the perspective of the UK context and reflects the PPI experience of PLWD, family carers and PPI leads mainly involved in UK-based research. Therefore, findings cannot be assumed to be generally applicable to every research context but must be considered in relation to the setting and sample characterising the realist evaluation discussed in this thesis. However, they certainly have translational potential due to the realist methodology employed and its focus on generative causation, which has led to identify mechanisms responsible for the outcomes of interest under specific contextual circumstances. The acknowledgement of these circumstances can help researchers discern whether findings from the DemRI study are relevant to their context of research or not.

7.9 Recommendations for future research

The DemRI study suggests causal processes explaining why PLWD and family carers may get involved in PPI under certain circumstances and outlines the resources necessary for researchers to ensure the successful implementation of PPI. However, a further investigation of the core processes obtained from the PTs developed could contribute to identifying or better explaining theoretical aspects (i.e., contexts, mechanisms and outcomes) of PPI that were missed or insufficiently explored due to the restrictions imposed by the COVID-19 pandemic.

A research team member responsible for the initiation and coordination of PPI (i.e., a PPI lead), emerged as a key facilitator of the involvement of PLWD and family carers if embedded in supportive organisational and environmental contexts. Future research might explore the leadership role of other research team members, including research partners, and investigate if and how collective leadership can lead to successful PPI in dementia research. Moreover, given the impact of the progressive nature of dementia on PLWD's involvement, research aimed at identifying the skills set and knowledge necessary for PPI leads to be effective in dementia research could be beneficial.

According to this study's findings, budged constraints deter researchers from engaging early and guaranteeing a flexible and responsive PPI strategy, thus challenging PLWD and family carers' involvement in the research process or their continuous contribution to it. In this context, gaining greater clarity on PPI costs in dementia research could help raise awareness among researchers as well as research funders about the economic resources necessary for the involvement of PLWD and family carers through PPI activities, thereby increasing the likelihood of their contribution to research and limiting the possibility of their withdrawal along the way.

The conduct of PPI in this study included virtual meetings due to the restrictions imposed by the COVID-19 pandemic. Many PPI activities have been held remotely over the last couple of years; advantages associated with using online platforms to conduct PPI include the contribution of public members who cannot attend in-person meetings because they are unwell or have caring responsibilities (Brighton et al., 2018). However, there are also many technical and logistical requirements that may represent an additional barrier to PPI in conjunction with the lack of personal contact (Lampa et al., 2021). An investigation of PLWD and family carers' experiences of virtual meetings could allow researchers to understand the challenges of this approach to PPI, ensuring that online platforms represent a valuable opportunity for them to contribute to research.

Finally, most of the current literature on PPI is drawn from researchers' experiences. When conducting PPI activities, researchers should consider the possibility of evaluating their implementation from the standpoint of public members, as already encouraged by the INVOLVE's (2018) guidelines. Notwithstanding the value of researchers reporting lessons learnt to advance PPI practice, the current study did benefit from the contribution of both research team members and public members (i.e., PLWD and family carers), which ensured that challenges to involvement were fully captured and plausible ways to overcome them were identified.

7.10 Summary of the chapter

Chapter 7 concluded this thesis. The chapter first revisited the research aims and objectives, explaining how they were met. Next, it summarised the main findings and discussed them in relation to the literature, underscoring the original contribution to the field of PPI in dementia research. Subsequently, it assessed the validity of the study and reported personal reflections on the challenges faced whilst carrying out the study. Finally, it documented the study's limitations and provided recommendations for future research.

7.11 Concluding remarks

Supporting and maximising PPI in dementia research is crucial to gain greater understanding of the ever-changing care needs of PLWD and their family carers. Finding ways that enable the inclusion of this population throughout the research cycle can contribute to the identification of adequate responses to these needs. Drawing on several theoretical and empirical sources, it was possible to provide the explanatory account of eleven PTs referring to the involvement of PLWD and family carers in research through PPI activities. Altogether, these accounts show how the ideal approach to PPI in dementia research operates through the enabled decision-making of research team members, PLWD and family carers, underscoring how this takes place at the centre of multiple relationships and systems. Creating a conceptual framework summarising the key elements that affect the success of a PPI strategy over time, findings from the DemRI study can prompt critical thinking about how to promote the enduring involvement of PLWD and family carers in the research process. This framework can also be used to stimulate a broader range of researchers to think differently about PPI, how it is designed and evaluated.

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Appendices

Appendix A. Evolution of PPI in the UK health service policy and provision

The rise of public participation and service user involvement

In the post-Second World War world, the political, economic, and social instability resulting from the challenges of the post-world wars periods, and the regression in between, encouraged many capitalist nations to adopt the welfare state model of provision (Clarke, Gewirtz and McLaughlin, 2000). Despite the differences in the range of benefits and population coverage among countries, adopting such model entailed guaranteeing a *'government-protected minimum standard of income, nutrition, health, housing and education, assured to every citizen as a political right, not as a charity'* (Wilensky, 1975, p.1). In the United Kingdom (UK), the rise of the British welfare state began with the Beveridge's (1942) report – *Social Insurance and Allied Services*. According to Beveridge, the introduction of a national flat rate insurance combining different types of benefits, such as health care, unemployment, and retirement benefits, would have helped eradicate the five 'Giant Evils' of the British society: squalor, ignorance, want, idleness, and disease. After the victory in the 1945 General Election, the Labour Government (1948-1951) – known also as Old Left – assured that it would eradicate the five Giant Evils by introducing several reforms of the welfare state. The *National Health Service* (NHS) *Act 1946* was among those reforms and aimed to improve the provision of healthcare services, which were until then regulated by a national health insurance model and characterised by hospitals under the municipal authority and charitable organisations (Greengross, Grant and Collini, 1999).

Under the *NHS Act 1946*, the healthcare system underwent a structural change, which entailed the nationalisation of hospitals, the establishment of a national network of general practitioners (GPs), and the foundation of community and domiciliary health services (Greengross, Grant and Collini, 1999). Although these three strands of the NHS were managed locally, they were financed centrally. Control over the NHS was upwards to the Minister of Health, and it was accountable to other ministries, which were expected to address citizen's concerns in Parliament (Cooper et al., 1995). The government held the duty to guarantee universal, free access to care at the point of delivery, to provide budget to the whole NHS, and to develop national policy frameworks. GPs were independent contractors expected to align with the centrally agreed national contract for services. The medical professional was given the responsibility to deliver care to patients and collaborate with nursing staff and lay administrators in the management of hospitals (Greengross, Grant and Collini, 1999). Within this new organisation of healthcare, the public was expected to passively accept health rights and medical care. This may explain why the NHS at its origin was largely perceived rooted in a paternalistic system of beliefs (Beresford, 2005; Rowe and Shephard, 2002).

In the 1960s, the rise of poverty, inequalities, and social discrimination encouraged the activism of social movements campaigning for social rights (e.g., rights to work, decent education and housing and adequate health services). The 1964 win at the UK General Election became an opportunity for the Labour Government to respond to these issues by promoting several urban interventions and community development programmes that required the active participation of the residents of the areas where these initiatives were implemented (Craig et al., 2011). The new government's initiatives, drawn upon the Community Action Programme implemented in the United States of America (USA) to overcome racial and poverty tensions, were expected to ensure well-integrated communities while also expanding the welfare state (Craig et al., 2011). However, concerns around paternalism already noted in the USA (Arnstein, 1969) were soon identified in the UK too, with decisions being made mainly by professionals and residents often being included for outreaching or education purposes (Craig et al., 2011). Nevertheless, these programmes did promote the development of community organisations, which soon assumed roles similar to those of local authorities by providing additional resources for community growth, education, and change. This context paved the way for the rise of 'collective action' rooted in philosophical ideas of 'empowerment' and 'conscientisation' (Craig et al., 2011), which, in the early 1970s informed the campaign of several new social movements (Beresford, 2002).

Throughout the 1970s and the 1980s, several campaigns for social change were promoted by the development of new – compared to those in the 1960s – social movements including disenfranchised people (e.g., black, disabled, lesbian and gay, and women's groups) who were concerned with political and personal change. Although these social movements had different agendas, they included people with personal experiences of struggle related to the denial of civil and human rights (Beresford, 2002). Therefore, they saw participating in policy and service provision decision-making as an act of self-advocacy, which was primarily framed in terms of 'collective action' (Campbell and Oliver, 1996). The public activism of these groups was enforced by the emergence of service users' movements (e.g., mental health service users), which included people with the shared experience of *'oppressive policies and provision'* (Beresford, 2005, p.473) aiming to challenge the dominance of the biomedical model in promoting health and illness. Meanwhile, with the advancement of the New Right (Conservative) political rooted in in market-orientated (that is, neoliberal) reforms, the government promoted the consolidation of capitalism within the healthcare system. Consequently, alongside social movements, more generic patient and consumer groups began to campaign for issues affecting health services or care they provided. The growth of consumer groups and patient organisations carried on throughout the 1980s, leading to the development of several alliances to support and amplify patients' and carers' voices (Beresford, 2002).

The 'bottom-up' pressure exercised by these movements, together with the absence of local implementation of national strategies, the documentation of poor service standards, and ensuing confusion around the management of health services, encouraged the government to reform the NHS structure (Greengross, Grant and Collini, 1999). Such reform came with the *NHS Reorganisation Act 1973*, which integrated the original tripartite structure of the healthcare system and provided, for the first time, political recognition of public participation in healthcare decisions through Community Health Councils (CHCs) (Hogg, 2007). CHCs were established to monitor health services, promote the coordination between NHS and local authorities, and represent the interests of patients and the public to NHS administrators. Before then, lay administrators were included in hospital management boards, but their role focused on guaranteeing favourable conditions of the hospital rather than questioning decision-making (Greengross, Grant and Collini, 1999). Therefore, the establishment of CHCs was considered one of the most significant aspects of the fist reorganisation of the NHS. However, they were not involved in decisions about service planning or delivery, thus having little impact on health legislation (Hogg, 2007). Moreover, they were often challenged by the resistance to change of NHS administrators – mainly medical professional (Gabe, Bury and Elston, 2005). Nevertheless, their existence fostered the development of various movements supporting service users' needs and, on certain occasions, contributed to the better allocation of public funds (Rowe and Shephard, 2002).

The emergence of consumer involvement

The rising of healthcare costs caused by several factors, including the ageing population and the availability of more advanced treatments (Gillies, 1997), became a matter of real concern in the late 1970s. This trend, which was also observed in several other capitalist nations, coupled with the continuous activism of social movements urging action to tackle social inequalities and raising poverty, made it clear that the post-world wars welfare state was in crisis (Castles, 2002). Under the leadership of Prime Minister Margaret Thatcher (1979-1990), the Conservative Government, driven by New Right political ideologies, promoted a reinvention of the welfare state, considering the current *'economically unproductive'* and *'socially damaging'* because creating a status of dependency between the state and the public (Clarke, Gerwitz and McLaughlin, 2000, p.2). As part of a broader anti-welfarist and anti-statist reforming plan, the New Right promoted the consolidation of the capitalism within the healthcare system by marketising reforms and encouraging service provision competition with little government control, thus bringing down the boundaries between the state and the market (Beresford, 2002; Clarke, Gerwitz and McLaughlin, 2000). Furthermore, it encouraged a shift of responsibility for welfare from the 'public sphere' to the 'private sphere', thereby restructuring the role of the state and its relationship with the public. Indeed, if post-wars the state led by the Old Left was viewed as the embodiment of austerity and paternalism, the New Right made the state being perceived as a 'power over' public members by fostering the privatisation of public sectors and reducing the benefits of service provision (Clarke, Gerwitz and McLaughlin, 2000).

In 1983, the Conservative Government commissioned Sir Roy Griffith – a British businessman – an inquiry into the management of the NHS in order to improve its efficiency and receive advice on how to lower the costs while guaranteeing the best possible service to the patients (Department of Health [DH], 1988). In his report, Griffith (1983) documented several concerns over the rise of healthcare expenditure and the lack of a clearly defined framework of decision-making in the management of the NHS. To overcome such issues, he gave several recommendations, including the introduction of general managers at each level of the NHS invested of the responsibility of assessing patient/consumer satisfaction and being responsive to their feedback (Calnan and Gabe, 2001). Before this report, there had been little emphasis on patients' perspectives and their level of satisfaction, making this policy document the first to address consumer involvement, albeit in a rudimentary form (Boote, Telford and Cooper, 2002). The connotation of the public as 'consumers' was formalised in the late 1980s in the White Paper *Working for Patients* (DH, 1989), which separated the bodies providing care (i.e., service providers) from those purchasing it (i.e., commissioners), thus introducing an internal market in the NHS.

The advancement of consumerism in the healthcare system became more apparent in the early 1990s. In 1991, with the publication of the *Patient's Charter* (DH, 1991), the Conservative Government established the patient's rights for NHS patients and encouraged providers to make more service user-orientated decisions. With the *Local Voice* (NHS Management Executive, 1992) document, the concept of involvement was extended to the public, thus exhorting commissioners to acknowledge the voice of local people in service planning through negotiations with the CHCs if necessary, as suggested by Griffith (1983). Although both documents created several involvement opportunities, they invited criticism for not being statutory, thereby making it possible for service providers and commissioners to avoid having an inclusive agenda (Rhodes and Nocon, 1998). They were perceived more as a way of monitoring the level of service and costs rather than reflecting people's priorities or addressing their needs (Calnan and Gabe, 2001). Additionally, the targets set were unclear and, as such, often resulted in more power being handed to NHS managers rather than patients (Boote, Telford and Cooper, 2002; Calnan and Gabe, 2001). Finally, this trend was mainly attributed to managerial imperatives of service performance, which focused on ensuring productivity improvement, efficiency, customer-orientated philosophy, and 'top-down' accountability (Clarke, Gerwitz and McLaughlin, 2000).

In the mid-1990s, the evidence of a 'democratic deficit' within the NHS was observed with little surprise (Cooper et al., 1995). However, NHS policy documents did move in direction of making the healthcare agenda more inclusive. Indeed, the NHS Executive (1994) included amongst the objectives of the NHS strategy plan for the year 1995-1996 to *'improve the quality of services and make them more responsive to the preferences of patients, users and carers through increased involvement of the public in decisions about their health services'*

(NHS Executive, 1994, p.12). This was also supported by mid-term objectives, which reiterate the importance of giving *'greater voice and influence to users of NHS services and their carers in their own care, the development and definition of standards set for NHS services locally and the development of NHS policy both nationally and locally'* (NHS Executive, 1995, p.5). The development of a patient partnership strategy which called for more collaboration between professionals and service users in decisions about care plans and increased responsiveness of services to local needs also complemented the aforementioned changes (NHS Executive, 1996). Whilst presented as a way to improve public accountability of NHS services, according to Calnan and Gabe (2001), in practice, the focus of involvement was mainly driven by a market logic, whereby public members were informed about options and asked about their preferences to improve the service (i.e., the product).

The involvement of the active citizen-consumer

Under the leadership of Tony Blair (1997-2007), the NHS underwent another structural change *'to rebuild public confidence in the NHS as a public service, accountable to patients, open to the public and shaped by their views'* (DH, 1997, p. 11). Consequently, the involvement of patients and engagement with the public was strengthened in different ways. For instance, health authorities were expected to involve public members in priority settings and service planning; health service commissioners were required to develop PPI as part of their role; and greater emphasis was given to the achievement of a well-informed and satisfied patient. In order to respond to social inequalities and health disparities (DH, 1998a), the newly elected Labour Government (New Left) introduced several health initiatives (e.g., the Health Action Zones and the Health Living Centres), which, together with statements of policy (DH, 1998b), provided an opportunity to promote greater involvement of service users and engagement with community members and voluntary organisations (NHS Executive, NHS Confederation and Institute of Health Service Management, 1998). This new approach to involvement reflected aspects of the Labour Government's agenda to tackle social exclusion and inequalities by promulgating a social-democratic renewal (Clarke, 2005), whereby public services are required to be more responsive to service users and the wider public, who are both consumers and citizens (Beresford, 2002).

Against this backdrop, the DH (1999a) published the first statutory guidance on PPI – *Patient and Public Involvement in the New NHS* – which urged NHS organisations to involve in decisions about services patients, service users, carers, and the public, along with local stakeholders, authorities, community organisations and health professionals. Terms such as 'partnership' and 'joined-up work' proper of the New Left's agenda entered the health service policy and provision (Clarke, Gerwitz and McLaughlin, 2000) as well as the medical care system, wherein health care professionals were encouraged '*to treat patients as equal partners in the decision-making process'* (DH, 1999a). Meanwhile, an increased interest in chronic health problems had led to a new conceptualisation of patients, carers and service users as 'experts' of their own problems (Williams and Grant, 1998; Wilson, 1999), encouraging the advancement of *person-centred planning* approaches – known as *person-centred care* in dementia care and services for older people (Dowling, Manthorpe and Cowley, 2006) – which were committed to challenge unequal power structures in the healthcare system (Ritchie, 2002; Stalker and Campbell, 1998). The Labour Government included this perspective in the *National Carers' Strategy* (Her Majesty's Government, 1999), the *Expert Patients' Programme* (DH, 2001), and the policy paper *Saving Lives: Our Healthier Nation* (DH, 1999b), which discussed the importance of involvement in the own personal treatment and care, in addition to monitoring the quality of care and provision of services available.

Following high-profile inquiries – Bristol Royal Infirmary Inquiry (2001), Royal Liverpool Children's Inquiry (2001), Shipman Inquiry (2001) – health services and clinical failings elicited the attention of the media affecting the public trust in the medical professional (Smith, 1998) and reinforcing the idea that the engagement of patients and the public was crucial to guarantee the safety and quality of services (DH, 2003). Against this backdrop, the government introduced several changes within the NHS to increase its accountability and performance and regain public confidence. For instance, a new system of patient and public involvement discussed in the *New NHS Plan* (DH, 2000) proposed the abolition of CHCs in favour of several new organisations: the Overview and Scrutiny Committees, responsible for locally monitoring the NHS performance; the Patient Advice and Liaison Service, dedicated to the complaints of patients within hospitals; the Independent Complaints Advocacy Service, provided by voluntary organizations under contract; and the Patient's Forum – later renamed PPI forums (PPIfs) – to be included in each NHS Trust, where 'Trust' are the government bodies of hospitals. The role of PPIfs included monitoring services, inspecting public and private premises, providing advice to the trusts, collecting the views of patients and their families, and developing annual reports with key recommendations for positive change. Put succinctly, their role partly covered the responsibilities of the CHCs, which, with the *NHS Reform and Health Care Professions Act 2002*, were replaced by PPIfs made statutory bodies within the NHS and Primary Care Trusts (Health Committee, 2007).

PPIfs were soon deemed complicated and fragmented, raising concerns on whether the new involvement structure would represent a barrier to public participation or confusion among the newly formed organisations, which appeared to have overlapping roles (Banks, 2001). Additionally, forums' members were expected to be chosen based on criteria entailing a mix of domains (e.g., representativeness, ordinariness, diversity, knowledge, and expertise), thus questioning purpose and value of involvement as much as the role of PPIfs, which was initially exclusively associated with 'representativeness' (Martin, 2008). Moreover, PPIfs were funded by not-for-profit organisations and run by groups of volunteers. Consequently, the lack of funds and capacity were amongst the first challenges (Hogg, 2007). After coupling the limited human and economic resources with the absence of funds allocated to facilitate user involvement, it became apparent that PPIfs were given very little priority compared to financial and performance targets (Banks,2001). Moreover, PPIfs were NHS-centred and focused solely on health care, thereby shadowing the importance of partnerships with social care and third sector organisations (Warwick, 2007), and creating situations where, mistakes were often repeated due to the lack of communication between organisations (Health Committee, 2007). Finally, there was a pervasive feeling that patients and public members were consulted only after taking decisions or making changes were made (Health Committee, 2007; Warwick, 2007).

Meanwhile, the government introduced several targets and established bodies, such as the National Institute for Clinical Excellence [28] and the Healthcare Commission[29], to monitor service performance and guarantee quality care while also tackling the so-called 'postcode lottery'. Based on the achievement of high-performance targets, services could apply for 'foundation trust' status and acquire more funds and subsequently, autonomy when it came

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[28] https://www.legislation.gov.uk/uksi/1999/220/made

[29] https://www.legislation.gov.uk/ukpga/2003/43/contents

to decision-making (DH, 2002). The government contended that the possibility of becoming a foundation trust would promote the increased responsiveness of services to local needs while also augmenting their accountability by allowing community members, including staff, to be elected as part of trust boards. However, in reality, these changes only put more pressure on service performance (Clarke, 2005), thereby making trust boards advisory groups in practice (Hogg, 2007). Additionally, the scant interest of patients and the public in this new form of involvement and the lack of diversity among people included in trust boards questioned their legitimacy, thus raising concerns over how such agenda was considered as a means to tackle inequalities and social exclusion (Cook, 2002). Given this context, the promotion of involvement was perceived more a means of manipulation to foster efficiency and cost-effectiveness of health services rather than a form of empowerment (Banks, 2001). Indeed, despite the initial criticism of the New Right marketisation reforms, the Labour government continued to emphasise value for money scrutiny and commitment to continuous improvement (Clarke, Gerwitz and McLaughlin, 2000).

Despite the Commission for Health Improvement’s (2004) identification of some successful examples of involvement, many remained still sceptical about PPIfs, as there was no evidence of their impact and their role did not seem different than the CHCs’ one (Health Committee, 2007; Hogg, 2007). Following increased concerns over the government’s prioritisation of ‘choice’ over ‘voice’ and encouragement of a ‘pragmatic’ performance orientation (i.e., ‘what counts is what works’) (Clarke, 2005), PPIfs were replaced in favour of Local Involvement Networks (LINks) in 2003. LINks were founded to increase the accountability of the healthcare system and let organisations include community members in decisions about local health and social services, thereby moving beyond the CHC’s and PPIfs’ sole focus on NHS organisations (Hogg, 2007). The ultimate aim of LINks was to strengthen the collaboration between NHS organisations, local communities, as well as voluntary organisations. However, their organisation invited a lot of criticism. Indeed, due to the unclear objectives and purpose, LINKs was deemed unfit to increase democratic accountability by promoting more inclusion in service planning (Hogg, 2007). Additionally, queries were raised about the conflict of interests characterising the organisations supporting LINKs and providing social services simultaneously (Health Committee, 2007).

Under the governance of Prime Minister David Cameron (2010-2015) and the newly elected Conservative and Liberal Democratic coalition, LINKs were replaced by the HealthWatch England and a network of local HealthWatches (DH, 2010a), which were established as 'patient voice' or 'consumer champions' of the quality of the healthcare system. Local authorities were expected to coordinate with local HealthWatches (DH, 2010a) and create Health and Wellbeing Boards (DH, 2011) that included public members, so that more participation could be promoted in local decisions that were usually taken by local authorities in collaboration with commissioners. To overcome the claim of democratic deficit at the local level, the government also introduced the joint health and well-being strategies (DH, 2010b), which attributed a more active role to public representatives by requiring their inclusion, alongside other key stakeholders, in decisions finalised to the local adaptation of national guidance. However, this led again to the concerns expressed in relation to previous involvement structures, such as the lack of clear scope and objectives as well as methods and funds, were once again raised (Petsoulas et al., 2015). In what appeared to be a continuation of the Labour's agenda, particular attention was also given to the theme of social exclusion. By introducing the *Equality Act 2010*, services were encouraged to tackle by making decision capable of challenging discriminations based on age, disability, gender reassignment, marriage and civil partnership, race, religion or belief, sex, and sexual orientation.

Meanwhile, findings from additional high-profile inquiries – Maidstone and Tunbridge Wells NHS Trust Inquiry (Healthcare Commission, 2007), Mid Staffordshire NHS Foundation Trusts (Mid Staffordshire NHS Foundation Trust Public Inquiry, 2010) – affected the public confidence in a way that questioned the management and organisational culture within the NHS (Holmes, 2013). This context fostered the development of several patient and public involvement key legislations to avoid repeating similar incidents in the future (Ocloo and Fulop, 2011). For instance, the *NHS Constitution for England* (DH, 2012a) was published to set the legal rights of patients and the public and inform them about the quality of services while also investing them of responsibilities, such as contributing to the NHS by ensuring the efficacy of its work and the accuracy of resource allocation. Additional key policy documents included: the *Health and Social Care Act 2012*, which established the duty of NHS organisations and service commissioners to consider PPI part of their decision-making process; the DH's (2012b) statutory legislative requirement to consult carers, patients, family members and general community members in the planning and delivery of health and social care services; and finally, the DH's (2013) response to the Mid Staffordshire scandal (Francis, 2013), which recommended PPI across all levels of healthcare organisations, exhorting a move towards *'an authentic partnership'* (p.18) with patients and the public. In 2015, the importance of developing a true partnership with public members was reinforced by the NHS England (2015), which advocated the engagement of patients, carers, and citizens in the process of change of health services as a means of guaranteeing well-being and prevent illness for all communities.

What can we learn from the past?

What can we learn from the past? First of all, the origin of PPI sits in the relationship between a provider, that is the state, and a recipient, that is the citizen. This relationship was rooted in the notion that only the state could deal with the social problems characterising the British society post-world wars. As a result, the state assumes the role of key provider of the social welfare, thus establishing a paternalistic relationship wherein the citizen is a passive recipient of social rights (Clarke, Gerwitz and McLaughlin, 2000). One of the achievements of the post-world wars welfare state under the Old Left was the NHS, which had a remarkable effect on the healthcare system. Indeed, by entitling everyone the right to access free medical care, the government reshaped the relationship between health services and the public (Greengross, Grant and Collini, 1999). However, this relationship was largely depending on a paternalistic model of relationships (Beresford, 2005; Rowe and Shephard, 2002), whereby citizens were at the end of a top-down chain of responsibilities (Cooper et al., 1995). Several years later, the New Rights defined the state-citizen type of relationship established by the Old Left as *'economically unproductive'* and *'socially damaging'* (Clarke, Gerwitz and McLaughlin, 2000, p.2). Consequently, they decided to reform the social welfare system providing citizens with more power over their welfare and consolidating the marketisation of health services. By bringing down the boundaries between the state and the market, the government headed by Prime Minister Margaret Thatcher entitled the public 'consumers' rights of information, access, choice, and redress of health services (Rowe and Shephard, 2002), thus encouraging a shift away from paternalism and promoting new opportunities for involvement (Clarke, Gerwitz and McLaughlin, 2000).

In the late 1990s, the relationship state-citizens underwent further changes resulting from the social policies emended to support the New Left's concern of 'liberating' the citizen from the state (Clarke, 2005). To do so, the Labour Government led by Tony Blair initiated the processes of 'activation', 'empowerment', and 'responsibilisation' of citizens, which Clarke (2005) defined as an *'hybrid'* (p.448) between the Old Left's social democratic and communitarism and the New Right's neoliberal political system. The government deemed this hybrid necessary in the context of the 'modern' world embedded in a 'consumerist age' (Newman and Vidler, 2006). The process of change began with entitling citizens to not only rights but also responsibilities towards themselves and others (Beresford, 2005), thus extending the concept of 'citizenship' to 'social citizenship' to address the negative consequences of the New Right's agenda, which were deemed responsible for the triumphalism of individualism over collectivism (Clarke, 2005). Within the context of healthcare, the 'active' citizen is the 'expert patient' who manages their own health and well-being with less inputs from hospital or GP. The 'empowered' citizen is a consumer with greater choice and, subsequently, voice, as choice is considered a condition on its own right but also a key resource for responsiveness and innovation of services. Finally, the 'responsible' citizen is a consumer who exercises choice reasonably and responsibly, thus avoiding unhealthy lifestyle or behaviour (Newman and Vidler, 2006). If the Old Left had contributed to the establishment of a paternalistic state-citizen relationship, the New Left appeared to 'abandon' citizens by creating a confused narrative of consumerist and democratic concepts (Clarke, 2005).

Second, the relationship state-citizen, along with its related 'top-down' driven changes, cannot be considered outside the social contexts wherein forms of democratic 'bottom-up' pressure influenced governments' decision-making. For instance, the campaigns of social movements conducted in the 1960s encouraged the government to promote the implementation of community programmes to tackle poverty, inequalities, and the social exclusion affecting minorities and disadvantaged (Craig et al., 2011). These programmes promoted a shift from a representative to a more participatory type of democracy, whereby residents of the community targeted were invited to participate in decisions affecting the area they lived in, and the public services offered there (Craig et al., 2011). In the later 1960s, the emergence of philosophical ideas such as 'empowerment' and 'conscientisation' fostered the development of new social movements, which included victims of oppressive forms of social policies and service provision who campaigned for political and personal change (Campbell and Oliver, 1996). Between the 1970s and the 1980s, the activism of these movements, coupled with the campaigning work of consumer groups and patient organisations, led to the development of several alliances amplifying patients' and carers' voices (Beresford, 2002). These alliances encouraged the government to reform the system of health provision by increasing its accountability and responsiveness (Rowe and Shephard, 2002).

Third, a constant theme driving the continuum of top-down policy legislation and bottom-up public pressure is the challenge to professional power and hegemony of the medical model of health. The concept of professionalism denotes the claim of a professional group to own a valuable type of expertise that entitles them to acquire and retain social or organisational power (Clarke, Gerwitz and McLaughlin, 2000). Signs of professional power were already documented in the early 1960s in the public sector wherein the public participation in community initiatives promulgated to tackle poverty, inequalities, and social discriminations was often documented as paternalistic in nature (Craig et al., 2011). In the late 1960s, challenges to professional power were posed by the public activism of right-based movements, including disenfranchised groups of people personally affected by the discriminatory or paternalistic nature of public services grounded in the dominance of the medical system of beliefs (Beresford, 2005). The collective action of these groups encouraged the discussion around the limitations and negative consequences of the biomedical model of health and illness (Campbell and Oliver, 1996) and urged the need for a shift towards a more shared model of decision-making, treatment, and care (Ritchie, 2002; Stalker and Campbell, 1998; Williams and Grant, 1998; Wilson, 1999), which were deemed necessary especially, after the serious cases of service and clinical failings documented in several high-profile inquiries (Ocloo and Fulop, 2011).

The move towards increased public participation in healthcare entered the (top-down) policy discourse in the early 1970s with the New Right's establishment of CHCs to increase NHS accountability and responsiveness (Hogg, 2007). Given the structural and organisational changes made to the system of provision during the Thatcherism, health services became monitored by market values, such as satisfaction and value-for-money, (Beresford, 2002; Rowe and Shephard, 2002) and the view of 'experts cannot be questioned' was replaced by ‘what counts is what works’ (Clarke, 2005; Rowe and Shephard, 2002). After condemning the ‘deference’ and ‘hierarchy’ characterising the NHS, the Labour Government elected in the late 1990s insisted on positioning themselves on the side of the active citizen-consumer (Newman and Vidler, 2006). Initiatives aligned with this political philosophy included emphasis on the following changes: collaboration among organisations across sectors (e.g., joined-up work, stakeholding, risk sharing, and relational contract) to deal with people’s needs holistically as opposite to individualistically (Clarke, Gerwitz and McLaughlin, 2000); partnership between health professionals and (modern) citizen-consumer on care planning or treatment; and newly founded bodies and forums to monitor the performance of NHS Trusts and encourage the involvement of users in service planning and delivery to increase responsiveness to their rather than producers’ needs (DH, 2000). The same emphasis was exerted by the government headed by Prime Minister David Cameron, even though the advancement of legislation and structural changes (Petsoulas et al., 2015).

Fourth, notwithstanding the role played by top-down forces introducing policy changes to address the concerns expressed by the public through bottom-up pressure, within the healthcare system, not many changes were documented. Why? First and foremost, the forces driving policy changes were embedded within a context wherein there was little control of the state over the market, both of which were not separated by boundaries as prior to the Thatcherism. Consequently, policy documents were often underpinned by contradictory yet interrelated political ideologies, which lacked coherence, guide, resources, and contextualisation, despite being presented harmonically on paper. For instance, even though founded as independent local bodies entitled to monitor health services and represent the interests of local people to NHS managers, the CHCs – first form of public participation recognised politically in healthcare – lacked legitimacy of involvement in decisions about service planning and delivery, thus having little opportunity of impact on health legislation (Hogg, 2007). Additionally, although entitled to provide (bottom-up) recommendations for service improvement, CHCs were expected to do so in a context highly dependent on the (top-down) professional power of medical professionals (Gabe, Bury and Elston, 2005) and the managerial imperatives of service performance (Clarke, Gerwitz and McLaughlin, 2000). Moreover, even though granted greater independency over time, CHCs lacked clarifications on aims and related relations with decision-making and management. As a result, they were often invited to provide inputs after changes were made (Hogg, 2007).

Finally, by being low-resourced and refusing to lose their independent status, once the demand increased due to the 'marketisation' of health services, CHCs were unable to absolve the tasks given or guarantee the role of bridge between the community and the NHS (Hogg, 2007). In summary, even though in place to promote public participation in health services, CHCs, as well as other involvements initiatives encouraged by non-statutory policy documents (e.g., *The Patient's Charter, Local voice*), were often perceived as means in the hand of powerholders (i.e., professionals or managers) (Calnan and Gabe, 2001).

All the above-mentioned issues became again a matter of concern when the Labour Government (New Left) announced the replacement of CHCs with PPIfs, whose structure was deemed even more fragile and less authoritative (Health Committee, 2007; Hogg, 2007). Indeed, PPIfs were expected to be regulated by voluntary organisations, thus losing the resources provided to CHCs by NHS regions and local authorities. In addition, their role was reduced to rights of information and visits to NHS premises (Hogg, 2007). Moreover, they were NHS-centred, thereby shadowing the importance of partnerships with social care and third sector organisations (Warwick, 2007), thus clashing with the joined-up working campaign promoted by the Labour's agenda. At the same time, the new PPI structure was not informed by any evaluation of previous forms of public participation, thereby neglecting to address challenges already experienced by the CHCs (Health Committee, 2007; Hogg, 2007). Furthermore, PPIfs were introduced alongside other bodies (Overview and Scrutiny Committees, Patient Advice and Liaison Service, Independent Complaints Advocacy Service) which were given similar roles, thus not recognising differences in purpose and objectives, and creating confusion among constituents' role (citizen, service users, patients, consumers, experts, community) (Hogg, 2007) as well as legitimacy of inclusion criteria (Cook, 2002; Martin, 2008). Finally, even though the new changes to the PPI system were justified by the interest in providing citizen-consumers with a greater 'voice' and 'choice', the possibility of equalising 'needs' and 'wants' seemed in contrast with the increased pressure on health services to reach specific performance targets (Newman and Vidler, 2016). Put it succinctly, PPIfs, like CHCs, appeared to mainly foster efficiency and cost-effectiveness of health services rather than addressing people's concerns and needs (Banks, 2001; Clarke, Gerwitz and McLaughlin, 2000).

Considering the similarities among the typology of challenges and contradictions characterising CHCs and PPIfs, as well as the subsequently created LINks and HealthWatches (Petsoulas et al., 2015), it appears evident that many of the challenges associated with PPI were caused by the governments' failure to understand the contested and multidimensional nature of PPI. Additionally, by neglecting the impact of contextual circumstances on the success of patients and the public involvement opportunities, several initiatives ended undermining each other. For instance, the possibility given to services to apply for 'foundation trust' status if high-performance targets were achieved, overshadowed the new system of PPI introduced to give greater voice to service users and patients (Banks, 2001; Clarke, Gerwitz and McLaughlin, 2000). The same can be said about the 'choice' initiatives introduced in the NHS, which stressed the prioritisation of a consumerist and managerial logic of evaluation (Newman and Vidler, 2006). Moreover, given the paternalistic nature of service provision and the high level of managerial and medical power (DH, 2001, p.9), the ambiguity on ensuring greater involvement in decisions about services and care planning without addressing first power imbalances reduced the possibility of inclusiveness in multiple occasions (Gabe, Bury and Elston, 2005; Newman and Vidler, 2006). Finally, considering 'empowered' those patients who are 'highly informed' and willing to contribute to decision-making by providing 'ideas' (DH, 2001, p.9), the government failed to recognise the democratic value of participation and the notion of experiential knowledge as expertise, allowing the endurance of the professionally driven model over the promotion of person-centeredness (Newman and Vidler, 2006).

Concluding remarks

1. The historical evolution of PPI is characterised by a continuous interplay of forces driven by contrasting, yet interrelated, political ideologies – consumerism and democracy – that have shaped changes of roles in state, the healthcare system (including health services and care practice), and the public, along with the relationships between them all. Therefore, PPI can be considered 'contested' and 'relational' in nature.
2. The tensions between public participation, managerial accountability and medical profession power have informed the operationalisation of PPI in practice, highlighting another aspect of the nature of PPI, that is its 'multidimensionality'. Indeed, PPI entails a political, instrumental, normative, and evaluative dimension, which depends upon the perception from a particular analytical position.

3. The under conceptualisation of PPI and the lack of guidance and evaluation have limited the understanding of its ‘contextual sensitivity’. Consequently, the policy support of involvement initiatives did not necessarily lead to greater inclusion of patients and the public in decision-making.
4. The lack of clarity in the relationship citizen-consumer, especially under the New Left, resulted in a confusing system of PPI, which, although introduced as a means to challenge democratic deficit and technocratic dominance within the healthcare system, undermined the agency of patients and the public and neglected the differences between the two.

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Appendix B. Ethical approval

Ethics Form Completed for Project: The Dementia Research Involvement Study: Exploring and Explaining the Involvement of People with Dementia and Family carers through PPI activities

Policy & Information Team, Newcastle University <noreply@limesurvey.org>
Tue 29-Jan-19 2:03 PM
To: Ester Bellavia (PGR) <E.Bellavia2@newcastle.ac.uk>

Ref: 10397/2018

Thank you for submitting the ethical approval form for the project 'The Dementia Research Involvement Study: Exploring and Explaining the Involvement of People with Dementia and Family carers through PPI activities' (Lead Investigator:Ester Bellavia). Expected to run from 01/03/2019 to 24/09/2021.

Based on your answers the University Ethics Committee grants its approval for your project to progress. Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. If you have any queries please contact res.policy@ncl.ac.uk

Best wishes

Policy & Information Team, Newcastle University Research Office

res.policy@ncl.ac.uk

Appendix C. Ethical approval: Amendment n.1

Ethics Form Completed for Project: The Dementia Research Involvement Study: Exploring and Explaining the Involvement of People living with Dementia and Family Carers

Policy & Information Team, Newcastle University <noreply@limesurvey.org>
Tue 09-Jul-19 8:03 PM
To: Ester Bellavia (PGR) <E.Bellavia2@newcastle.ac.uk>

Ref: 14045/2018

Thank you for submitting the ethical approval form for the project 'The Dementia Research Involvement Study: Exploring and Explaining the Involvement of People living with Dementia and Family Carers' (Lead Investigator:Ester Bellavia). Expected to run from 24/09/2018 to 24/09/2021.

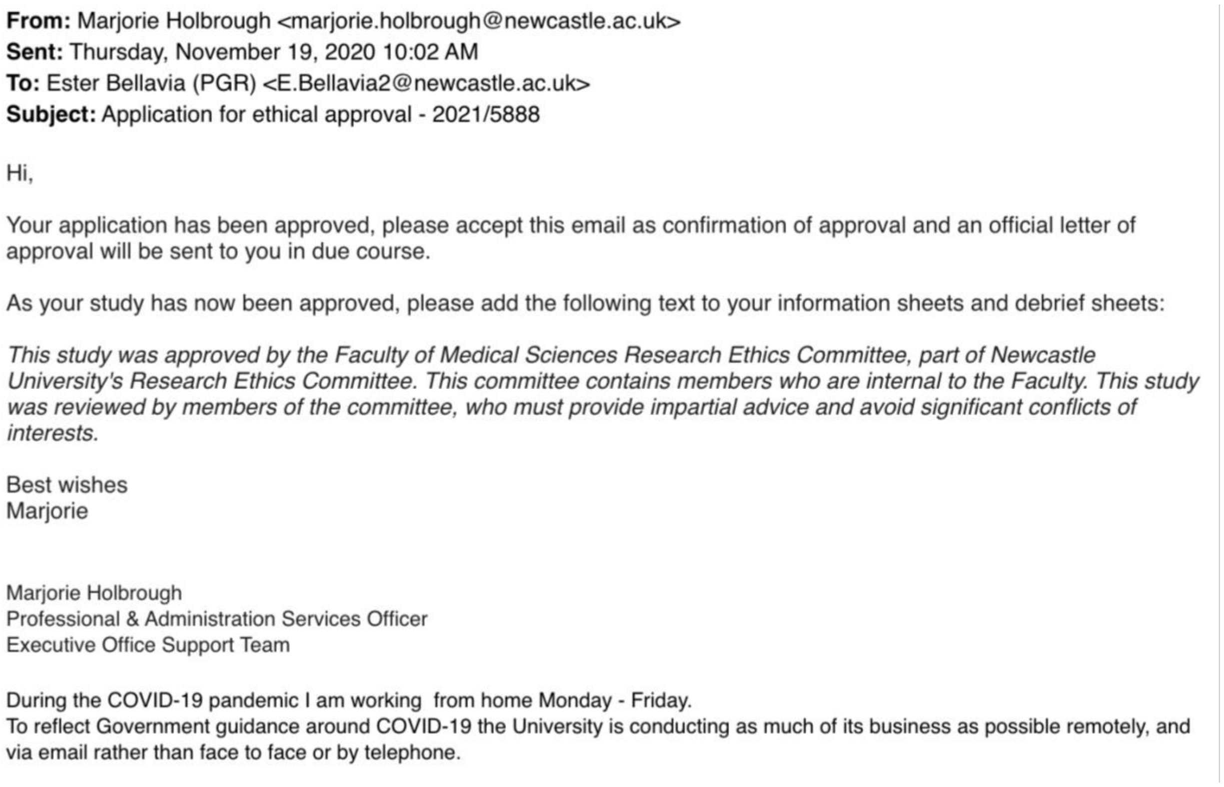
Based on your answers the University Ethics Committee grants its approval for your project to progress. Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. If you have any queries please contact res.policy@ncl.ac.uk

Best wishes

Policy & Information Team, Newcastle University Research Office

res.policy@ncl.ac.uk

Appendix D. Ethical approval: Amendment n.2



From: Marjorie Holbrough <marjorie.holbrough@newcastle.ac.uk>
Sent: Thursday, November 19, 2020 10:02 AM
To: Ester Bellavia (PGR) <E.Bellavia2@newcastle.ac.uk>
Subject: Application for ethical approval - 2021/5888

Hi,

Your application has been approved, please accept this email as confirmation of approval and an official letter of approval will be sent to you in due course.

As your study has now been approved, please add the following text to your information sheets and debrief sheets:

This study was approved by the Faculty of Medical Sciences Research Ethics Committee, part of Newcastle University's Research Ethics Committee. This committee contains members who are internal to the Faculty. This study was reviewed by members of the committee, who must provide impartial advice and avoid significant conflicts of interests.

Best wishes
Marjorie

Marjorie Holbrough
Professional & Administration Services Officer
Executive Office Support Team

During the COVID-19 pandemic I am working from home Monday - Friday.
To reflect Government guidance around COVID-19 the University is conducting as much of its business as possible remotely, and via email rather than face to face or by telephone.

Newcastle University

Faculty of Medical Sciences
Newcastle University
The Medical School
Framlington Place
Newcastle upon Tyne
NE2 4HH, United Kingdom

04 January 2021
Ester Bellavia
Population and Health Sciences

FACULTY OF MEDICAL SCIENCES: ETHICS COMMITTEE

Dear Ester

Title: The Dementia Research Involvement study: Exploring and explaining the involvement of people living with dementia and family carers through patient and public involvement activities
Application: 2021/5888/2020
Start date to end date: 01/11/2020 to 01/09/2021

On behalf of the Faculty of Medical Sciences Ethics Committee, I am writing to confirm that the ethical aspects of your proposal have been considered and your study has been given ethical approval.

The approval is limited to this project: **2021/5888/2020**. If you wish for a further approval to extend this project, please submit a re-application to the FMS Ethics Committee and this will be considered.

During your research project you may find it necessary to revise your protocol. Substantial changes in methodology or changes that impact on the interface between the researcher and the participants must be considered by the FMS Ethics Committee, prior to implementation. *

At the close of your research project, please report any adverse events that have occurred and the actions that were taken to the FMS Ethics Committee. *

Yours sincerely

Marjorie Holbrough
On behalf of Faculty Ethics Committee

cc. Professor Daniel Nettle, Chair of FMS Ethics Committee
Mrs Kay Howes, Research Manager

*Please refer to the latest guidance available on the internal Newcastle web-site.

Appendix E. Phase I: Recruitment material

The DemRI Study – Letter of Invitation

I would like to invite you to participate in the DemRI study which aims to understand how best to involve people living with dementia and family carers in research.

This study is part of the PriDem programme you are already involved in, and it will be conducted as a part of my PhD.

Participation in this research is entirely voluntary, and you may change your mind at any time. A participation information sheet is provided with more details about the study and answers to questions frequently asked.

If you would like to take part, please, complete the consent form included in this envelope and give it back to the research team.

If you have any questions or would like to discuss the study in more details, get in touch with me (see details below).

I look forward to hearing from you.

Kind Regards,
Ester Bellavia
PhD Student at Newcastle University

Contact Details
Email: E.Bellavia2@newcastle.ac.uk
Telephone: 01912082103 – 07444014902

Work Address
Biomedical Research Building, Level 2
Campus for Ageing and Vitality
Newcastle upon Tyne
NE4 5PL

The DemRI Study
Participation Information Sheet

Before you decide whether to participate or not, we want you to understand why the research is being done and what it would involve for you.

What is the DemRI study?

The DemRI study is a research project linked to the PriDem programme, and it aims to understand how best to involve people living with dementia and family carers in research.

Why is it important?

It is important to involve people living with dementia and family carers in shaping health and social care policies and practice; however, there has been little research to find out what is the best way to do that. In the PriDem programme, we are trying a new approach – the Dementia Care Community. I am interested in finding out what you think of this approach – which aspects you enjoy and whether you feel able to get your message across.

How can I take part in the study?

If you choose to participate, you will be asked to complete a consent form. Once you have done that, data will be gathered from your previous, or future, contributions to the Dementia Care Community. Additionally, you might be asked to participate in an interview and/or group discussions.

What will happen if I don't want to carry on with the study?

Your participation in this study is voluntary, and you are free to withdraw at any time. If you decide to withdraw, it will be up to you to decide whether the information collected will still be used.

Will my taking part in the study be confidential?

All information collected about you during the research will be kept strictly confidential and stored in a secure, locked office on a password-protected database. Any information used in reporting the findings will be anonymised.

What will happen to the findings of the study?

The findings of the study will be used for a PhD thesis and are likely to inform the PriDem programme. Moreover, we will report findings through academic and non-academic journals, blogs, social events, and conferences. At the end of the study, we will send you a summary of the findings.

What happens to my details when the study ends?

All research data will be kept securely at the University for five years. During this time, all precautions will be taken to maintain your confidentiality.

Who is conducting the study?

This research is conducted by a team which includes a PhD student (Ester Bellavia) and her two supervisors (Professor Dame Louise Robinson and Dr Susan Hrisos).

Who has funded the study?

The study has been funded by the Alzheimer's Society.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by the Newcastle University Faculty of Medical Sciences Research Ethics Committee.

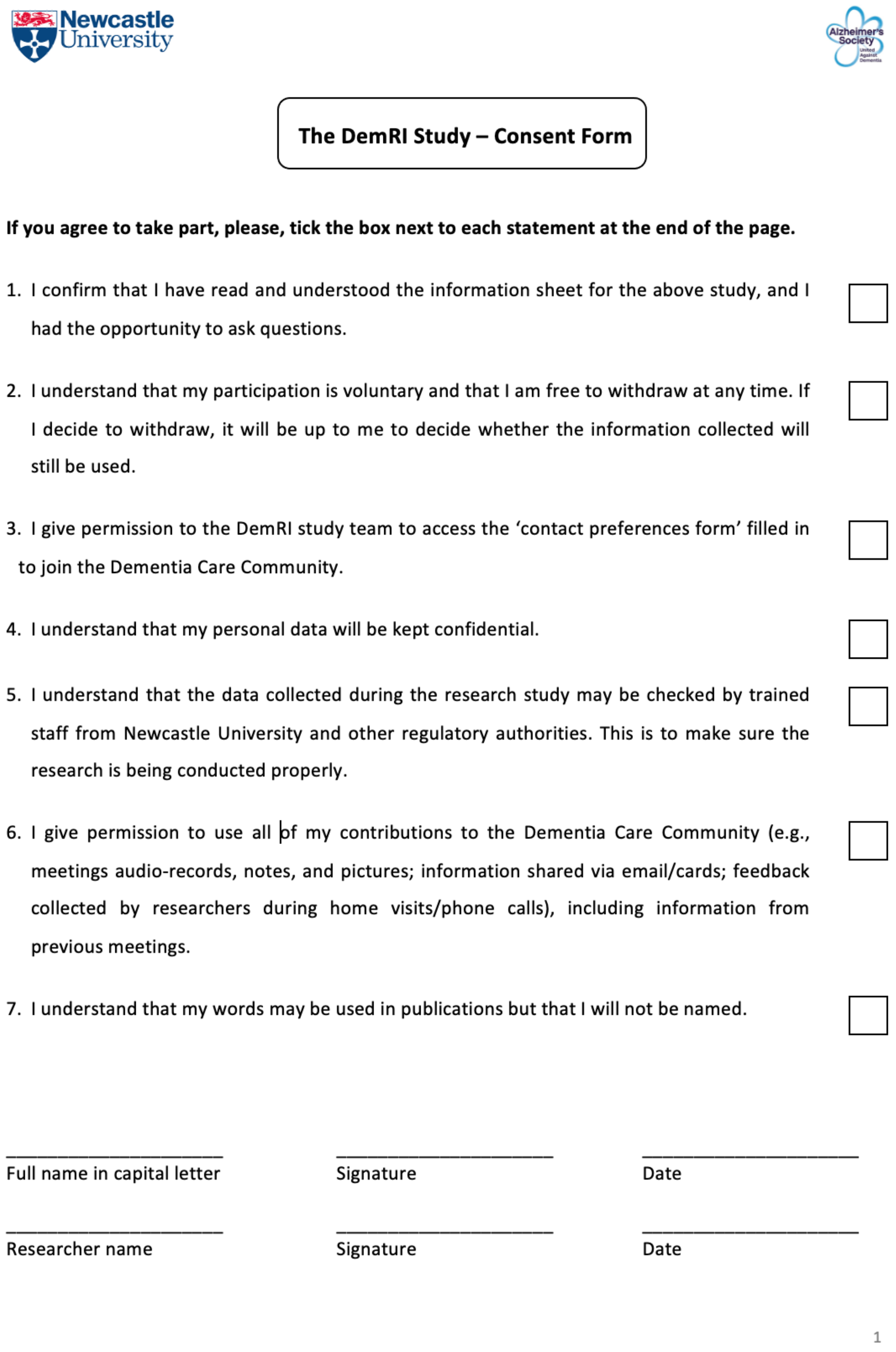
What if I have other questions?

If you have any questions, you can contact Ester Bellavia or the supervisory team via the research study lead Professor Dame Louise Robinson (see details below).

Contact details

Ester Bellavia PhD Student at Newcastle University
Biomedical Research Building, Level 2
Campus for Ageing and Vitality
Newcastle upon Tyne, NE4 5PL
Email: E.Bellavia2@newcastle.ac.uk
Telephone: 0191 2082103 – 07444014902

Louise Robinson Director Newcastle University Institute for Ageing
Professor of Primary Care and Ageing
Biomedical Research Building, Level 2
Campus for Ageing and Vitality
Newcastle upon Tyne, NE4 5PL
Email: a.l.robinson@ncl.ac.uk
Telephone: 0191 2087013



The DemRI Study – Consent Form

If you agree to take part, please, tick the box next to each statement at the end of the page.

1. I confirm that I have read and understood the information sheet for the above study, and I had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time. If I decide to withdraw, it will be up to me to decide whether the information collected will still be used. ☐

3. I give permission to the DemRI study team to access the 'contact preferences form' filled in to join the Dementia Care Community. ☐

4. I understand that my personal data will be kept confidential. ☐

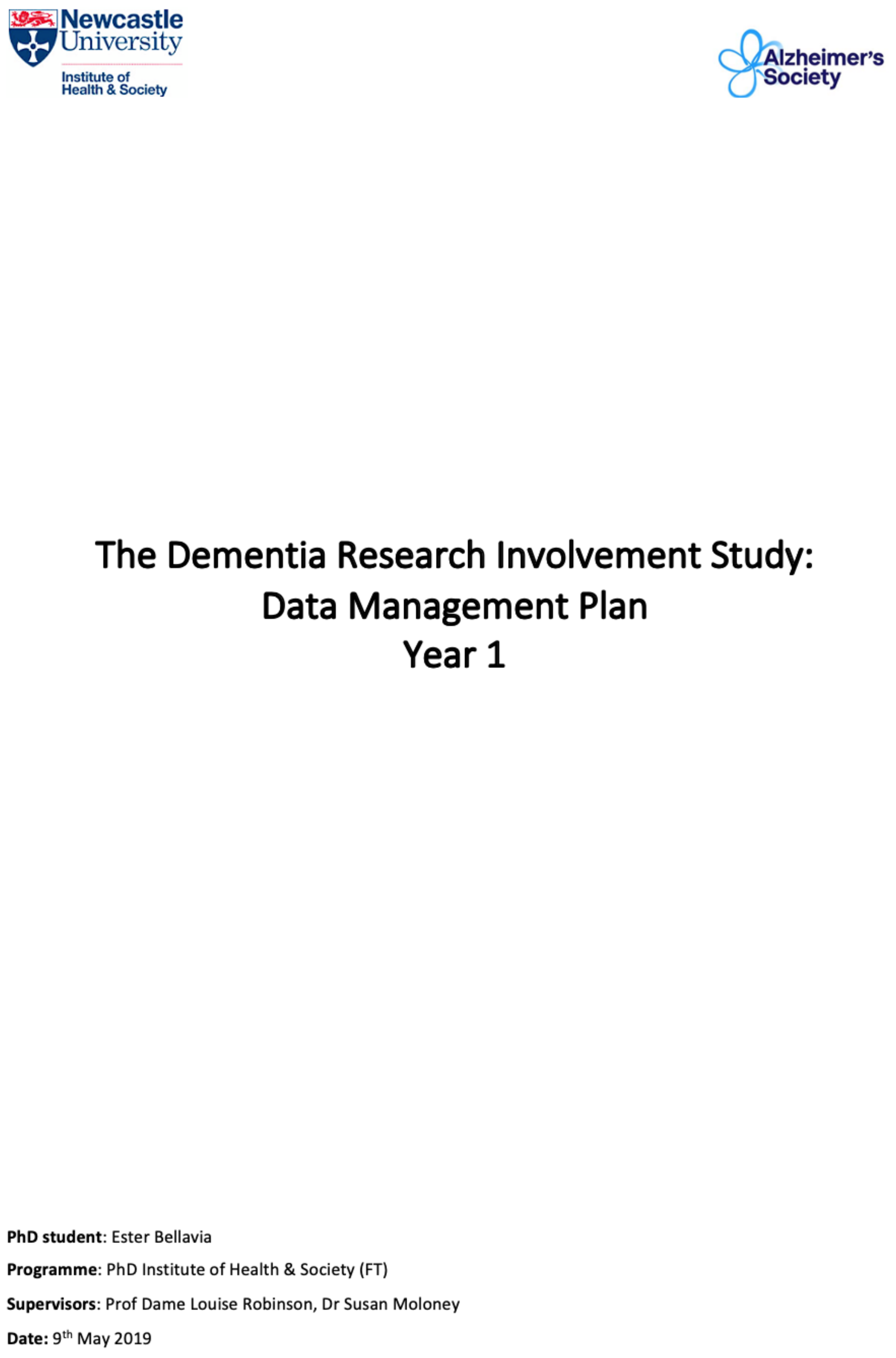
5. I understand that the data collected during the research study may be checked by trained staff from Newcastle University and other regulatory authorities. This is to make sure the research is being conducted properly. ☐

6. I give permission to use all of my contributions to the Dementia Care Community (e.g., meetings audio-records, notes, and pictures; information shared via email/cards; feedback collected by researchers during home visits/phone calls), including information from previous meetings. ☐

7. I understand that my words may be used in publications but that I will not be named. ☐

______________________	______________________	______________________
Full name in capital letter	Signature	Date
______________________	______________________	______________________
Researcher name	Signature	Date

Appendix F. Data management plan n.1



Newcastle University
Institute of Health & Society

Alzheimer's Society

The Dementia Research Involvement Study:
Data Management Plan
Year 1

PhD student: Ester Bellavia

Programme: PhD Institute of Health & Society (FT)

Supervisors: Prof Dame Louise Robinson, Dr Susan Moloney

Date: 9th May 2019

RESEARCH STUDY

The Dementia Research Involvement Study: Exploring and Explaining the Involvement of People Living with Dementia and Family Carers through PPI Activities

DESCRIPTION OF THE DATA

The research study entails a realist synthesis of evidence which will be informed by the conduct of a qualitative study. Data will be generated from observation, review of sources in document/image formats, and verbatim transcription of audio-recorded interviews and focus groups. In line with the Newcastle University data management policy, data will be stored in the following formats: textual data in Microsoft Word (.doc/.docx); image data in JPEG (.jpeg, .jpg, .jp2) or PNG (.png); and audio data in MPEG-1 Audio Layer 3 (.mp3) or audio interchange file (.aif).

DATA MANAGEMENT AND SECURITY

Data will be stored in a Newcastle University networked computer and held securely for 5 years after completion of the study. The computer holding the data will be password protected; users' identifiers and passwords will restrict the access to supervisors, PriDem project team, and Newcastle University regulatory authorities. It will be considered the possibility of using the Newcastle University cloud storage that includes the 'OneDrive' tool which secures online storage, offline access, and one-off sharing. In compliance with the Data Protection Act 2018 and the General Data Protection Regulation, individual participant personal information and data obtained as a result of this study are considered confidential. Transcripts and field notes will be anonymised and kept in locked cabinets in university premises accessible only by smartcard. A software package (QSR Nvivo 11) will facilitate the storage and management of data. I will monitor the data as an ongoing activity. Monitoring of data will include confirmation of informed consent, source data verification, data storage and transfer procedures, local quality control checks, and back up of local databases. Should any issues arise, I will inform the supervisory team and, if required, I will involve the Newcastle University Research Data Management (RDM) team.

INTELLECTUAL PROPERTY RIGHTS AND DATA OWNERSHIP

The intellectual property of the data generated will remain with Newcastle University.

RESPONSIBILITIES

I am responsible for the data management, and I will review the plan developed to ensure the success of a long-term strategy. I undertook the 'Creating Data Management Plan' online workshop offered by the Faculty of Medical Sciences Graduate School. Additionally, I consulted with the Newcastle University RDM team on possible strategies as part of my early data management planning. I will attend any other relevant training to respond appropriately to the challenges that may arise during the conduct of the research study. The supervisory team will review data management procedures and assist with quality assurance by discussing regularly data collected and methods used to gather them.

RELEVANT INSTITUTIONAL POLICIES

Storage and back up	https://research.ncl.ac.uk/rdm/working/
Organising data	https://research.ncl.ac.uk/rdm/working/organise/
Data access	https://research.ncl.ac.uk/rdm/working/dataaccess/
Data sharing	https://research.ncl.ac.uk/rdm/sharing/

AUTHOR OF THE DATA MANAGEMENT PLAN

Ester Bellavia, PhD student, Newcastle University

DATA MANAGEMENT PLAN REVIEWED BY

Dr Chris Emmerson, Research Data Manager, Newcastle University

Appendix G. Data management plan n.2

The Dementia Research Involvement Study:
Data Management Plan
Year 2

PhD student: Ester Bellavia

Programme: PhD Population Health Sciences (FT)

Supervisors: Prof Dame Louise Robinson, Dr Susan Moloney

PPI advisor: Dave Green

Date: 24th March 2020

RESEARCH STUDY

The **Dem**entia **R**esearch **I**nvolvement (DemRI) study focuses on the involvement of people living with dementia and family carers through Patient and Public Involvement (PPI) activities. The ultimate aim of the DemRI study is to develop an evaluative framework which explains the generative cause of specific outcomes embedded in different contexts and resulting from the prolonged collaboration between researchers and people involved. The research design of the study entails three phases with a collection of primary and secondary data over time.

DESCRIPTION OF THE DATA

The data collected during the first phase of the DemRI study includes information organised in tabular, textual and image formats. According to the Newcastle University (NU) Research Data Management (RDM) *organising data* policy, the data collected to date are stored in the following file formats: tabular data in Excel (.xls, .xlsx); textual data in Microsoft Word (.doc, .docx) or PDF (.pdf); and image data in JPEG (.jpeg, .jpg, .jp2), PNG (.png) or PDF (.pdf).

DATA MANAGEMENT AND SECURITY

The data collected are held into the personal NU networked computer and will be stored securely for five years after completion of the DemRI study. The network containing the data is password-protected, and users' identifier and password restrict the access. In compliance with the Data Protection Act 2018 and the General Data Protection Regulation, participants' personal information and data obtained from them are considered confidential. Therefore, in line with ethical research principles, paper copies of the study documentation are kept in a locked cabinet at the Biomedical Research Building[*] which is accessible only by a smartcard. Indeed, e-copies are stored in the personal *@newcastle.ac.uk* OneDrive storage that allows access from outside the campus and facilitates the one-off sharing with supervisors.

The software package NVivo 12 was initially employed to organise and review the analysis conducted on paper. Following the Covid-19 outbreak and the related lockdown measures, the use of the software has been postponed. Reasons can be found in difficulty to work with the software through RAS and impossibility of storing it along with all the data collected into a personal computer due to memory storage and ethical reasons. However, details about the data collected and analysed to date are documented briefly in the research study progress report Year 2 and accurately in the study audit trail, which can be shared with authorised people upon request. It is expected to restart the analysis on NVivo when clearer directions on alternatives will be provided by the NU.

The data collected to date are monitored as an ongoing activity. Monitoring of data includes source data verification, data storage and transfer, quality control checks, and back up of OneDrive storage and database. No issue has been reported to date; should any arise, the supervisory team will be informed and, if necessary, the NU RDM team will be involved.

INTELLECTUAL PROPERTY RIGHTS AND DATA OWNERSHIP

The intellectual property of the data generated will remain with NU. The overall data obtained from the conduct of the DemRI study will be stored and shared accordingly to the decisions taken by the PriDem programme team and in respect of funders' (Alzheimer's Society) and NU's RDM policies.

TRAINING

Following the NU *Creating Data Management Plan* training attended in 2019, an update of the knowledge base was planned for the 18th of March 2020. Due to the Covid19 outbreak, the face-to-face workshop led by the NU RDM team was cancelled. While waiting for its eLearning version, a course available on The University of Edinburgh website (https://mantra.edina.ac.uk) was undertaken. Additionally, for the second consecutive year, Dr Chris Emmerson–NU RDM manager–was involved in the development of this document to which he contributed providing suggestions and sharing resources. Currently, no other RDM-related learning needs have been identified; should new challenges arise, additional training will be considered to respond to those appropriately.

RESPONSIBILITIES

The student conducting the research project is responsible for the management of the data collected. Supervisors will be continuously informed about RDM procedures implemented so that they can review them, ensuring quality and adherence to the policies. The current RDM plan will be reviewed as the research progresses to ensure the success of a long-term strategy.

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[*] Newcastle University Campus for Ageing and Vitality, Newcastle upon Tyne

RELEVANT INSTITUTIONAL POLICIES

Storage and back up	https://research.ncl.ac.uk/rdm/working/
Organising data	https://research.ncl.ac.uk/rdm/working/organise/
Data access	https://research.ncl.ac.uk/rdm/working/dataaccess/
Data sharing	https://research.ncl.ac.uk/rdm/sharing/

AUTHOR OF THE DATA MANAGEMENT PLAN

Ester Bellavia, PhD student Population Health Sciences, Newcastle University

DATA MANAGEMENT PLAN REVIEWED BY

Dr Chris Emmerson, Research Data Manager, Newcastle University

Appendix H. Material developed for theory-building purposes

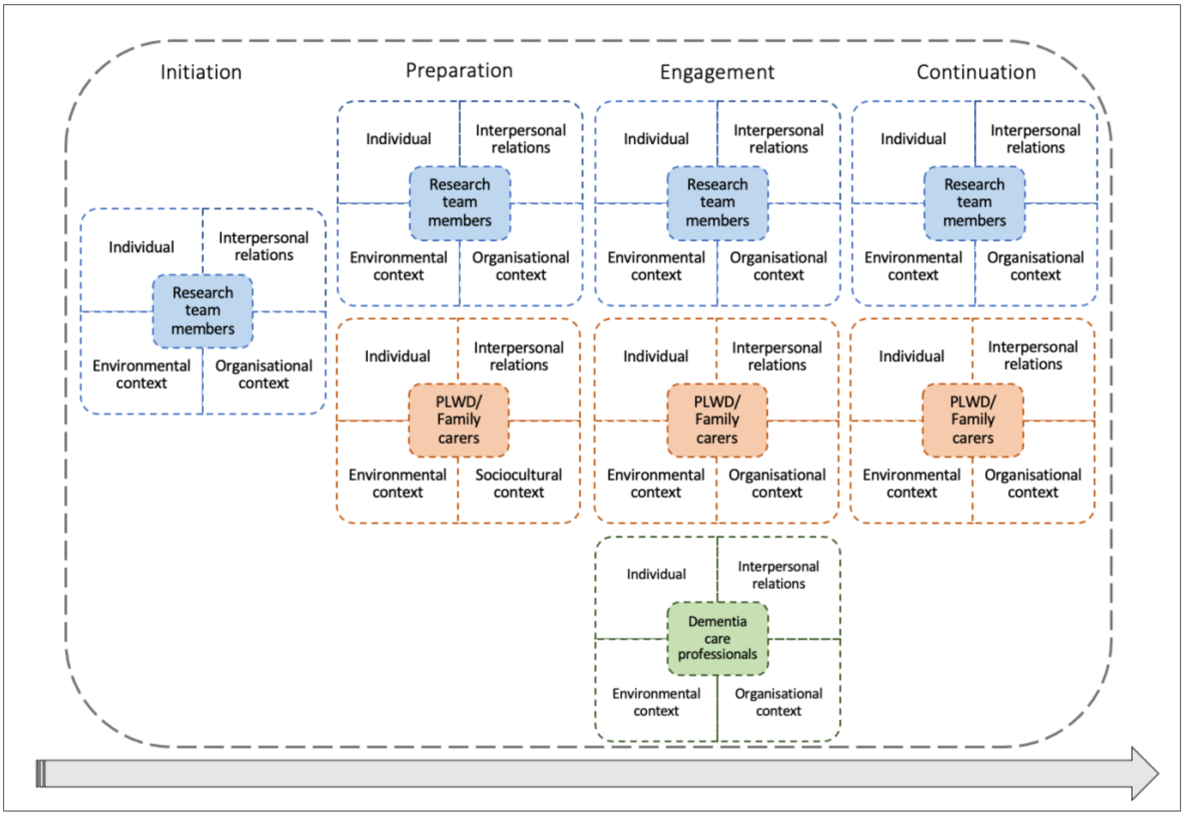
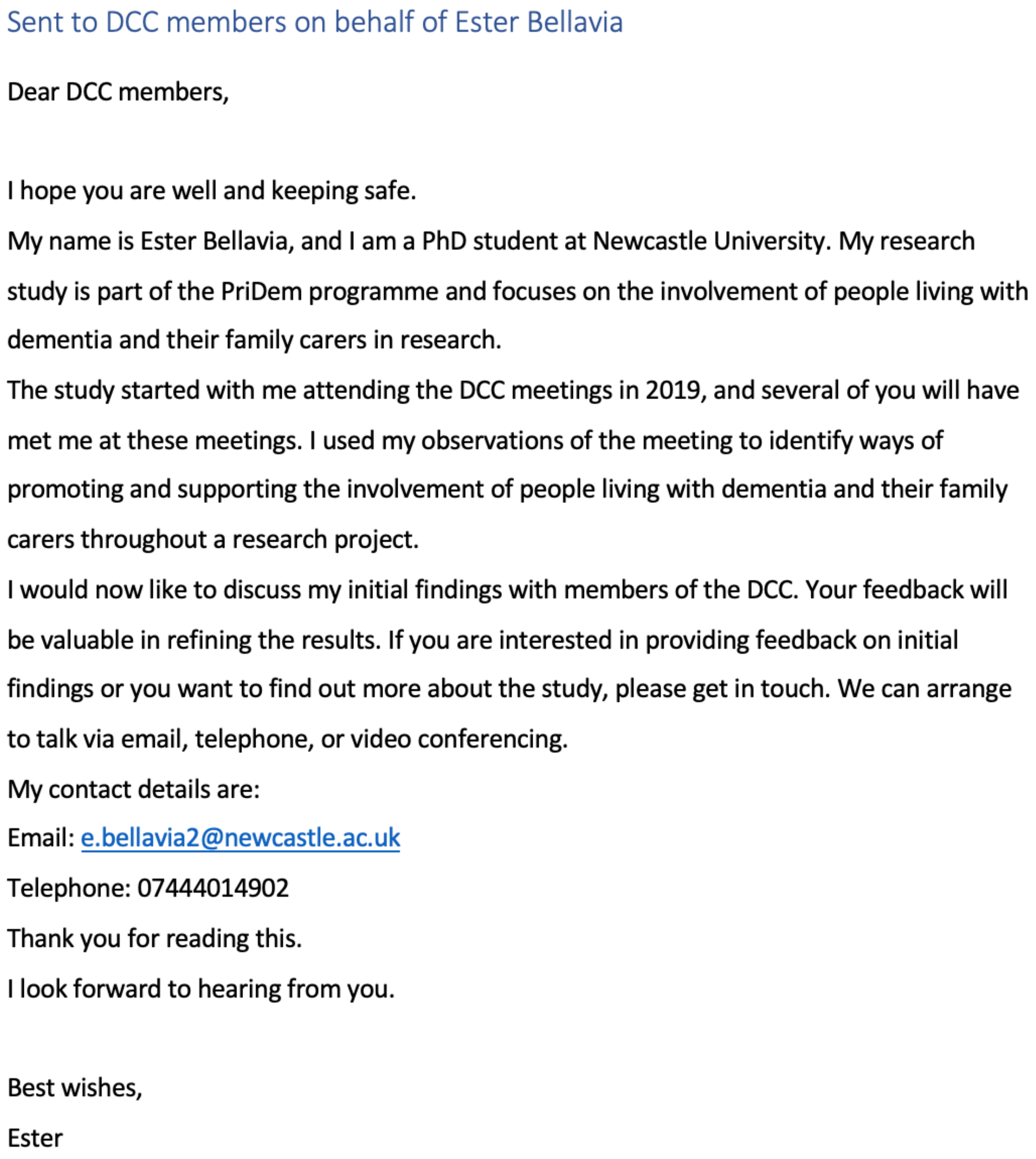


Figure 1. PPI system dynamic
Key. Broken lines = open boundaries; arrow = time

Table 1. Questions informing the theory-building process

	Phase			
Actors	Initiation	Preparation	Engagement	Continuation
Research team members	• Why does the research team want to use PPI? • What strategies is the team planning to adopt to guarantee PPI throughout the research programme? • Do the organisational or environmental contexts affect researchers' reasoning? How, if at all?	• Is there any interaction with the population of interest before their recruitment for PPI purposes? • Are all research team members involved in this phase? • Do the organisational or environmental contexts affect preparation for PPI? How, if at all?	• How are PPI activities implemented? • Are there any differences based on the options of involvement offered? • Are all research team members involved in this phase? Are there any differences in roles? • Do the organisational or environmental contexts affect engagement? How, if at all?	• Is there any strategy in place to guarantee continuous involvement? • Does the research team collaborate to maintain continuous involvement? • Do organisational and environmental contextual factors affect continuous involvement?
PLWD & family carers	N/A as the initiation refers to those who start the involvement	• Is there any difference between PLWD and family carers? • Can the relationship between PLWD and their family carers affect their willingness to join a research team or how they do so? • Can the sociocultural context affect their assumptions about collaborating with researchers? • Can the environmental context influence PLWD and their family carers' decisions?	• Do PLWD and family carers differ in how they engage in PPI activities? • Do PLWD and family carers entertain any relationship with the research team carrying out the PPI activities? • Can the organisational or environmental context surrounding the implementation of PPI activities affect PLWD and or family carers' engagement? • Is there any change over time?	• Are there any differences between PLWD and their family carers in what can promote continuous involvement? • Do the relations developed with research team members affect decisions on continuous involvement? • Is there any aspect of the organisational context that can influence PLWD and or family carers' reasoning?
Dementia care professionals	As above	N/A, as the focus of the DemRI study is limited to PLWD and family carers	• What is the difference between dementia care professionals and other actors involved in PPI activities? • Are there any relations with the team or other people involved that could affect the unfolding of PPI activities? • Can their organisational context or related environmental context affect how they interact with PLWD and their family carers in PPI activities?	N/A, as the focus of the DemRI study is limited to PLWD and family carers

Appendix I. Phase II: Invitation email



Sent to DCC members on behalf of Ester Bellavia

Dear DCC members,

I hope you are well and keeping safe.

My name is Ester Bellavia, and I am a PhD student at Newcastle University. My research study is part of the PriDem programme and focuses on the involvement of people living with dementia and their family carers in research.

The study started with me attending the DCC meetings in 2019, and several of you will have met me at these meetings. I used my observations of the meeting to identify ways of promoting and supporting the involvement of people living with dementia and their family carers throughout a research project.

I would now like to discuss my initial findings with members of the DCC. Your feedback will be valuable in refining the results. If you are interested in providing feedback on initial findings or you want to find out more about the study, please get in touch. We can arrange to talk via email, telephone, or video conferencing.

My contact details are:
Email: e.bellavia2@newcastle.ac.uk
Telephone: 07444014902
Thank you for reading this.
I look forward to hearing from you.

Best wishes,
Ester

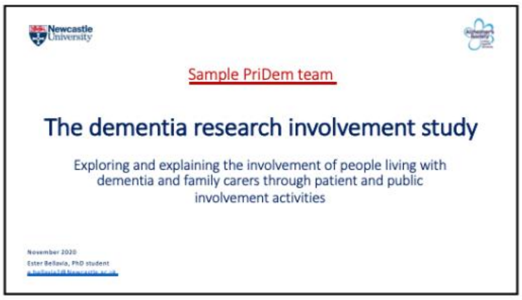
Appendix J. Lay summary

In 2017, the Alzheimer's Society funded the PriDem programme to respond to the need for better support for people living with dementia and family carers after diagnosis. The PriDem programme aims to develop a new way of supporting people who receive a diagnosis of **dem**entia and their families. Ideally, this new model of care will be led by GPs who provide **pri**mary care services. This explains the reason for naming the research programme as **PriDem**. To achieve this aim, the PriDem research team is working with a Patient and Public Involvement (PPI) group called Dementia Care Community (DCC). The DCC includes people living with dementia, family carers, health and social care professionals and representatives of dementia-friendly community initiatives. The research study I discuss in this report is complementary to the PriDem programme, and it is known as the DemRI study. The acronym **DemRI** comes from the full title of the study:

*'The **Dem**entia **R**esearch **I**nvolvement Study: Exploring and explaining the involvement of people living with dementia and family carers through PPI activities'.*

The DemRI study focuses on how people living with dementia and family carers work with other DCC members and PriDem programme team when involved in research-related activities. The main aim of this complementary study is to understand how best to actively involve people with dementia and family carers in research. Through my research, I will explore how people living with dementia and family carers have been involved so far. Then, I will explain what a good involvement practice entails by identifying what works, for whom, when how and why. Finally, I will create a framework to support and evaluate future research aiming to actively involve people with dementia and family carers.

Appendix K. Phase II: Material for consultation



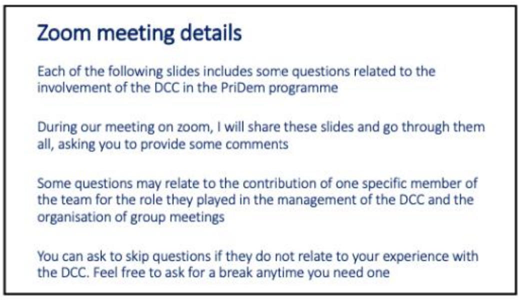
Sample PriDem team

The dementia research involvement study

Exploring and explaining the involvement of people living with
dementia and family carers through patient and public
involvement activities

November 2020
Ester Bellavia, PhD student
[illegible]

1



Zoom meeting details

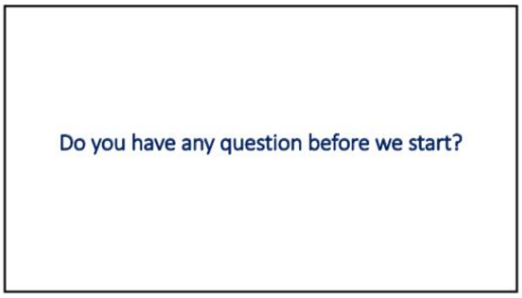
Each of the following slides includes some questions related to the involvement of the DCC in the PriDem programme

During our meeting on zoom, I will share these slides and go through them all, asking you to provide some comments

Some questions may relate to the contribution of one specific member of the team for the role they played in the management of the DCC and the organisation of group meetings

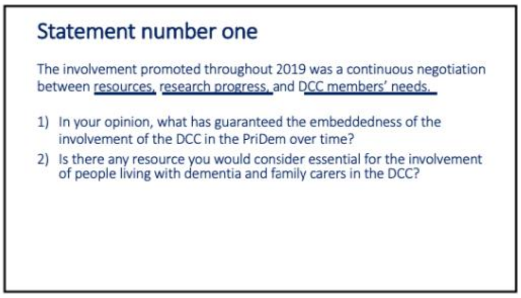
You can ask to skip questions if they do not relate to your experience with the DCC. Feel free to ask for a break anytime you need one

2



Do you have any question before we start?

3

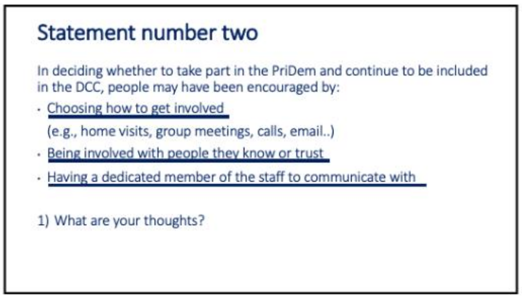


Statement number one

The involvement promoted throughout 2019 was a continuous negotiation between resources, research progress, and DCC members' needs.

1) In your opinion, what has guaranteed the embeddedness of the involvement of the DCC in the PriDem over time?
2) Is there any resource you would consider essential for the involvement of people living with dementia and family carers in the DCC?

4



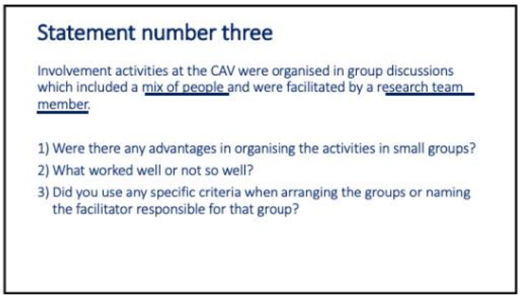
Statement number two

In deciding whether to take part in the PriDem and continue to be included in the DCC, people may have been encouraged by:

- Choosing how to get involved
  (e.g., home visits, group meetings, calls, email..)
- Being involved with people they know or trust
- Having a dedicated member of the staff to communicate with

1) What are your thoughts?

5

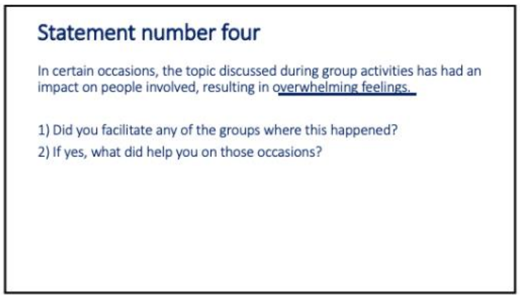


Statement number three

Involvement activities at the CAV were organised in group discussions which included a mix of people and were facilitated by a research team member.

1) Were there any advantages in organising the activities in small groups?
2) What worked well or not so well?
3) Did you use any specific criteria when arranging the groups or naming the facilitator responsible for that group?

6

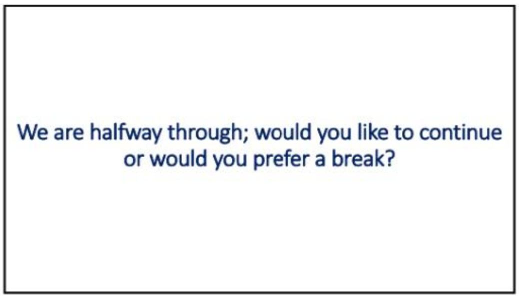


Statement number four

In certain occasions, the topic discussed during group activities has had an impact on people involved, resulting in overwhelming feelings.

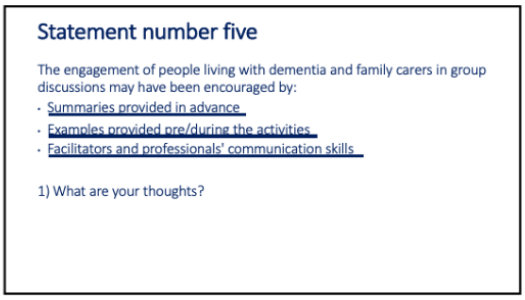
1) Did you facilitate any of the groups where this happened?
2) If yes, what did help you on those occasions?

7



We are halfway through; would you like to continue or would you prefer a break?

8

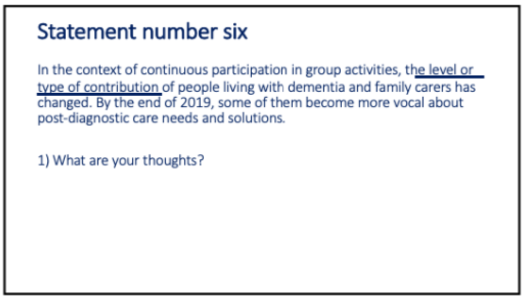


Statement number five

The engagement of people living with dementia and family carers in group discussions may have been encouraged by:

- Summaries provided in advance
- Examples provided pre/during the activities
- Facilitators and professionals' communication skills

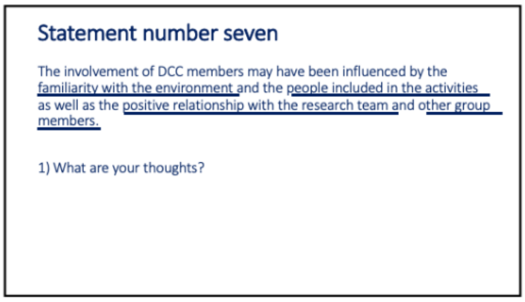
1) What are your thoughts?



Statement number six

In the context of continuous participation in group activities, the level or type of contribution of people living with dementia and family carers has changed. By the end of 2019, some of them become more vocal about post-diagnostic care needs and solutions.

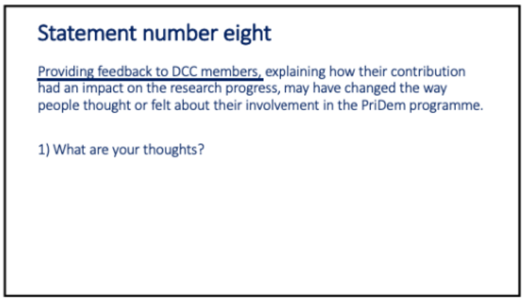
1) What are your thoughts?



Statement number seven

The involvement of DCC members may have been influenced by the familiarity with the environment and the people included in the activities as well as the positive relationship with the research team and other group members.

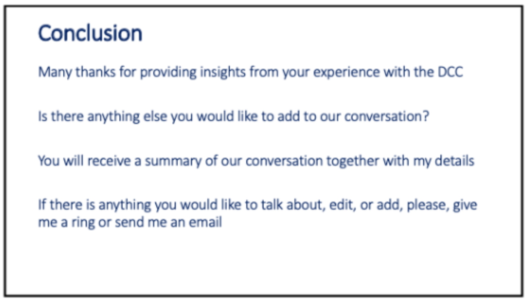
1) What are your thoughts?



Statement number eight

Providing feedback to DCC members, explaining how their contribution had an impact on the research progress, may have changed the way people thought or felt about their involvement in the PriDem programme.

1) What are your thoughts?



Conclusion

Many thanks for providing insights from your experience with the DCC

Is there anything else you would like to talk about, edit, or add, please, give me a ring or send me an email

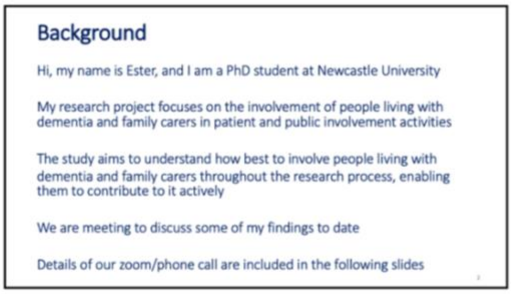
Sample Others

The dementia research involvement study

Exploring and explaining the involvement of people living with dementia and family carers through patient and public involvement activities

November 2020
Ester Bellavia, PhD student

1



Background

Hi, my name is Ester, and I am a PhD student at Newcastle University

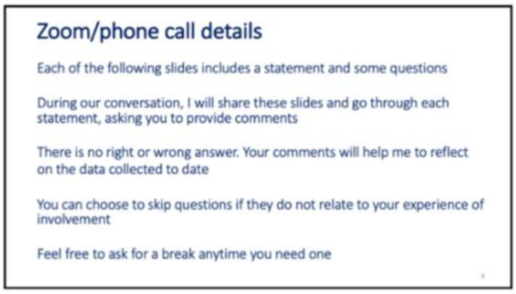
My research project focuses on the involvement of people living with dementia and family carers in patient and public involvement activities

The study aims to understand how best to involve people living with dementia and family carers throughout the research process, enabling them to contribute to it actively

We are meeting to discuss some of my findings to date

Details of our zoom/phone call are included in the following slides

2



Zoom/phone call details

Each of the following slides includes a statement and some questions

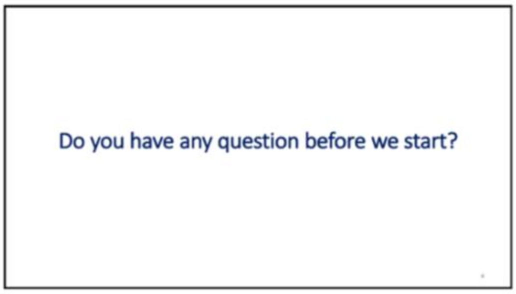
During our conversation, I will share these slides and go through each statement, asking you to provide comments

There is no right or wrong answer. Your comments will help me to reflect on the data collected to date

You can choose to skip questions if they do not relate to your experience of involvement

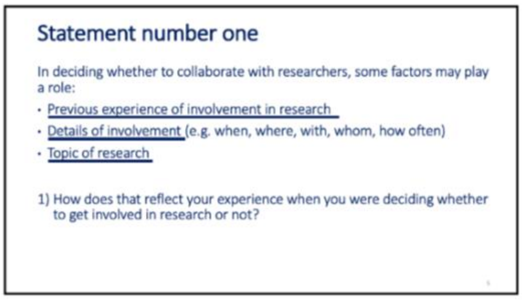
Feel free to ask for a break anytime you need one

3



Do you have any question before we start?

4



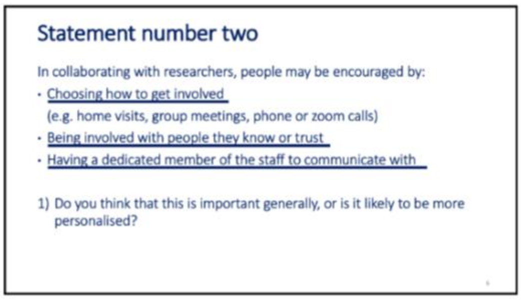
Statement number one

In deciding whether to collaborate with researchers, some factors may play a role:

- Previous experience of involvement in research
- Details of involvement (e.g. when, where, with, whom, how often)
- Topic of research

1) How does that reflect your experience when you were deciding whether to get involved in research or not?

5



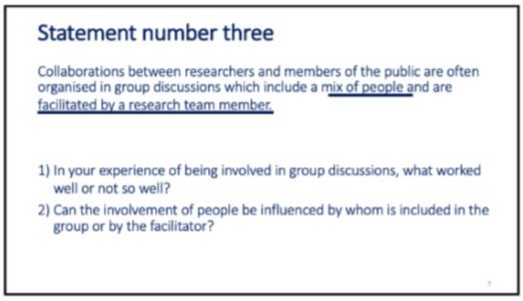
Statement number two

In collaborating with researchers, people may be encouraged by:

- Choosing how to get involved
  (e.g. home visits, group meetings, phone or zoom calls)
- Being involved with people they know or trust
- Having a dedicated member of the staff to communicate with

1) Do you think that this is important generally, or is it likely to be more personalised?

6

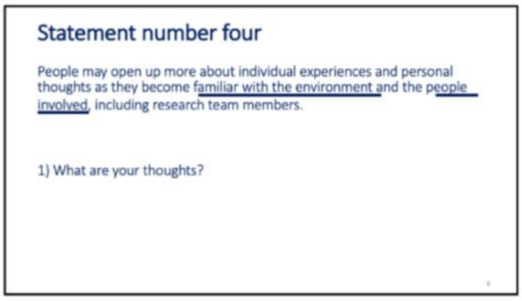


Statement number three

Collaborations between researchers and members of the public are often organised in group discussions which include a mix of people and are facilitated by a research team member.

1) In your experience of being involved in group discussions, what worked well or not so well?
2) Can the involvement of people be influenced by whom is included in the group or by the facilitator?

7

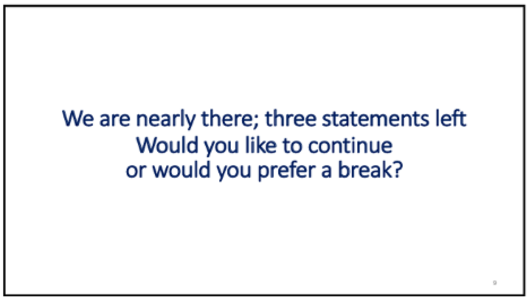


Statement number four

People may open up more about individual experiences and personal thoughts as they become familiar with the environment and the people involved, including research team members.

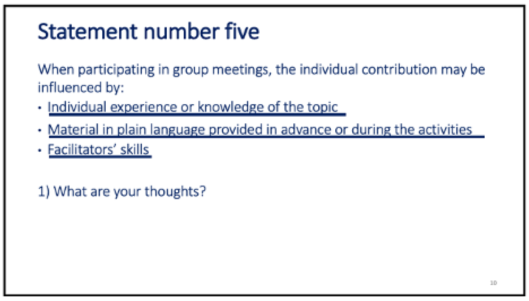
1) What are your thoughts?

8



We are nearly there; three statements left
Would you like to continue
or would you prefer a break?

9



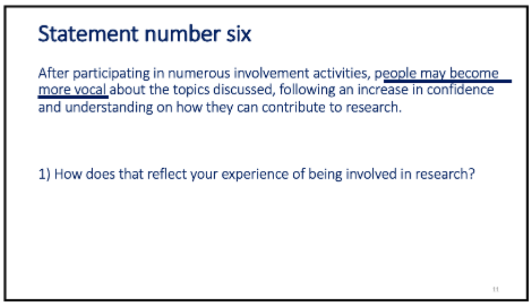
Statement number five

When participating in group meetings, the individual contribution may be influenced by:

- Individual experience or knowledge of the topic
- Material in plain language provided in advance or during the activities
- Facilitators' skills

1) What are your thoughts?

10

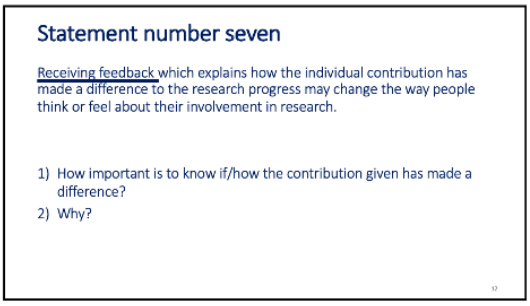


Statement number six

After participating in numerous involvement activities, people may become more vocal about the topics discussed, following an increase in confidence and understanding on how they can contribute to research.

1) How does that reflect your experience of being involved in research?

11

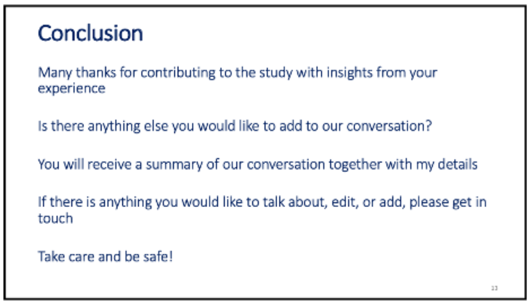


Statement number seven

Receiving feedback which explains how the individual contribution has made a difference to the research progress may change the way people think or feel about their involvement in research.

1) How important is to know if/how the contribution given has made a difference?
2) Why?

12



Conclusion

Many thanks for contributing to the study with insights from your experience

Is there anything else you would like to add to our conversation?

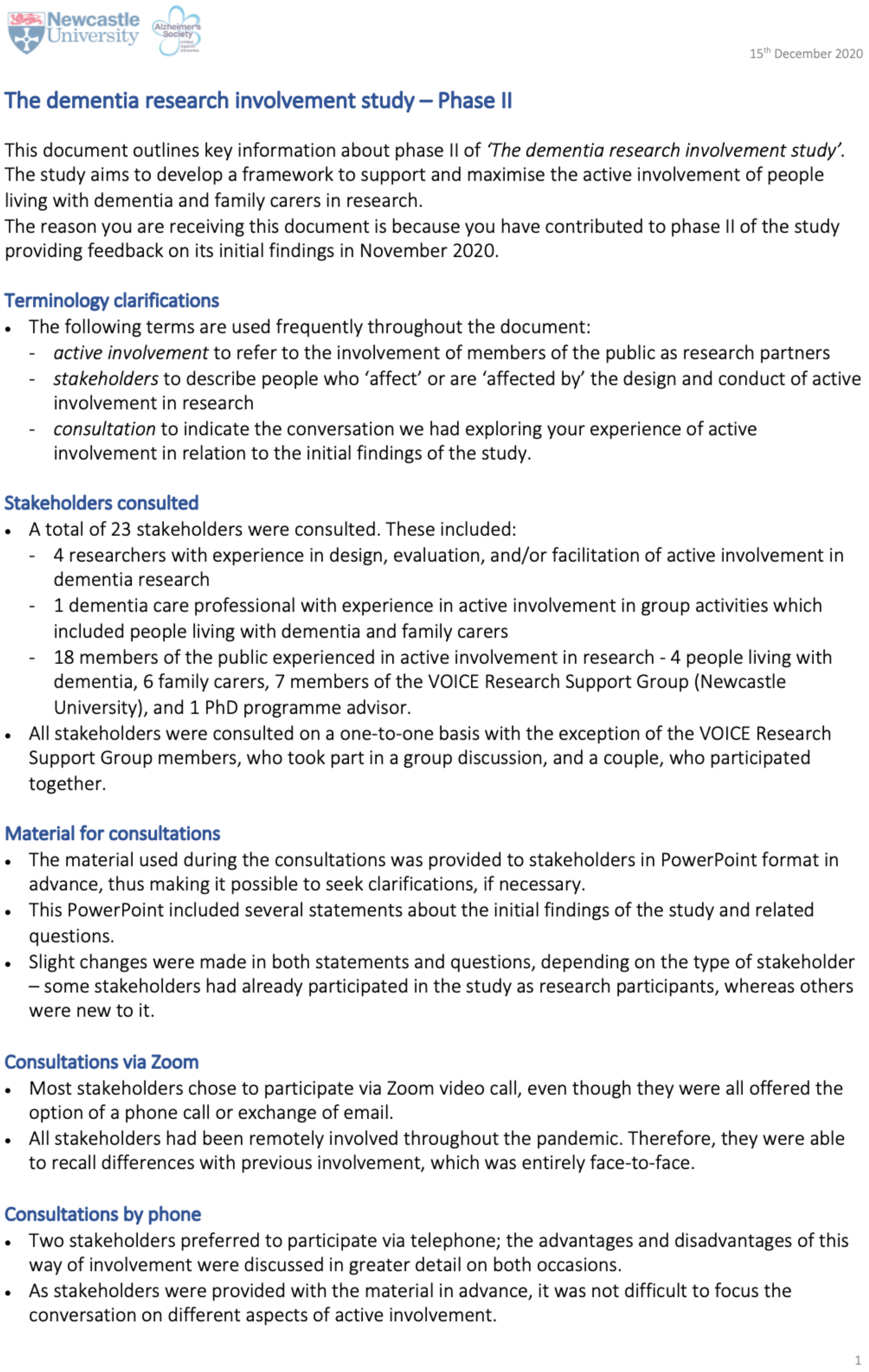
You will receive a summary of our conversation together with my details

If there is anything you would like to talk about, edit, or add, please get in touch

Take care and be safe!

13

Appendix L. Phase II: Research update for stakeholders involved



15th December 2020

The dementia research involvement study – Phase II

This document outlines key information about phase II of *'The dementia research involvement study'*. The study aims to develop a framework to support and maximise the active involvement of people living with dementia and family carers in research.
The reason you are receiving this document is because you have contributed to phase II of the study providing feedback on its initial findings in November 2020.

Terminology clarifications

- The following terms are used frequently throughout the document:
  - *active involvement* to refer to the involvement of members of the public as research partners
  - *stakeholders* to describe people who 'affect' or are 'affected by' the design and conduct of active involvement in research
  - *consultation* to indicate the conversation we had exploring your experience of active involvement in relation to the initial findings of the study.

Stakeholders consulted

- A total of 23 stakeholders were consulted. These included:
  - 4 researchers with experience in design, evaluation, and/or facilitation of active involvement in dementia research
  - 1 dementia care professional with experience in active involvement in group activities which included people living with dementia and family carers
  - 18 members of the public experienced in active involvement in research - 4 people living with dementia, 6 family carers, 7 members of the VOICE Research Support Group (Newcastle University), and 1 PhD programme advisor.
- All stakeholders were consulted on a one-to-one basis with the exception of the VOICE Research Support Group members, who took part in a group discussion, and a couple, who participated together.

Material for consultations

- The material used during the consultations was provided to stakeholders in PowerPoint format in advance, thus making it possible to seek clarifications, if necessary.
- This PowerPoint included several statements about the initial findings of the study and related questions.
- Slight changes were made in both statements and questions, depending on the type of stakeholder – some stakeholders had already participated in the study as research participants, whereas others were new to it.

Consultations via Zoom

- Most stakeholders chose to participate via Zoom video call, even though they were all offered the option of a phone call or exchange of email.
- All stakeholders had been remotely involved throughout the pandemic. Therefore, they were able to recall differences with previous involvement, which was entirely face-to-face.

Consultations by phone

- Two stakeholders preferred to participate via telephone; the advantages and disadvantages of this way of involvement were discussed in greater detail on both occasions.
- As stakeholders were provided with the material in advance, it was not difficult to focus the conversation on different aspects of active involvement.

1

What has changed

- Encouraged by stakeholders' feedback, data previously collected was reviewed to ensure that crucial aspects of involvement were not overlooked.
- Different perspectives on the matter of discussion were highlighted and then further explored in the literature.
- An additional list of potential barriers to active involvement was developed and integrated within the initial version of the involvement framework to allow for their investigation during the interviews that will take place in the next phase of the study.
- The initial draft of interview questions was edited, following inputs on the formulation of questions used for consultation purposes.
- Terminology related to elements characterising the involvement framework was also revised to enhance clarity and better reflect inputs received.

What could I have done better?

- It would be great if you could provide your feedback on the consultation either by filling in the anonymous text box you can access through clicking on https://www.smartsurvey.co.uk/s/8AWF61/ or by sharing it via email or telephone.
- If you prefer, I am happy to arrange a phone or video call to discuss your feedback – see contact details below.

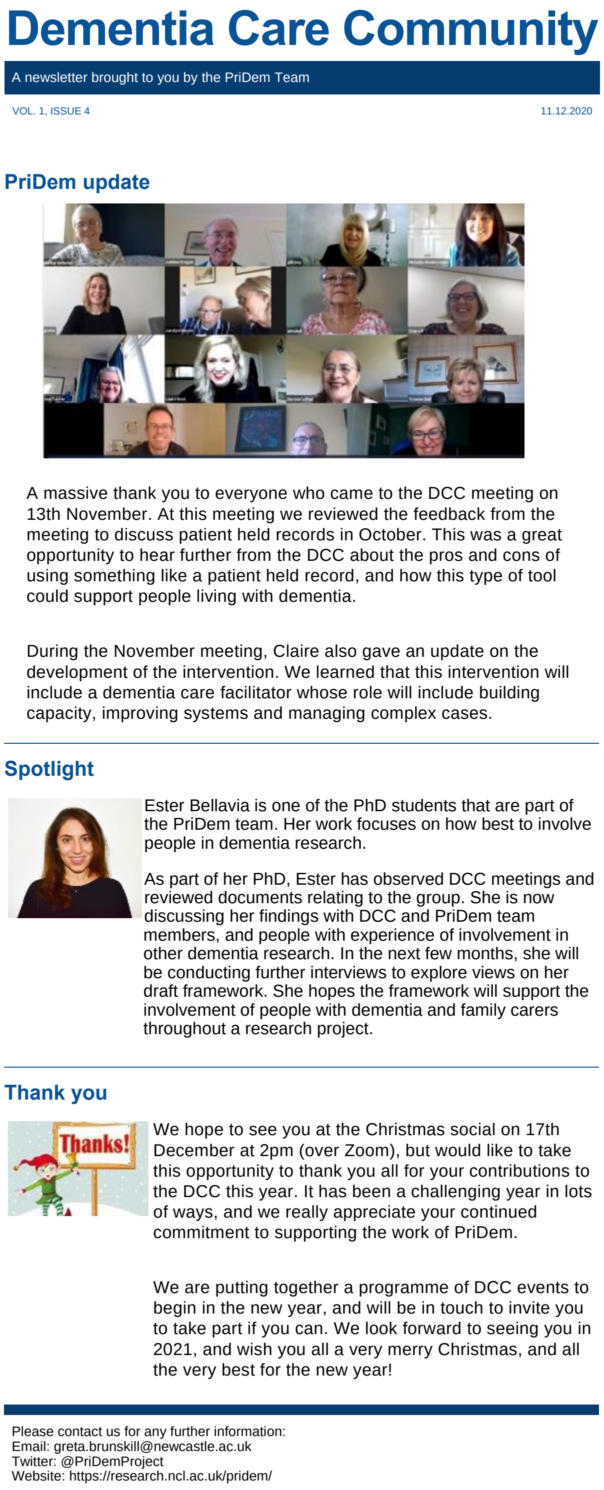
Next steps

- Recently, a new ethics approval was granted to collect interviews during phase III of the study, which is scheduled for 2021.
- The aim of the next phase is to consolidate the framework developed and edit it further, if needed.
- You will be kept informed about the rest of the research process and related outcomes unless you are no longer interested. Kindly, let me know if that is the case – see contact details below.

Author of the document

Ester Bellavia
PhD student at Newcastle University
Member of the PriDem programme team https://research.ncl.ac.uk/pridem/ourproject/phdstudents/
Contact details:
- telephone: 07444014902
- email address: e.bellavia2@newcastle.ac.uk

Appendix M. Phase II: Research update for DCC members



Dementia Care Community

A newsletter brought to you by the PriDem Team

VOL. 1, ISSUE 4 11.12.2020

PriDem update

A massive thank you to everyone who came to the DCC meeting on 13th November. At this meeting we reviewed the feedback from the meeting to discuss patient held records in October. This was a great opportunity to hear further from the DCC about the pros and cons of using something like a patient held record, and how this type of tool could support people living with dementia.

During the November meeting, Claire also gave an update on the development of the intervention. We learned that this intervention will include a dementia care facilitator whose role will include building capacity, improving systems and managing complex cases.

Spotlight

Ester Bellavia is one of the PhD students that are part of the PriDem team. Her work focuses on how best to involve people in dementia research.

As part of her PhD, Ester has observed DCC meetings and reviewed documents relating to the group. She is now discussing her findings with DCC and PriDem team members, and people with experience of involvement in other dementia research. In the next few months, she will be conducting further interviews to explore views on her draft framework. She hopes the framework will support the involvement of people with dementia and family carers throughout a research project.

Thank you

We hope to see you at the Christmas social on 17th December at 2pm (over Zoom), but would like to take this opportunity to thank you all for your contributions to the DCC this year. It has been a challenging year in lots of ways, and we really appreciate your continued commitment to supporting the work of PriDem.

We are putting together a programme of DCC events to begin in the new year, and will be in touch to invite you to take part if you can. We look forward to seeing you in 2021, and wish you all a very merry Christmas, and all the very best for the new year!

Please contact us for any further information:
Email: greta.brunskill@newcastle.ac.uk
Twitter: @PriDemProject
Website: https://research.ncl.ac.uk/pridem/

Also available online:

https://research.ncl.ac.uk/media/sites/researchwebsites/pridem/DCC%20newsletter%20Dec%202020.pdf

Appendix N. Phase III: Recruitment material

Email of invitation

Dear ______,

I would like to invite you to participate in the research study I am conducting as part of my PhD programme at Newcastle University.

The study, which has been funded by the Alzheimer's Society, aims to understand how best to support the involvement of people living with dementia and family carers in patient and public involvement activities.

You have been contacted because I am aware of your experience of involvement in research-related activities, and I would benefit from discussing with you some of the study findings during the course of an interview.

A participant information sheet has been attached to this email to provide more details about the study and answers to questions frequently asked.

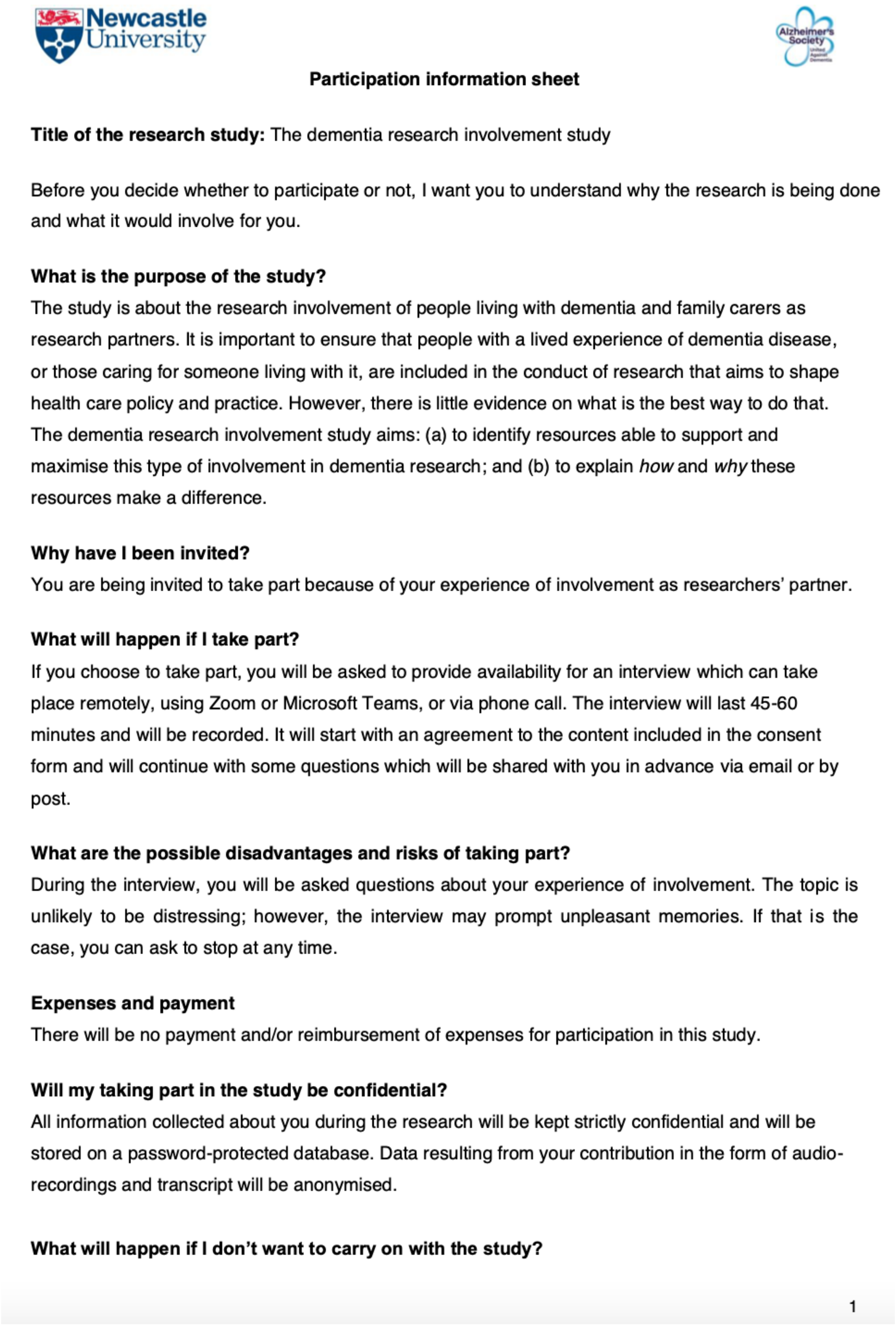
A consent form has also been included to inform you of the terms of agreement in case of participation.

If you would like to take part in the study or discuss the research in more in detail, please, get in touch using the following contact details:

Email: e.bellavia2@newcastle.ac.uk
Telephone: 07444014902.

I look forward to hearing from you.

Kind Regards,
Ester Bellavia



Participation information sheet

Title of the research study: The dementia research involvement study

Before you decide whether to participate or not, I want you to understand why the research is being done and what it would involve for you.

What is the purpose of the study?

The study is about the research involvement of people living with dementia and family carers as research partners. It is important to ensure that people with a lived experience of dementia disease, or those caring for someone living with it, are included in the conduct of research that aims to shape health care policy and practice. However, there is little evidence on what is the best way to do that. The dementia research involvement study aims: (a) to identify resources able to support and maximise this type of involvement in dementia research; and (b) to explain *how* and *why* these resources make a difference.

Why have I been invited?

You are being invited to take part because of your experience of involvement as researchers' partner.

What will happen if I take part?

If you choose to take part, you will be asked to provide availability for an interview which can take place remotely, using Zoom or Microsoft Teams, or via phone call. The interview will last 45-60 minutes and will be recorded. It will start with an agreement to the content included in the consent form and will continue with some questions which will be shared with you in advance via email or by post.

What are the possible disadvantages and risks of taking part?

During the interview, you will be asked questions about your experience of involvement. The topic is unlikely to be distressing; however, the interview may prompt unpleasant memories. If that is the case, you can ask to stop at any time.

Expenses and payment

There will be no payment and/or reimbursement of expenses for participation in this study.

Will my taking part in the study be confidential?

All information collected about you during the research will be kept strictly confidential and will be stored on a password-protected database. Data resulting from your contribution in the form of audio-recordings and transcript will be anonymised.

What will happen if I don't want to carry on with the study?

Your participation is voluntary, and you are free to withdraw at any time.

What will happen to the findings of the study?

The findings of the study will be used to inform a PhD thesis and are likely to be shared through academic and non-academic journals, blogs, social events and conferences. Your contribution will remain anonymous.

Who is conducting the study?

This research is conducted by a research team which includes a PhD student (Ester Bellavia) and her two supervisors (Professor Dame Louise Robinson and Dr Susan Moloney).

Who has funded and organised the study?

The study has been funded by the Alzheimer's Society and is sponsored by Newcastle University.

Who has reviewed the study?

This study was approved by the Faculty of Medical Sciences Research Ethics Committee, part of Newcastle University's Research Ethics Committee (Ref no: 2021/5888/2020). This committee contains members who are internal to the Faculty. This study was reviewed by members of the committee, who must provide impartial advice and avoid significant conflicts of interests.

What if I have other questions?

If you have any questions, you can contact Ester Bellavia or her supervisory team by using the contact details provided below.

Ester Bellavia, PhD student, Newcastle University
Telephone: 07444014902
Email: e.bellavia2@newcastle.ac.uk

Prof Dame Louise Robinson, Newcastle University
Email: a.l.robinson@ncl.ac.uk

Dr Susan Moloney, Newcastle University
Email: susan.hrisos@ncl.ac.uk

Consent form

Title of the research study: The dementia research involvement study
Name of researcher: Ester Bellavia, PhD student
Name of supervisors: Prof Dame Louise Robinson, Dr Susan Moloney

If you decide to participate in the study, you will be asked to agree to the following statements during our call, before the interview takes place.

1. I confirm that I have read and understood the information provided about the study, and I had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.

3. I understand that my words will be recorded and transcribed for research analysis purposes.

4. I understand that my words may be used in publications, but I will never be named.

5. I understand that the information collected during the study may be checked by trained staff from Newcastle University and other regulatory authorities. This is to make sure the research is being conducted properly.

6. I agree to take part in the above study.

Appendix O. Phase III: Interview schedule

Patient and public involvement leads

1. How, if at all, do you think that an early engagement with members of the public, or people living with dementia and their family carers in this specific case, influences decision-making about ways of involvement?
2. Do you find that providing people with options of how they can get involved and giving them the possibility to change their initial choice, can affect their involvement? How?
3. Thinking about a time when a plan was needed for the next involvement activity, how were decisions made to enable the involvement of public members and encourage their engagement?
4. Do you find that providing some material before involvement activities affects how people feel about their participation in group discussion and their contribution? How?
5. Are people involved usually provided with a team member’s contact details in case they need for clarifications? What would encourage them to get in contact if in doubt?
6. Do you find that people involved in group activities may be influenced by the composition of the group? For instance, would the presence of care professionals or peers affect their engagement in the conversation? How?
7. Thinking about facilitators’ role in group discussions, what could they do to ensure all participants engage in the conversation?
8. Do you find that the communication skills of a family carer or a dementia care professional may influence how well people living with dementia engage in group discussions? How?
9. Can you think of a time when people involved openly shared their personal experience during a group conversation? What do you think enabled them to do so?
10. Can you think of a time when people involved were asked to collaborate with others on potential solutions to the issue explored by the research project? What would help them provide ideas, in addition to their lived experience?
11. Do you find that acknowledging people for their contribution influences the way they feel about involvement? How?

People living with dementia and family carers

1. Thinking about when you first decided to collaborate with researchers on a study, what influenced your decision? Why?
2. How would you feel about being involved in a way that is adaptable to your preferences and changing needs or priorities? Would that affect your involvement? How?
3. When you are invited to participate in a group meeting, do you prepare for it? Does the research team help you prepare, for example, by sending some material in advance? How does being prepared affect you and your participation in group meetings?
4. Are you usually provided with a team member's contact details who you can reach to ask for clarifications on involvement activities? What would encourage you to get in contact with them?
5. When invited to contribute to a group discussion, would the presence of care professionals or peers influence your confidence to engage in the conversation? How?
6. Could you describe a facilitator who you really liked? What do they do during group discussions that makes people engage in the conversation?
7. Do you find that the communication skills of a family carer or a dementia care professional may influence how well people living with dementia engage in group discussions? How?
8. Can you think of a time when you felt comfortable to openly share your experience of caring for someone living with dementia? What was it that enabled you to do so?
9. Can you think of a time when you were asked to collaborate with others on potential solutions to the issue explored by the research project? How did you come up with ideas? What did help you in addition to your lived experience?
10. How would it make you feel knowing that your contribution has made a difference in the research progress? Would that have bearing on future involvement in research or your commitment to it? How?

Appendix P. Theoretical changes throughout the three-phase realist evaluation

In this appendix, I included an overview of the theoretical changes characterising the programme theories during the three-phase realist evaluation discussed in this thesis. The colour coding system used to document these changes is explained in the table below (see Table 1).

Table 1. Colour coding system

Colour	Meaning
Red	New theoretical element (i.e., contexts, mechanisms or outcomes)
Purple	Improving proposition clarity
Green	Changes post-synthesis

Text box 1. Programme Theory 1

Phase I: Candidate programme theory (v.1.3–16th October 2020)

If there is a clear PPI strategy (C_1) supported by funders (C_2) and host organisation (C_3), then the presence within the research team of an involvement coordinator responsible for facilitating the involvement of PLWD/family carers and engaging with them early (M_1), encourages the research team to consider ways of involvement more tailored to PLWD/family carers (M_2), leading to a flexible and inclusive approach to involvement (O_1).

Phase II: Candidate programme theory (v.1.2–13th January 2021)

If there is ~~a clear PPI strategy~~ a well-established plan of involvement supported by funders and host organisation, in the context of accessible dementia-related local support services (C), then the presence, within the research team, of an involvement coordinator responsible for facilitating the involvement of PLWD/family carers, and their early engagement with PLWD/family carers within the community (M), encourages the research team to consider ways of involvement more tailored to PLWD/family carers (M), leading to a flexible and inclusive approach to involvement (O).

Phase III: Programme theory (v.1.3–13th May 2021)

If ~~there is a~~ the research team develops a well-established plan of involvement which is supported by funders and host organisation, in the context of accessible dementia-related local support services (C), then ~~the presence, within the research team, of an involvement coordinator responsible for facilitating the involvement of PLWD/family carers, and their early engagement with PLWD/family carers within the community~~ the early engagement with the community of an involvement coordinator responsible for facilitating the inclusion of PLWD and family carers in the research programme (M) encourages the research team to ~~consider ways of involvement more tailored to PLWD/family carers~~ adopt a reflective approach to decision-making (M), leading to ~~a flexible and inclusive approach to involvement~~ the involvement of PLWD and family carers (O) because of the tailored involvement strategy (O) resulting from the increased researchers' understanding of this population's concerns and needs (O).

Text box 2. Programme Theory 2

Phase I: Candidate programme theory (v.1.2–18th September 2020)

Relevant *cases* informed the following theory included in the list of CPTs version 1.2 during Phase I:

If PlWD/family carers have no prior relationship with researchers (C_5) and minimal or none experience of involvement in PPI activities (C_6), then a continuous communication and interaction with research team members (M_9), make PlWD/family carers feel confident and secure (M_9), leading to the development of a relationship with the research team (O_5).

Phase II: Relevant information (v.1.2–13th January 2021)

Some stakeholders have provided information supporting Cs and Ms but were insufficient on their own to explain the link with the outcome of interest.

Phase III: Programme theory (v.1.3–13th May 2021)

If the involvement coordinator conducts early engagement activities with PLWD/family carers who are included in existing local support groups (C) and are new to research (C), then the relationship among group members and the ongoing positive interaction between group members and the involvement coordinator (M) encourage PLWD/family carers to feel comfortable and safe (M), leading to their involvement (O) because they overcome research-related fear and apprehension (O) and discuss openly involvement-related concerns or needs (O).

Text box 3. Programme Theory 3

Phase I: Candidate programme theory (v.1.3–16th October 2020)

If PLWD/family carers have no prior relationship with researchers (C_5) and minimal or none experience of involvement in PPI activities (C_6), then the endorsement of the team by community workers/volunteers (M_6), and the interaction with a PPI coordinator dedicated (M_7) make PLWD/family carers feel confident and secure (M_9), leading to their involvement (O_4).

Phase II: Candidate programme theory (v.1.2–13th January 2021)

If PLWD/family carers have no prior relationship with researchers ~~and minimal or none experience of involvement in PPI activities~~ and are new to active involvement in research (C), then the perceived value of the research based on lived experience and the endorsement from peers, community workers and volunteers (M), ~~and the interaction with a research team member they consider to be dedicated~~ make PLWD/family carers feel ~~confident and secure~~ comfortable and safe (M), leading to their involvement (O).

Phase III: Programme theory (v.1.3–13th May 2021)
If PLWD/family carers ~~have no prior relationship with researchers and are new to active involvement in research and are new to active involvement in research~~ are invited for the first time (C) to collaborate with unknown researchers (C) on a research programme that aims to improve dementia care (C), then the perceived value of research based on their lived experience and the endorsement from peers, community workers and volunteers (M) ~~make~~ encourage ~~PLWD/family carers~~ them to feel comfortable and safe (M), leading to their involvement (O) because they overcome research-related fear and apprehension (O).

Text box 4. Programme Theory 4

Phase I: Candidate programme theory (v.1.3–16th October 2020)

a. If PLWD/family carers have no prior relationship with researchers (C$_{5}$) and minimal or none experience of involvement in PPI activities (C$_{6}$), then a flexible and inclusive involvement practice (M$_{5}$), makes PLWD/family carers feel confident and secure (M$_{9}$), leading to their involvement (O$_{4}$).
b. If PlWD/family carers are invited to participate regularly in group activities (C$_{9}$), then an involvement practice continuously responsive to their communicated or tacit needs (M$_{16}$) makes them feel valued and capable (M$_{17}$) leading to their involvement/continuous involvement and engagement (O$_{7}$).

Phase II: Candidate programme theory (v.1.2–13th January 2021)
If PLWD/family carers are invited to contribute to a research programme over time and are new to active involvement in research (C), then the opportunity to choose how to get involved and to change decision as the involvement unfolds and personal needs change (M), make PLWD/family carers feel confident, valued, and supported (M), leading to their involvement/continuous involvement (O).

Phase III: Programme theory (v.1.3–13th May 2021)
If PLWD/family carers are invited ~~to contribute to a research programme over time and are new to active involvement in research~~ for the first time to collaborate with researchers throughout a research programme (C), then the opportunity to choose how to get involved and the option to change their decision as the involvement unfolds and personal preferences or needs change (M) encourage PLWD/family carers to feel confident and valued ~~and supported~~ (M), leading to their involvement/continuous involvement (O) because of the support perceived (O) and the acknowledgement of their role in the research programme (O).

Text box 5. Programme Theory 5

Phase I: Candidate programme theory (v.1.3–16th October 2020)
If PlWD/family carers participate in group activities that include a mix of people (known/unknown, health/social care professionals) with different experiences/ perspectives (C$_{11}$), then an accessible narrative provided of the topic of discussion provided beforehand (M$_{25}$) makes them feel confident (M$_{28}$) leading to their engagement in the conversation, sharing experience and or factual knowledge (O$_{9}$).

Phase II: Candidate programme theory (v.1.2–13th January 2021)
If PLWD/family carers ~~participate in group activities that include a mix of people~~ are involved in group discussions about dementia care (C), then ~~an accessible narrative provided of the topic of discussion provided in advance~~ a jargon-free summary about the subject of discussion provided beforehand and an accessible and familiar point of contact should they need clarification (M) makes them feel confident (M), ~~enabling them to better engage in the conversation, sharing experience and or factual knowledge~~ leading to their engagement in the discussion (O).

Phase III: Programme theory (v.1.3–13th May 2021)
If PLWD/family carers are ~~involved~~ invited to participate in group ~~discussions~~ activities about dementia care throughout a research programme (C), then a jargon-free summary about the subject of discussion provided beforehand ~~and an~~ together with an accessible and ~~familiar~~ approachable point of contact should they need clarification (M) ~~make~~ encourages them to feel confident and valued (M), leading to their engagement in the ~~discussion~~ activities (O) because they are better prepared to meet the activities demands (O) and to their continuous involvement in the research programme (O) as they are acknowledged for their role in it (O).

Text box 6. Programme Theory 6

Phase I: Candidate programme theory (v.1.3–16th October 2020)
If PlWD/family carers participate in group activities that include a mix of people (known/unknown, health/social care professionals) with different experiences/perspectives (C$_{11}$), then a supportive and non-judgemental group facilitator (M$_{18}$) and peer support (M$_{22}$) make them feel valued and accepted (M$_{21}$), leading to their contribution to group activities, sharing personal experiences and thoughts (O).

Phase II: Candidate programme theory (v.1.2–13th January 2021)
If PLWD/family carers ~~participate in group activities that include a mix of people (known/unknown, health/social care professionals) with different experiences/perspectives~~ are involved in group discussions about the care they receive and are new to a collaborative relationship with care professionals (C), then a ~~supportive, non-judgemental~~ a skilled group facilitator and the presence of peers (M) ~~make them feel valued and accepted~~ make them feel confident (M), ~~leading to their contribution to group activities, sharing personal experiences and thoughts~~ leading to their engagement in the discussion (O).

Phase III: Programme theory (v.1.3–13th May 2021)
If PLWD/family carers are ~~involved in group discussions about the care they receive~~ are invited to discuss dementia care issues ~~and are new to a collaborative relationship with care professionals~~ in groups including dementia care professionals with whom they have no experience of collaboration (C), then ~~a skilled~~ group facilitator with good facilitation skills along with the presence of peers (M) ~~makes~~

encourages PLWD/family carers to feel confident, comfortable and safe (M), leading to their engagement in the discussion (O) because they feel well-equipped and overcome involvement-related fear and apprehension (O).

Text box 7. Programme Theory 7

Phase I: Candidate programme theory (v.1.3–16th October 2020)

If there is a clear PPI strategy (C_1), then the continuous evaluation of involvement practice carried on in different ways (e.g., monthly meetings, documentation of involvement process, feedback cards, involvement coordinator) (M_{10}) encourage the team to employ a reflective approach to decision-making (M_{14}) leading to the implementation of an involvement practice continuously responsive to the communicated or tacit needs of PLWD/family carers (O_6).

Phase II: Candidate programme theory (v.1.2–13th January 2021)

If ~~there is a clear PPI strategy~~ the research team believes in the value of active involvement and aims to promote it throughout the research programme (C), then ~~the continuous evaluation of involvement practice carried on in different ways (e.g. monthly meetings, documentation of involvement process, feedback cards, involvement coordinator~~) a collective assessment of involvement as experienced by team members and people involved (M) makes the research team ~~to employ a reflective approach~~ apply learning to future decision-making (M), leading ~~to the implementation of an involvement practice~~ to an involvement approach continuously informed by the tacit or communicated needs of PLWD/family carers involved (O).

Phase III: Programme theory (v.1.3–13th May 2021)

If the research team is well-supported, ~~believes in the value of the active involvement~~ values the contribution of PLWD/family carers, and aims to promote it throughout the research programme (C), then an ongoing collective assessment of ~~involvement~~ the involvement practice as experienced by team members and people involved (M) ~~makes~~ encourages the research team to apply learning to future decision-making (M), leading to ~~an involvement approach continuously informed by the tacit or communicated needs of PLWD/family carers involved~~ the continuous involvement of PLWD and family carers in the programme (O) because of the responsive involvement practice implemented (O).

Text box 8. Programme Theory 8

Phase I: Relevant cases

Relevant *cases* present in the data collected during Phase I include*:*

a. 2 PLWD involved in the activities with their family carers at the university venue
b. 2 PLWD involved in the activities with their family carers at the dementia hub.

Phase II: Candidate programme theory (v.1.2–13th January 2021)

If family carers or dementia care professionals are committed to collaborate with researchers and value the involvement of PLWD (C), then they can use their communication skills to interpret the needs of the relative/person they are caring for/trained to care for (M) and make them feel confident (M), leading to their engagement (O).

Phase III: Programme theory (v.1.3–13th May 2021)

If family carers or dementia care professionals are committed to collaborate with researchers and value the ~~involvement~~ inclusion in group activities of PLWD who may experience involvement challenges due to their dementia diagnosis or stage (C), then they can use their knowledge to anticipate or interpret the needs of the relative they care for/person they are trained to care for and use their communication skills to (M) encourage PLWD to ~~feel confident~~, comfortable and safe (M), leading to their engagement in the activity (O) because they overcome involvement-related fear and apprehension (O) as well as adverse involvement circumstances (O).

Text box 9. Programme Theory 9

Phase I: Candidate programme theory (v.1.3–16th October 2020)

If PlWD/family carers regularly participate in group activities that include a mix of people (known/unknown, health/social care professionals) with different experiences/perspectives (C_{11}), then the positive relationship developed with the research team and other group members (M_{29}) make them feel confident and secure (M_9) to be open and honest about personal challenges/needs (O_{11}).

Phase II: Candidate programme theory (v.1.2–13th January 2021)

If PLWD/family carers regularly participate ~~in group activities that include a mix of people (known/unknown, health/social care professionals) with different experiences/perspectives~~ in group conversations with professionals about the care they receive (C), then ~~then the positive relationship developed with the research team and other group members~~ an established trusting relationship with the research team and a positive relationship with other members of the group (M) make them feel ~~confident and secure~~ comfortable and safe (M), leading to their being open about personal challenges and needs (O).

Phase III: Programme theory (v.1.3–13th May 2021)

If PLWD/family carers ~~regularly participate~~ are involved with dementia care professionals in group ~~conversations~~ activities ~~about~~ focused on the care they receive (C) as part of an ongoing collaborative relationship (C), then ~~an established~~ the trusting relationship developed with the research team and ~~a positive relationship with~~ other ~~members of the~~ group members (M) ~~make~~ encourages them to feel comfortable and safe (M), leading to their engagement in the activities being open about personal challenges and needs (O) because they overcome involvement-related fear and apprehension (O).

Text box 10. Programme Theory 10

Phase I: Candidate programme theory (v.1.3–16th October 2020)

If PlWD/family carers regularly participate in group activities that include a mix of people (known/unknown, health/social care professionals) with different experiences/perspectives (C_{11}), then the exchange of knowledge along with accessible narrative (M_{30}) make PLWD/family carers feel confident (M_9), leading to their contribution with new and informed perspectives of the topic discussed (O_{12}).

Phase II: Candidate programme theory (v.1.2–13th January 2021)

If PLWD/family carers ~~regularly participate in group activities that include a mix of people (known/unknown, health/social care professionals) with different experiences or perspectives~~ engage in conversations about dementia support planning with care professionals over time (C), then ~~the exchange of knowledge~~ an increased understanding of current practice from a different perspective along with accessible narrative (M) make PLWD/family carers feel confident (M), leading to their contribution with new and informed perspectives (O).

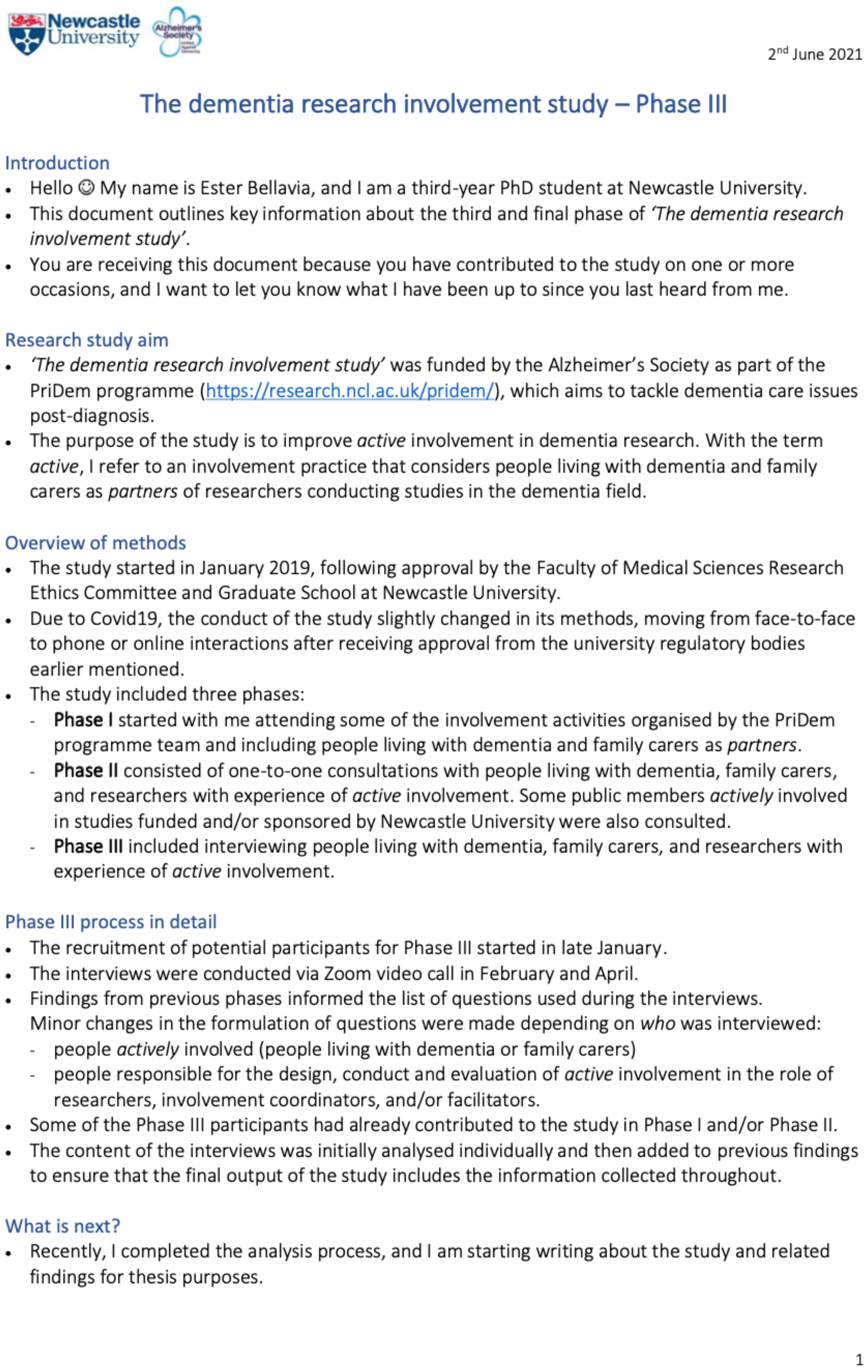
Phase III: Programme theory (v.1.3–13th May 2021)
If PLWD/family carers engage in group conversations about dementia support planning with dementia care professionals (C) ~~over time~~ as part of an ongoing collaborative relationship built on trust (C), then ~~an increase understanding of current practice from a different perspective along with a summary of options~~ the effective communication among group members conveyed with accessible narrative (M) ~~make~~ encourages ~~PLWD/family carers~~ them to feel confident, comfortable and safe (M), leading to their ~~contribution~~ engagement in the conversation with new and informed perspectives (O) because they feel well-equipped (O) and overcome involvement-related fear and apprehension (O).

Text box 11. Programme Theory 11
Phase I: Candidate programme theory (v.1.3–16th October 2020)
If PlWD/family carers regularly participate in group activities that include a mix of people (known/unknown, health/social care professionals) with different experiences and perspectives (C_{11}), then the acknowledgement of their contribution (M_{31}) and explanation of its impact to the research progress (M_{32}), makes them valued (M_{17}), leading them to commit to the research activities (O_{13}).

Phase II: Candidate programme theory (v.1.2–13th January 2021)
If ~~PlWD/family carers regularly participate in group activities that include a mix of people (known/unknown, health/social care professionals) with different experiences and perspectives~~ there is an established collaborative relationship between PLWD/family carers and the research team (C), then ~~the acknowledgement of their contribution to the research progress~~ keeping PLWD/family carers updated on the research progress and acknowledging their contribution to it (M) makes them feel valued (M), leading to their continuous involvement in group activities (O).

Phase III: Programme theory (v.1.3–13th May 2021)
If there is an established collaborative relationship between PLWD/family carers and the research team (C), then keeping PLWD/family carers updated on the research progress and ~~acknowledging~~ explaining their contribution to it (M) ~~makes~~ encourage them to feel confident and valued (M), leading to their continuous involvement ~~in group activities~~ in the research programme (O) because they feel well-equipped (O) and are acknowledged for their role in it (O).

Appendix Q. Phase III: Research update for interviewees and Phase II stakeholders



2nd June 2021

The dementia research involvement study – Phase III

Introduction

- Hello ☺ My name is Ester Bellavia, and I am a third-year PhD student at Newcastle University.
- This document outlines key information about the third and final phase of *'The dementia research involvement study'*.
- You are receiving this document because you have contributed to the study on one or more occasions, and I want to let you know what I have been up to since you last heard from me.

Research study aim

- *'The dementia research involvement study'* was funded by the Alzheimer's Society as part of the PriDem programme (https://research.ncl.ac.uk/pridem/), which aims to tackle dementia care issues post-diagnosis.
- The purpose of the study is to improve *active* involvement in dementia research. With the term *active*, I refer to an involvement practice that considers people living with dementia and family carers as *partners* of researchers conducting studies in the dementia field.

Overview of methods

- The study started in January 2019, following approval by the Faculty of Medical Sciences Research Ethics Committee and Graduate School at Newcastle University.
- Due to Covid19, the conduct of the study slightly changed in its methods, moving from face-to-face to phone or online interactions after receiving approval from the university regulatory bodies earlier mentioned.
- The study included three phases:
    - **Phase I** started with me attending some of the involvement activities organised by the PriDem programme team and including people living with dementia and family carers as *partners*.
    - **Phase II** consisted of one-to-one consultations with people living with dementia, family carers, and researchers with experience of *active* involvement. Some public members *actively* involved in studies funded and/or sponsored by Newcastle University were also consulted.
    - **Phase III** included interviewing people living with dementia, family carers, and researchers with experience of *active* involvement.

Phase III process in detail

- The recruitment of potential participants for Phase III started in late January.
- The interviews were conducted via Zoom video call in February and April.
- Findings from previous phases informed the list of questions used during the interviews. Minor changes in the formulation of questions were made depending on *who* was interviewed:
    - people *actively* involved (people living with dementia or family carers)
    - people responsible for the design, conduct and evaluation of *active* involvement in the role of researchers, involvement coordinators, and/or facilitators.
- Some of the Phase III participants had already contributed to the study in Phase I and/or Phase II.
- The content of the interviews was initially analysed individually and then added to previous findings to ensure that the final output of the study includes the information collected throughout.

What is next?

- Recently, I completed the analysis process, and I am starting writing about the study and related findings for thesis purposes.

- I will keep you informed about further progress unless you are no longer interested. Kindly let me know if that is the case–see contact details below.

What could I have done better?

- I would appreciate it if you could provide some feedback on your experience of being involved in the study via email or by filling the anonymous text box you can access by clicking on the following link: https://www.smartsurvey.co.uk/s/EAIOY8/.
- If you prefer, I can arrange a phone or video call to discuss your feedback more in detail–see contact details below.
- Feel free to ignore this request if you do not have time or have already provided comments ☺.

Conclusions

- Many thanks for participating in the study and for taking the time to read this document.
- If you have questions or want to receive a printed copy of this document, please, let me know–see contact details below.

Author of the document and contact details

- Ester Bellavia, PhD student at Newcastle University
- How and when to get in touch:
  - You can use my telephone number 07444014902, Monday to Friday from 10 am to 3 pm
  - You can send me an email at e.bellavia2@newcastle.ac.uk, any day/time. I will get back to you as soon as I can.

Acknowledgements

- I want to express my gratitude to those involved in Phase II who have provided suggestions about the format and content of the research feedback I sent on 15th December 2020. This version was informed by the comments received, some of which were provided anonymously.
- This document was reviewed by Dave Green–PPI advisor of my PhD programme and active member of the health research community (https://research.ncl.ac.uk/behscipru/people/davegreen.html).

Appendix R. Phase III: Research update for dementia hub members

Young At Heart ULO & Research involvement

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If you wonder whether this is an invite to one of the entertaining activities organised by the great team managing the Young At Heart ULO group, it is not, unfortunately. But I wish you could hold on for a few minutes before stopping reading. You may be surprised by what I am about to tell you.

By the way, I am Ester Bellavia, and I am the smiley one up in the middle ☺

Some of you met me at the LiveWell Dementia Hub in Stockton-on-Tees in 2019.

I am a PhD student at Newcastle University and as part of my PhD programme,

I conducted a research study funded by the Alzheimer's Society.

The study aimed to understand how best to involve people living with dementia and family carers in research as partners, ensuring they help shape future dementia-related research and care services. In 2019, some of the people attending the meetings organised by the Young At Heart ULO team contributed to my study, sharing experiences of research involvement, if any, and discussing potential challenges to their inclusion in research. Also, on more than one occasion, they allowed me to observe their engagement in research-related activities taking place at the LiveWell Dementia Hub.

Why am I writing to you now? Drumroll, please …

Because, firstly, I want to thank you for the opportunity given if you were among those involved in the study. Unfortunately, the pandemic outbreak interrupted what we started together, but luckily it did not stop the research. Your contribution was added to the one provided by others included in the study.

Secondly, to inform you that I am writing a summary of the research study conducted, and I will share details with you later in the year.

Lastly, to let you know that I am happy to answer your questions and have a chat with you about the study, whether you contributed to it or not.

You will find my contact details at the end of the text.

Until we see each other again …

Stay safe
take and Care

A special thanks to those involved in the organisation and management of the Young At Heart ULO group. In particular, thank you, Alison, for the support given now and pre-pandemic.

Thank you, Anne, Neil, and Laraine, for being always welcoming and helpful when I was at the meetings at the LiveWell Dementia Hub.

Contact details

Ester Bellavia
Telephone: 07444014902
Email: e.bellavia2@newcastle.ac.uk

Also available online:

https://mailchi.mp/efcc0bab84c7/young-at-heart-ulo-research-involvement-update

Appendix S. Phase III: Research update for DCC members

Dementia Care Community

VOL. 2, ISSUE 3

JULY 2021

A newsletter brought to you by the PriDem team

PriDem update

PriDem
tailored, local, timely dementia support

•As the phrase 'PriDem intervention' does not really convey what our work is about, we decided it would be useful to develop a logo and strapline to use on posters and information sheets about the study. Emily Spencer, a new researcher in the team, developed some initial logo ideas, and we discussed these with a small group of the DCC in June. Interestingly, there was a strong agreement about the key parts of the PriDem intervention that the logo should represent. These included the ongoing, tailored support that the intervention aims to provide to people living with dementia and their families. Here is the finished product, we hope you like it!

- Greta has been drafting a paper about the DCC to submit to a journal. We feel the DCC is an example of how public involvement in research can work well, and hope that our experiences will encourage other research teams to involve people with a mix of perspectives in their projects. We have invited two members of the DCC to co-author the paper, and hope to submit this soon.
- We are keen to make a return to holding some DCC meetings in person when we can. We will continue using Zoom and contact by telephone, email and post for now, but will review this as the guidance continues to evolve.

Spotlight on Ester Bellavia, PhD student

Since we last heard from Ester in December 2020, she has been continuing her work focused on how best to involve people with dementia and family carers in the research process. Here she gives us an update:

"I began my study by developing ideas about successful ways to involve people in research through observing DCC meetings and speaking to some DCC members and others with similar involvement experiences. More recently, I explored these ideas further by interviewing people with dementia, family carers and those who facilitate their involvement in research. I have now begun writing my thesis, and I will update you all with my findings in the coming months. Thank you to everyone who has contributed to my study and supported me throughout the research. If you have any questions, feel free to get in touch. Until we meet again, stay safe and take care!"

Next steps

Topics we would like to discuss with the DCC in the next couple of months:

- How can we capture the impact of the DCC
- Developing a user-friendly website for PriDem

We will be in touch to invite small groups to take part in these discussions. If any of the topics are of particular interest to you, please get in touch with Greta using the details below.

Please get in touch if you need any further information

Email: greta.brunskill@newcastle.ac.uk

Phone: 0191 208 7963 (please note, this is a voicemail facility where you can leave a message)

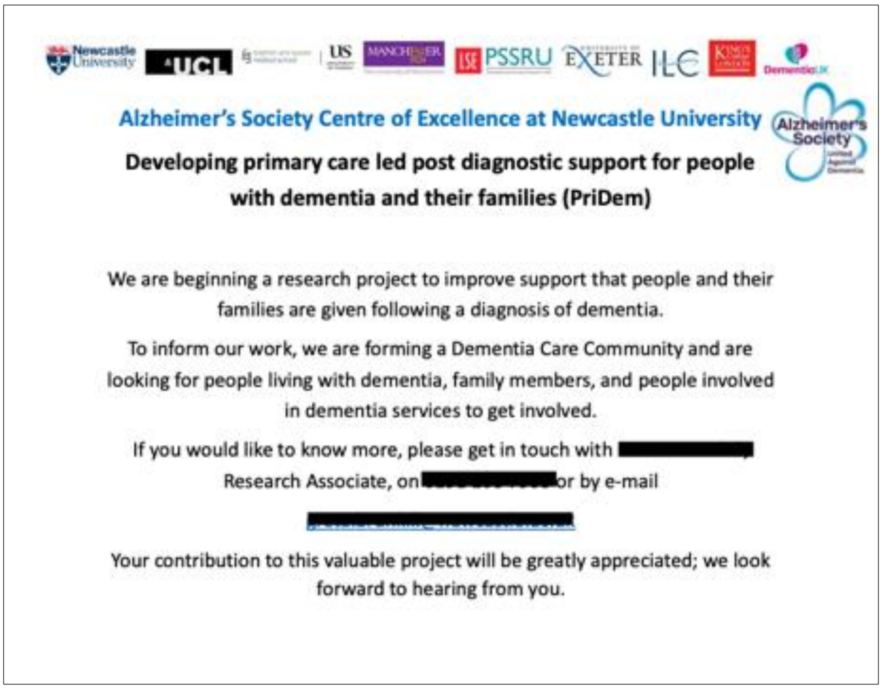
Twitter: @PriDemProject

Website:https://research.ncl.ac.uk/pridem/

Also available online:

https://research.ncl.ac.uk/media/sites/researchwebsites/pridem/DCC%20newsletter%20July%202021.pdf

Appendix T. Dementia Care Community adverts



Alzheimer's Society Centre of Excellence at Newcastle University

Developing primary care led post diagnostic support for people with dementia and their families (PriDem)

We are beginning a research project to improve support that people and their families are given following a diagnosis of dementia.

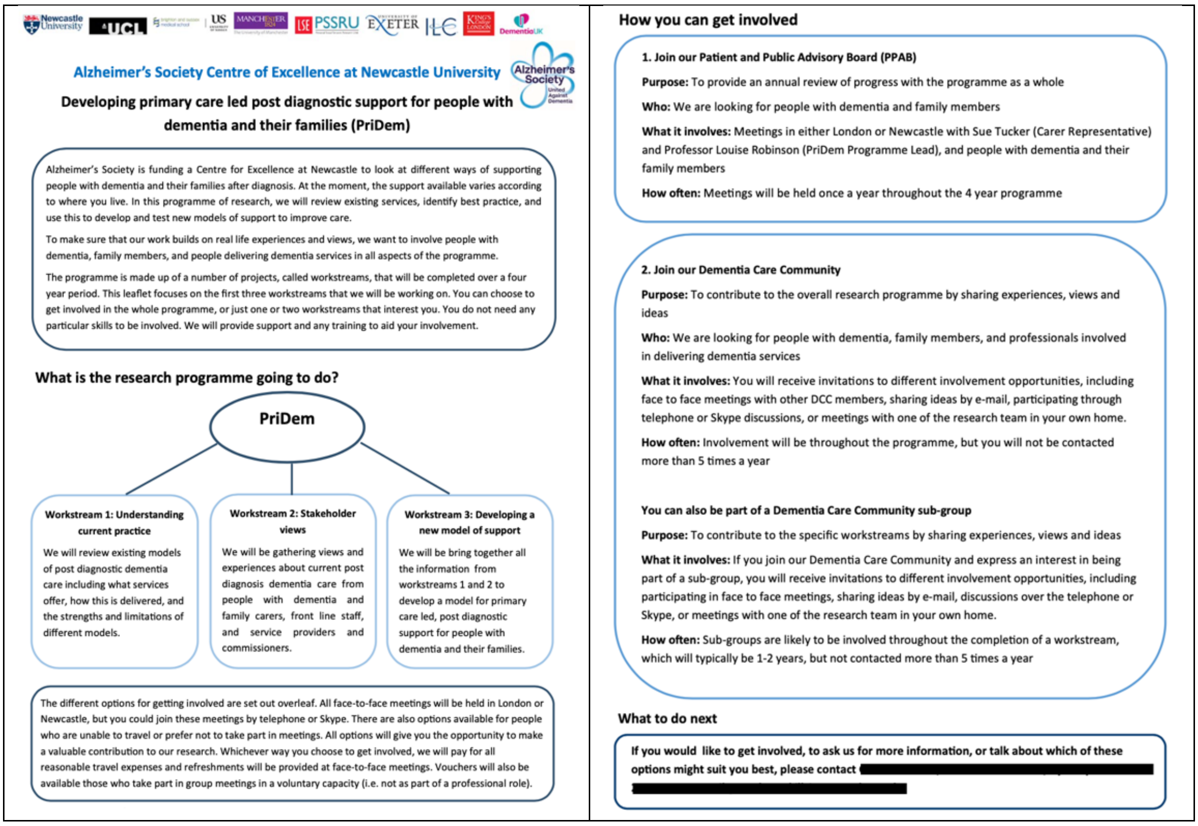
To inform our work, we are forming a Dementia Care Community and are looking for people living with dementia, family members, and people involved in dementia services to get involved.

If you would like to know more, please get in touch with [redacted] Research Associate, on [redacted] or by e-mail

[redacted]

Your contribution to this valuable project will be greatly appreciated; we look forward to hearing from you.

Figure 1. PriDem programme brief advert



Alzheimer's Society Centre of Excellence at Newcastle University

Developing primary care led post diagnostic support for people with dementia and their families (PriDem)

Alzheimer's Society is funding a Centre for Excellence at Newcastle to look at different ways of supporting people with dementia and their families after diagnosis. At the moment, the support available varies according to where you live. In this programme of research, we will review existing services, identify best practice, and use this to develop and test new models of support to improve care.

To make sure that our work builds on real life experiences and views, we want to involve people with dementia, family members, and people delivering dementia services in all aspects of the programme.

The programme is made up of a number of projects, called workstreams, that will be completed over a four year period. This leaflet focuses on the first three workstreams that we will be working on. You can choose to get involved in the whole programme, or just one or two workstreams that interest you. You do not need any particular skills to be involved. We will provide support and any training to aid your involvement.

What is the research programme going to do?

PriDem

Workstream 1: Understanding current practice

We will review existing models of post diagnostic dementia care including what services offer, how this is delivered, and the strengths and limitations of different models.

Workstream 2: Stakeholder views

We will be gathering views and experiences about current post diagnosis dementia care from people with dementia and family carers, front line staff, and service providers and commissioners.

Workstream 3: Developing a new model of support

We will be bring together all the information from workstreams 1 and 2 to develop a model for primary care led, post diagnostic support for people with dementia and their families.

The different options for getting involved are set out overleaf. All face-to-face meetings will be held in London or Newcastle, but you could join these meetings by telephone or Skype. There are also options available for people who are unable to travel or prefer not to take part in meetings. All options will give you the opportunity to make a valuable contribution to our research. Whichever way you choose to get involved, we will pay for all reasonable travel expenses and refreshments will be provided at face-to-face meetings. Vouchers will also be available those who take part in group meetings in a voluntary capacity (i.e. not as part of a professional role).

How you can get involved

1. Join our Patient and Public Advisory Board (PPAB)

Purpose: To provide an annual review of progress with the programme as a whole

Who: We are looking for people with dementia and family members

What it involves: Meetings in either London or Newcastle with Sue Tucker (Carer Representative) and Professor Louise Robinson (PriDem Programme Lead), and people with dementia and their family members

How often: Meetings will be held once a year throughout the 4 year programme

2. Join our Dementia Care Community

Purpose: To contribute to the overall research programme by sharing experiences, views and ideas

Who: We are looking for people with dementia, family members, and professionals involved in delivering dementia services

What it involves: You will receive invitations to different involvement opportunities, including face to face meetings with other DCC members, sharing ideas by e-mail, participating through telephone or Skype discussions, or meetings with one of the research team in your own home.

How often: Involvement will be throughout the programme, but you will not be contacted more than 5 times a year

You can also be part of a Dementia Care Community sub-group

Purpose: To contribute to the specific workstreams by sharing experiences, views and ideas

What it involves: If you join our Dementia Care Community and express an interest in being part of a sub-group, you will receive invitations to different involvement opportunities, including participating in face to face meetings, sharing ideas by e-mail, discussions over the telephone or Skype, or meetings with one of the research team in your own home.

How often: Sub-groups are likely to be involved throughout the completion of a workstream, which will typically be 1-2 years, but not contacted more than 5 times a year

What to do next

If you would like to get involved, to ask us for more information, or talk about which of these options might suit you best, please contact [redacted]

Figure 2. PriDem programme flyer

Appendix U. Detailed description of DCC meetings across settings

University venue

The university venue chosen for the Dementia Care Community (DCC) meeting was a research centre situated on a National Health Service (NHS)'s campus, which included some hospital departments providing adult and paediatric care. Located a few miles away from the city centre, the research centre was surrounded by a small car park outside of which there was a bus stop. There was a small step leading into the entrance of the building and an alternative access for wheelchairs. On the day of the meeting, there would be a sign at the entrance, indicating the number of the floor of the meeting, which could be reached using the stairs or the lift. Once attendees reached the indicated floor, there would be another sign inviting them to press the bell. A receptionist would let them in and, if available, escort them to the main room (see Figure 1). Attendees could come to the main room if arrived within 30 minutes before the meeting started. Alternatively, they could wait in a café based on the ground floor and regularly visited by NHS staff, patients, and researchers.

Figure 1. Main room at the university venue

In comparison to the breakout rooms (see Figure 2), where a small number of DCC members participated in group activities, the main room was bigger, brighter, and close to the toilets. Usually, the meeting would start and finish in the main room, where attendees could get drinks and snacks provided. Due to the limited availability of rooms on the same floor on the day of the DCC meeting, the main room was sometimes used as a breakout room.

Figure 2. Breakout room at the university venue

The second floor of the research building typically was used to host the DCC meetings. Only on one occasion (5th March 2019) no room was available in that floor, due to which three different rooms were booked on the first floor instead. The second floors included a small kitchen adjacent to the main room, two breakout rooms, and different offices. The working space of all members of the research team was based on that floor. All rooms used for the group activities included a screen connected to a computer, a few tables grouped together, some chairs, a whiteboard, as well as some curtains covering glass doors. To avoid distractions, these curtains were closed during the meeting. Everything else (e.g., papers, pens, drinks and snacks) was set up and then packed away by the research team each time.

On arrival, DCC members were invited to sign a register, grab a sticker with their name on it and collect notepads, pens, a printed copy of the PowerPoint presentation used during the meeting, a free-car parking tag and a travelling expenses disclaimer form, if they had reached the building on their own (see Figure 3). From March 2019 onwards, upon explicit request, DCC members started receiving the agenda of the meeting and the topics to be discussed beforehand. However, a printed copy was also provided on the day of the meeting. The table where all the materials were kept, including some stuff for the group activities (e.g., blue tack for posters and post-it notes), was in the main room and remained there until the meeting ended, thus ensuring that people unable to arrive on time could access it.

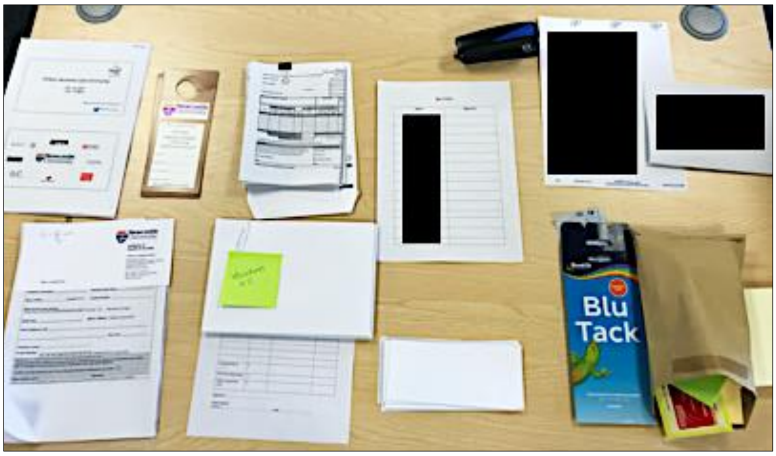


Figure 3. Material for attendees at the university venue

The format of the meeting at the university venue followed a fixed structure. After entering the main room, it could be seen that the meeting would start at 1.30 pm. Following an introduction to the objectives of the meeting and a brief update on the PriDem programme, DCC members were assigned to a small group – A, B, or C – by the DCC coordinator. The DCC coordinator would plan the organisation of these groups in collaboration with the PriDem programme PPI lead. The recurrent criteria informing decision making included the importance of creating a fair balance between providers of care services (i.e., professionals) and recipients of these services (i.e., people living with dementia [PLWD] and family carers). As the involvement progressed, other criteria were included, such as increased awareness of DCC members' experiences, personalities, and skills and their explicit requests.

By 2 pm, each attendee was assigned to a small group (i.e., 6 to 8 people) and already in a breakout room ready to initiate one of the two activities planned for the day. Each group was assigned to a researcher who was responsible for facilitating the activity. The duration of one activity was approximately 40-50 minutes. Thereafter, facilitators were asked to invite group members to move back to the main room for a break. The organisation of groups and the duration of the activity would be the same throughout the meeting. While waiting for all attendees to gather in the main room, research team members would summarise the inputs received in key points to report to everyone before concluding the meeting. The meeting commencing at 1.30 pm would generally end at 4 pm for DCC members and at 4.30 pm for research team members, who spent the extra time tidying up and discussing first impressions and concerns, if any.

During data collection, each DCC meeting at the university venue included two activities, with the exception of the first two meetings, which were mainly spent to introduce the programme and the team, agree on the terms of collaboration, and share individual experiences of the services. Each activity was laid out for group members on a poster (see Figure 4) and simultaneously showed on the screen present in the rooms (see Figure 2). Group members were invited to contribute verbally, by writing on a post-it note to attach to the poster, or by taking notes to share later with team members. Usually, group facilitators documented the conversation by using post-it notes or by completing a table including some prompts for discussion. Before the activity started, an audio recorder was positioned in the middle of the table and switched on to record the discussion after seeking approval from group members. All the recordings obtained from these meetings were transcribed and then reviewed by team members for involvement and research purposes. The topic of the activities designed for the meetings hinged upon the progress of the PriDem programme and the aims of the workstreams during which they took place.

Figure 4. Example of group activity at the university venue

Approximately a couple of weeks after each meeting, DCC members would receive the vouchers for their participation and a summary of the meeting attended, including insights from the activities and how they unfolded in different groups. Usually, the manner in which the contribution impacted the PriDem programme's progress was explained during the introduction of the following meeting.

Memory café

The memory café included in the PriDem programme was founded by the Alzheimer's Society in 2014 with the aim of providing an opportunity for PLWD and family carers to socialise and receive support. Those attending the café had usually been referred by the charity organisation helpline system or the social workers involved in their care. The café took place every second Tuesday of the month from 2 pm to 4 pm in a community room (see Figure 5) that hosted the social events of several local groups. This specific room was located on the first floor of a large grocery and general merchandise store situated nearly four miles away from the city centre. This store had metro and bus stops nearby, along with a spacious, free carpark. At the entrance of the store, there was a café on the left, where PLWD and family carers used to have lunch before attending the meeting. Heading straight, it was possible to find the stairs or the lift that would have taken to the first floor, where the community room was based. The room was located in between two doors; one would have given access to the administrative store staff's office and the other one to a small kitchen for them. There was only one toilet reserved to visitors on the first floor, and it was in front of the community room's door. Additional toilets were available on the ground floor.

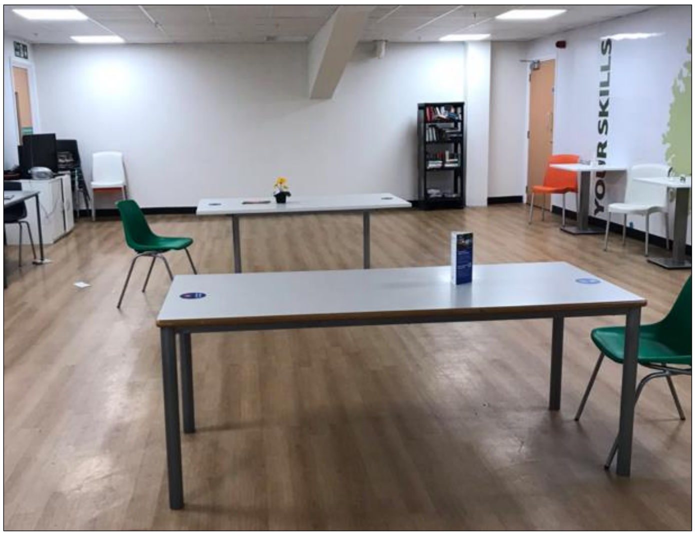


Figure 5. Meeting room at the memory café

Before the meeting, the community room was empty, as tables and chairs were stored in a deposit that could be accessed via a door inside the room. Typically, the memory café's facilitator and the volunteers would arrive earlier to get the space organised and prepare the material they would require for the social activities of the day (e.g., quiz, music bingo and memory books). Located in a corner inside the room there was a small kitchen, which was used to make drinks for the attendees. People attending the meeting would bring the snacks they shared with others during the activities.

Upon arriving at the café, PLWD and family carers used to begin conversing with each other, while having hot drinks and snacks. Everyone picked their seat of choice, with PLWD usually sitting next to their family carers. The café usually commenced with a small introduction of all the attendees, during which people introduced themselves and shared some details of their experience of dementia, whether as a person living with the condition or a family carer. Then, the café facilitator would share some pertinent and local information, including news about services available and opportunities for being involved in social activities (e.g., singing for the brain, games for the brain and memory walks). Next, approximately 30 minutes were dedicated to a fun group activity, following which, the DCC coordinator would take over for about 45 minutes.

The format of the DCC meeting at the memory café had a fairly straightforward structure. It would usually begin with the DCC coordinator reiterating key information about the PriDem programme, providing a brief update on the progress made, and explaining the impact of the DCC on the PriDem. Then, the focus of the session would be the activity planned for the day, which typically entailed a group discussion prompted by a list of questions readout of loud by the DCC coordinator or supported by posters (see Figure 6) similar to those created for the meetings held at the university venue (see Figure 4). Despite the fact that additional material (e.g., pens, post-it notes and notepads) for personal notes or contributions were made available on the table, all attendees would verbally share their thoughts and experiences. While the activity took place, the café facilitator and volunteers remained seated at the same table, observing the interaction among people and assisting the research team if necessary. At the memory café, DCC members participated in the activity together, regardless of the number of people present.

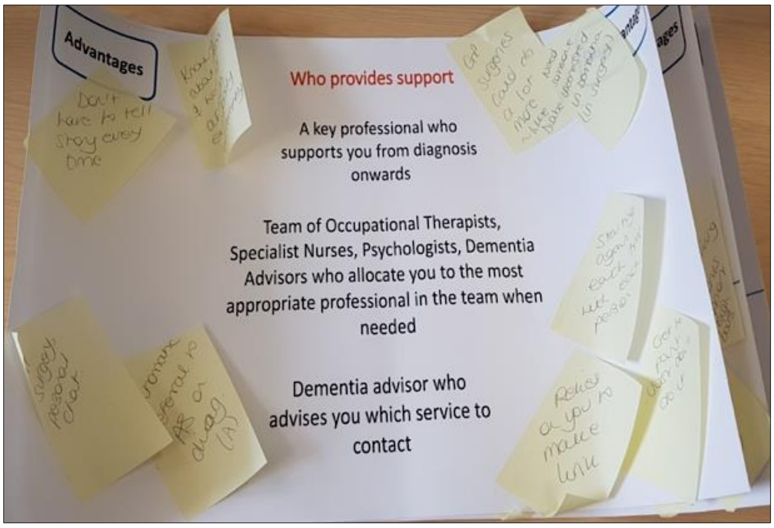


Figure 6. Example of group activity at the memory café

At the end of the group activity, the café facilitators would invite everyone to enjoy an approximately 15-minutes break. During this break, some people would continue to converse with the DCC coordinator, asking questions or sharing some details they had not discussed during the activity. Others would chat to each other about national and or local news or personal matters. After this break, the café facilitator would go over some reminders about upcoming local events, check on people's caring needs, and ask attendees whether they were willing to have the DCC coordinator visit again in the future. The café concluded at 4 pm for everyone, except for the café facilitator and the volunteers, who had to reorganise the room and have a meeting about the session.

Dementia hub

The dementia hub included in the PriDem programme was founded in 2015 as a community-based service provided in a locality of the North East for those interested in gaining information, support or training related to dementia. The hub, which was supported by several local organisations, was open to the public from Monday to Friday between 10 am and 3 pm. The first Tuesday of each month the hub hosted a user-led group set up by and for PLWD and their carers from 2 pm to 4 pm. People interested in joining this group could register online on the group's website or call the hub, where a receptionist would provide details of the meeting and address related queries. The building hosting the hub was situated in a residential area in a town located nearly forty miles away from the city where other DCC members gathered. Close by the hub, there was a bus stop and a small, free car park. The hub was organised on one floor divided into two rooms separated by a door: the hall (see Figure 7) and the meeting room (see Figure 8). The hall was at the entrance of the building, with the receptionist's desk on the right. On the left, there was a calendar of the activities hosted by the hub, some flyers about dementia and related care services offered locally, and a couple of tables surrounded by large vintage armchairs. The meeting room was bigger and brighter; it also comprised several tables and chairs, a kitchen and a fridge, as well as interactive board connected with speakers. The toilet services were accessible through a door located next to the interactive board.


Figure 7. Dementia hub hall


Figure 8. Meeting room at the dementia hub

The majority of PLWD and family carers coming to the café were local and knew each other, as they had been regular visitors for a long time. A total of three meetings were arranged between the DCC coordinator and the dementia hub facilitator for the involvement of this user-led group's members in the PriDem programme. On each of these three instances, there were at least a couple of new visitors. All these meetings included mainly PLWD, as their family carers coming to the hub preferred to remain in the hall talking to each other.

After arriving at the hub, PLWD and family carers would enter the meeting room at the hub to say hi to everyone. Then, PLWD would stay in the meeting room, picking a seat of their choice. Family carers would move to the hall, where volunteers would organise a small table with a kettle, some mugs and snacks. The hub usually began with the facilitator standing in front of the interactive board, welcoming everyone, and reminding them of the plan for the day, which had been made available in advance via email or post. Then, the DCC coordinator would take over for approximately 60 minutes. In each of the meetings documented during the data collection, PLWD also took part in a fun activity (e.g., quiz, bingo and memory cards game) led by the hub facilitator before or after the research activity.

The format of the DCC meeting at the dementia hub had a structure similar to the one held at the memory café. It generally began with the DCC coordinator reiterating key information about the PriDem programme, providing an update on its progress, and informing on the impact that the DCC had on it. Then, they would explain the research activities of the day, which involved all attendees together, except for the meeting held in October 2019, when two research team members – the DCC coordinator and the PriDem programme PPI lead – were at the hub. The activity undertaken at the hub would entail a group discussion supported by questions reported on a poster (see Figure 9) where answers were documented. The hub facilitator and the volunteers would sit elsewhere in the meeting room during the activity, observing the course of events and offering support if believed necessary.

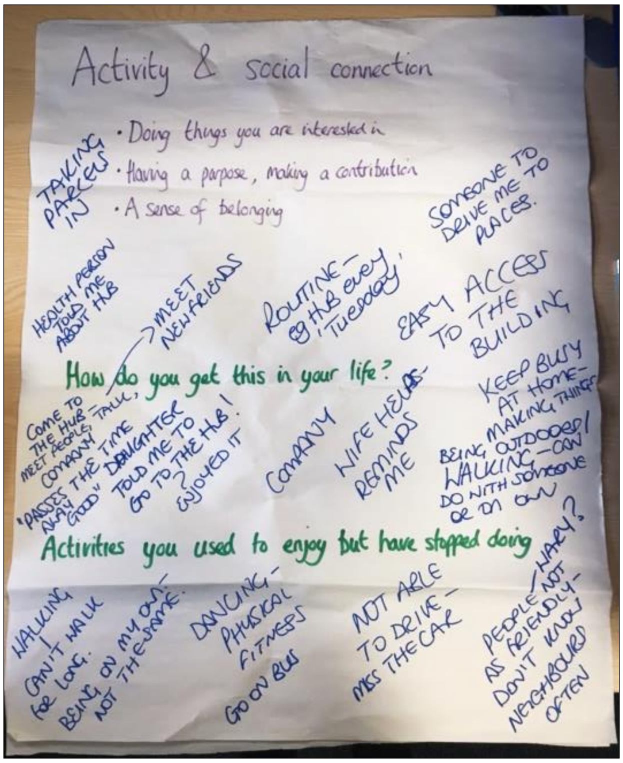


Figure 9. Example of group activity at the dementia hub

Once the time given to the DCC coordinator was coming to an end, the hub facilitator and the volunteers would inform the family carers in the hall and would begin to organise the space. The last 10 minutes of the meeting were led by the hub facilitator ending the meeting with some salient reminders before turning on the music for a sing-along moment. Before leaving, attendees would leave a free money offer to the hub facilitator in order to provide for drinks, snacks and additional material required for the fun activities organised.

Appendix V. RAMESES II reporting standards for realist evaluations

Table 1. Adapted from RAMESES II reporting standards for realist evaluations

TITLE			Where in the thesis
1		In the title, identify the document as a realist evaluation	Front page: 'exploring & explaining'
SUMMARY OR ABSTRACT			
2		Journal articles will usually require an abstract, while reports and other forms of publication will usually benefit from a short summary. The abstract or summary should include brief details on: the policy, programme or initiative under evaluation; programme setting; purpose of the evaluation; evaluation question(s) and/or objective(s); evaluation strategy; data collection, documentation and analysis methods; key findings and conclusions. Where journals require it and the nature of the study is appropriate, brief details of respondents to the evaluation and recruitment and sampling processes may also be included. Sufficient detail should be provided to identify that a realist approach was used and that realist programme theory was developed and/or refined.	Abstract
INTRODUCTION			
3	Rationale for evaluation	Explain the purpose of the evaluation and the implications for its focus and design	Chapter 3
4	Programme theory	Describe the initial programme theory (or theories) that underpin the programme, policy or initiative	Chapter 5
5	Evaluation questions, objectives and focus	State the evaluation question(s) and specify the objectives for the evaluation. Describe whether and how the programme theory was used to define the scope and focus of the evaluation	Chapters 1, 3
6	Ethical approval	State whether the realist evaluation required and has gained ethical approval from the relevant authorities, providing details as appropriate. If ethical approval was deemed unnecessary, explain why	Chapter 3
METHODS			
7	Rationale for using realist evaluation	Explain why a realist evaluation approach was chosen and (if relevant) adapted	Chapter 3
8	Environment surrounding the evaluation	Describe the environment in which the evaluation took place	Chapters 3
9	Describe the programme policy, initiative or product evaluated	Provide relevant details on the programme, policy or initiative evaluated	Chapter 4
10	Describe and justify the evaluation design	A description and justification of the evaluation design (i.e. the account of what was planned, done and why) should be included, at least in summary form or as an appendix, in the document which presents the main findings. If this is not done, the omission should be	Chapter 3

		justified and a reference or link to the evaluation design given. It may also be useful to publish or make freely available (e.g. online on a website) any original evaluation design document or protocol, where they exist	
11	Data collection methods	Describe and justify the data collection methods – which ones were used, why and how they fed into developing, supporting, refuting or refining programme theory. Provide details of the steps taken to enhance the trustworthiness of data collection and documentation	Chapter 3
12	Recruitment process and sampling strategy	Describe how respondents to the evaluation were recruited or engaged and how the sample contributed to the development, support, refutation or refinement of programme theory	Chapter 3
13	Data analysis	Describe in detail how data were analysed. This section should include information on the constructs that were identified, the process of analysis, how the programme theory was further developed, supported, refuted and refined, and (where relevant) how analysis changed as the evaluation unfolded	Chapter 3
RESULTS			
14	Details of participants	Report (if applicable) who took part in the evaluation, the details of the data they provided and how the data was used to develop, support, refute or refine programme theory	Chapter 3
15	Main findings	Present the key findings, linking them to contexts, mechanisms and outcome configurations. Show how they were used to further develop, test or refine the programme theory	Chapters 5, 6
DISCUSSION			
16	Summary of findings	Summarise the main findings with attention to the evaluation questions, purpose of the evaluation, programme theory and intended audience	Chapter 7
17	Strengths, limitations and future directions	Discuss both the strengths of the evaluation and its limitations. These should include (but need not be limited to): (1) consideration of all the steps in the evaluation processes; and (2) comment on the adequacy, trustworthiness and value of the explanatory insights which emerged. In many evaluations, there will be an expectation to provide guidance on future directions for the programme, policy or initiative, its implementation and/or design. The particular implications arising from the realist nature of the findings should be reflected in these discussions	Chapter 7
18	Comparison with existing literature	Where appropriate, compare and contrast the evaluation's findings with the existing literature on similar programmes, policies or initiatives	Chapter 7
19	Conclusion and recommendations	List the main conclusions that are justified by the analyses of the data. If appropriate, offer recommendations consistent with a realist approach	Chapter 7
20	Funding and conflict of interest	State the funding source (if any) for the evaluation, the role played by the funder (if any) and any conflicts of interests of the evaluators	Chapter 3