Efficacy, acceptability and experiences of very low energy diets in adults with type 2 diabetes

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Abstract

Aims: Type 2 diabetes (T2DM) has traditionally been regarded as an irreversible and progressive chronic condition. Recent evidence suggests that T2DM can be reversed by dietary restriction of energy intake through very low energy diets (VLEDs), indicating its potential for the treatment of one of the most prevalent chronic conditions associated with overweight and obesity around the world. VLEDs represent the most rapid, non-surgical method of weight loss (WL), but evidence showing acceptability of VLEDs and their short- and long-term efficacy in people with T2DM is limited. This PhD project aims to: 1) determine efficacy of VLEDs for weight loss and diabetes remission; 2) explore peoples` experiences with adherence to VLEDs; and 3) evaluate acceptability of VLEDs. In order to determine long-term sustainability of weight loss through VLEDs, this project further aimed to 4) explore peoples` experience with weight maintenance following weight loss through VLEDs; 5) evaluate acceptability of different plans for weight loss maintenance (WLM); and 6) explore changes in peoples` experiences from the beginning of weight loss through to weight loss maintenance. **Methods:** A mixed-methods approach was used to achieve the above aims. *Chapter 1* provides a review of literature relating to T2DM and its treatments. *Chapter 2* gives an overview of the relevant theoretical perspectives and provides a theoretical background to this PhD project. To determine efficacy and acceptability of VLEDs from the existing literature, *Chapter 3* presents a systematic review of controlled trials and qualitative studies of individuals with T2DM that compared the efficacy of VLEDs with standard care, minimal interventions and other WL interventions. *Chapter 4* briefly describes the Counterbalance Study, which investigated the principle determinants of long term reversal of T2DM, consisting of a 2-month WL period with VLEDs, followed by a 6-month WLM phase. The Counterbalance Study was independent of this project, but provided a platform for all qualitative work I have conducted within this PhD. In *Chapters 5 and 6*, I employed qualitative methods to explore experiences with a VLED amongst people with T2DM, who were engaged on the Counterbalance Study, and to determine acceptability of the VLED as an intervention for weight loss and diabetes remission. For this study, I interviewed 15 of 30 participants in the Counterbalance Study at the start and the end of the VLED. I conducted thematic analyses to find out about peoples` motivation to take part in the Counterbalance study, their experiences, their perceived barriers and facilitators to adherence with the VLED, about behavioural strategies they used

to overcome the barriers, and about their views on acceptability of the VLED. In *Chapters 7 and 8*, I employed the same qualitative methods and interviewed 16 and 15 participants of the Counterbalance Study after the WL and the WLM phases respectively. The interviews aimed to explore peoples` experiences with the WLM phase including their motivation, experience, barriers and facilitators to adherence, behavioural strategies they employed, and support needs at this stage. In the last empirical chapter (Chapter 9), I analysed the narratives of 11 participants who were interviewed at all three stages (baseline, end of WL and end of WLM) to identify themes of change, and to find out how peoples` experience of WL relates to experience of WLM.

Results: *Chapter 1* described T2DM and its complications, comorbidities and the impact of T2DM on peoples` health and the economy. It provided an overview of the current invasive and non-invasive treatments of T2DM, introduced VLEDs and the existing evidence of their efficacy and acceptability.

Chapter 2 provided an overview of the psychological literature relevant to WL, WLM and eating behaviours. It introduced the behaviour change theories relevant to this thesis, discussed their strengths and weaknesses, and discussed their utility in health psychology research. This chapter also provided a springboard for hypotheses that I further explored in the qualitative studies in Chapters 5-9. The systematic review in *Chapter 3* identified 9 controlled trials that were included in meta-analyses and narrative syntheses. These analyses showed that VLEDs induced greater WL than minimal interventions, standard care or low energy diets, and equal WL compared to bariatric surgery, at 3 and 6 months. It also showed that a larger difference in energy prescription between the intervention and the comparator arms is associated with larger differences in WL and fasting blood glucose levels at 3 months. No qualitative studies were suitable for inclusion in the systematic review, however acceptability of VLEDs was suggested by attrition rates, which did not differ between the VLED and the comparator groups at any measurement point. The qualitative study of peoples` experiences with and acceptability of VLED in *Chapters 5 and 6* found that the VLED was perceived as generally highly acceptable among motivated individuals involved in a clinical study. The following themes reflected the experience of people with a WL through VLEDs: 1) improving health-related quality of life and 2) enhancing appearance, which were the main motives for the participants to take part in the study; 3) exceeded expectations, and 4) positive feedback loop, which stimulated the continuous motivation to adhere with the diet, and 5) facilitation of adherence,

including behaviour-regulation strategies that the people used to overcome barriers to adherence.

In *Chapter 7 and 8*, I extended the qualitative enquiry to the WLM phase of the Counterbalance Study: The following themes reflected the participants` experience with and acceptability of the WLM phase: 1) shifting of goals, 2) from uncertainty to regaining control, transcending which was the notion of a 3) shifting identity. Uncertainty about transition to regular food and weight maintenance and a progress towards building healthier habits and growing control of behaviour was a common denominator of the themes. To facilitate successful WLM, people used behaviour-regulation strategies of monitoring and compensation by physical activity and calorie restriction. Acceptability of the WLM phase and WLM success were related with: 1) preference for a WLM plan; and 2) satisfaction with WL and WLM outcomes. The participants also evaluated which intervention features were useful and offered suggestions for improvement of the intervention.

Lastly, in Chapter 9 I identified changes in the peoples` experiences with weight management over time. The results show that success during WL and WLM is facilitated by the experience of transition from behavioural inter-dependency (with other people) to behavioural independence, and by adaptation of their mindset from a regimented one during WL to more flexible one during WLM. The interviews also showed that behaviour change can be “contagious” and other people may benefit from one`s behaviour change. The longitudinal narratives also highlighted the shift in identity people experience during the process of behaviour change.

Conclusions: The empirical studies in this PhD project found that VLEDs are effective and acceptable for WL and remission of T2DM among highly motivated individuals within a clinical setting. People who struggle adhering to a VLED or WLM following a VLED may use behaviour regulation strategies identified in this PhD to facilitate adherence. Social support was an important facilitator both, WL and WLM. The WL and WLM interventions can be improved by enabling the participants to meet each other to exchange experience, tips and to support each other. Monitoring and providing feedback on performance during the WL and WLM phases stimulates continuous effort and clinical support beyond WLM might facilitate long-term sustainability of the achieved outcomes. Future studies should explore efficacy and acceptability of VLEDs in a primary care setting, with more limited resources.

List of abbreviations and terms

T2DM	Type 2 diabetes mellitus or adult-onset diabetes.
BGL	Blood glucose levels
PGL	Plasma glucose levels
BMI	Body Mass Index
GI	Glycaemic Index
WL	Weight loss
WLM	Weight loss maintenance
VLED	A very low energy diet comprising of less than 800 kilocalories per day.
LED	Low energy diet
BT	Behavioural treatment
SBT	Standard behavioural treatment
ICD	Intensive conventional diet
RYGB	Roux-en-Y gastric bypass
FBG	Fasting blood glucose
Kcal (energy)	kilocalorie
MRC	Medical Research Council
CONSORT	Consolidated Standards of Reporting Trials
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
Adherence	The extent to which a participant closely follows or “sticks with” the prescribed diet/weight maintenance plan.
TDF	Theory Domains Framework, a theoretical framework used for initial coding of the qualitative evidence.
Coding	A process of reviewing of a passage of a transcript followed by assignment of a category to that passage that best describes the essential message within.
A quote	A verbatim transcription of a person`s statement.
A theme	A broader pattern or an analytical category important for description of a phenomenon within data, related to a specific research question
A sub-theme	A pattern or analytical category within a theme, adding to understanding of a phenomenon related to a specific research question.
A mind map	A visual representation of themes and relationships between them
Behaviour-regulation strategy	A set of behaviours developed to facilitate achievement of a goal.

Chapter 1
Introduction

1.1 Definition of type 2 diabetes mellitus (T2DM)

Diabetes mellitus is an inherited or acquired metabolic disorder characterised by chronically increased levels of blood glucose (hyperglycaemia), with disturbances of carbohydrate, fat and protein metabolism. Blood glucose levels (BGL) increase due to insufficient or lacking insulin secretion by the pancreas, the body`s inability to use insulin properly, or both (World Health Organisation, 2006a). Figure 1 depicts the function of pancreas in BGL regulation. A healthy pancreas produces two complementary hormones: insulin produced by β-cells, and glucagon produced by α-cells. Insulin helps BGL regulation by enabling transportation of BG into tissue cells, where it is stored and transformed into its inactive form glycogen, and therefore assists lowering of BGL. Glucagon, on the other hand, is released when BGL are low, such as during energy expenditure, stress or digestion. Glucagon triggers conversion of glycogen in tissues back to glucose, increasing blood glucose levels and making it available as a source of energy for the body. In diabetes, this cycle is disturbed. The pancreas either does not produce insulin at all, produces insufficient amounts of it, and/ or the receiving tissues have become desensitised to insulin action (insulin insensitivity).

1.2 Diagnosis of T2DM

Diabetes is diagnosed when a) after at least 8 hours of fasting, the BGL exceed or are equal to 7.0mmol/L (126mg/dL); or b) when after 2 hours of consuming 75 g of glucose, the BGL are greater than or equal to 11.1 mmol/L (200mg/dL); or 3) when a random plasma glucose test in a patient with symptoms of hyperglycaemia or hyperglycaemic crisis reveals BGL greater than or equal to 11.1 mmol/L (200mg/dL); or d) when the average BGL over the past three months reveals that the amount of glucose attached to haemoglobin (glycosylated haemoglobin) is greater than 6.5% (the A1c or HbA1c test) (American Diabetes Association, 2015).

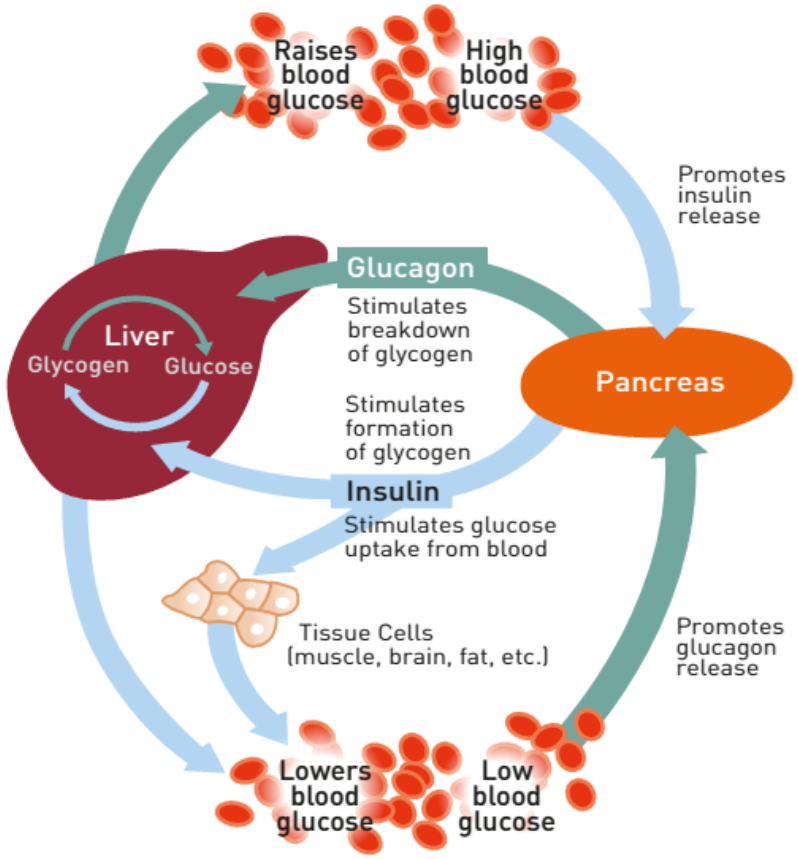

Figure 1. Functional pathway of insulin production and its effects on blood glucose levels. (Adapted from IDF Diabetes Atlas, 6th edn. Brussels, Belgium: International Diabetes Federation, 2013).

1.3 Epidemiology and complications of T2DM

Development of T2DM has been related with a number of risk factors, such as obesity and overweight, unhealthy diet, lack of physical activity, non-white ethnic backgrounds, higher socio-economic status (Morewitz, 2006), genetic predispositions (Mohan, Shanthirani, & Deepa, 2003), previous presence of impaired glucose tolerance, being aged 40 years or older, hypertension and history of gestational diabetes (Mokshagundam & Broadstone, 1998).

Acute complications of diabetes include hypoglycaemia (low levels of BG), hyperglycaemia (elevated levels of BG) and infections. In the long term, diabetes can cause damage to various organs, mainly eyes, kidneys, nerves and blood vessels as a result of diabetic retinopathy, nephropathy, neuropathy or atherosclerosis (World Health Organisation, 2006b). Diabetes is one of the leading causes of blindness, lower limb amputations and kidney failures (International Diabetes Federation, 2003), which represent only few of the consequences of the disorder, in addition to

diminished quality of life or shortened life expectancy (Gu, Cowie, & Harris, 1998b; Redekop *et al.*, 2002; Rhodes *et al.*, 2012; Rubin & Peyrot, 1999).

1.4 Prevalence of diabetes

The most prevalent types of diabetes are Type 1 (T1DM), also known as insulin-dependent or early-onset diabetes, and Type 2 (T2DM), known as non-insulin-dependent or adult-onset diabetes. While T1DM usually develops in childhood or adolescence and people affected by it require external insulin provision, T2DM often develops in adulthood and does not necessarily require insulin treatment.

Within the past 20 years, prevalence of T2DM has increased substantially. In 1997, the estimated prevalence of diabetes by 2010 was 221 million people worldwide. The number climbed to 285 million when estimated in 2009. This trend is likely to continue, with a diabetic population of 333 - 380 million people worldwide in 2025 and up to 592 million or 8.8% of population suffering from diabetes in the 20 years to come (Table 1). The latest report of the International Diabetes Federation (IDF) stated that the prevalence of diabetes was 387 millions of people world-wide in 2014 (International Diabetes Federation, 2014).

In the UK specifically, the prevalence of T2DM will peak around 2036, which will be approximately 20% higher than in 2000 (Bagust, Hopkinson, Maslove, & Currie, 2002).

The available data show that almost every year exceeds its past estimates in the size of population with diabetes. In addition, the latest report of the International Diabetes Federation estimated that up to 46% of 382 million people with diabetes are yet undiagnosed (International Diabetes Federation, 2013a). The latest IDF`s report stated that the prevalence of diabetes in the UK was 2.45 million or 5.38% of adult population in 2014 (International Diabetes Federation, 2014).

Table 1. *Global estimates of diabetes prevalence*

Reference	Year of publication	Global estimates of diabetes prevalence by year % of the world`s adult population (number of people in millions).									
		1995	1997	2000	2003	2007	2010	2013	2025	2030	2035
(Amos, McCarty, & Zimmet, 1997)	1997	2.08 (118)	2.10 (124)	2.50 (151)			3.2 (221)				
(International Diabetes Federation, 2003)	2003				5.1 (194)				6.3 (333)		
(Wild, Roglic, Green, Sicree, & King, 2004)	2004			2.83 (171)						6.05 (366)	
(International Diabetes Federation, 2006)	2006					6.0 (246)			7.3 (380)		
(International Diabetes Federation, 2009)	2009						6.6 (285)			7.8 (438)	
(International Diabetes Federation, 2013a)	2013							8.3 (382)			8.8 (592)

1.5 Mortality in diabetes

With the increasing prevalence of diabetes and its associated complications, the rate of deaths attributable to diabetes has also increased. Table 2 provides an overview of the proportion of deaths from all-causes attributable to diabetes world-wide. The latest reports estimated a 15.9% increase in diabetes-attributable risk in people between the age of 20-79 between 2010 and 2011 and an increase of 10.8% between 2011 and 2013.

Table 2. *Global estimates of deaths attributable to diabetes: % of all-cause deaths (number of deaths in millions).*

Reference	Year of publication	Global estimates of the proportion of deaths attributable to diabetes			
		2000	2010	2011	2013
(Roglic *et al.*, 2005)	2005	5.2% (2.9)			
(Roglic & Unwin, 2010)	2010		6.8 (3.96)		
(International Diabetes Federation, 2013b)	2013			8.2 (4.6)	
(International Diabetes Federation)	2015				8.4 (5.1)

Differences in mortality rates and life expectancy between people with and without diabetes have also been reported (Gatling, Tufail, Mullee, Westacott, & Hill, 1997; Gu *et al.*, 1998b). Young adults with diabetes lose approximately 15 years from average remaining life expectancy in comparison with their non-diabetic counterparts (Rhodes *et al.*, 2012), while those aged 55-64 lose approximately 8 years and aged 65-74 approximately 4 years of the median life expectancy compared with people without diabetes (Gu, Cowie, & Harris, 1998a).

1.6 Quality of Life in Diabetes

Perhaps an equally important implication of diabetes from a patient perspective is the quality of life (QoL) following diagnosis. Although research into QoL in people with diabetes is limited, an association between depression and poor glycaemic control has been found (Lustman *et al.*, 2000). Interestingly, depression has been found to be associated with a 60% increased risk of T2DM, while T2DM was only associated with only a 15% increase in the risk of depression (Mezuk, Eaton, Albrecht, & Golden, 2008). On the other hand, obesity and overweight have been found to increase the risk of depression by 55% and 27%, respectively. This is relevant, as

the majority of people with T2DM are overweight or obese (Astrup & Finer, 2000; Wilborn *et al.*, 2005). It could be hypothesised that initial obesity or overweight contribute to development of depression and that physical inactivity known to be associated with depression (Camacho, Roberts, Lazarus, Kaplan, & Cohen, 1991; Weyerer, 1992) further increases the risk of T2DM.

A comprehensive review on self-perceived QoL among adults with diabetes (Rubin & Peyrot, 1999) has found that although people with diabetes have lower QoL than people without a chronic illness, they have a better QoL than people with most other chronic diseases such as heart disease, angina, recent myocardial infarction and gastrointestinal and chronic lung problems. However, the presence of diabetes complications, particularly two or more complications, was found to diminish QoL. Gender differences were found in reporting of symptoms of depression or anxiety as well as in treatment satisfaction, with more impact of diabetes on women's lives. Surprisingly, duration of the condition was not found to be associated with diminished well-being.

Another study investigated the use of insulin as part of treatment and found that this seemed to decrease the QoL in people with T2DM (Redekop *et al.*, 2002), although when compared with people with T1DM, their health-related QoL was still better (Rubin & Peyrot, 1999). Such findings highlight the importance of tailoring treatments of diabetes appropriate to the type of diabetes, the number of diabetes complications, or gender.

1.7 Economic burden of diabetes

The rapidly increasing prevalence of diabetes poses a significant burden on national healthcare systems. The increasing numbers of both diagnosed and undiagnosed populations require healthcare priorities to be shifted towards treatment and prevention of diabetes and its associated comorbidities. A BMI increase of 10 kg/m2, with added antihypertensive or antidiabetic treatment and certain diabetes complications increase direct annual medical costs by 10-30 %, and an insulin treatment increases the cost by 60-90% compared to annual medical costs for people with T2DM, with a BMI of 30 kg/m2, and no diabetes complications (Brandle *et al.*, 2003). Table 3 shows the estimated economic burden associated with T2DM world-wide. The estimates clearly reflect the changes in diabetes prevalence (Table

1) and it can also be noticed, that similarly to the prevalence data, the current healthcare costs estimates exceed their past estimates of the economic burden associated with the treatment of diabetes and its complications.

Table 3. *Global estimates of total healthcare costs of diabetes (in International dollars in billions)*

Reference	Year of publication	Global estimates of total* healthcare costs of diabetes (in billions of International dollars†)					
		2007	2010	2013	2025	2030	2035
(International Diabetes Federation, 2003)	2003				213-396		
(International Diabetes Federation, 2006)	2006	286.1			> 381.1		
(International Diabetes Federation, 2009)	2009		>418			>561	
(International Diabetes Federation, 2013a)	2013			>581			>678

*Total healthcare costs include all episodes of care for people with DM: DIABETES-related healthcare as well as episodes of care in which DIABETES is not the primary reason for healthcare encounter (e.g. a treatment for breast cancer in people with DIABETES.
†International Dollar is a currency accounting for differences in the relative purchasing power of different currencies.

In the UK, slow population growth estimated to be no more than 3% by 2060, will contribute to ageing of the population. This will be reflected in an increased number of people with T2DM, as more people develop the disorder, with important implications for the NHS budget. It is predicted that the increase in prevalence of T2DM will lead to an approximately 25% increase in healthcare costs between 2035 and 2045. However, due to the ageing of the population during this period, and thus reduction in the number of economically active people, the relative economic burden will increase by 40-50% compared to 2000 (Bagust *et al.*, 2002).

Although most of the data presented so far represent both, Type 1 and T2DM, more than 90% of people with diabetes suffer from the latter (International Diabetes

Federation). In addition, most factors contributing to development of T2DM are potentially modifiable. This is why this thesis will focus on T2DM in particular.

1.8 Association of T2DM with overweight and obesity

Overweight and obesity are strongly associated with T2DM (Guh *et al.*, 2009; Must *et al.*, 1999). Three measures are frequently used to determine the level of obesity and associated body composition: the Body Mass Index (BMI), waist-to-hip ratio (WHR) and waist circumference (WC).

The BMI is calculated by dividing the body weight (kg) by height (m) squared. Table 4 represents the various ranges of BMI for the purposes of classification of healthy weight, under- or overweight and three levels of obesity in adults (National Institute for Clinical Excellence, 2014).

The BMI has been used as a practical and easily measured indicator of obesity for decades, however, it is not without limitations. For example, it may not provide accurate results in sportsmen, whose muscle mass, weighing more than fat mass, is generally higher than that of average population and therefore they have a higher BMI; in pregnant women, in children and young people, where age and gender-specific BMI cut-off points should be applied, in people of certain ethnic origin such as south Asian, and in older people, due to age-related change in body composition (Nevill, Stewart, Olds, & Holder, 2006; Prentice & Jebb, 2001).

Complementary measures of obesity, especially in relation to the risk of developing T2DM for which central obesity has been found to increase the risk, have been designed to account for some of these limitations. Both WHR, calculated by waist measurement divided by hip measurement, and WC, measured at the natural waist across the umbilicus without compression of the tissue, have been found more informative (Bener *et al.*, 2013).

Table 4. *Obesity classification table. (Adapted from NICE. (2014)*

Classification	BMI (kg/m2)
Underweight	< 18.5
Healthy weight	18.5 – 24.9
Overweight	25 – 29.9
Obesity I	30 – 34.9
Obesity II	35 – 39.9
Obesity III	40 or more

The suggested cut-off points are >94 and >102 cm for men and >80 and >88 cm for women for prediction of increased and substantially increased risk of metabolic syndrome2, respectively (World Health Organisation, 2011).
Although not everyone who is overweight or obese develops T2DM, a number of studies have shown that central or abdominal adiposity specifically is a strong predictor of T2DM (Carey *et al.*, 1997; Cassano, Rosner, Vokonas, & Weiss, 1992; Freemantle, Holmes, Hockey, & Kumar, 2008; Ohlson *et al.*, 1985), with WC being better at predicting T2DM than WHR or BMI (Bener *et al.*, 2013; Wang, Rimm, Stampfer, Willett, & Hu, 2005). Increased abdominal adiposity increases the risk of T2DM more than twofold on average (Freemantle *et al.*, 2008).

Generally, weight increases when energy intake exceeds energy expenditure. Increased energy intake and insufficient energy expenditure lead to elevation of insulin levels in the blood stream by stimulating the pancreatic beta cells to produce enough insulin to transport the excess energy in the form of glucose from the blood stream into the surrounding tissues. Over time, lack of energy expenditure leads to excess accumulation of glucose in tissues (glycogen) as fat and to a further increase in weight. The glucose-receiving tissues become saturated and desensitised to insulin action. This means that the excess glucose keeps on circulating in the blood stream rather than being stored as a source of energy, together with the inefficient insulin. As a result, the pancreatic beta cells reduce or stop secreting insulin due to the elevated levels of it in the blood stream or due to exhaustion, which may lead to

[2] Metabolic Syndrome is a cluster of risk factors linked with development of atherosclerotic cardiovascular diseases and Type 2 DM.(Moller & Kaufman, 2005)

the requirement for additional insulin to be delivered to the body externally, in order to reduce the BGL.(Leahy, 2005).

1.9 Weight-loss treatments

It is clear from the evidence, that WL in individuals with T2DM is important in order to alleviate the associated health complications, decrease the medical costs spent on anti-diabetic, anti-hypertension and other drugs, and improve patients` QoL. The limited evidence suggests that intentional WL can decrease mortality risk of an individual with diabetes by 25%, with best outcomes achieved by 9-13 kg weight reduction (Aucott *et al.*, 2004).

A healthier and balanced diet, physical activity and/or behaviour therapy to aid WL, increase metabolism and lower elevated BGL are the first recommended steps in managing T2DM. When these alone or combined are not sufficient, pharmacotherapy (in form of glucose-lowering agents or/and insulin treatment) and ultimately, bariatric surgery can be considered (Morewitz, 2006).

Limited ability of people with T2DM to adopt / maintain the necessary lifestyle changes for different reasons (pain in joints, low mood, lack of energy etc.) and seriousness of the disease often lead to more costly treatments. Outlined below are the most common WL treatments for people with T2DM, that are expected to improve BGL.

1.9.1 ***Non-surgical treatment options***

The latest NICE guidelines for overweight and obesity recommend a WL of at least 5% of body weight and include a range of recommendations for commissioning of effective lifestyle weight management programmes. Programmes considered effective for WL should be multi-component, addressing dietary intake, physical activity and behaviour change, and delivered by a multidisciplinary team. They should last at least 3 months, with at least fortnightly sessions with a “weigh-in”, with tailored WL, dietary, and physical activity goal-setting with trained personnel. Use of behaviour-change techniques is also encouraged, specifically problem solving, goal setting, and instruction on how to carry out certain activities, planning social support, self-monitoring and giving feedback on performance (NICE, 2014).

NICE recommendations for management of T2DM in adults are centred on tailoring of care to every patient, educating patients, their carers and family members about diabetes and providing dietary advice, with minimal mention of physical activity (NICE, 2014). Both guidelines lack provision of specific advice relating to diet and physical activity.

A number of systematic reviews that have assessed efficacy of dietary, pharmacological, and behavioural interventions or their combination (Ajala, English, & Pinkney, 2013; Avenell, Broom, Brown, Poobalan, & Aucott, 2004; Dombrowski, Avenell, & Sniehotta, 2010; Franz, 2004; Franz *et al.*, 2007; Gallagher, Armari, White, & Hollams, 2013). These studies add more evidence to the recommendations as to what interventions are most effective for WL. Below is a short summary of the findings.

1.9.1.1 Summary of evidence for non-surgical weight loss interventions

Low carbohydrate and Mediterranean diets have been found to lead to greater WL than other diets in people with T2DM. Low-carbohydrate, low – GI, Mediterranean, and high-protein diets also led to greater improvements in glycaemic control compared with low-fat, high-GI, low-protein diets and diets recommended by the American Diabetes Association and the European Association for the study of Diabetes (Ajala *et al.*, 2013).

A review of long-term effects of treatments for obesity and implications for health (Avenell, Broom, Brown, Poobalan, & Aucott, 2004) found that low-fat diets were associated with greater WL than were pharmacological agents (Orlistat, Sibutramine, and Metformin), although the latter were found to provide additional health benefits. An exercise programme and/or a behavioural treatment added to a diet further improved WL. This study did not find sufficient evidence to assess low and very low energy diets.

Another systematic review, however, has found that diet only led to better weight outcomes than diet combined with physical activity, or physical activity alone (Dombrowski *et al.*, 2010).

Lastly, two reviews (Curioni & Lourenco, 2005; Franz *et al.*, 2007) have found that diet and exercise led to larger WL than diet or exercise alone, both in the short- and the long-term. The review by Franz and colleagues (Franz *et al.*, 2007) also included 7 studies using meal replacements, which, similarly to Orlistat, led to WL of about 9 kg at 6 months; and 11 studies using very low energy diets (VLEDs), which resulted in twice that WL at 6 months, and a considerable weight regain within 3 years of follow-up.

Most reviews reported small sample sizes and small number of included studies as limitations, therefore conclusions based on these reviews can only be drawn with caution. There is little evidence on the use of VLEDs in particular, despite their effects on WL and improvements in BGL.

This thesis focussed on updating the knowledge of efficacy, safety and acceptability of VLEDs in people with T2DM according to the current evidence, by conducting a systematic review (described in detail in Chapter 3: Methods).
The next section describes VLEDs in more detail.

1.9.2 ***Very low energy diets (VLEDs) for weight loss***

Very low energy diets are defined as diets comprising of 250-800 kcal/day (National Heart Lung and Blood Institute, 1998,) and have been used since around 1970 (Tsai & Wadden, 2006a) to induce rapid WL in obese people. Using VLEDs in treatment of uncomplicated obesity resulted in good clinical results (Pekkarinen & Mustaioki, 1997), but a number of medical complications due to imbalanced nutritional content, and have therefore not been considered safe. Over the last 20 years, VLEDs have been re-designed to provide optimal nutrition, and have been reported clinically safe in a small number of studies, with an average WL of 10% of body weight and improvements in BGL (Amatruda, Richeson, Welle, Brodows, & Lockwood, 1988; Henry & Gumbiner, 1991; Pekkarinen & Mustaioki, 1997).

As seen from the reviews above, there is limited evidence that VLEDs are more effective for WL than other non-surgical interventions, although low energy diets (LEDs, 800 – 1500 kcal/d) lead to similar long-term WL (Norris *et al.*, 2009), have similar attrition rates (Tsai & Wadden, 2006a; Wing, Marcus, Blair, & Burton, 1991),

and fewer side effects (Rössner & Flaten, 1997). There has been an ongoing debate about whether or not there is an advantage of using VLEDs over LEDs due to the similar outcomes in the long term, the less extreme nature of the LEDs and thus hypothetically better treatment adherence. On the other hand, VLEDs induce almost twice the short-term WL compared to LEDs (Tsai & Wadden, 2006a) and more WL compared to other less aggressive calorie restricted dietary interventions (Franz, 2004; Ryttig K, Flaten, & RÖSsner, 1997). These findings suggest that VLEDs may be the second best solution for long-term WL, however, if appropriate and effective maintenance follows such diet, VLEDs may have the potential to become irreplaceable in rapid, short-term WL in obese individuals with T2DM and potentially improve their glycaemic parameters.

1.9.2.1 Acceptability of VLEDs

Adherence is arguably an indirect measure of acceptability of an intervention and hypothetically a predictor of intervention success. Higher adherence to any dietary programme is associated with better WL outcomes (Alhassan, Kim, Bersamin, King, & Gardner, 2008), although certain diets are easier to adhere to than others. For example, low-carbohydrate diets have been reported to be more difficult to adhere to than low-fat or Mediterranean diets (Greenberg, Stampfer, Schwarzfuchs, & Shai, 2009). VLEDs are high –protein diets, thus also low in carbohydrates, so adherence to them could be similarly problematic. Furthermore, adherence to VLEDs has been found to decrease dramatically during a VLED repeated over time (Smith & Wing, 1991), implying that a multitude of dietary attempts do not necessarily lead to additional WL benefits.

A Cochrane review (Nield *et al.*, 2009) on dietary advice for treatment of T2DM in adults only reported 2 studies that had treated people with VLEDs (the same ones as in the review by Norris et al, 2009) and provided very vague reports of adherence to VLEDs.

Qualitative evidence is also a good source of information about acceptability of VLEDs. However, due to VLEDs still being quite a re-discovered approach to WL and management of T2DM, qualitative studies are sparse. In one study, focus groups were held a year after the intervention with participants who had participated in a 3-months long VLED followed by a corset vs. no-corset treatment and lifestyle advice for 9 months (Östberg, Wikstrand, & Bengtsson Boström, 2011). The participants`

motivation to join the programme, experience of the VLED (psychological and physiological reactions; support, pitfalls and related costs), and retrospective views of the diet and the corset treatment were discussed. Health-related fears such as the prospect of cardiovascular diseases and diabetes were perceived as the main threats and seemed to be the main motivation for participation in the study. The identified barriers to WL were mostly related to external rather than internal factors, such as work-related stress or life events, although physical injuries and tiredness also played a role. Last, but not least, body image, identity, support network and increased psychological well-being seemed to have added to a positive evaluation of the VLED. This study has shown that undergoing a VLED should not be of great difficulty to obese individuals and that its benefits outweigh its costs. However, there are two possible shortcomings in using focus groups at a 1-year follow-up: self-presentation and recall bias. Although focus groups may be a suitable and productive method of data collection in evaluation research, participants in focus groups may be prone to, depending on the group dynamics, reporting positive rather than negative experiences due to perceived social pressure, or lack of self-confidence. Participants in focus groups may also be reluctant to express and discuss their own experiences or may conform to the most present opinions in the group. Given the interviews took place a year after the WL initiation with a WLM programme following it, it is probable that the recall of the participants` experience was not accurate.

Another qualitative study comparing people`s experiences across four commercial WL programmes has found that the main motivation for participants to enrol in a WL program was increasing self-worth by losing weight, rather than health concerns. This finding underlines the importance of conducting a study with people with T2DM, since their motivation might be driven by different factors compared to diabetes-free individuals.

Adherence and acceptability of VLEDs in people with T2DM are under-researched. To my best knowledge, no qualitative studies have explicitly explored patient acceptability, experience with and adherence to VLEDs in this population. Due to the lack of both quantitative and qualitative evidence on this topic, the aims of this thesis were to determine efficacy and acceptability of VLEDs in people with T2DM and to explore experiences of people with T2DM with a VLED in a qualitative study.

1.9.3 ***Surgical treatment options***

Where non-surgical approaches to WL fail, some surgical treatments may be helpful. A surgical therapy for morbid obesity, a bariatric surgery, represents a group of effective treatments of obesity and its comorbidities. On average, a loss of approximately 60% of excess weight can be achieved by bariatric surgery, with biliopancreatic diversion with duodenal switch providing the best results, followed by gastroplasty, gastric bypass, and gastric banding (Buchwald, Avidor, Braunwald, & et al., 2004). A complete diabetes resolution through bariatric surgery can be achieved in about 78%, and an improvement or resolution can be seen in about 87% of patients (Buchwald *et al.*, 2009). Below is a short description of the most frequent bariatric procedures.

1.9.3.1 Gastric bypass

Laparoscopic Roux-en-Y gastric bypass was first described in 1994 (Wittgrove, Clark, & Tremblay, 1994). It is an irreversible procedure causing restriction and malabsorption of food by creating a small pouch at the top of stomach, which is directly attached to the small intestine, bypassing the rest of the stomach and duodenum. This procedure enables less food to be held in the stomach as well as less calories to be absorbed by bypassing the bowel.

1.9.3.2 Gastric banding

Laparoscopic adjustable gastric banding was also first reported in 1994 (Belachew, Legrand, Defechereux, Burtheret, & Jacquet, 1994). This procedure is reversible and purely restrictive. In gastric banding, a small band is placed around the top of the stomach in order to divide it into a smaller pouch on top and a larger pouch under the band. The purpose of this surgery is to decrease food intake by decreasing the size of the stomach, so it takes less food for a patient to feel full. The band can be adjusted after the surgery.

1.9.3.3 Sleeve Gastrectomy

Sleeve gastrectomy was originally part of the biliopancreatic diversion with duodenal switch procedure (Regan, Inabnet, Gagner, & Pomp, 2003) and was later recognised as a standalone bariatric treatment (Clinical Issues Committee of the American Society for Metabolic and Bariatric Surgery, 2010). In sleeve gastrectomy, large part of the stomach is removed, so that less food can be eaten and the patient feels full earlier.

1.9.3.4 Biliopancreatic diversion with a duodenal switch

This procedure is one of the most complicated types of WL surgeries and was first described in 1998 (Hess & Hess, 1998; Marceau *et al.*, 1998) as a novel procedure combining restriction and malabsorption. Similarly to the sleeve gastrectomy, a large proportion of stomach is removed in this procedure. The middle section of the intestine is cut off, and the last part of the intestine is attached to the duodenum. The middle section of the intestine is not removed from the body, but is re-attached to the end of the intestine, allowing bile and pancreatic juices to flow through this part of the intestine. The combination of a smaller-sized stomach and a shorter small intestine leads to a decrease in food intake and calorie absorption at the same time.

Although all of these treatments provide excellent clinical results, they also introduce several post-operative complications (Buchwald *et al.*, 2004; Buchwald *et al.*, 2009; Franco, Ruiz, Palermo, & Gagner, 2011). Furthermore, an economic evaluation has shown that bariatric surgery is a more effective intervention than non-surgical interventions for long-term WL, though variability in costs is large and therefore cost-effectiveness cannot be determined with a high level of certainty, other than being more costly than non-surgical interventions (Picot *et al.*, 2010). Due to bariatric surgeries being costly and complicated procedures, there are restrictions as to who is eligible to receive them. In the UK, one must have a BMI > 40 kg/m2, or have a BMI > 35 kg/m2 and another serious health condition, that can be improved by WL (such as T2DM). Adults, who have been diagnosed recently and have a BMI of 30 – 34.9 kg/m2 may also be considered for bariatric surgery (NHS Choices, 2015).
Around 86% of people with T2DM are overweight or obese, around 52% are obese and only 8% are morbidly obese (Daousi *et al.*, 2006). Public Health England has estimated that in 2012, 62% of adults were overweight or obese, 24.7% were obese and 2.4% were severely obese (Gatineau *et al.*, 2014). This means that most people with T2DM would not qualify for a bariatric surgery and even if they did, they would have to undergo non-surgical interventions first (NHS Choices, 2015), which makes the bariatric surgery less accessible to most people who could benefit from it.

In summary, a VLED is an efficacious non-invasive intervention for WL in obese people, but their efficacy, safety and acceptability for use in people with T2DM has not been determined. Speedy weight gain tends to occur after WL through VLEDs

and a WLM programme should follow after VLEDs to achieve optimal results in the long-term.

1.10 Weight loss maintenance (WLM)

There is no consistent definition of what a successful WLM is. It has been recommended, that long-term WLM in adults be a change of < 3% in body weight, although these recommendations vary among guidelines such as those by the World Health Organisation (WHO), the Institute of Medicine (IOM), and the National Heart, Lung and Blood Institute (NHLBI) (Stevens, Truesdale, McClain, & Cai, 2005).
As a matter of general consensus, a cut-off point of ≥ 5% or ≥ 10% WL kept off for at least 1 year is used in most quantitative and qualitative studies (Avenell, Broom, Brown, Poobalan, & Aucott, 2004; Byrne, Cooper, & Fairburn, 2004; Dombrowski, Knittle, Avenell, Araújo-Soares, & Sniehotta, 2014a; Douketis, Macie, Thabane, & Williamson, 2005; Hindle & Carpenter, 2011; Reyes *et al.*, 2012; Sciamanna *et al.*, 2011; Wing & Hill, 2001), although the 10% WL may be more protective than smaller WL (Barte *et al.*, 2010).
Weight loss tends to peak and plateau around the 6th month from the start of a WL programme for most interventions (Dombrowski *et al.*, 2010; Franz, 2004; Franz *et al.*, 2007). It is important that the effect of WL within the first 6 months is not undone by ineffective WLM afterwards. It has been shown that keeping the lost weight off is beneficial for prevention of T2DM. A study by Penn and colleagues (Penn, White*, et al.*, 2013) has found that participants with impaired glucose tolerance, who maintained a WL of ≥ 5% at 1 year, had 65% lower incidence of T2DM and that the incidence rate decreased with longer successful WLM. This is particularly important for prevention of recurrence of T2DM once it has been improved or reversed in people with T2DM who have lost weight.

Out of WL interventions, bariatric surgery was found to lead to 25-75 kg WL after 2-4 years, pharmacologic therapy to 5-10 kg after 1-2 years and dietary/lifestyle therapy leading to less than 5 kg WL after 2-4 years (Douketis *et al.*, 2005). The problem with surgical or pharmacologic therapies is, that they are costly and do not necessarily lead to a behaviour change, which would be desirable for patients and cost-effective for health services from a long-term perspective.

A more optimistic scenario of long-term WLM has been laid out by Wing and Hill (Wing & Hill, 2001), who analysed data from a National Weight Control Registry in the US. The database is a collection of yearly questionnaires from self-selected participants, who have lost at least 13.6 kg and have kept it of for at least 1 year. According to the Registry, the average WL reported by the participants was 30 kg, with average WLM period (keeping a 10% WL off for 1 year) of 5.5 years. Majority of the participants reported having modified both, diet and exercise; and self-monitored frequently, thus changed their behaviours, in order to succeed at WLM.
The reason why people may struggle to successfully maintain their WL may be, that different strategies need to be employed during the WL and the WLM phases. A national survey exploring practices associated with successful or unsuccessful WL and WLM has found that out of 36 weight control practices, only 8 were associated with both, WL and WLM (Sciamanna *et al.*, 2011). Four practices were associated with WLM, but not WL: eating a diet rich in low-fat protein, exercise routine, rewarding oneself for adhering with the exercise/diet plan, reminding oneself of the need to control the weight. Developing exercise and dietary routines, together with self-monitoring of weight and exercise are the most reported successful WLM strategies. Other strategies of successful WLM include greater initial WL, meeting self-determined WL goals, control of over-eating, but avoiding food deprivation and having effective coping skills (Dombrowski *et al.*, 2014a; Elfhag & Rössner, 2005; Hindle & Carpenter, 2011; McKee, Ntoumanis, & Smith, 2013; Reyes *et al.*, 2012; Wing & Hill, 2001; Wing & Phelan, 2005). The change in diet and physical activity combined has been found to result in a 20% greater sustained WL after 1 year compared to diet alone (Curioni & Lourenco, 2005) .

External factors also influence one`s success at WLM. For example, a review on the effect of extended care has found that extended care after WL lead to a maintenance of additional 3.2 kg over 18 months post-intervention (Ross Middleton, Patidar, & Perri, 2012) and another study found that regular follow-ups, supervised exercise, dietary counselling and social support facilitated WLM (Perry, Hickson, & Thomas, 2011).

In addition to the previously stated aim of exploring the experience with and adherence to VLEDs in people with T2DM, I also aimed to explore the experience of WLM after a significant WL through VLEDs in people with T2DM.

1.11 Conclusions

Current evidence is limited in showing how effective and acceptable VLEDs are in the short term and how to best maintain the lost weight. In this PhD, I aimed to determine the efficacy and acceptability of VLEDs among people with T2DM as well as explore peoples` experience with WL through VLEDs and with WLM following it, in terms of their perceived barriers and facilitators of adherence to a VLED. I also aimed to identify the behavioural strategies that help people overcome the barriers and enhance the facilitators and to identify the support needs they may have during the process of behaviour change and maintenance.

Chapter 2

A review of key perspectives of behaviour change theories for weight management.

2.1 Introduction

There are a number of ways overweight and obesity can be prevented and treated, however, some weight management interventions are more effective than others. In order to best support behaviour change, it is important to understand the process of change and to identify the active intervention ingredients. Behaviour change theories provide testable hypotheses that guide intervention development and implementation. The UK Medical Research Council's guidance for developing and evaluating complex interventions (Campbell et al., 2000, 2007; Craig et al., 2008; Glanz & Bishop, 2010) advocates use of theory as an integral step in intervention design, evaluation, and in evidence synthesis. Behaviour change theories help identify and target antecedents of behaviour and the causal determinants of change (Hardeman et al., 2005; Michie & Abraham, 2004; Michie et al., 2008) and select, and/or refine and tailor behaviour change techniques (Michie & Prestwich, 2010; Michie et al., 2008; Rothman, 2004). Theoretically identified mechanisms of action (i.e., mediators) can be investigated to gain further understanding of how an intervention works (Michie & Abraham, 2004; Rothman, 2004, 2009). This allows researchers to determine whether unsuccessful interventions failed because the intervention had no effect on the hypothesised mediator or because the hypothesised (and successfully influenced) mediator had no effect on behaviour (Michie & Abraham, 2004; Rothman, 2004, 2009), thus facilitating more efficient refinement of the intervention. Theory also summarises the cumulative knowledge of how to change behaviour across different populations, behaviours and contexts. Finally, theory-based interventions provide an opportunity in which theory can be tested. This aids development of more useful theories which, in turn, supports intervention optimisation (Michie et al., 2008; Rothman, 2004).

Intervention effectiveness may be affected by a number of factors such as intervention content, mode of delivery, the nature of the targeted condition,

intervention length and intensity, and others. In order to identify which intervention features contribute to intervention efficacy, it is important that studies report whether or not their intervention is based on a theory, and whether or not the intervention is more or less efficacious because of that. Some evidence suggests that theory-based behaviour-change interventions are more efficacious than those not based on a theory, irrespective of the theory used, and that interventions based on one theory are more efficacious than interventions based on a combination of theories (Gourlan *et al.*, 2016). Others have found that reporting or not reporting a theoretical background does not make a difference to intervention effectiveness (Prestwich *et al.*, 2014). Given that just under 60% of studies targeting change in physical activity or eating behaviours report that their interventions are theory-based (Prestwich *et al.*, 2014), it may be the lack of explicit reporting rather than the lack of efficacy of theory-based interventions making the evidence inconclusive, as some of the studies not reporting a theory may still have used constructs that link to one theory or another. The Medical Research Council recommends that the best practice is to develop interventions systematically, using the best evidence and appropriate theory (Craig *et al.*, 2008).

The aim of this thesis is to identify 1) the motives of people who took part in a weight management programme using VLEDs (the Counterbalance study), 2) barriers and facilitators of adherence with it, and 3) behavioural strategies facilitating WL and WLM and 4) to understand peoples` experience with the WL and WLM interventions. This chapter aims to provide an overview of theoretical perspectives in health psychology relevant to weight managemen. It provides a theoretical background and a framework of analysis to the qualitative work I have conducted during this PhD and it reviews the current theoretically derived hypotheses of motives, barriers to and facilitators of adherence with a WL and WLM interventions.

2.2 Theoretical determinants of behaviour initiation and maintenance

Motivation (used interchangeably with intention) to engage or not to engage in behaviours that may be beneficial to a person`s health together with other determinants of behaviour have been central to behaviour change theories. With T2DM being strongly associated with overweigh and obesity (Astrup & Finer, 2000; Hauner, 2010), weight management is important for people with T2DM from healthcare professionals` and public health perspectives. However the perspective of an individual attempting to lose weight may be different, taking into account that

patients and general practitioners often attribute different causes to the patient`s weight status (Ogden *et al.*, 2001). There is a variety of reasons why people wish to manage their weight better, most of them related not only to health, but to other desires, such as looking and feeling better (Alm *et al.*, 2008; Brink & Fergusson, 1998; Santos, Sniehotta, Marques, Carraça, & Teixeira, 2017; Vartanian, Wharton, & Green, 2012), which usually come with successful WL and maintenance, achieved by only about 20% of dieters (Wing & Phelan, 2005).

Early theories of behaviour change suggested that people were motivated to engage in health behaviours if they perceived themselves to be susceptible enough to a certain condition and the condition was severe enough (the Health Belief Model (HBM) (Becker, Maiman, Kirscht, Haefner, & Drachman, 1977; Hochbaum, 1958; Rosenstock, 1974). For example, considering oneself as being at risk of developing T2DM promotes engagement in the planning of change (Penn, Dombrowski, Sniehotta, & White, 2013) and receiving high-fear messages about obesity helps mothers manage their children`s weight better (Becker *et al.*, 1977). According to the HBM, people engage in health behaviours to avoid negative consequences. The *Theory of Reasoned Action* (TRA) (Ajzen & Fishbein, 1970) and its later extension, the *Theory of Planned Behaviour* (TBP) (Ajzen, 1985) proposed that the role of attitudes and beliefs and expectations were key to peoples` motivation to behaviour change. In comparison with the HBM, the motivation to act in these models is determined by one's attitude towards a behaviour and subjective norms (whether others approve or disprove of a behaviour) rather than by fear. This implies that people may engage in health-behaviours not only to avoid negative consequences, but also to enhance their health. Such motivation is expected to be the main reason to taking part in a WL programme using VLEDs among the participants in this study, who already have T2DM and for whom fear of worsening of their health would be anticipated as opposed to fear of developing a condition, although the fear of developing T2DM comorbidities in the future may also play a role in their motivation.

What the above models did not fully acknowledge was how interaction of people with their environment can shape behaviour because they affect each other, which Bandura referred to, within his Social Cognitive Theory (Bandura, 1989, 1998), as "reciprocal determinism". Self-efficacy[3], outcome expectancies and barriers are

[3] One`s belief in their capability to perform in a way that influences events affecting their life in the desired direction by achieving goals (Bandura, 1994)

hypothesised to be the key determinants of intentions and behaviour and have helped to explain the intention-behaviour gap, when intentions did not always translate into behaviour. The role of self-efficacy in the formation of motivation to change and its role in behaviour maintenance was further emphasised in the Health Action Process Approach theory (HAPA)(Schwarzer, 2008; Schwarzer *et al.*, 2003b) in which self-efficacy is the strongest predictor of behavioural intentions and is specific to all stages of progression towards behaviour change (action/task, maintenance and recovery self-efficacy).

The general assumption of these behaviour change models (also called continuum models) is that motivation or intention is the main predictor of behaviour and that there are various determinants of motivation ranging from perceived susceptibility, severity and risk, attitudes towards a behaviour, beliefs, social norms, cognitions, self-efficacy, and environmental and other factors. In contrast to the continuum models, stage models propose that behaviour change happens in stages and that every stage may be influenced by a different set of factors. Behaviours observed at each of the stages are conceptualised as qualitatively different and an inclination to change behaviour increases with progression from one stage to another. One must pass through all stages to achieve the desired outcome, although achieving it is not inevitable and progression from one stage to another is reversible (e.g. in case of lapse) (Weinstein, Rothman, & Sutton, 1998) . The Trans-theoretical Model (TTM) (Prochaska & DiClemente, 1983) distinguishes the following stages an individual needs to pass through to achieve behaviour change: 1) *Pre-contemplation* (no desire to change behaviour within the next 6 months), 2) *Contemplation* (considering behaviour change within the next 6 months), 3) *Preparation* (acknowledging the need for change, planning to make a start of the change within the next 3 months), 4) *Action* (active behaviour change lasting up to 6 months), and 5) *Maintenance* (continuation of action for more than 6 months), and 6) *Termination* (old behaviour is no longer a threat and new behaviour has become a routine). It is also acknowledged that a relapse can occur at any stage and it may be an alternative last stage instead of Termination (Prochaska & Velicer, 1997). Bandura's self-efficacy construct (Bandura, 1994) has also been adapted in the TTM and it refers to the increasing behavioural mastery with progression from one stage to another. Decisional balance, a list of pros and cons related with a particular action, changes with stage progression (Prochaska *et al.*, 1994). For example, people who are overweight have

a different proportion of pros and cons related with regular exercise behaviour in overweight at different stages (Sarkin, Johnson, Prochaska, & Prochaska, 2001).

Both HAPA and the TTM have acknowledged behaviour maintenance as part of the behaviour change process. Many theories imply that behaviour maintenance is achieved once behaviour initiation is achieved and repeated, but behaviour initiation and maintenance are two distinct phases of the behaviour change process, otherwise people who would successfully adopt a new behaviour would not fail to maintain it (Rothman, 2000a). Rothman suggests that the difference between behaviour initiation and maintenance is in the decisions a person needs to consider. A number of the previously discussed models included the weighing of pros and cons and a favourable expectation of future outcomes in deciding whether or not to engage in behaviour initiation, while the decision to maintain a behaviour depends on the person`s experience with behaviour initiation and the desirability of continuation of the new behaviour, which also depends on the level of satisfaction with the achieved outcomes. While behaviour initiation can be seen as an approach-based self-regulatory process (reducing the difference between the current and the desired state), behaviour maintenance is more of an avoidance-based self-regulatory process (maintaining a difference between the current and the undesired state) (Rothman, Baldwin, & Hertel, 2004). In order to better capture the process of transition from behaviour initiation to maintenance, Rothman and colleagues (Rothman *et al.*, 2004) suggested different stages of behaviour change: initial response, continued response, maintenance and the creation of habit.
The difference between behaviour initiation and maintenance is pronounced in weight management research. Even though WL interventions are relatively successful (Jolly *et al.*, 2011), attrition and relapse rates are high (Tsai & Wadden, 2006c) and even if WL programmes are completed and behaviour initiation is achieved, but is not sustained, much of the benefits from interventions can be diminished if not completely negated (Avenell, Broom, Brown*, et al.*, 2004a; Dombrowski *et al.*, 2014a). A review by Franz and colleagues has shown that even though WL interventions including VLEDs are most effective, there is little benefit left if the behaviour change is not sustained over time (Franz *et al.*, 2007).
Kwasnicka and colleagues (Kwasnicka, Dombrowski, White, & Sniehotta, 2016) have conducted a robust review of behaviour change maintenance theories and have identified five overarching themes reflecting the theoretical explanations of behaviour

maintenance over time and in different contexts: maintenance motives, self-regulation, resources, habit and environmental and social influences. Variability of behaviour determinants across time and contexts have otherwise been touched upon very little by the behaviour initiation oriented theories. Although there is an assumption, e.g. in the stage theories that, on a timeline, one stage lasts a particular amount of time and that one stage precedes the next one, none of the theories have explicitly described the relationship of current behaviour to future outcomes and how the attached value of these outcomes changes at different times, which is applicable to both behaviour initiation and maintenance. Such "connectedness beliefs" and "temporal valuations" are central to the Temporal Self-Regulation Theory (TST) (Hall & Fong, 2007), which proposes that short-term benefits of undesirable behaviours may override any long-term benefits of the desirable behaviours in the heat of the moment. Hall and Fong (2007) propose that the reasons why intentions do not always translate into behaviour are that either intentions are not perfectly translatable into behaviour, that that they are not reported accurately, or that they sometimes change just before a behaviour should happen. This is because people have dominant behavioural responses to certain situations (*behavioural prepotency*) and their engagement in behaviours is also determined by their executive control resources, or their capacity to self-control in critical situations (*self-regulatory capacity*). Pre-potency is hypothesised to be influenced by norms towards the behaviour, habit, and a drive state facilitating or inhibiting behaviour, while the executive function may be influenced by the person`s ability to efficiently adapt to changing performance rules (mental flexibility), working memory, and the ability to suspend prepotent responses (inhibition). This theory is easily applicable to weight management behaviours. For example, a person trying to lose or maintain weight has a craving when they are bored. According to the TST, depending on how the person reacted to such situation in the past and on their self-control capacity, they may resist the temptation or not. Not resisting the temptation is much more attractive in situ and would have the short-term benefit of making the person feel satisfied, although it would defeat the long-term benefit of resisting, which might change their dominant behavioural response in the future and help them lose/maintain weight in the end, but it is associated with a cost – increased and prolonged levels of self-control.

The TST considers both rational and irrational processes, internal capacities, time and context of behaviours. Hall and colleagues (Hall, Fong, & Cheng, 2012) have

examined the relationship between time perspective and weight management behaviours (avoidance of fatty foods and physical activity) among people newly diagnosed with T2DM over a 6-months period. They found that future-oriented individuals reported better management behaviours and this relationship was mediated by strength of intentions, adjusted for demographic, body composition and disease variables. The same result was reported in a cross-sectional study on attempts to quit smoking among almost 9000 individuals (Hall, Fong, Yong*, et al.*, 2012). Natural orientation towards long-term goals may therefore facilitate behaviour change.

The notion that behaviour is not only determined by rational but also irrational or impulsive thinking had been developed in dual-process theories. These suggest that there are two distinct modes of information processing, mostly recognised in literature as the impulsive and the reflective systems (Hofmann, Friese, & Wiers, 2008; Strack & Deutsch, 2004) or System 1 and System 2 (Kahneman & Frederick, 2002) and others (for overview see Evans et al., 2008). The impulsive system processes information automatically, unconsciously, intuitively, and quickly, while the reflective system is characterised as deliberate, controlled, analytic and slow (Evans, 2008). The notion of the internal conflict that these two systems create within an individual has been beneficial to a better understanding of peoples` WL and maintenance behaviours and the barriers they have to overcome. Hofmann and colleagues (Hofmann, Rauch, & Gawronski, 2007) demonstrated the influence of the impulsive system on eating behaviour in a study where they assigned participants into an emotion suppression or an emotion flow task, after which the participants were offered to taste candies. They found that only participants who were in the depletion condition ate more candies, as a function of automatic positive attitudes towards them and despite their dietary restraint standards, which were positively associated with candy consumption in this group, but negatively associated with candy consumption in the non-depleted group. Hofmann, Friese and Wiers (Hofmann *et al.*, 2008; Hofmann, Friese, & Wiers, 2011) later suggested a framework for prediction of health-related behaviours which combined both influences together with situational moderators that tip the balance between the reflective versus impulsive systems and have reviewed a vast amount of literature on the moderators of the weight of the system`s antecedents of behaviour including cognitive load, depletion of resources, trait self-control, working memory capacity, alcohol consumption, habituality of

behaviour, mood, affect and motivation to control one`s behaviour. The range of studies of various health behaviours included in the review consistently suggested that automatic or impulsive reactions predict suboptimal health behaviours in highly habitual individuals with depleted resources.

Tension between the two systems creates a conflict between multiple goals that an individual may hold at the same time. Goal conflict is key in weight management and Stroebe and colleagues suggested that restrained eaters (chronic dieters) often fail in their weight management attempts due to the conflict between incompatible goals related with their eating behaviours: the hedonic (eating for enjoyment) and the control (trying to regulate wright) goals (Stroebe, Mensink, Aarts, Schut, & Kruglanski, 2008). Restrained eaters are more sensitive and reactive to food cues and get a stronger incentive from palatable food than non-restrained eaters (Fedoroff, Polivy, & Herman, 1997). Perhaps everyone is familiar with Mischel and colleagues` delay of gratification study (better known as the Marshmallow experiment) (Mischel, Shoda, & Rodriguez, 1989) in which he demonstrated that focusing on abstract/"cold" (shape, colour, etc…) rather than on arousing/"hot" qualities (palatable, smell, crunchiness, etc..) of a reward determines the length of gratification delay. On the other hand, thinking about arousing qualities of a comparable object that is not a reward facilitates gratification delay. One of the reasons restrained eaters struggle resisting temptations is that they are more likely than non-restrained eaters to spontaneously activate hedonic thoughts after being primed by arousing properties of food (Papies, Stroebe, & Aarts, 2007, 2008) and that these happen outside of the eater`s awareness. In addition, Baumeister and colleagues showed in a series of experiments that self-regulatory resources are limited and their continuous use leads to depletion of self-regulatory capacity (Ego-depletion) (Baumeister, Bratslavsky, Muraven, & Tice, 1998; Vohs & Heatherton, 2000). Restrained eaters may therefore have to put more effort into resisting temptations than non-restrained eaters and they need to do it by inhibiting hedonic thoughts, however this is difficult in the increasingly stimulating foodscape.

2.3 How useful are behaviour change theories for weight management?

There has been notable progress in the development of health behaviour change theories and their ability to predict and explain behaviour in the past decades, although even the predominant theories are still some way from providing

satisfactory explanations of behaviour. For example, the TPB has been perhaps the most widely used and tested behaviour-change theory, and its core determinants (attitude, subjective norm and perceived behavioural control) explain 39 to 45% of the variance in intention (Armitage & Conner, 2001; Hagger, Chatzisarantis, & Biddle, 2002; McEachan, Conner, Taylor, & Lawton, 2011; Trafimow, Sheeran, Conner, & Finlay, 2002), while the whole model explains 19 to 34% of behaviour (Armitage & Conner, 2001; Godin & Kok, 1996; Hagger *et al.*, 2002). In weight management research, the TPB explains 32% and 42% of the variance in the intention to change eating and exercise behaviours, respectively (Godin & Kok, 1996; McEachan *et al.*, 2011). The HBM, TRA and TPB have progressively improved our understanding of the determinants of weight management behaviours. While the HBM explained 57% of the variance in intention and 29% in dieting, the TPB explained 67% of the variance in intention and 35% in dieting (Nejad, Wertheim, & Greenwood, 2005). In people with T2DM, the SCT explains 52-59% of the variance in intentions, however this does not always translate into long-term behaviour change (Plotnikoff, Lippke, Courneya, Birkett, & Sigal, 2008) and other determinants of behaviour need to be accounted for during the maintenance of behaviour change.

Self-efficacy itself explains 15-53% (Allen, 2004), with the full SCT model explaining 40-55 % of variance in physical activity (Anderson, Wojcik, Winett, & Williams, 2006; Conn, Burks, Pomeroy, & Cochran, 2003; Rovniak, Anderson, Winett, & Stephens, 2002). Self-efficacy is therefore key to understanding behaviour and it being associated with social support, affect and frequency of physical activity (McAuley, Jerome, Elavsky, Marquez, & Ramsey, 2003) further supports inclusion of socio-cognitive variables in behaviour change models and a shift towards more complex models.

Seven constructs of the HAPA model (risk-perception, action self-efficacy, outcome expectancies, maintenance self-efficacy, action and coping planning, behavioural intention, and recovery self-efficacy) explain around 80% of the variation in both physical activity (Rohani, Eslami, Ghaderi, Jafari-Koshki*, et al.*, 2016) and healthy diet (Rohani, Eslami, Ghaderi, bidkhori, & Raei, 2016) in people with T2DM. The model has been further tested in predicting changes in psychological, body composition and cardiovascular risk outcomes in overweight and obese adults with respect to participation in physical activity (Hattar, Pal, & Hagger, 2016), generally confirming the relationships suggested by HAPA. The limited available evidence suggests that using HAPA-based or HAPA-like interventions targeting physical

activity and diet to promote WL are effective in the short and the long-term (Smith, Murray, Greaves, Hooper, & Abraham, 2014). However, contrary to some of its assumptions, changes in risk perception do not always result in changes in intention, which was also found in studies on fearful communication (Peters, Ruiter, & Kok, 2013). Another study found that only risk awareness and (recovery) self-efficacy contributed to the independent prediction of healthy eating among people with T2DM, but the overall model did not (MacPhail, Mullan, Sharpe, MacCann, & Todd, 2014). The results around the role of risk awareness in weight management studies with people with or without diabetes might raise the possibility that people with diabetes (and perhaps with other health conditions) give health threats more weight than people without a chronic condition do. Future theories of behaviour change informing interventions for people with a health condition might seek to explore this hypothesis further.

2.4 Shortcomings of behaviour change theories

Progress in the development of behaviour change theories has enabled further elaboration of the models and consideration and testing of new constructs and theories. Although there was support for many of the models initially, (Armitage & Conner, 2000; Janz & Becker, 1984; Taylor *et al.*, 2006), they also attracted critique from health psychology researchers. The HBM has been criticised for lack of definition of its constructs and interactions between them (Sheeran & Abraham, 1996), its weak predictive power in most health behaviours (Harrison, Mullen, & Green, 1992; Taylor *et al.*, 2006) and in comparison with later models, its failure to incorporate constructs that were later considered strong predictors of behaviour, such as self-efficacy and intentions/goals.

The TPB has been criticised for a number of reasons regarding validity and utility (Sniehotta, Presseau, & Araújo-Soares, 2014) (Hardeman *et al.*, 2002), and its over-reliance on subjective perception of events and rational decision-making and not taking into account the role of emotions, unconscious or other influences. For example, it has been shown that other environmental, psychosocial and demographic variables predict behaviour beyond the TPB (Conner & Armitage, 1998; Sniehotta *et al.*, 2013), demonstrating that that changing individual cognitions is not sufficient to create behaviour change. In addition, the TPB predicts self-reported behaviour better than observed behaviour (Armitage & Conner, 2001), which may be problematic for

interpretation of studies on weight management in particular. These are mostly reliant on self-reports that can be considerably inaccurate given that people tend to under-report their calorie intake by 47%, while they over-report their physical activity by 51% (Lichtman *et al.*, 1992).

Similarly, one reason why much of the evidence based on the TTM is limited or inconclusive (Taylor *et al.*, 2006) is the lack of definition of the instruments to assess the stages of change, the variables involved in progression from one stage to another, or that the model is poorly applied in interventions, focussing on the single variable of stage and neglecting the constructs of self-efficacy, decisional balance or the processes of change (Bridle *et al.*, 2005; Horwath, 1999; Spencer, Adams, Malone, Roy, & Yost, 2006; Spencer, Wharton, Moyle, & Adams, 2007).

There is limited evidence of effectiveness of TTM-based health behaviour interventions in general across a number of health behaviours (Bridle *et al.*, 2005). Dietary or physical activity interventions based on the TTM produce minimal sustainable WL in overweight and obese adults, although such interventions may lead to improvements in physical activity and dietary habits (Mastellos, Gunn, Felix, Car, & Majeed, 2014). Some stage-matched interventions for people with T2DM result in an increase in physical activity frequency and length (Kirk, Mutrie, MacIntyre, & Fisher, 2003) and help people follow a healthier diet, improve diabetes outcomes and increase wellbeing (Andrés, Gómez, & Saldaña, 2008; Arafat, Mohamed Ibrahim, & Awaisu, 2016), while others are inconclusive (Salmela, Poskiparta, Kasila, Vähäsarja, & Vanhala, 2009).

Similarly to the TPB, this model has been criticised (Sutton, 2001; West, 2005a, 2005b) for not taking into consideration unconscious processes, habit, and the role of rewards and punishment in behaviour (West, 2005a). Some evidence shows that a simple contemplation or desire predict behaviour better than the TTM (Abrams, Herzog, Emmons, & Linnan, 2000; Pisinger, Vestbo, Borch-Johnsen, & Jørgensen, 2005). In addition, the arbitrarily defined stages of change were found to be a linear function of the TPB constructs (Armitage & Arden, 2002), suggesting that the TTM may be considered a pseudo-stage model, potentially excluding people who may benefit from interventions on the basis of being at the wrong stage (West, 2005a), which is why that model may serve best as only a proxy measure of behaviour.

Overall, there is little empirical evidence to support the idea that people progress through the stages in a given order and that stage-matched interventions are more effective than non-stage-matched ones (Sniehotta & Aunger, 2010) and a review by

the National Institute for Clinical Excellence (NICE) has concluded that there is little evidence that the use of TTM-based behaviour change strategies are better than alternative, “reasonably constituted” approaches (Taylor *et al.*, 2006).

In summary, there is much criticism of the above models. Their constructs are often imprecisely described and can be difficult to operationalise, test and accept or refute (Ogden, 2003; Sheeran & Abraham, 1996). They rely on and assume a strong association between intention and behaviour. While they explain a moderate proportion of the variance in intention, they fall short of explaining variance in behaviour, perhaps due to the moderate correlation between them (Godin & Kok, 1996; Orbell & Sheeran, 1998), with people translating their intentions into goals only 53% of the time (Sheeran, 2002). Tests of the theories relying on correlational data may overestimate the models` predictive power, which is why theories should be tested in experimental or quasi-experimental, rather than correlational designs (Weinstein, 2007).

2.5 Behaviour regulation strategies for weight management

Many of the theories discussed so far overlap in suggesting what determinants affect behaviour and show that weight-management behaviours are complex and that determinants of behaviour often depend on the particular behaviour and population concerned. Many also serve to explain rather than to change behaviour. In order to determine which intervention components are most effective in changing behaviour and how these link with the theoretical constructs associated with behaviour change, a group of psychology researchers identified 53 behaviour-change techniques (BCTs) they would use to change 12 previously identified key determinants of behaviour listed in the Theory Domains Framework (TDF) (Fishbein *et al.*, 2001; Michie, Johnston, Francis, Hardeman, & Eccles, 2008): 1) knowledge, 2) skills, 3) social/professional role and identity, 4) beliefs about capabilities, 5) beliefs about consequences, 6) motivation and goals, 7) memory, attention and decision processes, 8) environmental context and resources, 9) social influences, 10) emotion regulation, 11) behavioural regulation, and 12) nature of behaviours. The exercise was based on expert opinion rather than evidence, and further work on development of BCTs based on research resulted in 26 BCTs and the theoretical frameworks they were associated with (Abraham & Michie, 2008). Later, a comprehensive expanded

taxonomy of 93 BCTs grouped independently of theoretical structure was proposed (Michie *et al.*, 2013a).

To identify BCTs effective in weight management, a meta-regression of effective BCTs for healthy eating and physical activity in 44.747 people was conducted and found that the technique “prompt self-monitoring of behaviour” explained 13% of the heterogeneity across all evaluations and that interventions using this technique produced larger effect sizes than interventions not using the technique, but only 38% of studies used this BCT. Using self-monitoring in combination with any of the other four techniques from the Control theory (Carver & Scheier, 1982) (setting goals, monitoring of behaviour, receiving feedback on performance, and review of goals) results in larger effect sizes than when the techniques are not used for both, physical activity and healthy eating (Burke, Wang, & Sevick, 2011). People with T2DM who use goal setting, goal review, and social support for both physical activity and eating behaviour in combination lose more weight than those who only use it for either or none of the behaviours (Hankonen *et al.*, 2015a). Additional BCTs effective in promoting positive changes in health behaviour, well-being and clinical outcomes in people with T2DM specifically are: feedback on performance, providing information on consequences of behaviour, providing information on the consequences to the individual, barrier identification/problem solving, action planning, motivating oneself, preparing for setbacks, prompt focus on past success, providing information on where and when to perform behaviour, prompting generalisation of target behaviour, use of follow-up prompts, prompt review of behavioural goals, planning social support/social change, time management, goal setting, knowledge acquisition, and frequent follow-up (monitoring)(Avery, Flynn, van Wersch, Sniehotta, & Trenell, 2012; Hankonen *et al.*, 2015a; Sherifali, Viscardi, Bai, & Ali, 2016; van Vugt, de Wit, Cleijne, & Snoek, 2013).

Furthermore, interventions underpinned by a behaviour-change theory or a model, longer interventions (>6 months), and interventions offering at least 10-14 contact hours delivered in person may be most beneficial to people with T2DM (Avery *et al.*, 2012; Pillay, Armstrong, Butalia, & et al., 2015). On the other hand, supervised physical activity, use of pedometers or different modes of intervention delivery are not associated with better glycaemic control (Avery *et al.*, 2012).

Despite the number of BCTs, fewer than a quarter are used in implementation of interventions for providers or patients (Presseau *et al.*, 2015) and less than 40% of people enact the BCTs (Hankonen *et al.*, 2015a). Some research shows that the

more BCTs people with T2DM use, the larger reduction in BMI they achieve, although it seems that the change in BMI is facilitated by a higher number of physical activity-specific rather than by a higher number of diet-specific BCTs (Avery *et al.*, 2012; Hankonen *et al.*, 2015b).

The BCTs have been widely adopted by the health psychology community and existence of a common taxonomy should facilitate designing of behaviour-change interventions, better comparison of interventions based on content due to clearer reporting, easier replication of studies, and development of theory. However, in contrast to some of the previous studies, other research with a non-diabetic sample concluded that neither the number of BCTs, nor BCTs related with self-regulation affected the effect sizes of physical activity interventions (O'Brien *et al.*, 2015). Some researchers also argue that such level of systematisation and categorisation of theory and peoples` individual behaviours may result into rigid ways of working restraining research novelty and removing variability that is vital to the health psychology discipline (Ogden, 2016).

2.6 Theory-driven assumptions of the current study

The participants in the Counterbalance Study were asked to restrain themselves to approximately 800 kilocalories a day for 8 weeks. According to the theories presented above, a number of possible experiences of the participants could be forecasted. First, due to the strong medical focus of the Counterbalance Study, I expected that the motivation of the participants to take part in it would almost solely be related with the possibility of diabetes remission in a short space of time. Participants could be assumed to not only want to reverse their diabetes, but also to prevent future health complications and comorbidities. Secondly, I assumed that the participants` environments (e.g. work, shopping facilities etc.) were not going to change and could be perceived as highly tempting due to exposure to food, smells, social events or simply eating behaviours of other people. This may be especially true for participants who had tried diets in the past and who would be "restrained eaters", fighting some of their hedonic thoughts triggered outside of their awareness. Increasing awareness of situations in which the participants normally turn to food might be a useful facilitator of adherence to the VLED and the WLM phases of the Counterbalance Study.

Due to the continuous and radical restriction of calorie intake during the 8 weeks of VLED followed by a 6-month WLM phase, it could be expected that the participants would report more deviations from the respective regimes over time. This is because the possibility of diabetes remission at the start of the VLED and the WL achieved at the beginning of the WLM would have provided extra resources to draw from initially, which would then diminish over time. This might be prevalent in people who would find the regimes difficult to follow, those who would dislike it, or those who would find themselves using regulatory resources for a prolonged period without becoming used to the regimes and making their behaviours habitual. Getting used to the regime early on or even allowing oneself a deviation from the regimes once in a while might decrease the tension between their long-term goal of diabetes remission and WLM and their short-term goal of temptation satisfaction, and might therefore actually facilitate adherence. Finally, in order to succeed on the VLED and the subsequent WLM, the participants might need additional self-regulatory resources or skills to overcome temptations and facilitate adherence.

2.7 Theory-derived behaviour regulation strategies and facilitators of behaviour change

Some research shows that people with T2DM might deal with additional barriers to healthy eating or physical activity differently compared to healthy people or people with other health conditions. For example, Plotnikoff and colleagues found that people with T2DM struggle with barriers and goal setting more than people with T1DM (Plotnikoff *et al.*, 2008). Other barriers to healthy diet in people with T2DM include over-eating caused by stress, difficulty resisting temptation to eat unhealthy food or making unhealthy food choices (Marcy, Britton, & Harrison, 2011), difficulty changing habits, lack of motivation (Booth, Lowis, Dean, Hunter, & McKinley, 2013) or misconceptions on the components of an appropriate diet, and even social pressures to eat a traditional diet in some cultures (Sohal, Sohal, King-Shier, & Khan, 2015).

Behaviour change theories have addressed such barriers by suggesting strategies to overcoming them. For example, Bandura distinguished between personal (e.g. tiredness), situational (e.g. competing goals), and contextual (e.g. health system) barriers to performance of health behaviours and suggested four strategies to improve one`s sense of self-efficacy: *mastery experience* (successfully overcoming obstacles), *vicarious experience* (seeing other people similar to oneself succeed),

social persuasion (being provided positive appraisal and placing them in situations that set them for success), and *stress reduction*. Kuhl`s has suggested in his Self-regulation theory (Kuhl, 1992) that *control of attention* ("Don't look at food"), *motivation* ("It feels good to be losing weight"), *emotion* ("Happy thoughts help me stick with the diet"), *failure* ("I put yesterday's lapse out of my head"), *encoding* (activating "perceptual filters" for weight loss-related cues), *environment* (removing food from the environment) and parsimony of *planning* ("Stop thinking when you should start. Start!") should facilitate overcoming obstacles to implementation and maintenance of intentions[4].

To overcome the problem of translating action into behaviour and promote initiation and execution of goal-directed behaviours, Gollowitzer (Gollwitzer, 1993) further proposed to use *implementation intentions*: plans of when, where and how a behaviour will be carried out in a specific context. Implementation intentions should help an individual prepare for critical situations and make them more aware of the cues they need to act on – hence they are often called action plans (AP) and they have a positive medium to large effect on goal attainment (Gollwitzer & Sheeran, 2006). Evidence from systematic reviews shows that AP are effective in promoting healthy eating, but not so much in diminishing unhealthy food consumption (Adriaanse, Vinkers, De Ridder, Hox, & De Wit, 2011) and are also effective in promoting physical activity (Bélanger-Gravel, Godin, Bilodeau, & Poirier, 2013). They have been tested for self-management behaviours in people with T2DM and were found to be significant predictors of self-monitoring of blood glucose (Nadkarni, Kucukarslan, Bagozzi, Yates, & Erickson, 2010), to help increase proactive coping, goal attainment and self-efficacy (Thoolen, de Ridder, Bensing, Gorter, & Rutten, 2008) and to support integration of social networks into peoples' diabetes self-management behaviour if specified together with their relatives (Vissenberg *et al.*, 2016). In addition, men and women with T2DM seem to prefer different action plans, with women putting more emphasis than men on exercise and medication, and less emphasis on monitoring-related action plans or no action plans at all (Nuovo, Balsbaugh, & Levich, 2009). Creating individualised action plans may be one of the mechanisms or behavioural strategies people with diabetes may make use of during a WL and maintenance attempts. In particular, creating action plans for situations

[4] Examples 1,2,3,4,and 6 have been adapted to weight loss behaviours

that may be perceived tempting may help overcome these temptations and avoid a dietary lapse.

With the theoretical barriers and facilitators of behaviour change in mind, I hypothesise that the following may be applicable and helpful in adherence to the WL and maintenance phases in my sample of participants: the experience of overcoming temptations during the two stages may increase the participants` self-efficacy despite the depletion of some of their self-regulatory resources and may provide them with more confidence and determination to continue. Being provided with positive feedback from the study staff and significant others may have a similar effect on their motivation and adherence. The importance of social support in the management of diabetes has also been highlighted in a systematic review of 132 randomised controlled trials evaluating behavioural programmes for people with T2DM, which found that interventions were more likely to be effective if they were delivered in person and that lifestyle and educational interventions including support led to clinically important improvements in glycaemic control, especially if offering more than 10 contact hours (Pillay *et al.*, 2015). In the current study, participants were coming for regular visits every week for the duration of the VLED and every month during the WLM phase, which should provide enough support and regularity to facilitate adherence with the regimes.

It may be that with the decreased calorie intake, people may experience decrease in their psychological resources (e.g. changes in mood or stress resilience capacity) and learning stress reduction techniques may help them overcome situations in which they may normally turn to food. For example, dieters who were asked to inhibit their emotional responses or those who were sat near tempting food (ice-cream) ate more food when than those who were allowed to express their emotions naturally or those sitting further away from food (Vohs & Heatherton, 2000). Diverting attention away from food or activities relating with food, rewarding oneself for achieving goals with non-food related rewards, focussing on successes rather than failures, removing food from the immediate environment and planning around eating may also facilitate adherence with the VLED and the WLM phase.

In addition, setting realistic expectations with regards to WL during the VLED period of the study may play a role in satisfaction with WL results and the subsequent motivation for WLM. For example, Foster and colleagues (Foster, Wadden, Vogt, & Brewer, 1997) showed that women participating in a WL programme expected to lose

at least 34% of their weight even though they were told to expect to lose between 5-15%. Such unrealistic expectations led to perceptions of a 17 kg WL as disappointing, with 47% patients not even achieving this disappointing weight goal. In order to increase the chances of T2DM remission, participants in the Counterbalance Study were asked to lose about 15kg. Higher expectations might affect the overall satisfaction with the programme, however since the primary goal of the study is remission of T2DM, WL should be less of a concern to the participants in this study as long as the physiological outcomes are achieved.

2.8 Summary

It is evident from the research to date, that although significant theoretical and empirical progress has been made in the field of health psychology, weight management behaviours of people with or without T2DM are still not understood as well as it would be desirable and they appear to be becoming more complex with the ever-changing foodscape. This chapter provided an overview of the health psychology theories and models of behaviour change relevant to WL and WLM, evidence of their effectiveness, summary of their strengths and weaknesses, and an overview of the behaviour change techniques and behaviour regulation strategies that might be useful facilitators of adherence, forming a strong conceptual and empirical basis to the work I have conducted in this PhD project.

Chapter 3

Efficacy and acceptability of very low energy diets in people with type 2 diabetes: a systematic review with meta-analyses[5]

3.1 Abstract

Aims: The review aimed to determine the efficacy and acceptability of VLEDs in overweight or obese adults with T2DM. Methods: Controlled trials and qualitative studies of individuals with T2DM undergoing VLEDs were eligible for inclusion. Suitable comparators were standard care, minimal interventions, other WL interventions, less intensive VLED interventions and VLEDs with additional components. Meta-analyses of changes in weight, levels of blood glucose and attrition rates were performed. Acceptability of VLEDs was to be assessed by attrition rates; number and seriousness of side effects; and by qualitative evaluations of the programmes. Results: Four randomised, 5 non-randomised controlled trials and no qualitative studies (21 references, 9 studies, 346 participants) were included in the review. Weight loss: Meta-analyses showed that VLEDs induced greater WL than minimal interventions, standard care or low energy diets, and equal WL compared to RYGB surgery, at 3 and 6 months. There was a positive linear relationship between the differences in energy prescription and the differences in WL between the intervention and the comparator groups at 3 months. Fasting blood glucose (FBG): Short-term effects of VLEDs on FBG were found. There was a positive linear relationship between the differences in energy prescription and FBG levels at 3 months. Acceptability: Attrition rates did not differ between the VLED and the comparator groups at any measurement point. Conclusions: VLEDs are effective in substantial WL among people with T2DM. Levels of adherence to VLEDs in

[5] The systematic review has been published as: Rehackova, L., Arnott, B., Araujo-Soares, V., Adamson, A. A., Taylor, R., & Sniehotta, F. F. (2015). Efficacy and acceptability of Very Low Energy Diets in overweight and obese people with Type 2 diabetes mellitus: a systematic review with meta-analyses. *Diabetic Medicine*, n/a-n/a. doi: 10.1111/dme.13005

Part of the study has previously been presented at the annual conference of the European Health Psychology Society and the UKSBM in 2013.

controlled studies appear to be high, although details about behaviour support provided are usually poorly described.

3.2 Introduction

Obesity accounts for 80-85 percent of the risk of developing T2DM (Hauner, 2010) and substantial WL reduces this risk (Sjostrom, Peltonen, Wedel, & Sjostrom, 2000). Sjöström and colleagues (Sjostrom *et al.*, 2000) have demonstrated that bariatric surgery reduced 8-year T2DM incidence by a fifth compared to untreated controls. Substantial weight reduction has also been associated with remission of T2DM (Dixon & O'Brien, 2002; Lim *et al.*, 2011; Pories *et al.*, 1992; Rubino & Gagner, 2002). The risk of developing T2DM after substantial WL remains reduced even when the weight lost is regained (Feldstein *et al.*, 2008).

Guidelines for the treatment of obesity recommend gradual WL with behavioral methods focusing on changing dietary habits and increasing physical activity/exercise (National Heart Lung and Blood Institute, 1998,; National Institute for Clinical Excellence, 2006, 2014; World Health Organisation, 2006b). These interventions generally produce small WL compared to bariatric surgeries, weight-loss medication and energy restrictive diets (Bray, 2008; Franz *et al.*, 2007; Gallagher *et al.*, 2013; Laddu, Dow, Hingle, Thomson, & Going, 2011). Interventions including very low energy diets (VLEDs) containing fewer than 800 kilocalories (kcal) per day, facilitate larger short-term WL in individuals without T2DM than other dietary interventions (Franz, 2004; Ryttig K *et al.*, 1997) and have potentially fewer side-effects and complications compared to bariatric surgeries (Brolin, 2002; Laddu *et al.*, 2011; Mun, Blackburn, & Matthews, 2001). Whether VLEDs are as effective in individuals with T2DM as they are in the general obese population is currently not known. Obese people with T2DM usually lose less weight in obesity treatments than obese people without T2DM (Guare, Wing, & Grant, 1995; Henry, Wiestkent, Scheaffer, Kolterman, & Olefsky, 1986; Wing, Marcus, Epstein, & Salata, 1987). However, a recent study suggests that more than 90% of the WL achieved in people without T2DM can be achieved in obese people with T2DM through a community-based 12-week long VLED (Rolland *et al.*, 2013). It has been suggested that a WL of 15-20% may lead to the normalisation of pancreatic function (Taylor, 2013) and the remission of T2DM (Dixon, O'Brien, Playfair, & et al., 2008).

Little is known about acceptability of VLEDs among people with and without T2DM. While VLEDs have been found acceptable in obese individuals with and without T2DM, acceptability measured by evaluation of the product`s taste, participants` hunger, nausea or vomiting, bowel function, emotional eating and social eating decreases over the course of a 12-week VLED (Colles, Dixon, Marks, Strauss, & O'Brien, 2006).

Previous systematic reviews including VLEDs have either included a very small number of studies or had a broader focus including other WL methods (Nield *et al.*, 2007; Norris *et al.*, 2009). Other relevant reviews are outdated and with several methodological shortcomings, such as combining controlled and uncontrolled studies in meta-analyses (Brown, Upchurch, Anding, Winter, & Ramìrez, 1996). The present systematic review with meta-analyses of controlled trials using VLEDs in overweight or obese people with T2DM aims to determine the efficacy of VLEDs for WL and glycaemic control. It also aims to provide an account of acceptability of VLEDs among people with T2DM, which could help to optimise VLEDs and improve the intervention experience in the future.

The objectives of this review were 1) to determine the immediate and long-term efficacy of VLEDs on weight and fasting blood glucose (FBG), 2) to explore recruitment rates, attrition and unintended outcomes in trials of VLEDs, 3) to explore whether the efficacy of VLEDs is related to specific intervention features (duration, the amount of kcal prescribed per day, intensity, behaviour change components, etc.), and 4) to explore facilitators and barriers to using VLEDs and any effects on mental and physical wellbeing in obese adults with T2DM.

3.3 Methods

This review is based on an *a priori* published protocol at the Centre for Reviews and Dissemination (CRD42012002065).

3.3.1 ***Eligibility criteria***

3.3.1.1 Study designs

Published and unpublished randomised and non-randomised controlled trials (RCTs and NRCTs, respectively) evaluating the efficacy of VLEDs as well as qualitative

studies to explore acceptability, barriers and facilitators of undergoing VLEDs were considered for inclusion in this review.

3.3.1.2 Participants

Participants were overweight or obese (mean BMI ≥ 25 kg/m^2) adults of 18 years or older with T2DM. Older studies using a different measure of obesity (e.g. being ≥10% above ideal body weight based on the Metropolitan Life Insurance Company`s tables (Company, 1983)), or studies in which the authors stated that participants were overweight or obese were also considered for inclusion.

3.3.1.3 Interventions

Studies eligible for inclusion used VLEDs comprising of ≤ 800 kcal/day in at least one intervention arm.

3.3.1.4 Comparators

Studies were eligible if they included a control arm receiving no or minimal intervention, or an alternative intervention. If both the intervention and the comparator arms received a VLED treatment, the more intensive treatment was considered the intervention and the less intensive treatment was considered a comparator arm. If a study compared 3 or more arms, the most intensive treatment was considered the intervention and the least intensive treatment was considered the comparator.

3.3.1.5 Outcomes

For quantitative studies, the outcomes of interest were: 1) weight lost, 2) fasting plasma glucose levels, 3) adherence (number of participants who closely followed nutrition recommendations; objective measures of adherence), 4) attrition rates (loss to follow-up, discontinuation), 5) recruitment rates, 6) adverse side-effects, and 7) change in medication. Information about motivation, perceived barriers, facilitators and experiences with VLEDs were planned to be extracted from qualitative studies.

3.3.2 ***Information sources***

A search through electronic databases was completed in February 2014. The databases searched were All EBM Reviews (1991), CAB Abstracts (1973), CINAHL (1994), Embase (1980), HMIC (1979), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) (1946), and PsychINFO (1806).I have hand-searched PubMed (1984), Web of Knowledge (1983), The Cochrane library and CRD.

I developed the search strategy in consultation with an experienced librarian and targeted two categories: 1) health condition (T2DM); and 2) Type of intervention (very low energy diet). Studies in any language with an English abstract were included in this review. I then obtained the original papers written in foreign languages and consulted them with native speakers to decide on inclusion or exclusion if abstracts did not provide satisfactory information to make a judgement; these included papers in French, Polish, Czech, German, Hungarian, Dutch and Japanese.

3.3.3 ***Search***

Appendix 1 shows an example of a full electronic search strategy for PsychINFO database.

3.3.4 ***Study selection***

Following initial search and de-duplication, I screened all titles/abstracts against a study inclusion screening form (Appendix 2). A random sample of all titles/abstracts was independently screened by a second reviewer (BA). Disagreements between us were resolved by discussion and a third coder was invited if agreement could not be reached. I have then obtained full text publications of studies meeting the initial inclusion criteria assessed them against a more detailed inclusion/exclusion form, followed by an independent assessment of a random sample of full texts by the second reviewer (BA). Disagreements between us were resolved by discussion and a third coder was invited if agreement could not be reached. The second reviewer and I were not blinded regarding names of authors, institutions or journals. Numbers of excluded studies and reasons for their exclusion were documented. Table 5 provides a short description of the intervention and the comparator arms in the included studies.

3.3.5 ***Data collection process***

Data from all papers included in the review were extracted using a data extraction form. I was not blinded regarding names of authors, institutions or journals. The second reviewer (BA) independently checked a random sample of the included papers. Where available, protocols of studies were obtained. Where data was unavailable or discrepancies occurred between reports of the same study, I

requested additional information from the corresponding authors, whom I re-contacted after two weeks if I did not receive a reply.

3.3.5.1 Data items

Information extracted from each study followed standard recommendations by Davidson and colleagues (Davidson *et al.*, 2003) and covered: a) Study design (duration and intensity of intervention, provider, setting, amount of energy prescribed , contact time, format of delivery, support provided); b) Participants (gender, age, years since diagnosis, participant flow – number of participants present at start and end points, % drop-out); c) Outcomes (attrition rates, objective measures of adherence, adverse events/side effects, change in medication due to the intervention); d) Information about intervention delivery (e.g. duration of the intervention, kilocalories administered per day, number of hospital visits, etc.; and e) behaviour change techniques used (Michie *et al.*, 2011). Data from multiple reports were extracted separately for each of the included studies and then combined across multiple data collection forms.

3.3.5.2 Behaviour change techniques

To identify active ingredients of the included studies, content of the intervention and the comparator arms was coded using the CALO-RE taxonomy of behaviour change techniques (BCTs) (Michie *et al.*, 2011). BCTs are observable and replicable methods for changing individual behaviour (Michie *et al.*, 2013b) and facilitate comparison and replication of intervention contents. I first coded the presence or absence of BCTs in all studies and a small sample (n = 5 studies) was checked by another reviewer (VAS) to ensure reliability of the coding. A BCT was coded only if the description of a technique clearly fell within the definition of the taxonomy.

3.3.5.3 Adverse events and compliance

Acceptability of VLEDs was to be assessed by attrition rates, by the occurrence and seriousness of side effects or adverse events, and by qualitative evaluations of the programmes.

3.3.6 ***Risk of bias***

Risk of bias of both RCTs and NRCTs was appraised using the Cochrane Collaboration's Tool for Risk of Bias Assessment (Barnaby, Deeks, Higgins, & Wells, 2008). This tool enables assessment of the risk of bias associated with sequence

generation, allocation concealment, blinding procedures, outcome data reporting, selective reporting, or other bias. I appraised the methodological quality of all included studies and 50% were independently assessed by the second reviewer (BA). Studies were judged as having “high”, “unclear” or “low” risk of bias and were tabulated accordingly (Table 6). Disagreements between us were resolved by discussion and a third coder was invited if agreement could not be reached.

3.3.7 ***Summary measures***

The summary measures were differences in means and odds ratios. Studies reporting sufficient data to calculate mean differences (MDs) or odds ratios (ORs) were considered for a meta-analysis using RevMan (version 5.1) ("Review Manager (RevMan)," 2014). Some variables (e.g. changes in medication, behaviour change techniques) were synthesised narratively.

3.3.7.1 Data imputation

Where not reported (n = 4), changes in mean weight and their respective standard deviations were calculated (Mean Change = mean at the end of intervention - mean at baseline). Standard deviations (SDs) were calculated using Avenell`s formula (Avenell, Broom, Brown*, et al.*, 2004b) for estimation of SDs of weight change specifically (SD = 5.915 + 0.283 * absolute mean change). Fasting blood glucose data were compared using final scores, as the available data did not include sufficient detail for calculations of the change SDs. Digitising software (Mitchell, 2007) was used to extract data presented in graphs (Silva *et al.*, 2012, September).

3.3.8 ***Synthesis of results***

3.3.8.1 Meta-analyses

Both randomised (RCTs) and non-randomised studies (NRCTs) were included in meta-analyses where outcomes were provided at 3 or 6 months (± 4 weeks). Statistical heterogeneity of the included studies was assessed using the chi-square and the I^2 statistics (Higgins & Thompson, 2002; Huedo-Medina, Sánchez-Meca, Marín-Martínez, & Botella, 2006). A random effects model was used to calculate effect sizes for weight, fasting glucose (FBG) and attrition outcomes.

3.3.8.2 Additional analyses

Providing financial incentives or requiring participants to pay for the VLED might affect motivation, adherence and WL (Rothberg, McEwen, Fraser, Burant, & Herman, 2013). Subgroup analyses were performed to consider differences in effects between trial arms in which the participants paid the cost of the VLED , or received any initially deposited money back as a financial incentive (Giles, Robalino, McColl, Sniehotta, & Adams, 2014) and those, in which the participants did not have any out-of-pocket expenses or were not financially incentivised for attendance and meeting pre-specified goals. Sensitivity analyses were performed prior to combining RCTs and NRCTs in meta-analyses in order to determine possible additional sources of heterogeneity and changes in effect sizes. An exploratory analysis to consider relationships between the presence or absence of behaviour change techniques (BCTs) and intervention effect sizes was planned to determine which BCTs are potentially associated with larger effect sizes.

3.4 Results

A total of 4,765 records were identified by the search. Approximately 10% of these references (n = 500) were independently screened by the second reviewer (BA) and an agreement rate of 84% was achieved. Disagreements were resolved by discussion. From the initial screening of abstracts/titles, 113 full-texts were obtained for a more detailed assessment. Approximately 10% of all full-texts (n = 11) were independently assessed for eligibility by the second reviewer (BA) and an agreement rate of 88% was achieved. Disagreements were resolved by discussion. From the 113 references, 93 were excluded for the following reasons: ineligible study design (n = 53); mean BMI <25 (n = 1); results for VLEDs and the comparator arms were not reported separately (n = 1); participants treated with VLED did not have T2DM (n = 8); the reported diet exceeded 800 kcal/d (n = 27); and unavailability of relevant information in order to apply the eligibility criteria (n = 3). Twenty-one records met the inclusion criteria, representing 9 primary studies (4 randomised and 5 non-randomised controlled trials) in total. No qualitative studies fulfilled the inclusion criteria for this review (Figure 2).

3.4.1 ***Study characteristics***

Appendix 3 provides a full summary of the characteristics of the included studies. References to excluded and included studies can be found in Appendix 4.

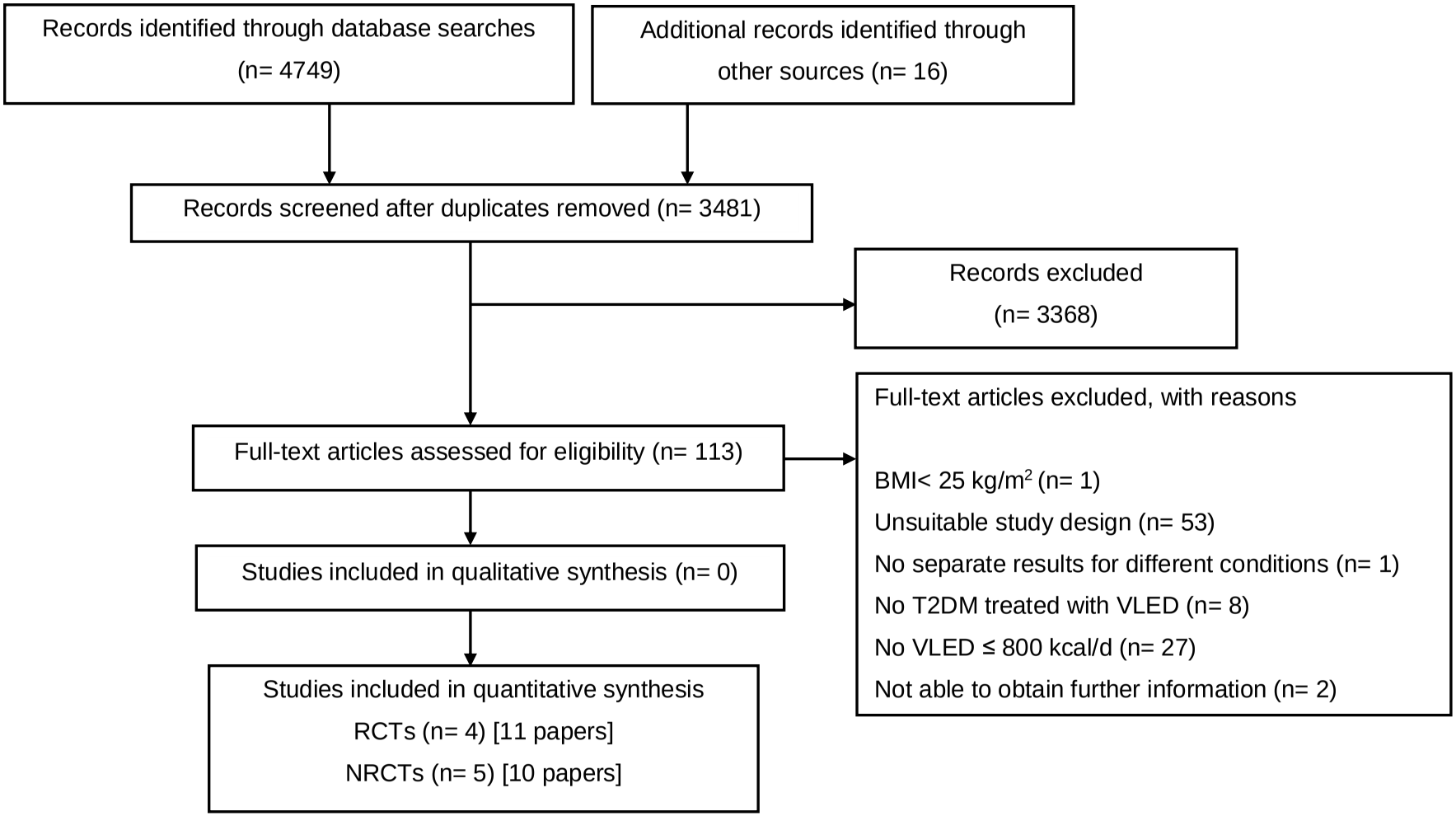

Figure 2. Flow diagram of studies included in and excluded from the systematic review (adapted from PRISMA, 2009).

3.4.1.1 Participants

The included studies represented a total sample of 346 participants (223 (women = 60%) in RCTs and 123 (women = 68%) in NRCTs) at baseline. The age range of participants was 40-70 years with mean BMI ranging from 30-51.

3.4.1.2 Settings

Limited information was provided about intervention settings and frequency of contact. Six studies reported that the VLED s were used by participants at home, with weekly (Anderson *et al.*, 1994; Paisey *et al.*, 2002; Snel *et al.*, 2012; Williams, Mullen, Kelley, & Wing, 1998; Wing, Marcus, Salata*, et al.*, 1991; Wing, Blair, Marcus, Epstein, & Harvey, 1994) and 3-weekly (Lips *et al.*, 2014) outpatient clinic visits for the duration of the programmes; one study reported delivery of VLED in a clinical research unit within a hospital (Jackness *et al.*, 2013); and one study did not provide information about the intervention setting or frequency of contact (Plum *et al.*, 2011).

3.4.1.3 Outcome measures

All studies reported data for WL and fasting blood glucose. Attrition was reported in 7 out of the 9 studies (Anderson *et al.*, 1994; Lips *et al.*, 2014; Paisey *et al.*, 2002; Snel *et al.*, 2012; Williams *et al.*, 1998; Wing, Marcus, Salata*, et al.*, 1991; Wing *et al.*, 1994). Two studies did not report attrition rates (Jackness *et al.*, 2013; Plum *et al.*, 2011). Information about the reasons for attrition was reported by three studies (Anderson *et al.*, 1994; Lips *et al.*, 2014; Williams *et al.*, 1998). Dietary adherence was monitored using self-monitoring food records (Williams *et al.*, 1998; Wing, Marcus, Salata*, et al.*, 1991; Wing *et al.*, 1994), urinary ketone levels (Paisey *et al.*, 2002; Wing *et al.*, 1994), weight lost (Paisey *et al.*, 2002; Plum *et al.*, 2011) and counting sachets used as meal replacements (Snel *et al.*, 2012). One study (Lips *et al.*, 2014) did not report adherence.

3.4.1.4 Interventions and comparators

As shown in Table 5, three studies compared different VLED delivery modes with additional intervention components: a VLED compared to a VLED including food (a recommended evening meal of approximately 500 kcal and 50g of protein) (Anderson *et al.*, 1994); a VLED compared to a VLED with exercise (Snel *et al.*, 2012); and two different modes of an intermittent VLED compared to a standard behaviour therapy (a restricted diet) (Williams *et al.*, 1998). The rest of the studies

compared VLEDs to other interventions: a VLED compared to a low energy diet (LED) (Wing, Marcus, Salata*, et al.*, 1991; Wing *et al.*, 1994); a VLED compared to a Roux-en-Y gastric bypass (RYGB) (Plum *et al.*, 2011); and a VLED compared to an intensive conventional diet with exercise advice (Paisey *et al.*, 2002). The length of the VLED phases varied substantially from 20 days (within a 20-week period) (Williams *et al.*, 1998), to 24 weeks (Wing *et al.*, 1994). Duration of the studies (beginning of a study until the last follow-up) ranged from 3 weeks (Jackness *et al.*, 2013; Lips *et al.*, 2014) to 5 years (Paisey *et al.*, 2002). Kilocalories administered ranged from 400 - 800 per day in 3-5 sachets for the VLED conditions and 400 – 1800 kcal per day for the comparator arms.

Table 5. *A summary of delivered interventions and control groups, duration and calories administered in the included studies.*

Study	Design	Interventions/ controls	Length (weeks)	Amount of kcal/d	Study duration
Anderson 1994	RCT	**VLED** At least 5 liquid supplements /d which provide 800 kcal with 80 g of high-quality protein + 2 vitamin/mineral tablets.	12	800	3m
		VLED including a meal At least 3 supplements /d which provide 320 kcal and 32 g of high-quality protein, 1 vitamin/mineral tablet, recommended evening meal of cca 500 kcal and 50 g of high-quality protein.	12	820	
Jackness 2013	NRCT	**VLED** Day 1: 360 kcal/d; Day 2-24: 500 kcal/d.	3	360-500‡	3w
		RYGB Post-operative VLED is assumed of cca 500 kcal/d until end of week 3**.**	N/A	360-500‡‡	
Lips 2013	NRCT	**VLED** Week 0-3: 600 kcal/d (intervention period); week 3-8: 800-1000 kcal/d; after 2 months: 1200 kcal/d.	8	600-800†	2m
		RYGB First 5 days after operation: <600 kcal/d; week 1-3: gradual increase to 700-800 kcal/d; week 3–month 3: 1200 kcal/d.	N/A	400-700‡‡	
Paisey 2002	NRCT	**VLED** VLED: 400-470 kcal/d for women, 540 – 670 kcal/d for men for 3-5 months and repeated in course of the study if appropriate. Subjects set weight loss targets and counselling was provided about weight loss maintenance after discontinuation of the VLED. One demonstration of low-fat cooking with printed instructions was provided. Monthly group discussions were available after stopping the VLED. Included weekly sessions (1.5-2 hrs) to measure outcomes.	24	400-670	5y
		ICD + exercise advice Low fat, low sugar and high fibre intake advised, 5-day self-report food records were collected and discussed individually, repeated every 6-8 weeks. Aerobic exercises with encouragement performed at each visit followed by a group discussion on nutrition. Included weekly sessions (1.5-2 hrs) to measure outcomes.	24	1800 - 2000♦	
Plum 2011	NRCT	**VLED** VLED: 800 kcal/d.	8	800	2m
		RYGB RYGB + subjects followed dietary instructions after the surgical intervention.	3	N/A	2m
Snel 2012	NRCT	**VLED** VLED of 450 kcal/d. A 1800 kcal/d diet reintroduced after the VLED and referred to routine care thereafter.	16	450	1.5y
		VLED + exercise VLED of 450 kcal/d + training min. of 30 min at 70% of max. aerobic capacity 4 d/week for + 1 hour in-hospital training. A 1800 kcal/d diet reintroduced after the VLED and referred to routine care thereafter.	16	450	

Williams 1998	RCT	**5-day VLED** Week 1: SBT (1500-1800 kcal/d); Week 2, 7, 12 and 17: VLED (400-600 kcal /d) for 5 consecutive days/wk; Week 18-20: SBT (1500-1800 kcal/d). Included a 20-wk behavioural treatment programme with weekly group meetings including instructions on behavioural modification, exercise and diet. Subjects used diaries to record daily caloric intake.	3*	400-600	5m
		SBT 1500-1800 kcal/d for 20 wks. Included a 20-wk behavioural treatment programme with weekly group meetings including instructions on behavioural modification, exercise and diet. Subjects used diaries to record daily caloric intake.	3*	1500-1800	
Wing, 1991	RCT	**VLED + BT** week 0–4: 1000 - 1500 kcal/d; week 5-12: 400-500 kcal/d; week 13-20: 1000 kcal/d; week 21-72: 1000 - 1500 kcal/d (weight maintenance). Included a 20-wk behavioural treatment programme with weekly group meetings including instructions on behavioural modification, exercise and diet. Subjects were given weekly exercise goals.	8	400-500	4.5y
		LED + BT Week 0-20: 1000-1500 kcal/d (intervention period); week 21-72: 1000-1500 kcal/d (weight maintenance). Included a 20-wk behavioural treatment programme with weekly group meetings including instructions on behavioural modification, exercise and diet. Subjects were given weekly exercise goals.	20	1000-1500	
Wing, 1994	RCT	**VLED + BT** weeks 0–12 and 24-36: 400 – 500 kcal/d + vitamins and supplements, otherwise 1000 - 1500 kcal/d. Included a 50-wk behavioural treatment programme with weekly group meetings including instructions on behavioural modification, exercise and diet. Subjects were given weekly exercise goals.	2x12	400-500	1y
		LED + BT week 0-48: 1000 - 1200 kcal/d (intervention period); Subjects were encouraged to keep their fat intake below 30% of the daily calorie intake. Included a 50-wk behavioural treatment programme with weekly group meetings including instructions on behavioural modification, exercise and diet. Subjects were given weekly exercise goals.	48	1000-1200	

RCT = randomised controlled trial; NRCT = non-randomised controlled trial; VLED = very low energy diet; LED = low energy diet; SBT = standard behavioural treatment; BT = behavioural treatment; RYGB = Roux-en-Y gastric bypass; ICD = intensive conventional diet (low fat, low sugar and high fibre); N/A = not applicable/available, w = week, m = month, y = year

*Intervention duration was 20 days;

**Study duration was 3 weeks.

‡ 360 kcal/day on day 1; 500 kcal/day on days 2-24.

‡‡ This range refers to a post-operative period in the RYGB group.

†600 kcal/d first 3 weeks; up to 800 kcal/d weeks 4-8.

♦ Healthy diet was advised, this would assume 1800 – 2000 kcal/d.

3.4.2 ***Risk of bias of included studies***

Table 6 summarises the risk of bias of the RCTs and NRCTs. Overall, there was a considerable lack of information reported on the categories of the risk of bias assessment tool and conclusions could not be made about the level of bias in the included studies. The highest risk of bias was associated with sequence generation and allocation concealment due to inclusion of non-randomised studies.

Table 6. *Risk of bias in the included studies. This table illustrates methodological quality of the included individual randomised and non-randomised controlled studies*

	Sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Anderson, 1994	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Jackness, 2013	High	High	Low	Unclear	Unclear	Low	Low
Lips, 2013a	High	High	Low	Unclear	High	Unclear	Low
Paisey, 2002	High	High	Low	Unclear	Low	Unclear	Low
Plum, 2011	High	High	Low	Unclear	Low	Unclear	High
Snel, 2012	High	Unclear	Low	Unclear	Low	Unclear	Unclear
Williams, 1998	Unclear	Unclear	Unclear	Unclear	Low	Unclear	Low
Wing, 1991	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Low
Wing, 1994	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Low

Note. “Low” (in green) = low risk of bias; “Unclear” (in grey) = unclear risk of bias; “High” (in red) = high risk of bias.

3.4.2.1 Assessment of heterogeneity

Inclusion of randomised and non-randomised studies in the meta-analyses introduced additional sources of heterogeneity in some analyses. However, its impact on the outcome measures is likely to be modest based on the physiological nature of the intervention.

3.4.3 ***Weight loss***

Forest plots of these meta-analyses are included in Appendix 5.

3.4.3.1 VLED versus Minimal intervention or standard care

Two studies (Paisey *et al.*, 2002; Williams *et al.*, 1998) provided sufficient details of WL to allow meta-analyses at 3 and 6 months. At 3 months, the observed difference in WL of 7.38 kg compared to controls was not significant [MD_3 = -7.38 kg; CI = -16.22, 1.47; p = 0.10; I^2 = 84%]. At 6 months, however, the intervention arms lost significantly more weight than the comparator arms [MD_6 = - 8.48kg; CI = -15.63, -1.34; p = 0.02; I^2 = 80%].

3.4.3.2 VLED versus LEDs

Two studies (Wing, Marcus, Salata*, et al.*, 1991; Wing *et al.*, 1994) reported WL outcomes at 3 and 6 months. Significant difference in weight change in favour of the intervention arm was detected at both, 3 and 6 months [MD_3 = -6.57; CI = -9.49, -3.65; p < 0.001, I^2 = 58%; MD_6 = -5.74, CI = -11.13, -0.35; p = 0.04; I^2 = 58%].

3.4.3.3 VLED versus Roux-en-Y gastric bypass (RYGB)

Short-term data from 2 studies (Jackness *et al.*, 2013; Lips *et al.*, 2014) showed a non-significant difference in weight change between the intervention and the comparator arms at 3 weeks [MD = 1.93; CI = -2.59, 6.45; p = 0.40; I^2 = 0%]. Data for longer-term analyses were not available.

3.4.3.4 Comparisons of VLED interventions of different intensities

Two studies compared different intensities of VLED interventions. One study (Anderson *et al.*, 1994) compared an intervention using full meal replacement (VLED, 800 kcal/d) with an intervention using partial meal replacement, including an evening meal within a similar energy prescription to the VLED only intervention (VLED + food, approximately 820 kcal/d). This study did not find differences in WL between the arms at 3 months [MD = -1.60; CI = -8.10, 4.90, p = 0.63]. Another study (Snel *et al.*, 2012) compared a VLED with a VLED with added exercise. This study showed a significant difference between the arms at 3 months demonstrating an additional WL effect of exercise [MD = 3.50; CI = 2.17, 4.83; p <0.001], but this effect was no longer significant at 6 months [MD = 4.00; CI = -5.20, 13.20; p = 0.39]. This was most probably reflecting reduced statistical power at 6 months due to loss to follow-up in the trial.

Due to high heterogeneity in the intervention as well as in the comparator arms, total differences in estimated energy prescriptions were plotted against differences in WL at 3 months between the intervention and the comparator arms as a more standardised measure of the effect of energy restriction on WL. Two studies comparing VLED with RYGB (Jackness *et al.*, 2013; Plum *et al.*, 2011) were excluded from this analysis because the nature of the comparator did not allow estimation of energy prescription at 3 months and/or no outcome measure at 3 months was reported for both arms. A positive linear relationship between the estimated differences was detected (Figure 3).

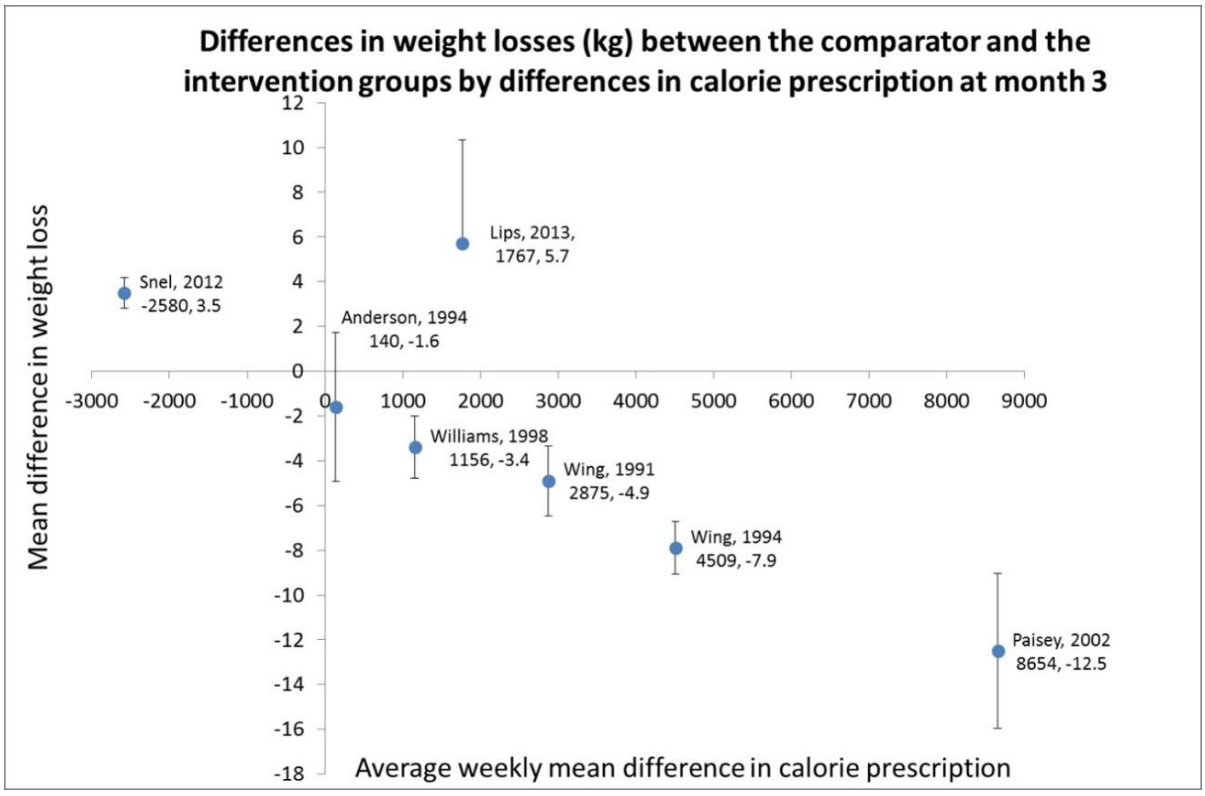

Figure 3. Association between differences in weekly energy (kcal) prescription and weight loss (kg) between the intervention and comparator groups.

Note. Labels represent author, year, average weekly calorie difference and difference in weight loss in kg. Calorie difference is calculated as comparator minus intervention. Positive values indicate lower calorie intake in the intervention group, negative values indicate lower calorie intake in the comparator group. Difference in weight change is calculated as weight change in the comparator group minus weight change in the intervention group. Positive values indicate greater weight loss in the comparator group; negative values indicate greater weight loss in the intervention group. VLED = Very low calorie diet; LED = Low calorie diet; ICD = Intensive conventional diet; BT = behavioural treatment; Ex = exercise. Comparisons: Anderson, 1994 (VLED vs. VLED including food as part of the diet); Paisey, 2002 (VLED vs. ICD + Ex); Snel, 2012 (VLED vs. VLED + Ex); Williams, 1998 (VLED vs. BT); Wing, 1991 (VLED + BT vs. LED + BT); Wing, 1994 (VLED + BT vs. LED + BT).

3.4.4 ***Fasting blood glucose (FBG) and changes in medication***

Forest plots of these meta-analyses are included in Appendix 6.

3.4.4.1 VLED only versus Minimal intervention or standard care

One study compared FBG outcomes between VLED and an intensive conventional diet and exercise programme (Paisey *et al.*, 2002) and found no significant differences at 1, 3, 6 and 12 months (MD_1 = -4.10; CI = -8.38, 0.18; p = 0.06; MD_3 = -5.10; CI = -10.87, 0.67; p = 0.08; MD_6 = -1.20; CI = -5.50, 3.10; p = 0.58; MD_{12} = -1.70; CI = -6.82, 3.42, p = 0.52, respectively) although differences at 1 and 3 months were close to significance. No differences in medication between the arms were reported and both arms still required medication at the end of the study (Paisey *et al.*, 2002).

3.4.4.2 VLED versus LED

Fasting blood glucose outcomes were described in sufficient detail in one study (Wing, Marcus, Salata*, et al.*, 1991) and showed a significant difference in FBG between the VLED and the LED arms at 4 months [MD = -1.60; CI = -2.90, -0.30; p = 0.02]. No evidence for sustained effects of VLED compared to LED on FBG at 6 and 12 months was found in a meta-analysis of two studies (Wing, Marcus, Salata*, et al.*, 1991; Wing *et al.*, 1994) [MD_6 = -1.01; CI = -2.28, 0.26; p = 0.12; I^2 = 38%; MD_{12} = -1.62; CI = -4.14, 0.91; p = 0.21; I^2 = 66%, respectively]. At 2 years, the measures of glycaemic control returned to baseline levels in both arms in one study (Wing *et al.*, 1994), with fewer participants in the VLED condition requiring medication (45% vs. 69% in the VLED and LED conditions respectively).

3.4.4.3 VLED versus Roux-en-Y gastric bypass (RYGB)

Two studies (Jackness *et al.*, 2013; Lips *et al.*, 2014) reported short-term FBG outcomes, resulting in a significant difference between the intervention and the comparator arms in favour of the VLED intervention at 3 weeks [MD = -1.27; CI = -2.11, -0.44; p = 0.003; I^2 = 0%]. This effect was not sustained at 3 months (Lips *et al.*, 2014) [MD = 0.10; CI = -0.84, 1.04; p = 0.84]. In one study (Plum *et al.*, 2011), all anti-diabetic medication was discontinued in the RYGB arm and decreased by 55% in the VLED arm after the intervention. In another study (Lips *et al.*, 2013), metformin was reintroduced in 4/15 (26.6%) participants in the RYGB arm and in 2/12 (16%) participants in the VLED arm after the interventions and the difference was not significant.

Total differences in estimated energy prescriptions were plotted against the differences in FBG levels at three months between the intervention and the comparator arms. A positive linear relationship was detected (Figure 4).

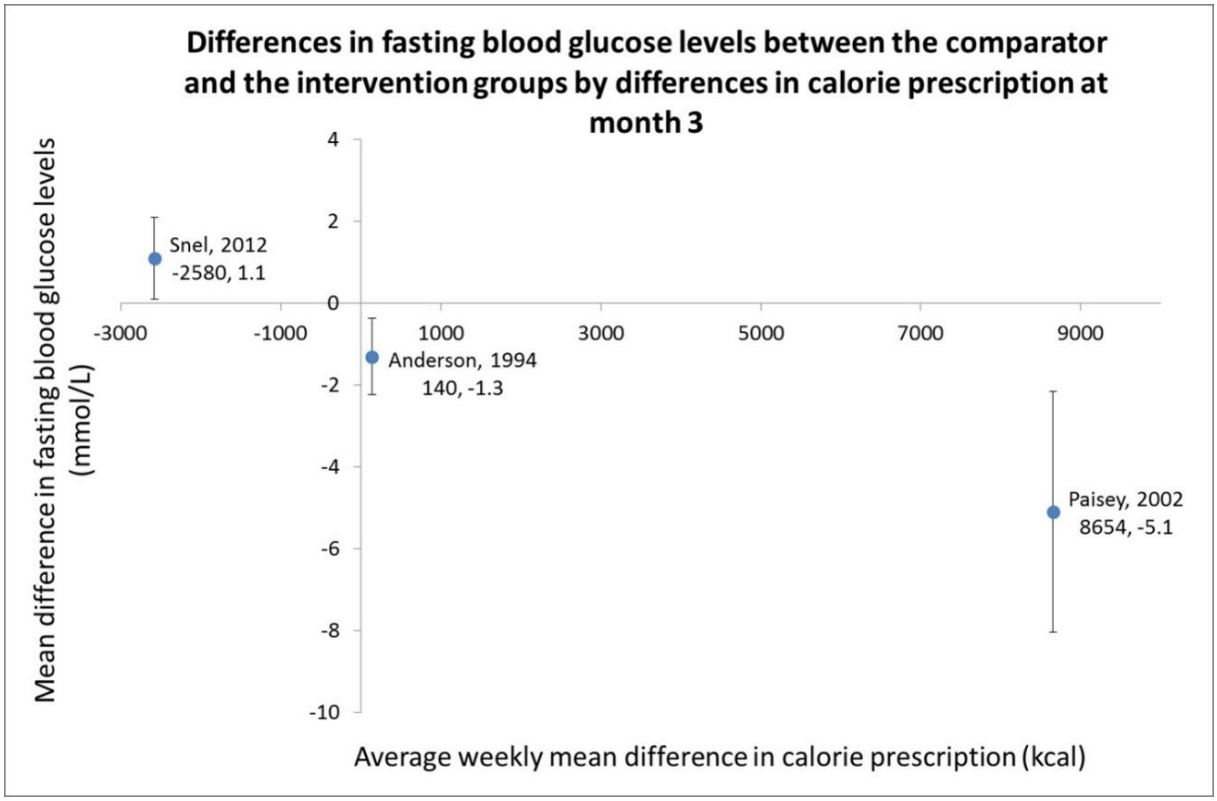

Figure 4. Association between differences in weekly energy (kcal) prescription and fasting blood glucose levels (mmol/L) between the intervention and comparator groups.

Note. Labels represent author, year, average weekly calorie difference and difference in weight loss in kg. Calorie difference is calculated as comparator minus intervention. Positive values indicate lower calorie intake in the intervention group, negative values indicate lower calorie intake in the comparator group. Difference in weight change is calculated as weight change in the comparator group minus weight change in the intervention group. Positive values indicate greater weight loss in the comparator group; negative values indicate greater weight loss in the intervention group. VLED = Very low calorie diet; LED = Low calorie diet; ICD = Intensive conventional diet; BT = behavioural treatment; Ex = exercise. Comparisons: Anderson, 1994 (VLED vs. VLED including food as part of the diet); Paisey, 2002 (VLED vs. ICD + Ex); Snel, 2012 (VLED vs. VLED + Ex); Williams, 1998 (VLED vs. BT); Wing, 1991 (VLED + BT vs. LED + BT); Wing, 1994 (VLED + BT vs. LED + BT).

3.4.5 ***Attrition***

Information about the number of lost to follow up at the outcome measurement points of interest were reported in two studies comparing VLED vs. minimal intervention or standard care (Paisey *et al.*, 2002; Williams *et al.*, 1998); in two studies comparing VLED vs. LED (Wing, Marcus, Salata*, et al.*, 1991; Wing *et al.*, 1994); and in two studies comparing VLED vs. RYGB (Jackness *et al.*, 2013; Lips *et al.*, 2014). Attrition rates did not differ between any of the intervention and the comparator arms at any outcome measurement point (Appendix 7).

3.4.6 ***Narrative synthesis***

3.4.6.1 Wellbeing

Wing and colleagues (Wing, Marcus, Blair*, et al.*, 1991) found that participants in both, VLED + BT and the LED + BT conditions experienced significant reductions in depression and anxiety. Similarly, Snel and colleagues (Snel *et al.*, 2012) reported improvements in physical functioning, physical ability, energy, health, and activity; and decrease in general fatigue, anxiety, and depression in both, the VLED and VLED + exercise conditions.

3.4.6.2 Side effects

Five out of 9 studies reported adverse events of treatments (Appendix 8). Most of these were similar between the intervention and the control arms and included headaches, cold intolerance, hunger pangs and fatigue. Serious adverse events included a hypoglycaemic episode (VLED condition), a non-fatal myocardial infarction (in both treatment arms: VLED and ICD) and one death (in the comparator arm: ICD) (Paisey *et al.*, 2002).

3.4.6.3 Cost effectiveness

Only one study (Collins & Anderson, 1995) reported data on cost-effectiveness and found significant prescription short- and long-term (at 1 year) cost savings as a result of using VLEDs in people with T2DM.

3.4.6.4 Behaviour change techniques (BCTs)

A total of 13 BCTs (M=2.67; SD=3.24; range 0-8) were used in the intervention and 13 BCTs were used in the comparator arms. Behavioural goal setting (n = 3), set graded tasks (n = 3), and relapse prevention/coping planning (n = 3) were the most frequently used BCTs. A lack of detailed information about the intervention content hindered clear identification of BCTs used in the included studies and there was insufficient data to explore relationships between BCTs and effectiveness (Appendix 9).

3.4.7 ***Additional analyses***

Three papers reported having incentivised participants financially for completion (Collins & Anderson, 1995), attendance, or meeting pre-specified goals (Wing, Marcus, Salata*, et al.*, 1991; Wing *et al.*, 1994). Another paper (Paisey *et al.*, 1998) stated that the VLED used in the programme was purchased by the participants. Subgroup analyses did not result in differences in attrition rates, changes in WL or FBG between those who paid for a programme and those who did not, at 3 or 6 months.

3.5 Discussion

Evidence for the effects and acceptability of VLEDs is currently limited. In this chapter, I analysed 9 studies, with a total of only 346 participants and considerable risk of bias in many studies. While the overall findings suggest that VLEDs lead to considerable WL and that there is a clear dose-response relationship between WL and improved glycaemic control, there remains a considerable amount of uncertainty about the effects and mechanisms. Evidence on the long-term efficacy of VLEDs on WL in people with T2DM is lacking. The meta-analyses of weight changes are based on a very small number of studies and small sample sizes, with no studies providing power analyses. Definitive information on long-term efficacy of VLEDs is currently inconclusive.

While this review found VLEDs as acceptable as other treatments among overweight or obese people with T2DM, limited rigor in reporting adverse events was noted, limiting the conclusiveness of this finding. Some of the included studies reported

increased physical and mental well-being in the intervention arms, but these changes did not differ from other comparator WL treatments. This is in line with previous research by Rothberg and colleagues (Rothberg *et al.*, 2014), who found weight reduction to be associated with improvements in health-related quality of life.

Adherence to a VLED regimen is crucial in order to maximise intervention effects. It has been shown that greater initial WL facilitates WLM if followed by an effective WLM programme (Astrup & Rössner, 2000). Without such maintenance programme, WL achieved through any method is followed by weight regain (Dombrowski *et al.*, 2014a). There is no evidence that rapid WL through VLEDs is associated with more rapid weight regain compared to other interventions (Saris, 2001). A direct comparison between participants randomly assigned to either a 12-week rapid or a 36-week gradual WL programmes found no differences between the study arms in the amount of weight regained within 3 years of a WLM programme (Purcell *et al.*, 2014). More studies with long-term follow up are needed to determine the relationship between rapid or gradual WL and WLM and also the effect of the WL method on outcomes related with T2DM. Further exploration of WL and WLM could also lead to identification of the best active ingredients for optimal WL and its maintenance in the future (Dombrowski *et al.*, 2014a).
The low attrition rates in the included studies suggest that: a) the trials attracted very motivated individuals with T2DM, who were determined to complete the programme they were involved in; or b) that adhering to VLEDs is not more demanding than adhering to other WL treatments, possibly because of additional motivation in response to the experience of considerable WL; or a combination of both factors. It is also possible that attrition rates are unsuitable indicators of acceptability of weight-loss treatments. Two of the 9 included studies did not report attrition. Both compared WL effects of RYGB against VLED. Given the small sample sizes of the studies (N=14 and N=25) any potential unreported withdrawal may have biased the results in relation to how acceptable the treatments are.

Only one study (Collins & Anderson, 1995) reported data on cost-effectiveness and found significant prescription short- and long-term (at 1 year) cost savings as a result of using VLEDs in people with T2DM. For these reasons, qualitative evaluations of

studies using VLEDs to reduce weight in overweight or obese individuals with T2DM should be carried out in the future. In-depth information could be obtained via qualitative studies aiming at exploration of peoples` experience with VLEDs as well as identification of specific barriers or facilitators of adherence to VLEDs in order to support them during WL.

3.6 Limitations

High-quality evidence on the use of VLEDs in overweight or obese people with T2DM is extremely limited. Non-randomised and randomised studies were combined in the meta-analyses, which increased the heterogeneity as well as the risk of bias; while only moderately increasing the sample sizes. In addition, outcomes at different time-points were pooled to allow for meta-analyses, which might have introduced further heterogeneity in the results. Secondly, all four RCTs were carried out in the USA, while 2 of the NRCTs were conducted in the Netherlands, two in the USA and one in the UK. Most of the high-quality research in this field has been conducted by a small number of research groups. Replication of their work would help determine the long-term weight-loss and metabolic control induced by VLEDs when used in the management of T2DM. Lastly, measures of adherence to the VLEDs were problematic across the trials. Some studies reported that adherence was individually confirmed by WL without providing specific data, other studies used subjective measures of dietary adherence susceptible to social desirability bias (Hebert, Clemow, Pbert, Ockene, & Ockene, 1995; Schoeller, 1990). The lack of information on patient experience from qualitative studies further prevents me from making conclusions about acceptability of VLEDs. Particularly this type of methodology is needed to determine whether or not VLEDs have the potential to be applied across wider settings such as in primary care and public health programmes.

3.7 Conclusions

VLEDs are effective in substantial WL among people with T2DM. Levels of adherence to VLEDs in controlled studies appear to be high, although details about behaviour support provided are usually poorly described.

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Chapter 4
Contextual Background for Chapters 5-9: Description of the Counterbalance Study

4.1 Introduction

Chapter 3 presented a systematic review with meta-analysis of controlled studies, which aimed to determine efficacy and acceptability of VLEDs among people with T2DM. The review showed that VLEDs are effective for substantial WL among people with T2DM in the short term and that levels of adherence to VLEDs in controlled studies appear to be high and equal to the comparator arms. However, there is lack of evidence on acceptability of VLEDs in this population as shown by the lack of qualitative studies that would on acceptability and potential issues surrounding attrition rates. A study aiming to achieve reversal of T2DM by using VLEDs, the Counterbalance Study, was ongoing at Newcastle University at the time of this PhD project.

The Counterbalance Study provided an opportunity to: a) fill in the knowledge gap on acceptability of VLEDs as a rapid WL method among people with T2DM; b) understand the experience of WLM after rapid WL, and; c) conduct an evaluation of the Counterbalance study to help refine and improve interventions using VLEDs in the future. I designed and conducted a qualitative evaluation of the two distinct phases of the Counterbalance Study, a rapid WL phase (WL phase, 8 weeks) using a VLED and a WLM phase (WLM phase, 6 months) afterwards. The current chapter describes the Counterbalance Study protocol and the interventions delivered, with the aim to lay out the context for the work conducted and presented in Chapters 5 to 9 of this PhD. The Counterbalance Study is described using the TIDieR checklist (Hoffmann *et al.,* 2014)

4.2 Aims of the Counterbalance Study

The Counterbalance Study explored the interaction between the length of T2DM diagnosis and its reversibility by using a VLED. This study also explored if the VLED

in conjunction with physical activity protects from further deterioration of beta cells after restoration of their function.

The research questions for the Counterbalance Study were as follows: 1) What is the interaction of duration of T2DM with potential reversibility of T2DM through a VLED?; 2) Does a high monounsaturated fat (Mediterranean) diet protect insulin secretion from longer term deterioration of pancreatic function after restoration of normality through a VLED?; 3) Does increased daily physical activity enhance this protection?; 4) Do changes in fat production from the liver relate to pancreas fat levels during hypocaloric dieting and during weight maintenance / weight gain?

4.3 Methods

4.3.1 ***Design***

The Counterbalance Study consisted of two phases, a weight loss (WL) phase and a weight loss maintenance (WLM) phase. The WL phase of the study was a single group before and after design and the WLM phase was a 2x2 randomised control trial (more details in sections 4.3.3.3 of this chapter).

The Counterbalance Study had been approved by the NHS Research Ethics Committee (ref. REC 12/NE/0208) and registered under the International Standard Randomised Controlled Trial Number ISRCTN88634530.

4.3.2 ***Participants***

The study planned to recruit 30 individuals with T2DM. Patients with T2DM were identified by local advertisement, posters and leaflets displayed in local GP surgeries and public places, and by word of mouth. Interested individuals were invited to contact the Counterbalance research team and were posted a full information leaflet about the study. If they wished to participate, they were invited to a screening, where the study was explained in detail and where questions were answered by the Counterbalance Study staff. A written informed consent was obtained from all participants.

Information about how the participants had found out about the Counterbalance Study was not recorded by the Counterbalance staff, but it was available in the narratives of all participants, who were interviewed in the qualitative study at baseline (n = 15). Most participants who took part in the baseline interviews were recruited into study via leaflets at retinal screening clinics (n = 8/15) and via word of mouth (n = 5/15). One participant was recruited via leaflets at the local council`s leisure facility (gym) and one had been recruited via an advertisement in a local chronicle. Out of those participants, who were interviewed at follow-up only, one participant was recruited via word of mouth and one saw an advertisement on a hospital`s intranet where the participant worked. Information about the most utilised channels of recruitment of the rest of the participants enrolled in the Counterbalance Study was unavailable.

4.3.2.1 Inclusion criteria:

a) participants with a diagnosis of T2DM of less than 4 years or more than 8 years;
b) participants with a level of HbA1c lower than 80 mmol/mol or 9.5%;
c) participants with a BMI between 28-40kg/m^2
d) participants aged between 25 - 80 years;
e) participants with a stable weight in the previous 6 months (within a range of 5kg).

4.3.2.2 Exclusion criteria:

a) participants under treatment with thiazolidinediones, GLP1 agonists or steroids;
b) participants with renal or hepatic dysfunction (Serum creatinine >150 micromol/l or ALT >2.5 times the upper limit of normal);
c) participants with contraindications for Magnetic Resonance Imaging (MRI);
d) participants who consume more than 3 units of alcohol per day for women and more than 4 units of alcohol per day for men;
e) participants with an allergy to soybean or eggs;
f) participants with habitual high monounsaturated fat diet or highly restrictive diet;
g) participants with an untreated thyroid disease;
h) participants prescribed with atypical antipsychotic medication; participants with an active cardiovascular disease;
i) participants with major contraindications to physical activity;
j) participants who do not speak English.

Participants needed to achieve the agreed WL between visits during the WL phase in order to stay in the Counterbalance Study.

4.3.3 ***Interventions***

The Counterbalance Study consisted of two main phases and a transition period between them as illustrated in Figure 5 below:

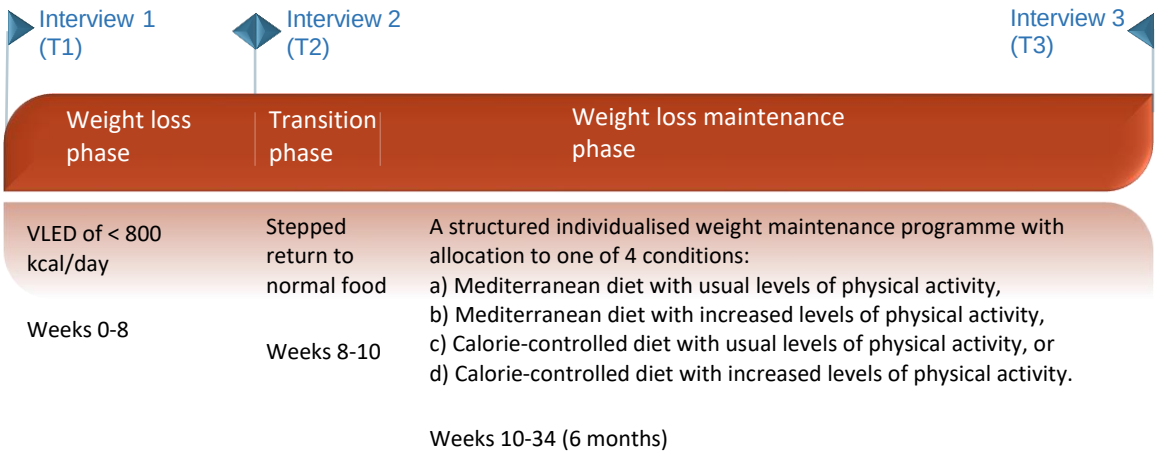

Figure 5. Illustration of the interview time points within the Counterbalance Study.
VLED = very low energy diet; forward/backward orientation of arrows indicates orientation of the interview questions on the future/past, respectively.

4.3.3.1 Weight loss phase of the Counterbalance Study using VLEDs

During the 8-week WL phase, participants consumed 800 kcal/day in total. Approximately 600 kcal/day came from 3 sachets of a liquid formula VLED (Optifast) used instead of meals. The VLED consisted of chocolate, vanilla and strawberry-flavoured drinks, a vegetable soup and a dessert in a form of sachets dissolvable in water. The participants were also allowed additional
240 g of vegetables per day, to equal 800 kcal per day altogether. In addition, they were asked to abstain from alcohol. All oral hypoglycaemic agents were discontinued prior to the start of the study.

The participants were asked to attend the Magnetic Resonance Centre (MRC) for 3 main visits: at baseline, week 10 and week 36. Each of these visits comprised of 1.5 half days of study. In addition, they attended the MRC at week 1, 4 and 8 during the

8 weeks of the WL phase for monitoring of biomedical measures, and to review their experience with the diet by the Counterbalance Study staff and nurses.

One-to-one support was provided weekly by telephone, e-mail and face to face to maximise adherence. Dietary compliance was monitored by changes in body mass, food diary and plasma ketone measurements. Participants were asked to measure and record their fasting and post-meal blood glucose levels 3 times a week. Only those participants who met their individual WL goals set by the study staff for weeks 1, 4, and 8 could continue on the study.

4.3.3.2 Food reintroduction

After the 8 weeks of WL, participants gradually returned to eating regular food in a two-week transition phase. During this phase, VLED shakes were gradually replaced by solid food; with one meal replacing a shake every 3 days.
Isocaloric intake (the amount of calories consumed equals approximately to the amount of energy expenditure) was determined from resting energy expenditure measured by indirect calorimetry using an open circuit calorimeter (Quark RMR; COSMED, Rome, Italy) and a canopy hood.

4.3.3.3 Weight loss maintenance phase of the Counterbalance Study

The 8-week WL phase was followed by a WLM phase lasting 6 months. During this period, the participants attended the MRC weekly for weight measures; and monthly for biomedical measures and assessment of dietary compliance with a 3-day food diary and by return of food packaging. They also attended at baseline, month 2 and month 6 of WLM for measurements of fatty acids composition of plasma triglyceride and measures of physical activity levels using Sensewear accelerometry. The participants were asked to wear the accelerometer for three 5-day periods at random points across the 6 months WLM phase.

The participants were randomly allocated to either a high monounsaturated fat (MUFA) or a usual mixed diet, and maximised physical activity or general lifestyle advice, using a computer programme at the beginning of the WLM phase.

The four allocation arms were as follows:
a) Mediterranean diet with usual levels of physical activity,
b) Mediterranean diet with increased levels of physical activity,
c) Calorie-controlled diet with usual levels of physical activity, or
d) Calorie-controlled diet with increased levels of physical activity.

Specific individualised dietary advice was provided by the study dietitian using a food exchange model, which facilitates replacing of foods high in saturated fat with foods high in monounsaturated fat.
Specific individualised advice by a chartered health psychologist was given to participants in the groups with increased physical activity. This included advice on behavioural strategies to facilitate adoption and maintenance of physical activity in daily life.

All participants were supported by a structured individualised program delivered by a chartered health psychologist, which included use of behaviour change techniques such as goal setting, action planning, and barrier identification, with monthly reviews. More details about intervention arms can be found in the protocol and the published studies (Steven *et al.*, 2016; Steven *et al.*, 2015; Steven & Taylor, 2015)

One-on-one support was available regularly in person at the MRC at Newcastle University, or via telephone for the duration of the study.
Continued telephone support and advice was available for at least 3 months after the study. The participants were invited to an evening reception after the study to provide feedback and results.

4.4 Conclusions

The present qualitative study was embedded in the context of the Counterbalance Study. It is based on semi-structured interviews conducted at baseline, after 8-week of VLED, and after 6 months of WLM. During this period participants` weight fell from 98.0±2.6 to 83.8±2.4 kg after the VLED and remained stable over 6 months (84.7±2.5 kg). Twelve of 30 participants in the Counterbalance Study achieved fasting plasma glucose <7mmol/l and achieved diabetes reversal after the VLED, and 13 of 30 were

diabetes-free after 6 months (Steven *et al.*, 2016; Steven, Lim, & Taylor, 2013). Experience of the participants with the WL, transition and the WLM phases of the Counterbalance Study is explored in Chapters 5 and 7. Evaluation of the VLED intervention as a WL and a diabetes remission intervention is presented in Chapter 6 and evaluation of the different WLM plans is presented in Chapter 8. A longitudinal qualitative study exploring change in the participants` narratives from the beginning through to the end of the study is presented in Chapter 9.

Chapter 5

A qualitative exploration of patient experiences with a very low energy diet for weight loss and diabetes remission

5.1 Abstract

Aims. This chapter aims to identify barriers and facilitators of adherence to an 8-week very low energy diet (VLED) for remission of type 2 diabetes (T2DM); and to identify behavioural strategies used to facilitate adherence with the VLED. Methods. Eighteen participants in the Counterbalance study took part in semi-structured interviews. Fifteen were interviewed before and sixteen after the 8-week VLED intervention. Thematic analysis was used to analyse the narratives. Findings. The prospect of diabetes remission, considerable WL and long-term health improvement provided participants with substantial initial motivation. This motivation was sustained through the experience of rapid WL, improvements in blood glucose, through availability of social support, and increased physical and psychological well-being. Participants addressed challenges to adherence by utilising behaviour-regulation strategies such as eliciting social support, removing food from the environment, coping planning, avoiding tempting situations or places, and self-distraction. Weight loss and improvements in blood glucose levels lead to a sense of achievement and a positive reinforcement of behaviour. Conclusions. Achieving rapid WL and improvements in blood glucose are highly gratifying and motivate to continuous effort to lose weight. Adherence to VLEDs can be facilitated by behaviour-regulation strategies.

5.2 Introduction

The majority of people with T2DM are overweight or obese (Astrup & Finer, 2000; Wilborn *et al.*, 2005) and return to normal blood glucose control can be achieved by substantial WL using a VLED (Lim *et al.*, 2011). Results of the systematic review of efficacy and acceptability of VLEDs in people with T2DM in Chapter 3 found that

VLEDs induce greater WL than minimal interventions, standard care or low energy diets at 3 and 6 months (Rehackova *et al.*, 2016). The systematic review highlighted the lack of evidence from qualitative studies about the experiences, barriers, facilitators and behaviour-regulation strategies of people with T2DM engaging on a WL intervention using VLEDs.

The current study complements the quantitative evidence from the systematic review by presenting results of a qualitative study exploring peoples` experiences with a VLED during the weight loss maintenance (WL) phase of the Counterbalance Study. It aims to identify the barriers and facilitators of adherence, behavioural strategies that people employ to overcome the barriers, and to identify the support needs of people undergoing a VLED.

5.3 Methods

This section focuses on description of the qualitative methods used for the evaluation of the WL phase of the Counterbalance Study, following the latest consolidated criteria for reporting of qualitative research (COREQ) (Booth *et al.*, 2014). The present qualitative study is based on semi-structured interviews conducted before and after the 8-week VLED. During this period weight of the Counterbalance Study participants fell from 98.0±2.6 to 83.8±2.4 kg, and 12 out of 30 achieved fasting plasma glucose <7mmol/l following return to isocaloric diet, i.e., achieved diabetes reversal (Steven *et al.*, 2016; Steven *et al.*, 2013).

5.3.1 ***Design***

This qualitative study comprised of analysis of semi-structured face-to-face, audio-recorded interviews guided by interview topic guides with open questions developed for baseline (T1) and post-intervention (T2) interviews as shown in Figure 6.

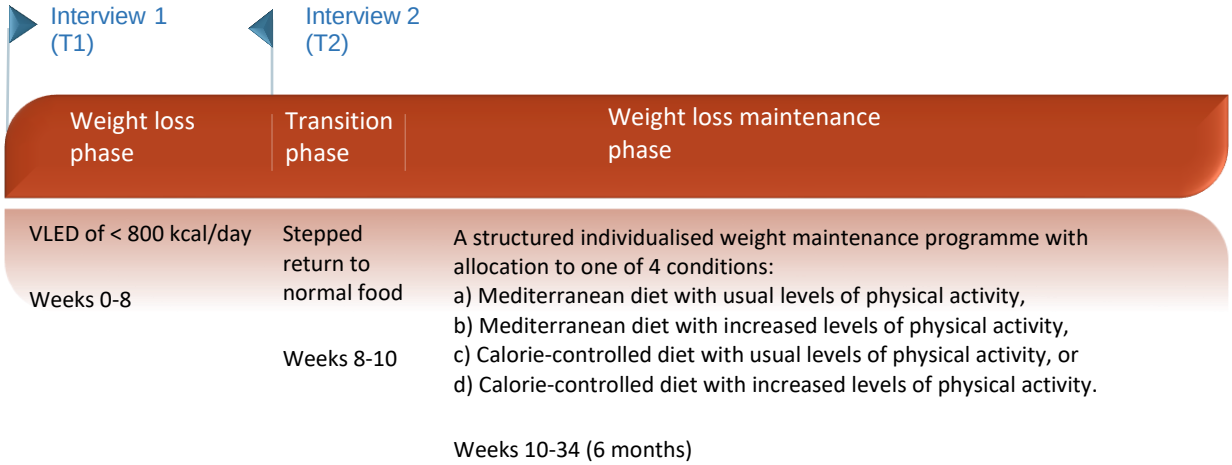

Figure 6. Illustration of the interview time points before and after the weight loss phase of the Counterbalance Study.
VLED = very low energy diet; forward/backward orientation of arrows indicates orientation of the interview questions on the future/past, respectively, considered in this chapter.

5.3.2 ***Sampling strategy***

A sample of 30 adults aged between 25-80 years, who had had T2DM for less than 4 or more than 4 years were recruited into the Counterbalance Study between July 2012 and September 2013. The trial was advertised using leaflets and by word of mouth. Adverts for the study were displayed in retinal screening clinics, local hospital, Newcastle University and several council leisure facilities. A full list of inclusion and exclusion criteria of the Counterbalance Study can be found in Chapter 4, and in the registered protocol (ISRCTN88634530).

5.3.3 ***Participants***

The number of participants recruited by each of the recruitment strategies was not recorded by the Counterbalance Study staff, but information about how the participants had learned about the Counterbalance Study was extracted from the participant interviews where possible.

Data collection for the qualitative evaluation was initiated at the end of March 2013, 8 months after the start of the Counterbalance Study. The reasons for the delay of the qualitative study were: 1) the decision to carry out a qualitative study, which was partially dependent on the results of the systematic review, was made after the Counterbalance Study start date; 2) an approval of an amendment of the protocol of

the Counterbalance Study was required in order to allow for participant interviews; 3) an application and approval of a research passport for the interviewer was required; and 4) appropriate training (interviewing skills, qualitative methodology, and Good Clinical Practice) needed to be in place before the start of the interviews.

All participants starting their VLED after the start date of the qualitative evaluation were invited to take part in the interviews. The interviews took place during scheduled full- or half- day visits of the participants to the clinic at baseline and the post intervention visits. Participants who discontinued the VLED or the WLM intervention or withdrew from the study were asked for permission to be interviewed as soon as possible afterwards, as they could have provided the study team with information essential to answer some of the research questions. These participants would be approached by a telephone contact by the interviewer rather than by the trial staff, and they could choose not to participate in this interview.

5.3.4 ***Interview protocol***

5.3.4.1 About the interviewer

I was a health psychology doctoral student with a master's degree in health psychology at the time of the interview study. I had received training in interviewing skills, qualitative methodology and Good Clinical Practice prior to commencement of the qualitative study. The participant – interviewer relationship was established at the first interview, where the purpose and reasons for carrying out the current study were explained. There was no incentive given to the participants for participation.

5.3.4.2 Interviews

The participants were interviewed at two occasions: at baseline (T1), at week 8 of the VLED (T2). The purpose of the two interviews was to capture the participants` expectations, behaviour or thinking over time, which would provide a unique insight into the WL through VLEDs. The T1 interview was designed to explore the participants` expectations of the VLED in relation to their weight, diabetes, or wellbeing. The T2 interview was designed to explore the actual experience of the participants` changes in weight, diabetes-related outcomes, wellbeing, and behaviour

and also prompt questions about their expectations of the WLM phase, which is further discussed in Chapter 7.

5.3.4.3 Interview documents

The interview topic guides were discussed with the multi-disciplinary supervisory team, and informed by the wider qualitative literature on adherence to WL treatments and theory-linked interview approaches (Francis, O'Connor, & Curran, 2012; Penn, Dombrowski*, et al.*, 2013). They included open-ended questions and prompts about the participants' experience with the VLED intervention.

The interview topic guides were piloted first with the help of three independent health psychology researchers in one-to-one mock interviews and were amended according to the feedback from the researchers. They were further amended after every participant interview as needed, by adding, changing or removing questions in order to accommodate for additional themes occurring during the interviews. To facilitate the interviews and future data analysis, field notes were also made during and after the interviews. The interview topic guides for interviews at T1 and T2 can be found in Appendices 10 and 11.

5.3.5 ***Interview procedure***

After participants contacted the Counterbalance Study staff, the study was explained in detail and the participants were given a Participant Information Sheet and a Participant Consent Form to sign, which also included a section about participation in interviews for the purposes of the Counterbalance Study qualitative evaluation. Informed consent for the interviews was integrated in the Counterbalance Study's consent procedure approved by Newcastle and North Tyneside 2 Ethics Committee (REC 12/NE/0208). The participants were then interviewed prior to/on commencement of the WL phase.

A screening room was available for interviewing on the half-day visits at times convenient to the participants, at the Institute of Aging and Vitality, Newcastle University. Alternatively, participants were interviewed in a testing room while blood samples were being taken and a nurse was present. In the latter case, a permission to conduct the interview was verbally obtained from the participant again and a

decision not to take part in an interview under these conditions was reiterated and respected.

5.3.6 ***Analysis***

Due to the intense nature of the intervention and the late start of the qualitative study, there was an “a priory” decision to interview all participants who would agree to take part, in order to minimise any data loss due to potential attrition and to assure that data saturation would be achieved.
All interviews were audio-recorded, anonymised and transcribed verbatim by experienced independent project secretaries, by an independent external transcriber and by the interviewer. The participants were not invited to comment on the content of the interviews, but they were encouraged to share any additional materials they would create for themselves if they wished to, such as diaries or notes.

5.3.6.1 Analytical strategy

Qualitative data analysis is, in general, a dynamic process of describing, classifying, and connecting of information, with concrete actions performed, such as familiarisation with data, labelling, reflecting, reviewing, and synthesising the information (Rapley, 2014).
My analytical strategy aimed to: 1) explore the motivation of participants to engage in an 8-week VLED intervention within a clinical study; 2) identify the barriers and facilitators to adherence to a VLED; and 2) to identify the support needs of participants and enable more individuals with T2DM to succeed with dietary diabetes remission through VLEDs in the future.
I followed principles of Thematic analysis, which is a “method for identifying, analysing, and reporting patterns (themes) within data” (Braun & Clarke, 2006). The steps in thematic analysis are as follows: 1) familiarisation with data, 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes, and 6) producing a report.

Due to the context of the qualitative study and the specific research questions I aimed to answer, my approach to analysis was more theoretical than inductive, what Braun & Clark refer to as “theoretical thematic analysis”. This approach is driven by

the researcher`s theoretical and analytic interest and linked with coding for specific research questions (Braun & Clarke, 2006). Keeping the research questions in mind throughout the coding process, the basis of my analytical framework consisted of coding of pre-defined theory-based themes, although any additional themes identified in the data were included in the coding framework. The initial themes were drawn from the Theoretical Domains Framework (TDF) which I have introduced in Chapter 2 (Michie *et al.*, 2005) and which has been previously used in other exploratory interview studies to identify barriers and facilitators to behaviour (French *et al.*, 2012; Penn, Dombrowski*, et al.*, 2013). The TDF, drawing on 33 psychological theories, was developed by a group of health psychology theorists, health psychologists and health service researchers in order to improve implementation of evidence-based guidelines and help identify the key constructs related with behaviour regulation and change. There are 2 versions of the framework available at the moment (Cane, O'Connor, & Michie, 2012; Michie *et al.*, 2005). After initial pen-and-paper coding of a number of interviews (n = 3) with both versions of the TDF, I decided to use the earlier version (2005) for the rest of the transcripts, as it responded to the data better than the latter (2011) version.

The following domains were coded in this study: 1) Knowledge; 2) Skills; 3) Social/professional role and identity; 4) Beliefs about capabilities; 5) Beliefs about consequences; 6) Motivation and goals; 7) Memory, attention and decision making; 8) Environmental context and resources; 9) Social influences; 10) Emotion; 11) Behavioural regulation; and 12) Nature of the behaviours.

A number of purposively chosen interview sections with different levels of complexity were then coded by myself and by one of the supervisors (VAS) to ensure consistent use of the coding framework and data interpretation, and few differences were resolved by discussion. After sufficient consistency was reached, I then coded, sorted by themes and summarised the rest of the data, using the NVivo v.10 software to support the data analysis.

Participants were not invited to comment on the findings was used. All representative quotes are annotated by gender, age and duration of diabetes.

5.4 Results

Altogether, 18 out of 30 participants enrolled in the VLED programme were interviewed in this qualitative study. Fifteen participants were interviewed at baseline (T1). One participant was excluded from the Counterbalance Study after 2 weeks due to not meeting the pre-specified WL goal of 2.8% of body weight. Sixteen participants were interviewed at follow-up (T2). Three participants missed the first interview and one participants missed the second interview. Reasons for not attending interviews were lack of time and work commitments of the participants, and unexpected scheduling issues with the software used to update participant appointments (a shared calendar). Table 7 provides an overview of the participants` characteristics.

The median length of the T1 interviews was 24 minutes (range=12-41 minutes). The median length of T2 interviews was 44 minutes (range =16-73 minutes), and included both, VLED and WLM related questions.

The results in this section are based on data gathered throughout both interviews and presented so that they reflect the experience wholly, while I also make comparisons between the expected and actual experiences where possible. I have identified 5 themes throughout these interviews: **1) Increasing health-related quality of life**; **2) Enhancing appearance** (themes 1 and 2 explained the participants` motivation to take part in the study); **3) Exceeded expectations**; **4) Positive feedback loop**; and **5) Facilitation of adherence**. The results are presented under the respective themes in the following sections. A mind map of the identified themes and relationships between as I perceived them are presented in Figure 7 at the end of this chapter.

Table 7. *Interview (T1 and T2) study participants` characteristics, Interview time points and changes weight, BMI and fasting plasma glucose levels.*

ID	Gender	Age (years)	T2DM duration (years)	T1	T2	Weight at T1 (kg)	BMI at T1 (kg/m^2)	FPG at T1 (mmol/L)	Weight loss at T2 (kg)	BMI change at T2	% Weight loss (kg) and BMI (kg/m^2) change at T2	FPG change at T2 (mmol/L)	% FPG change at T2 (kg)
1	man	67	3.5	X	X	106	34.6	7.39	-16.90	-5.5	-15.94	-2.25	-30.48
2	woman	61	11	X	X	87.4	33.1	15.43	-13.00	-4.9	-14.87	-6.79	-44.03
3	woman	65	3	X	X	87.4	33.5	11.88	-11.70	-4.5	-13.39	-4.20	-35.33
4	woman	42	1		X	112.9	36.4	8.89	-13.30	-4.3	-11.78	-2.64	-29.71
5	man	44	2.5	X	X	106.5	36.4	12.65	-12.90	-4.4	-12.11	-5.48	-43.33
6	man	54	0.5	X	X	90.9	32.4	6.70	-16.30	-5.8	-17.93	-1.50	-22.35
7	man	65	13	X	X	119.80	41.0	13.54	-16.70	-5.7	-13.94	-6.48	-47.87
8	man	64	9	X	X	90.00	29.4	11.99	-8.30	-2.7	-9.22	-3.91	-32.59
9	man	49	9.5	X	X	97.5	31.8	14.21	-16.70	-5.5	-17.13	-9.16	-64.45
10	man	52	1	X		107.6	34.0	11.5					
11	woman	47	2.5	X	X	109.5	39.0	6.93	-17.20	-6.1	-15.71	-1.67	-24.04
12	woman	35	1.5		X	102.2	38.0	9.42	-15.00	-5.6	-14.68	-3.97	-42.17
13	man	69	8.5	X	X	105.2	37.7	8.84	-18.00	-6.5	-17.11	-5.11	-57.79
14	man	59	10	X	X	96.2	32.9	6.92	-15.20	-5.2	-15.80	-1.98	-28.57
15	man	69	3.5	X	X	108.6	33.1	8.45	-22.20	-6.8	-20.44	-3.81	-45.07
16	woman	64	12	X		119.2	45.7	15.43	-14.90	-5.7	-12.50	1.11	7.19
17	woman	70	15	X	X	74.3	31.5	12.54	-8.80	-3.7	-11.84	-5.71	-45.49
18	man	69	18		X	104.2	32.2	17.32	-14.50	-4.5	-13.92	-5.44	-31.41

Note. T2DM = type 2 diabetes mellitus; FPG = fasting plasma glucose; B = Baseline interview; T1= Interview at the beginning of the VLED; T2 = Interview at the end of the weight loss phase. Highlighted in pink is a participant who discontinued the Counterbalance Study, and whose data were not included in any further analyses. Highlighted in green are participants who achieved normal-range FPG levels (<7.0mmol/L). Highlighted in grey are participants who achieved borderline normal FPG levels (slightly over 7.0mmol/L, maximum was 7.68 mmol/L). Negative values represent a decrease; positive values represent an increase.

Asking the participants about their motivation to take part in the programme, about their expectations of it, and about what they believed would happen as a consequence of the VLED resulted in complex answers, reflecting the variety in individual circumstances, experience, and drives.

Two main themes were evident throughout the participants` narratives: 1) Increasing quality of life and 2) Enhancing appearance. Due to T2DM being associated with overweight and obesity, there was an obvious overlap between these two themes. However, it was important to make the distinction between them due to the different meanings of each of the motives in the participants` narratives. The following sections elaborate on each of the themes, with their related sub-themes and examples of participants` narratives.

5.4.1 ***Theme 1: Increasing health-related quality of life***

The theme of increasing quality of life encompassed several sub-themes, which represent the complexity of motivation of the participants to take part in the Counterbalance Study. The identified sub-themes illustrate that the participants` desire to improve their quality of life in the future was underpinned by their motivation to 1) lose weight definitely; 2) decrease their health risks; b) increase their chances of good quality family life in older age; and 3) understand diabetes and its effects better.

5.4.1.1 Definite weight loss

Prior to coming onto the Counterbalance Study, many participants had tried to lose weight through various diets. Some participants had lost weight over the years before coming onto the study and managed to maintain that WL, but wanted to lose more weight. Others had lost weight and regained it; and some did not manage to lose weight, mostly due to the unacceptability of the diet they tried had engaged on. The previous attempts to lose weight sometimes resulted in moderate success, but often failed due to slow WL, boredom with the WL regime or dislike of it, and eventually resulted weight re-gain.

"I've been on other diets where I've been on the diet and I've got bored with it, and it seems very slow, and then I get off the diet and the weight goes back on again" (WOMAN, 61 YEARS, T2DM 11 YEARS).

Taking part in a relatively short WL intervention promising substantial WL was therefore perceived motivational. It was expected to provide a "kick start" to the WL

and behaviour change, as opposed to slower, progressive weight change they had experienced during their previous WL attempts.

"And having been on different diets in the past. Yes they've worked for so long but then you slip back into your old routine and I thought this might have been the ideal opportunity to get a good kick start and hopefully get the weight off and keep it off" (WOMAN, 47 YEARS, T2DM 2.5 YEARS).

5.4.1.2 Decreasing health risks

Many participants considered the Counterbalance Study to be their last chance to lose weight and improve diabetes and were considering taking part in the study a long-term investment in their health. By taking part, they were attempting to un-do some of the negative effects of diabetes to their health that had already been incurred and avoid future health complications.

"It would be fantastic to come off the end of the study with a clean bill of health, in a situation where I can control my weight at a lower level, knowing that any future illnesses might not be coming my way, because I've taken some action now"
(MAN, 49 YEARS, T2DM 9.5 YEARS).

Other participants had previously experienced diabetes in their families or knew someone who had suffered from it, and were aware of the potential consequences of the illness that they wanted to avoid. The quote below is from a participant who saw a parallel between himself and his father, who had had diabetes and later a heart attack, which he believed could have been prevented had his father taken more control of his diabetes. The heart-attack resulted in his father having to be cared for by the participant. This event made him think about preventability of damage to his own health in order to increase his quality of life in the future, which motivated him to improve his health before it is too late to take control.

"…he's in a position that partly he doesn't need to be in if he'd done certain things…I just thought to myself I can do more about this by participating in this programme…That could be life extending and it's the quality of life. It's not the extension of life. I'm not bothered about that"
(MAN, 69 YEARS, T2DM 3.5 YEARS).

5.4.1.3 Family life in older age

Age therefore played an important role in the participants` decision to take part in the study. Most of the participants were close to or had reached the retirement age by the time of the interviews, and they wanted to make the most of their time at this stage in life by improving their quality of life.

"I want to enjoy the life that I've got, if it's 10 years. I know people who've died in their 50s. I'm almost in my 60s. If I get 5, 10, 15 years I'd just like them to be good. And it might be 30 but I wouldn't want 30 if it was going to be miserable. I would rather have 20really good ones. Who wants 10 years in an old people's home with incontinence and dementia? I've seen it. I see it every day" (MAN, 49 YEARS, T2DM 9.5 YEARS).

The potential improvements in health, mobility, fitness and energy were also hoped to enable the participants enjoy their family life and to be around their loved ones for as long as possible. Some of the participants were carers for their partners or parents and felt responsible for keeping fit enough to be able to take care of their relatives, while others wished to live long enough to see their grandchildren grow up and they felt that the potential future diabetes complications may eventually decrease their quality or length of life in the future.

"Anything that will make my health a little bit – because I am older than my wife. It's my second wife. She's quite a few years younger. So she wants me to stay around for as long as I can"
(MAN, 54 YEARS, T2DM 0.5 YEARS).

5.4.1.4 Understanding diabetes

The diagnosis of T2DM and a start of a treatment had caused confusion among many of the participants with regards to dietary recommendations and self-management. Despite having attended various post-diagnosis programmes aimed at healthy eating, physical activity and management of diabetes offered by the NHS (e.g. the DESMOND programme), the participants felt overwhelmed by the amount of information. As a result of the information overload, their difficulty processing it, or due to their lack of interest in diabetes over time, they ended up lacking knowledge essential to management of their diabetes.

"My GP is brilliant but I think when he diagnosed it I was pushed into the Desmond programme then at the same time into the weight management and what was the other, oh the dietician and everybody involved in such a short space of time that I felt as if I was bombarded with too much"
(WOMAN, 47 YEARS, T2DM 2.5 YEARS).

In addition, lack of healthcare professionals` time to explain the condition in depth often resulted in the participants looking for healthy eating advice from other sources in addition to the advice they had been given, which led to both, more understanding and dietary adjustments, and to being misinformed about certain dietary restrictions or recommendations in some cases.

By taking part in the Counterbalance Study, some of the participants were hoping to learn more about diabetes, and about how it affects their bodies individually. They were interested in changing their eating behaviours to facilitate management of their diabetes; in being able to maintain these behaviours in the future; and in achieving a lifestyle change.

"I want to know how my body works. I want to know how the liver is functioning. I want to know how the glucose and that works and I want to know what happens when you do go on a low calorie diet like that"
(WOMAN, 64 YEARS, T2DM 12 YEARS).

Most of the themes related with the possibility of diabetes reversal tapped into the participants` efforts to increase their quality of life in the future, to prevent further health complications, and to be able to live a good life for as long as possible. However, it seemed that a well-controlled diabetes affected the participants` day-to-day lives minimally. It was the medication used for diabetes management that was the major source of complaints among those treated with medication. The participants complained about the number and frequency of drugs they were prescribed to use, the side effects, and weight gain associated with some of the drugs, which was counter-productive to their WL efforts. Some of the most discussed side-effects were urination at night time, which led to disturbed sleep and tiredness during the day; weight gain; or feeling sick.

"I hate taking tablets, and I'm on six a day, so… I mean I'll try anything to get rid of it. If it goes, great. If it doesn't, well, at least it's helped. Well, it will have helped. I might come off the tablets, I don't know; just be a diet only"
(MAN, 44 YEARS, T2DM 2.5 YEARS).

The narratives imply that if the participants did not need to take medication for their diabetes, diabetes itself would not pose a particular burden to the participants` day to day life, although it might lead to complications in the future.

5.4.2 ***Theme 2: Enhancing appearance***

Both men and women wished to be able to dress in more appealing clothing, gain more self-confidence, and feel better about their bodies as a consequence of the WL. For example, the quote below highlights the lack of choice in clothing for people of larger sizes, which has been found one of the sources of environmental obesity stigma (Lewis, Thomas, Blood, Castle, Hyde, & Komesaroff, 2011), and also how wearing these makes the participant feel less attractive than they would like to feel. It

also highlights the association of smaller clothing with feeling good about themselves, and a sense of attractiveness.

"It is, new clothes that make me feel good and that are much smaller than the ones I currently wear, and that would be fine, that would be a nice thing to have. You know, just to be able to walk into a store and go, "Which one of these, not at the moment, out of those five, that one's probably the least offensive"
(MAN, 67 YEARS, T2DM 3.5 YEARS).

Another aesthetic concern was that the participants might lose weight in the "wrong" places on the body, that their skin would become loose, or that they would lose muscle and strength, but these were considered "good concerns" to have. These motives again highlight the participants` awareness of what an acceptable body image is, the importance of the "right" proportions and body composition among both men and women.

"Only that I have got a fair bit of weight on here and when I did lose weight in my 20s I had a problem with skin tone, so loose skin and that's a concern. I think there'll be a cosmetic concern for me and I may have to decide about what to do about that if I can do anything about it"
(MAN, 59 YEARS, T2DM 10 YEARS).

The participants also reflected on the many physical and psychological implications of excessive weight that they have to deal with on a daily basis, such as not being able to engage in activities they would like to, being ashamed of the shape or size of their body, feeling less attractive than they would like to feel, or not being able to dress in clothing they would feel comfortable in. The burden of overweight or obesity presents itself in the life of participants daily as opposed to the burden of diabetes as a health condition, which was mostly expected to present itself in the future. This may explain why WL was found a slightly stronger motive to taking part in the Counterbalance Study, than was the potential to reverse T2DM, although this observation was very subtle due to the nature of the relationship between overweight and T2DM.

5.4.3 ***Theme 3: Exceeded expectations***

Before the VLED intervention, participants identified several potential barriers to adherence including hunger or lack of enjoyment of the diet, and they were uncertain about their ability to regulate their behaviour in tempting situations. The follow-up interviews found that many of these expectations were not fulfilled, and that there were other, positive consequences of the VLED.

5.4.3.1 Hunger, temptations and dietary lapses

Vast majority of the participants perceived adhering to the VLED as considerably easier compared to what they had expected at baseline. This was especially related to their anticipation of hunger and their perceived and actual self-efficacy to deal with temptations. The perception of hunger varied individually. To some participants, hunger did not present a particular barrier in adhering with the VLED, because it was perceived as a rational and expected consequence of energy restriction, while very few needed to make more efforts to regulate their behaviour when feeling hungry. In addition, hunger seemed to diminish within the first week of the VLED, although it became more noticeable again towards the last weeks of the VLED.

"I was so surprised, compared to what I was eating to what I have been eating over the last weeks I really would have thought that I would have been hungry from the moment I opened my eyes to the moment I closed my eyes, but I wasn't" (WOMAN, 42 YEARS, T2DM 1 YEAR).

The perception of hunger however did not seem to affect the participants` reported adherence with the VLED, which came as a surprise to many participants. While low levels of hunger might facilitate adherence, those who felt hungry more often seemed to have developed strategies to prevent deviations from the diet, which are further discussed below under *Behavioural strategies*. Hunger was not a reason for the reported dietary deviations.

Most participants revealed having experienced temptations at some point during the 8 weeks of the VLED, although these were much less frequent than the participants had anticipated. Some of the participants had given in on a rare occasion. Both temptations, but more so deviations from the VLED were also rarely reported. When reported, they were usually associated with emotional distress, special events or followed an environmental trigger.

Feelings of sadness, loneliness or stressful experiences tented to weaken the participants` willpower and increase the attractiveness of a temptation, although it rarely led to an actual lapse. The quote below if from a participant who was a nurse

and who reported having almost given into temptation after she had experienced a cardiac arrest on the ward.

"I was so frazzled I went up to the desk and there was some chocolates right in front of us and I was so tempted to have one but I walked away from them, although I have to say I walked up to the tin and lifted the lid 3 times but each time I just walked away from it because I thought no, because that would have felt like I had given in and I didn't want to do that" (WOMAN, 35 YEARS, T2DM 1.5 YEARS).

Both, environments outside as well as inside of the participants` homes presented challenges to adherence with the VLED. For example, one participant described how she almost gave into temptation passing by a chip shop after a difficult day and how support from her friend made her not give into that temptation.

"That was a bad day that day. Honestly I finished work and I pass the chip shop every Friday evening and I was like "oh fish and chips, fish and chips." And as I passed I was like oh there's not a parking space, I'll go home. So I went home. So I had – I think it was my...I don't know if it was a soup or a shake that day I had and then my friend text "are you alright?" and I sent him one back saying "no, very nearly had fish and chips but didn't, but really fancy a pizza now". And he rang and he was like "Don't you dare!" and I was like "well the thing is I'd have to get in the car and go and get it." That's because there's not a pizza place near me and he's like don't go there. So after a stern talking to on the phone I didn't" (WOMAN, 47 YEARS, T2DM 2.5 YEARS).

Social events such as birthdays or infrequent family visits were situations in which there was abundance of food and in which the pressure to eat along was elevated and required more resilience, but most participants reported not being particularly tempted in presence of food after a couple of weeks on the VLED.

"Oh yeah she had a party out in the children's activity. I just brought my shakes with me. My grandson had a birthday a couple of weeks ago and I survived that. Never had any birthday cake or anything like that so"
(WOMAN, 70 YEARS, T2DM 15 YEARS).

The most frequent trigger foods were comfort food or "treat" items, such as ice-cream, chocolate, fish-and chips, or alcohol, and smelling food seemed more triggering than seeing food.

"I've not, when I've had to be around people eating I have, so I know the beginning first few weeks I was going to lunch after everybody else had been to lunch so I couldn't smell anybody's food, I couldn't see it. I isolated myself a bit. But then I'd say definitely the last 3 to 4 weeks my normal little crowd that I was going to lunch with, I was going to lunch with them again and it didn't matter what they were eating it didn't bother me as much" (WOMAN, 42 YEARS, T2DM 1 YEAR).

When it came to actual lapses, these followed both, an impulse (caused by presence or smell of food), and reflection (deliberation and a subsequent conscious decision to go off the diet as a result).

"That she [wife] *had just cooked the chicken and I pinched the leg and then I pinched the other one and that's as far as...that's the only time"*
(MAN, 44 YEARS, T2DM 2.5 YEARS).

"…We've always been away together so going away on my own and doing something on my own is I find that difficult…normally away on holiday you would enjoy eating out and doing a bit more in that respect and I was on milkshakes for a week. So that was when I missed the wine really…I had it lying in the cupboard for 2 or 3 days before I made my mind up to have it, yes…I was even by then locked into this is going to work and I wouldn't want it not to work so I just made sure it was a tiny bottle of wine. I didn't want to take a big one and risk the possibility of drinking that. So yeah I knew exactly what I was doing…but other than that through the 8 weeks we [I] *stuck with it"*
(MAN, 69 YEARS, T2DM 18 YEARS).

Too few participants reported having deviated from the diet to make conclusions about what the situations are in which there is a higher risk of lapse. Though a number of participants planned to avoid their usual social circles or events such as birthdays, work lunches, or holidays prior the VLED, these did not pose a particular barrier to adherence during the VLED. In fact, most participants reported that although they were tempted in such situations, they managed to stick with the diet and thought that it was more difficult or awkward for other people to eat around them.

"…she was like "I'm not going to eat in front of you." I'm going "you might as well." So I got into the habit of taking her to the local cafe, and buying her a meal and me having a cup of fruit tea and she thought that was very strange but and people say well how are you not tempted by the food but I wasn't, I genuinely wasn't. It was just completely focused on this is a result that I want"
(MAN, 59 YEARS, T2DM 10 YEARS).

5.4.3.2 Rapid initial weight loss and improvements in blood glucose levels

The rate and the amount of WL and the decrease in BGL exceeded expectations of many participants, which largely contributed to the continued motivation to comply with the VLED and to an overall high satisfaction with the outcomes of the WL phase. Many have reported losing weight quickly within the first couple of weeks and then continuing to lose at a rate of approximately 1.5 kg a week. The speed of WL also motivated the participants to continue losing weight after the WL phase, because they realised that it was possible, and wanted to achieve their personal weight goals rather than the study weight goals only.

"I think it's been the initial the weight loss, how quick it's gone off, but obviously that's because of the very low calorie diet, but I think that's the bit that's motivating us [me] *to continue"* (WOMAN, 47 YEARS, T2DM 2.5 YEARS).

Seeing the changes in weight and BGL quickly were encouragements in themselves and facilitated reinforcement of behaviours supporting adherence with the VLED. This motivational boost within a few weeks of the start of the WL phase was important especially because of the general decrease in energy and increase of boredom halfway through the diet.

"I have found every week there has been something that has been different. So in the first week I noticed I was just feeling a little bit better, brighter, you know, more upbeat. In the second week friends who I hadn't seen for a little while were actually saying to me, "Oh goodness you've lost a lot of weight." So that's encouraging" (WOMAN, 61 YEARS, T2DM 11 YEARS).

5.4.4 ***Theme 4: Positive feedback loop***

This theme demonstrates how the positive feedback that the participants received from their social circles, from the study staff, but also including the participants physiological and psychological responses to the intervention facilitated adherence with the intervention.

5.4.4.1 Social support and feedback

Feedback and support from other people played an important role in preparation for the WL phase of the Counterbalance Study, and if received, this facilitated the participants` behaviour regulation and adherence during the VLED. Various aspects of social feedback and support have been identified in the interviews. For example, some participants who shared households with other people often reported that their significant others had altered their own eating behaviour in order to facilitate adherence of the participant. This included eating at different times, refraining from offering trigger food, preparing the allowed vegetables for the participant to snack on while cooking, warning the participants before cooking, so that they could engage in another activity, reminding them of what they were or were not allowed to eat, or even embarking on their own WL alongside the participants` WL.

"…especially when you're walking through the kitchen with a mother that's always cooking and preparing it's so easy to just, you know, but she's got quite wise to it actually, because she knows that I can only have vegetables there would always be a little plate on the side with some carrot sticks in it or cauliflower stalks and these are things that I like and I'd eat before this diet anyway so I'd just pick" (WOMAN, 42 YEARS, T2DM 1 YEAR).

Similar changes in other peoples` behaviours in response to the changes in the participants` behaviours are further discussed in Chapter 9, under the theme "Contagiousness of behaviour".

A number of participants have reported that their friend or a relative had gone through a similar programme before and had given them advice and words of encouragement before and during the VLED. Having a buddy system in place was found greatly helpful for the purposes of experience sharing and to receive encouragement.

"My wife was similarly overweight to me…She spends most of her life in a wheelchair but she's managed to lose an almost identical amount to me…so it's good to be able to do it with someone else rather than on your own…I first learnt about this plan through my brother who is also a diabetic and he's been through this exercise and he also lost about 3 stone" (MAN, 69 YEARS, T2DM 18 YEARS).

A small number of participants did not have the need for social support and preferred to "do their own thing", especially when being confident in their ability to adhere with the VLED. In rare cases, lack of social support also inspired motivation to finish the 8-week VLED.

As discussed previously, social events could be challenging to the participants` adherence, although from the limited reported data it seems that it was situations in which they were alone rather than accompanied, when a temptation led to a lapse. This may be due to the social pressure the participants created by broadcasting taking part in the study at the start of the WL phase. The quote below represents how willpower, high levels of motivation, and planning also facilitated adherence during social events.

"If there was a meal being cooked that was particularly attractive, smell and stuff like that, that I might then just walk out of the house and go for a walk, just get out of the environment completely. They were all strategies that I had in place that I didn't have to use. I just my willpower was so strong that it didn't stop me. I've made barbeques, I've made bacon sandwiches, I've made meals that I would have killed for and just handed them over and said there you are, enjoy, and then I went on and just had whatever I was allowed to have…What I did was I actually had to plan when to eat so I actually ate before" (MAN, 49 YEARS, T2DM 9.5 YEARS).

Chapter 9 further discusses a change in the participants` role within their social relationships (from needing support to being the supporter), the change in their lifestyle independence and its social contagiousness.

The opportunity to take part in a small medical study under close supervision gave the participants sense of exclusivity and responsibility, which seemed to contribute to considerably high levels of initial and continuous motivation, self-efficacy and adherence. The participants referred to not wanting to let the study staff down or spoil the results of the study by not adhering to the diet, and they saw taking part in the study as an opportunity to potentially help other people with diabetes in the future:

"I've been accepted on the study and it's all for diabetes study so you've got to give your bit, you know… I know if I do slip and mess up then it's been a bit of a waste of time for the study staff in a way and it's a waste, it's just totally spoilt it" (WOMAN, 47 YEARS, T2DM 2.5 YEARS).

Regular weighing and monitoring at the clinic was expected to facilitate adherence with the VLED, and served as an added motivation to help them adhere to the diet:

"*I'd dabbled with diets, not very effectively, and I thought this would provide me with the ideal disciplined way of doing it. In other words, if I've screwed up someone's going to shout at me"* (MAN, 67 YEARS, T2DM 3.5 YEARS).

The regular monitoring and contact provided social as well as physiological feedback essential to the participants` continuous motivation. However, despite the amount of social support available to the participants, whether provided by the study staff or by their significant others, colleagues or clients, most felt that it was their personal responsibility to comply with the VLED. The reason was that due to the recruitment limits for the study, the participants considered taking part in it an exclusive opportunity to attempt to reverse their diabetes and lose weight. They were highly motivated not to disappoint the study staff or distort results for the study, because they were being aware of the efforts the study staff had put in, and the potential future implications of the Counterbalance Study.

"There's no point in being in half hearted, you've got to either do as you…these people have been doing it for a while. I know it's relatively new research, but they know what their aims are the know how to achieve it so if you don't take advice and follow the plan properly then really you're cheating yourself, nobody else" (MAN, 69 YEARS, T2DM 18 YEARS).

"Well to be honest, you say support, it's just someone holding your hand and if you're going to do something like this you've really got to have it within you I think because someone can sit there and talk to you and tell you yeah in 8 weeks you're going to have lost this and you don't do that, but it's not going to help your stomach and the growling. No matter how kind or helpful or supportive that person wants to be, to me it's not really going to help me, not after I've just gone out the door and I'm at home. So really myself" (MAN, 67 YEARS, T2DM 3.5 YEARS).

5.4.4.2 Changes in physiological wellbeing

Majority of the participants felt gradually fitter over the period of the programme, after a WL of about 1-1.5 stones (approximately 6-9.5 kg). The increased levels of fitness were related with being able to do the same activities for longer or at a higher intensity, and being able to function better in their daily life. For example, participants reported improvements in activities such as walking, climbing stairs, doing work around the garden or the house or running and fell-walking.

Some participants have also perceived decrease in skeletal or muscular pain and realised how ill they had felt before.

"So and I now realise that I feel better inside, not just looking better on the outside but I feel better on the inside which is a really big part of it. I think that it's more important than the weight loss to a certain extent because I just feel I don't feel ill and that's how I felt before. I just felt so ill all the time so that's a good thing" (WOMAN, 42 YEARS, T2DM 1 YEAR).

However, many also reported increased tiredness in the first phase of the 8 weeks. This was due to the considerable decrease in calorie intake, which impacted on the participants` ability to be physically active to the extent they had been prior embarking on the VLED, which usually improved soon after regular food was re-introduced into their diets.

"And I suppose the fact that I played a game of football with my youngest grandson. Well played football, kicked a ball about for 40 minutes, which was something that wouldn't have happened beforehand"
(MAN, 65 YEARS, T2DM 13 YEARS).

Another form of feedback that the participants received was from their own bodies. The participants learned about how their bodies responded to calorie restriction and food and also observed their behaviours during the 8 weeks, particularly in situations when they felt tempted, which helped them be more mindful of their relationship with food, and enable making changes for the long term.

"You can't do it as a short term thing and even a medium term thing. It's got to be a change for life otherwise you just end up back where you started. There wasn't any point in going through the whole thing if you don't take notes of what you've learnt from it" (MAN, 69 YEARS, T2DM 18 YEARS).

"It's made me more conscious of where extra calories slip in, especially on the ward when they have huge tubs of chocolates on the desk every day. Or huge tins of biscuits" (WOMAN, 35 YEARS, T2DM 1.5 YEARS).

5.4.4.3 Changes in psychological wellbeing

The amount of WL, improved physical fitness, sense of achievement and compliments from other people have all contributed to the participants` improved perception of psychological wellbeing and happiness. Most of the participants experienced that their mood remained quite stable, despite their anticipation of irritability or grumpiness. The majority of participants felt better about themselves, felt happier, less ill, and more optimistic about their future. Both men and women reported becoming generally more confident in their bodies and being pleased with the change in their body shape.

"I'm quite pleased with myself at the mind-set that I got myself in to to actually get me through. Really pleased with the results. According to Sarah I've lost neigh on 3 stone. I'm the slimmest I've been since I was about 18, something like that" (MAN, 49 YEARS, T2DM 9.5 YEARS).

"My flexibility was good before. It's far, far better now. So overall flexibility is better which is good from a fitness and an exercise point of view. Strength has dropped quite significantly but that's to be expected and I can build that up again. I've very happy. Very happy, you know. I feel great. I look far better" (MAN, 69 YEARS, T2DM 8.5 YEARS).

Rapid changes in WL would not occur without notable changes in the size of clothing, providing additional motivation to keep up through compliments and encouragement from others. The change in the size of clothing also helped the participants` self-confidence, feelings of wellbeing and sense of attractiveness and it also served as a way of measuring their WL success.

"I wouldn't say it's a particular weight amount. I've got a rough idea in my head but because I've not weighed that for a very long time is that the weight that I should be going down – I think of it more as in a clothes size. Now I know I've definitely dropped 2 dress sizes, possibly 3, so if I could lose another 2 I think, especially with my height I know I'll be a lot better"
(WOMAN, 42 YEARS, T2DM 1 YEAR).

"My dresses at work. They started to look really big on us [me]*, like a tent on us* [me]*, huge. But I still didn't think that I had lost that much weight even though my dresses were quite loose because when I looked in the mirror I still thought I looked quite big, to me"* (WOMAN, 35 YEARS, T2DM 1.5 YEARS).

A transition from more lose to tighter clothing as well as a change in colour preference from darker to lighter was noticeable in a number of participants during the follow-up interviews, which may also underline the positive changes in the participants` bodily and psychological satisfaction. However, due to the WL phase

lasting for 2 months and participants starting at different times of the year, it cannot be ruled out that this happened as a result of seasonal changes.

5.4.5 ***Theme 5: Facilitation of adherence***

A number of different types of behavioural strategies were employed by participants to supress or avoid hunger or cope with situations where an increased risk of lapse was identified. Some participants reported having prepared their strategies prior to the start of the VLED, while others developed their strategies during the VLED, although there was little difference in what strategies have been employed overall. The most frequently employed strategies to overcome the above barriers to adherence with the VLED were: 1) Elicitation of social support; 2) Removing food from the environment; 3) Avoidance of tempting situations or places; 4) Distraction and finding alternative activities; and 5) Coping planning. These were often used in combination. Below are examples of the most frequently used behavioural strategies.

5.4.5.1 Elicitation of social support

Some of the potential difficulties related with taking part in the VLED intervention were identified by the participants before they started on the diet. Behaviour regulation strategies (Appendices 12 and 13) were put in place in anticipation of the difficulties and to facilitate a lapse-free start of the WL phase. Additional strategies were then developed with the progression of VLED and the participants` changing needs.

"Broadcasting" taking part in the study among friends, family, co-workers and clients via social media or personal discussions was meant to provide the participants with social support, understanding and external pressure to adhere to the diet. Such social disclosure facilitated adherence with the VLED, for example, when their colleagues did not offer trigger foods or removed these from participant`s reach or sight.

"…if it's anyone's birthday in the office block, they always buy cakes and biscuits and things…and the desk where I work there's always a spare desk…it's always clear – and that's where the cakes always used to get put…But not while I was on the diet so they moved them to a different office so they weren't and but didn't even offer me because they knew" (MAN, 54 YEARS, T2DM 0.5 YEARS).

Seeking information and advice from relatives and friends who had undergone the same or a similar programme in the past; or planning to avoid social events also

show the importance of the social environments that the participants regularly encounter, and the need for social support.

"Oh yes I've broadcast that widely so that I've got – Just so that I know I've got support there if I need it and that I'm not feeling pressured by them if I go out with them. They're not saying well why aren't you eating this, come on have some, but they're going to say but you're on your study so you can't have that. The support is going to be there" (WOMAN, 47 YEARS, T2DM 2.5 YEARS).

A number of participants had a form of an informal buddy system in place prior to the start of the VLED. This included, for example, their partners and families making changes to their eating routines for the duration of the diet or a friend taking part in the same or in a similar programme to facilitate the participants` adherence.

"To do it, she'll back me all the way. To be honest with you, she could do with losing weight so she's a little bit like we'll do it together sort of thing"
(MAN, 69 YEARS, T2DM 3.5 YEARS).

5.4.5.2 Removal of food from the environment

Another strategy developed prior to the start of the VLED included removal of food from the participants` immediate environments such as at home or at work, mostly by giving or throwing the last stocks away. This was expected to help reduce potential temptations and dietary deviations during the WL phase.

"*What we've done is, I mean, the fridge is empty now. And I`ve just been waiting for that leaflet to see what we can eat, and then we'll go shopping on Saturday, and I'll get all the stuff in that we can eat. That's my plan*"
(MAN, 64 YEARS, T2DM 9 YEARS).

In addition to removing food, some participants were planning to get more involved in activities unrelated with food to shift their attention away from food; or planning to avoid places or situations, where they might experience temptations.

"*I'm thinking instead of actually standing an hour cooking, preparing meals so on I do an hours sketching or something you see so it's sort of like substituting the things that are associated with food with other interesting things. I've got a long list of jobs which I should haven't done which I haven't done which I'm, I feel I can, I can do because I feel that I have more time*"
(WOMAN, 65 YEARS, T2DM 3 YEARS).

Most participants had a number of strategies in mind to start with and the next quote reflects the complexity of the preparatory behaviours that some of the participants had thought of.

"*I have some various things that I've planned to do, just to help me keep myself occupied. I've also agreed with the family that if, particularly in the early days, I have a craving, or they're having their main meal, that I will actually just walk out of the house, and go for a walk, just to get out of the environment that I'm in with regards to*

that. I've got some box sets of DVDs to watch of some favourite programmes. I've got some books lined up to actually read. The strategy that I've got going to work, I've always been somebody who ate a very light lunch, so swapping one of the shakes for what I normally had for lunch"
(MAN, 49 YEARS, T2DM 9.5 YEARS).

A specific concern of many participants was, that milk was not allowed in the VLED and participants anticipated difficulties to abstain from having coffee without milk. Some of them were thinking of giving up coffee altogether for the duration of the WL phase because of this, which they expected might potentially decrease their energy levels during the WL phase even more.

Removing food from the participants` usual environments was among the first and immediate strategies employed. Removal of food was attempted in both their homes and at workplaces. Participants who worked outside their homes often asked their colleagues or clients not to offer them any treats. To prevent cravings and snacking, the participants often replaced the trigger food with allowed alternatives, such as vegetables and water.

"To be honest I was always ready for the shake. I was never thinking oh, I'm great, you know what I mean. And I suppose as I got farther into it I'd got myself used, and what I used to do when I went in the kitchen, I always had a glass of water or a bottle of water in the fridge so as soon as I went in the kitchen I would drink the water and that sort of stopped me eating anything or tasting anything. So the water was a big help" (WOMAN, 70 YEARS, T2DM 15 YEARS).

5.4.5.3 Avoidance

Avoidance strategies were identified at various levels, and occurred mostly within the first couple of weeks from the start of the VLED with progressive decrease in use once the participants got used to the regime. These included avoidance of activities related with snacking (e.g. watching TV); avoidance of places where there was lack of choice of healthier food options (e.g. spending time in pubs); or eating with others (e.g. work lunches). Smell of food was one of the barriers to adherence with the VLED and the quote below is an example of how some participants found a way to avoid being exposed to smells or vision of food and decreasing the chances of temptation by ordering their shopping online.

"I order it [shopping] *from either Sainsbury's or Waitrose. Do it online and have it delivered…Then you're not subjected to smells and things"*
(MAN, 65 YEARS, T2DM 13 YEARS).

The avoidance-related behaviour-regulation strategies tended to fade away with progression of the WL phase due to the early motivational boost related with changes in weight and BGL, and their increased behaviour regulation self-efficacy.

I know the beginning first few weeks I was going to lunch after everybody else had been to lunch so I couldn't smell anybody's food, I couldn't see it. I isolated myself a bit. But then I'd say definitely the last 3 to 4 weeks my normal little crowd that I was going to lunch with, I was going to lunch with them again and it didn't matter what they were eating it didn't bother me as much"
(WOMAN, 42 YEARS, T2DM 1 YEAR).

5.4.5.4 Distraction

Distraction was often associated with avoidance, and used when avoidance was not always possible or as complementary strategy to avoidance. Distraction and/or finding alternative activities and keeping busy in general were used to divert the attention from thinking about food when hunger levels increased, whether food was present or not. Many participants reported going for a walk, gardening, or reading as their replacement activities. They also tended to spend more time on hobbies that they did not have much time for before the WL phase, and reducing the time spent watching television due to being in the habit of snacking or because they did not want to be tempted by adverts promoting food.

"I mean we never watched any live television during it (VLED) *which meant that everything could be pre-recorded so that I wasn't bombarded with food adverts or some things like that…My grandchildren when they came visiting were aware of what they could do and they weren't allowed to eat in front of me so I vanished if they were about or they used a different room"*
(MAN, 65 YEARS, T2DM 13 YEARS).

"Because if you sit still for 5 minutes or you're watching one of your chick flicks or whatever the thing is oh popcorn would be nice but you just I just don't sit and watch any movies. I went and mowed the lawn"
(WOMAN, 42 YEARS, T2DM 1 YEAR).

5.4.5.5 Coping planning

Preparation of food/snacks often helped the participants prevent snacking on food not allowed on the VLED. For example, preparation of food in batches and freezing it, so that there would always be food ready when the participants got hungry was one of the strategies. Having food ready would limit the time between starting to be hungry and eating and that would reduce the possibility of cravings or snacking on food not allowed on the VLED.

"People at work used to say you can make me some of that. Because it's really – I used to like whizz it down with a spinner and so it's really really thick and by the time you had a bowl of that at lunchtime – and I used to, again if I was away for 3 days I would take 3 portions and just stick them in the fridge at work"
(MAN, 54 YEARS, T2DM 0.5 YEARS).

Some other participants mentioned carrying vegetables in their pockets or bags, so that they would have a healthy option at hand in case they would get hungry suddenly or if they had found themselves in a tempting situation.

"I made sure that I had all my 3 shakes and I think I put some of the peppers or carrots in a little bag so I was able to nibble those, just discreetly and without…just so often I nibbled one instead of having crisps, you know, because when you're out you sometimes feel like having crisps so I just brought some little carrot wedges with me"
(WOMAN, 70 YEARS, T2DM 15 YEARS).

Taking part in social events normalised after a couple of weeks on the diet, and it was common for the participants to either bring their own VLED shake or a salad to a restaurant with them, or to choose the healthiest option possible off menus ahead of dining out, which facilitated adherence during those events.

"I know the restaurants that we're going to so I knew exactly what I was going to have and as I say everywhere it was salads"
(MAN, 54 YEARS, T2DM 0.5 YEARS).

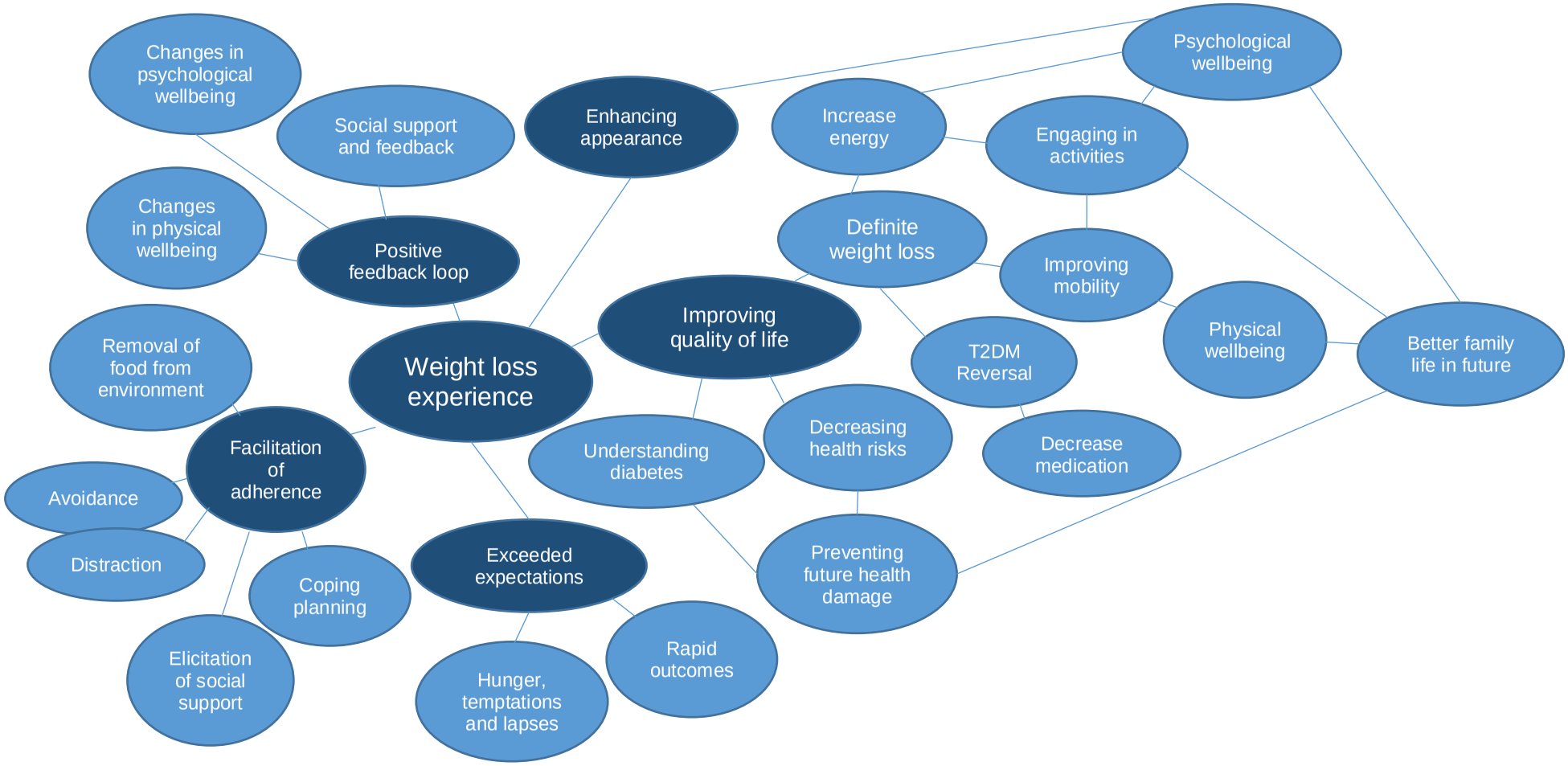

Figure 7. A mind-map of themes illustrating experience with the weight loss phase of the Counterbalance Study.
Highlighted in dark blue are core themes, highlighted in light blue are peripheral themes. Size of the oval shapes does not represent richness of data or how substantial a theme was.

5.5 A model of psychological, behavioural and environmental determinants of weight loss experience in the Counterbalance Study

Following the VLED for 8 weeks was perceived by the participants as easier than expected at baseline. Hunger, lack of food variability within the VLED, emotional distress and environmental triggers represented barriers to adherence, while social support, being involved in a research study and obvious initial rapid WL and improvements in BGL facilitated adherence to the VLED. Participants` reported social activities were mostly affected at the beginning of the diet and but this improved over time, with increasing self-efficacy. Five behaviour main regulation strategies were identified: 1) Elicitation of social support; 2) Removing food from the environment; 3) Avoidance; 4) Distraction; and: 5) Coping planning. Overall increased physical and psychological well-being were the main additional benefits, while tiredness and constipation were the drawbacks of using the VLED.

Based on the results from the baseline (T1) and follow-up (T2) interviews, I created a working model of psychological, behavioural and environmental determinants of WL experience in Counterbalance Study, presented in the next section. I used the qualitative data and the way the narratives where presented by participants over time (often associating distinct themes in one single sentence or answering one or more questions of the topic guide at the same time) as guidance to postulating hypothesis on how the main themes related to each other in Figure 8.

Interplay of three types of determinants can be identified within the model, which are colour-coded: environmental (green), personal (pink) and behavioural (blue). These three have been previously identified by Bandura in his Social Cognitive Theory (SCT) (1986). The SCT is a comprehensive theory of motivation and action stressing the importance of reciprocal interaction between personal and environmental influences and behaviour and it proposes that people have self-regulatory abilities through which they exercise control over their behaviour. One of the core concepts of SCT is *Self-efficacy*, the belief that a person is or is not able to carry out a task successfully.

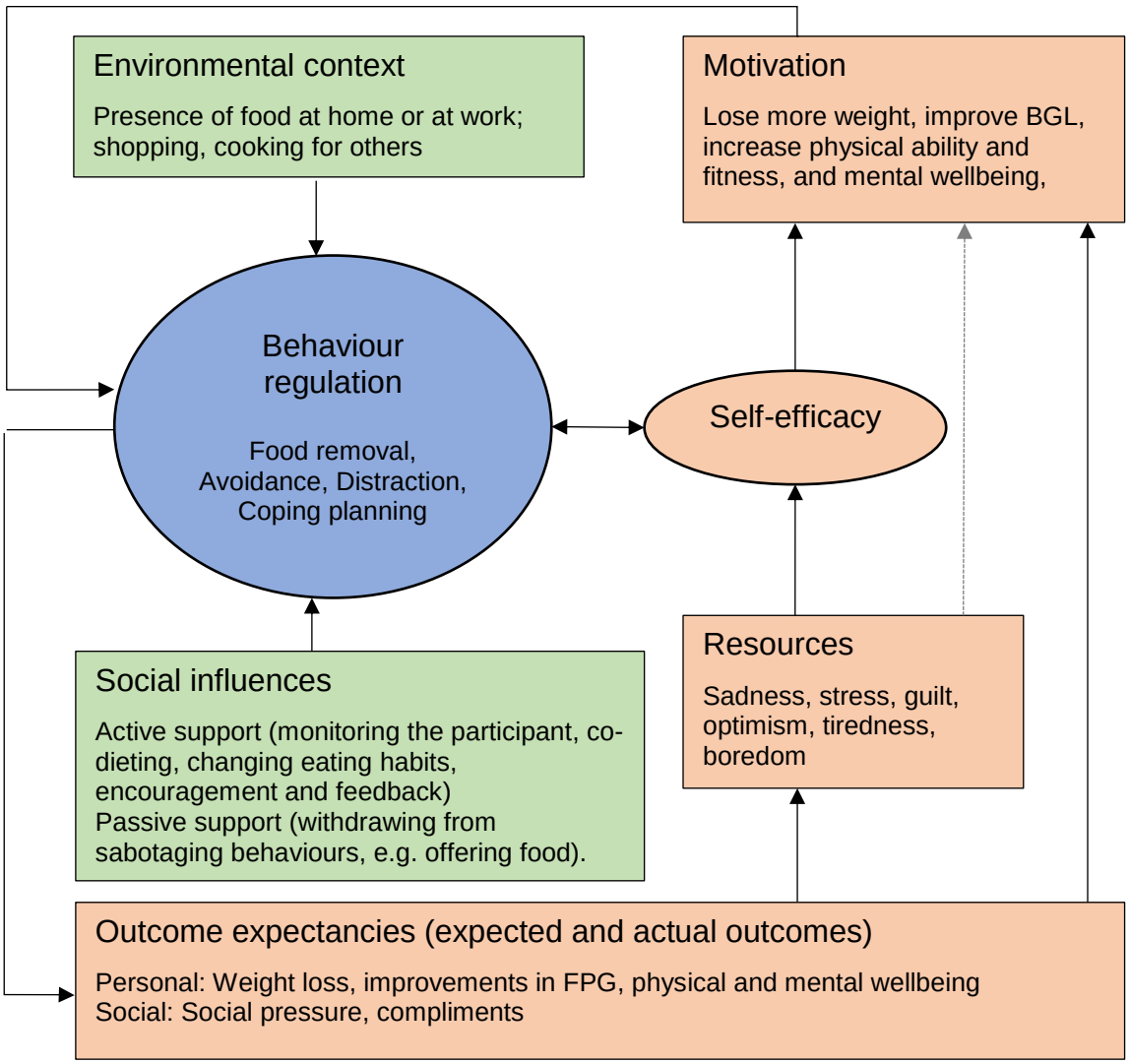

Figure 8. A model of psychological, behavioural and environmental determinants of weight loss experience.
Highlighted in pink are psychological determinants; highlighted in green are environmental determinants and highlighted in blue are regulatory behaviours. Full line represents relationships substantially supported by data; dotted lines represent relationships that need further exploration. The direction of arrows does not imply causality.

The model illustrates that behavioural responses to *Social influences* and *Environmental contexts* affected one`s belief in one`s capability to adhere with the diet (*Self-efficacy*). Successful behavioural responses (evaluated through achieved personal and social outcomes) reinforced self-efficacy and the increased self-efficacy looped back to future *Behaviour regulation* skills. This finding corresponds with concept of *Mastery experience* within the SCT (Bandura, 1986), which proposes that the most influential source of self-efficacy is one`s previous performance. Outcomes that are interpreted as successful increase self-efficacy and those that are interpreted as unsuccessful decrease self-efficacy. Only a handful of lapses were admitted during T3 interviews and reportedly 1) only happened once or twice and were

considered an exemption from a rule, and 2) were mostly planned ahead and were not regretted, which may have helped prevent feelings of guilt or shame and may be the reason why they did not seem to negatively affect self-efficacy. However, no conclusions can be made about the association between unsuccessful behavioural responses and self-efficacy as it may be that some lapses stayed unreported due to feelings of shame, disappointment, or self-presentation bias. *Outcome expectancies and actual outcomes* clearly affected the participants` ongoing *Motivation*, *Emotion and Self-efficacy*.

Fast changes in weight, improvements in BGL, and increased physical and mental wellbeing were highly encouraging and facilitated reinforcement of behaviours supporting adherence with the VLED, while increasing the participants` perception of self-efficacy and positive emotion. In SCT (Bandura, 1977), expectations of mastery affect initiation as well as persistence of coping behaviour, which may explain how the positive experience of achieving the participants` outcome expectancies was looped back into future behaviour-regulation, where it was further either supported or disrupted by social and physical environments, requiring coping skills (behaviour-regulation strategies).

The SCT distinguished between two types of outcome expectancies – personal and social. Our data illustrates that except for the personal outcome expectancies above, social outcome expectancies played an important role in one`s behaviour regulation. For example, receiving compliments and support from significant others as well as the regular visits to the clinic formed social outcome expectancies. Participants often talked about how they did not give into temptation because they thought the Counterbalance Study staff might find out through the metabolic tests or because they did not want to spoil the research results. This perception of expected judgement by others or the estimate of social pressure is recognised as a *Subjective norm* within the Theory of Planned Behaviour (TPB) (Ajzen, 1985), which proposes that positive expectations of outcomes (attitude), subjective norms, together with perceived behavioural control (self-efficacy) and form intentions (motivation), which lead to enacting of behaviour, and that perceived behavioural control (self-efficacy) also affect behaviour directly. In our study, *Environmental contexts* (e.g. presence and smell of food) tended to be barriers, while *Social influences*, mainly in the form of social support, tended to be facilitators of behaviour regulation. At the same time, the

theme of *Social influences* was perceived to be more central and have more influence on *Behaviour regulation* than had *Environmental contexts* in the narratives of the participants. This can explain why a buddy system or social support as *Social outcome expectations* or *Subjective norms* may help override environmental or emotional triggers.

Resources, in the form of energy levels, stress, and emotion, also affected the participants` ability to self-regulate. The limited data on lapses in our study indicate that low level of positive resources seem to be associated with some of the situations, in which the participants felt most tempted or when they deviated from the VLED. Baumeister and colleagues (1998) have developed a hypothesis of ego depletion, according to which the ability to self-regulate decreases with the prolonged effort to self-regulate, as a result of diminished resources, comparing one`s capacity to self-regulate to a muscle, which gets tired over time. Similarly, Hoffman and colleagues (2006) have demonstrated, that when self-regulation resources are low, people tend to switch to automatic attitudes and behaviour as opposed to when the resources are high. I have found, that high resources had a positive impact on the participants` ability to adhere with the WLM. However, due to potential under-reporting of lapses in our study, limited conclusions can be made about the effect of lowered resources on the ability to follow a WLM programme.

5.6 Discussion

The aim of this study was to explore the experience with a VLED for WL and diabetes remission using a qualitative methodology. The following section discusses the results within the existing body of evidence.

The National Weight Control Registry in the US (NWCR) is a registry of self-selected adults who have lost at least 13.6 kg and have kept it off for at least 1 year. The registry had more than 4000 members in 2005 and it reported that 83% of its members back then experienced a “trigger” for their WL. Most of the triggers were medical (23%), reaching an all-time highest weight (21.3%) and their reflection in the mirror (12.7%) (Klem et al., 1997), suggesting that most people who embark on WL may have health-related motives. Health motives for WL have also been found associated with better WL outcomes in the short-term as well as in the long-term (Gorin, Phelan, Hill, Wing, 2004). Findings from this qualitative study show that the main source of motivation for WL and potential T2DM reversal were related to both,

health and appearance, which were sometimes triggered by life events such as being diagnosed with T2DM, having seen the consequences of T2DM in other people and wanting to avoid them, or being able to conceive a baby, which were similar in nature to the medical triggers of members of the NWCR and also relate to the “life crises” as described by Ogden and Hills (2008). A study using a UK representative sample (Sniehotta, 2015) revealed that appearance based motives where key in engaging in WL efforts (63.6% of women and 55.4% of men). In the current study, WL emerged as a slightly stronger motive in the participants` narratives than the potential to reverse diabetes. I hypothesise that this may be for two reasons. First, well controlled diabetes does not seem to burden participants as much as overweight and obesity do in terms of their quality of life. Overweight and obesity have social and psychological implications in the form of stigma, perceived body-image and physical disability (Carey, Small, Yoong, Boyes, Bisquera, & Fisher, 2014). It was mostly when the participants were treated with diabetes-related medication, that reducing or stopping their medication, mostly due to unwanted side effects and weight gain, became one of their main health-related motives for taking part in the Counterbalance Study. Looking into the narratives this seemed mostly due to unwanted side effects and weight gain. This hypothesis was also supported by the finding that some participants intended to lose weight even after they managed to achieve normal or near-normal FBG levels (≤ 7.0 mmol/L) at the end of the WL phase of the Counterbalance Study. Similar conclusions were made in a qualitative study of exploring peoples` experiences and expectations before and after four commercial WL programmes, including those using meal replacements, in which the main motivation for participants (with mean BMI of 32 kg/m^2) to enrol in the WL programmes was lack of self-esteem and confidence, and the expectation of increased intrinsic sense of worth through WL (Herriot, Thomas, Hart, Warren, & Truby, 2008).

Second, T2DM has until recently been considered an irreversible, chronic condition. Therefore it may be that even though many participants were hoping to be able to reverse it, they may have been sceptical of the actual possibility of reversal to start with.

Previous research has also shown that both, appearance and health are the two major motives for WL (Brink & Ferguson, 1998; Vartanian, Wharton, & Green, 2011) and that they are also related, due to the perception that “beautiful” often means

“healthy” (Kwan, 2009). This finding may have implications for future studies in terms of design, recruitment and pitching of the aims to future participants. Since appearance-related motives for WL tend to be positively related with body image concerns, while health-related motives were negatively related with body image concerns (Vartanian, Wharton, & Green, 2011), health benefits should be emphasised in future studies in order to achieve the best health and psychological outcomes.

Frequency of monitoring and feedback from the study staff on weight and BGL in the form of weekly appointments at the clinic was a substantial facilitator of adherence to the VLED and WL in this study and a well-documented phenomenon in a number of systematic reviews (Burke, Wang, & Sevick, 2011; Perry, Hickson, & Thomas, 2011; Madigan, Daley, Lewis, Aveyard, & Jolly, 2015). Individuals who self-weigh regularly during WL attempts lose significantly more weight and also consume fewer calories than people who do not monitor their weigh regularly (Steinberg, Tate, Bennett, Ennett, Samuel-Hodge, & Ward, 2013).

A systematic review of the effectiveness of lifestyle weight management programmes found that the key factors promoting WL were regular appointments, recognising responsibility, positive attitude and support from others and dietitians (Perry, Hickson, & Thomas, 2011), which is much in line with our findings of the importance of social support.
Other factors associated with successful engagement in the WL phase seem related with the feeling of responsibility due to being involved in a research study and the positive reinforcement loop discussed within the working model of psychological, environmental and behavioural determinants of WL in section 5.14. of this chapter.

Environmental triggers required more self-regulatory strategies to be employed in order to keep adhering with the VLED. Four strategies to overcome the environmental triggers were identified in the participants` interviews: 1) removing food from the environment; 2) avoidance of tempting situations or places; 3) distraction and finding alternative activities; and 4) coping planning. A cross-sectional survey or a random sample of 1165 participants, out of which 926 were overweight (Sciamanna et al., 2011) examined the association of 36 practices used in the past week and the success in WL (≥ 10% in the past year) and WLM (≥ 10% lost and

maintained in the past year). It identified 18 practices associated with successful WL. In comparison with strategies or “practices” that people successful at WL employ as provided by the survey, only 6 were found to be associated with the results of the qualitative study, and these were: participating in a WL programme, eating a lot of vegetables, planning meals ahead of time, thinking about how much progress they`ve made, monitoring their WL goal, weighing themselves. The rather small overlap in the practices that the general weight-loss population use and those used by our study participants also highlights that the nature of the VLED is very different to the nature of other dietary interventions and therefore future interventions using VLEDs should include participant training of skills specific for behaviour-regulation during a WL programme using VLEDs.

5.7 Limitations

The Counterbalance Study was conducted at a university grounds, with a well-equipped magnetic resonance centre and with resources (time, staff) devoted to this study. Receiving this level of care and support is unlikely in a primary care setting due to time or staff limitations. In addition, participants who took part in the Counterbalance Study were very motivated, sometime recruited through word of mouth, meaning that they had a-priori social support in place, potentially increasing their level of motivation beyond that which would be found in the general population. In addition, being involved in a research study and not wanting to distort the research results provided substantial motivation to adhere with the VLED regime during the WL phase of the Counterbalance Study. These three issues need to be taken into consideration when interpreting the results of this qualitative study in terms of generalisability. It is probable, that the general population of adults with T2DM would be less motivated, less supported by their GPs or specialist nurses due to lack of resources such (e.g. time, staff available, technical equipment) and potentially achieve less favourable outcomes that the participants in the Counterbalance Study did as a result. Although the generalisability of the findings may be limited, providing insights into the participants` experience with the VLED contributes to the qualitative body of evidence, as no such previous research has been conducted. Future studies conducted in a more natural setting, such as across GP practices, with limited resources should be conducted, so that effectiveness, rather than efficacy of the use of VLEDs for WL and reversal of T2DM can be determined, with potential extensive public health implications.

Another limitation was the late recruitment of participants into the qualitative study. The recruitment for the qualitative study started half-way through the timeframe of the Counterbalance Study, and therefore only half of the participants were interviewed. It is possible that interviews with the rest of the participants might have brought up additional themes and result in differential explanations of the determinants of behaviours related with adherence with the VLED. However, it was felt, that data saturation was reached quite early into the qualitative study (around interview 9 or 10) within the available interviews, and therefore it is unlikely that important themes have been missed out.

Future studies could replicate this qualitative study with a sample of participants ideally recruited through GP practice lists to ensure heterogeneity of participant characteristics rather than a larger sample, which could potentially bring to light other themes that may have been missed out.

5.8 Conclusions

Very low energy diets for WL and remission of T2DM among individuals with T2DM were perceived highly acceptable for the duration of 8 weeks. The perceived barriers to adherence with the VLED during the WL phase of the Counterbalance Study were hunger, lack of variability of food, social events, stressful or emotional situations, while the facilitators of adherence were social support, feeling of responsibility and involvement in a research study, and rapid WL and improvements in BGL. Improvements that could be made to the WL phase suggested by the participants included the option to meet with other participants to exchange information, experience, compare progress and provide each other support. In addition, it might help improve adherence to the VLED if coping strategies were discussed with the participants and social disclosure was encouraged before starting the WL phase. Most participants wished to lose more weight after the WL phase, which should be taken into considerations in future studies including both, WL and WLM phases with a weight management programme.

Chapter 6

Acceptability of a very low energy diet as a weight loss and diabetes remission intervention.

6.1 Abstract

Aims: This chapter aims to explore acceptability of a VLED as an intervention for weight loss (WL) and diabetes remission. Methods: Participants enrolled in the Counterbalance Study took part in semi-structured interviews at baseline and after the VLED intervention. Thematic analysis was used to analyse narratives related to features of the provided VLED intervention. Results: Fifteen participants took part at the baseline interview and sixteen took part at the follow-up interview. The following themes were identified as relevant to the participants' evaluation of acceptability: 1) Ease of preparation of the VLED, 2) Taste and consistency of the VLED, 3) Format of delivery of the intervention, 4) Perceived hunger, and 5) Satisfaction with outcomes of the VLED (weight, blood glucose, wellbeing). Adhering to the VLED was perceived as easier to than the participants expected at baseline. The VLED was easy to prepare and the flavours were overall perceived as acceptable, with varying degrees of liking among the participants. Hunger levels varied individually, but were generally perceived as low, with increased levels in the beginning and at the end of the intervention. Participants also made suggestions for improvement of the VLED. These included increasing the variety of flavours to choose from and an opportunity to meet other participants. Conclusions: Overall, The VLED intervention in this study was perceived acceptable as a WL intervention among people with T2DM. It could be improved by offering a wider variety of flavours and the opportunity to exchange experiences with other people in the programme.

6.2 Introduction

Chapter 5 focussed on the psychological and behavioural aspects of the WL experience of people with T2DM engaged on an 8-week long VLED intervention. The results showed that the participants benefitted greatly from the achieved WL. Adherence to dietary programmes is key to achieving the intended WL outcomes (Alhassan *et al.*, 2008), and acceptability of a diet may facilitate adherence. The systematic review in Chapter 3 (Rehackova *et al.*, 2016) pointed out that many

studies imply acceptability of VLEDs by good physiological outcomes, few side-effects, and high completion rates and this is common in other VLED weight loss studies in general (Anderson, Grant, Gotthelf, & Stifler, 2006; Basciani *et al.*, 2015; Gudzune *et al.*, 2015; Ryttig, Flaten, & Rossner, 1997; Tančić-Gajić *et al.*, 2012; Tsai & Wadden, 2006b; Wikstrand, Torgerson, & Boström, 2010). Some studies do not report how acceptability was assessed (Dhindsa, Scott, & Donnelly, 2003), or they do not measure it at all (Rolland *et al.*, 2013). There are several factors which affect acceptability of a diet that have more to do with individual preferences rather than physiological outcomes or attendance rates. Consumer research finds that composition of foods such as protein bars and shakes impacts on the flavour, aroma and appearance liking of a product (Childs, Yates, & Drake, 2007). Composition of diets may affect satiety (Greenberg *et al.*, 2009), which in turn may affect acceptability and adherence to the diet.
Previous studies evaluating the acceptability of VLEDs from the perspective of individual preferences included variables such as preoccupation with food and eating, liking and convenience, disruptiveness of the diet to daily life, experience of a variety of symptoms and mood (Foster *et al.*, 1992), or easiness of use (Basciani *et al.*, 2015; Love *et al.*, 2016), and found VLEDs perform well on these criteria.

Another criterion for evaluation of acceptability of a VLED intervention is hunger, as it is a significant predictor of weight change (Batra, Das, Salinardi, Robinson, Saltzman, & Scott, 2013; Batra, Das, Salinardi, Robinson, Saltzman, Scott*, et al.*, 2013). Foster and colleagues (Foster *et al.*, 1992) found decreases in hunger during and beyond the VLED period, which they attributed to a decreased in enjoyment of the VLED as compared to the participants` pre-VLED diet, even though the VLEDs were evaluated as very acceptable. A different study found that over time, people who are successful in WL tend to report less hunger than people who achieve less WL, but in contrast to the Foster study, they also tend to perceive the diet more palatable (Åberg, Edman, & Rössner, 2008). While hunger feelings perceived during the VLED are not necessarily different to hunger feelings perceived on a balanced diet, some people may have difficulties with adherence at specific times of the day, usually in the evening (Ryttig *et al.*, 1997). Evaluation of hunger perceived during the VLED therefore seems important in determining acceptability of the intervention.

In the Counterbalance Study, acceptability was partially evaluated by an assessment of side-effects, and more details on these can be found in the published paper (Steven *et al.*, 2016). The aim of the current chapter was to complement this evaluation by the participants` perspectives on acceptability of the VLED intervention. I aimed to explore acceptability of the VLED as a WL intervention in terms of satisfaction with the diet and satisfaction with outcomes, and to compare the results with the limited evidence on acceptability of VLEDs. It also aimed to gather suggestions for improvement to the WL phase and to determine the most suitable recruitment strategy for a study promoting fasting, rapid substantial WL and the potential of diabetes remission.

6.3 Methods

Methods employed in this chapter are described in Chapter 5 and any additional procedures different to those described in chapter 5 are described below.

6.3.1 ***Participants***

Narratives of participants who took part in interviews at the beginning and at the end of the VLED intervention (T1, T2) (as shown in Figure 9) were analysed.

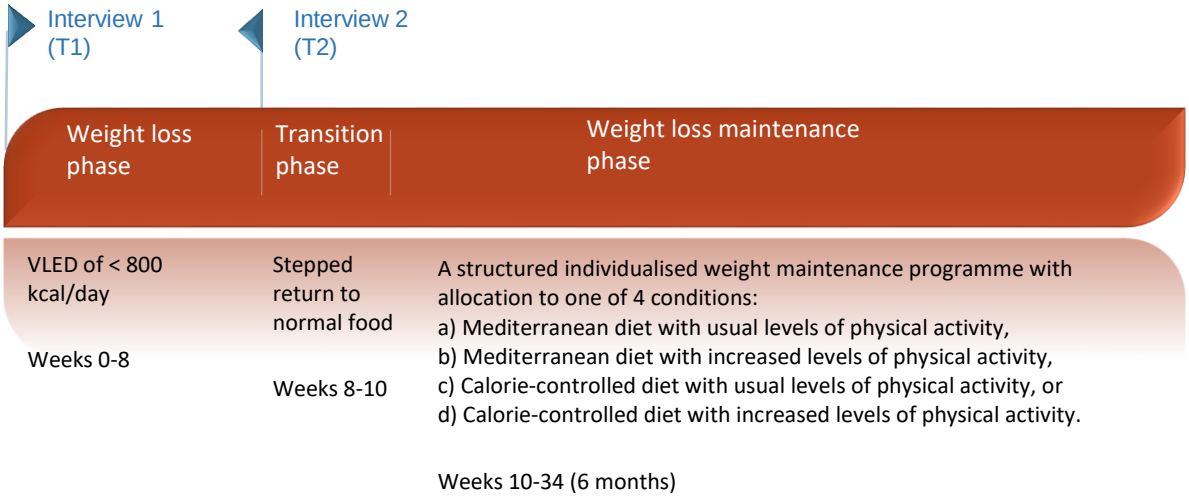

Figure 9. Illustration of the interview time points before and after the weight loss phase of the Counterbalance study.
VLED = very low energy diet; forward/backward orientation of arrows indicates orientation of the interview questions on the future/past, respectively, considered in this chapter.

6.3.2 ***Interviews***

The purpose of the T1 interviews was to explore the participants` expectations of the VLED intervention. T2 interviews aimed to capture the participants` experiences with the VLED in terms of acceptability of it as a WL and diabetes remission intervention.

6.3.2.1 Interview documents

Questions about acceptability of the VLED intervention were included in the interview topic guides for T1 and T2 interviews (see figure 6 in Chapter 5), which had been piloted first in mock interviews as described in Chapter 5. The interview topic guides for interviews at T1 and T2 can be found in Appendices 10 and 11. They included the following open-ended questions and prompts about the participants' experience with the VLED intervention: "*What are your expectations of the very low energy diet?*"; "*You have now completed the VLED phase of the programme. Could you please tell me about your overall experience of it*?" (Prompts: cravings/satisfaction, temptations to break the diet), "*How satisfied are you with the very low energy diet?*"; "*How satisfied are you with the outcomes you have achieved?*"(Prompts: weight lost, ease of following, food allowed, energy levels, dosage); "*Would you change anything about the diet?*"; "*What was your experience of the diet in comparison with other diets you have tried?*"; "*What kind of support (if any) would you have appreciated during the second phase of the VLED?*" (Prompts: from the team/relatives)". To facilitate the interviews and data analysis, field notes were made during and after the interviews.

6.3.2.2 Interview procedure

The interview procedures are described in the Methods section of Chapter 5.

6.3.3 ***Analysis***

All interviews were audio-recorded, anonymised and transcribed verbatim. The participants were not invited to comment on the content of the interviews due to time constraints. During the interviews, they were encouraged to share any additional materials they would have created for themselves.

6.3.3.1 Analytical approach

The analytical strategy and the coding process employed are described in more detail in Chapter 5, section 5.3.6. For Chapter 5, narratives were first organised by the TDF domains (Michie *et al.*, 2005). Narratives relating to evaluation of the VLED

intervention in this chapter were gathered separately under a broader domain entitled "VLED intervention evaluation", which was added to the coding framework. This domain gathered quotes in response to the questions asked about acceptability of the VLED intervention, but other relevant narratives identified in interviews at any stage of the study were also included in this domain. Narratives within this domain were first coded line by line and were annotated with a label of a potential theme. The identified themes were then reviewed and refined, before synthesizing them in the results section. The analysis was facilitated by creating mind-map of themes and the relationships between them as I perceived them during the process, which is presented in Figure 10 at the end of this chapter.

6.4 Results

Fifteen participants were interviewed at T1 and sixteen were interviewed at T2. Analyses in this chapter are based on the same interviews as those in Chapter 5. The following themes of the participants` evaluations of acceptability of the VLED intervention were identified: **1) Ease of preparation of the VLED; 2) Taste and consistency of the VLED**; **3) Hunger**; **4) Format of delivery**; and **5) Satisfaction with outcomes**. The participants also offered suggestions for improvements of the intervention, which could be considered in future interventions. The themes are described below and they are illustrated with quotes re annotated by gender, age and duration of diabetes.

6.4.1 ***Theme 1: Ease of preparation of the VLED***

The ease of preparation of the VLED meal replacements was appreciated mainly because the participants did not have to spend time shopping for food, preparing food, or making decisions about either, and they knew exactly what they were to eat every day:

"*I had 5 flavours and that was it so it didn't take much thought*" (WOMAN, 42 YEARS, T2DM 1 YEAR). The shakes were to be mixed up with water in a shaker provided by the research team, and unless the participants preferred a warm meal, shaking up the bottle was all they had to do: "*Well a simpleton could follow it because there's not a lot of food and lot to do with it. Add cold water to this and that's it*" (MAN, 67 YEARS, T2DM 3.5 YEARS).

Most participants found the VLED easy to prepare, however those who spend considerable time working in a car or without access to water might find preparation more problematic, or may need to plan to bring water with them:

"*The soup was a bit of a chew on, purely and simply because when I'm at work, I work in the car, so it's easy to get a bottle of water out the boot and shake it up, but obviously if it's soup and it needs warming up, but not really, because I'd just have the soup on the teatime when I was in the house"* (MAN, 69 YEARS, T2DM 3.5 YEARS).

6.4.2 ***Theme 2: Taste and consistency of the VLED***

The various tastes and consistency of the sachets were generally well accepted, although some participants had prior negative expectations associated with the VLED. For example, participant 12 said:

"*I remember when I had my first milkshake I was like this is going to be horrible. It's going to taste disgusting, it's going to be dead powdery, I'm not going to enjoy it and I remember how pleasantly surprised I was and how creamy it was because the strawberry one it's really creamy"* (WOMAN, 35 YEARS, T2DM 1.5 YEARS).

The participants usually had a preference or a dislike for a specific taste, in which case they were allowed to exchange the flavours for the ones they preferred, and were given tips on how to improve the flavour. For example, they were advised to add spices to soups or crushed ice to shakes to make them more palatable and less tedious over time. However, taste preferences and liking of the specific flavours varied considerably among the participants, which reflects on the need to tailor the VLEDs to the participants` preferences if possible. The quotes below illustrate two different perceptions of the various flavours of the VLED:

"*I thought the soup was disgusting and certainly needed stuff adding to it to make it acceptable. I even converted it into curry sauce on occasions. Albeit a Thai style one by adding lemon grass and Gaeng Gai. The chocolate pudding was okay. I found the dessert was fine. Sometimes I did alter it by adding things like almond essence and ginger essence and so on but they were alright. The vanilla shake at a pinch was okay. The strawberry one was like the soup, quite disgusting. Not my style at all I'm afraid*" (MAN, 65 YEARS, T2DM 13 YEARS; lost 16.7 kg).

"One of them, the morning one, is a shake. The lunch one was a soup and it was quite a thick soup as well. It was, if you make it with just a little water, it's more of a porridge than a soup. And then the evening one the dessert, the vanilla dessert is absolutely gorgeous. Delicious but it also has a nice consistency as well so with just the Optifast I was having a drink, a soup and a dessert. It's like an Angel Delight dessert" (MAN, 49 YEARS, T2DM 9.5 YEARS; lost 16.7 kg).

Although the taste preferences varied, this did not seem to affect adherence with the VLED much, as most participants lost the prescribed amounts of weight by the end of the 8 weeks. This may suggest, that preference of flavours does not necessarily affect adherence. Therefore, tailoring of the flavours to the participants` preferences

might help people feel more at ease and comfortable with the diet they are following rather than to improve their adherence.

6.4.3 ***Theme 3: Perceived Hunger***

Given that the VLED consisted of approximately 800 kilocalories per day, many participants reduced their calorie intake to this level from much higher levels, which led to anticipations of hunger, potentially resulting in lack of satiety, increased temptations, dietary lapses, and an overall difficulty adhering with the VLED. However, as reported in Chapter 5, within "*Theme 3: Exceeded expectations"* with regards to hunger, temptations and dietary deviations, hunger was not the primary reason for the reported lapses. The theme suggested, the levels of hunger reported by the participants were generally very low, and although some participants felt hungrier than others, this was a rare occurrence. The following quotes further illustrate that the participants were not as hungry as they had initially anticipated, even though they were consuming only 800 kilocalories per day:

"Well I just felt that it didn't make me hungry. I wasn't hungry, I wasn't craving anything at all" (MAN, 65 YEARS, T2DM 13 YEARS).

I did think Christ, how am I going to manage on 3 drinks a day, but absolutely fine. The way I felt was I felt a little bit disgusted in myself that I'd been eating so much and all of a sudden I was like, you're managing fine on 3 shakes a day, and previously I could have my tea and 10 minutes later I could be like I'm starving, and eat a packet of biscuits or a packet of crisps. And it just amazed me that you didn't need it, basically" (MAN, 69 YEARS, T2DM 3.5 YEARS).

Reflection on one`s past behaviour was critical and the realisation that one could live on a much lower amount of food (meal replacements) a day was part of formation of a shift in identity, which I discuss in detail in Chapter 9, within a longitudinal exploration of change during the Counterbalance Study.

In contrast to the above narratives, some participants reported how difficult it was to know that there was no regular meal involved in the diet.

Respondent: I was hungry sometimes. I was hungry. But I knew, I said because I knew it was going to be only for a set time, I knew it was just for 8 weeks, and once I got to week 4 I thought well I'm half way there and then I was thinking God, it's going to finish, they're going to finish, you know, and so the worry was I had of moving from the diet to proper food. Oh it was difficult. It was difficult in the beginning. It was difficult. It was hard.

Interviewer: What was the hardest part?

Respondent: I think just being hungry and just knowing that I couldn't, knowing that I wasn't going to have a meal, that I just had to have the shakes. (WOMAN, 70 YEARS, T2DM 15 YEARS).

It seems from the quote above, that this participant considered the shakes just "shakes" rather than "meals". Perceiving this lack of a regular meal may have created a feeling of deprivation and attentional bias towards regular meals and an increased desire for them. It may be important for some people, that meal replacements are as close to regular meals in terms of texture, flavour, or perhaps in the way they are prepared (e.g. warming up) to increase acceptability and adherence. This may in turn affect satisfaction with the meal and satiety, decreasing the perceived hunger. It is unclear from the interviews what the reason for satiety in some people and hunger in others were, and the possible explanations are offered in the discussion section of this chapter.

Appraisal of the VLED experience fluctuated over time. Majority of the participants found the initial 2-3 weeks easier than expected in relation to levels of hunger and getting used to the regime. This tended to change mid-way through the VLED, when the participants reached the peak of their learning, experimenting with flavours and getting used to the regime. Many of them started to perceive the diet as tedious or monotonous, which became more apparent within the last 2-3 weeks of the diet due to lack of variability in the allowed food or lack of solid food. This was, in most cases overcome by experimenting with flavours being added to the shakes and soups, without increasing their calorie content:

"Towards the last week and a half I got bored. Boredom set in but that was all. I mean boredom in the sense of..., just lack of variety, It's just the fact that it's the same day after day. You've got a limited range of choices, a limited range of shops; you're travelling from one place to another. It's all of that that was more difficult, but I wouldn't like to overstate it because it's only 8 weeks. It's not like it's a big chunk of your life is it really?" (MAN, 59 YEARS, T2DM 10 YEARS).

6.4.4 ***Theme 4: Format of delivery***

Although not being a feature of the VLED intervention, format of delivery was also evaluated by the participants. Format of delivery included evaluations of frequency, intensity and time burden associated with assessments during the visits to the research centre. The participants were asked to attend the clinic at baseline, week 1, week 4, and week 8. The visits at baseline and week 8 lasted 1.5 days each, while the visits at week 1 and 4 lasted for about 2 hours. Visits to the research centre were

part of assessment procedures, but from the perspective of the participants, they were often viewed as intervention procedures instead. This was reflected in narratives similar to the one below, in which the participant stresses the importance of coming to the research centre for assessments as it provided him with motivation to adhere to the VLED:

"*The regular visits where I'm getting weighed, my blood sugars taken because that also then gives you a target. If I knew that I was coming here once a month on a Friday to get weighed that then gives you quite a little bit impetus*" (Man, 49 YEARS, T2DM 9.5 YEARS).

The format was generally perceived as appropriate to the aims of the Counterbalance Study. Intensity of the visits at the clinic did not seem to pose a problem for the 11 participants, who were in employment at the time of their baseline interview, and several participants reported that they did not have to take days off work to come to the clinic, which seems to demonstrate that employers were also supportive of their employees taking part in the study.

6.4.5 ***Theme 5: Satisfaction with outcomes of the VLED intervention***

On average, WL of all participants interviewed in this study[6] was 14.7 kg, BMI decreased by 5.1 points and blood glucose levels decreased by 4.02 mmol/L from baseline until the end of the 8 weeks of VLED (to see which participants achieved normal levels of BMI and plasma glucose, see Table 7). Outcomes of all participants in the Counterbalance Study were similar and are reported in the published paper (Steven & Taylor, 2015).

The rate and the amount of WL and the decrease in blood glucose levels exceeded expectations of many participants, which contributed to an overall high satisfaction with the outcomes of the VLED intervention:

"*Very happy. I was at my diabetic check-up last week at the GPs and my nurse was practically doing cartwheels, to say the least. My cholesterol has come from 7 point something down to 3.3 so she's taken us off my Statins. She said my blood sugar is now that of a normal person, not of a diabetic and in 6 months since I was last there I've lost 3 stone 2 pounds so she was over the moon*" (WOMAN, 47 YEARS, T2DM 2.5 YEARS).

Many have reported losing weight quickly within the first couple of weeks and then continued to lose at a rate of about 1.5 kg a week. The fast WL and improvements in

[6] The participant excluded from the Counterbalance study was not included in any of the analyses

BGL also had a motivational effect on the participants` adherence with the VLED and their sense of achievement:

"*Very happy. I didn't think I would lose as much as what I have on this first part, like first 10 weeks. I didn't think I would lose as much weight as I have lost so I was really chuffed when I've lost this much. Definitely"* (WOMAN, 35 YEARS, T2DM 1.5 YEARS).

Chapter 5, within "*Theme 4: Positive feedback loop*" in section "*Changes of physiological wellbeing*" and "*Changes in psychological wellbeing*" further discusses how these achievements facilitated the continuous motivation to adhere with the diet.

6.4.6 ***Theme 6: Suggestions for improvement to the VLED intervention***

When asked about suggestions to improve the VLED intervention, it became apparent that most participants would have welcomed an opportunity to meet other participants in order to exchange their experience and tips, and to socialise with people who are going through the same programme. Only a few individuals preferred to get through the programme on their own. Having the opportunity to compare progress and experience with others was perceived as a potential source of motivation to stay on track:

"I think comparison helps. I mean I've asked questions all the way though about how is it going in the study and it's all of those things isn't it? It's about how am I doing in relation to other people. Am I doing better than other people because that's always nice to know if you are. When I came in after week 1 or week 2 and I'd only lost a very small amount of weight and then that's quite worrying. But it's good because like we're going to keep on track because I've got to lose this damn weight. So there's all of that. I think comparisons as long as they're done in the right way are there to be helpful…You don't need to know any personal information, just enough information to know that you're on track" (MAN, 59 YEARS, T2DM 10 YEARS).

Some suggested inclusion of possible food variations or alternatives (vegetables, fruits, spices) in the information sheet as a guidance. This would prevent the participants from choosing potentially unsuitable ingredients and reduce the repetitiveness of the diet due to the limited flavour options:

"I was happy with it. Maybe's some different more flavours, but I know they're restricted to what flavours they're getting given off the supplier. But no, happy with the shakes, soups and dessert. The vegetables I did start to struggle with in the end because there's only so many things you can do with the veg you're allowed" (WOMAN, 47 YEARS, T2DM 2.5 YEARS).

One of the features of the Counterbalance Study that the participants liked was receiving information about their resting metabolic rate and magnetic resonance

imaging (MRI) scans of their abdominal area. Receiving biofeedback in the form of viewing the MRI scans from of the participants` own bodies before and after the 8 weeks has been perceived as rewarding, and it provided additional motivation to keep the weight off or lose more weight after the VLED:

"*I've learnt a lot about the effects, looking at the scans, they were tremendous. Seeing a whole body scan before and after*" (MAN, 69 YEARS, T2DM 18 YEARS).

Providing such feedback in future studies may help the participants stay focussed on their goals.

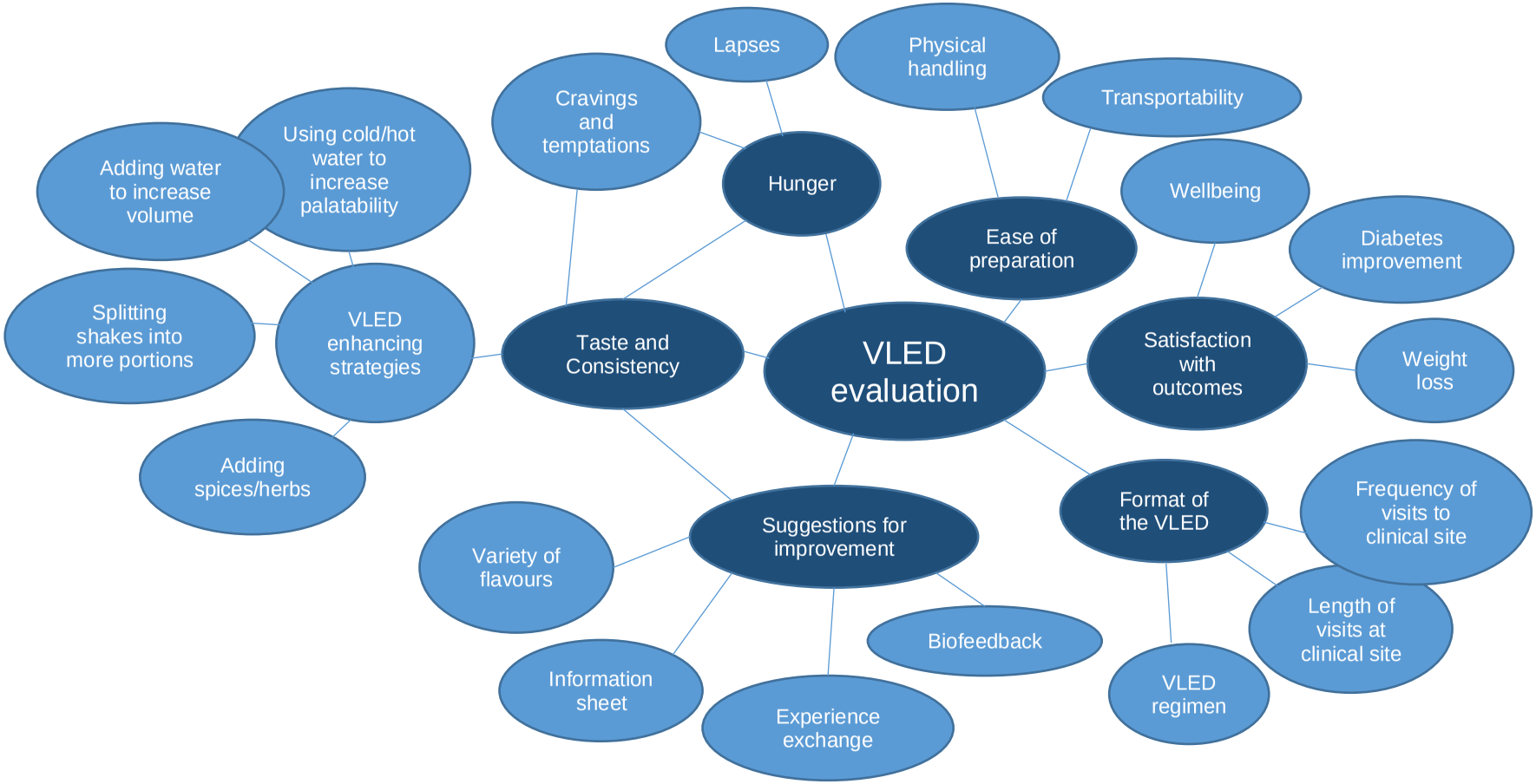

Figure 10. A mind map of themes relating to evaluation of the VLED intervention.
Highlighted in dark blue are core themes, highlighted in light blue are peripheral themes. Overlapping bubbles suggest overlap in themes. Size of a bubble does not represent richness of a theme.

6.5 Discussion

This study aimed to evaluate acceptability of a VLED within the clinical context of the Counterbalance Study. The following themes were identified in the participants` narratives that the evaluation of acceptability was based upon: ease of preparation of the VLED, taste and consistency of the VLED, perceived hunger, format of delivery of the intervention, and satisfaction with outcomes. The participants also offered ideas for improvement to the VLED intervention.

Participants reported overall low levels of hunger during the VLED. While this may appear somewhat counter-intuitive, it is in line with previous research on the role of cravings and hunger in WL (Batra, Das, Salinardi, Robinson, Saltzman, Scott*, et al.*, 2013). For example, Foster and colleagues (Foster *et al.*, 1992) compared three different VLEDs consisting of 420, 660 and 800 kilocalories per day. People in all three conditions reported significant decreases in hunger compared with their pre-VLED diets, and there were no differences in the changes in hunger among the conditions. This may be encouraging to people trying to lose weight, as it means that any dietary restriction may lead to a decrease in appetite, and that the restriction does not have to be as severe as possible. In addition, the reduction in hunger in the study persisted beyond the treatment (12 weeks after the end of the VLED), which indicates sustainability of the effects in the short-term, and possible facilitation of WLM.

Easiness of the VLED preparation as well as the flavour, consistency and texture of the VLED were also the characteristics that contributed to the overall acceptability of the VLED intervention. In the current study, preparation of the VLED was perceived as simple, which took away duties normally associated with preparation of food from making shopping lists, making choices, through the logistics of shopping, to cooking. The VLED was perceived as easy to use, which is in line with findings from previous qualitative and quantitative studies of acceptability of VLEDs (Basciani *et al.*, 2015; Love *et al.*, 2016).

The participants` preferences of the VLED flavours and evaluations of palatability varied greatly. In anticipation of increased adherence and WL, they were given the option to replace the flavours they did not like for the ones they did.

However, this did not seem to affect the outcomes in this study. Yancy and colleagues (Yancy *et al.*, 2015) have tested the effect of diet choice on WL and they found that completion rates, dietary adherence, and WL were similar between people who chose a diet they preferred and those who were randomly allocated to a diet. In other studies, participants who received their preferred diet lost even less weight than those assigned to a diet (Borradaile *et al.*, 2012; Burke *et al.*, 2007). A likely explanation for this result in this qualitative study might be that those who did not find the VLED as palatable as others focused on the medical reason for taking part in the study and on their perception of the diet as a treatment, and as something that had to be done. Considering this diet as a treatment was repeated in the narratives, and taking part in a clinical study further reinforced this perception and facilitated adherence with the VLED. Another explanation may be that everyone did like at least one of the flavours to which they turned to, which would mean that everyone maximised their satisfaction with the products, which was further enhanced by experimenting with the flavours by adding spices, aromas or vegetables to the shakes.

In addition to these results, I have also described in Chapter 5, how participation in a research study itself served as additional motivation to adhere to the VLED due to the regular monitoring of outcomes by the researchers at the research clinic. Attendance at clinic meetings and programme adherence are positively associated with WL and WLM (Chao *et al.*, 2000; Meffert & Gerdes, 2010; Smith & Wing, 1991), while attrition is a barrier to successful WL (Gardner, Kiazand, Alhassan, & et al., 2007; Honas, Early, Frederickson, & O'Brien, 2003; Teixeira *et al.*, 2004).Future programmes should aim to assure regular attendance of meetings by the patients in order to achieve the best possible adherence and outcomes.

6.6 Conclusions

A structured and intensive 8-week long VLED for WL and diabetes remission is acceptable amongst people taking part in a study with clinical supervision. Flavours and texture of the VLED were perceived generally highly acceptable, with considerable differences in flavour preferences between individuals. Feelings of hunger were generally low throughout the diet, although increases may be expected within the first couple of days and during the last week or two. The participants

suggested including more choice of flavours in the programme as well as meeting other participants in order to share experience. The quote from participant CB 17 represents a good summary of these findings:

"I think it's been well thought out, the shakes are all very tasty. I'm not saying they fill you up, I think you do get, particularly the last 2 to 3 weeks, I think you're having 3 a day and either a portion of soup or if I was going to the restaurant I would have a salad or a plate of vegetables. It does get a bit monotonous which is why I think they do it only for 8 weeks. I think if they said you had to do it for 3 months I think you'd get a lot more people falling off it in the last 3 to 4 weeks. I think you've got 5 choices of the meals as well and I went on the internet and they do quite a few more" (MAN, 54 YEARS, T2DM 0.5 YEARS).

Chapter 7

A qualitative exploration of patient experiences with weight loss maintenance after weight loss with an 8-week long very low energy diet

7.1 Abstract

Aim: This chapter aimed to explore experiences of people with a 6-month weight loss maintenance (WLM) intervention received after substantial weight loss (WL) in a 2-month very low energy diet intervention (presented in Chapter 5). It also aimed to identify barriers and facilitators to adherence to the WLM intervention and to identify behaviour-regulation strategies people used to facilitate adherence with WLM. Methods: Data were collected in semi-structured, face-to-face interviews conducted before and after the WLM phase. Thematic analysis was used to analyse the data. Results: Sixteen participants were interviewed before and fifteen were interviewed after the WLM phase. Most participants still wanted to lose weight before and after the WLM phase and they kept moving their goal posts despite remission of T2DM and previous substantial WL. Narratives relating to the transition from WL to WLM highlighted the uncertainty that people face once they have to rely on their own resources and reduced clinical supervision. Regaining control of self-regulation behaviours and developing new routines was key to successful WLM. Critical events and a shift in identity further transcended the process of regaining control and finding balance. Conclusions: Transitioning from a stage of weight loss with VLEDs to a stage of weight maintenance, and weight maintenance itself, seem to present more challenges to self-regulation than trying to lose weight. Successful weight maintenance was characterised by developing new routines and gaining confidence, shifting of goals, and a shift in identity towards a new, healthier self.

7.2 Introduction

Some theories of behaviour change (Prochaska & DiClemente, 1983; Rothman, 2000b; Rothman *et al.*, 2004; Schwarzer, 1992; Schwarzer, 2008; Schwarzer *et al.*, 2003a) put emphasis on the distinction between behaviour initiation and behaviour

maintenance. One of the reasons for WLM to be thought of as a distinct stage of behaviour change rather than continuation of behaviour initiation is the lack of long-term sustainability of the initial, and often successful, behaviour change (Avenell, Broom, Brown, Poobalan, & Aucott, 2004; Avenell, Brown*, et al.*, 2004; Dombrowski *et al.*, 2014a; Franz *et al.*, 2007; Tsai & Wadden, 2006c). Some of the barriers to sustained behaviour maintenance identified in previous research included lack of self-regulatory capacity (Hall & Fong, 2007; Hoefling & Strack, 2008; Hofmann *et al.*, 2007; Klem, Wing, McGuire, Deagel, & Hill, 1997; Strack & Deutsch, 2004), depleted resources (Baumeister *et al.*, 1998; Vohs & Heatherton, 2000), and habits (Hofmann *et al.*, 2008, 2011; Rothman *et al.*, 2004).

A systematic review of theoretical explanations of behaviour maintenance (Kwasnicka *et al.*, 2016) identified, in addition to the above, maintenance motivation and environmental and social influences as important determinants of WLM. Research further highlights that successful WLM encompasses use of behaviour-regulation skills such as self-monitoring (Dombrowski *et al.*, 2014a), good portion size control (Reilly *et al.*, 2015), and maintaining consistent eating habits (Wing & Phelan, 2005).

Successful WLM may have benefits for the wellbeing of people.

Epiphaniou and Ogden (Epiphaniou & Ogden, 2010b) found that successful WL maintainers showed improvements in their social interactions, dietary habits and that they felt more confident and “liberated” after. The changes in identity also took form of a more positive attitude towards one`s self and re-directed attention from their bodies and weight towards activities.

The current chapter aims to further explore experiences of people with a WLM intervention after significant WL; to identify barriers and facilitators to adherence; and to identify behaviour-regulation strategies that facilitate adherence.

7.3 Methods

The present qualitative study is based on interviews conducted with a sub-sample of participants in the Counterbalance Study before and after 6-months of WLM. During this period, weight of all 30 Counterbalance Study participants stayed stable, at levels similar to their post-VLED weight (83.8±2.4kg post_VLED; and 84.7±2.5 kg 6 months later). Thirteen out of 30 achieved normal levels of fasting plasma glucose

(<7mmol/l) following return to isocaloric diet, i.e., achieved diabetes reversal (Steven *et al.*, 2016).

7.3.1 ***Design***

Interviews analysed in this chapter were conducted at the end of the WL phase at month 2 (T2, this is also the start of the WLM phase), and at the end of the WLM phase at months 8 (T3) of the Counterbalance Study (Figure 11).

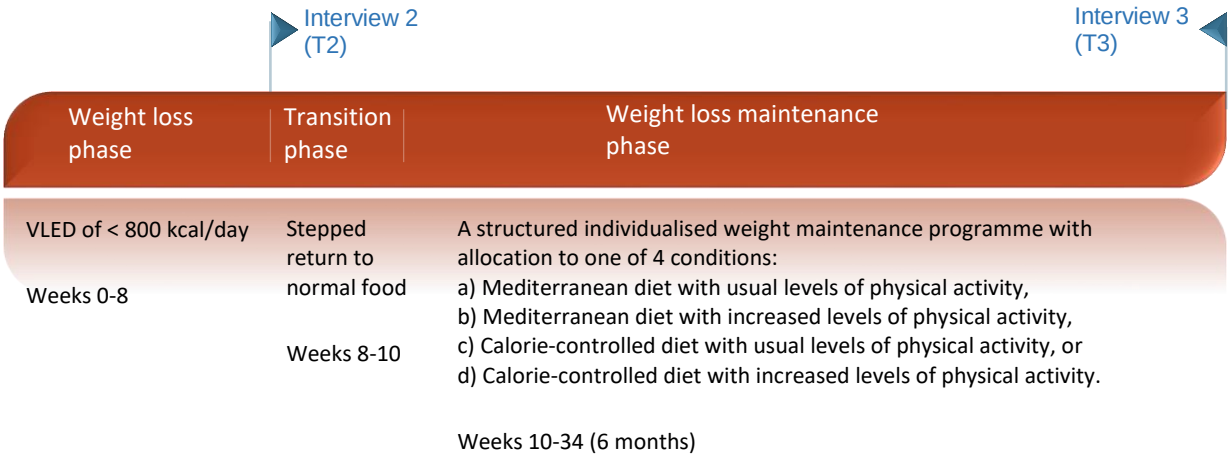

Figure 11. Illustration of the interview time points before and after the WLM phase of the Counterbalance Study.
VLED = very low energy diet; forward/backward orientation of arrows indicates orientation of the interview questions on the future/past, respectively.

7.3.2 ***Participants***

Details of the sampling strategy of the Counterbalance Study can be found in Chapter 3, section 3.4, and in Chapter 5, section 5.2.2. For this study, all participants who had been interviewed at T1, and any other participants at the stage of WLM at the time of this study were invited to take part in the interviews.
Data collection for the current qualitative study was initiated at the end of May 2013, 2 months after the WL phase of the participants interviewed at T1. It was running parallel to the data collection for the qualitative study presented in Chapter 5, which explored the participants` experience with the WL phase of the Counterbalance Study.

The interviews took place during scheduled full- or half- day visits of the participants to the clinic at the end of the WL phase and the end of the WLM phase.

Participants who discontinued the WLM intervention or withdrew from the study were asked for permission to be interviewed as soon as possible afterwards, as they could have provided the study team with information essential for the qualitative evaluation (further presented in Chapter 8). These participants would be approached by the myself rather than by the Counterbalance Study staff, and they could choose not to participate in this interview.

7.3.3 ***Interview protocol***

7.3.3.1 About the interviewer

Details about my background and training I had undertaken before conducting the interviews are described in Chapter 5, section 5.3.4.

7.3.3.2 Interviews

The participants were interviewed at two occasions: at week 8 (T2, end of the WL phase) and at month 8 (T3, end of the 6-month WLM phase). Since the interviews at T2 included questions about the participants` experiences with the WL phase as well as their expectations of the WLM phase, only parts of the interviews relevant to WLM at this interview point were considered in this chapter.

Questions about the participants` expectations of the WLM phase and their goals for after the Counterbalance Study were also asked at the T2 interviews. The last interview (T3) intended to explore the participants` reflections on the WLM as well as on the Counterbalance Study overall.

7.3.3.3 Interview documents

Details of the process of developing interview topic guides for T2 and T3 interviews are described in Chapter 5, section 5.3.4. The interview topic guides used in the study can be found in Appendices 11 and 14.

Questions asked at T2 relevant to this chapter were: "*What are your positive and negative expectations of the 6-month weight loss maintenance phase of the programme?*"; "*Have you tried a weight maintenance programme before?*" *(If yes; prompts were: "What have you tried?*"; "*How did it go?*"; "*Why did you stop?"; "What worked and what didn`t?*"; *"What was the result?*"; "*What made it easier/more difficult for you to comply with the programme?*"); "*How confident are you that you can complete this phase of the programme?*" *(Prompts: weight goals, fitness level, energy, self-confidence, creating habits).*

Questions asked at the follow-up interview (T3) relevant to this chapter were: "*Could you please tell me about your overall experience of the diet you have had?*"*(Prompts: cravings/satisfaction, temptations to break the diet, mood, motivation, barriers /facilitators of adherence, weight lost, strategies you have used to stick to the diet, support you have received from family and friends?);* "*Has anything changed in your life since the end of the VLED?*"; "Have you experienced any lapse(s)/deviations from the amount of calories recommended within the last 6 months?"; "*What additional support would you have appreciated during the weight loss maintenance phase of the programme and why?*".

7.3.4 ***Interview procedure***

After the participants were about to complete the WL or the WLM phase of the Counterbalance Study, the study staff notified me about the participants` visit to the clinic and an interview was arranged. A screening room was available for interviewing on the half-day visits at times convenient to the participants, at the Institute of Aging and Vitality, Newcastle University to minimise the potential burden to the participants. Alternatively, participants were interviewed in a testing room while blood samples were being taken and a nurse was present. In the latter case, a permission to conduct the interview was verbally obtained from the participant again and a decision not to take part in an interview under these conditions was reiterated and respected.

7.3.5 ***Analysis***

My analytical strategy aimed to: 1) explore the experiences of participants engaging in a WLM intervention after substantial WL; 2) identify barriers and facilitators to adherence; 3) identify behaviour-regulation strategies used to facilitate adherence; and to 4) identify the support needs of participants during WLM.
Narratives of all participants who were interviewed at either or both T2 and T3 interviews were analysed in this chapter.

I used Thematic analysis (Braun & Clarke, 2006), described in more detail in Chapter 5, section 5.3.6, to analyse the narratives. I first coded the pre-defined theoretical domains from the Theoretical Domains Framework (Michie *et al.*, 2005) described in detail in the Chapter 5, section 5.3.6.

The following domains were coded in this study: 1) Knowledge; 2) Skills; 3) Social/professional role and identity; 4) Beliefs about capabilities; 5) Beliefs about consequences; 6) Motivation and goals; 7) Memory, attention and decision making; 8) Environmental context and resources; 9) Social influences; 10) Emotion; 11) Behavioural regulation; and 12) Nature of the behaviours.
A few purposively chosen interview sections with different levels of complexity were then coded by myself and by one of the supervisors (VAS) to ensure consistent use of the coding framework and data interpretation. Differences were resolved by discussion. After sufficient consistency was reached, I then coded the rest of the interviews line-by-line with the TDF framework at the level of the domains above. More complex narratives were coded by multiple domains. The data were therefore analysed within and across the domains to better understand the relationships between the domains, which resulted in identification of themes and sub-themes at each of the interview stages presented in this chapter.

In addition, I also conducted an inductive analysis focussing on the comparison of participants who were more and less successful at WLM. All available transcripts of the more and less successful participants were analysed over time on an individual level. The most successful participants were considered those, who lost more than 5% of their baseline weight by the end of the WLM phase (T3), in addition to the WL achieved by the end of the WL phase (T2). The least successful participants were considered those, who regained more than 5% of their baseline weight between the end of the WL phase (T2) and the end of the WLM phase (T3). The 5% was an arbitrary but meaningful cut-off point resulting from the weight data at the end of the WLM phase.
The data analysis included reading of the available interview transcripts of one participant at a time rather than cross-sectionally. I was sensitive to the differences in the participants` narratives that could explain the differences in the achieved WLM outcomes. I first coded the interviews line-by-line and I noted any questions or ideas on the margins of the interview transcripts. I then refined the codes, synthesized them into themes and compared the identified themes between the more and the less successful participants.

Participants were not invited to comment on the findings. The results are complemented by representative quotes annotated by gender, age and duration of diabetes.

NVivo v.10 software was used to support the data analysis. I also used coding stripes, cluster analyses, and mind-maps to facilitate my understanding of the data and the relationships across the themes.

7.4 Results

The results of this section are organised by the themes and sub-themes identified in the analysis. The main themes identified in this study were: **1) Shifting of goals**; **2) From uncertainty to regaining control**; and **3) Identity shift**. The results are supported by quotes annotated by gender, age and duration of diabetes. A mind map of the identified themes and relationships between them as I perceived them is presented in Figure 12.

7.4.1 ***Participants***

Eighteen out of thirty participants enrolled in the WLM phase of the Counterbalance Study were interviewed at either or both interview time points (T2 and/or T3). Sixteen participants were interviewed at T2 and fifteen were interviewed at T3. Out of these, 13 attended both T2 and T3 interviews, 3 were only interviewed at T2 and 2 were only interviewed at T3.

Reasons for not attending interviews were lack of time and work commitments of the participants, and unexpected scheduling issues with the software used to update participant appointments (a shared calendar).

7.4.2 ***Interview length***

The T2 interviews that included questions about both WL and WLM lasted 44 minutes on average (range 16 – 73 minutes). The T3 interviews lasted 42 minutes on average (range 27- 69 minutes).

Table 8 shows the demographic data, interview time points and outcome data for participants who took part at either T2 or T3 interviews.

Table 8. Interview (T2 and T3) study participants` characteristics, Interview time points and changes weight, BMI and fasting plasma glucose.

ID	Sex	Age	T2DM duration (years)	Allocation	T2	T3	% Weight change at T2 (kg)	% FPG change at T2 (mmol/L)	% Weight change at T3 (kg/m^2)	% FPG change at T3 (mmol/L)
1	man	67	3.5	MD	X	X	-15.94	-30.48	-13.87	-3.75
2	woman	61	11	MD	X	X	-14.87	-44.03	-5.38	2.16
3	woman	65	3	MD	X	X	-13.39	-35.33	-22.20	-21.31
4	woman	42	1	MD+PA	X		-11.78	-29.71	-10.01	-13.36
5	man	44	2.5	MD	X	X	-12.11	-43.33	-10.89	-45.79
6	man	54	0.5	CC	X	X	-17.93	-22.35	-15.51	-14.07
7	man	65	13	CC	X	X	-13.94	-47.87	-14.61	-60.08
8	man	64	9	MD+PA	X		-9.22	-32.59	-7.78	-15.83
9	man	49	9.5	MD+PA	X	X	-17.13	-64.45	-20.10	-59.14
10	man	52	1							
11	woman	47	2.5	CC	X	X	-15.71	-24.04	-21.37	-31.89
12	woman	35	1.5	CC +PA	X	X	-14.68	-42.17	-25.83	-36.87
13	man	59	10	MD	X	X	-17.11	-57.79	-11.69	-34.67
14	man	69	8.5	MD+PA	X		-15.80	-28.57	-15.90	-17.01
15	man	69	3.5	MD+PA	X	X	-20.44	-45.07	-18.78	-21.16
16	woman	64	12	CC		X	-12.50	7.19	-9.98	-18.71
17	woman	70	15	CC +PA	X	X	-11.84	-45.49	-13.73	-26.19
18	man	69	18	CC +PA	X	X	-13.92	-31.41	-17.18	-34.62
19	woman	63	10	MD		X	-14.58	-32.79	-6.10	-11.07

Notes. T2DM = type 2 diabetes mellitus; FPG = fasting plasma glucose; MD = Mediterranean diet (high Mono-unsaturated fatty acids diet); CC = calorie-restricted diet estimated by the participants` resting energy expenditure; PA = increased physical activity; T2 = interview at the end of the weight loss phase; T3 = interview at the end of the weight maintenance phase; highlighted in green are participants who achieved normal-range FPG levels (<7.0mmol/L). Highlighted in grey are participants who achieved borderline normal FPG levels (slightly over 7.0mmol/L, maximum was 7.70 mmol/L). Negative values represent a decrease, positive values represent an increase. Changes in weight and FPG are calculated from baseline values. Participant highlighted in grey was excluded from the Counterbalance Study.

The first part of each paragraph represents results based on analyses of interviews of all participants interviewed at T2 and/or T3. Where applicable, the second part of each paragraph focuses on differences between the more and the less successful weight maintainers, and on how these differences may explain the level of WLM success.

7.4.3 ***Theme 1: Shifting of goals***

The theme of shifting goals illustrates that most participants wanted to continue to lose weight after the WL phase, even though they achieved the required WL, and in many cases, diabetes remission.

7.4.3.1 Positive reinforcement

It was expected that the participants would embark on the WLM intervention after the 8 weeks on a VLED, but many shifted the goal posts for WL and blood glucose levels further instead. This was because the impact of the WL achieved at the end of the VLED intervention on the participants` health and their physical and psychological wellbeing positively reinforced successful behaviour regulation, increased self-efficacy, and the experience of mastery. This was mostly apparent in the participants` narratives of expected and actual outcomes, which often exceeded their baseline expectations (further described in Chapter 5).

"I want to lose more weight. I feel like I've lost more than I actually have done. I think it's just over 2 stone so to me I can see yeah I've lost 3 and a half stone but I know as well I was about 6 stone overweight so I do need to lose at least another couple of stone, I know that. And if that helps me to carry on feeling better yeah I'm focused on doing that" (WOMAN, 42 YEARS, T2DM 1 YEAR).

7.4.3.2 Satisfaction with outcomes

Because of this experience of a positive reinforcement loop, more than half of the participants still wished to lose weight during the WLM phase and as described in Chapter 9, many still wanted to lose weight after the WLM phase. One of the reasons was, that even though their weight and blood glucose levels had come down dramatically, they had not come down to the normal range (FBG≤ 7.0 mmol/L; BMI≤ 25 kg/m^2), or down to a level they would be satisfied with. Some simply wanted to see how far down the blood glucose levels and weight could be pushed.

"I think it's been the initial the weight loss, how quick it's gone off…I've done 2 and a half stone now and it's not impossible to do another 2 and a half stone but it will possibly take longer than this has. But I think once you've had that big loss you don't

want to go back the other way, you want to continue going forward. So yeah I'm motivated, I'm there" (WOMAN, 47 YEARS, T2DM 2.5 YEARS).

Some participants still required medication (e.g. blood pressure, cholesterol etc…) after the WL phase, which was a frequent complaint and, as described in Chapter 5, a strong reason to taking part in the Counterbalance Study in the first place. Another underlying reason for wanting to lose more weight was ultimately related with the wish to reduce the number of medications they were prescribed, or to stop them altogether if possible, if this was not achieved by the end of the WL phase.

"I don't think the readings have come down far enough. The staff says oh they're great, champion, wonderful but I'm not happy. I want them to come down more; I want to lose more weight. I don't want to turn anorexic but I just want to lose a bit more weight and see if I can get the readings lower…if I can get that down and the doctor says right come off them blood tablets we'll see what you're like and I stay normal, champion. And I can keep off the Metformin, great" (MAN, 44 YEARS, T2DM 2.5 YEARS).

Whether or not the participants were taken off medications after the WL phase or during the WLM phase played an important role in their WLM success. Being taken off diabetes and other medication as a result of the WL, in addition to removing some of the side effects related with medication, was perceived as life-changing and it gave the participants sense of improved physical and mental health, a diabetes-free status, and provided further motivational boost and reinforcement of their behaviours. On the contrary, re-introduction of medication led to loss of hope for the remission of diabetes and diminished efforts during WLM. The examples of quotes below illustrate the role of medication in the narratives of 2 participants, out of which one lost more weight and the other regained weight during the WLM phase.

More successful participant:
"…And I`ve stopped statins for the cholesterol as well. I also used to take antidepressants for nearly 22 years. And in October, I didn`t realise I was doing it, but I just stopped taking them, and it wasn`t until I ordered a repeat prescription for something else, and I was like, "God, I`m meant to take those". And when I looked I hadn`t had them for about 4 weeks"
(WOMAN, 47 YEARS, T2DM 2.5 YEARS).

Less successful participant:
"…because I`d had the blow, and it still feels like a huge blow of having to go back on Metformin. I was prescribed the Metformin again when I came for a visit before the holidays…That felt like a failure. Complete and utter failure. Cause I hadn`t had the Metformin for quite a while and I had to go back on it again, so part of me was feeling very down. Like what is the point, you know, I`m clearly diabetic I`m gonna stay diabetic…I would sneak things I shouldn`t have, because I would think, what the hell" (WOMAN, 61 YEARS, T2DM 11 YEARS).

Although the theme of shifting goals may seem suggestive of dissatisfaction with the achieved outcomes, evaluation of acceptability of the VLED as an intervention in Chapter 6 shows that this was not the case for most participants. The motivation of participants to achieve more was driven by their success in achieving the initial goals and they were therefore more confident and keen on improving the outcomes as much as they could. The discrepancy between the participants` personal goals and the study`s goals however had implications for adherence with the WLM intervention, which is discussed in more detail in Chapter 8.

7.4.4 ***Theme 2: From uncertainty to regaining control***

In contrast to the overall positive effects of the VLED intervention on the participants` wellbeing, many also expressed worries and uncertainties about transitioning back to regular food, and about their ability to maintain their weight in the long-term. Before the Counterbalance Study, many participants felt that they had no control of their diabetes, or of their self-regulatory behaviours. During the WL phase, some managed to reverse their diabetes by their own effort, which provided them with a sense of better control over their health. In addition, compared with the WLM phase, the WL phase provided more intense clinical supervision and the participants benefitted from intensive support from the Counterbalance staff, which was often also perceived as a source of external control, affecting the participants` self-regulatory behaviours (further described in Chapter 5). The theme of regaining control encompasses these sub-themes: 1) adapting to the new regime, 2) developing new routines, and 3) use of behaviour-regulation strategies, described further below.

7.4.4.1 Adapting to the new regime

Some participants were worried about losing control over their eating behaviours during the WLM phase, which they thought would erase all the effort and the results achieved during the WL phase. The nature of the VLED intervention was very regimented, which also meant that the participants did not have to make decisions about food shopping or cooking, because they knew exactly what they were going to have and when. Compared to the WL phase, the WLM phase was much less structured and the participants were therefore concerned about their ability to control their behaviour during this period, mostly due to the reduced clinical supervision and lack of maintenance-facilitating behaviours in place. It seemed as if they did not know whether they could trust themselves with regards to eating the WLM diet.

"I'm a little bit worried, I don't know, that I lose control, and I don't want to lose control. I'm a bit worried that I might – well I know I won't splurge on foods that I haven't had for the past 8 weeks but I just don't want to – I don't know…I just don't want to start eating unhealthy again and I'm frightened that if I have one unhealthy thing it's going to lead on to another and on to another and I'm a bit worried. So I need it to be as structured as I can get it"
(WOMAN, 47 YEARS, T2DM 2.5 YEARS).

"The diet is so regimented that actually the 8 weeks once you get into it were a breeze because you always knew what you were going to eat at each meal, what you were allowed to eat whereas when you come off the diet you've got freedom again, you can take things and eat things and it's just trying to educate myself into another regime if you like where I know what I can and cannot eat"
(MAN, 49 YEARS, T2DM 9.5 YEARS).

Many participants struggled with adherence to their maintenance plan when they changed environments (usually during holidays) within the first couple of weeks of WLM. Holidays seemed particularly challenging not only because of the abundance of food, but also because of alcohol, which some participants identified as a potential barrier. The role of changing environments during the initial stages of WLM is discussed in more detail in Chapter 9 under the sub-theme "Holiday hiccup".

7.4.4.2 Developing new routines

Participants felt that they had developed routines with regards to their eating behaviours during the WL phase due to the relative simplicity of the regime. The prospect of transition to regular foods was intimidating for some, as they feared that they might not be able to adopt healthier behaviours, and that they would slip back into their old, less healthy habits and undo the work they had put into the WL phase. This perception was further aggravated by essentially having been removed from regular food for the duration of the WL phase. Many participants never lost as much weight in the past, or they were never satisfied with their weight, which is why few had experience with WLM. WLM was therefore associated with uncertainty in the participants` narratives. They were uncertain about their ability to develop healthier routines than the ones they had in the past, and they were worried about the effects of the transition and the WLM phases on their weight and blood glucose levels.

"I'm quite wary about introducing foods back in mainly because I didn't want to get into the way I was eating before. I used to be really bad at snacking in between meals and things and I don't want to get back into doing that so I think I'm quite conscious about what I'm eating at the moment and I would like to continue to be conscious about what I'm eating" (WOMAN, 35 YEARS, T2DM 1.5 YEARS).

Limited data from the interviews indicate that having been able to develop healthier habits related with shopping, cooking, eating appropriate portion sizes or physical activity helped the participants stay on track with WLM. For example, the participants often referred to ”getting used to” the WLM regime, creating “routines” with regards to nutrition and physical activity, and finding the right balance for them between their eating and physical activity routines and their behaviour-regulation strategies.

“..the routine’s better in terms of keeping an eye on the weight and the little things like if you’re going out for a meal at the pub or whatever, which we do occasionally, I start the day before, have a bit less the day before and a bit less the day after and that keeps the weight right, balances it out” (MAN, 69 YEARS, T2DM 18 YEARS).

7.4.4.3 Facilitation of adherence

Uncertainty related with transition to regular food and fear of slipping back to old habits not only reflects the relative difference in the participants` perceived WL and WLM self-efficacy (indicating that these are two distinct phases of behaviour change), it also highlights the participants` awareness of the differences between their pre- and post-WL behaviours, and a change in their relationship with food. This awareness resulted in the participants employing different behaviour-regulation strategies (Appendix 16) to those used during WL. Use of these strategies facilitated adherence with the maintenance plan by balancing out any deviations in adherence. If used successfully, they gave the participants a sense of increased self-efficacy and control.

Two behaviour-regulation strategies were used predominantly during the WLM phase: a) monitoring and b) compensation. The section below describes how these strategies were used to overcome barriers to adherence.

Monitoring

Monitoring was employed in many forms. Most participants used food diaries to monitor their calorie intake. This was easy enough for them to do, as food diaries had initially been given away to them by the Counterbalance Study staff if the participants struggled to keep their weight off. Some of the participants then kept using such diaries throughout the WLM phase.

“It was a spreadsheet and it was on my screen all the time so as soon as I had a cup of coffee I just used to copy and paste from the last one”
(MAN, 54 YEARS, T2DM 0.5 YEARS).
“I did slip, occasionally and have a bag of crisps and things, but on the whole I’ve been alright, but I had to make sure that I monitored it”
(WOMAN, 70 YEARS, T2DM 15 YEARS).

Another form of monitoring was weighing food, or reducing portion sizes to meet the recommended calorie allowance. The participants often reduced the number of meals they would order when eating out, ordered smaller sizes of drinks or shared meals and desserts with others.

"So I'm still having what I want but it's a lot less. It's a smaller amount compared to what I would have had, and plus I count them in my calories now as well which I never used to do" (*WOMAN*, 35 YEARS, T2DM 1.5 YEARS).

Determining appropriate portion size seemed particularly challenging. The participants often made references to feelings of uncertainty about what and how much they should or should not eat to avoid slipping into their old eating habits.

"and I found it actually the reverse now is more difficult which is going back on to normal food and just making adjustments like getting portion size right"
(MAN, 69 YEARS, T2DM 18 YEARS).

"I think now I'm going to have to actually think and make the decision not to have that extra couple of roast potatoes and perhaps might leave that other third glass of wine until tomorrow unless it's a really good occasion"
(MAN, 67 YEARS, T2DM 3.5 YEARS, allocation).

All participants mentioned having struggled with the portion sizes, but the more successful participants managed to stick with what they knew was an appropriate portion size. The main reason why they did so seemed to depend on how much they valued their previous WL and the effort they had put into WLM or further WL, and they were constantly reminding themselves of it. The participants who were more successful at WLM were also able to find healthier options or eat smaller portions when eating out and in situations with limited food choices, which was perceived as more difficult by the less successful participants.

More successful participant:
"So I`m still having what I want, but it`s a lot less. It`s smaller amount compared to what I would have had, and plus I count them in my calories now as well, which I never used to…I do the same when I go to restaurants and I pick food out as well. I don`t have starters anymore and I don`t have desserts anymore. I just have a main course and if the main course is over 500 calories, I won`t eat them" (WOMAN, 35 YEARS, T2DM 1.5 YEARS).

Less successful participant:
"I was with lots of friends and there was a meal included in the price of the ticket. It was a buffet but everything on it was pastries, breads, crisps. There wasn`t one healthy thing on the table, no one, no salad, not anything…So I had some sandwiches, what else did I have, I had some crisps, but stuck away from the pastries and things like that, and also that night I had some wine, so that`s probably why" (WOMAN, 63 YEARS, T2DM 10 YEARS).

Becoming more aware of the contents of food helped the participants look for healthier alternative foods when shopping or eating out.

"Well, I love sausages, especially the hot dog ones. But I've stopped eating them and I'm now getting the Quorn ones…I'm getting used to it now. It's become more or less a habit. I buy Quorn this and Quorn that and then I eat more salads" (MAN, 44 YEARS, T2DM 2.5 YEARS).

"As soon as you put the kettle on to make the tea or the coffee you got the biscuits out as well. But I've got past that stage and if I still fancy something now I would have a yogurt or something similar"
(MAN, 69 YEARS, T2DM 18 YEARS).

Increased awareness as an indicator of shifting identity is further discussed in Chapter 9.

Regular weight monitoring at home and monthly visits to the clinic presented a particularly strong motivation for weight regulation during both, the WL and the WLM phases. The participant mentioned below was one of those, who struggled most with environmental and emotional triggers, as well as with the lack of support during WLM. Her quote is an example of the complexity of situational decision-making processes, considering the presence of the environmental trigger of seeing food, while thinking about the achieved outcomes, the potential impact of her action, and the expected emotional response to it.

"Well it was like you want some ice cream go and get some. No you don't want any ice cream, you're just being greedy. You want some ice cream go and get some. Well which one would I get? And then looking at all the different flavours and then thinking that will be so tasty and delicious and then I thought yeah, but I've got breakfast bars at home and they're only 99 calories. And then it's like yeah but ice cream is so much tastier. And it was like a mini conversation in my head and then in the end I just thought no, because you'll kick yourself if when you go and get weighed next week you've put weight on. So don't do it. So I didn't. But it was a full on 5 minute conversation in my head with myself" (*WOMAN*, 35 YEARS, T2DM 1.5 YEARS).

"I've actually gone and bought some digital scales now because that was a banned substance that was never in the house. So I'll be able to monitor it yeah" (WOMAN, 42 YEARS, T2DM 1 YEAR).

Compensation

Compensation was understood as an amendment to diet or physical activity in order to "rectify" any dietary deviations before or after a lapse. Two main compensatory strategies were identified: compensation by regulating eating behaviours and

compensation by physical activity. One form of compensation was to eat less and /or exercise more before or after an event such as birthdays or holidays.

"There's been temptations and I have, at times, given into those temptations but it's been a case of then just if I have a day off it's just getting back on the diet and the food that I've eaten and the exercise the next day"
(MAN, 49 YEARS, T2DM 9.5 YEARS).

"What I've learned from it is just how quickly your weight changes either by reducing food or increasing it, so both ways, and how quickly you need to monitor it. Rather than say I'll start on a diet next week or cutting down next week, start now, start today and do it straight away. And if you know you're going for some special meal somewhere then what I would do is cut down the day before and then again the day after and balance it and that seems to work"
(MAN, 69 YEARS, T2DM 18 YEARS).

Another form of compensation was alternating days of calorie restriction and unrestricted eating (e.g. when on holidays); or restricting eating/increasing physical activity for a couple of days as soon as weight increase was registered.

I'm certainly determined to be monitoring my weight, more than I ever used to. I didn't bother before, but now I will be, and if I see a slight increase then 800 calories a day for a few days gets it back again doesn't it?"
(MAN, 65 YEARS, T2DM 13 YEARS).

"If I fancy not a bar of chocolate, but say a Mars Bar or a Snickers or something, I would just have one. I don't say, "Oh, I can't have that because I've already had 15 calories," I would go to 18 that day and just try to be a little bit careful over the next couple of days" (MAN, 54 YEARS, T2DM 0.5 YEARS).

Adapting to the WLM regime, developing new routines to help establish the changes in the new lifestyle, and using behaviour-regulation strategies contributed to a better control of the participants` behaviours during WLM.

7.4.5 ***Theme 3: Identity shift***

Transcending the WLM experience was a shift in identity. A shift in identity represented changes in the way the participants compared themselves with others; changes in the perception of their body and in their psychological wellbeing, but also changes in their eating behaviours that were healthier compared to their eating behaviours before the study.

Some of the participants seemed to have experienced a shift identity by separating themselves from and being more judgemental towards other people who were overweight or obese, which seems to have helped them keep their goals in mind during the WLM phase. Reflecting back on the data analysis of the more and less

successful maintainers, both groups seemed to have experienced this shift. Both groups seemed to have become more judgemental towards people larger than themselves or people eating large portions of food.

More successful participant:
"Ehm, like if I`m out for a nice meal and I spot someone looking over, I`m like "Oh my goodness, have I got too much on my plate?" That kind of thing. Or they are looking at me…"Oh gosh, she`s fat, look what she`s got on her plate, no wonder she is". But then, I think, "Oh no, I`m not! That`s just my brain`s interpreting them glancing". I mean they may have just been glancing over as if…to glance. But yeah, sometimes I still think of it. Like a fat person."
(WOMAN, 47 YEARS, T2DM 2.5 YEARS).

Less successful participant:
"The odd thing is it`s made me very conscious of fat women. You know when you walk into a supermarket and you`re walking behind somebody really fat pushing the trolley. And I think to myself "eee, lass, you need to lose weight, look at the state of you, you need to be on a diet". But that was me. You know, maybe not quite as bad cause I tend to choose people very much bigger than I ever was, but I`m very conscious of other people`s size in a way that I never used to be. Or if I was, I was accepting of it"
(WOMAN, 61 YEARS, T2DM 11 YEARS).

A more detailed description of the theme of shifting identity is further presented in Chapter 9.

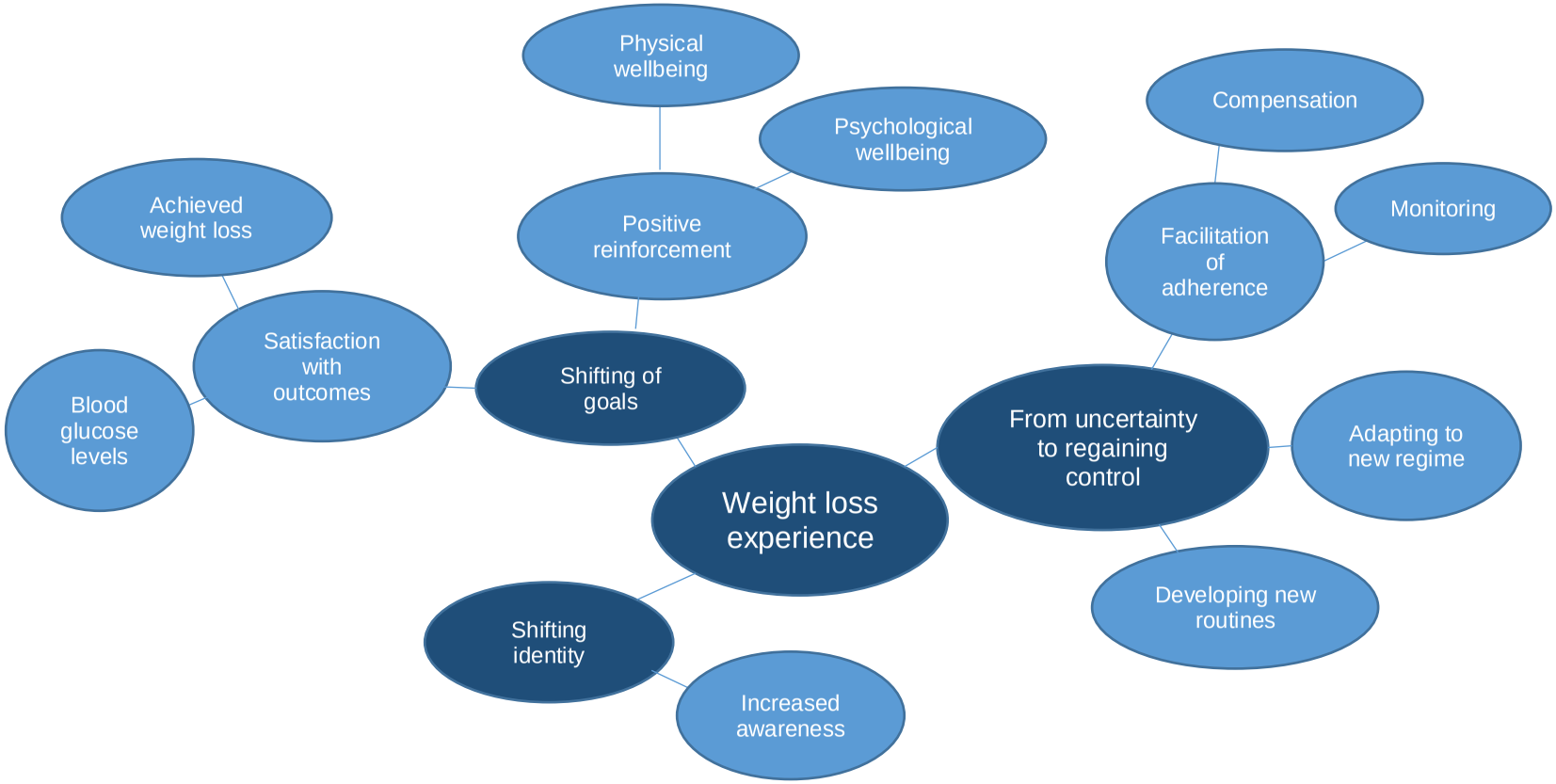

Figure 12. A mind map of themes illustrating experience with the weight loss maintenance phase of the Counterbalance Study. Highlighted in dark blue are core themes, highlighted in light blue are peripheral themes. Size of the oval shapes does not represent richness of data or how substantial a theme was.

7.5 A model of psychological, behavioural and environmental determinants of weight loss maintenance experience in the Counterbalance Study

The transition from WL to WLM and the following WLM were generally perceived as more difficult than the participants anticipated at the beginning of the WLM, mostly due to the considerable uncertainty about this phase at the start. Most participants still intended to lose weight during the WLM phase due to the positive reinforcement of behaviours and the achieved outcomes during the WL phase. Lack of behaviour regulation, inability to determine and adhere with appropriate portion size, reintroduction of medication and perceived lack of clinical supervision were considered barriers to WLM. On the other hand, being able to follow the WLM plan in different environments, developing new routines, having monitoring and compensatory behaviour-regulation strategies in place, a positive shift in identity, and the ability to control and adhere to appropriate portion sizes facilitated WLM.

Based on the results from the baseline (T2) and follow-up (T3) interviews, I created a working model of psychological behavioural and environmental determinants of WLM experience in the Counterbalance Study, which is presented in the next section. The complexity of the narratives (often associating distinct themes in one single sentence or answering one or more questions of the topic guide at the same time) served as guidance to postulating hypotheses about the relationships between the themes presented in Figure 12.

The working model of determinants of WLM (Figure 13) is similar to the model of determinants of WL, in that its determinants can be seen as environmental (green), personal (pink) and behavioural (blue), as suggested by the SCT (Bandura, 1986) and also in that the nature of the interaction between the main determinants is comparable. In addition to the WL model, the WLM model also includes habit as one of the determinants affecting behaviour-regulation. The differences between the two models can be deducted from the differences in the sub-themes related with the determinants, rather than from the composition of the model. For example, it can be seen from the model, that different behaviour regulation strategies were required during WLM (monitoring, compensation) as opposed to WL (avoidance, removal of food, finding alternatives, coping panning). Similarly, the environmental triggers were different to the WL phase (time away and shopping during WLM vs. presence of food at home or at work; shopping, cooking for others during WL) and lastly, resources

seemed to have been triggered by slightly different events (re-introduction of medication, shift in identity, uncertainty) in comparison to the WL phase (guilt, boredom, tiredness).

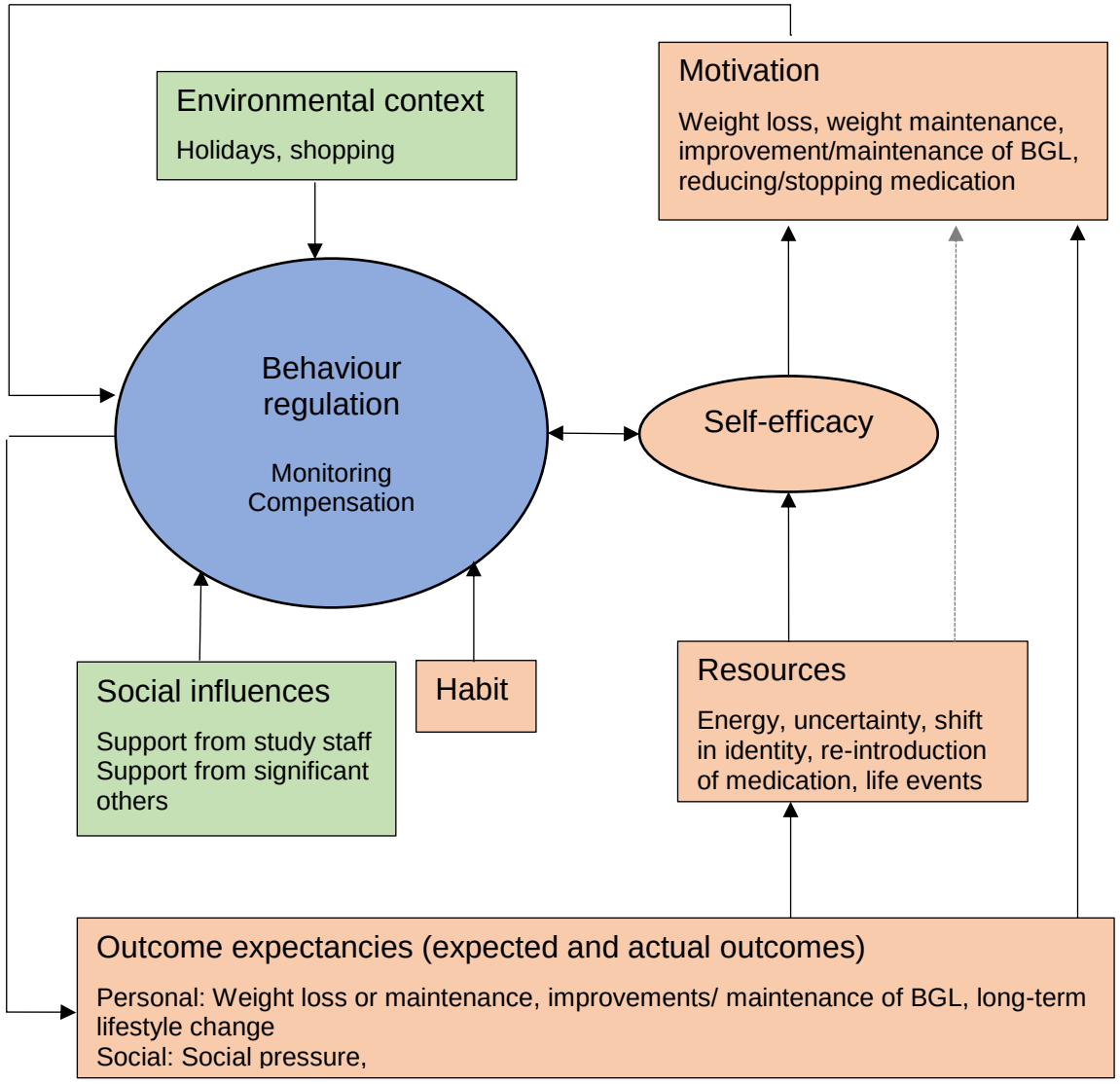

Figure 13. *A model of psychological, behavioural and environmental determinants of weight loss maintenance experience.*
Highlighted in pink are psychological determinants; highlighted in green are environmental determinants and highlighted in blue are behavioural determinants. Full line represents relationships substantially supported by data; dotted lines represent relationships that need further exploration.

Different behaviour-regulation strategies were also used predominantly during the WLM phase (compensation, monitoring) compared to the WL phase (food removal, avoidance, distraction, coping planning). The need for different behavioural responses during WL and WLM has been previously stressed by Sciamanna and colleagues (2011), who have identified that out of 36 behavioural strategies, only 8

were used for both, WL and WLM, while the rest of them were used predominantly for either WL or WLM, and only 14 of them were associated with WLM only.

7.6 Discussion

This study aimed to explore peoples` experiences with WLM after significant WL through a VLED; to identify barriers and facilitators of adherence, and to identify behaviour-regulation strategies used to facilitate adherence.
Three themes were identified in the baseline and follow-up interviews: 1) Shifting of goals; 2) From uncertainty to regaining control; and transcending these was a 3) Shifting identity.

Counter-intuitively, the transition and the WLM phase seemed to have been overall more challenging to adhere to than the intense WL phase using VLED, mostly due to the reduced intensity of clinical supervision (including support and monitoring of weight and FBG levels), diminished dietary guidance or lack of previous experience with WLM and therefore lack of maintenance behaviour-regulation skills. Transition from the VLED to WLM caused considerable uncertainty among the participants, which may explain why some of the participants relied on behavioural strategies developed during the WL phase, such as self-monitoring and finding food alternatives/problem solving, and even planning to use meal replacement as a weight- regulation strategy, which was also previously found to improve WLM after a WL through low or very low energy diets (Johanssoon, Neoovius, & Hemmingsson, 2014). In addition, it was crucial to develop new eating habits, and use problem-solving skills in situations that could potentially trigger a relapse into old eating behaviours, such as when eating out or during social events. This is in line with previous research on exploring differences and similarities between successful and unsuccessful WL maintainers which found that found that WL maintainers tend to engage in positive self-talk, use problem solving skills, weigh themselves regularly and use behaviour-regulation strategies used during WL (Reyes et al., 2012; McKee; Ntoumanis, & Smith, 2013; Elfhag & Rossner, 2005).

Rothman`s framework of behaviour-regulation (Rothman, 2000b) suggests that while behaviour change initiation can be predicted by favourable expectations, behavioural maintenance can be predicted by satisfaction with outcomes. Dissatisfaction with outcomes is more likely in individuals who re-gain weight but not those who maintain

it (Byrne, Cooper, Fairburn, 2003), while reaching a self-determined weight goal is with successful WLM (Elfhag & Rossner, 2005).

In this study, most people still wanted to lose weight after WL and also after WLM. This supports the finding from Chapter 5, that the VLED was more acceptable than it had been anticipated, and that the positive reinforcement through achieved outcomes and improvements in overall wellbeing encourage further WL during an actual WLM phase. On the other hand, it may imply that further weight loss was attempted due to dissatisfaction with outcomes, however, the data in Chapter 8 show that this was not necessarily the case as (as presented in Chapter 5) the outcomes often exceeded the participants` expectations.

Evidence of peoples` expectations of WL and WLM is very limited, but some other studies have found that people wanted to lose more weight after a WL intervention was finished. For example, Herriot and colleagues (Herriot, Thomas, Hart, Warren, & Truby, 2008) found, that participants in the condition with meal replacements planned to stop the dietary programme after it was finished, although they appeared to want to lose more weight and increase exercise in the future. In a trial of weight loss maintenance intervention for adults 92% of people at the beginning and 76% of people at the end of the WLM intervention still wanted to lose more weight (Simpson *et al.*, 2015). This may have implications for adherence with a WLM programme, as they may not be ready to make that transition. According to the Trans-theoretical model of behaviour change (Prochaska & DiClemente, 1983), that suggests that behaviour change happens in stages (pre-contemplation, contemplation, preparation, action and maintenance), interventions that are not matched to the stage of an individuals is at are more likely to be ineffective (Zimmerman, Olsen, & Bosworth, 2000). Assessing whether or not people want to continue to lose weight may be crucial to the success of WLM interventions. Longer follow-up of participants who have lost weight would likely allow evaluation of the relationship between satisfaction with outcomes and WLM, as more people would achieve their personal WL goal.

The model of psychological, behavioural and environmental determinants of WLM that I proposed based on the findings in this study reflects the determinants of WLM identified in previous studies. For example, a systematic review of theoretical explanations of WLM behaviours by Kwasnicka and colleagues (Kwasnicka *et al.*, 2016) identified the following themes: maintenance motivation, self-regulation, resources, habits, and environmental and social influences. All of these themes map

onto the results of this study and also onto the constructs of the Social Cognitive Theory (SCT) (Bandura, 1986), which stresses the importance of interaction of cognitions, environment and behaviour. In the SCT, outcome expectancies, self-efficacy and barriers are the main determinants of behaviour. Results of this study underline the importance of maintenance behaviour-regulation strategies to overcome barriers. Overcoming barriers increased the self-efficacy of the participants, which further led to achieving outcomes and further positive outcome expectancies. In this study, self-monitoring and compensation were identified as the main behaviour-regulation strategies, which also included finding alternatives to food, and controlling portion sizes. Being able to control portion size is a crucial self-regulation skill during WLM (Reilly *et al.*, 2015). A Cochrane review including 72 randomised controlled trials reviewed the evidence of how much consumption of food and drinks changes depending on the size of portion or tableware (Hollands et al., 2015). The review found, that adults tend to consistently chose more food and larger drinks as opposed to smaller portions when they are offered them, and estimated that choosing larger portions would result in approximately 12-16% change in the average daily energy intake of UK adults. The finding highlights the importance of environmental triggers and the of one`s ability to determine and adhere with appropriate portion sizes despite the environmental triggers in order to succeed in WLM. In addition, participants who were more successful in WLM also did not feel particularly limited by their WLM regime and experienced more satiety with regards to food due to the dietary changes they had made. This, together with the increased physical ability and activity after the WL, widened the dietary and exercise possibilities of the participants, supporting the finding of (Ogden, 2010) that successful WL maintainers report fewer benefits of eating and more choice over healthy food and physical activity.

Reintroduction of medication was perceived as an indicator of health and considered a milestone in the process of diabetes remission in this study. Having to start taking medication after all the efforts related with WL was a critical event, which was disappointing and demoralising for some participants, resulting in less hope and motivation to keep the weight off, whilst becoming medication-free or reducing the number of required medication was perceived motivational and facilitated further WLM efforts. Critical events or “life crises” as described by Ogden and Hills (Ogden & Hills, 2008) were identified as triggers for behaviour initiation, but also as triggers for

sustained behaviour change, if three sustaining conditions are met: disruption of function (the initial unhealthy behaviour loses its function), the person perceives that there is effectively little choice and a need to pursue a healthier behaviour and the person adheres to a specific set of behaviours. Data from this qualitative study show that breaking the relationship with regular food for 8 weeks during the WL phase led to increased awareness of food intake after the during WLM and to the development of new eating habits. This is an example of disruption in function of food in the participants` life before the WL. Inability to follow the new proposed eating regime on the other hand contributed to less successful WLM.

The general, as well as the more detailed analyses comparing the successful and the less successful weight maintainers showed that a shift in a person`s bodily identity towards a healthier one may have been an important facilitator of WLM, together with the ability to stick with one`s healthy eating routines or habits. A study by Epiphaniou and Ogden (2010) found effects of WL on a person`s identity and their WLM success. In their qualitative study, 10 women were interviewed after 1 year of successful WLM of at least 10% of their weight. They found that successful WL maintainers showed improvements in their quality of life through improved social interactions, dietary habits and changes in identity. The changes in identity also took form of a more positive attitude towards one`s self and re-directed attention from their bodies and weight towards activities. The current study also found that WL enabled the participants to take on new activities mainly due to increased physical mobility and that the shift in the body-related identity improved the participants` self-confidence, but I did not find that the shift would direct peoples` focus away from their bodies at this stage as suggested by Epiphaniou and Ogden (2010). One explanation might be that self-regulation skills such as monitoring, which has previously been found one of the most effective WLM strategiy (Dombrowski *et al.*, 2014a; Klem *et al.*, 1997), requires attention to be focussed towards weight on a regular basis rather than away from it. According to the National Weight Control Registry in the US (NWCR), which is a registry of self-selected adults who have lost at least 13.6 kg and have kept it off for at least 1 year, eating a low calorie diet, self-monitoring of weight and maintaining consistent eating habits are among the strategies associated with successful WLM (Wing & Phelan. 2005). The NWCR had more than 4000 members in 2005 and at that time, more than 44% of its members weigh themselves at least once a day and 31% weight themselves at least once a week. The members who

weigh themselves frequently scored higher on a measure of cognitive restraint and therefore act similarly to people who were successful at WL for years after their WL (Klem et al., 1997), which is in contrast with the findings of Epiphaniou and Ogden (2010). On the other hand, the participants in our study were only half-way through the timeframe of the Epiphaniou and Ogden`s (2010) study and the NWCR`s inclusion criterion, which means that the development of habitual self-regulatory skill such as monitoring and the shift in identity and may not have been complete at the end of the WLM phase of the Counterbalance Study, 6 months after the official end of the WL phase. Although 6 months post-WL is considered a medium-term follow-up from a research perspective, it can be considered a fairly short time from the participants` perspective. Results of the NWCR also showed that the single best predictor for successful WLM is the length of successful WLM, more specifically, that people who manage to maintain their weight for 2 years are more likely to keep the weight off the next year in comparison with those, who regain weight within 2 years (Wing & Phelan, 2005).

7.7 Limitations

The WLM phase of the Counterbalance Study lasted for 6 months, which also equalled the period of time between the T2 and T3 interviews. Recall of the participants` experience may therefore not have been as accurate as during the VLED phase. This was also reflected in the richness of the data collected during the WLM phase, which is, in comparison with the VLED phase, less dense.

Some of the interview results indicated that the participants` previous experience with WLM might have been beneficial to the WLM phase of the Counterbalance Study. This is because the participants may have already developed some of the skills or knowledge associated with successful WLM that worked for them. It should not be assumed that participants coming onto a WL and WLM programme have been unsuccessful in the past. In this study, some participants had lost weight prior to coming onto the study and had been successful in maintaining it in the past. It would be useful to make comparisons between the number of the participants` past WL and WLM attempts and WLM skills and link these with their ability to successfully lose or maintain weight in the future. During the interviews, I asked the participants` about their past WL and WLM attempts and strategies, however, these questions were used to encourage the participants to engage in the interview and facilitate recall. No

further prompts to explore their past WL and WLM experience in detail were used. In the future, it would be useful to obtain more detailed information on these past behaviours by using both questionnaire based methods as well as interviews to gain more insights into the participants` weight management history, as it may affect their current weight management practices.

7.8 Conclusions

Transitioning from loss with VLEDs to weight maintenance seemed to present more challenges to self-regulation than trying to lose weight. Successful weight maintenance was characterised by developing new routines and gaining confidence and control over new behaviours, shifting of goals, and a shift in identity towards a new, healthier self. Satisfaction with weight loss outcomes, preparedness to start a weight maintenance plan, and weight maintenance plan preference are further explored in Chapter 8 as potential factors affecting weight maintenance outcomes.

Chapter 8

A qualitative evaluation of acceptability of dietary and physical activity plans for weight maintenance

8.1 Abstract

Aim: To explore acceptability of different combinations of dietary and physical activity plans during a 6-month WLM (WLM) programme after WL through a 2-month very low energy diet (VLED). Methods: Participants in the Counterbalance Study were allocated to one of the following groups: a) Mediterranean diet with usual levels of physical activity (MD), b) Mediterranean diet with increased levels of physical activity (MD+PA), c) Calorie-controlled diet with usual levels of physical activity (CC), and d) Calorie-controlled diet with increased levels of physical activity (CC+PA). Data were collected via semi-structured interviews at the end of the 6-month WLM. Thematic analysis was used to analyse the narratives. Results: Analyses were conducted at the level of dietary plan mainly. Eight participants in the MD condition (with and without increased level of physical activity) and seven participants in the CC condition (with and without increased level of physical activity) took part in the interviews. Three themes on acceptability were identified in the interviews: 1) Dietary preference and adherence; 2) Satisfaction with outcomes; 3) Useful intervention features and suggestions for improvement. No substantial differences in acceptability of the dietary plans were identified between the groups. This likely resulted from: 1) the participants` general preference for the MD and their potential lack of adherence to their dietary plan when allocated to the CC condition; and 2) the participants` overall increase in physical activity, which may have affected the interventions that included increased physical activity plan. Conclusions: Satisfaction with WL outcomes and preference for a WLM plan may affect adherence to a WLM plan. Future WLM interventions should consider preparedness of people for a WLM intervention, as wanting to lose weight during WLM may interfere with adherence to the intervention and outcomes.

8.2 Introduction

Studies consistently show that even if WL is achieved, much of it is regained within 1 to 5 years (Dombrowski, Knittle, Avenell, Araújo-Soares, & Sniehotta, 2014b; Kramer, Jeffery, Forster, & Snell, 1989; Perri, 1998; Stalonas, Perri, & Kerzner, 1984; Wadden & Frey, 1997; Wadden, Sternberg, Letizia, Stunkard, & Foster, 1989), with only about 20% of people maintaining their weight in the long-term (Wing & Phelan, 2005). Acceptability of WLM plans may increase the likelihood of adherence with a WLM plan and success in achieving one`s WLM goal. Research on WLM has accelerated within the last decade, with many studies trying to identify the predictors of successful WLM (Greaves, Poltawski, Garside, & Briscoe, 2017, In Press; Klem *et al.*, 1997; Kwasnicka *et al.*, 2016; Kwasnicka, Dombrowski, White, & Sniehotta, 2017; Teixeira *et al.*, 2010; Teixeira, Silva, Mata, Palmeira, & Markland, 2012; Wing & Phelan, 2005), but only very few explore acceptability of each of the WLM approaches that they study, which may be key to WLM success.

Participants in the Counterbalance Study were randomised to two diets: Mediterranean (MD), and calorie-controlled (CC). The Counterbalance researcher estimated each participant`s calorie intake per day in order to maintain the achieved WL before they started the WLM phase. Mediterranean diet has been previously found acceptable among British older adults (Lara *et al.*, 2015). Adherence to MD is associated with many health benefits such as reduced mortality from cardiovascular disease or cancer, reduced incidence of Alzheimer`s and Parkinson`s diseases (Sofi, Abbate, Gensini, & Casini, 2010; Sofi, Cesari, Abbate, Gensini, & Casini, 2008), and possibly the prevention of obesity (Buckland, Bach, & Serra-Majem, 2008). It was therefore hypothesised, that the MD would have superior benefits to WLM compared to a calorie-controlled diet, which would result in higher acceptability of it, e.g. in terms of satiety or liking. Although some studies found that different diets may have different effects on satiety (Jönsson, Granfeldt, Erlanson-Albertsson, Ahrén, & Lindeberg, 2010), other studies show that satiety, satisfaction with a diet, and attendance rates tend to be similar among WL diets with different composition of macronutrients, as long as they are calorie-reduced (Sacks *et al.*, 2009). Satisfaction with the WLM dietary plans in terms of liking or dietary preference were therefore also explored in this qualitative study.

Both dietary plans in the Counterbalance Study included either usual or increased levels of physical activity. A systematic review of Dombrowski and colleagues (Dombrowski *et al.*, 2014b) evaluated 45 trials on maintenance of WL of at least 5% for at least 12 months in a sample of 7788 people. They found that while interventions focusing on diet only were effective for WL, WL was best maintained over time in interventions targeting both, diet and exercise. It would therefore be expected that participants prescribed increased physical activity levels would manage to maintain more WL than participants in the group with usual levels of physical activity. The current study aims to explore whether the physical activity was adhered to and whether this might result in different outcomes compared to participants allocated to usual levels of physical activity.

There is only a small number of qualitative studies exploring people`s experiences with WLM (Byrne, Cooper, & Fairburn, 2003; Epiphaniou & Ogden, 2010b; Greaves *et al.*, 2017, In Press; Hindle & Carpenter, 2011; Metzgar, Preston, Miller, & Nickols-Richardson, 2015; Reyes *et al.*, 2012; Sarlio-Lähteenkorva, 2000), however, these do not explicitly evaluate the particular maintenance approaches that the participants engaged in. The Medical Research Council`s guidance for evaluation of complex interventions (Moore *et al.*, 2014) recommends that participant interaction with intervention be explored in order to help identify the potential mechanisms of impact of the intervention, or the reasons for its effectiveness or lack thereof. Assessing participant's perspectives on acceptability is a form of understanding their levels of interaction with the prescribed intervention.

The aim of the current study is to conduct a qualitative evaluation of the participants` perspectives of acceptability of the Mediterranean and the calorie-controlled diets with and without increased levels of physical activity, as WLM approaches in the Counterbalance Study.

8.3 Methods

8.3.1 ***Design and participants***

Interviews analysed in this chapter were conducted with participants at the end of the WLM phase (T3, week 36) of the Counterbalance Study (Figure 14). After interviews at T2 (end of WL phase), participants were allocated to one of four structured individualised WLM plans: a) Mediterranean diet with usual levels of physical activity

(MD), b) Mediterranean diet with increased levels of physical activity (MD+PA), c) Calorie-controlled diet with usual levels of physical activity (CC), and d) Calorie-controlled diet with increased levels of physical activity (CC+PA).

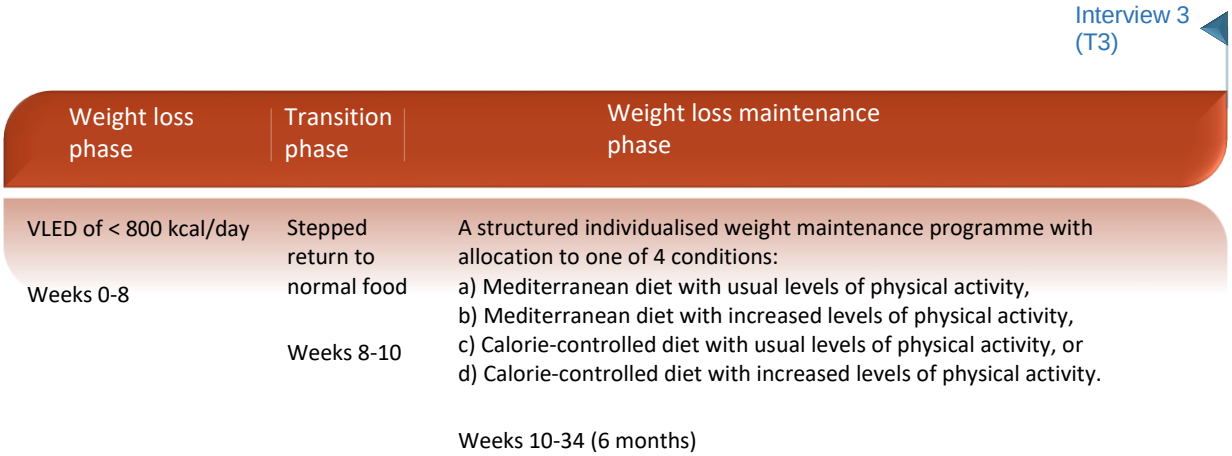

Figure 14. *Timing of the T3 interviews within the Counterbalance Study discussed in this chapter.* VLED = very low energy diet; forward/backward orientation of arrows indicates orientation of the interview questions on future/past, respectively

8.3.2 ***Interviews***

The purpose of T3 interviews was to capture the participants` perspectives on acceptability of the WLM dietary and physical activity plans. Acceptability was evaluated via narratives relating to the participants interaction with their allocated plan that might have affected their adherence to the programme and their outcomes.

8.3.2.1 Interview documents

Questions about the participants` experience with the WLM plans were included in interview topic guides for T3 interviews (Appendix 14), which had been piloted with 3 health psychology researchers, as described in Chapter 5. I have made notes during and after the interviews with the participants to further facilitate discussion with them and aid the analytical stage.

I was blind to participant allocation. Questions about acceptability of the WLM plans were therefore broad and not referring to the specific allocations. Many participants revealed their allocation during the T3 interviews, which then allowed me to probe with more specific questions about it.

The interview topic guides at T3 included the following open-ended questions and prompts about the participants' experiences with the WLM phase in general: "*Could you please tell me about your overall experience of the weight maintenance diet?*

(Prompts: cravings/satisfaction, temptations to break the diet, mood, motivation, barriers /facilitators of adherence, weight lost)"; "*How satisfied are/were you with the diet?*"; "*How satisfied are you with the results of the weight loss maintenance phase of the programme?*"; "*What additional support would you have appreciated during the weight loss maintenance phase of the programme and why?*". Some participants mentioned that they had created their own charts, or took photographs of themselves before and after the intervention. I then prompted all other participants to share such materials, that I could use for analyses, if they wished to.

8.3.2.2 Interview procedure

The interview procedures are described in the Methods section of Chapter 5. Participants signed a consent form prior to the interviews, and the interviews took place in a private screening room or in the clinical room.

8.3.3 ***Data analysis***

All interviews were audio-recorded, anonymised and transcribed verbatim. The participants were not invited to comment on the content of the interviews, however, they were invited to participate in a workshop where the results were shared and discussed.

8.3.3.1 Analytical approach

The analytical strategy and the coding process employed in this chapter is described in more detail in the Methods section of Chapter 5. For Chapters 5 and 7, the Theoretical Domains Framework (TDF)(Michie *et al.*, 2005) was used to initially organise the data.

All narratives relating to the participants` evaluations of acceptability of the WLM plans analysed and described in this chapter were gathered separately under a broad domain entitled: "Weight maintenance evaluation", which was added to the coding framework. Narratives gathered within this domain were first coded line by line and then synthesised into themes. Each theme was then saved as a separate document, which included quotes representing the theme, organised by the four allocation groups. This way it was possible to make comparisons in the narratives relating to the same themes between participants allocated to the different maintenance plans.

Participants were allocated to the WLM conditions randomly by the Counterbalance staff, and only a sub-sample of them took part in the interview. The number of

participants in the conditions with increased physical activity, who took part in the interview, was low and unevenly distributed across the conditions. Analysing the narratives by the 4 conditions would likely lead to lack of data saturation and richness, therefore I analysed the narratives at the level of the 2 dietary plans (MD with and without physical activity vs. CC with and without physical activity), noting any differences between them that were specific to the physical activity conditions. Due to my blinding to participant allocation during data collection, data specific to evaluation of the WLM plans were analysed post-hoc in interviews containing this information – all participants revealed their allocation during the conversation.

8.4 Results

Fifteen participants were interviewed at T3. Analyses in this chapter are based on the same interviews as those in Chapter 7.

Eight of the fifteen participants who took part at the T3 interview were allocated to a Mediterranean diet with increased or usual levels of exercise. Seven were allocated to a calorie-controlled diet with increased or usual levels of exercise. Table 9 below shows distribution and characteristics of participants who took part at T3 interview in each of the conditions. Details of each of the conditions are further specified in Chapter 4 (Description of the Counterbalance Study).

Table 9. Interview (T2 and T3) study participants` characteristics, Interview time points and changes weight, BMI and fasting plasma glucose

Allocation	Nr.	Gender	Age	T2DM	T3	% WL at T2	% WL at T3	% FPG change at T2	% FPG change at T3
Mediterranean diet	1	man	67	3.4	X	-15.94	-13.87	-30.48	-3.75
	2	woman	61	11	X	-14.87	-5.38	-44.03	2.16
	3	woman	65	3	X	-13.39	-22.20	-35.33	-21.31
	5	man	69	3.5	X	-12.11	-10.89	-43.33	-45.79
	13	man	59	10	X	-15.8	-15.9	-28.57	-17.10
	19	woman	63	10	X	-14.58	-6.10	-32.79	-11.07
Mediterranean diet + PA	9	man	49	9.5	X	-17.13	-20.10	-64.45	-59.14
	15	man	44	2.5	X	-20.44	-18.78	-45.07	-21.16
Calorie-controlled diet	6	man	54	0.5	X	-17.93	-15.51	-22.35	-14.07
	7	man	65	13	X	-13.94	-14.61	-47.87	-60.08
	11	woman	47	2.5	X	-15.71	-21.37	-24.04	-31.89
	16	woman	64	12	X	-12.50	-9.98	7.19	-18.71
Calorie-controlled + PA	12	woman	35	1.5	X	-14.68	-25.83	-42.17	-36.87
	17	woman	70	15	X	-11.84	-13.73	-45.49	-26.19
	18	man	69	18	X	-13.92	-17.18	-31.41	-34.62

Notes. PA = physical activity; T2DM = type 2 diabetes mellitus; WL = weight loss; WLM = weight loss maintenance; FPG = fasting plasma glucose; T2 = end of the weight loss phase at week 8; T3 = end of the weight loss maintenance phase at month 8; highlighted in green are participants who achieved normal-range FPG levels (<7.0mmol/L, diabetes remission). Highlighted in grey are participants who achieved borderline normal FPG levels (slightly over 7.0mmol/L). The other participants did not achieve diabetes remission. Negative values represent a decrease; positive values represent an increase. Percent weight loss/FPG change at T2 and T3 was calculated as a proportion of weight loss/FPG decrease achieved at T2 and T3 in relation to baseline values, indicating how much of the weight loss /FPG decrease achieved from baseline to T2 was maintained at T3.

Narratives of the two groups were compared and the following themes were identified: **1) Dietary preference and adherence**; **2) Satisfaction with outcomes**; **3) Useful intervention features and suggestions for improvement**.

All representative quotes are annotated by gender, age, duration of diabetes, and allocation. A Mind map representing the themes and the relationships between them as I interpreted them is included in Figure 15 at the end of this chapter.

8.4.1 ***Theme 1: Preference of maintenance plan and adherence with it***

The narratives indicated minimal differences in the participants` preferences for which WLM plan they preferred to be allocated to. Allocation preference seemed key to adherence with the dietary plan, although the results including the whole sample of the Counterbalance Study surprisingly showed no differences in outcomes between any of the groups (personal communication with Prof. Taylor). The results of this qualitative evaluation below illustrate and discuss why there may have been no differences.

8.4.1.1 Dietary plan and adherence with it

Six out of eight participants allocated to the MD liked it and were pleased that they had been allocated to it, with some of them having a strong preference for it:

"*I was apprehensive to the random selection of the maintenance phase because I wanted it to be the MUFA* (Mediterranean diet) *and it was. That was perfect. And I would have done it, whatever it was, but really it was good*" (WOMAN, 65 YEARS, T2DM 3 YEARS; MD).

One participant did not like Mediterranean style diet in general (Participant 5), but this did not seem to affect his WLM. On top of this, he managed to push his blood glucose even further down, to normal levels, at month 6. Another participant seemed to have followed the MUFA as prescribed, even though it may have conflicted with his personal goal of losing more weight and eating a high-protein diet, which he would have preferred. Overall, most participants in the MD were satisfied with their allocation, which may have facilitated adherence to it.

On the other hand, preferences of the participants in the CC condition were often different to what they had been prescribed. For example, two participants (Participants 17 and 27) said explicitly that they would have preferred to be allocated to the MD:

"*I'd liked to have said can I go on the Mediterranean diet… I would have liked to have tried that one, instead of just going on to ordinary food, and that's when you're eating your ordinary food you're tempted to eat a bit more, but whereas if you're thinking I'm doing a different diet, it's different*" (WOMAN, 64 YEARS, T2DM 12 YEARS, CC).

It seemed as if the participants thought that following a formal-style diet with structure would have been better and easier than following self-devised diets (CC, eating a regular diet with restricted calorie intake), even though they would still be striving to eat the daily amount of calories estimated for them to maintain weight. This may indicate that some of them were not prepared or confident enough to make appropriate food choices themselves. In addition, one of the participants, who would have preferred the MD, said that his "*diet tends to be Mediterranean in style in any case*" (MAN, 65 YEARS, T2DM 13 YEARS, CC). It seems likely that the participants who would have preferred the MD adapted the CC diet so that it included elements of the MD that they preferred. Only one participant (Participant 11) was glad not to have been allocated to the MD, as she did not like nuts, seeds or fish. Another participant (Participant 23), who`s partner was also losing weight through Slimming World, followed that diet unintentionally, as her partner was the main cook and prepared most of the meals for them:

"*He's a fabulous cook. He tries his new recipes out on us which is quite tasty but he does Slimming World so he uses all their recipe books from there*" (WOMAN, 35 YEARS, T2DM 1.5 YEARS, CC+PA).

8.4.1.2 Physical activity plan and adherence with it

In addition, some participants were asked to increase their levels of physical activity, while others were asked to do only as much physical activity as they used to do before the study. However, as discussed in Chapter 5, the VLED phase resulted in the participants` increased mobility and an overall increase in physical and psychological wellbeing. As a result, people in the study became naturally more physically active than they were before the study and they were keen on doing more physical activity due to increased energy levels. On the other hand, people who had been physically quite active before the study and were allocated to the increased physical activity group, would not be able to increase their exercise much more, and would therefore keep it approximately at the pre-study levels:

"*My exercise level's not a great deal different to where it was. So even when I was overweight I still did pretty much the same level of exercise, yeah. But now I find it a bit easier, maybe a bit more enjoyable*" (MAN, 69 YEARS, T2DM 18 YEARS, CC+PA).

This may have had further implications for adherence with the WLM plans with increased levels of physical activity, especially for people who had been asked to engage in their usual levels of physical activity, as many were likely engaging in levels of physical activity higher than they were asked to. In addition, compensation by physical activity was, alongside compensation by calorie restriction, one of the main strategies used to prevent or mitigate weight regain (see Chapter 7, section Regaining control). This means that if the participants gained some weight and the calorie-restriction strategy was either not efficient enough or not being completely adhered to, participants would also increase physical activity to get back to the weight they were satisfied with.

"In particular, I think that one with extra exercise as well I think it would have been easier. I haven't not exercised but I quite enjoy going out on my bike with my son and because I'm not supposed to be doing extra exercise I haven't done as much. I've got a standing bike in the garage which I can go on like a cross-trainer, which is a bike as well, I can sit on that. So I've been using that a little bit. I certainly did last month when I needed to get the weight off, I used that a little bit more"
(MAN, 54 YEARS, T2DM 0.5 YEARS, CC).

8.4.1.3 Differences in outcomes between the maintenance groups

Although there were no differences in outcomes in the full Counterbalance sample, narratives of those interviewed within each group (MD vs CC), showed opposing tendencies in terms of satisfaction with their allocation preference and outcomes. While most participants in the MD liked their allocation, most also regained at least some of the weight. In the CC condition, the two participants who would have preferred the MD, and were presumably dissatisfied with their allocation, were the only ones who regained weight. The other participant allocated to CC, who likely employed a Mediterranean-style diet, lost the least weight, while the one who was glad not to have been allocated to MD lost the second highest amount of weight during the WLM. She was only beaten by the participant, who was essentially following a Slimming world diet (Participant 12).

Although no definite conclusions can be drawn from a small sample of participants like the one involved in the T3 interviews in this study, they show that it may be possible that for some people, allocation to a preferred diet facilitates adherence. However, since the majority of participants who preferred and followed the MD, whether fully or partially (within both groups), regained weight, the data also suggest that liking a diet too much may lead to weight gain, potentially due to over-eating.

8.4.2 ***Theme 2: Satisfaction with outcomes***

8.4.2.1 Motivation for further weight loss during and after weight maintenance

The results of Chapter 7 previously showed that more than half of the participants intended to lose more weight after the VLED phase, and many of them did lose weight during the WLM. However, this often did not reflect on dissatisfaction with the weight lost during the VLED. Rather, this result showed the increased confidence of the participants, and the positive reinforcement received during the WL phase using a VLED . As one participant explained:

"*I`m not giving up on that last stone, I just know it`s gonna take longer to get it off, but I`m aiming for it. Want to be there…I didn`t think I would do as well as I did. I was very pleased I have, so that gives me even more to go on and get the last one off*" (WOMAN, 47 YEARS, T2DM 2.5 YEARS, CC).

In the MD group, every participant wanted to lose more weight after the WLM phase. In the CC group, 6 of the 7 participants also wanted to lose more weight. This includes both; those that were successful and those that were unsuccessful in WLM. While the intention to lose weight by the less successful maintainers during the maintenance stage was driven by their desire to achieve their post-VLED weight, successful maintainers wanted to lose more weight because they knew they were able to. Only one participant (Participant 17) was content with his achieved WL and maintained weight:

"*I was quite happy. I finished at about 11 stone 12. Twelve stone is like the mark that I've set now so 2 pound above that and I'll try to get that back off*" (MAN, 54 YEARS, T2DM 0.5 YEARS, CC).

Interestingly, this participant did not achieve T2DM remission at any point, which indicates that remission of T2DM was probably not the main motivation for him to lose weight and it further highlights that many participants were perhaps more motivated by appearance or wellbeing rather than by their medical condition. Another explanation could be that he did not want to lose more weight due to a lack of effect on his wellbeing, but this was not the case, as he reported that at the end of the VLED, he was "*quite happy at this size I am now and in fact so I think its maintenance, if I can keep it at that I'll be quite happy*" (MAN, 54 YEARS, T2DM 0.5 YEARS, CC).

8.4.2.2 Individual goals and adherence with a maintenance plan

The results of this evaluation show that both, satisfaction and dissatisfaction with weight motivate people for further WL. What seems more important for WLM is the preparedness of individuals to embark on it. The continuous effort to lose weight explains why many participants were not as adherent with the WLM plans as they were asked to be. Their personal goals of further WL were different to the study`s goals of WLM, and this may have further contributed to the lack of difference in outcomes between the groups during the maintenance phase.

Respondent: I want more. I want to lose more weight and I'm going to continue to lose more weight.
Interviewer: During the weight maintenance?
Respondent: Yes. Oh yes.
Interviewer: So how much more would you like to lose?
Respondent: Another 3 stones minimum.
Interviewer: 3 stones?
Respondent Yeah.
Interviewer: Okay. And how much have you lost until now?
Respondent: About 3 stone, yeah.
(MAN, 65 YEARS, T2DM 13 YEARS)

However, since weight and T2DM remission were not the only motives for people to take part in the study (see Chapter 5, sectioin 5.4.1), WL and T2DM remission were not the only indicators of satisfaction with outcomes. Some participants reflected on how important the changes in their physical and psychological wellbeing during the study were, together with changes in their behaviour and identity shift (see Chapter 9, section 9.4.4).

"*I'm sorted. I'm definitely sorted. As I said, when I came here I didn't have a real clue about what to eat and all the rest of it and I didn't even know what cous cous was until I came here. And peppers were just the bits that I picked off when you got a salad or something, but now I eat the lot. And it's been a learning curve and I think I've come out a better person for it so happy days. That's all I'm bothered about*"
(MAN, 49 YEARS, T2DM 9.5 YEARS, MD+PA).

8.4.3 ***Theme 3: Useful intervention features and suggestions for improvement***

Features of the WLM intervention that the participants found most useful varied little between the MD and the CC conditions. The results below illustrate which features of the intervention were perceived most useful, whether or not these differed between

the groups, and what could be improved about the intervention.

8.4.3.1 Support received during the WLM stage

Although the frequency of participant visits to the study site was lower during the WLM than during the WL phase, both groups appreciated the support from the study staff provided when it was needed. The researchers (also intervention deliverers) could be contacted by the participants by e-mail or telephone at any time had they had any queries or concerns in-between the visits. While only a small number of participants used this opportunity, the majority reported that they did not particularly need this support, although they were aware of the possibility to use it. In case the participants did contact the study team, they were satisfied with the speed and content of the reply. This was received particularly well, mostly because the participants felt that the staff made an effort to answer any questions with patience and clarity, and the support was individualised.

"*The support's been good. Whether it was Carl or any of his colleagues, they're there on the phone, they're there on email, you get a response from email usually within an hour or so. So no, the support's been good. They answer any questions you have and I like to ask questions about how I'm doing*"
(MAN, 69 YEARS, T2DM 18 YEARS, CC).

Similarly to the results in Chapter 6, the participants suggested they would have liked to meet other participants during the WLM phase and even after that, to help each other maintain their weights through support, comparison, and experience-sharing.

"*I think somebody else from the programme, maybe. It's just getting to know them because they never tell you who else is in it or how you can get in touch with them. It would be handy, even after the programme, just to get some telephone numbers so you can ring up and chat with other people that's been on it and see how they're doing and possibly help each other*" (MAN, 69 YEARS, T2DM 3.5 YEARS, MD).

A few other participants suggested that if this programme was to be delivered in Primary Care, there should be a role-model available to support people alongside any involved healthcare professionals, which would provide additional motivation and understanding from someone who has been through the programme successfully.

"*So that at one level you`ve got the professional advice between this programme and the primary care environment, but it might also want selective people who have been through the programme to be involved with a particular primary care outlet. If you have somebody who`s been through the programme assigned to that place, who could assist in one way or another, somebody`s who`s got quite a good understanding of what we`re trying to achieve and why*"
(WOMAN, 61 YEARS, T2DM 11 YEARS, MD).

Lastly, follow-up visits after the end of the study were suggested as a means of continuous support and monitoring for participants who thought this would prevent them from regaining weight.

"I think an annually follow up, but I know that wouldn't be possible, but I think that would be a big help, for me personally, because you think oh I'm coming back in a year" (WOMAN, 70 YEARS, T2DM 15 YEARS, CC+PA).

8.4.3.2 Individual provision and revision of a food diary

Participants in both groups mentioned that when they struggled following their dietary and physical activity plan, they often contacted the study staff and were offered a meal planner to fill in for a week or two. The Counterbalance Study researcher would then review these diet sheets and provide individual feedback and advice on which foods were appropriate and which ones were not, until the participants were confident in following the appropriate diet.

"*The transition was quite difficult, more difficult than I thought and it did appear that within the last 6 months I`ve had 2 or 3 spells when I think I`ve sort of lost the plot of it, but I talked to Sarah about this and I`ve had and, she gave me a meal planner, which was extremely helpful, because t kind of focused my attention, it gave me a sort of routine. I didn`t use it very precisely, but I used it as a guideline, so it helped to reduce the portion size*" (WOMAN, 65 YEARS, T2DM 3 YEARS, MD).

"*She gave me some diet stuff, diet sheet, so that got me into the way of thinking what I could have for breakfast and substitute it with if I didn`t want that*" (WOMAN, 47 YEARS, T2DM 2.5 YEARS, CC).

8.4.3.3 Individual estimation of appropriate calorie intake

For the participants in the CC group mainly, estimation of the basal metabolic rate and individual calorie plan was one of the most useful features of the WLM phase. One of the reasons is that they felt more aware of and educated about the calorie content of food, and were therefore able to choose foods with lower calorie content, that would keep them within the limits of the daily recommended calorie intake. Another advantage was that knowing the minimum and maximum thresholds for WLM enabled them to easily switch between WL and WLM when needed.

"*I was told to stick to 1,800, but I try to keep it down to 1,500 max. But of late I've been doing sort of 1,500 with 800 to try and take the weight off a little more quickly because I want to be down below 100 kilos before Christmas, and I've only got 1.7 kilos to go now"* (MAN, 65 YEARS, T2DM 13 YEARS, CC).

8.4.3.4 Provision of a pedometer

Participants allocated to a condition with a plan of increased physical activity liked that they were given pedometers to track their daily steps. This allowed them to compare their calorie intake with their estimated calorie expenditure and facilitate further WL if that was their goal.

"*I: What things have been most useful to you during the programme?*
R: The pedometer, which you're not getting back"
(MAN, 49 YEARS, T2DM 0.5 YEARS, MD+PA).

"*It's a great motivator, and this does make me get up and makes me, I'm supposed to 10,000 steps a day, and I try to do it. I did 15,000 yesterday, but this motivates me*" (WOMAN, 70 YEARS, T2DM 15 YEARS, CC+PA).

The pedometer provided in the Counterbalance Study was one attachable to the arm and some people thought it was too bulky, impractical and that it was missing some of the features that current activity trackers have, such as giving instant feedback. Using more attractive, smaller pedometers that the participants can wear on their wrist or more discreetly was suggested as an improvement.

"*I think, well yeah, these things* (pedometers) *are horrible…I think they were saying next time they're going to have a wrist watch thing which is going to be better… It's uncomfortable, you've got to sleep in it, you've got to, you wear it all the time, and it's not very comfortable and a wrist watch one… And some things are quite tight so it's quite difficult to get underneath your sleeves…. I wasn't getting the feedback from that, whereas I've just got it today, but that's more than a month ago, it's about 8 weeks ago… Because it's quite interesting this, because I go to the gym and that and I wanted to know which activities probably burned up the most calories and things*"
(WOMAN, 63 YEARS, T2DM 10 YEARS, MD).

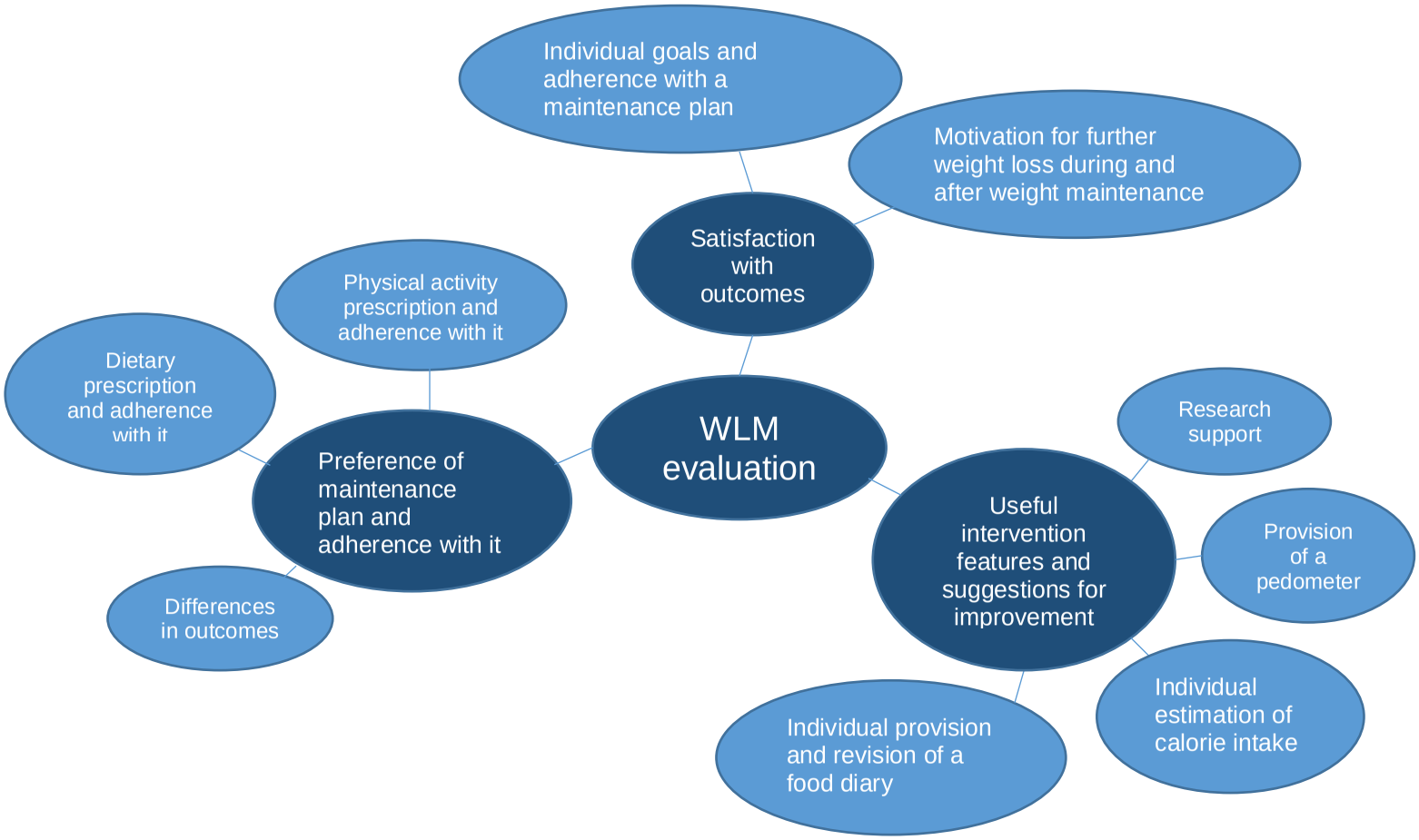

Figure 15. A mind map of themes relating to evaluation of the weight maintenance dietary plans.
Highlighted in dark blue are core themes, highlighted in light blue are peripheral themes. The sizes of the oval shapes are unrelated to the amount evidence, quality, or data saturation WLM = weight loss maintenance

8.5 Discussion

Contrary to expectations, this qualitative study did not identify substantial differences in acceptability of the 2 dietary plans (Mediterranean and Calorie-controlled diets, including their exercise levels). This finding was supported by the results of the Counterbalance Study, which also found no differences in weight or diabetes outcomes between the four different groups at the end of the 6-month WLM period. This qualitative evaluation helps explain these results.

Firstly, interviews at T2 (reported in detail in Chapter 7) highlighted that most participants wanted to keep losing weight after the WL phase. This means that they were not prepared or willing to start WLM yet, and felt that the dietary and physical activity plans targeting WLM, were not applicable to them at that stage. The participants` personal goals were likely in conflict with the study`s goals, which possibly contributed to the apparent lack of adherence to the plans. Similar issue was identified in process evaluation of the WILMA trial (Weight Loss Maintenance in Adults)(Simpson *et al.*, 2015). This trial aimed to assess, among others, acceptability and adherence with a more or less intensive variation of a 12-month motivational interviewing intervention to support WLM in 170 people with a BMI ≥ 30kg/m^2, who had lost at least 5% of their weight during the previous year in comparison with the control group. The study reported that 92% of participants wanted to lose weight at baseline. In addition, 76% of participants still wanted to lose weight at follow-up of the WLM intervention. Only a minority of participants in the WILMA trial were prepared to maintain their weight, which may have affected their adherence with and the of the WLM intervention. Satisfaction with achieved WL is therefore key to motivation to lose or maintain weight and preparedness for WLM should be assessed before people start on a WLM intervention, as it may be ineffective in those who still aim to lose weight.

Kwasnicka and colleagues (Kwasnicka *et al.*, 2017) used ecological momentary assessment to identify individual predictors of adherence to a WLM plan and they found that maintenance motivation and satisfaction with outcomes, together with self-regulation, habit and environmental context, consistently predicted WLM plan adherence. Data reported in this chapter showed that both, satisfaction and dissatisfaction with WL and maintenance outcomes motivated people to lose more

weight after the VLED phase and further after the 6 months of WLM. The difference between people driven by dissatisfaction and satisfaction was, that satisfaction-driven people were generally those who managed to lose more weight during WLM and were aiming to move the goal post even further, while dissatisfaction-driven people regained some of the weight and aimed to achieve their original goal (usually their post-VLED weight).

According to the Goal setting theory (Locke & Latham, 2002, 2006; Locke, Shaw, Saari, & Latham, 1981), setting challenging goals leads to better performance. Challenging goals may create high expectations and these may affect WL as well as WLM success, though evidence is inconclusive about the role of very high or unrealistic expectations in the long-term maintenance of WL (Ames *et al.*, 2005; Finch *et al.*, 2005; Jones, Harris, Waller, & Coggins, 2005; Linde, Jeffery, Finch, Ng, & Rothman, 2004; McKee *et al.*, 2013; Teixeira *et al.*, 2004). Half of the people losing weight set unrealistic goals that they do not manage to achieve (Foster *et al.*, 1997; Hindle & Carpenter, 2011). Because they are not satisfied with their new weight they might be more likely to regain it (Byrne *et al.*, 2003). Rothman (Rothman, 2000b) further argues that while outcome expectations may be key for behaviour initiation, behaviour maintenance depends on satisfaction with the achieved outcomes. Although baseline personal WL goals of people in the Counterbalance Study were not measured, the participants anticipated WL of between 2 to 4 stones (approximately 13-25 kg). Knowing the participants` personal goals could have provided more insight into whether or not setting manageable or challenging goals helps achieve them, and whether this could facilitate better WLM. Some evidence shows that WL goals do not necessarily predict short or long-term WL (Jeffrey, Wing, & Mayer, 1998), while others found that greater initial WL improve WLM (Astrup & Rössner, 2000; Saris, 2001).

Secondly, most participants in this study would have preferred to be allocated to Mediterranean diet and those, who were allocated to the calorie-controlled condition, but had wanted to be allocated to the Mediterranean one instead, tended to lose the least weight among their peers in the same group. On the other hand, people who were allocated to the condition of their preference regained at least some of the lost weight. The results are therefore somewhat inconclusive. Although the data are very

limited, they suggest that allocation preference may facilitate goal achievement, but liking a diet too much may lead to over-consumption and weight gain. Previous studies found that the opportunity to follow a diet of one`s preference as opposed to being assigned to a diet does not seem to impact on adherence with dietary plan at 6 months (Moore, McGrievy, & Turner-McGrievy, 2015), or improve outcomes (Yancy *et al.*, 2015). Although there were no differences in outcomes among the Counterbalance Study participants between any of the conditions, the role of satisfaction with the specific WLM plan should be explored in future studies in order to determine whether or not it may increase acceptability of a WLM intervention and improve participant experience with it.

Lastly, many participants would have welcomed continuous support from the Counterbalance Study staff during the WLM or an opportunity to meet other participants in order to discuss their experience. Some even suggested acting as role-models for any participants in the future. Previous research has shown that sustained support promotes successful WLM. For example, the “Keep it off” (Sherwood et al., 2012) trial allocated 419 adults who had recently lost ≥ 10% of weight to a guided or a self-directed WLM intervention. The guided intervention consisted of phone calls and e-mail communication with participants and by providing encouragement to self-monitor diet and exercise using booklets. This trial found the guided participants were 1.37 times more likely maintain their weight at 24 months compared to the self-guided participants. A systematic review of the effect of extended care on WLM found that extended care, defined as at least two sessions delivered in person or via telephone focussing on continuing support for behaviours related with weight management, led to a WLM of additional 3.2 kg over 18 months post-intervention (Middleton, Patidar, & Perri, 2012). Increasing the frequency of passive or active support by the study staff may facilitate WLM in future programmes and may be beneficial for the participants who struggle during the WLM.

8.6 Limitations

A major limitation of this study is that I was blind to participant allocation at both interviews. This meant that the questions asked were broad rather than specific to allocation, unless the participants revealed their allocation themselves during the T3

interview. This resulted in suboptimal data richness and likely a lack of data-saturation.

Analyses by allocation (2x2 factorial design) would result in a very small number of participants in some conditions and an uneven distribution of them across the groups. The narratives were therefore analysed at the level of dietary plan only, which provided more balanced samples. The low number of participants and analyses of merged groups prevented me from making specific evaluations of each of the conditions. However, I made a conscious effort to be sensitive to differences in the participants` experiences that related to the plans of physical activity, which resulted in a number of recommendations for improvement and helped explain some of the reasons for the lack of efficacy of the WLM intervention.

Lastly, participants interviewed in the study were not invited to comment on interviews since the analysis of the data was finished after the study had terminated. However, part of the Counterbalance Study`s Public and Patient Involvement strategy included a meeting of the researchers and the participants at the end of the study, where preliminary results of the study were presented. I presented preliminarily results of this qualitative study and engaged in discussions of these results with the participants at this meeting, which provided an opportunity for the participants to comment on the results.

8.7 Conclusions

Satisfaction with WL outcomes and preference of a WLM plan may affect adherence to a WLM plan. Mediterranean diet was preferred to a calorie-controlled diet by most participants in this study, however, the Counterbalance Study reported no differences in outcomes between participants in the different conditions. This means that while a dietary preference may not be associated with outcomes, it may improve acceptability of the maintenance plan. Future WLM interventions should consider readiness and motivation of every individual to engage in WLM, as they may still want to lose weight. Having the goal to continue to lose weight may interfere with the potential effectiveness of such interventions.

Chapter 9

A longitudinal exploration of patient experiences with weight loss and weight maintenance

9.1 Abstract

Aim: This chapter aimed to explore changes in experiences over time in people engaged on an 8-month intervention including a 2-month weight loss (WL) phase with a very low energy diet and a 6-month structured weight loss maintenance phase (WLM) following it. Methods: Data were collected in semi-structured interviews at baseline, week 8 (end of the WL phase), and month 8 (end of the WLM phase). An inductive thematic analysis was used to analyse the data. Results: Eleven participants attended all three interviews. The following themes of change in the participants` experiences were identified across time: 1) Independence of behaviour, representing the process of change from one`s limited ability, to acquiring the confidence in one`s ability to engage in health behaviours, that are independent of other people`s health behaviours; 2) Contagiousness of behaviour, illustrating how the participants` new behaviours affected other people`s behaviours; 3) Mindset adaptation reflecting on the different attitudes required for successful WL and WLM; and a 4) Shift in identity, representing the changes in how the participants perceived themselves. Conclusions: The current chapter identified changes in the participants` experiences throughout the WL and WLM phases, and how these experiences related with each other over time. The findings help understand the process of behaviour change better and may be used as indicators of behaviour change in future studies.

9.2 Introduction

The previous chapters provided accounts of participants` experiences of the WL and WLM phases of the Counterbalance Study (Chapter 5 and 7, respectively). These were followed by the participants` evaluations of acceptability of a VLED as a WL and a diabetes remission intervention (Chapter 6); and of the different dietary and physical activity WLM plans following the WL (Chapter 8). The research presented in those chapters aimed to identify the main barriers and facilitators of adherence at

each stage of the weight management process, so that the clinical team could optimise the intervention in the future. The chapters therefore focussed on each of the phases separately. As the level of retention of participants in the qualitative study was good, the dataset also gave an opportunity to explore how the participants` experiences changed over time, which is the purpose of the current chapter.

Qualitative longitudinal research enables better understanding of change and the reasons behind it, as well as the role of time in peoples` experiences (Cavers *et al.*, 2012; Holland, Thompson, & Henderson, 2006). Lewis (Lewis, 2007) highlighted different types of change that a researcher may be looking for in longitudinal qualitative research: 1) a narrative change, or the way people tell their stories over time, 2) reinterpretation of stories by the participant, 3) reinterpretation of the participant`s stories by the researcher as he/she learns more about the participant, and 4) absence of change. Longitudinal interviews can also help understand changes in needs or opinions (Baker, Zabora, Polland, & Wingard, 1999; Murray *et al.*, 2009) within the participants` context (Pettigrew, 1990). Explaining the nature and the meaning of such changes through interpretation is, after description and analysis, the final stage of longitudinal qualitative analysis, which can be guided by questions about the context that affects the changes, themes that emerge through time, or how the changes relate to each other (Saldana, 2003). In this chapter, I aim to provide an account of change within the participant experience with the Counterbalance Study from a longitudinal perspective. This is to provide further insight into weight-related behaviour change over time.

9.3 Methods

9.3.1 ***Design and participants***

Only data from participants who attended all three interviews, at baseline (T1), at the end of the WL (T2), and at the end of the WLM (T3) phases of the Counterbalance Study (Figure 16), were analysed in this chapter.

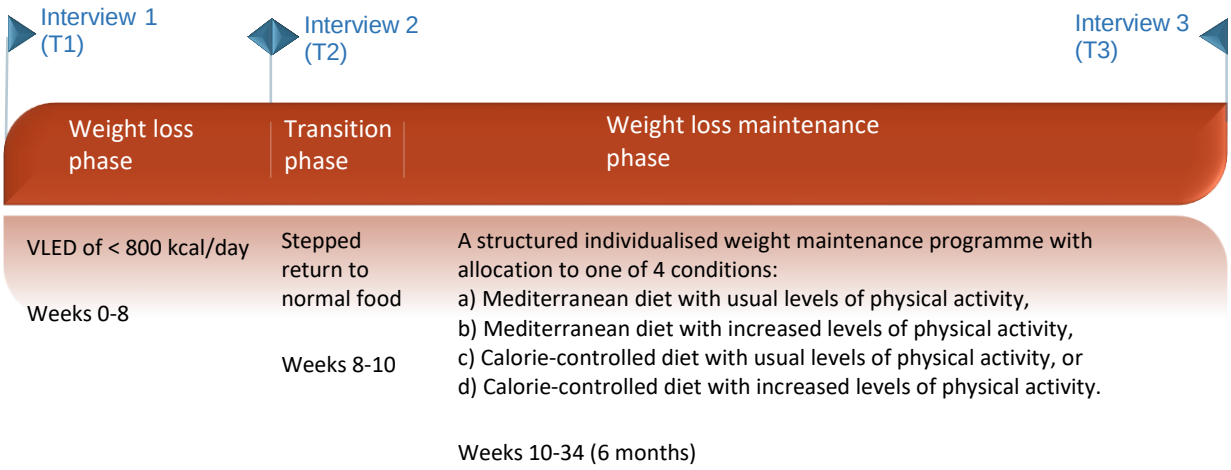

Figure 16. Timing of the T1, T2 and T3 interviews across the three phases of the Counterbalance Study discussed in this chapter.
VLED = very low energy diet; forward/backward orientation of arrows indicates orientation of the interview questions on future/past, respectively.

Data collection for this qualitative study began in March 2013 and finished in May 2014. Details about how I approached the participants can be found in the Methods section of Chapter 5.

9.3.2 ***Data analysis***

I conducted a longitudinal analysis of semi-structured, audio-recorded, face-to-face interviews guided by interview topic guides with open questions developed for T1, T2, and T3 interviews (Appendices 10, 11, and 14).

I employed an inductive thematic analysis approach (Braun & Clarke, 2006) to the individual narratives across time. The inductive thematic analysis differs from the theoretical thematic analysis that I conducted in the previous qualitative studies in that it is strongly grounded in the data, and the themes may not be explicitly related to the questions that the participants were asked. The coding is open compared to the coding for the pre-specified research questions, and is independent of theoretical frameworks. The current analysis focussed on identification of higher order themes, and themes that over-arch some of the results already reported in the previous chapters.

The analytical process included retrieval of the relevant interview transcripts, audio-recordings and field notes, and an open coding by hand, to identify themes across the three interviews for each of the participants. I read each of the physical transcripts several times to familiarise myself with the data. I used the transcript

margins to annotate ideas and the initial codes, and to note down further questions. I then synthesised the various codes into themes of change, notes, and questions for every participant in a table with participant identification numbers in rows and stages of interviews in columns. I identified themes across time for each participant and synthesised these across the participants to examine broader patterns in this sub-sample. I then reviewed the themes, further refined them and defined them before writing up the results.

The analysis was facilitated by mind-maps of themes and the relationships between them as I perceived them, which is presented in Figure 17.

The current analysis complements and expands on some of the results in the previous qualitative chapters, to which I will refer as appropriate.

9.4 Results

Eleven out of nineteen participants who took part in the qualitative study attended all three interviews (at baseline, at the end of the VLED, and at the end of the WLM phase of the Counterbalance Study). Table 10 presents the participants characteristics together with their weight and diabetes outcomes over time.

The analyses resulted in the following over-arching themes that were present in the interviews across time: **1) "Independence of behaviour",** representing the process of change from one`s limited ability, to acquiring the confidence in one`s ability to engage in and make decisions about one`s health behaviours, that are independent of other people`s behaviours, within the shared social contexts; **2) "Contagiousness of behaviour",** illustrating how the new behaviours of participants can spill over into the social relationships as if they were contagious, resulting in other people making changes to their behaviour as an unintended effect of the intervention; **3) "Mindset adaptation"**; reflecting on the different attitudes required for successful WL and WLM, and a **4) "Shift in identity**", representing the changes in how the participants perceived themselves over time. Below are the themes explained in more detail, supported by examples of the participants` narratives annotated with gender, age, and duration of diabetes.

9.4.1 ***Theme 1: From inter-dependence to independence of behaviour***

The previous qualitative chapters reflected on the significance of social support during the WL stage and on how the reduced (in comparison with the WL phase), but

continuous support from the Counterbalance Study staff was key to WLM. One of the most important themes identified in the longitudinal analysis was also grounded in the social context of the participants.

9.4.1.1 Behavioural inter-dependence

Prior to WL, participants often displayed signs of what I interpreted as *behavioural inter-dependence*. Behavioural inter-dependence can be understood as a limited ability to make decisions regarding health behaviours (e.g. physical activity, eating, shopping, etc…) that are very different from the behaviours of the person`s social environment, mostly from his/her family, which was implied in the interviews in different ways. One indicator of behavioural inter-dependence was the tendency to speak in terms of "we" rather than "I" when the participants were talking about the changes they would have to make during the WL phase:

"*We said, "Well if we're going to do it we're going to do it together", partly because we'd be able to support one another; partly because it's something that we've talked about before now and aspired to improving our health*"
(WOMAN, 61 YEARS, T2DM 11 YEARS).

Participants who had this tendency were more relationship- than self-oriented and their motivation to take part in the study included being able to help others (e.g. the researchers, or other people with diabetes in the future), rather than participate purely or mostly for their own benefit. This may further reflect on how eating behaviours represent one of the ways people relate one to another, and on how the need to conform to social norms evolving around eating makes it harder for people to make their own decisions, without violating the social norms.
Another indicator was reliance on, or expecting other people to adjust their behaviours for the duration of the WL phase:

"*We will no longer go out for meals during that period of time. Neither of us go out to pubs and clubs and things like that, we just don't do it*" (MAN, 65 YEARS, T2DM 13 YEARS).

These and similar strategies were meant to facilitate adherence to the VLED *because* the participants` and their family behaviours were so inter-dependent and because it would have been too difficult for them to follow the programme completely by themselves. Behavioural inter-dependence at this initial stage was especially pronounced in participants who were taking part together, those who`s partners decided to lose weight at the same time, or in participants who`s partner was the

main cook in the family. Being or not being the main cook in the family played a role in how much decision-making power about the behaviours, especially related with healthy diet, the participants felt they would have in the future, and it also pointed at the independence potential during the process of behaviour change. For example, the diet of participant 1 who said "*..if she doesn't cook it I'll never get it!*" (MAN, 67 YEARS, T2DM 3.5 YEARS) was clearly decided by his wife, who was the main cook in the family before the VLED. Some participants even reported how their partner`s behaviours affected them in a negative way and made it harder to follow a healthier diet:

"*…it didn`t help obviously husband at the time bringing chocolate in and things like that and "Have it, it won`t harm*!" (WOMAN, 47 YEARS, T2DM 2.5 YEARS).

Table 10. *Longitudinal study participants` characteristics, interview time points and changes weight, BMI, and fasting plasma glucose levels over time.*

ID	Gender	Age (years)	T2DM duration (years)	Weight at T1 (kg)	BMI at T1 (kg/m^2)	Weight loss at T2 (kg)	BMI at T2 (kg/m^2)	Weight loss at T3 (kg)	BMI at T3 (kg/m^2)	FPG at T1 (mmol/L)	FPG change at T2 (mmol/L)	FPG change at T3 (mmol/L)
1	man	67	3.5	106	34.6	-16.9	29.1	-14.7	29.8	7.39	-2.25	-0.28
2	woman	61	11	87.4	33.1	-13	28.2	-4.7	31.3	15.43	-6.79	0.33
3	woman	65	3	87.4	33.5	-11.7	29.0	-19.4	26.1	11.88	-4.20	-2.53
5	man	44	2.5	106.5	36.4	-12.9	32.0	-11.6	32.5	12.65	-5.48	-5.79
6	man	54	0.5	90.9	32.4	-16.3	26.6	-14.1	27.4	6.70	-1.50	-0.94
7	man	65	13	119.80	41.0	-16.7	35.3	-17.5	35.0	13.54	-6.48	-8.14
9	man	49	9.5	97.5	31.8	-16.7	26.4	-19.6	25.4	14.21	-9.16	-8.40
11	woman	47	2.5	109.5	39.0	-17.2	32.9	-23.4	30.7	6.93	-1.67	-2.21
13	man	69	8.5	105.2	32.9	-18	27.7	-12.3	27.7	8.84	-1.98	-3.06
15	man	69	3.5	108.6	33.1	-22.2	26.4	-20.4	26.9	8.45	-3.81	-1.79
17	woman	70	15	74.3	31.5	-8.8	27.8	-10.2	27.2	12.54	-5.71	-3.29

Note. ID = participant identification number; T2DM = type 2 diabetes mellitus; FPG = fasting plasma glucose; B = Baseline interview; T1= Interview at the beginning of the weight loss phase; T2 = Interview at the end of the weight loss phase. Highlighted in green are participants who achieved normal-range FPG levels (<7.0mmol/L). Highlighted in grey are participants who achieved borderline normal FPG levels (slightly over 7.0mmol/L, maximum was 7.68 mol/L). Negative values represent a decrease, positive values represent an increase.

Due to the different weight management histories and the different social circumstances of the participants, the level of behavioural inter-dependence varied between them, as well as across the WL and WLM phases. While some of the participants were more independent than others to start with, many progressed notably during the VLED. Some achieved behavioural independence towards the end of the WLM phase, with few not achieving it yet by the end of the study. The progress from behavioural inter-dependence to more independence over time is further expanded and illustrated below.

9.4.1.2 Formation of behavioural independence

There was a slight shift in most participants` ability to exhibit more independent health behaviours after WL. The achieved rapid changes in weight, blood glucose and wellbeing seemed to have stimulated the participants` weight management self-efficacy, and a sense of being in-charge of their weight and health in anticipation of transition to regular food and the WLM phase. An indicator of behaviours shifting towards independence was, for example, not avoiding social events, being able to cook for others without eating the same food, or eating around others while only having their shake. As one participant put it:

"*I've made barbeques, I've made bacon sandwiches, I've made meals that I would have killed for and just handed them over and said there you are, enjoy, and then I went on and just had whatever I was allowed to have*" (MAN, 49 YEARS, T2DM 9.5 YEARS).

At the same time, some participants still had feelings of shame, discomfort or awkwardness in situations where they were drinking their food around others, which was mostly related with not wanting to be excluded from what others were doing, or not wanting to have to explain what they were doing to strangers, rather than with their inability to resist temptations:

"*…I just used to say I'm sorry I can't and I just used to go and disappear for 10 minutes, quarter of an hour, have either one of my soups or one of my shakes and then come back*" (MAN, 54 YEARS, T2DM 0.5 YEARS).

This means that while they were comfortable following a prescription that is better for their health at home and in public, they were still anticipating certain discomfort and potential stigma from people who were outside of their close social circle.

The level of behavioural independence tended to fluctuate during this period. For example, participant 1, who was previously quite dependent on his wife`s behaviours

gained more independence during the WL phase, but put his wife back “in-charge” during the transition to WLM, as a way of postponing a potential slip back to old habits, until he was ready to deal with such situations by himself. His wife became his “guardian” in the sense that she watched what he was eating, barred him from the kitchen, told other people not to offer him anything and cooked meals for him during the transition and the WLM phases. This was facilitated by her being the main cook in the family, further highlighting the importance of the lifestyle decisions made by a significant other:

“*I’m hoping I actually make the decision not to put – well it won’t be my decision, it’s my wife’s decision, I’ve got no hope at all of influencing that. I won’t be getting the big portions apparently so I’m told*” (MAN, 67 YEARS, T2DM 3.5 YEARS).

Another participant who was previously also dependent on her friend`s behaviours described how she realised that she had different needs to her friend during the transition period:

“*I think I`ve come to the conclusion that I really need to measure very carefully. We stopped measuring, we weighed the food religiously before we prepared it. But we stopped that when we came off the Optifast diet, we stopped weighing the food, partly because we`d got clear picture in our head of what it should look like. But we`re beginning to feel it`s possible creeping up again…*” (WOMAN, 61 YEARS, T2DM 11 YEARS).

The participant started distinguishing between her own and “their” needs and although she still spoke in terms of “her and her friend” as a unit, it is clear that she is thinking more about herself at this point and that she made some progress towards more independent health behaviours that would be better for her.

9.4.1.3 Progression towards behavioural independence

There was a noticeable shift towards independence of behaviours amongst most participants at the end of the WLM phase. A good example of this transition is a participant who was able to not only cook for others, but also cook different meals for his family and for himself, feeling that it did not pose a difficulty for him. This may have been facilitated by the fact that he was the main cook in the family and could therefore make decisions about cooking and eating:

“*I quite often cook something that looks far tastier than what I’m having for the rest of the family but it doesn’t bother me at all*” (MAN, 54 YEARS, T2DM 0.5 YEARS).

Another participant stopped meeting his friends in a pub and had them come over to his allotment instead, which meant that he still got to see his friends while leading a healthier lifestyle, dismissing the worry about missing out on social relationships and events, that many people had in the beginning of the programme:

"*I have my allotment and stuff like that and they tend to call in and get their weekly donation of vegetables and things like that so yeah, I still see them*" (MAN, 65 YEARS, T2DM 13 YEARS).

The level of shifting behavioural inter-dependence may affect the success during WL and WLM, which can be illustrated on an example of two housemates (Participant 2 and 3), who were taking part in the study at the same time. It was clear from the narratives of these participants that participant 2 was more dependent on participant 3 than the other way in the beginning. Both lost similar amounts of weight after the VLED, however participant 2 then re-gained 10 kilograms within the first 2 months of WLM. This was affected by a number of factors: It seemed easier for participant 3 to maintain her weight, while participant 2 struggled and felt like she was lacking her friend`s understanding and support. Participant 3 also socialised with other people more at this point, which left participant 2 feeling excluded, which may also reflect on her dependence on her friend. Secondly, participant 2`s parent became poorly and required care during the WLM phase. Participant 2 had a naturally caring personality and tended to put other people first, and at that point her priority shifted from taking care of herself to taking care of her parent, which led to a neglect of her own health. This may indicate, that the shift towards more independent health behaviours had not been completed, otherwise the participant would have been able to follow her WLM regime even though another person in her social environment had different needs. It can also indicate that time perspective and evaluation of short and long-term priorities in this particular situation resulted into this participant allocating her cognitive, emotional and time resources and skills to another cause, which was more urgent than focusing on her personal long-term goal, which she could return to later. Third, participant 2 also experienced a critical event during the WLM period (reintroduction of diabetic medication), which seems to have contributed to her negative thinking. Because she was also naturally over-analytical, this may have led to her thinking about all of the possible negative scenarios, resulting in a lot more worry than perhaps other people would have experienced, which made it difficult to find motivation to change the situation.

"*I sit down, every day, and ask myself "why, what have I been doing, how has this impacted on my blood, is there anything I could have done differently?"…In a way it doesn`t really matter what answer I come up with, what matters is that I`m actually sitting down trying to analyse it and that means I`m just thinking about it*" (WOMAN, 61 YEARS, T2DM 11 YEARS).

Participant 3, on the other hand, had a clearer sense of independence from the beginning, which further developed over time. Her approach to WLM was accepting and although she did not lose as much weight as she had hoped for, this did not prevent her from continuing her efforts to lose weight during the WLM phase. Participant 3 seemed to allocate less time than participant 2 to behavioural analysis, which may have helped her avoid rumination about the potential slips.

"*I haven`t had a quiet time where I could just sit and hmmmm about the diet and just reflect on it, I haven`t really had that time to do that, so that` really helped me*" (WOMAN, 65 YEARS, T2DM 3 YEARS)

In addition, she experienced a positive identity shift (defined and described in section 9.4.4. of this chapter) during the WLM phase. Although both spent some time in environments different to their usual environment (e.g. holidays or visiting relatives), participant 3 managed to get back on track, while participant 2 lost her motivation due to regain of most of her weight and the associated low mood.

Achieving a good level of behavioural independence and an identity shift (discussed later in this chapter in section 9.4.4.) are rewarding and important milestones on the journey towards behaviour change and maintenance. Additional findings relevant to identity shift and how this might affect the success in WLM can be found in Chapter 7.

9.4.2 ***Theme 2: Contagiousness of behaviour***

9.4.2.1 Motivation for behaviour change

It was apparent from the narratives that the behaviour change the participants adopted during the WL and maintenance phases penetrated through their relationships and sometimes affected other people`s behaviours, as if they were contagious. Contagiousness of behaviour presented itself in the form of changes in other peoples` eating or exercise patterns as a result of the changes the participants had made in their own behaviours. It is the unintended influence of the participants` new behaviours on their relationships. For example, the reason why some of the

participants took part in the study (as described in Chapter 5) had to do with them knowing someone else who had taken part in it or who had had a similar successful behaviour change experience:

"*…my ex-mother-in-law basically said to me one of my friends has just done this course… and she's really fit and she's lost loads of weight…So I just said to her can you get me a name and the contact details or whatever I need"* (MAN, 69 YEARS, T2DM 3.5 YEARS).

Similarly, participants of the Counterbalance study passed the information on and inspired other people to take part:

"*I've tried to encourage people and I do believe two of your volunteers have come because of my persuasion*" (MAN, 65 YEARS, T2DM 13 YEARS).

9.4.2.2 Minimising discrepancy

One reason for contagiousness of behaviour is a level of behavioural inter-dependence as described in the previous section. The difference between behavioural inter-dependence and contagiousness is, that while behavioural inter-dependence represents the effect of other people and relationships on one`s behaviour, contagiousness of behaviour represents the participants` influence on other people`s behaviours. Contagiousness of behaviour represents the changes other people made to their behaviours in order to minimise the discrepancy between the participants` and their own behaviours, either to make the process of change easier for the participant or for themselves. An example can be demonstrated on the case of participant 6, whose new behaviours affected the way he socialised, and this in turn affected the behaviours of people who socialised with him:

"*I would have said we went out for a drink, not just going out for one or two beers, like a drink and a meal out we'd probably do it at least once a month. I think now it's probably once every other month. And I think we tend to not go for a meal and then go for a big drink afterwards. We do one or the other. Again it's not just me and my wife, we have a group of friends and they've sort of changed*" (MAN, 54 YEARS, T2DM 0.5 YEARS).

9.4.2.3 Unintended benefits for others

Another reason for contagiousness of behaviour is the chance for other people to indirectly benefit from the participant`s behaviour change. For example, once participant 1 started on the diet, his wife started losing weight too, which started and supported a healthy competition between them:

"*…because my wife's on to this Slimming World thing now so there's no way I can sneak back round. However, I'm beaten really so I might as well give in gracefully*" (MAN, 67 YEARS, T2DM 3.5 YEARS).

Other participants inspired their relatives to increase their physical activity "*…she's saying that she thinks she wants to get more exercise and so she wants to come out on some of the walks that I do"* (MAN, 49 YEARS, T2DM 9.5 YEARS).

Contagiousness of behaviour did not only affect the eating and physical activity levels of other people. In some cases, it also had positive effects on the relationship of the involved people. For example, when participant 5 was starting on the diet, he was hoping that this would motivate his wife to lose weight too. His wife not only embarked on her own WL, but what was more noticeable over time was how the change in his behaviour improved his overall wellbeing, and how this affected their relationship in a very positive way. Their relationship went from discrepancy and negativity towards more support and alignment:

"*it helped away with the wife and all because she was helping us* (me) *so I was helping her and now we're getting on great*" (MAN, 44 YEARS, T2DM 2.5 YEARS).

What sometimes happened as a result of the mutual efforts and the increased self-efficacy of the participants was, that the participants changed from needing to be supported, to becoming the supporters. In the case of participant 5, having gone through the WL and maintenance made him more understanding of his wife`s struggles and he started supporting her more:

"*Well it's made me understand her more because she's overweight and she's got bad knees and all I would say is "oh go to the doctor". But now I'm saying well come on a diet with me*" (MAN, 44 YEARS, T2DM DURATION 2.5 YEARS).

Another participant attempted to help her daughter become more physically active:

"*she's a bit overweight my daughter. I'm trying to, I'm going to buy her a Fitbit for Christmas*" (WOMAN, 70 YEARS, T2DM 15 YEARS).

Some participants went as far as suggesting that they would be willing to act as role-models for people who decide to undergo the programme in the future.

The longitudinal evidence shows how positive results can impact not only on the participants` lives, but also on the lives of their families, which may in turn further support more behaviour change in the participants. This however requires willingness of significant others to support the person making a change.

9.4.3 ***Theme 3: Mindset adaptation***

The longitudinal analysis further highlighted that the WL and WLM required different mindsets and therefore, ideally, an adaptation of one`s mindset over time. The Oxford Dictionary of English defines "mindset" as "The established set of attitudes held by someone" (*Oxford dictionary of English*, 2003). Participants` motivation; their beliefs about what needed to be done in order to be successful and about their capacity to behave accordingly; their beliefs about consequences if they do or do not comply with the behaviours; and their beliefs about the programme were together focussed on achieving the desired goals and shaped these attitudes and mindsets:

"From the interview that I had before I started I was told that this is something that would really help me out. It has and so from that point of view everything that I've been told has been true, everything that I've done has worked so my expectations are that that will continue for the next 6 months and I cannot really think of a downside" (MAN, 49 YEARS, T2DM 9.5 YEARS)

9.4.3.1 Personal traits

The nature of the WL phase required a disciplined mindset and people who, in the baseline interviews, referred to themselves as "pig-headed", "determined" or "disciplined", and those who described themselves as having a tendency to stick to a decision once it had been made, seemed to consider these traits part of the required mindset, and an advantage. The VLED imposed a strict dietary regime and required no deviations, which seemed to have suited participants who were particularly good at focusing their attention on a specific goal. The fact that the VLED intervention was part of a medical study further reinforced the importance of complete adherence due to the increased feeling of responsibility and "giving back", that I also described in Chapter 5. One participant described how the VLED was different from ordinary diets and why this way of looking at the study helped him get into the right mindset and follow the diet with no deviations:

"*…had it been a diet yes the odd thing would have slipped past me but I didn't. My mindset was that this is something; this is a treatment if you like. It's 8 weeks out of my life and if I can't give it my full support over that 8 week period what am I doing on it?*" (MAN, 49 YEARS, T2DM 9.5 YEARS).

The personal traits and the importance of the study to the participants may have facilitated adherence with the WL phase, although similar statements were sometimes made during the follow-up interviews too.

9.4.3.2 Holiday hiccup

Given that the VLED lasted for a fixed period of time, the mindset required to adhere with it was very much affiliated with this period only. This may explain why many people experienced what I call a *holiday hiccup,* when they came off the diet. A *holiday hiccup* represents unexpected weight regain during a temporary change of environments (usually, but not exclusively during holidays), mostly due to an over-estimation of the participants` perceived resilience towards weight gain after a significant WL, and due to switching off of the WL mindset once the 8 weeks were over. The holiday hiccup often occurred shortly after the end of the WL phase and in the early stages of the WLM phase. The participants were often surprised by how quickly the weight came back on once they loosened up their efforts, even for a short period of time:

"*To be fair it was one of them holidays where I was running, cycling, swimming all day and then I came home and I've put lots of weight on and I couldn't believe it. But like I say I was just over eating to be fair, but I got back on my diet when I came home… I think it's what I needed. If I'd have been away for a fortnight I think I would have probably been back on the tablets for diabetes*" (MAN, 69 YEARS, T2DM 3.5 YEARS, self-reported weight gain of 6 kg in a week).

On the other hand, because the holiday hiccup more often than not happened soon after the start of the WLM phase, it served as a reminder to the participants that the challenge was not over and that they had to put conscious effort into WLM. While the WL phase required the participants to distance themselves from their old behaviours, the aim of WLM was to keep the distance constant or increase it further. To be able to achieve that, they needed to employ the appropriate mindset, as the one required for WL differed, as discussed below, from the one required for WLM.

9.4.3.3 From rigid to flexible restraint

In contrast to the WL phase, successful WLM was a much longer process and required a level of flexibility in order to be sustainable. It required an adaptation of the mindset. The process of WLM was more sensitive to weight fluctuations than the WL process not only due to the length of the phase and a relative decrease in intensity, but also due to the reduced clinical supervision, leaving the participants to their own devices:

"*I like regimented things, and being told you could only have soups and shakes and so much vegetables per day was spot on for me but then it comes down to "you take control". I`m not very good at that. So it`s been difficult that bit*" (WOMAN, 47 YEARS, T2DM 2.5 YEARS).

Similar to the process of developing behavioural independence, finding the right balance and an individual "recipe" for WLM success was achieved at different stages to different levels in different people, with many people still only "*getting the hang of it*" (WOMAN, 65 YEARS, T2DM 3 YEARS) towards the end of the 6 months of WLM. Table 10 shows that majority of the participants maintained the weight or lost more weight over time, and irrelevant of the maintained weight, they almost unanimously agreed that it was important to approach WLM with a more open and forgiving mindset compared to the mindset at the WL phase. They realised that some of the cravings or triggers would never go away and that it is better to acknowledge it, accept it, give in occasionally and move on rather than live a restricted life that would potentially result in much larger lapses. From this perspective, eating something tempting served as a treat or a reward rather than being thought of as a regular snack. Including trigger foods in the diet was crucial for satisfaction of cravings and curiosity (e.g. "Do I still like this?"; "Will I manage to only have one piece?"; "What does this taste like now?"), and as long as the participants knew they were able to get back on track easily, having treats occasionally would not present a threat to WLM:

"*My lifestyle has changed completely, it's changed forever, but I'm afraid I don't care what anyone says, holidays are continuing to be sacrosanct. I'm not going to force myself into abstinence during holiday periods*" (MAN, 65 YEARS, T2DM 13 YEARS).

While WL is a finite process that usually has a start and an end when the ideal weight is reached, WLM could be compared to a lifestyle, which takes time to develop and sustain. Understanding that WLM is a process that cannot be completed in a short space of time, and which may be seen as a lifetime effort, may help prevent people from switching the WLM mindset off and help them focus on the long-term sustainability of their new behaviours.

9.4.4 ***Theme 4: Shift in identity***

In Chapter 5, I described how complex the motivation of the participants to take part in the Counterbalance Study was. It was not only determined by the potential WL and diabetes remission. It was very much rooted in the participants` desire to improve their eating habits, to look and feel better, to have more energy, to prolong life – to improve their existence and essentially to become "different people" to whom they

were at the beginning, to become happy, healthy, and non-diabetic people. Identity therefore included mental representations of their selves and the feelings associated with them.

This process seems akin to a shift in identity and it was noticeable across the WL and WLM phases. Below is a description of the two sub-themes illustrating a shift in identity: *increased awareness* and *reflection on past behaviour*. A shift in identity has been previously partially described in Chapter 7, section 7.4.5).

9.4.4.1 Increased awareness

Increased awareness was the first sign of a shifting identity and behaviour change. Participants often commented on how much more aware they became of the triggers such as unhelpful thoughts, stress or the environment, of their feelings of hunger and satiety, and mostly awareness of the calorie content of the food that they now eat:

"*I think nowadays I concentrate far more carefully on what I'm eating than ever I've done before. I simply didn't give any consideration to what was going inside in the past*" (MAN, 65 YEARS, T2DM 13 YEARS).

Many participants also noticed that they became more aware of other peoples` weight or shape and were often critical of it, thinking they should *"get a little bit of weight off, just a little bit at a time*"" (WOMAN, 70 YEARS, T2DM 15 YEARS). The participants started noticing changes in their own behaviour and attitudes that were different from their old ones and marked the beginning of identity shifting, which was notable at the end of the VLED.

Thinking of oneself as a "not fat" anymore contributed to the continuous effort and motivation to keep the weight off in the future. As participant 1 put it:

"*I would not like to get fat and the way you see an awful lot of people, especially in this country now, not even as an old man, I wouldn't like to get that way. So that might keep me on the straight and narrow*" (MAN, 67 YEARS, T2DM 3.5 YEARS).

Participants who completed the identity shift often referred to themselves as being "converted", and they were determined the change was forever and that there was no way back. They also wanted other people, especially healthcare professionals to recognise that they were no longer diabetic, which did not always meet their expectations. For example, one participant described how he got upset because his practice nurse was treating him as any other "diabetic", when he was diabetes free:

"*…she didn't really understand or knew what was actually going on with me and she was treating me as if I was the same as every other diabetic that she sees"* (MAN, 49 YEARS, T2DM 9.5 YEARS).

9.4.4.2 Reflection on past behaviour

Reflection on the participants` own behaviours in the past was another indicator of identity shift that the increased awareness led to. The reflection focussed on dietary and physical activity habits in the past. Being able to take a step back and make such reflection may be easier when the reflection cannot hurt their self-image, which may imply that people making reflective statements became sufficiently different over time, or have changed their behaviours enough, so that they were able to make critical judgements about their previous behaviours. For example, participant 1 admitted that he was using excuses for lack of exercise in the past:

"*I've put on a bit more weight and made all the excuses you can find including not taking the dog out for a walk because it's raining. Yeah you can rapidly get to that but I'm aware of that, my head hasn't been stuck that far in the sand. I've had one eyebrow open*" (MAN, 67 YEARS, T2DM 3.5 YEARS).

Similarly participant 5 was critical about his unhealthy dietary habits in the past: "*I've been an idiot. I have. That's swilling beer down and eating bacon and fatty things and bread and potatoes. If I'd known then what I know now I wouldn't have had diabetes, if that makes sense. I didn't know I had diabetes when I was doing all this and then when I did find out I had it they put me on tablets and they were bringing the readings down to normal-ish, so I was just still eating the same rubbish*" (MAN, 44 YEARS, T2DM DURATION 2.5 YEARS).

The increased awareness, reflections on past behaviour, and feeling like a different person were the internal processes of identity shift. In addition to these internal processes of recognition, there were external processes that affirmed that the participants had gone through a process of change. Participants often described events in which they were reminded externally that they are or look like a different person now:

"*The man in the waiting room said "Are you looking for the little lady" and they said "yes" and that was me!. So, "little" is funny, because, well, it`s had quite an impact on me because I thought I don`t feel like a little person. And little meant, you know, is that about ability, intellect, and intelligence? All those things, those words, felt applied to everything and not just my physical shape"* (WOMAN, 65 YEARS, T2DM 3 YEARS).

Comments from other people, compliments on appearance, changes in the size of clothes, maintaining a diabetes and medication free status all served as a reminder of the new self.

Figure 17. A mind-map of themes of change over time.
Highlighted in dark blue are core themes, highlighted in light blue are sub-themes. An overlap indicates greater connectedness of themes. Size of the oval shapes does not represent richness of data or how substantial a theme was.

9.5 Discussion

The present chapter aimed to explore peoples` experiences with the WL and WLM stages of the Counterbalance Study over time and how these experiences relate to each other. The longitudinal analyses resulted in identification of four themes of change: a change in the level of behavioural inter-dependence; contagiousness of behaviour; adaptation of mindset; and a shift in identity.

People in the study regained more control over their eating patterns. Over time, they grew less dependent on other people`s eating patterns and even influenced (or tried to influence) the behaviours of their significant others in some instances. Previous research on the development of eating patterns indicates that socially connected individuals influence each other`s food choices and diets (Patrick & Nicklas, 2005; Pedersen, Grønhøj, & Thøgersen, 2015; Videon & Manning, 2003; Zarychta, Mullan, & Luszczynska, 2016). Modelling, or adjusting one`s food intake according to their companion`s food intake may be one of the mechanisms of shared eating patterns (Herman, Roth, & Polivy, 2003) (Vartanian, Spanos, Herman, & Polivy, 2015), which may facilitate or sabotage weight management efforts. People observe how much their companions eat in order to identify and not deviate from the social norms related with eating. A review of 69 social modelling studies found that the effect of modelling is increased when people want to create a social bond with the model, or perceived themselves to be similar to the model (Cruwys, Bevelander, & Hermans, 2015). The importance of social bonds in eating behaviour was further ascertained by the study of Christakis and Fowler (Christakis & Fowler, 2007), who evaluated the nature and extent of obesity within a social network of 12.067 people over 32 years. They found that people`s chance of becoming obese increases with their significant other becoming obese over time and that this spread of obesity would appear within three degrees of separation (three relationships apart). In addition, this effect was not observed in socially disconnected individuals (e.g. neighbours, strangers in the same geographical area) – socially connected individuals living distances apart would still show this pattern. Amongst the different family relationships, spouses tend to be the most concordant in eating patterns over time (Pachucki, Jacques, & Christakis, 2011). Participants in this study often referred to how the of support from their spouses and friends, in the form of changing their own behaviours that were more concordant with the participants` new behaviours, facilitated adherence with the regimes. This made changing the participants` behaviours easier as they did not

have to allocate resources to dealing with the discrepancy between their and their family behaviours on a daily basis, as well as it provided benefits to their significant others.

The Self-determination theory (Deci & Ryan, 1985) and the Action control theory (Kuhl, 1992) both propose that behaviour change and its sustenance are driven by intrinsic rather than by extrinsic motivation. Behaviour maintenance requires new values and regulation to be internalised and integrated with one`s sense of self. Successful WL and maintenance therefore result from dieting that is driven by internalised motivations. Internal motivation was identified as a predictor of successful weight management in previous reviews (Elfhag & Rössner, 2005; Teixeira, Going, Sardinha, & Lohman, 2005). A study of motivational predictors of WL and WLM in a programme including a 6-month VLED with a 23-month follow-up found that people with more intrinsic motivation lost more weight and maintained greater WL over time than people with more extrinsic motivation (Williams, Grow, Freedman, Ryan, & Deci, 1996). A shift towards more independent health behaviours of the participants in the current qualitative study reflected on the recognition of the participants own needs and their ability to behave in accordance with these needs, illustrating stronger internal motivation to follow a diet that is best for them and for their goals, whether it was further WL or WLM. Results of this study support findings from the previous studies, explaining why gaining behavioural independence and social support, often through the contagion of the new behaviours, were crucial to WL and WLM.

The results also demonstrated that WL and WLM require different mental attitudes. While the strict nature of the VLED required a closer attentional focus, WLM required a more flexible approach in order to be sustainable in the long term. WLM was understood as a long process likely to be accompanied by fluctuations in weight within a certain range. This was reflected in the participants adopting a more flexible mindset, which allowed including consumption of trigger foods or treats in the WLM plan. According to the Ego-depletion (Baumeister *et al.*, 1998) and the Goal conflict theory (Stroebe, van Koningsbruggen, Papies, & Aarts, 2013), having to resist temptations for periods of time would lead to using up of one`s self-regulatory resources, leading to a lapse eventually. This lapse might then be more serious than if one allowed himself or herself the occasional treat (Fedoroff *et al.*, 1997). The

counteractive control theory (Trope & Fishbach, 2000) suggests that exposure to food temptations can even enhance self-regulation by strengthening the importance of the dieting goal, goal intentions and goal-directed behaviour, as long as the long-term outcomes are valuable and the short-term cost of a lapse is moderate, rather than very high or very low. In their Prospect theory, Kahneman and Tversky (Kahneman & Tversky, 1979) proposed that in making choices between alternatives that include risk or uncertainty, people tend to prefer avoiding loss to acquiring equivalent gains. This is due to the increased value of what they already have (also known as the “endowment effect” in behavioural economics (Kahneman, Knetsch, & Thaler, 1991; Tversky & Kahneman, 1991) or the “mere ownership effect” in social sciences (Beggan, 1992)) in relation to the changing reference point and the magnitude of change, and because psychologically, losses have approximately twice the weight of gains of the same value (Kahneman *et al.*, 1991). Applied to weight management behaviour, this means that people who have lost and maintained weight may value their achievement more than people who have been less successful and the length of time of WLM may further strengthen or increase this value. Over time, the reference point for their weight and their new identity shift further away from their original positions, which may also shift the short-term cost of a lapse that was previously very large into the medium zone, where they are now able to self-regulate it.

Furthermore, flexible eaters lose more weight and are better at WLM and the reason for this might be that flexible eaters are not, as opposed to restrained eaters, preoccupied with body shape or food, which means that they spend less cognitive resources on WLM. Flexible eaters are more preoccupied with diet-related cognitions, which mostly reflect awareness of food content, which may help WLM (Westenhoefer *et al.*, 2013).

Not avoiding deprivation is therefore key to successful WLM and this finding was supported by other studies (McKee *et al.*, 2013).

The theme of mindset shifting has not been explicitly addressed in the literature, perhaps due to the fuzziness of the term. However, other qualitative studies found that avoidance of dichotomous thinking and adopting a more flexible approach to WLM and a self-forgiving attitude are important during WLM (Byrne *et al.*, 2003; Ohsiek & Williams, 2011). Furthermore, successful weight maintainers do not diminish their efforts to keep the weight off over time, and are vigilant to fluctuations in their weight (Chambers & Swanson, 2012). The realisation that some problematic

behaviour issues would not change despite a behaviour change was part of identity reappraisal (Kearney & O'Sullivan, 2003), which was supported by our data on mindset adaptation.

A shift in identity was found to be a process transcending both the WL and the WLM phases. They were indicated by increased awareness and reflection on past behaviour, which facilitated creation of psychological distance between the participants` old and new behaviours and identities and the realisation of their new ones. This is in line with findings from previous research. For example, a qualitative meta-review of key moments in achieving behaviour change in behaviours such as smoking, weight management, recovery from substance abuse, exercise and cardiovascular risk reduction (Kearney & O'Sullivan, 2003) found that increased awareness and critical reappraisal of self were one of the first indicators of the new identity and a step towards behaviour change across these behaviours. If the reappraisal was successful, it lead to more behaviour change and strengthening of the new identity. People avoid products that are associated with undesired identity (White & Dahl, 2006, 2007), which may further facilitate the continuous effort to change behaviour through the participants making healthier food choices more in accord with their healthier, new identity.
Previous research has also found that reflection on the past was part of the reconstruction of one`s old identity after WL (Sarlio-Lähteenkorva, 2000). Before WL, people often perceive themselves as restrained, which affects their social interaction, eating habits and the perception of themselves through the lenses of their body shape. After WL, the narratives of identity reflect on improved social interactions and self-image, and more relaxed dietary habits without the feeling of deprivation (Epiphaniou & Ogden, 2010a).

Another finding of the this study was that people who lost weight became more aware of and judgemental towards other people`s weight or shape. According to the Social comparison theory (Festinger, 1954) people are driven to gain accurate self-evaluations of their opinions and abilities by comparing themselves to others, in order to be able to reduce the uncertainty in defining their selves. Making such comparisons may have therefore served as a process of anchoring of the new identity and behaviour sustenance. Downward comparisons (comparison with a heavier person) are associated with increased thoughts of physical activity and with

an increased likelihood of dieting (Rancourt, Leahey, LaRose, & Crowther, 2015), thus helping people to sustain their weight management efforts. Another study found that feelings of inadequacy and unfavourable social comparisons are associated with higher disinhibition and susceptibility to hunger, while reassured self, positive social comparisons, and weight-related positive affect are associated with dietary restraint (Duarte *et al.*, 2017). I made a comparison earlier in this qualitative study between two housemates who were taking part in the Counterbalance Study together, but one managed to maintain her weight and the other one did not. One of the reasons hypothesised earlier was that the identity shift was not completed for participant 2 due to the weight regain, which was likely the main reason. However, social comparison with her more successful friend may have further reminded her of the difference between them, promoting more disinhibited eating, and negative affect, which was also notable in her narratives. On the other hand, her friend who was making positive (downward) social comparison benefitted in the sense of being reminded of her success and possibly sustaining her WLM efforts even more. It may therefore be important for people who are losing or maintaining weight to be able to make more downwards than upwards comparisons, as these may indirectly affect the outcomes of their weight management efforts.

9.6 Limitations

The focus on the narratives of participants who attended all three interviews only may limit the conclusions. People who did not attend all interviews may have been less successful in their WL or WLM, and such experience would have been excluded from the analyses. Although the reasons for not attending the interviews were mostly related with lack of time, it is possible that some participants preferred not to talk about their experience, or that they just did not like to be interviewed.

Another limitation is, that no second coder was involved in the coding of the data for this chapter. This may have influenced the types of themes I have identified. However, I have discussed my interpretations of the quotes and the themes with my supervisory team, which, together with my good knowledge of the data, should minimise the impact of the lack of second-coding on the results.

Lastly, analysis of the data in this study was more interpretative than in the previous qualitative chapters of this thesis. An interpretative approach involves more empathy, insight, use of personal experience, and a more elaborate search for meaning, resulting in higher level themes which offer better understanding of the data and how

it relates to reality. On the other hand, this research was conducted over time and therefore changes necessarily happened not only in the lives of the participants, but in my own life too. This may have affected the themes I identified and the way I interpreted the data, although by having designed, conducted and analysed the interviews, the level of my familiarity with the data may suggest that the potential bias should not be large.

9.7 Conclusions

Findings from this longitudinal study highlight the changes that occurred in the participants` narratives over time during WL and WLM, and how these experiences related with each other. The results illustrate that the participants experienced a shift from behavioural inter-dependence to more independence; that their behaviours had unintended effects on other people and their relationships with them; and a shift in their perceptions of themselves. In addition, the study showed that different mindsets may need to be employed during WL and WLM in order to succeed. The current chapter contributes to the limited longitudinal qualitative evidence from weight management studies.

Chapter 10
General discussion

The aim of this thesis was to determine the efficacy and acceptability of using VLEDs in adults with T2DM and to explore their experience during WL and WLM. Efficacy and acceptability were initially explored by a systematic review of controlled studies and qualitative reports. Experiences with VLEDs including in-depth perspectives on acceptability during WL and WLM were evaluated by a qualitative evaluation of the Counterbalance Study. The current chapter discusses the main findings of the thesis and their implications. The structure follows the RE-AIM framework (Glasgow, McKay, Piette, & Reynolds, 2001). The RE-AIM framework has been developed to improve quality of reporting of studies and to enhance translation of public health research into practice. RE-AIM stands for *Reach* of the intended target population, *Efficacy* or *effectiveness*, *Adoption* by target staff, settings, or institutions, *Implementation* consistency, costs and adaptations to intervention during delivery, and *Maintenance* of intervention effects in individuals and settings over time.

10.1 Reach

The aim of this thesis was to determine the efficacy, acceptability and experiences with using VLEDs in adults with T2DM and to explore their experience during WL and WLM. Efficacy, acceptability, and experiences were initially explored by a systematic review of controlled studies and qualitative reports. Experiences with VLEDs including in-depth perspectives on acceptability during WL and WLM were evaluated by a qualitative evaluation of the Counterbalance Study. The current chapter discusses the main findings of the thesis and their implications. The structure follows the RE-AIM framework (Glasgow, McKay, Piette, Reynolds, 2001). The RE-AIM framework has been developed to improve quality of reporting of studies and to enhance translation of public health research into practice. RE-AIM stands for *Reach* of the intended target population, *Efficacy* or *effectiveness*, *Adoption* by target staff, settings, or institutions, *Implementation* consistency, costs and adaptations to intervention during delivery, and *Maintenance* of intervention effects in individuals and settings over time.

10.2 Efficacy

The systematic review presented in Chapter 2 provides an overview of available evidence of efficacy of VLEDs in people without T2DM and contributed to the evidence by providing an overview and meta-analyses of efficacy of VLEDs for WL and improvements in BGL among adults with T2DM. The results suggest that evidence for the effects and acceptability of VLEDs is currently limited. The review included 9 studies, with a total of only 346 participants and considerable risk of bias in many studies. The overall findings suggest that the greater the energy restriction prescription the greater the WL and improved diabetes control, however, the meta-analyses of weight changes in our review, were based on a very small number of studies most with small sample sizes.

10.3 Adoption

No qualitative evidence of acceptability of VLEDs in people with T2DM was identified through the systematic review, but the limited quantitative evidence on attrition rates suggested, that VLEDs might be as acceptable as other dietary interventions. The systematic review (Chapter 2) highlighted, that although there are a number of studies using VLEDs in people with T2DM focusing on physiological outcomes, few focused on psychological outcomes. The longitudinal qualitative evaluation contributes to the knowledge gap relating to acceptability of VLEDs. In addition, it also provides insights into psychological and behavioural outcomes among people with T2DM, who take part in a WL study using VLED, followed by a WLM programme. Our focus was on the perceived barriers and facilitators of WL and WLM and the behavioural strategies to overcome the barriers.

Only one study, which was not included in the systematic review (T2DM diagnosis of participants could not be confirmed) explored experience of adults with a VLED in primary care, and found that the 3-month VLED treatment was positively evaluated and acceptable among obese adults (Östberg *et al.*, 2011).

Results of our qualitative evaluation show somewhat mis-matched anticipations of the WL and the WLM phases of the Counterbalance Study. I found, that the WL phase, which was anticipated by participants to be very difficult, was largely acceptable due to the fact that the participants did not feel as hungry as they thought they would be, the taste and textures of VLED was generally well tolerated and

satisfaction with the achieved outcomes as well as the support received from the study staff. On the other hand, transition to regular food and the subsequent WLM were perceived as more difficult than expected by the participants due to diminished social support, environmental triggers, lack of self-regulation skills and life events. Findings from both the WL phase and the WLM phase stress the importance of social support, whether from significant others, or from the staff involved in the study. In this study, 9 out of the 18 participants were ‘buddies’ to each other or had a “buddy” not involved in the Counterbalance Study, which had to do with the Counterbalance Study using word of mouth as part of the recruitment strategy. Moreover, as the results of both Chapter 5 and Chapter 6 have shown, many of the participants would have welcomed the opportunity to meet other participants to receive more support. Our study therefore suggests that having a “buddy”, who is going through a similar experience or has knowledge of that experience, is important during both WL and WLM. The need for social support and its association with WL or WLM has been documented previously, for example, in a study of prediction of WL by social support (Kiernan et al., 2012), 267 obese women were randomised into two group-based behavioural WL programmes. Measures of social support were taken at baseline and weight was assessed at 6 months of the intervention. The study found that women who experienced less frequent support from friends were most likely to lose more than 5% of their baseline weight. The authors hypothesised that it is the lack of support from friends that may drive the women into seeking group-based interventions. Although the results of the Kiernan study (2012) seem counter-intuitive at first, they may explain why in the Counter-balance support from the study staff seemed so important, or why a buddy system with people who go through the same programme was suggested by participants. I hypothesise that this is because of the understanding of the nature of the programme and their experience with it of those people directly involved in the study, which may not be as well understood by the family or friends, unless they too have been through a similar programme. The study by Ostberg and colleagues (2011) also found that a group setting which provided space for sharing experiences with other participants and competition between them was found helpful to the participants. Similarly to our results, they also found that social disclosure, whether at home or at workplace, facilitated adherence with the VLED.

We found that people use different behaviour-regulation strategies during the WL and the WLM phases of the Counterbalance Study. The difference between the strategies

typically employed during the two distinct phases of weight management has been previously documented in a cross-sectional survey or a random sample of 1165 participants, out of which 926 were overweight (Sciamanna et al., 2011). The survey examined the association of 36 practices used in the past week and the success in WL (≥ 10% in the past year) and WLM (≥ 10% lost and maintained in the past year), The study found that out of the 36 practices, only 8 were common for both WL and WLM. While the Counterbalance Study was qualitatively different from the diets the Sciamanna survey participants may have tried, due to the almost complete replacement of food (except for vegetables) in counter-balance, some of the strategies associated with successful WL in the Sciamanna (2011) study were found in our study, and are presented in brackets in the next paragraph alongside the strategies found by Sciamanna and colleagues (2011). These were: drinking plenty of water (*Finding alternatives/Compensation*); limiting the amount of unhealthy food at home (*Food removal*); avoiding eating or drinking too much while eating out (*Avoidance*); and planning before going shopping and portion control (*Coping Planning*). Similarly to the Sciamanna study (REF), thinking about the WL goal and reminding oneself of why it is important to lose weight, were important motives in our study. Different strategies were found to be associated with successful WLM in the Sciamanna (REF) study: portion control (*Monitoring*); an exercise routine (*Compensation/habit*); reading food labels (*Monitoring*), thinking about their weight goal (*Monitoring*); weighing oneself (*Monitoring*). Reminding oneself of how much progress they have made and why it is important to keep the weight off were the main motives during WLM phase in our study.

The implications of these findings are that future WL or WLM interventions should provide participants with skills training for the appropriate behaviour-regulation strategies relevant to the WL and WLM phases of their weight management to achieve optimum adherence and long-term physiological and psychological outcomes.

10.4 Implementation

The interviews were implemented consistently during the qualitative study. All participants were interviewed at the same site and most of them were interviewed in the same room, with the exception of a few, who were interviewed in a clinical study room next door. They were interviewed at the same time-points of their WL and WLM

phases, using pre-developed interview topic guides. Individual interaction with the participants naturally varied, being dependent on participant individual communication skills, and therefore the length of interviews and the depth of information gained also varied. The extent to which the WL and WLM interventions of the Counterbalance Study were delivered as intended cannot be fully evaluated. The protocol of the Counterbalance Study aimed to support participants by weekly meetings and e-mail or phone calls as needed. However, the interviews with the participants indicated that the study staff may have provided support beyond the level implied by the study protocol, by actively approaching participants by e-mail or telephone between their appointments to see how they were doing, and to provide advice. This may have resulted in the study staff unintentionally delivering a number of different behaviour change techniques (Abraham & Michie, 2008; Michie, Ashford, Sniehotta, et al., 2011; Michie, Richardson, Johnston, Abraham, Francis, Hardeman, Eccless, & Cane, 2013) within the intervention, of different intensities to different participants. The form, frequency or content of the support provided was not recorded. It may be, that the additional support, of unknown extent, may explain the high levels of motivation of the participants and hence acceptability of the VLED.

In addition to the previous recommendation to include participant training for specific behaviour-regulation skills during the respective weight management phases, studies should also include detailed mapping of behaviour-change techniques provided in their interventions to facilitate fidelity of intervention delivery, adoption of the learned skills, and support adherence to the WL and WLM programmes.

10.5 Considerations for implementability of the Counterbalance Study in primary care

Although it was clear from the interviews, that the WL and the WLM interventions were well accepted among the participants on the whole, when asked about whether the participants thought the whole programme would be as successful on a larger scale, for example in a primary care setting, many were rather sceptical of such implementation. The main barriers to implementation the participants saw were lack of time of the primary care staff, lack of motivation of the staff, lack of staff, lack of incentives for the staff, and lack of equipment such as magnetic resonance scanners. An important aspect of the WL and the WLM interventions was, that it provided the participants with a feeling of exclusivity and importance. They believed that if the

interventions were offered to many patients as routine care and if they were provided by their GPs, it wouldn`t feel as exclusive or unique anymore. That would mean that people might not take the treatment as seriously as they did when being involved in a research study. This observation may need to be taken into account in delivery of this intervention on a population level in the future.

Another barrier to implementation might be lack of commitment on the participants` side. Majority of the participants believed that people who would want to be successful on such programme would have to be committed, which they did not assume they would be, which reflects on the highly motivated sample of individuals involved in this study.

10.6 Maintenance

The last follow-up of participants in the Counterbalance Study was 6 months after the end of the WL phase. I found that the WLM phase of the Counterbalance Study was perceived more difficult to adhere to than the WL phase. I discussed in Chapters 6 and 8, that the participants would have liked additional and ongoing support after both WL and WLM phases, which also highlights the longitudinal nature of behaviour change. It could not be established, to what extent the effect of the WL phase using VLED for WL and diabetes remission can be sustained in the long-term, and I encourage longer follow-ups of participants in future studies.

10.7 Strengths of the current study

The main strength of this PhD was the combination of quantitative (a systematic review) and longitudinal qualitative (interviews) methods. The systematic review was the first to collect and present evidence of efficacy of VLEDs for WL and T2DM reversal. The qualitative evaluation was the first to explore peoples` experiences in medically supervised intervention for WL and remission of diabetes, followed by a WLM intervention, and has enabled me to compare the experiences of the two distinctive weight management stages. Through the interviews, I was able to identify specific barriers and facilitators of adherence and behaviour-regulation strategies that people use to deal with them. The longitudinal nature of the interview study has also enabled us to compare the WL and WLM stories of participants, who were less or more successful at WLM.

10.8 Limitations

One of the limitations of this study discussed in more detail in Chapter 2 was, that the systematic review included a small number of studies of moderate heterogeneity, with an overall small sample size, which potentially makes the effect sizes less precise and conclusions of the efficacy less reliable.

One of the limitations of the qualitative study not discussed in the previous results chapters is the broad scope of our interviews. Due to the lack of qualitative evidence on the experience of VLEDs for WL and T2DM remission among adults, there was no a-priori starting point, such as a psychological model of determinants of adherence to WL and WLM programmes, or a predictive study of WL and WLM directing this work. Attempts were made to address all potential issues relating to adherence by using the TDF (Michie, Johnston, Abraham, Lawton, Parker, & Walker, 2005; Cane, O`Connor, & Michie, 2012) to guide development of the interview schedules, which provided us with some certainty of covering the main theoretical themes that could be important. On the other hand, it became increasingly apparent during the interviews, but more so when analysing the data, that the interview outputs were too broad. While a variety of issues related with adherence with the WL and WLM phases were addressed in the interviews, the broadness of the data prevented us from making more in-depth conclusions about the specific contexts or reasons explaining the participants` behaviours. Our study was therefore more exploratory than explanatory. However, the results of our study may be greatly useful in future WL and WLM studies, which can focus on a more in-depth understanding of the barriers, facilitators and behaviour-regulation strategies I have identified within the context of the Counterbalance Study.

Another limitation is that I used themes of the Theoretical Domains Framework (Michie *et al.*, 2005) to organise peoples` narratives into during the initial stages of coding in Chapters 5 to 8. Use of the pre-defined themes may have potentially resulted in omission of themes that might have been identified with an approach more grounded in data. However, because I conducted the interviews, transcribed parts of interviews, and conducted the analysis, the probability that a substantial theme would not be included is low.

The disadvantage of the longitudinal interview study was that not all participants were able to take part in all interviews due to other commitments or lack of time. As the qualitative studies were conducted alongside the Counterbalance Study, efforts were made to minimise participant burden by conducting interviews at the times the participants were at the clinic. However, sometimes this would interfere with the length of the interviews and the availability of the participants. As some of the interviews were missing, it is possible that saturation of the data was not reached in some themes and that I may have missed important additional themes.

10.9 Recommendations for future research

I have carried out a thorough systematic review and a qualitative evaluations of the WL and WLM phases of the Counterbalance Study. However, despite the efforts to provide the highest quality evidence, there is level of uncertainty about the generalisability of the results. First, the systematic review included a small number of studies, with unclear risk of bias and a small sample size. However, if the effect size estimates are reliable, and the VLEDs are considered highly acceptable as found in the qualitative evaluation, then these findings could lead to a change in the recommendations on WL, which currently discourage the use of VLEDs for WL and recommend a gradual and slow WL (NICE guideline Nr. 53, 2014).

Second, the participants enrolled in the Counterbalance Study were self-selected, very motivated, and shared similar demographic characteristics. The scalability of the Counterbalance Study therefore cannot be determined. Studies with more representative primary care populations of various demographics, and across different centres would provide an estimate of effectiveness and scalability of VLED interventions for WL and T2DM remission in the general population.

Such study, the Diabetes Remission Clinical Trial (DiRECT) has recently been funded by Diabetes UK. It is the first trial to use VLEDs for WL and T2DM remission in a primary care setting. Its aim is to further investigate the long-term outcomes of using VLEDs in general practices across Glasgow, Edinburgh and Newcastle. A qualitative evaluation of the DiRECT trial, informed by the findings of this PhD work, has been embedded within this trial and will provide the opportunity to explore experiences with VLED among a more representative T2DM population.

Appendix 1. Example of a search strategy in the systematic review – PsychINFO database

1. diet.mp. or exp Diets/	7. diabetes.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
2. calor$.mp.	8. 5 or 6 or 7
3. energ$3.mp.	9. 4 and 8
4. 1 and (2 or 3)	10. limit 9 to human
5. diabetes mellitus.mp. or exp Diabetes Mellitus/	11. limit 10 to adulthood <18+ years>
6. exp Diabetes/	

Appendix 2. Systematic review inclusion and exclusion screening form

Study ID (1st author`s name, year) Reviewer: ……..

……

Report ID: ……

NOTES:

Q1. Does at least one of the treatments in the study comprise of a diet of ≤ 800 kcal/day alone or a combination of a diet of ≤ 800 kcal/day and other intervention component/s?	YES ↓	UNSURE ↓	NO (EXCLUDE)
Q1. Are participants in the treatment group* diagnosed with type 2 diabetes?	YES ↓	UNSURE ↓	NO (EXCLUDE)
Q2. Is the Mean BMI of the VLCD treatment group or individual BMI ≥25?	YES ↓	UNSURE ↓	NO (EXCLUDE)
Q3. Is the Mean BMI of the VLCD treatment group or individual BMI 18 years old or older?	YES ↓	UNSURE ↓	NO (EXCLUDE)
Q4. Does the paper report a randomised controlled trial / Non-randomised controlled study/ Qualitative study?	YES ↓	UNSURE ↓	NO (EXCLUDE)
FINAL DECISION	**INCLUDE**		**EXCLUDE**

*Treatment group = very low calorie diet (VLCD) alone or a VLCD + other intervention component.

Appendix 3. Description of studies included in the systematic review[7]

Randomised controlled trials

Study ID	Methods	Participants	Interventions	Outcomes	Notes
Anderson, 1994 Collins, 1995	Randomisation: Stratified by gender, BMI and insulin use. Allocation concealment: unclear ITT: no	Inclusion criteria: T2DM for > 1 year, 40-70 years, 30≤ BMI ≥40kg/m2, serum creatinine ≤176μM, serum cholesterol ≤7.8mM, serum triglycerides ≤ 22.6mM, no recent cardiovascular events Exclusion criteria: Not stated Gender: women/men: 19/21 Age: Not stated per groups Body weight(kg): mean (SD) a: 105.1 (3.4) b: 104.3 (3.2) Baseline comparability: yes	Active intervention length a: 12wks, b: 12 wks Description of intervention a: at least 5 liquid supplements /d which provide 800 kcal and 80 g of high-quality protein, 2 vitamin/mineral tablets; b: at least 3 supplements /d which provide 320 kcal and 32 g of high-quality protein, 1 vitamin/mineral tablet, recommended evening meal of cca 500 kcal and 50 g of high-quality protein. a + b: Subjects paid $100 for the weight loss programme which was fully refundable upon completion and $25 per week for the liquid supplements, which was not refundable. Participants kept records of their supplement/food intake and physical activity caloric expenditure; subjects were taught how to estimate PA energy expenditure. Records were collected and reviewed weekly. Subjects attended weekly 90-min behaviour and nutrition education group classes. Allocated: a: 20, b: 20 Completed: a: 20, b: 19 at 12 weeks % dropout: a: 0%, b: 5% Assessed: a + b: 37 at baseline, week 12 and 24	Points of follow-up: a + b: weeks 0, 12, 24 Outcomes measured Body weight, BP, serum glucose, glycosylated haemoglobin, TC, TG	Sponsorship: Health Management Resources (Boston, MA)

T2DM = type 2 diabetes mellitus; VLED = very low energy diet; BMI = Body Mass Index; BP = blood pressure; TC = total cholesterol; TG = total triglycerides.

Continued

[7] The main studies are in **bold**, other papers relating to the study are listed below the main studies.

Study ID	Methods	Participants	Interventions	Outcomes	Notes
Williams, 1998	Randomisation: Randomised by blocks (FPG after 2 weeks off diabetes medication (<7.8, 7.8 – 11.1, >11.1 mmol/l)). Allocation concealment: unclear ITT: no	Inclusion criteria: T2DM, 30-70 years, 20% above ideal body weight based on Metropolitan Life Insurance norms, not receiving insulin therapy at the time of recruitment. Exclusion criteria: Subjects with a history of liver, renal or heart diseases that would contraindicate the use of a VLED were excluded. Gender: women/men: a: 11/7, b: 9/9, c:11/7 Age: years (SD): a: 54.1 (7.0), b:51.4 (7.9), c: 50.3 (8.6) Body weight(kg): mean (SD) a: 98.9 (17.6) b: 103.5 (16.8), c: 104.8 (13.7) BMI (kg/m^2): mean (SD) a: 35.0 (5.2) b: 35.4 (5.4), c: 37.3 (4.8) Baseline comparability: yes	Active intervention length a: 20wks, b + c: 20wks (20 days within the 20 weeks on a VLED) Description of intervention a: SBT: 1500-1800 kcal/d for 20 wks b: Week 1: SBT (1500-1800 kcal/d); Week 2: VLED (400-600 kcal /d) for 5 days/wk; Week 3-17: VLED (400-600 kcal/d) for 1 day/wk; otherwise SBT (1500-1800 kcal/d); Week 18-20: SBT (1500-1800 kcal/d) c: Week 1: SBT (1500-1800 kcal/d); Week 2, 7, 12 and 17: VLED (400-600 kcal /d) for 5 consecutive days/wk; Week 18-20: SBT (1500-1800 kcal/d) a + b + c: 20-wk behavioural treatment programme with weekly group meetings including instructions on behavioural modification, exercise and diet. Subjects used diaries to record daily caloric intake and exercise. Techniques for stimulus control, modifying cognitions, relapse prevention and self-reinforcement were presented/taught. Subjects were given a calorie goal of 1500 – 1800 kcal/d and were encouraged to keep their fat intake below 20% of the daily calorie intake. Diaries were reviewed weekly and subjects were given individualised comments to ensure compliance with the protocol. Allocated: a: 18, b: 18, c: 18 Completed: a: 16, b: 16, c: 15 at 20 weeks % dropout: a: 11.1%, b: 11.1%, c: 16.2% Assessed: a + b + c: 54 at baseline, 49 at week 10, 47 at week 20.	Points of follow-up: a + b + c: weeks 0, 3, 10 and 20 Outcomes measured Body weight, BMI, FPG, HBA1c, insulin, TC, TG.	Sponsorship: National Institutes of Health Research Training in Diabetes and Endocrinology
T2DM = type 2 diabetes mellitus; VLED = very low energy diet; BMI = Body Mass Index; FPG = fasting plasma glucose; TC = total cholesterol; TG= total triglycerides.					

Continued

Study ID	Methods	Participants	Interventions	Outcomes	Notes
Wing, 1991a Wing, 1991b	Randomisation: Randomisation procedure not stated. Allocation concealment: unclear ITT: no	Inclusion criteria: T2DM, 35-70 years, 30% above ideal body weight based on Metropolitan Life Insurance norms Exclusion criteria: Subjects with a history of liver, renal or heart diseases that would contraindicate the use of a VLED were excluded. Gender: information provided only for 33 completers: women/men a: 12/4, b: 13/4 Age: information provided only for 33 completers: years (SD): a: 51.9 (9.9), b:50.6 (7.7) Body weight(kg): information provided only for 33 completers: mean (SD) a: 104.5 (21.5) b: 102.1 (11.7) BMI (kg/m^2): information provided only for 33 completers: mean (SD) a: 38.1 (5.7) b: 37.34 (4.7) Baseline comparability: yes	Active intervention length a + b: 20wks + maintenance meetings at weeks 24, 28, 46 and 72 Description of intervention a: LED: week 0-20: 1000 - 1500 kcal/d (intervention period); week 21-72: 1000 - 1500 kcal/d (weight maintenance) b: VLED: week 0–4: 1000 - 1500 kcal/d; week 5-12: 400-500 kcal/d; week 13-20: 1000 kcal/d; week 21-72: 1000 - 1500 kcal/d (weight maintenance) a + b: 20-wk behavioural treatment programme with weekly group meetings including instructions on behavioural modification, exercise and diet. Subjects were given weekly exercise goals. Techniques for stimulus control, modifying cognitions, relapse prevention and self-reinforcement were presented/taught. Subjects deposited $150 which was earned back weekly for meeting set goals. Subjects used diaries to record exercise and food intake and completed a self-reported measure of PA and the use of behavioural strategies. Allocated: a: 19, b: 17 Completed: a: 16, b: 17, at both, week 20 and year 1 % dropout: a: 15.8%, b: 0% Assessed: a + b: 36 at baseline, week 20 and year 1	Points of follow-up: a + b: weeks 0, 20, 72 Outcomes measured Body weight, BMI, FPG, insulin, HBA1c, TC, TG, PA, use of behavioural strategies, depressive symptomatology, anxiety, hunger.	Sponsorship: Western Pennsylvania Affiliate of the American Diabetes Association and the National Institutes of Health (Bethesda, Md)

T2DM = type 2 diabetes mellitus; VLED = very low calorie diet; LED = low energy diet; BT = behavioural treatment, BMI = Body Mass Index; PA = physical activity; FPG = fasting plasma glucose; TC = total cholesterol; TG = total triglycerides. Continued

Study ID	Methods	Participants	Interventions	Outcomes	Notes
Wing, 1994a Harvey, 1993 Smith, 1991 Wing, 1994b Wing, 1995 Wing, 1996	Randomisation: Randomisation procedure not stated. Allocation concealment: unclear ITT: no	Inclusion criteria: T2DM, 30-70 years, 30% or 18 kg (22.7 kg in Harvey 1993) above ideal body weight based on Metropolitan Life Insurance norms Exclusion criteria: Subjects with health problems that would contraindicate the use of a VLED were excluded, including liver or renal diseases, cancer or recent myocardial infarction. Gender: women/men: a: 30/18, b: 30/15 Age: years (SD): a: 51.3 (8.7), b:52.3 (10.7) Body weight(kg): mean (SD) a: 107.7 (18.7), b: 105.8 (19.4) BMI (kg/m^2): mean (SD) a: 38.3 (6.52) b: 37.42 (6.13) Baseline comparability: yes	Active intervention length a + b: not clear, Figure 1 (p. 355) shows 48 weeks, authors mention 50 weeks in the abstract and 52 in the body of the paper. Description of intervention a: LED + BT: week 0-48: 1000 - 1200 kcal/d (intervention period); Subjects were encouraged to keep their fat intake below 30% of the daily calorie intake. b: VLED + BT: weeks 0–12 and 24-36: 400 – 500 kcal/d + vitamins and supplements, otherwise 1000 - 1500 kcal/d; a + b: 50-wk behavioural treatment programme with weekly group meetings including instructions on behavioural modification, exercise and diet. Subjects were given weekly exercise goals. Behavioural lectures focused on techniques for stimulus control, preplanning, relapse prevention, modifying cognitions, and self-monitoring, self-reinforcement and role-playing. Subjects deposited $150 which was earned back weekly for meeting set goals and attending sessions. Subjects used self-monitoring diaries to record food intake and expenditure and were periodically contacted by telephone to assess dietary lapses. Allocated: a: 48, b: 45 Completed: a: 41, b: 38, at 1 year assessment % dropout: a: 14.6%, b: 15.6% Assessed: a: 41, b: 38 at year 1 (for overall effects) a: 33, b: 34 at months 0, 3, 6, 9 and 12	Points of follow-up: a + b: months 0, 3, 6, 9 and 12 Outcomes measured Body weight, BMI, FPG, insulin, urinary ketones, HBA1c, TC, TG, dietary lapses and triggers, cravings or desires,	Sponsorship: National Institutes of Health (Bethesda, Md)
T2DM = type 2 diabetes mellitus; VLED = very low energy diet; LED = low calorie diet; BT = behavioural treatment FPG = fasting plasma glucose; TC = total cholesterol; TG = total triglycerides; HBA1c = glycosylated haemoglobin. Continued					

Non-randomised controlled studies

Study ID	Methods	Participants	Interventions	Outcomes	Notes
Jackness, 2013	Randomisation: Allocation by patient preference Allocation concealment: no ITT: no	Inclusion criteria: T2DM, 18-65 years, BMI>35kg/m^2 HbA1c = 6.5-12% (48-108mmol/mol) Exclusion criteria: Use of thiazolidinedione or insulin at a dose of >60 units/d; use of dipeptidyl peptidase-4 inhibitor or GLP-1 receptor agonist for >12 months; fasting triglycerides > 400mg/dL; weight change >5% in the previous 3 months, or significant illness Gender: women/men a: 8/6, b: 7/4 Age: mean (SD); a: 51.9 (2.0), b:44.6 (3.0) Body weight(kg): mean (SD) a: 114.2 (6.6) b: 121.4 (6.7) BMI (kg/m^2): mean (SD); a: 39.2 (1.0) b: 43.2 (2.3) Baseline comparability: yes	Active intervention length a + b: 3 weeks Description of intervention a: VLED: day 1: 360 kcal/d; day 2-24: 500kcal/d b: RYGB b: in the RYGB condition, post-operative VLED is assumed of cca 500 kcal/d until end of week 3 Allocated: a: 14, b: 11 Completed: Assumed: a: 14, b: 11 % dropout: Assumed a: 0%, b: 0% Assessed: a + b: 25 at baseline and follow-up at week 3	Points of follow-up: a + b: week 3 (21 ± 1day) Outcomes measured: Weight, FPG fructosamine, C-peptide, insulin, Sg, Si, AIR, ACPR,	Sponsorship: NIH grant DK072011, NCRR grant UL1 RR024156, pilot grant from Columbia Diabetes Research Center NIH grant DK63608, NIH T32 Training Grant DK07271

T2DM = type 2 diabetes mellitus; VLED = very low energy diet; RYGB = Roux-en-Y gastric bypass; BMI = Body Mass Index; FPG = fasting plasma glucose; HBA1c = glycosylated haemoglobin; AIR = acute insulin response to glucose, Sg = sensitivity of glucose elimination to insulin; Si = insulin sensitivity; ACPR = acute c-peptide response;

Continued

Study ID	Methods	Participants	Interventions	Outcomes	Notes
Lips, 2013a Lips, 2013b Lips, 2013c	Randomisation: Allocation by patient preference Allocation concealment: no ITT: no	Inclusion criteria: T2DM, age: 18-65, BMI≥ 35kg/m^2, participants must have failed to lose weight or to maintain long-term weight loss despite appropriate non-surgical methods. Exclusion criteria: Smoking; age>65; any chronic disease other than diabetes, including psychiatric illness. Gender: women/men a: 12/0, b: 15/0 Age: mean (SD): a + b: 51.0 (7.1) Body weight(kg): mean (SD) a: 112.0 (17.7) b: 121.4 (15.9) BMI (kg/m^2): mean (SD) a: 40.2 (6.4) b: 43.5 (4.2) Baseline comparability: yes.	Active intervention length a + b: 3 months Description of intervention a: VLED: week 0-3: 600 kcal/d (intervention period); week 3-8: 800-1000kcal/d; after 2 months: 1200 kcal/d b: RYGB: first 5 days after operation: <600 kcal/d; , week 1-3: gradual increase to 700-800 kcal/d; Week 3 – month 3: 1200 kcal/d Allocated: a: 12, b: 15 Completed: a: 12, b: 15, at week 3 a: 10, b: 11, at month 3 % dropout: a: 16.7%, b: 26.7% Assessed: a + b: 27 at baseline, 22 at week 3 and month 3.	Points of follow-up: a + b: weeks 0, 20, 72 Outcomes measured Body weight, BMI, FPG, insulin, HBA1c, TC, TG, PA, use of behavioural strategies, depressive symptomatology, anxiety, hunger.	Sponsorship: Center for Translational Molecular Medicine project grant PREDICCt (01C-104); unrestricted grant from the Dutch Obesity Clinic.

T2DM = type 2 diabetes mellitus; VLED = very low energy diet; RYGB = Roux-en-Y gastric bypass, BMI = Body Mass Index; PA = physical activity; FPG = fasting plasma glucose; TC = total cholesterol; TG = total triglycerides; HBA1c = glycosylated haemoglobin. Continued

Study ID	Methods	Participants	Interventions	Outcomes	Notes
Paisey, 2002 Paisey, 1998 Paisey, 1995	Randomisation: Allocation by patient preference Allocation concealment: no ITT: no	Inclusion criteria: T2DM and non-T2DM, 25-70 years, obese Exclusion criteria: Not stated Gender: women/men a: 7/7, b: 11/3, c: 13/6 Age: years (SD): a: 53.9 (5.7), b:55.4 (7.3), c: 50.3 (8.8) Body weight (kg): mean (range) a: 99.5 (90-111) b: 96.5 (82-112), c: 103.0 (90-119) BMI (kg/m^2): mean (range) a: 34.0 (31-38) b: 36.0 (31-42), c: 36.0 (35-41) Baseline comparability: unclear	Active intervention length a + c: 3-5 months with possible repetition within the 3-year study b: 3 years Description of intervention a + c: VLED: 400-470 kcal/d for women, 540 – 670 kcal/d for men for 3-5 months and repeated in course of the study if appropriate. Subjects paid for the VLED themselves (£24/week for men, £18/week for women). Subjects set weight loss targets and counselling was provided about weight loss maintenance after discontinuation of the VLED. One demonstration of low-fat cooking with printed instructions was provided. Monthly group discussions were available after stopping the VLED. c: ICD + exercise: Low fat, low sugar and high fibre intake advised, 5-day self-report food records were collected and discussed individually, repeated every 6-8 weeks. Aerobic exercises with encouragement performed at each visit followed by a group discussion on nutrition. a + b + c: Parallel weekly sessions (1.5-2 hrs) to measure outcomes took place. Allocated: a: 14, b: 14, c: 19, d: 5 (d: non-diabetics in the ICD group excluded from analysis because of low numbers) Completed: a: 14, b: 14, c: 19 at month 3, 6, 12 % dropout: a: 0%, b: 0%, c: 0% Assessed: a: 14, b: 14, c: 19 at month 3, 6, 12, then annually	Points of follow-up: a + b + c: months 0, 3, 6, 12, 24, 36, 60 Outcomes measured Body weight, BMI, BP, waist, waist/hip ratio, urinary ketones, FPG, serum fructosamine, TC, TG, hepatic and renal function, QoL	Paisey, 1995 reports 14, 14 and 19 participants in diabetic VLED, diabetic ICD and non-diabetic VLED respectively, however the report from 1998 and 2002 report 15, 15 and 19 participants for the same groups. We used the smaller sample size for our analyses, for which the weight data was available. There may be a typing mistake in the amount of calories; Paisey, 1995 reports 540 – 670 kcal/d, while Paisey, 1998 reports 540 – 570 kcal/d for men. Sponsorship: Torbay Hospital Special Medical Projects Grant Fund, the Torbay Branch of the BDA, University of Plymouth.
T2DM = type 2 diabetes mellitus; VLED = very low energy diet; ICD = Intensive conventional diet; BP = blood pressure; TC = total cholesterol; TG = total triglycerides; QoL = quality of life; FPG = fasting plasma glucose. Continued					

Study ID	Methods	Participants	Interventions	Outcomes	Notes
Plum, 2011 (study 2)	Randomisation: Allocation by patient preference Allocation concealment: no ITT: no	Inclusion criteria: Subjects with FPG ≥ 126 mg/dl or on antidiabetic medication + self-reported history of T2DM Exclusion criteria: Use of thiozolidinedione or insulin at dose > 50 IU/d, weight change >5% within the past 3 months, significant illness Gender: women/men a: 4/3, b: 5/2 Age: years (SEM): a: 51.7 (3.5), b:50.0 (3.9) Body weight: mean (SEM) a: 122.7 (7.0) b: 132.0 (8.0) BMI (kg/m^2): mean (SEM) a: 43.3 (1.8) b: 46.8 (3.1) Baseline comparability: unclear	Active intervention length a + b: until 7-10 % of body weight lost reached Description of intervention a: VLED: 800 kcal/d b: RYGB + subjects followed dietary instructions after the surgical intervention Allocated: a: 7, b: 7 Completed: a: 7, b: 7, at both pre- and post-intervention % dropout: a: 0%, b: 0% Assessed: a: 7, b: 7, at both pre- and post-intervention	Points of follow-up: a: dependent on reaching the weight loss goal Outcomes measured Body weight, BMI, glucostatic measures, peptides, lipids, body composition	There is probably a typing mistake in the age stated, since the mean age for group b: is 5.0 instead of 50.0 or perhaps 55.0. Sponsorship: National Institutes of Health, National Center for Research resources, New York Obesity Research Center, Deutche Forschungsgemeinschaft
T2DM = type 2 diabetes mellitus; VLED = very low energy diet; RYGB = Roux-en-Y Gastric Bypass; FPG = fasting plasma glucose. Continued					

Study ID	Methods	Participants	Interventions	Outcomes	Notes
Snel, 2012 Snel, 2011	Randomisation: First 13 participants assigned to condition “a”, the rest to condition “b” Allocation concealment: no ITT: no	Inclusion criteria: Insulin-dependent T2DM, BMI> 30 kg/m^2, insulin use > 20 IU/d with or without glucose-lowering medication, fasting plasma C-peptide level> 0.8ng/mL and a 2-fold increase of the basal C-peptide level in response to administration of 1 mg glucagon intravenously. Exclusion criteria: Smoking, known history of CVD and/or other chronic or endocrine disease, weight change within the past 3 months and silent myocardial ischemia, signs of depression or antidepressant medication Gender: women/men a: 5/8, b: 8/6, c: 26/28, d: 26/28 Age: years (SEM): a: 56.0 (2.0), b:59.0 (2.0) Body weight: mean (SEM) a: 114.0 (5.0) b: 113.0 (6.0), c: 112.0 (3.0), d: 73.0 (2.0) BMI (kg/m^2): mean (SEM) a: 36.4 (1.1) b: 37.9 (1.4), c: 37.6 (0.7), d: 23.8 (0.3) Baseline comparability: unclear	Active intervention length a + b: 4 months c + d: obese and lean controls measured at baseline only Description of intervention a: VLED + ex: 450 kcal/d + training min. of 30 min at 70% of max. aerobic capacity 4 d/week for + 1 hour in-hospital training. Weekly visits at hospital for support, outcome measures and heart-rate monitor readings. b: VLED: 450 kcal/d a + b: A 1800 kcal/d diet was reintroduced after the VLED and referred to routine care thereafter. Allocated: a: 13, b: 14, c: 54, d: 54 Completed: a: 13, b: 14 % dropout: a: 0%, b: 0% Assessed: a: 13, b: 14 at month 0, 4, 6 and 18	Points of follow-up: a + b: months 0, 4, 6, 18 Outcomes measured Body weight, BMI, waist, fat mass, BP, HR, HbA1c, FPG, fasting insulin, HOMA-IR, TC, TG, FFA, QoL (well-being, fatigue, anxiety, depression,	Sponsorship: Roba Metals BV, The Netherlands; Nutrition & Santé, Belgium.
BMI = Body Mass Index; BP = blood pressure; HR = heart rate; FPG = fasting plasma glucose; HOMA-IR = homeostatic model assessment of insulin resistance; TC = total cholesterol; TG = total triglycerides; FFA = free fatty acids, QoL = quality of life Continued					

Appendix 4. A list of references to studies excluded from the systematic review.

No BMI BMI>25 kg/m2

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Appendix 5. Meta-analyses of weight loss – forest plots

Weight loss (RCTs only)

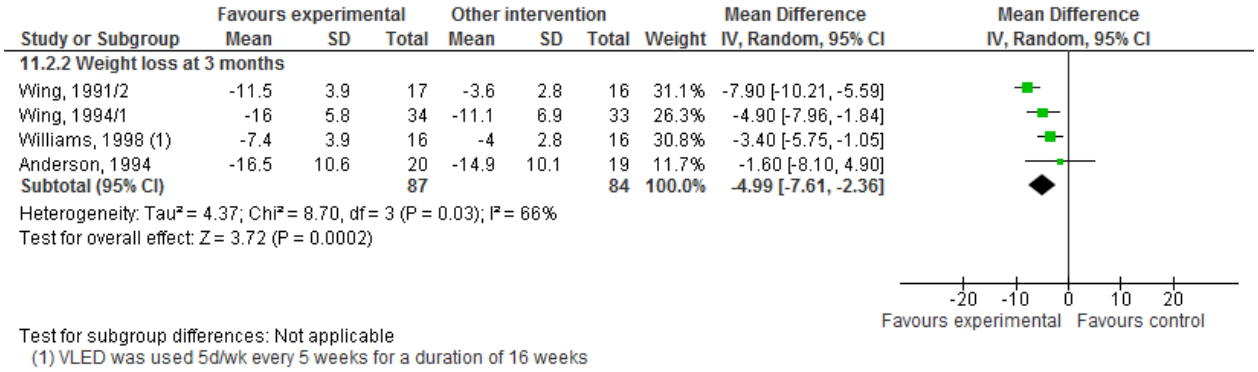


Figure 1. Forest plot of mean differences (MD) in weight change between intervention (VLED) and control groups (BT; BT; SBT; VLED + food, respectively) at 3 months, 95% confidence intervals.

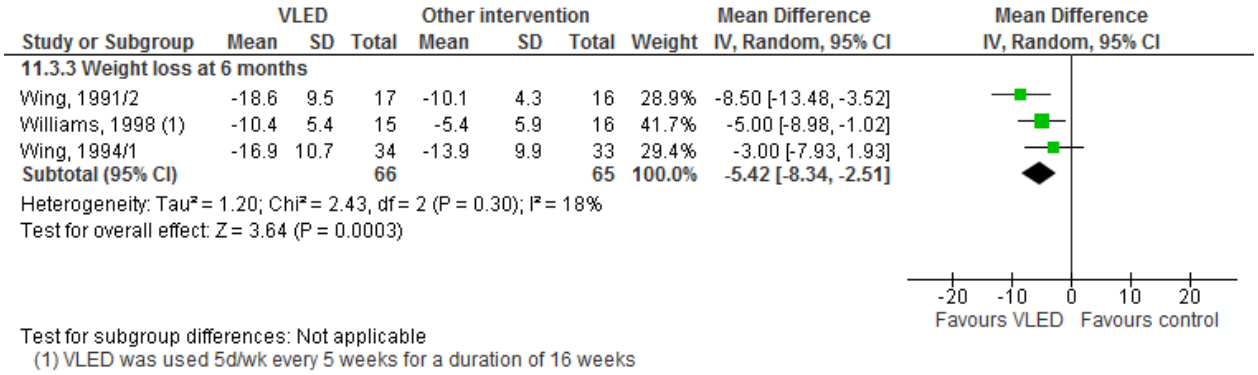


Figure 2. Forest plot of mean differences (MD) in weight change between intervention (VLED) and control groups (BT; SBT; BT, respectively) at 6 months, 95% confidence intervals.

Weight loss by comparisons

VLED only vs. VLED with additional components

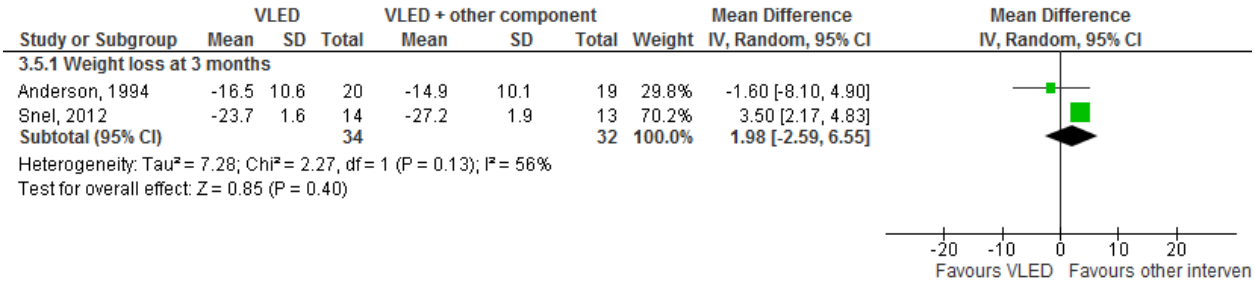


Figure 3. Forest plot of mean differences (MD) in weight change between intervention (VLED) and control groups (VLED + food; VLED + exercise respectively) at 3 months, 95% confidence intervals.

VLED only vs. minimal intervention or standard care

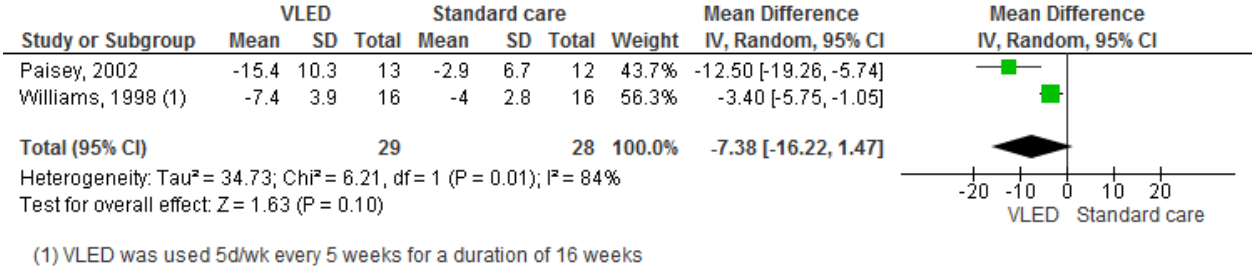


Figure 4. Forest plot of mean differences (MD) in weight change between intervention (VLED) and control groups (ICD; SBT, respectively) at 3 months, 95% confidence intervals.

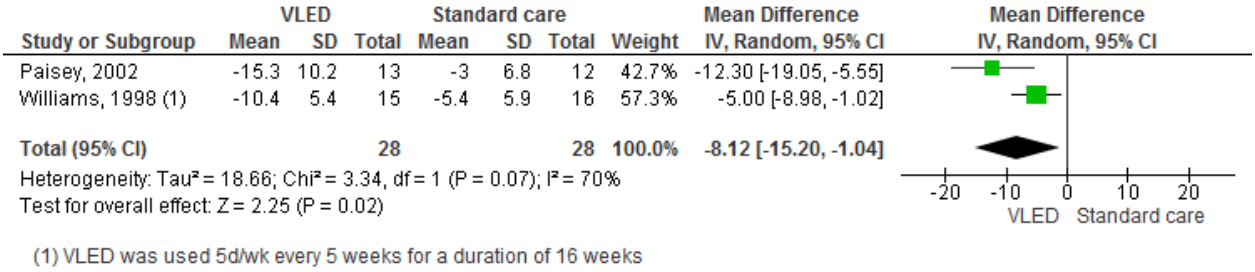


Figure 5. Forest plot of mean differences (MD) in weight change between intervention (VLED) and control groups (ICD; SBT, respectively) at 6 months, 95% confidence intervals.

VLED + BT vs. LED + BT

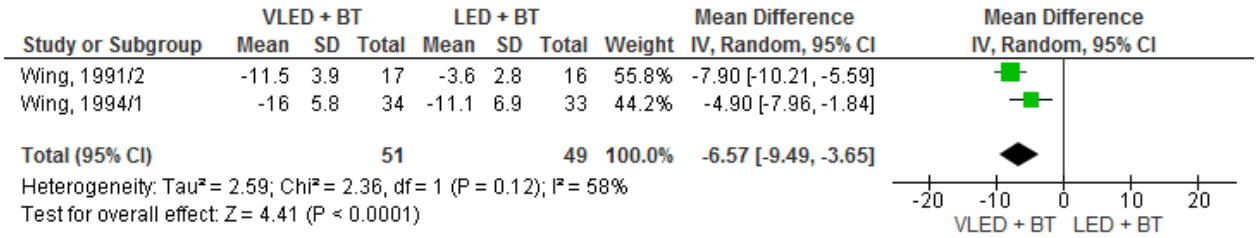


Figure 6. Forest plot of mean differences (MD) in weight change between intervention (VLED + BT) and control groups (LED + BT) at 3 months, 95% confidence intervals.

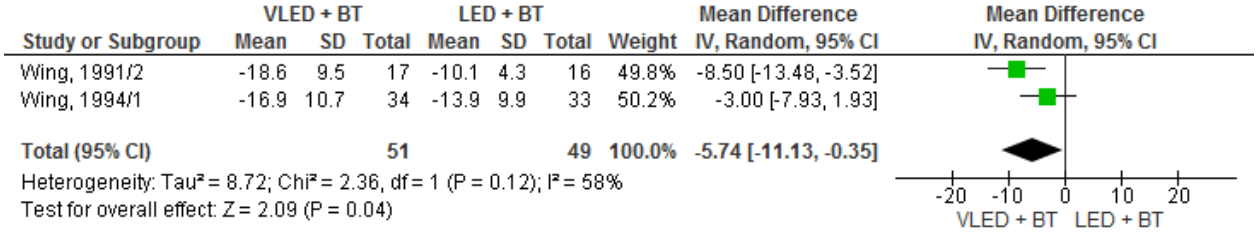


Figure 7. Forest plot of mean differences (MD) in weight change between intervention (VLED + BT) and control groups (LED + BT) at 6 months, 95% confidence intervals.

VLED vs. RYGB

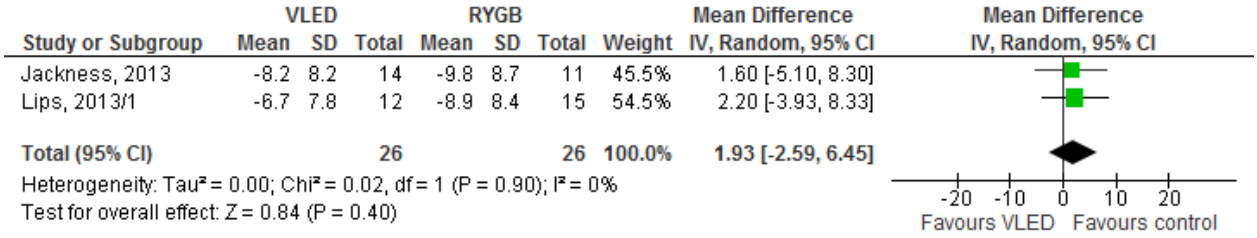


Figure 8. Forest plot of mean differences (MD) in weight change between intervention (VLED) and control groups (RYGB) at 3 weeks, 95% confidence intervals.

Appendix 6. Meta-analyses of blood glucose levels–forest plots

Blood glucose levels by comparisons

VLED vs. VLED + additional component

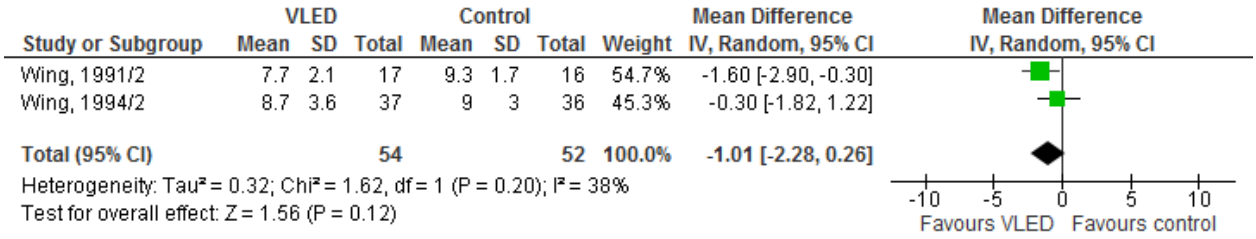


Figure 9. Forest plot of mean differences (MD) in fasting plasma glucose levels between intervention (VLED) and control groups (VLED + food; VLED + exercise) at month 6, 95% confidence intervals.

VLED vs. VLED + other component

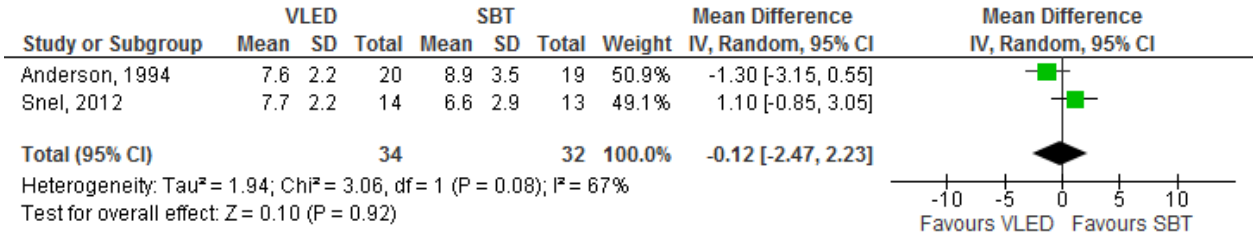


Figure 10. Forest plot of mean differences (MD) in fasting plasma glucose levels between intervention (VLED) and control groups (VLED + food; VLED + exercise) at month 3, 95% confidence intervals.

VLED + BT vs. LED + BT

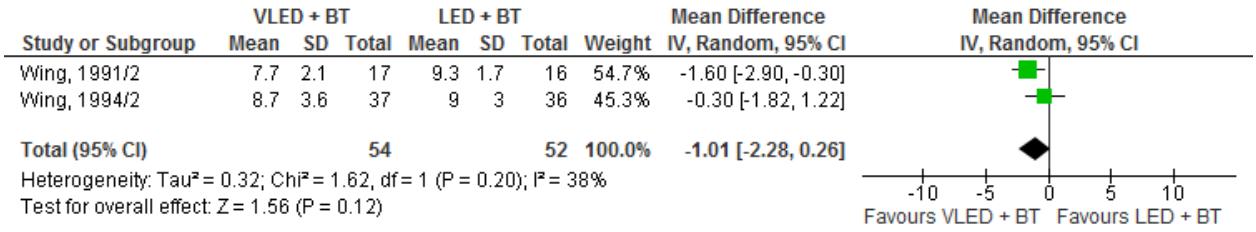


Figure 11. Forest plot of mean differences (MD) in fasting plasma glucose levels between intervention (VLED + BT) and control groups (LED + BT) at month 6, 95% confidence intervals.

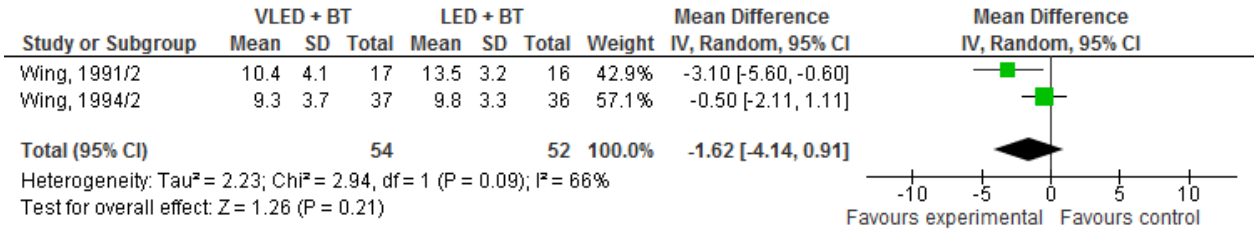


Figure 12. Forest plot of mean differences (MD) in fasting plasma glucose levels between intervention (VLED + BT) and control groups (LED + BT) at month 12, 95% confidence intervals.

VLED vs. RYGB

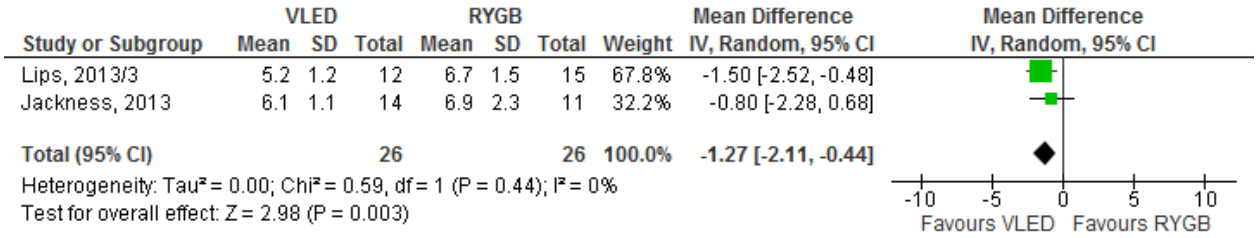
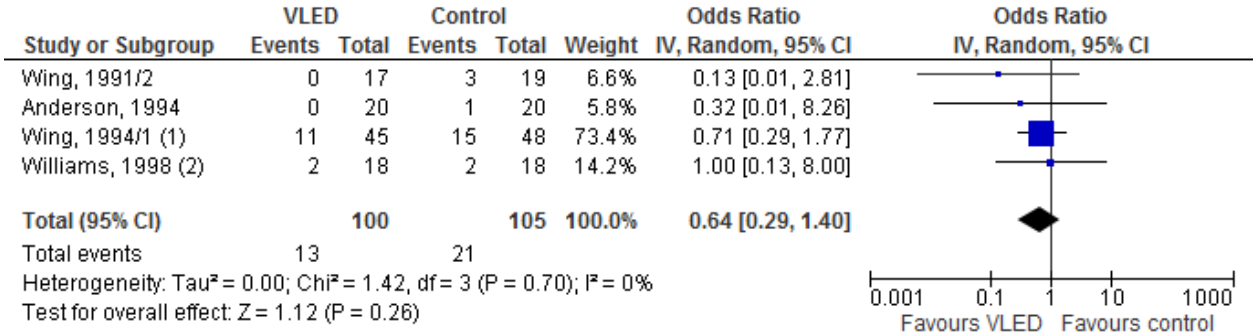


Figure 13. Forest plot of mean differences (MD) in fasting plasma glucose levels between intervention (VLED) and control groups (RYGB) at week 3, 95% confidence intervals.

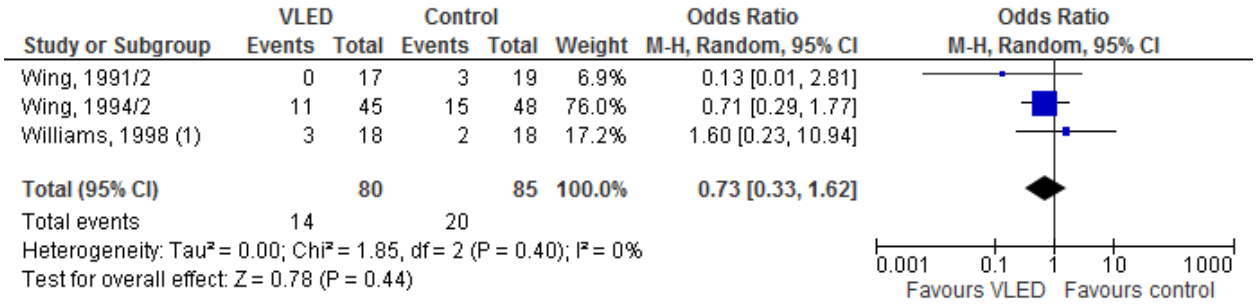
Appendix 7. Meta-analyses of attrition – forest plots

VLED vs. Comparators, overall meta-analyses



(1) Participants who completed all assessments at all time points
(2) VLED was used 5d/wk every 5 weeks for a duration of 16 weeks

Figure 14. Forest plot of odds ratios (OR) with 99% confidence intervals, showing attrition in intervention and control groups in RCTs at month 3.



(1) VLED was used 5d/wk every 5 weeks for a duration of 16 weeks

Figure 15. Forest plot of odds ratios (OR) with 99% confidence intervals, showing attrition in intervention and control groups in RCTs at month 6.

Attrition by comparisons

VLED only vs. minimal intervention or standard care

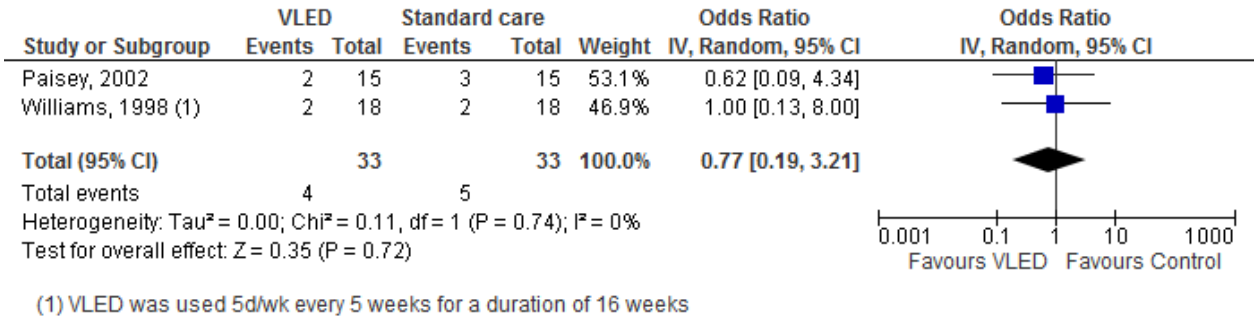


Figure 16. Forest plot of odds ratios (OR) with 95% confidence intervals, showing attrition in intervention and control groups (ICD and SBT respectively) in RCTs and NRCTs at month 3.

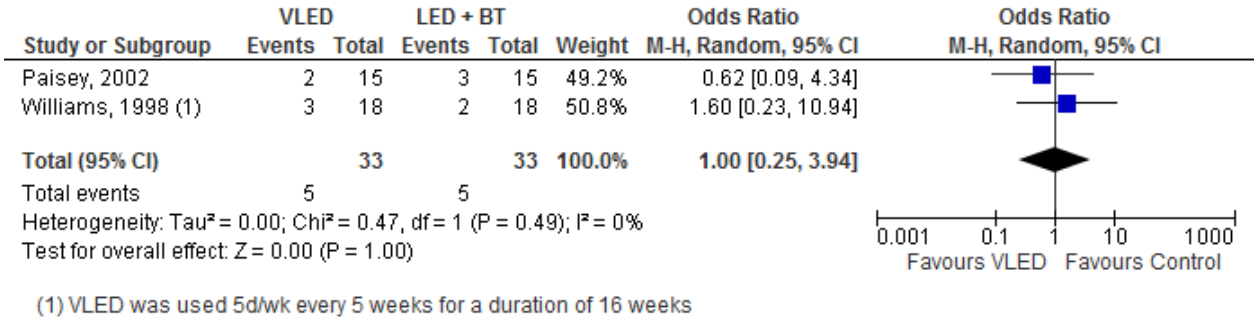


Figure 17. Forest plot of odds ratios (OR) with 95% confidence intervals, showing attrition in intervention and control groups (ICD and SBT respectively) in RCTs and NRCTs at month 6.

VLED + BT vs. LED + BT

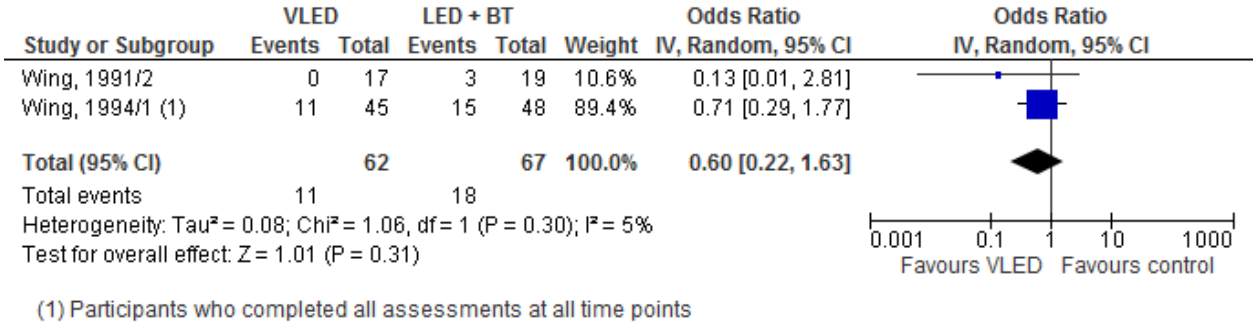


Figure 18. Forest plot of odds ratios (OR) with 95% confidence intervals, showing attrition in intervention and control groups at month 3 and 6 (attrition remained the same).

VLED vs. VLED + other component

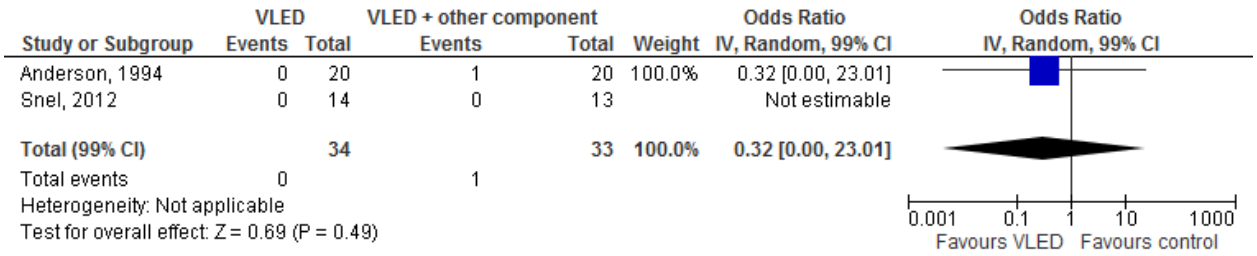


Figure 19. Forest plot of odds ratios (OR) with 99% confidence intervals, showing attrition in intervention and control groups at month 3.

Appendix 8. Reported adverse events per condition in studies included in the systematic review.

Study ID Reported side effects and adverse events	**Anderson, 1994**		**Williams, 1998**$^{\Delta}$			**Wing, 1991**		**Wing, 1994**		**Plum, 2011**†		**Jackness, 2013**†		**Lips, 2013**		**Snel, 2012**†		**Paisey, 2002**	
	VLED	VLED + Food	1-day VLED	5-day VLED	BT	VLED + BT	LED + BT	VLED + BT	LED + BT†	VLED	RYGB	VLED	RYGB	VLED	RYGB	VLED	VLED + Exercise	VLED	ICD
Constipation	X	X				X	X	X											
Diarrhea	X	X				X	X												
Dizziness	X	X				X	X												
Fatigue	X	X																	
Flu/sore throat	X	X																	
Headache	X	X																X	
Hunger pangs																		X	
Vomiting	X	X				X	X												
Weakness						X	X												
Muscle cramps	X	X																	
Syncope	X	X																	
Cold intolerance						X	X	X											
Hair loss/ telogen effluvium								X										X	
Dry skin						X	X												
Serious hypoglycaemic episode																		X	
Non-fatal MI																		X	X
Blurred vision	X	X																	
Elevated levels of uric acid						X													
Mild post-operative complications															X				
Death																			X•

• Primary reason for death was biliary cirrhosis; Δ Reported no side effects; † Side effects not addressed. The presence of an adverse event is marked X.

Appendix 9. Behaviour change techniques used in studies, coded by the CALO-RE taxonomy

Study Name		Follow-up	Anderson 1994		Snel 2012		Jacknes s 2013		Lips 2013		Plum 2011		Paisey 2002		Williams 1998		Wing 1991		Wing 1994	
Intervention vs. comparison			VLED vs. VLED + food		VLED vs. VLED + Exercise		VLED vs. RYGB		VLED vs. RYGB		VLED vs. RYGB*		VLED vs. ICD		5-day VLED vs. LED		VLED vs. LED		VLED vs. LED	
							VLED Vs. RYGB								VLED vs. LED					
Effect size (Weight loss, kg)		3 months	-0.15		2.00				0.52				-1.43		-1.00		-2.32		-0.77	
		6 months											-1.40		-0.88		-1.14		-0.29	
Effect size (FPG, mmol/L)		3 months	-0.45		0.42				0.09				-0.63							
		6 months			0.36								-0.20				-0.84		-0.09	
			I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
CALO-RE BCTs																				
Goal setting (behaviour)															X	X	X	X	X	X
Goal setting (outcome)											X	X	X	X		X				
Barrier identification/problem solving																			X	X
Set graded task															X	X	X	X	X	X
Prompt review of behavioural goals															X	X			X	X
Provide rewards contingent on successful behaviour																	X	X	X	X
Provide feedback on performance														X	X	X				
Instruction on how to perform the behaviour						X							X	X	X	X				
Environmental restructuring															X	X	X	X		
Model/demonstrate the behaviour													X	X						
Prompt practice																			X	X
Relapse prevention/coping planning															X	X	X	X	X	X
General communication skills training																			X	X

Note. The presence of a BCT is marked X. Only BCTs coded in either the intervention of the comparator groups are presented. I = Intervention; C = Comparator; FPG = fasting plasma glucose

* Outcome measures were taken at different time points; after 3 weeks in the RYGB group and after 8 weeks in the VLED group;

Appendix 10. Topic guide for T1 interviews

Interviewer`s protocol

Hello NAME, my name is Lucia and I am a member of the research team carrying out the Counterbalance study. We will meet several times during the study to see what your experience of the programme is and how you are doing overall. Everything we will talk about is confidential and anonymous and only very few members of the team will be able to look at the content of the interviews for the purposes of analysis. I will use a recorder so that I can go back to what we will have talked about, but please try to ignore the recorder if possible and make yourself comfortable, this will be a very informal conversation. You can stop the interview or withdraw completely at any time.

Feel free to interrupt me with questions if you have any. Should we start with the interview?

Interview questions

1. How did you learn about the Counterbalance programme?
2. What influenced your decision to take part in the Counterbalance programme? [Prompts]: Social environment, Health concerns, Self-image, Life events...
3. Are there any changes happening in your life at the moment?
4. Have you tried a diet like this before?
5. [If yes]: What have you tried? How did it go? Why did you stop? What worked and what didn`t? What was the result? What made it easier/more difficult for you to comply with the programme?
6. What are your both positive and negative expectations of the very low calories diet?
7. What do you hope to achieve by the end of the Counterbalance programme and beyond?

Appendix 11.Topic guide for T2 interviews

Interviewer`s protocol

1. Greet and explain the purpose of the interview.
2. Ensure that the participant understands that the interview is confidential.
3. Support to be as open as possible.
4. Explain that the interview will be audio-recorded, ask participants to ignore the recorder if possible.
5. Remind them that they can stop or withdraw from the interview at any time.
6. Ask whether they have any questions/concerns.

Interview questions

1. You have now completed the VLED phase of the programme. Could you please tell me about your overall experience of it? (Prompts: cravings/satisfaction, temptations to break the diet, mood, motivation, barriers /facilitators of adherence, weight loss, and strategies used to succeed, support from friends and family members, GP experience after coming off the diet?)
2. How satisfied are you with the very low calorie diet and the outcomes you have achieved? [Prompts: weight lost, ease of following, food allowed, energy levels, dosage,.]
3. Have you noticed any week-to-week changes within the last 4 weeks? (same prompts as above)
4. What has the transition period been like?
5. Would you change anything about the diet?
6. What was your experience of the diet in comparison with other diets you have tried?
7. Have you experienced any lapse(s) within the last 4 weeks of the VLED?
   [If yes] Can you tell me more about specific situation/s when this has happened? How did you feel after you had lapsed? Has anything changed since the lapse (for example did you put any measures in place to reduce the chance of it happening again?
   [If not] What helped you successfully continue with the regime/ overcome your temptations? Did you have a strategy from the start? If so, would you mind describing it? How did you feel like after you resisted possible temptations? Has anything changed since then?
8. What kind of support (if any) would you have appreciated during the second phase of the VLCD? [from the team/his relatives; VLCD-related]
9. How did you find these interview sessions during the VLCD?
10. Has anything in your life changed within the last 4 weeks of the VLCD? [Prompts: physiological or psychological changes; any circumstances different from when they started the diet or different from the end of the first 4 weeks].

Ask whether the participant continues with the weight maintenance phase

[if yes] continue with the questions below

[if not] ask whether he would be able to spare a few minutes telling you about the reasons he does not wish to continue (use Topic guide No. 3)

11. What are your positive and negative expectations of the 6-month weight loss maintenance phase of the programme?
12. Have you tried a weight maintenance programme before?
13. [If yes]: What have you tried? How did it go? Why did you stop? What worked and what didn`t? What was the result? What made it easier/more difficult for you to comply with the programme?
14. How confident are you that you can complete this phase of the programme? [Prompts: weight goals, fitness level, energy, self-confidence, creating habits]
15. What kind of support (if any) would you appreciate at this stage of the programme?

Appendix 12. A list of strategies that the participants found helpful for their adherence with the VLED.

Group	Strategy
Food removal	1. Throwing away/giving away/eating up leftovers before starting on a diet 2. Not buying undesired food in 3. Hiding undesired food out of sight 4. Freezing undesired food so that it`s not immediately available during a craving
Avoidance of	5. Places where there is limited choice or lack of healthy food options 6. Watching TV to avoid looking at food adverts or habitual snacking 7. Social events with abundance of food 8. Shopping in shopping centres – shopping can be done online instead 9. Eating with other people
Planning	10. Planning the logistics of being on a diet – e.g. food shopping/cooking/eating times/attendance at social events etc.. and coming to terms with the plan 11. Thinking about and preparing food for the next day 12. Cooking in batches and freezing food for quick healthy meals 13. Carrying healthy nibbles around (e.g. carrot s ticks, pieces of apple etc..) 14. Carrying a bottle of water around
Hunger management	15. Drinking water throughout the day 16. Drinking water when starting feeling hungry 17. Spreading meals throughout the day 18. Adding spices and herbs to shakes to increase variability and palatability 19. Drinking the VLED shakes hot or very cold to increase palatability 20. Getting active/distracting oneself from thinking about food (e.g. gardening, hobbies etc..) 21. Adding more water to the VLED shakes to increase volume 22. Chewing a gum or a sugar-free mint 23. Going to bed earlier 24. Allowing oneself a taste of food to satisfy curiosity and prevent cravings 25. Self-talk and negotiation when tempted, weighing the pros and cons of eating undesired food 26. Reminding oneself of their goals 27. Reminding oneself of their success 28. Becoming aware of situations in which one feels tempted 29. Being kind to oneself after a lapse and carrying on with the plan
Social	30. Telling other people about one`s weight loss attempt to prevent temptations from others, to get support and understanding and to increase commitment to one`s weight loss plan 31. Getting a weight loss buddy to share experiences and tips with, to be accountable to and to facilitate adherence (this would ideally be a partner). 32. Getting monitored by a third party – e.g. asking one`s GP practice for regular weigh-ins

Appendix 13. A list of behaviours of other people that the participants found helpful for their adherence with the VLED.

1. Giving compliments on effort, appearance, energy etc.
2. Eating at different times
3. Refraining from offering food
4. Giving the person notice before cooking
5. Reminding the person of what they are or are not allowed to eat and drink
6. Embarking on their own weight loss alongside the person
7. When asked, giving advice from relevant experience
8. Encouraging the person to keep going
9. Cooking meals for themselves or getting ready meals If the person on the diet is the main cook at home
10. When cooking, leaving pieces of vegetables on the side for the person to nibble on
11. Not buying in unhealthy food
12. Joining the person in non-food related activities
13. Enabling time off work for regular appointments
14. Healthcare professionals: providing regular monitoring of weight and blood glucose levels
15. Healthcare professionals: providing physical feedback on the person`s health outcomes (e.g. graphs, scans etc..)
16. Healthcare professionals: providing individualised behavioural support
17. Healthcare professionals: explaining in detail any queries the person may have in relation to the diet and their health
18. Healthcare professionals: being available to respond to queries by telephone or e-mail in-between appointments if needed.

Appendix 14. Topic guide for T3 interviews

Interviewer`s protocol

1. Greet and explain the purpose of the interview.
2. Ensure that the participant understands that the interview is confidential and materials used will be looked at by a very small team of researchers. Support to be as open as possible.
3. Explain that the interview will be audio-recorded, ask participants to ignore the recorder if possible.
4. Remind them that they can stop or withdraw from the interview at any time.
5. Ask whether they have any questions/concerns.

Interview questions

1. Could you please tell me about your overall experience of the diet you have had? (Prompts: cravings/satisfaction, temptations to break the diet, mood, motivation, barriers /facilitators of adherence, weight lost, strategies you have used to stick to the diet, support you have received from family and friends?).
2. Has anything changed in your life since the end of the VLED?
3. How satisfied are/were you with the diet?
4. How satisfied are you with the results of the weight loss maintenance phase of the programme?
5. Have you experienced any lapse(s)/deviations from the amount of calories recommended within the last 6 months?
6. [If yes] Can you tell me more about specific situation/s when this happened? What did you feel like after the lapse? How did you get back on track following the lapse? Has anything changed since then?
7. [If not] What helped you stick to the diet and overcome any possible temptations? Did you have a strategy in place? How did you feel after you managed to resist? Has anything changed since then?
8. What additional support would you have appreciated during the weight loss maintenance phase of the programme and why?
9. Do you feel you have learned anything from this phase of the study that you can continue to use once the study ends?
10. To what extent do you feel you could have followed this programme with the same degree of success if it was run in primary care?
11. If you could add anything else to the programme what would it be?
12. If you could change anything about the programme what would it be?
13. What three things have been most useful to you while following this programme?
14. Finally are there any other comments you would like to make about the programme?
15. What would be your message to a person who is thinking of taking part in this programme?

Appendix 15. Topic guide for interviews with participants who withdrew from the study

Interviewer`s protocol

1. Greet and explain the purpose of the interview.
2. Ensure that the participant understands that the interview is confidential and materials used will be looked at by a very small team of researchers. Support to be as open as possible.
3. Explain that the interview will be audio-recorded, ask participants to ignore the recorder if possible.
4. Remind them that they can stop or withdraw from the interview at any time.
5. Ask whether they have any questions/concerns.
6. Thank for participation at the end of the interview.

Interview questions

1. Could you tell me again why did you decide to take part in the Counterbalance programme?
2. Could you describe the circumstances or reason(s) that meant you made the decision to leave the programme at this point?
3. What parts of the programme did you find most difficult? Could you tell me why?
4. What parts of the programme did you find easiest to manage or most enjoyable?
5. What do you think would have helped you to stay in the programme possibly to the end?
6. Are you still trying or planning to lose weight (if yes, how are you planning to do it)?
7. Finally would you ever consider taking part in a study of this kind again (Prompt: If answer a simple yes or no ask: could you please explain your answer?

Appendix 16. A list of strategies that the participants found helpful for their adherence with a weight maintenance plan

Group	Strategy
Monitoring	1. Keeping a daily food diary 2. Keeping a daily physical activity diary 3. Regular weighing 4. Regular physical activity 5. Losing a bit more weight than the goal to allow for weight fluctuation (e.g. during stressful periods, holidays, festive seasons etc…) Portion control: 6. Adjusting portion size according to recommendations (e.g. from books with pictures of what a portion size looks like on a plate) 7. Getting smaller plates 8. Buying smaller bottles /ordering smaller glasses of alcohol 9. If eating out, ordering more starters rather than a starter and a main meal or sharing a main meal. 10. Weighing food on kitchen scales when cooking at home 11. Cutting food into smaller pieces 12. Throwing away old oversized clothes
Planning	13. Looking at menus ahead of eating out to be able to choose the healthiest option 14. Eating before going out to avoid unhealthy foods and cravings 15. Planning meals and buying ingredients for the meals rather than “for the fridge” 16. Doing smaller and more frequent shopping to get fresh fruits and vegetables 17. Making a shopping list and sticking to it 18. Avoiding shopping aisles with unhealthy food 19. Cooking from scratch
Finding alternatives	20. Reading food labels when buying food 21. Looking for healthier alternatives to one`s choice when buying food
Compensating	22. Increase physical activity before or after eating too much 23. Reduce calorie intake before after eating too much

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