WEIGHT GAIN PREVENTION DURING THE CHRISTMAS HOLIDAY PERIOD: EXPLORING EFFECTIVENESS AND PARTICIPANT EXPERIENCES OF A BEHAVIOURAL INTERVENTION

By

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ABSTRACT

Weight is increasing in the population and holidays, such as Christmas, have been identified as high-risk periods. This thesis presents the development of a behavioural intervention to prevent weight gain over the Christmas period, its evaluation in a Randomised Controlled Trial (The Winter Weight Watch study), and an exploration of participant experiences of the intervention. The possible mechanisms of action of the intervention are also explored.

The intervention consisted of encouragement to regularly self-weigh and record weight, physical activity calorie equivalent (PACE) information about commonly consumed festive foods and drinks and weight management tips. The hypothesised main mechanism of action was that each component would promote restraint of energy intake, preventing weight gain over Christmas.

The RCT showed the intervention to be effective in preventing weight gain. At follow up the difference in weight between intervention and control groups (adjusting for baseline weight) was -0.49kg. Conscious energy restraint scores increased in the intervention group. The qualitative study showed that participants found the concept of weight gain prevention at Christmas acceptable. Self-weighing and PACE information were key drivers in encouraging restraint of energy intake. PACE information mainly prompted participants to restrain energy intake rather than increase physical activity

In conclusion, the developed intervention prevented weight gain during the Christmas period and was acceptable to participants. PACE information and self-weighing were found to be key drivers of self-regulatory behaviours. These findings hold promise for preventing weight gain during high risk periods.

DEDICATION

DEDICATED TO MY PARENTS JOHN AND LIZ; MY HUSBAND JON-KRIS; AND MY THREE WONDERFUL CHILDREN, OSCAR, JUDE AND CONNIE.

ACKNOWLEDGEMENTS

I would firstly like to thank the research team involved with the Winter Weight Watch study for their hard work and support; Ryan Griffin, Sue Clifford and Janice Gunnell. Thank you also to Alice Sitch and Christina Easter for their statistical input to the published paper and to the PPI group. I would also like to thank all of the workplaces, schools and social media pages for supporting the recruitment stage of the trial. Thank you also to each person who expressed an interest or participated in the study, without whom this research would not be possible.

I would like to express my sincere thanks to my supervisory team; Dr Miranda Pallan; Dr Amanda Farley and Professor Amanda Daley. Dr Miranda Pallan; thank you for agreeing to 'take me on' halfway through my studentship at a tricky stage and for your vital input, time and kindness. Dr Amanda Farley: your support with data collection during the RCT and involvement in the qualitative work in particular was invaluable: thank you for your time and patience. Professor Amanda Daley; thank you for giving me the opportunity and for all of your time, advice, patience and encouragement. I have gained so much from working with you all and it's because of you that I have enjoyed this experience so much. Thank you also to my PhD friends Janice and James for their support.

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STATEMENT OF CONTRIBUTIONS

The work presented in this thesis has arisen from the original research idea proposed by Professor Amanda Daley and Dr Amanda Farley to secure the University of Birmingham's Medical School Studentship award. Prior to commencement of the studentship, I worked to develop the study protocol deciding on inclusion/exclusion criteria, outcome measures, recruitment procedures and trial implementation. This work was undertaken prior to commencement of the studentship to obtain ethical approval to commence the study in time for the Christmas period. Upon commencement of the studentship, I further developed the intervention, refining intervention components and producing the intervention materials. I was the principal investigator for both of the studies included in this thesis.

For the RCT, I developed the materials for the Winter Weight Watch study with support from my supervisors. I formulated the recruitment strategy, developed the training manual, delivered the training to researchers and conducted most of the home visits at baseline and follow up. I developed the statistical analysis plan with my supervisors. For the published paper, I wrote the first draft and finalised the version for publication with input from supervisors. Analysis of the primary and secondary outcomes was conducted by Christina Easter and Alice Sitch, which I then re performed for the thesis chapter. I also independently analysed additional outcomes not included in the published paper for the thesis chapter.

For the qualitative study, I wrote the protocol with support from my supervisors. I applied for and obtained ethical approval for the study. I developed the topic guide with supervisory support and sampled and recruited participants. I conducted all of the interviews and transcribed half of these. The coding framework was developed iteratively with Dr Amanda Farley following independent, initial coding. I conducted the analysis and wrote the chapter.

I am the author of this thesis and have received supervisory support from Dr Miranda Pallan, Dr Amanda Farley and Professor Amanda Daley.

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LIST OF ABBREVIATIONS

BMI	Body mass index
CI	Confidence interval
DXA	Dual Energy X Ray Absorptiometry: a method of assessment used for percentage body fat, fat mass, and fat-free mass
IMD	Index of multiple deprivation: the official measure of relative deprivation for small areas in England
kg	Kilogram
kcal	Kilocalorie
kJ	Kilojoule
MPH	Miles per hour
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PACE	Physical activity calorie equivalent
RCT	Randomised controlled trial
SD	Standard deviation: a statistic used to measure the variance relative to the mean value
SE	Standard Error: the approximate standard deviation of a statistical sample population
WHO	The World Health Organisation
WWW	The Winter Weight Watch study

OVERVIEW OF THE THESIS

CHAPTER 1

Chapter 1 presents an introduction to the thesis, briefly describing the background, development of an intervention and testing of the intervention. The introduction also sets out the aims and objectives of the thesis.

CHAPTER 2

Chapter 2 presents a review of the current literature. The review begins by examining the current evidence around overweight and obesity, the aetiology, the impact upon health and the prevalence. The incidence of weight gain is also explored, establishing the high-risk occasions for weight gain to occur. The evidence pertaining to the prevention of weight gain is also examined and the effectiveness of weight gain prevention interventions explored.

CHAPTER 3

Chapter 3 presents the development of an intervention to prevent weight gain during the Christmas holiday period. The chapter describes, in detail, the process of intervention development, the identification and selection of a theoretical basis, and the evidence relating to theory and the intervention components. The chapter also sets out a logic model hypothesising the mechanisms of action for how the intervention will work to produce the desired outcome of weight gain prevention.

CHAPTER 4

Chapter 4 presents the quantitative research which tested the intervention developed and described in Chapter 3. The Chapter describes the randomised controlled trial (The Winter Weight Watch Study) which tested the effectiveness of the intervention on preventing weight gain during the Christmas holiday period. The outcomes of the trial are reported according to CONSORT guidelines.

CHAPTER 5

Chapter 5 describes the nested qualitative study. Background, philosophical positioning, aims and objectives, analyses and methods are presented. The main themes arising from the analyses are presented in this chapter, including a comparison of participants' descriptions to the hypothesised mechanisms of action proposed in the logic model. This chapter adds to the quantitative findings, building a more complete picture of how the intervention worked based on the direct experiences of the individuals involved.

CHAPTER 6

Chapter 6 presents the discussion for the work presented in this thesis. The discussion includes the results of an evaluation of the proposed logic model presented in Chapter 3 and presents a revised logic model for the intervention. Additionally, an examination of the implications for future practice and policy is also described based on the findings of the work. Overall conclusions based on the research presented in this thesis are also represented.

CHAPTER 1

1.0 INTRODUCTION

This research was funded by the University of Birmingham's Medical School studentship award. A list of publications arising from this work is available in Appendix 1.

1.1 Background

Obesity is a global public health concern. Excess weight shortens and reduces quality of life and is linked to a number of non-communicable diseases such as type 2 diabetes, cancer and cardiovascular disease [1-3]. The costs of treating obesity are placing intense pressure on health services [4]. Furthermore, the prevalence of obesity has doubled in over 70 countries since 1980 [5] and an annual increase in weight among populations is reported [6]. Studies demonstrate that this weight increase is largely attributable to discrete episodes, such as holiday periods [7], rather than a sustained excess of daily energy intake. The average weight gain per holiday is reported as 0.4-0.9 kg per holiday occasion [7]. Further studies have identified that the Christmas period is a particular occasion where weight gain is common and that the weight gained is not fully lost, persisting into the summer months [8]. Consequently, weight gain prevention is identified as a key strategy for obesity prevention by a number of health organisations [9-11]. Despite this, there is limited evidence relating to the effectiveness of interventions in adults and no evidence of the effectiveness of interventions targeting high risk occasions for weight gain such as holiday periods. The aim of this research is to investigate behavioural strategies for preventing weight gain in the adult population during occasions where the proclivity for weight gain is great. Therefore, this thesis presents the development of such an intervention, evaluates its effectiveness using a randomised controlled trial design, and explores the participant experiences and intervention mechanisms of action through a

nested qualitative study. Finally, the thesis concludes by discussing the implications of the results.

1.2 Development of a weight gain prevention intervention

The prevention of weight gain requires an individual to assess and alter both their dietary and physical activity behaviours [12]. Rigorous intervention development is key to maximising the prospect of effectiveness and may be guided by a framework produced by the Medical Research Council for the development of complex interventions [13, 14]. The MRC's framework for intervention development is broad and encompasses all complex interventions, providing three initial phases which focus predominantly on development of the intervention and its theoretical basis: 1) identifying the evidence base; 2) identifying and developing theory; 3) modelling the processes and mechanisms of action and their interactions. These phases were adopted as part of the development of the behavioural intervention tested in this thesis and are described in detail in Chapter 3. Phase 2 of the framework focuses on the identification of an appropriate theoretical basis for the intervention; evidence suggests that behavioural interventions informed by theoretical approaches can increase the prospect of effectiveness [15] and that the use of theory in interventions is often poorly described or omitted in the reporting of trials [16]. In consideration of this, a range of theories were explored, and self-regulation theory and the habit formation model were identified as theoretical frameworks on which to base the intervention development. In line with phase 3 of the framework, a logic model, modelling the mechanisms and processes for how the intervention would produce the desired outcome was developed for the intervention. The logic model hypothesised that the intervention components would promote the conscious restraint of energy intake, which would lead to weight gain prevention.

1.3 Testing of a weight gain prevention intervention

To test the intervention, a randomised controlled trial was identified as the most appropriate study design. RCTs enable a cause-effect relationship to be determined between a treatment (intervention) and the specified outcome [17]. The random allocation of participants and the concealment of allocation ensures that any differences in characteristics across study arms are due to chance. Bias and confounders can also be limited through blinding and intention to treat (ITT) analysis.

1.4 Exploring the intervention

In addition to analysing the effectiveness of the intervention, it was important in this case to understand the views of those who had experienced it. The combination of qualitative and quantitative research is increasingly used in health services research, particularly in trials of complex interventions [18]. Qualitative research can provide an enriched understanding of an intervention [19]. In this work, the qualitative research enabled a deeper understanding of: i) how participants may use the intervention to prevent weight gain and their experience of this; ii) their thoughts and feelings about the novel component of this work: weight gain prevention at Christmas; and iii) their suggestions for improvements and enhancements to the intervention. Mixed methods research enables integration of the findings of research and may provide readers with an increased confidence in the results [20]. The combination of quantitative and qualitative research methods as a mixed methods approach in this work aimed to ensure true integration of findings, support the validity and credibility of the outcomes and help to provide a broader perspective to research questions.

1.5 Aims and Objectives

The aim of this thesis is to evaluate the effectiveness of a multicomponent behavioural intervention that intended to prevent weight gain during the Christmas period, and to explore participants' experiences of the intervention.

The thesis objectives were as follows:

1. To examine the evidence around overweight and obesity and the associated burden on health, high risk periods for weight gain, strategies for weight gain prevention, and effective interventions. This is presented in Chapter 2.
2. Using the published literature, identify components of a weight gain prevention intervention targeting high risk periods for weight gain that are underpinned by behavioural theory. This is presented in Chapter 3.
3. To evaluate the effectiveness of a multi-component behavioural intervention to prevent weight gain during the Christmas holiday period (developed in objective 2) in a randomised controlled trial. This is presented in Chapter 4.
4. To explore the acceptability and experiences of participants engaging with the intervention and any barriers/facilitators they may have experienced.
5. To explore the intervention mechanisms of action of the intervention. Objectives 4 and 5 will be met through a qualitative study nested within the RCT. This is presented in Chapter 5.
6. To provide conclusions on the effectiveness of the intervention to prevent weight gain during high risk occasions and the mechanisms through which this is achieved, ideas for future research and implications for future public health policy. This is presented in Chapter 6.

CHAPTER 2

2.0 LITERATURE REVIEW

This chapter aims to present a review of the literature in relation to overweight and obesity and the prevention of weight gain. Weight gain amongst populations is explored, outlining the high-risk periods for weight gain. The overview of literature provides the rationale for the weight gain prevention intervention that is the focus of this thesis.

2.1 The burden of overweight and obesity

Obesity is a leading cause of preventable death across the world [21]. A systematic evaluation assessed the global trends in prevalence and the disease burden of obesity in 125 countries between the years 1990 and 2015 [22]. The evaluation estimated the prevalence of overweight and obesity in adults and children using the comparative risk assessment method [23] from the Global Burden of Disease study from 1990 – 2015 [22]. Globally, 603.7 million adults and 107.7 million children were estimated to be obese in 2015 with the prevalence of obesity doubling in over 70 countries since 1980. Additionally, high BMI accounted for four million deaths and 120 million disability-adjusted life years worldwide in 2015. In the United Kingdom, the prevalence of overweight and obesity was reported to be 68% and 58% for women and men respectively in 2015 [24]. Obesity prevalence in the UK has increased from 15% in 1993 to 27% in 2015. Furthermore, 2016/17 saw 617,000 hospital admissions citing obesity as a factor for the admission [25]; an increase of 18% from the previous year.

2.1.2 The definition of obesity

Obesity is defined as an excess or abnormal accumulation of adipose tissue which may impair health [21]. The most widely used measure of obesity is Body Mass Index (BMI) (formally

known as the Quetelet index), an index for weight to height classification. In 2000, the WHO published international BMI benchmarks for classifying overweight and obesity based on obesity related disease risk [26]. In adults, overweight is defined as a BMI of ≥25kg/m² and obesity as a BMI of ≥30kg/m². BMI is widely used as an indicator of the degree of overweight and obesity at a population level. On an individual level however, using BMI has some disadvantages as it does not distinguish between body fat and muscle mass thus individuals with a high ratio of lean muscle mass may be misclassified as overweight or obese despite not having an excess accumulation of body fat [27]. BMI is also known to underestimate obesity in some ethnic groups due to ethnic variations in body composition [28]. Caution therefore needs to be observed when assessing obesity using BMI at an individual level.

Table 1: The International Classification of adult underweight, overweight and obesity according to BMI.

Classification	**BMI (kg/m²)**	
	Principal cut-off points	**Additional cut off points**
Underweight	**<18.50**	**<18.50**
Severe thinness	<16.00	<16.00
Moderate thinness	16.00 – 16.99	16.00 – 16.99
Mild thinness	17.00 – 18.49	17.00 – 18.49
Normal range	**18.50 – 24.99**	**18.50 – 22.99**
		23.00 – 24.99
Overweight	**≥25.00**	**≥25.00**
Pre-obese	25.00 – 29.99	25.00 – 27.49
		27.50 – 29.99
Obese	**≥30.00**	**≥30.00**
Obese class I	30.00 – 34.99	30.00 – 32.49
		32.50 – 34.99
Obese class II	35.00 – 39.99	35.00 – 37.49
		37.50 – 39.99
Obese class III	≥40.00	≥40.00

Source: Adapted from WHO, 1995, WHO, 2000 and WHO 2004 [9, 26].

2.1.3 The classification of obesity

Obesity was introduced to the International Classification of Diseases (ICD) in the 1950s. The ICD Obesity is currently listed under ICD-10 code E66. A review conducted by the European Association for the Study of Obesity proposed novel criteria to redefine the classification of overweight and obesity (ICD-11) believing this to improve the assessment of patients leading to more clinically meaningful diagnoses. Obesity is classified as a disease due to both the increased mortality and morbidity associated with it. A meta-analysis analysing all-cause mortality reported that relative to normal weight, a BMI of >30kg/m² was associated with significantly higher all-cause mortality [29]. In addition to increased mortality rates, there is also evidence to demonstrate that obesity significantly increases the risk of morbidity as it is a risk factor for chronic illnesses such as type 2 diabetes, heart disease and cancer [30, 31]. Furthermore, many other co-morbidities are associated with obesity such as sleep apnoea, arthritis, non-alcoholic fatty liver disease, depression and low mood, gout and infertility [32]. The associated morbidity of overweight and obesity in particular, place a large burden on the National Health Service (NHS). The NHS costs attributable to being overweight and obese are estimated to reach £9.7 billion by 2050 [30]. With rates continuing to increase, associated costs will place ever increasing pressure on health services.

2.2 The causes of overweight and obesity

The aetiology of overweight and obesity is greatly multifaceted. Interacting factors including physical, environmental, social, genetic and economic can all contribute to and exacerbate obesity. The UK government's Foresight programme produced a report in 2007 which set out the many causal factors of obesity and how they interact with one another to contribute to and exacerbate the condition [33]. The Foresight report identified some of the underlying drivers that

influence diet and physical activity in the population. This section describes some of these contributing factors.

2.2.1 Energy intake

Overweight and obesity are caused by a sustained imbalance between energy consumed and energy expended. Energy is measured in kilocalories (calories) or kilojoules. Energy imbalance resulting in overweight and obesity is an intake of calories that exceeds corresponding energy expenditure [34]. In other words, when energy intake is greater than energy output for a sustained period, the excess calories are stored in the body as fat and weight gain occurs. Energy intake is in the form of calories contained within food and drink. Energy output is measured through the calories expended through physical activity and metabolic processes such as temperature regulation, digestion and respiration.

Environment is recognised as a contributing factor to obesity due to the prevalence and promotion of energy dense foods and drinks, encouraging overconsumption. The availability and accessibility of highly palatable, inexpensive, readily available, energy-dense foods, which are often provided in large portion sizes, add considerably to daily caloric intake [35, 36]. Overconsumption can also be driven by hedonic hunger or hedonic hyperphagia which is an overconsumption driven by pleasure rather than biological need [37]. Individuals, therefore, respond and are driven to consume due to the sight, sound, smell or even the thought of highly palatable food. The desire to eat can therefore be driven equally by either biological need (energy deficit) or a reward response (pleasure) [38]. Studies using functional brain imagery pinpoint the mechanism of action involved in the hedonic response [39]. In contrast to the homeostatic response where the stimulation to eat is in response to depleted energy stores, the hedonic pathway is stimulated in response to the presence of highly palatable foods,

overriding the homeostatic response during periods of energy abundance: the food environment. The hedonic response subsequently triggers the reward response system resulting in the release of dopamine and the sensation of pleasure and reward [40]. Significantly for obesity research, studies have demonstrated that obese individuals may have a reduced pleasure response stimulated by dopamine making them more likely to over consume highly palatable foods in order to experience the associated reward [41-46]. Overcoming these environmental triggers to over consume is challenging for individuals. Simple, effective strategies are therefore highly important to support individuals to prevent weight gain.

In the UK, current recommendations for daily calorie intake are 2500 for men and 2000 for women [47]. Data from the National Diet and Nutrition Survey (NDNS) revealed that adults reported that they typically consume 1800 calories each day (mean); 18-20% below the recommended daily intake or the estimated average intake (EAR) for energy [48]. Given that overweight and obesity are increasing, it is unlikely that the population are consuming too few calories. These data are therefore likely to be subject to underreporting: a common issue in dietary assessment studies using self-reported data [49-51]. A further validation study with a sub-set of NDNS respondents (using the doubly labelled water (DLW) method, the gold standard for the measurement of total energy expenditure [52, 53], and extensively used for validation of dietary assessment methods), energy intake was shown to be 34% greater than that reported. Consequently, further analyses using Health Survey for England (HSE) data [54] demonstrated that energy intakes were in excess of daily recommendations on average (195 kcal). The HSE comprises a series of annual surveys conducted amongst adults living in private households covering topics related to health and factors affecting health. The HSE uses a complex random probability design using postcodes to broadly represent the population. According to these data, overweight and obese adults on average consumed 320

excess calories per day. In response to this, Public Health England initiated a calorie reduction campaign recommending a distribution of calories across meals: 400:600:600 [55]. Daily calorie intake recommendations remain unchanged.

2.2.2 Energy expenditure

As the energy balance equation includes both energy intake and energy expenditure it is important to explore trends in energy expenditure as well as energy intake to describe the aetiology of overweight and obesity. Energy expenditure occurs as a result of physical activity or metabolic processes (resting energy expenditure and thermogenesis). In 2012, 31.1% of adults were reported to be physically inactive worldwide according to surveillance data from 122 countries [56]. In the UK, current physical activity recommendations for good health are for adults to engage in at least 150 minutes of moderate intensity physical activity per week [57]. According to data from the HSE's 2016 report, 66% of men and 58% of women were meeting the Government's target of 150 minutes of moderate intensity physical activity per week [58]. Participants were asked how often they engaged in physical activity and for how long. Trend analysis showed little difference in self-reported activity levels since the previous HSE survey conducted in 2012. However, these findings should be interpreted with caution due to the self-report nature of data collection [59]. Objectively measured data from accelerometers found that only ~6% of adults were meeting the Government target [60]. Analysis of the long term secular trends in physical activity levels are not in accordance with the rate of increase in obesity levels and therefore may not be the most influential factor when considering the rising prevalence of obesity [61].

2.3 Weight gain

As discussed, overweight and obesity are most commonly caused by increases in energy intake without compensatory increases in energy expenditure. At a population level body weight increases annually [62, 63]. Furthermore, population weight tracking studies highlight that rather than small, steady and sustained increases in weight, the majority of annual weight gain happens rapidly during discrete periods of time [64]. One study in particular demonstrated that the Christmas period was responsible for the majority of weight gained annually across three different countries [8].

2.3.1 High risk occasions for weight gain: narrative reviews

Narrative reviews have reported the evidence relating to the impact of the holiday season on body weight. A narrative review by Diaz-Zavala and colleagues, published in 2017 [7], conducted a search on databases using the keywords "holiday/holidays" and "weight gain/obesity". Researchers defined the holiday season as typically starting from the last week in November to the first or second week of January. They also specified that studies must include at least one measurement of weight or BMI before and after the holiday season. In total, 15 studies were selected for inclusion in the review [8, 64-76]. Studies were split into the following groups; adults in the general population (n=6) [64, 66, 68-71], adults seeking to lose weight (n=6) [65, 67, 72, 75-77], motivated self-monitoring adults (n=1) [8], college students (n=1) [74] and children (n=1) [73]. Studies demonstrated a consistent increase in body weight during the holiday period. This was true for all studies including adults from the general population (n=6) except for one, where no significant changes in body weight were observed during the holiday period [71]. However, this outlying study was conducted amongst only a small number of participants (n=34) and may therefore be considered less applicable at a population level.

Four of the other adult studies included in the review reported increases in weight of between 0.6 to 0.9kg [66, 68-70] with one reporting an increase of 0.4kg [64]. In the studies including adults seeking to lose weight, increases in body weight were also reported (0.3-0.9kg), but these increases were only significant in two of six studies. Motivated, self-monitoring people also increased their weight during the holiday occasion. Importantly, the review also noted that the BMI of participants impacted on the amount of weight gained with a number of studies reporting that their obese and overweight participants gained more weight than their normal weight counterparts [64, 70, 73, 74, 78].

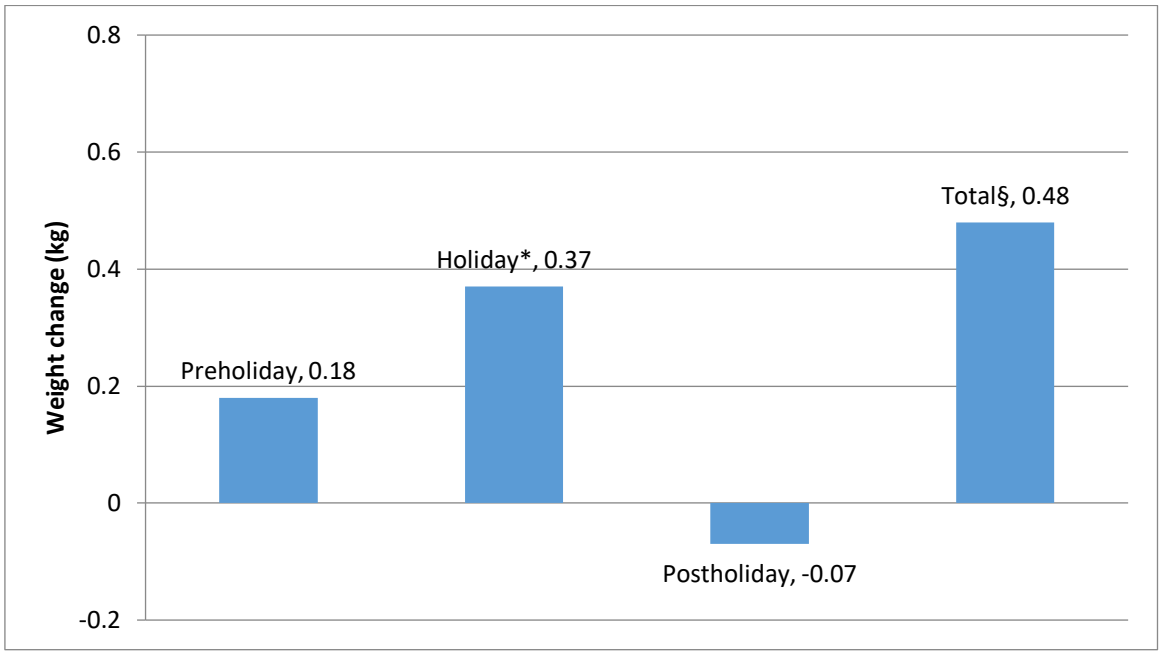
Another review published in 2014 by Schoeller and colleagues [6], analysed data from eight studies tracking body weight over the year [64, 66, 70, 72-74, 79, 80]. Methods used in the selection of studies were not specified. This narrative review reported average holiday weight gain to be between 0.4kg and 0.7kg, similar to that found by Diaz-Zavala and colleagues. Seven studies conducted amongst adults and one amongst children were included. Six out of the seven adult studies reported an increase in weight during the holiday season [64, 66, 70, 72, 79, 80]. Although one study reported no increase in weight, an increase in fat mass (measured by DXA) was observed which was consistent with other studies where body composition was measured. This is concerning due to the negative impact of increased fat mass on mortality [81, 82]. Holiday weight gain was reported to be the largest contributor to annual weight gain, and importantly these gains were shown to be frequently retained post-holiday (3 months post mid-January). As in the Diaz-Zavala review, obese and overweight participants gained more weight than participants with a BMI in the healthy range, suggesting that these groups may be more susceptible to greater weight gains during holiday periods

2.3.2 Primary research studies: weight gain and holidays

One important study included in both reviews is worthy of individual mention here. Yanovski and colleagues investigated weight gained during holiday occasions amongst a sample of 195 American adults [64]. This study demonstrated a seasonal increase in body weight between mid-November and mid-January. Methods included the recruitment of participants for a purpose of studying the "seasonal changes in vital signs" through the use of advertisements. Participants were included if they were aged 18 years and above, of good general health status and willing to participate in all study visits. Body weight was measured to the nearest 0.01kg over four time points every 6-8 weeks to determine weight change for three identified periods: pre-holiday (late September-mid November); holiday (mid-November to mid-January); and post-holiday (mid-January to early March). Additionally, participants were also weighed again the following October to assess the changes in body weight over a one-year period. Participants were blinded to the main outcome of interest (body weight) by researchers completing additional measurements at each study visit. Results showed a significant change in weight during the study. Mean weight was increased significantly during the holiday period (0.37 ± 1.52kg; range, -6.96kg to 4.07kg). When compared to their weight in the previous September/October, participants had an average net weight gain of 0.48 ± 2.22kg at the February/March measurement point (range, -9.33kg to 8.02kg). Therefore, significantly, these data show the average annual holiday weight gain was not lost during the 3-month post-holiday period. The study also reported that the average annual weight gain was 0.62kg (0.62 ± 3.03kg), meaning that the holiday weight gain (0.37kg) accounted for 65% of the average annual weight gain amongst the study population. Furthermore, analysis of data from participants with weight gains of greater than 2.3kg demonstrated that the relative incidence

of a higher weight gain was greatest among those who were obese, a finding of clinical importance due to the risk of obesity-related conditions.

Figure 1: Weight change during holiday phases* adapted from Yanovski et. al. [64]



*Weight change in 195 subjects. Pre-holiday: interval from late September or early October, to mid-November (before Thanksgiving); Holiday: winter holiday interval from mid-November to early January (after New Year's Day); Post-holiday: interval from early January to late February or early March; Total: interval from first measurement in late September or early October to last measurement in late February or early March. *P<0.001, weight increase during the Holiday interval and P<0.002, Holiday vs. Post-Holiday interval. §P<0.003 weight increase over total measurement period from September to March.

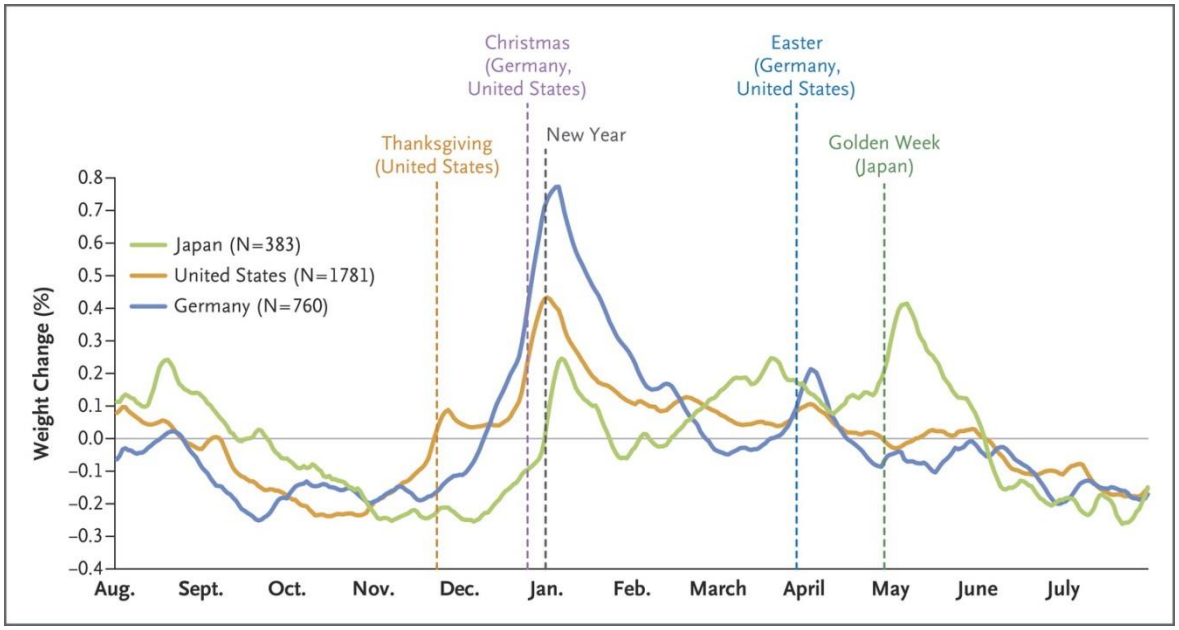
Weight tracking studies have also demonstrated that there may be particular times of the year when body weight increases more rapidly [8]. One such study observed the seasonal variation in body weight along with variations in food intake and physical activity levels [80]. The study was a prospective observational design and data were collected from 593 participants who took part in the Seasonal Variation of Blood Cholesterol (SEASONS) study [83, 84]. The SEASONS study was designed to analyse the seasonal changes in blood lipids and to ascertain the contributing factors to this such as diet and physical activity levels. Participants were aged between 20 and 70 years, with 63.6% classified as overweight or obese according to BMI. Analysis of data from quarterly time points during a 1-year period, showed that body weight peaked in the winter (December 21st – January 20th) ($p=<0.001$ winter versus summer) and varied by 0.5kg throughout the year. Daily caloric intake was 86 kcal greater during the autumn season (21st September – 20th December) and calories derived from total fat and saturated fat also peaked during the autumn. Additionally, physical activity was observed to be at its lowest level during the winter season.

Another study tracked the weight gain of different populations during national holiday events: Thanksgiving in the US, Golden Week in Japan and Christmas in Germany [8]. Weights were reported through the use of wireless scales which provided the daily weight change of 2924 participants from these three countries. Researchers normalised the daily weights of participants by subtracting starting weights at the beginning of August and dividing by participants' average weight over the year to produce a weight change curve. The curve was then smoothed over a 7-day period and averaged over all participants in each country. A maximum weight 10 days post-holiday was determined to ascertain any difference between pre- and post-holiday weights. Results showed that weight increased during the holiday events selected in each country. Overall, the minimum annual weight gain was 0.7% (0.6kg)

post-Thanksgiving in the United States; 1% (0.8kg) in those from Germany during Christmas-New Year period; and 0.7% (0.5kg) in participants from Japan during Golden Week. Additionally, weight increased significantly within 10 days following Christmas Day in all three countries. Furthermore, continued weight tracking demonstrated that only around half of the weight gained was lost immediately following the holiday event, and that half of the weight gained was retained for six months or longer. Figure 2 details the annual holiday weight gain patterns in three countries.

To summarise, previous studies demonstrate that weight gain during holiday periods is common, with weight gains not fully compensated for following the holiday event.

Figure 2: Annual holiday weight gain patterns in three countries adapted from Helander et. al. [8]



2.4 Weight gain at Christmas

The Christmas holiday period is a particularly high-risk time for weight gain. As reported by Helander and colleagues [8], average weight increased significantly across three countries during the Christmas period. Causes of weight gain at Christmas are wide-ranging. Christmas falls within a time of public holidays in the UK and many other countries, where a break from routine leads to a prolonged period of opportunity to over consume and be sedentary. On Christmas day alone, it has been reported that 6000 calories may be consumed by an individual [85]: three times the recommended daily allowance. Hull and colleagues analysed changes in body composition in addition to body weight during the holiday occasion of Thanksgiving to New Year [74]. One hundred male and female students were recruited with an age range of 18-40 years. Data were collected at three time points during the Thanksgiving to New Year holiday season. Unlike previous studies, these results showed no overall change in body weight during the pre-Thanksgiving to the post-New Year holiday period (71.3 ± 14kg versus 71.2 ± 15kg, difference -0.1kg, p=0.71). However, a significant increase in percentage body fat (25.9 ± 9% versus 27.0 ± 9%, p=<0.05) and fat mass (1.1%, 0.8kg) was observed. This indicated that dietary intake was increased during the period. Due to the negative impact of additional fat mass on health, this study was important in highlighting that damaging changes in body composition occur during the holiday season even if changes in body weight are not observed.

Characteristically people enjoy a more relaxed lifestyle and participate in more social events during the Christmas period which puts them in situations where energy intake can be increased. Studies have demonstrated that energy consumption is increased through: the availability of a greater variety of foods [86] (many of which are energy dense [87]); the opportunity to consume larger portion sizes [35]; and eating with friends and family [88]. In a

study using hypothetical high risk tasks to assess coping strategies and dietary lapsing, participants reported that family celebrations provided the greatest challenge for eating restraint [89]. Changes in routine, the increased availability of foods, additional social events and being away from home are all typical occurrences during holiday occasions and can lead to overconsumption of energy-dense foods, increased alcohol consumption, increased snacking and reduced physical activity levels. Additionally, the risk of overconsumption posed by the Christmas holiday is coupled with the holiday occurring during the winter months where daylight hours are shorter and the weather is generally colder which particularly affects body weight due to the effect on mood and increased energy consumption [90].

Even experienced weight controllers have demonstrated that weight gain prevention at Christmas is a challenge [75]. One study reported the weight change of participants undergoing treatment for obesity who were already consistently utilising behavioural strategies proven to support weight management, to ascertain whether they were able to continue to successfully manage their weight (or prevent weight gain) during the Christmas holiday period [91]. These participants had been enrolled in the programme for an average of 51 weeks and were asked to consistently self-monitor all food consumed. Weight change was measured weekly during three holiday weeks (Thanksgiving, Christmas/Hanukkah and New Year's Eve). Participants gained 500% more weight per week during the holiday weeks compared with non-holiday weeks. Notably, participants gained weight despite being consistent self-monitors of food intake indicating that self-regulation of food is challenging during holiday occasions even for those who consistently self-monitor.

The effect of energy expenditure and physical activity during holiday occasions has been assessed. Stevenson and colleagues assessed changes in body weight, body fat percentage and

blood pressure during the holiday season of Thanksgiving to New Year's Day [70]. They conducted a single-blinded, observational study where 148 participants (100 female, 48 male) attended a total of two research appointments, the first in mid-November and the second in early January. Weight change was measured along with height, percentage body fat, blood pressure, heart rate and self-reported physical activity. Researchers categorised participants as non-exercisers or exercisers according to their level of activity reported at their second visit ('exerciser' = >150 minutes of moderate intensity exercise per week). Results showed a significant increase in average body weight of 0.78kg ± 0.1kg (95% CI 0.57-0.99kg) along with an average percentage body fat increase of 0.5% ± 0.2% (95% CI 0.12-0.77%) in all study participants. When assessing differences between the exerciser and non-exerciser groups, no significant differences were found for changes in body weight (0.86 ± 0.2 versus 0.70 ± 0.1kg), percentage body fat (0.7 ± 0.3% versus 0.3 ± 0.3%) or BMI (0.3 ± 0.1 versus 0.2 ± 0.1 kg/m²).

These findings suggest that exercise had no protective effect on holiday weight gain. This could be because the number of calories being consumed is so high and substantially more than participants were able to expend through exercise over this period. Furthermore, analyses showed that obese participants (BMI ≥ 30kg/m²) demonstrated significantly greater increases in percentage body fat when compared with normal weight participants (BMI <25 kg/m²) (1.6 ± 0.5% versus 0.2 ± 0.2%). In addition, obese participants were the only group to demonstrate a significant increase in systolic blood pressure (6.6 ± 2.3 versus 0.7 ± 1.6 mmHg respectively). No significant differences between BMI groups were observed for weight change. This study demonstrated that exercise did not appear to have a protective effect against holiday weight gain and that obese participants were most likely to show the greatest increases in percentage body fat.

A further study assessing the impact of energy expenditure on holiday weight gain was conducted by Cook et. al [66] through a secondary analysis of previously published data from the Observing Protein and Energy Nutrition (OPEN) study. The OPEN study was originally conducted to assess dietary measurement error by comparing data from self-reported questionnaires with objective biomarkers: doubly labelled water for total energy expenditure (TEE) and urinary nitrogen for protein consumption [92]. The secondary analysis assessed whether holiday weight gain was reduced in participants with a high TEE as measured at the start of the holiday event (n=443). Baseline TEE and change in body weight over the Christmas holiday period in the year 1999-2000 was examined in all participants. During the study, body weight and TEE were measured twice: mid-September to early October 1999 and mid-January to early March 2000. Results showed that a high TEE did not affect the amount of weight gained during the holiday as no relationship between body weight and TEE were observed. The average holiday weight gain was reported as 0.9kg in men and 0.6kg in women, a greater amount than observed in other studies. Additionally, two thirds of participants gained 0.5kg or more during the 90-day study.

2.5 The prevention of weight gain

The treatment of obesity through lifestyle change demonstrates little success on a long term basis with weight often being regained and lifestyle changes not sustained [93]. An alternative strategy is to focus on the prevention of weight gain. This prevention approach is recommended by a number of public health agencies [9, 12]. Specifically, WHO has recommended that the prevention of weight gain should begin early in life and include adults whose BMI falls within the normal range [9].

2.5.1 The prevention of weight gain: Systematic reviews

Systematic reviews have identified relatively few trials aimed at the prevention of weight gain in adults alone, and very few interventions have focused on the prevention of weight gain in populations during high risk occasions such as holidays. Lombard and colleagues' 2009 systematic review [94] focused on published intervention studies with a stated specific aim to prevent weight gain, and the inclusion of a comparator group as part of the trial. The review aimed to examine the features of effective and ineffective weight gain prevention interventions in adults to inform the future development of interventions. Therefore, components, intensity and delivery modes were investigated as well as the effect sizes of interventions. Ten papers were included in the review, detailing nine weight gain prevention intervention studies, all of which were RCTs. With regards to weight outcomes, most interventions reported only small differences in weight between groups, adjusting for baseline weight. Five out of the nine trials reported a significant difference in the mean weight between the intervention and control groups of 1.0kg to 3.5kg. The remaining four studies reported no significant difference in weight between groups at follow up. The review concluded that weight gain prevention interventions are scarce despite the scale of the rise in obesity levels, as only nine randomised controlled trials of weight gain prevention intervention targeting adults in ten years have been reported. Furthermore, no trials were reported to have tested brief interventions, all evaluated interventions were more intensive, requiring behavioural changes to both diet and physical activity levels. The review authors commented that interventions were difficult to compare due to the large heterogeneity; components, length and intensity of interventions differed widely. For example, there was a large variation, from 13 weeks to 5 years, in the length of interventions, however most were between 1 and 3 years in duration. There was also variation in the measurement tools used.

The authors reported failure to identify components of successful interventions due to the variation between interventions. However, they did identify that the less intensive interventions incorporating self-monitoring of weight in addition to general dietary advice, physical activity recommendations and behaviour change components could be more successful at preventing the small gains in weight observed in populations over time. The more intensive interventions were not always more successful.

A further systematic review was undertaken of strategies to prevent weight gain among adults [95]. As opposed to Lombard's review, Hutfless and colleagues investigated the evidence around specific strategies for weight management: diet, physical activity and self-monitoring. The review included studies incorporating the specific strategies for weight management and those with 1-year follow up data. Studies with weight loss or maintenance of weight loss as an aim were excluded. Eleven trials and eleven observational studies were included in the review. Similar to Lombard's review, this review reported a lack of evidence for effective weight gain prevention interventions targeting adults. Most studies had focused on weight loss and weight loss maintenance, rather than the prevention of weight gain in the population. Additionally, the strength of the evidence for all strategies was low which was somewhat due to the high risk of bias in the included studies. Overall, the review reported that although the evidence was weak, some strategies, such as low-fat diets, may be effective in preventing weight gain. Additionally, no study was identified by the review to focus on preventing weight gain amongst individuals with a healthy BMI.

A further systematic review assessed the effectiveness of long-term lifestyle interventions on the prevention of weight gain [96]. Brown and colleagues reached a similar conclusion to Lombard and Hutfless, finding that the evidence was limited for lifestyle intervention trials focusing on the prevention of weight gain in adults. They found large heterogeneity across trials, making the comparison of effective intervention components difficult. In particular, the evidence for lifestyle interventions focusing on weight gain prevention in normal weight adults in the community was very limited.

Two systematic reviews, both published in 2012, assessed the evidence for weight gain prevention interventions among young adults [97, 98]. Young adulthood is a high risk time for weight gain with observed gains more rapid in this group compared to those observed previously [99, 100]. Consistent with the reviews in the general adult population, these reviews concluded that there was generally a lack of strong evidence pertaining to weight gain prevention. Hebden and colleagues conducted their systematic review of RCTs evaluating weight gain prevention interventions in young adults. They also conducted a meta-analysis within the systematic review using the body weight outcomes [97]. Following a literature search, they identified eight trials for inclusion in a meta-analysis with nine included in a systematic review of RCTs. They found a combined weighted mean change of -0.87kg (95% CI = -1.56, -0.18) in intervention participants and 0.86kg (95% CI = 0.14, 1.57) in control participants. Further post hoc meta-regression analyses found an association between interventions of longer durations (≥4 months) and weight loss (-1.62, 95% CI = -3.21, -0.04, p=0.045). As was the case with the systematic reviews focused on the general adult population, they found the overall evidence of effectiveness for weight gain prevention in this group unclear. Again, this was due to the heterogeneity of lifestyle interventions.

2.5.2 The prevention of weight gain: evidence from individual studies

Although the systematic reviews identified very few interventions focusing specifically on the prevention of overweight and obesity in the general population (including healthy weight individuals), one such trial has been published [101]. The CHOICES (Choosing Healthy Options in College Environments and Settings) RCT (published in 2016) randomly assigned 441 college students to a 24-month intervention or control group. The intervention consisted of a taught course delivered over one semester focusing on diet, physical activity, stress management and sleep: all behaviours related to achieving weight maintenance. Additionally, students were able to access an online social network related to the course where they could self-monitor, goal set and interact with other participants through an online discussion forum. Participants randomised to the control group received health promotion information and measurement visits quarterly. Results demonstrated no significant difference in weight and BMI between groups (net difference between groups at 24 months: weight, 0.253 kg (p=0.7); BMI, 0.092 (p=0.6)). The trial did, however, report a significant difference between groups for the prevalence of BMI ≥25 at 24 months through an exploratory analysis. Nearly 14% of the intervention participants who were obese or overweight at the start of the trial transitioned to a healthy weight compared to 4% in the control group (p=0.02). This is a useful study looking at a weight gain prevention using a 24-month intervention for young adults, and although no significant difference in BMI across groups was observed, the reduction of the prevalence of overweight and obesity may have significance at population level.

2.5.3 The prevention of weight gain: evidence from systematic reviews of weight loss maintenance trials

In addition to evidence from specific weight gain prevention trials, evidence from weight loss maintenance trials can also be useful for examining the effectiveness of intervention components. A systematic review of RCTs for weight loss maintenance in obese adults following clinically significant weight loss reported that lifestyle interventions which help people to manage their weight in the longer term by regulating dietary intake and increasing physical activity are lacking and should be a focus of future research [102]. Evidence included in the review was from RCTs with 12 months of follow up, including adults who had previously lost ≥5% of their initial body weight 24 months prior to the initiation of the weight maintenance intervention. Surgical interventions were excluded. Interventions included behavioural, pharmacological, meal replacement or supplement components, either alone or in combination. A total of 45 trials were included. Results showed that weight regain prevention was possible through behavioural and/or pharmacological means. Goal setting, self-monitoring of weight and behaviour, action plans for weight control through dietary and physical activity behaviours and relapse prevention were the four key features of successful weight maintenance interventions identified by this review. Importantly, this review demonstrated that weight gain prevention is possible using comprehensive behaviour modification methods including both dietary and physical activity elements, however, this is in a specific population who have already achieved weight loss.

2.5.4 The prevention of weight gain at Christmas: Evidence from intervention studies

No weight gain prevention intervention trial has specifically targeted the Christmas period. However, there are a few trials worthy of review to explore strategies to prevent weight gain at Christmas. One recently published trial (June 2019) assessed the effectiveness of daily self-weighing (DSW) and graphical feedback (GF) on the prevention of weight gain in adults during the Thanksgiving and Christmas holiday period in the United States [103]. The single blinded RCT recruited 111 adults with a BMI of ≥18.5 kg/m^2 and who were not attending a weight loss programme, to participate in the study through online and paper adverts which were distributed at a university in the United States. Participants attended three visits at the university's laboratory: pre-holiday (1 week prior to Thanksgiving); post-holiday (1 week after New Year's Day); and follow up (14 weeks later). Data were collected on the following measures: height; body weight; waist circumference; hip circumference; blood pressure; and body composition (using DXA). Perceptions of foods, food selections, stress and sleep patterns were also assessed using validated questionnaires. The intervention consisted of DSW with GF. Participants randomly allocated to the intervention group were provided with a Wi-Fi scale and asked to weigh themselves daily, at the same time of day, under the same conditions (for example wearing the same items of clothing or no clothing). The Wi-Fi scales automatically uploaded the participants' weight to a central database. Participants were also provided with a 'target' weight (their baseline weight: the mean of their first four weights) and told not to exceed it during the study. GF appeared immediately on the screen of the scale once the participant's weight had registered. The target weight was also provided on the graph as a solid line. No other information was provided to participants about how to manage their weight. Participants allocated to the control group received no information but attended all three study visits at the laboratory. At the follow up stage, 104 participants had completed the

study (93.7%). Results showed that the intervention group's mean weight did not significantly change between Thanksgiving and New Year's Day (visits 1 and 2) (−0.13 ± 0.27 kg, $p < 0.001$) whereas the control group's mean weight significantly increased (2.65 ± 0.33 kg, $p < 0.001$). At the follow up stage (14 weeks after New Year's Day), the control group demonstrated some weight loss (−1.14 ± 0.43 kg, $p = 0.01$), however there was a significant retention of weight gain as 57% of weight gained was not lost. Analyses per BMI category showed that the overweight and obese participants in the intervention group demonstrated a mean weight loss during the study (−1.46 ± 0.62 kg, $p = 0.01$) whereas normal weight participants had no weight change (0.33 ± 0.27 kg, $p = 0.01$). Although there were some limitations (imbalances of characteristics across groups, convenience sample), this trial is significant as it demonstrates that weight gain prevention using DSW and GF alone may be successful in preventing weight gain during the holidays.

A further trial of interest tested whether a maintenance strategy (self-monitoring + liquid meal replacement) affected holiday weight gain during the holidays [104]. The study recruited 58 adults aged 25-60 years from a university population (staff and students) who were randomly allocated to a treatment (n=27) or a control group (n=31). Participants were matched for weight and researchers classified a BMI of ≥27 kg/m² as overweight. Participants were weighed at the beginning and end of the one-month study period. Participants allocated to the control group were required to track their meals while intervention participants were required to track their meal replacements, weight, and holiday-related eating events and report their perceptions in relation to seven weight maintenance statements. Additionally, participants allocated to the treatment group were required to exchange two regular meals with a commercial liquid meal replacement. The meal replacement was intended to be used for holiday events during the period, such as parties or dinners. Results showed a mean weight

loss of 0.06lbs (±2.8lbs) in the intervention group compared to a mean weight gain of 1.36lbs (±2.6lbs) in the control group. Researchers assessed the level of 'success' across groups. Success was defined as weight maintenance or loss. Overall, the treatment group participants had a significantly greater rate of 'success' compared to control group participants at 59% compared to 18%.

A further useful study was conducted in a workplace during the Thanksgiving to New Year holiday period [76]. This uncontrolled study tested whether a workplace intervention entitled 'The Lean Plate Club Holiday Challenge' could result in weight maintenance from Thanksgiving to New Year. The Lean Plate Club is a newspaper column produced by the Washington Post consisting of diet and physical activity advice to encourage readers to achieve a healthier weight. A web-based programme is also available. Anecdotal evidence from users of the Lean Plate Club suggested that the programme supported people to both lose weight and prevent weight gain. The Lean Plate Club Holiday Challenge was initiated to test whether the anecdotal findings of the Lean Plate Club were reliable and whether the programme could support participants to maintain their weight during the holiday period. Employees from the Washington Post were recruited from three sites to participate in the study and a competition across sites was established. Participants were weighed at the beginning and end of the study. The intervention involved the provision of reduced calorie meals in the workplace canteens, information on healthy eating and physical activity, goal setting in relation to weight and physical activity and encouragement to self-weigh via a weight chart. 10% of employees enrolled in the study (n=290) and 75% completed the challenge (n=217). Results showed that 176 participants achieved or exceeded the goal of weight maintenance during the Holiday challenge. Furthermore, a mean weight loss of 1.09kg was observed amongst the 176 participants despite the goal of weight maintenance being set.

In summary, trials assessing the prevention of weight gain in adults during holidays are lacking and there is a need for trials in this area. The evidence reviewed suggests that weight gain prevention is possible during the Christmas period using behavioural strategies to alter dietary intake and increase physical activity. Specifically, regular self-weighing, recording of weight and working towards a behavioural goal shows some promise of success. Previous interventions have varied in length and the less intense interventions demonstrated similar effectiveness suggesting that brief, low agency interventions have the potential for success.

2.6 Summary of evidence

Obesity is a continuing, global public health concern [5], impacting on morbidity and mortality [29, 82] and placing a financial burden on health services [4]. With the main cause of overweight and obesity being a sustained increase in energy intake in the absence of an increase in energy expenditure (energy imbalance) [81], it is pertinent to analyse weight patterns of populations to establish when and why weight gain occurs. Observational studies show that on average, the population gains weight year on year [105]. To add context to this, population weight tracking studies are valuable in establishing whether weight gains are due to a slow and steady increase in weight over the year or are due to more discrete periods where weight is gained more rapidly. One such study demonstrated that key holiday occasions in three different countries resulted in an increase in weight [8]. Furthermore, the Christmas holiday period saw weight increase in participants across all three counties. Narrative and systematic reviews also corroborate this finding that weight increases during holiday occasions on average by between 0.4kg to 0.9kg [6, 7]. Having established that increases in body weight are likely during holiday occasions, interventions to counteract this may be useful. Interventions to treat established obesity have demonstrated little long-term success. The need for large, sustained lifestyle changes, combined with high levels of physical activity may be the reason for the lack of

success, proving too demanding for individuals. The prevention of weight gain is a key public health priority in order to stabilise rising levels of overweight and obesity. Therefore, interventions focusing on the prevention of weight gain at high risk periods through small dietary and physical activity changes may be a useful strategy. However, evidence from systematic reviews suggest that this is an area in need of further research, particularly amongst the general population across all BMI categories. Currently, no trial has tested a brief, multicomponent intervention to prevent weight gain over the high-risk holiday period of Christmas. In response to this evidence gap, this thesis presents the development and evaluation of a weight gain prevention intervention, delivered over the Christmas period, targeting the general population.

CHAPTER 3

3.0 INTERVENTION DEVELOPMENT

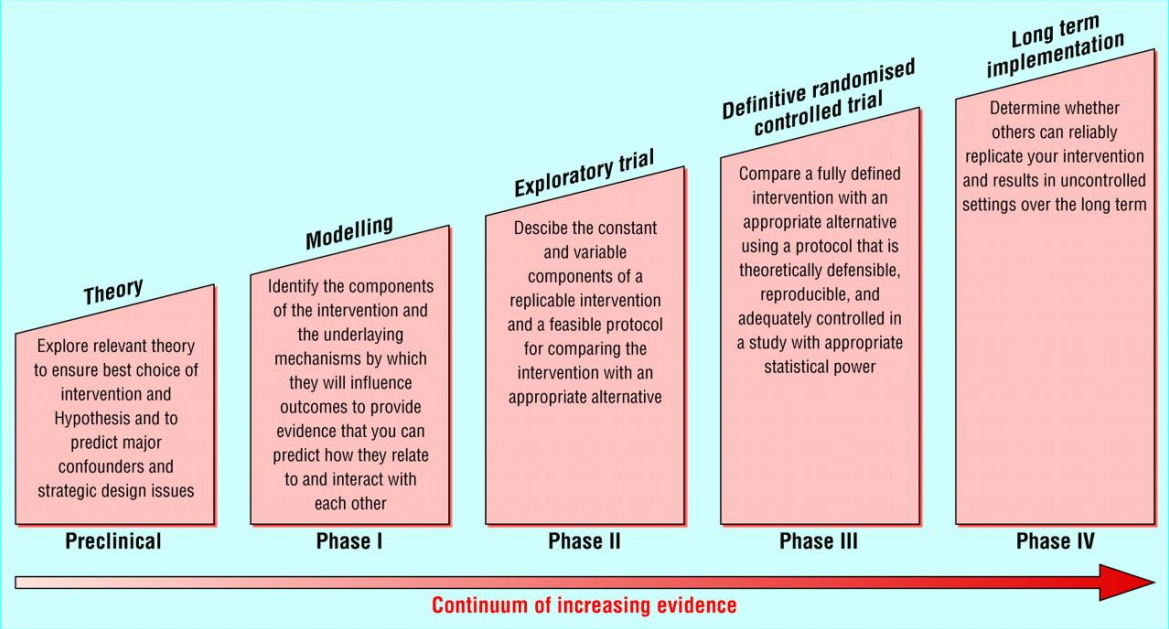
This chapter sets out the theoretical underpinning and describes the development process of the intervention tested in the Winter Weight Watch Study, which aimed to prevent weight gain over the Christmas holidays.

3.1 Intervention development

Rigorous and theoretically informed intervention development is key to maximising effectiveness. To help researchers and funders to adopt appropriate methods when designing and developing interventions, the Medical Research Council (MRC) published a framework in 2000 for the development and evaluation of complex interventions [106]. Complex interventions are widely used in healthcare and are characterised as interventions containing several interacting components. Therefore, their design and evaluation can be problematic as the heterogeneity of interventions means that standardisation can be difficult. The MRC framework proposes a phased approach to development which is shown in Figure 3. According to the framework, researchers are recommended to fully define the theoretical basis of the complex intervention components and the overall intervention through thorough preliminary work, so that the elements of the intervention can be delivered effectively and assessed accurately. In 2008, the MRC published an updated framework which addressed some of the limitations of the original framework by providing more examples of intervention development and evaluation [14]. A further update to the guidance is expected in 2019. The 2019 update will address some of the gaps in the 2000 and 2008 guidance as well as the inclusion of new methodological developments. Although the MRC's framework for intervention development is broad and encompasses all complex interventions, there are three

distinct phases which are useful to support intervention developers: 1) identifying the evidence base; 2) identifying and developing theory; 3) modelling the processes and mechanisms of action and their interactions. In accordance with this, this chapter describes the role of theory and theory selection for this intervention, the development of a logic model and the selection of intervention components. A review of the evidence of effectiveness relating to these intervention components is also presented.

Figure 3: Phases of the MRC framework for the development and evaluation of complex intervention [13].



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3.2 Theoretical underpinning

Included in the MRC's guidance for the development of complex interventions is an emphasis on the importance of identifying and developing a theoretical basis. Interventions for weight management are most likely to be successful by targeting behaviours to influence energy balance (e.g. diet and physical activity). Furthermore, these behaviourally targeted interventions have been shown to be effective for both weight and health outcomes in the short term [107], although there is a lack of evidence for sustained effects of these interventions. Developing such interventions, where behavioural change is required, should include thorough theoretical underpinning to maximise the chance of effectiveness [13, 14, 108]. There are a number of behaviour change theories that describe mechanisms of action and moderators of change concerning a particular behaviour. Behaviour change theories help us to understand, predict and explain behaviour change, aiding both development and evaluation of interventions. Despite the identified importance of the need for a theoretical basis to behavioural interventions, there is a lack of guidance relating to the selection of appropriate theories [15] and a large number of behaviour change theories exist for developers to choose from. For instance, 83 behaviour change theories were identified as having potential for use in public health interventions as part of work to compile a comprehensive resource for researchers [109]. In addition, evidence for the effectiveness of health interventions underpinned by theory is mixed. Gourlan and colleagues conducted a meta-analysis investigating 82 RCTs evaluating interventions designed to increase physical activity, all of which were theory based. The meta-analysis aimed to determine the effect of theory based physical activity promoting RCTs; measure their efficacy against theoretical objectives; and compare the efficacy of RCTs underpinned by a single theory versus multiple theories. Analyses showed that the theoretical underpinning of interventions significantly promoted the physical activity

behaviours of participants (d=0.31, 95% CI: 0.24 to 0.37), with no efficacy detected between the number of theories used (single vs. multiple). Conversely, a further meta-analysis assessing the use of theory in dietary and physical activity interventions found no significant associations with theory use and effectiveness [110]. The task of selecting appropriate theory in intervention development thus requires researchers to form hypotheses based on prior knowledge of human behaviour in the context of the desired change. In the case of weight management, this can be particularly challenging as two behaviours are targeted: both dietary and physical activity behaviours, which may require different theoretical positions.

3.2.1 Theory use in weight management interventions

There are a wide range of theories that have previously been used in weight management interventions. The use of theory can help to optimise behaviour change interventions by promoting the deeper understanding of the mechanisms of how behaviours can change [111].

Despite the value of theoretical underpinning, it is often omitted or poorly described in the reporting of weight management trials. One systematic review on the effectiveness of behavioural interventions delivered in primary care for weight loss reported that only five of 15 studies included in the review described the theoretical basis of interventions [16]. Of these, the theories used were social cognitive theory [112], the trans theoretical model [113] and self-regulation theory [114] (behavioural self-management). Other commonly used theories in weight loss interventions include the theory of planned behaviour [115] and self-determination theory [116]. A brief description of commonly used theories is compiled in Table 2. More recently research has begun to use self-regulation theory and/or the habit formation model to guide the content of interventions. Self-regulation theory and the habit formation model both promote

the adoption and continuation of positive health behaviours, such as consuming lower calorie foods or increasing daily physical activity.

Table 2: Brief description of commonly used theories in behavioural weight management interventions.

Theory name	Description
Self-determination theory (SDT) [116]	A theory relating to individual motivation as a predictor of an individuals' performance and outcomes related to wellbeing. The theory focuses on the extent to which behaviour is self-motivated and self-determined. Intrinsic and extrinsic motivations are differentiated. Intrinsic motivation is driven by the individual for rewards. Extrinsic motivation is externally driven, i.e. performing the behaviour to achieve an external goal. Three types of psychological need are described as being drivers of intrinsic motivation: autonomy, competence and relatedness.
Self-regulation theory (SRT) [117]	A theory of the individual regulation of thoughts, feelings and behaviours to achieve a desired outcome. Here, the individual is responsible for achieving goals through their own monitoring, assessment and contribution to behaviours.
Habit formation theory (HFT) [118]	A theory of the process of changing a behaviour through the development of habit so that it becomes subconscious. 'Habit' is the repetition of a certain behaviour so that the individual does not require conscious thought to complete. The formation of habits is the process by which habits become automatic and effortless. During habit formation, there are three main parts to the process: the cue, the behaviour and the reward. The cue is the antecedent of the behaviour (habit). The behaviour is the habit being formed. The reward is the positive feedback which causes the continuation of the 'habit loop'.
The theory of planned behaviour (TPB) [115]	A theory suggesting that behaviour change is governed by individual intention to perform the identified behaviour and the individual's perceived control over it. 'Intentions' are defined as the amount of effort an individual is prepared to exert to perform the behaviour. Intentions sustain

	motivation. Intention predisposes an individual to carry out a particular behaviour. Perceived behavioural control is a measure of how confident the individual is to carry out the behaviour. Perceived behavioural control is a moderator of intention and behaviour. The incorporation of goal setting may increase the predictive ability of the theory possibly by strengthening the intentions around behaviour implementation.
The trans theoretical model (TTM) [113]	A theory consisting of a two-level model to describe when, why and how an individual may change behaviour. Level one describes stages of change and level two how an individual will move through the stages. These stages are named stages which describe the behavioural and psychological stages an individual may take to change their behaviour. Included within this are other behavioural constructs such as self-efficacy and decisional balance, as the TTM incorporates constructs from other health behaviour change theories.
Social cognitive theory (SCT) [112]	One of the most commonly applied theories to weight management interventions. SCT centres upon behaviour change occurring because of the observation and repetition of behaviour within the environment (reciprocal determinism). In other words, behaviour may be changed through knowledge gained through observation, social interaction and continued exposure to the desired behaviour. Learned behaviour is at the centre of this behaviour change theory. According to the theory, there are three determinants to influencing the replication of an observed behaviour: self-efficacy (high or low), skills (requirements to complete behaviour) and rewards. Self-efficacy has been analysed extensively in weight management and is considered as a powerful determinant of SCT [119].

3.2.2 Theory use in weight gain prevention interventions

As discussed in chapter 2, the evidence relating to the overall effectiveness of weight gain prevention interventions is scarce in adults, a challenge compounded by the lack of theoretical consideration within extant studies. In a systematic review assessing the utilisation of psychological models and behaviour change techniques in weight gain prevention interventions in children and adults [120], only two of the nine included interventions had a description of the theoretical underpinning which, in both cases, was social cognitive theory [114]. In Lombard's systematic review of weight gain prevention interventions in adults, again, most of the studies did not describe any behavioural theoretical underpinning although all included a combination of behavioural change components or techniques. Additionally, the review identified several key behavioural techniques as effective in helping to change lifestyle behaviours, with self-monitoring of behaviour, a key component of self-regulation theory, identified as particularly useful.

From the potential theories available, and in the absence of clear evidence of the link between theory and effectiveness of interventions, the study team agreed that the most appropriate theoretical basis for the intended behaviour change was self-regulation theory with the habit formation model [118] as a supplementary framework. The justification for selecting these theories is explained in the following sections.

3.2.3 Self-regulation

The study team identified that participants would need to employ self-regulation as the underlying key process by which they modify their dietary and physical activity behaviours over the Christmas period to achieve weight stability. This is due to the challenging environment presented by the Christmas period where there is an abundance of high calorie

foods available and the tendency to be more sedentary due to a change in routine (i.e., a break from work, more time at home). This therefore requires an individual to consciously employ self-regulation processes such as conscious efforts to monitor oneself, evaluate and appraise against set goals (in this case weight stability) which can reinforce behaviour. Self-regulation has been described as a process that has three distinct stages: self-monitoring, self-evaluation and self-reinforcement. Self-monitoring is a method of systematic self-observation, periodic measurement and recording of target behaviours (e.g. weight) with the goal of increasing self-awareness. Self-evaluation is the process of evaluating oneself against goals or target behaviours. Self-reinforcement is the continuation of these behaviours in response to self-monitoring and self-evaluation. The awareness fostered during self-monitoring is considered an essential initial step in promoting and sustaining behaviour change.

3.2.4 Habit formation

In developing this intervention, in addition to the three processes within self-regulation, consideration was given to the notion that habitual actions help to support and promote behaviour change through automaticity and repetition of behaviours often in response to cues [121]. Ultimately, these actions then become effortless, without the requirement of conscious thought to complete [122]. Habit formation is particularly useful in weight management as it helps to sustain behaviours important for weight management and habit-based interventions have shown success in the promotion and continuation of weight management behaviours [123]. In the context of this intervention, it was hypothesised that the role of habit formation would be to support the self-monitoring process of self-regulation in terms of dietary and physical activity behaviours.

3.3 Intervention components

3.3.1 Selection of intervention components

The selection of intervention components followed the identification of the underpinning theoretical basis of self-regulation theory and habit formation. Selection of appropriate intervention components was based on theory and evidence base. The following paragraphs describe and summarise the selection process and the evidence base for each intervention component.

3.3.2 Conscious restraint of energy intake

Conscious restraint of energy intake or dietary restraint is the cognisant control of food intake. Studies have demonstrated that it may help individuals to avoid weight gain, support weight loss and weight loss maintenance [124, 125]. The conscious restraint of energy intake provides a buffer against weight gain, even with consumption of a high fat diet [124]. Encouraging the restraint of energy intake was considered to be integral to achieving the outcome of weight gain prevention in this intervention.

A review of levels of restraint of energy intake in participants from weight loss maintenance studies by Wing and Phelan [126], reported that successful weight loss maintainers had high levels of restraint (mean score of 7.1) when assessed using the validated assessment tool for restraint: the Three Factor Eating Inventory [127]. As a comparison, the score reported by the maintainers was similar to that of individuals engaged in an obesity intervention actively trying to lose weight. Demonstrating restraint of energy intake therefore appeared to be a key feature of weight maintenance.

Furthermore, an RCT conducted amongst women (aged 25-45 years) tested the effectiveness of weight gain prevention intervention (delivered through either through group sessions or

through printed means) versus a control on weight gain prevention and behavioural outcomes, such as the restraint of energy intake. Although the intervention was not associated with weight gain prevention, analyses of the successful weight maintainers demonstrated higher levels of restraint of energy intake associated with successful weight gain prevention [128]. Restraint of energy intake may also be particularly beneficial during times of food abundance and increased sedentary behaviour [124], typical of the Christmas period, in which this intervention will take place. Dietary restraint may be achieved through simple strategies to promote self-regulation [128]. Self-regulation of eating behaviours is required to achieve the restraint of energy intake. With this in mind, the selection of intervention components centred on self-regulation with the aim of achieving the restraint of energy intake.

3.3.3 Self weighing

Self-weighing was included as an intervention component to promote the application of the features of self-regulation theory and habit formation. Self-weighing, as a form of self-monitoring, can show individuals how their behaviour affects their weight, allowing them to adjust their behaviour to achieve their goals. In the development of this intervention, it is hypothesised that encouragement to regularly self-weigh may help to prevent weight gain in different ways. Firstly, self-weighing and documenting weight against a set target may raise an individual's awareness of the behaviours that influence their weight (dietary intake and physical activity) and encourage them to act [129]. Secondly, self-weighing acts as both a prompt and reward to individuals who control their dietary intake and physical activity behaviours. In this case, due to the likelihood of the overconsumption of calories during the Christmas period, it was hypothesised that individuals would prevent weight gain predominantly through the restraint of energy intake rather than through the increase of physical activity. Self-weighing provides prompts and feedback to demonstrate increased

restraint of energy intake, which some studies have shown to be useful in weight gain prevention [130], and rewards for demonstrating such restraint (and increasing physical activity) following positive feedback from the weighing scales. Rewards can enhance motivation and confidence to adhere to behavioural change, such as following a healthy diet and increasing physical activity, thereby reducing the potential for weight gain. Confidence in one's ability to make behavioural changes is known as 'self-efficacy' [114]. Increased self-efficacy is often a target of behavioural weight management interventions and is positively correlated with greater weight loss [131, 132]. This enhances motivation to prevent weight gain. Finally, self-weighing can promote healthy habits to encourage weight gain prevention. Self-weighing is one such behaviour that could become habitual, thus performed throughout life, ultimately becoming automatic and effortless. With respect to weight gain prevention, self-weighing may be particularly influential as it encourages the individual to reflect on weight changes, and in particular weight gain, and to take action in response to this.

Systematic reviews of the impact of self-weighing in weight management interventions report that self-weighing may improve weight outcomes (weight loss and weight gain prevention) [133-136]. Moreover, self-weighing appears to be more effective as part of a multi component intervention [133, 137]. Shieh and colleagues' systematic review included 22 articles reporting outcomes of weight loss or weight gain prevention interventions among overweight and obese participants [134]. Although they concluded that self-weighing is likely to improve weight outcomes for both weight loss and weight gain prevention, they were unable to distinguish how self-weighing differed in weight loss and weight gain prevention interventions. This trial will explore the role of self-weighing specifically in weight gain prevention.

In addition to the theoretical basis and supporting evidence base for including regular self-weighing in the intervention, in practical terms, it is a relatively simple intervention for health professionals to encourage. The demands on the individual are low, making it simple for people to understand and implement.

In this intervention, self-weighing is hypothesised to play a role in promoting the restraint of energy intake through enabling self-regulation, with the formation of habits supporting this behavioural change, consistent with the habit formation theoretical framework.

3.3.4 Adverse effects of self-weighing

Consideration should be given to the potential that regular monitoring and recording of weight may lead to adverse psychological outcomes. Some studies have suggested that regular self-weighing may lead to psychological distress [138, 139], body dissatisfaction [140] and unfavourable dietary behaviour such as binge eating and skipping meals [141]. However, a recently published study (2019) [142] examined the psychological outcomes and eating behaviours of 599 young adults (18-35 years) engaging in daily self-weighing to prevent weight gain and found no adverse psychological outcomes or eating behaviours associated with daily self-weighing. A further systematic review of five, self-weighing longitudinal studies published in 2015 concluded that there was no evidence to suggest that promoting regular self-weighing resulted in an increase in adverse psychological outcomes [136]. A meta-analysis published in 2016 evaluated the relationship between self-weighing and psychological outcomes using data from 23 RCTs and correlation studies [143]. The analyses included the assessment of four psychological outcomes: affect (levels of depression and anxiety); disordered eating (binge eating, restraint); psychosocial functioning (levels of stress and self-esteem); and body-related attitudes (body image and body dissatisfaction). The

analyses found no association between self-weighing and disordered eating and body related attitudes, in accordance with Zheng's [136] findings. The analyses did find a negative relationship between self-weighing and levels of stress and self-esteem (psychological functioning), although this was small (-0.8, 95% CI -0.14 to -0.03). Analysis of moderating factors on self-weighing showed that weight status did not impact negatively on psychological outcomes and actually had a positive impact on body related attitudes among overweight and obese participants.

In summary, there is no conclusive evidence to suggest that self-weighing is associated with adverse psychological outcomes.

3.3.5 PACE information

Physical activity calorie equivalent (PACE) information is a way of presenting information on the energy content contained within foods combined with the expenditure or the activity equivalent in relation to that energy content. By providing information in this way, individuals may reduce their energy intake and/or increase physical activity levels in the attempt to manage their weight. Here, PACE information has been included in the intervention to promote the restraint of energy intake, and more broadly, enable individuals to consciously employ self-regulatory strategies, linked to self-regulation theory. It is hypothesised that boosting the restraint of energy intake could be achieved through the inclusion of specific information relating to the energy content associated energy expenditure of food and drinks. As the consumption of energy-dense foods and drinks is typically increased at Christmas [80], providing information on the energy 'costs' of these foods may promote the restraint of energy intake whilst simultaneously encouraging physical activity. Relating the PACE information to these energy dense foods typically consumed during the

Christmas period but not at other times of the year, may be particularly beneficial. Studies have shown that the public frequently underestimate the calories contained in foods [144, 145] and/or do not understand the amount of physical activity required to expend energy dense foods [146]. In addition, there is evidence to show that through the increased awareness of the calorie content of foods through the provision of simplified information, calorie consumption is reduced [147].

Previous studies have shown the provision of PACE information to be useful in reducing the number of calories chosen from menus or consumed at meals times by the public whilst also encouraging them to be more physically active [148-150]. Antonelli and colleagues recruited adults from 47 states in the United States to participate in a study looking at hypothetical fast food menus. Participants (n=823) were randomly assigned to one of four hypothetical generic fast food menus: no labels, calories only, calories plus minutes to walk or calories plus miles to walk. Researchers measured the number of calories 'ordered' by participants per group. Results showed that the calorie plus minutes to walk group 'ordered' the fewest calories (median 1140 kcal, pairwise comparison to no labels group: p=0.0001). Antonelli's findings were similar to those of Dowray and colleagues [149] but may be more generalisable due to the study population recruited. In 2016, the Royal Society for Public Health (RSPH) called for the introduction of PACE labelling on foods and drinks as part of a strategy to reduce calorie intake [151]. The RSPH stated that based on evidence, the provision of PACE information would assist consumers to make more informed choices through the provision of calorie information in this contextualised manner.

While PACE information/labelling appears promising in helping the public to understand the energy costs of foods, its inclusion in this weight gain prevention intervention at a high-risk time for weight gain will add valuable evidence regarding its effectiveness. With Christmas being a period typical for the overconsumption of energy [68, 85], increased sedentary behaviour and reduced physical activity, strategies to raise awareness of the calorie content of foods and drinks commonly consumed during this period are worthy of investigation.

3.3.6 The 10TT

The final intervention component selected for inclusion was brief information previously tested for its effectiveness on weight loss: the 10TT ('10 Top Tips'). Lally and colleagues assessed the effectiveness in an RCT [152]. The individual tips were developed around a set of everyday eating and physical activity behaviours that have been shown to be associated with weight loss. A table detailing the scientific rationale for each tip is available in Appendix 2. Each tip was combined with advice on the repetition of eating and physical activity behaviours, consistent with habit formation theory [118]. Additionally, the 10TT intervention also asked participants to weigh themselves regularly. The first trial conducted to test the 10TT was a small randomised study [152]. Participants were recruited from workplaces and were included if they were adults with a BMI of ≥25 kg/m^2. Participants (n=104) were allocated to one of three experimental conditions: the intervention (10TT leaflet) with weekly weighing (WW); the intervention (10TT leaflet) with monthly weighing (MW), or the comparator ('no treatment'). Weight was measured for all three conditions at baseline, week four and week eight and for those in the intervention groups, weekly or monthly for a further six months (32 weeks). Intention to treat analyses showed that those receiving the intervention lost significantly more weight than comparators after 8 weeks (10TT+MW: -2.0kg, SD=2.13, 10TT+WW: -1.48kg, SD=1.54, no treatment: -0.4kg, SD=1.53). Researchers followed

participants up for 32 weeks and reported that weight loss continued to -3.8kg for those who completed the study (completers: 69%).

Further testing of the efficacy of the 10TT intervention in a primary care setting has been conducted in a separate trial [153]. This two-arm randomised trial recruited adults with obesity from 14 primary care providers in England. Participants (n=537) were allocated to the intervention (10TT leaflet plus self-monitoring) or usual care. Weight was measured at six time points over 24 months. Results at three months showed a significant difference in weight change between the intervention and comparator group of -0.87kg (95% CI: −1.47 to −0.27; p=0.004). At 24 months, the usual care group had lost the same amount of weight as the 10TT group who had maintained weight loss. Results from a qualitative study indicated that participants experienced increases in automaticity of self-weighing [154], in line with a systematic review suggesting this was a key indicator of success [132]. This trial demonstrated that the 10TT could be a useful, low intensity weight management intervention suitable for brief periods.

In this intervention, the inclusion of the 10TT information was hypothesised to facilitate the conscious restraint of energy intake by promoting the process of self-evaluation of diet and physical activity behaviours. This will then lead to the consequent regulation of these behaviours and subsequently, the reinforcement of those behaviours, consistent with self-regulation theory.

3.4 Behaviour change techniques

Behaviour change techniques are the fundamental behavioural components of an intervention. In other words, they are the practices most likely to result in the desired behavioural change. Establishing the behavioural techniques to be used as part of a behaviour change intervention requires a clear understanding of which behaviours are the easiest to change and will result in the greatest impact. Identifying these behaviour change techniques is an important part of intervention development and supports replication, evaluation and fidelity [15, 155]. Complex behaviour change interventions typically consist of several behaviour change techniques used in combination as part of the complete intervention. The use of behaviour change techniques helps researchers and practitioners to work together in a more streamlined manner as techniques can be reliably communicated, interpreted and practised supporting the translation of research into practice [156]. Additionally, the compilation of behaviour change techniques into taxonomies promotes this shared practice even further. One such useful taxonomy for weight management interventions was developed by Michie and colleagues [157]. The taxonomy was initially developed as a 28-item taxonomy in response to poor reporting of intervention content in research papers and has since been updated to include additional behaviour change techniques (the CALO-RE taxonomy). The purpose of the taxonomy is to ultimately improve replicability, implementation and evidence synthesis by enhancing the specification of interventions described in publications. The CALO-RE taxonomy itself is a 40-item list of behavioural components of key behaviour change techniques such as prompt self-monitoring, goal setting and problem solving. In 2013, the CALO-RE taxonomy was further refined into one comprising of 93 behaviour change techniques within 16 health domains [156]. Meta-analyses have examined the effectiveness of the taxonomy on health behaviour change interventions and have reported that their combined use is associated with greater intervention

effectiveness [108, 158]. It is therefore recommended that intervention developers assess interventions according to the taxonomy, describing the behaviour change techniques, to improve intervention fidelity, reproducibility, reporting and evaluation. As part of the development process for this intervention, once defined, components of the intervention were mapped to the CALO-RE taxonomy. Table 3 details the behaviour change techniques within the intervention. In brief, 'prompt self-monitoring of behavioural outcome', 'prompt review of outcome goals', 'prompt self-monitoring of behaviour' and 'prompt practice' were the key behavioural change techniques used associated with self-weighing. The PACE information was associated with 'providing information on the consequences of behaviour in general' and 'set graded tasks' and 'provide instruction on how to perform the behaviour' were the behavioural change techniques associated with the 10TT intervention component.

Table 3: Behaviour change techniques used in the WWW study based on CALO-RE taxonomy [166].

Behavioural change technique	Description
Intervention group	
Prompt self-monitoring of behavioural outcome	Participants were instructed to weigh themselves regularly (ideally every day) and record on the weight chart provided.
Provide information on the consequences of behaviour in general	Information was provided on weight gain at Christmas and the health implications of excess weight. PACE information was included to highlight to participants the energy 'costs' of festive food and drinks.
Provide information on where and when to perform the behaviour	Participants were recommended to weigh regularly at the same time of day, wearing similar amounts of or no clothing.
Barrier identification/Problem solving	Participants were asked if they had weighing scales. If no access to scales, suggestions to use publicly accessible scales or borrowing scales were offered.
Goal setting (outcome)	Participants were set a goal of not gaining more than 0.5kg of their baseline weight.
Prompt self-monitoring of behaviour	Participants were asked to record their weight as measured in the provided chart.
Prompting generalisation of a target behaviour	Self-weighing is promoted in such a way for the individual to adopt it as part of their everyday routine.
Provide instruction on how to perform the behaviour	Participants were provided with both written and verbal instructions on when and how to weigh themselves. The 10TT were recommended for participants to follow as a method to limit their weight gain over the Christmas (study) period. PACE information was provided to prompt restraint of eating and drinking whilst simultaneously encouraging physical activity.
Model/demonstrate the behaviour	Participants were weighed by the researcher and shown how to record their weights and the variation from baseline.
Prompt practice	Participants were asked to weigh themselves on their own scales during baseline data collection.
Plan social support/social change	Participants were recommended to let family members and friends know that they were taking part in the study in order

	to support them to avoid gaining weight over the Christmas period.
Comparator group	
Provide information about behaviour health link	The health consequences of excess weight were set out in the general information leaflet.
Provided general encouragement	General health information was provided.
Provide feedback on performance	Participants' follow up weight was provided to them at the end of the study period.

3.5 Logic model for the intervention

In line with the MRC framework for the development of complex interventions, a logic model, which schematically represents the theoretical basis of complex interventions, should be developed as part of good intervention development practice. A logic model should set out the intervention components and their proposed interactions and associations to form a hypothesis for the potential effectiveness of the intervention. Additionally, the development of a logic model is important to support evaluation and learning. The Process Evaluation Framework, a guidance document produced by the MRC in 2015, recommended that a logic model encompass four key aspects to support evaluation [159].

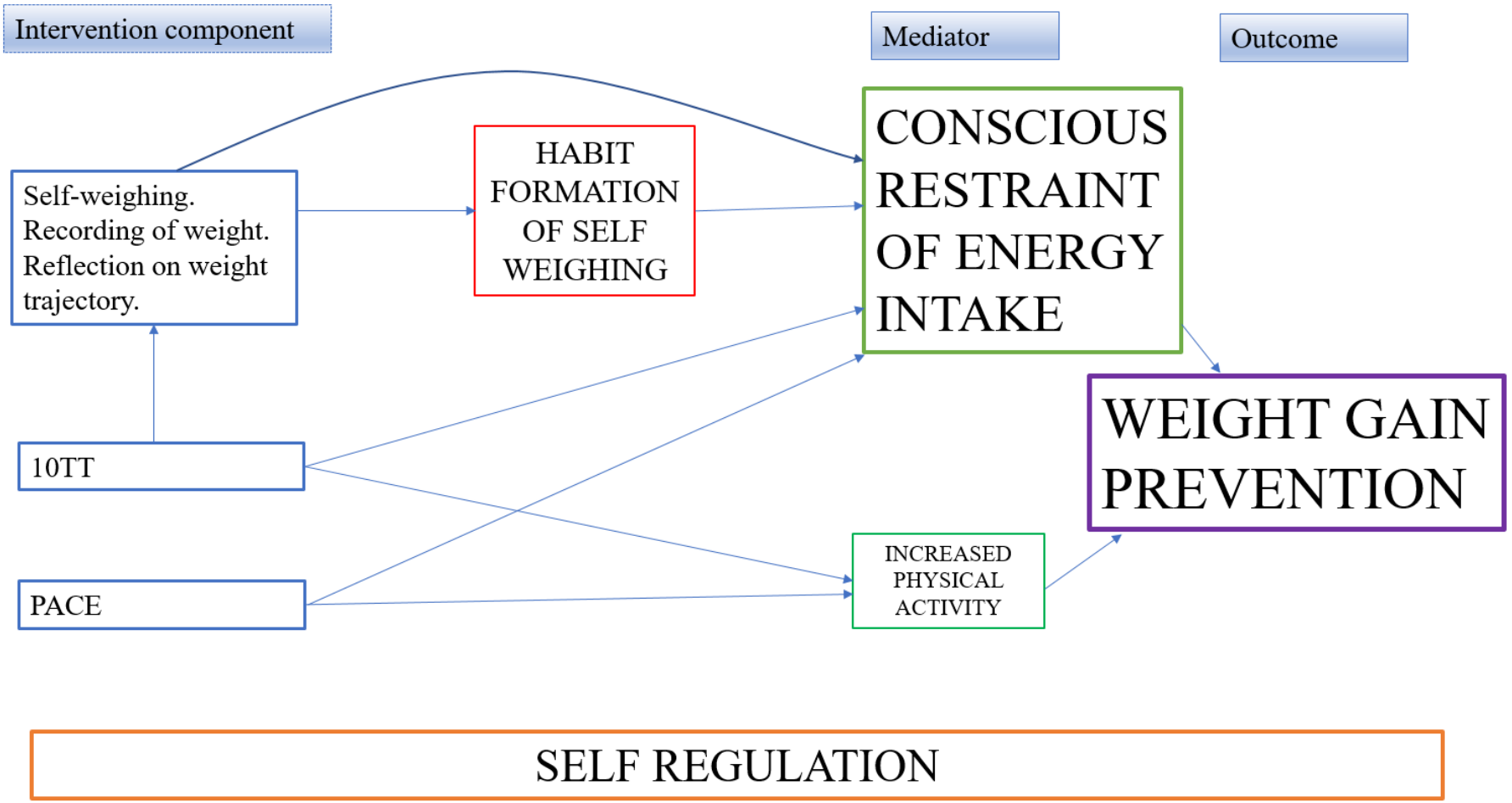
1. Implementation: Detail on how and what the intervention delivers.
2. Mechanisms: The interacting mechanisms of action on how the intervention works to produce behavioural change.
3. Outcomes: The outcomes that the intervention is centred on achieving.
4. Context: Reference to the external factors that the intervention may influence and how these may be influenced.

The initial logic model developed for this intervention is displayed in Figure 4. The intended outcome of the intervention was to achieve weight gain prevention. The mediators of this outcome were hypothesised to be the conscious restraint of energy intake and increased physical activity, due to their effect on energy balance.

The intervention components to effect the behavioural change were: regular self-weighing, including the recording of weight and reflection on weight trajectory; physical activity calorie equivalent information (PACE) of commonly consumed foods and drinks (seasonally and culturally appropriate); and previously tested brief information in the form of ten top tips for

weight management (10TT). It was hypothesised that each intervention component would contribute to the development of the conscious restraint of energy intake with self-regulation being the theoretical basis of the intervention and behavioural change, and the formation of habits as a supplementary theory relating to achieving sustained behaviour change.

Figure 4: Logic model for the theoretical basis and mechanisms of action of the Winter Weight Watch Study.



3.5.1 Development of the logic model

Identifying which causal or contextual factors are modifiable, which have the greatest scope for change, and who would benefit most is an important consideration for intervention development. The literature relating to the high-risk periods for weight gain has shown that weight gain during holiday occasions is common, with the Christmas holiday period a particularly high-risk time for indiscriminate weight gain. The causes of weight gain at Christmas are numerous but a key component is the relaxation of behaviours central to weight management, particularly dietary intake. Therefore, developing a weight gain prevention intervention at this time requires an individual to moderate their dietary intake in a somewhat challenging environment, where overconsumption is common.

To develop the logic model for an intervention to prevent weight gain during the Christmas period, the study team met as a group to discuss the theoretical considerations, the required behavioural changes and the mechanisms of action. The study team comprised a group of four individuals with expertise and experience in behaviour change interventions, complex interventions, weight management and health research. The study team met on three occasions where several iterations of the logic model were discussed, amended and outlined. The final logic model was subsequently agreed and finalised and is presented in Figure 4.

3.6 Summary: The Winter Weight Watch Study

In line with the MRC framework, the development of the theoretical basis of a complex intervention is important and guides the inclusion of behaviour change techniques and selection of intervention components. According to the current evidence base, effective weight gain prevention interventions incorporate self-regulation and the formation of habits conducive to weight management to affect changes to dietary intake and physical activity.

The components included in the Winter Weight Watch study intervention have self-regulation and habit formation as underpinning theories and there is evidence to suggest that these components are effective.

The Winter Weight Watch study tests the effectiveness and the experiences of participants who took part in this developed brief, behavioural, weight gain prevention intervention and explore its proposed mechanisms of action through two interrelated studies: a randomised controlled trial and a nested qualitative study.

CHAPTER 4

4.0 RESULTS FROM A RANDOMISED CONTROLLED TRIAL ASSESSING THE EFFECTIVENESS OF A MULTI COMPONENT INTERVENTION TO PREVENT WEIGHT GAIN OVER THE CHRISTMAS HOLIDAY PERIOD (THE WINTER WEIGHT WATCH STUDY)

This chapter is based on the following published paper: Mason F, Farley A, Pallan M, Sitch A, Easter C, Daley AJ et al. Effectiveness of a brief behavioural intervention to prevent weight gain over the Christmas holiday period: randomised controlled trial BMJ 2018; 363 :k4867.

Contributors: AD conceived the original idea for the study with input from AF. I developed the trial methods and processes and developed the trial materials with some administrative support. I coordinated and delivered the trial with administrative support. I wrote the first draft of the paper with input from all other authors. I developed the statistical analysis plan for the trial with input from my supervisors and statisticians (AS and CE). CE conducted the statistical analyses reported in the published paper with support from AS. I re-ran these published analyses and I conducted further statistical analyses of the process measures included in this chapter.

4.1 Introduction

Holiday periods are a high risk for weight gain, with the Christmas holiday period in particular posing a high risk for indiscriminate weight gain which is not subsequently lost. Weight gain prevention interventions are scarce and there is a need to establish the effectiveness of interventions, and their components, to prevent weight gain, as set out in Chapter 2. To my knowledge there are no published randomised controlled trials that have

tested the effectiveness of an intervention to prevent weight gain during the Christmas holiday period. This chapter reports a trial evaluating the effectiveness of the intervention described in Chapter 3, which aims to prevent weight gain during the Christmas holiday period amongst adults living in the UK.

4.2 Participants and methods

4.2.1 Design

The study was a two-group, single blinded RCT designed to test the effectiveness of a brief behavioural intervention comprising encouragement to regularly self-weigh, tips for weight management and information on the physical activity calorie equivalent (PACE) of festive foods and drinks to prevent weight gain over the Christmas holiday period. Participants were individually randomised to the trial groups. The study was granted full ethical approval by the University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee (approval number ERN_16-0673) on 28th July 2016. A copy of the approval is available in Appendix 3. The trial was registered with the ISRCTN trial registry, ISRCTN15071781. This trial has been reported in line with CONSORT (see Appendix 4).

4.2.2 Participants

Participants were recruited from local workplaces, social media and local schools (parents) through the circulation of flyers and posters. The recruitment materials used in the trial are available in Appendix 5. Human resources departments and company communication officers at local businesses were contacted to see if they would agree to circulate our recruitment materials to their employees through their usual method of communication, e.g. company intranet page, whole staff email, and company newsletter. Schools that had previously engaged with research at the university in other trials were contacted for their agreement to

distribute study recruitment materials to parents. In total, 32 primary schools (of 98 approached) in the West Midlands agreed to distribute the recruitment call to parents of school children by means of a flyer with cover letter which was sent home with children. Additionally, 14 workplaces (out of 20 approached) agreed to distribute the recruitment call to employees through their standard means of employer to employee communication. Social media pages (Twitter and Facebook) were also set up for the trial, where tweets and posts were regularly made during the recruitment phase directing interested potential participants to the trial website. The trial website provided some details of the trial and asked interested potential participants to contact the study team to be screened for eligibility via telephone. Appendix 5 shows an example of the study website and social media pages. Potential participants contacted the research team who then completed the initial screening procedures. Participants were informed that this was a study concerned with weight gain during the winter months. They were not told explicitly that the study was assessing the impact of the intervention on the prevention of weight gain during Christmas.

4.2.3 Inclusion criteria

Participants were eligible for inclusion if they were aged 18 years or more with a BMI ≥20 kg/m^2. This BMI is above the lower limit of the healthy weight category and so was chosen to ensure that participants who were towards the lower cut off or underweight were not encouraged to actively prevent weight gain, and therefore risk loss of weight, which may render them underweight.

4.2.4 Exclusion criteria

Participants were excluded if they were currently pregnant, planning a pregnancy in the next three months, or breastfeeding. These exclusion criteria were chosen due to their potential

impact on weight gain. Participants were also excluded if they were unable to understand English sufficiently to provide consent.

4.2.5 Settings

Once participants had been screened for eligibility, they were asked to attend two appointments (baseline and follow up) with a researcher, either at their home, or another convenient location (i.e. workplace, community venue, university). To assess potential contamination effects, we recorded where participants had heard about the study during eligibility screening. Appointments were scheduled 5-8 weeks apart. Baseline and follow up appointments were arranged at the same time, and participants were sent a text message and letter reminding them of their scheduled appointments one week in advance to reduce the possibility of missed appointments and reduce loss to follow up.

4.2.6 Data collection

Baseline data collection took place pre-Christmas in 2016 and 2017 (21st November and 16th December) with follow up taking place post-Christmas in 2017 and 2018 (4th January and 10th February) respectively. Data relating to participants' socio-demographic characteristics and lifestyle behaviours were also collected through a questionnaire booklet distributed to participants at baseline and follow up. To assess accessibility and generalisability of the intervention we collected data on whether participants had access to weighing scales at home. To reduce the risk of selection bias, participants were blinded to their group allocation. Prior to randomisation, there was no discussion of any element of the intervention with participants. The recruitment materials requested volunteers for a study about winter weight gain.

4.2.7 Intervention group

As described in Chapter 3, the multi-component intervention was underpinned by self-regulation theory [160] and the habit formation model [118] and aimed primarily to promote restraint of energy consumption.

Participants allocated to the intervention group received a four-page A4 leaflet containing an explanation of why people typically gain weight over Christmas, how much weight people typically gain over Christmas and the health implications of excess weight, by means of an introduction to the rationale of the study. The three components of the intervention were also included within this sheet: self-weighing record chart; PACE information; and the 10TT. The participant intervention sheet is available in Appendix 6. For the self-weighing intervention component, participants were instructed by the researcher to weigh themselves regularly during the study period, ideally daily, and record their weights in the chart provided in the intervention sheet. Researchers weighed participants and recorded their weight on the case report form. At this point, participants were asked to weigh themselves on the scales they would be using for the duration of the intervention so this weight could be written on the weight chart in the intervention sheet. This was to allow for the potential variation between scales and to enable participants to record their first weight on the weight chart in the intervention sheet in the presence of the researcher. Participants' 'maximum weight' was then calculated by the researcher based on the weight from the participant's own scales plus 0.5kg and written on the intervention sheet. Participants were advised that the goal was not to allow their weight to go above their maximum weight. As discussed in Chapter 2, average increases in weight during the Christmas holidays are reported to be between 0.4kg and 0.9kg [7]. Therefore, the explicit goal of the intervention was for participants to avoid gaining more than

0.5 kg (1 lb) of their baseline weight (i.e. weight stability). This also allowed for some flexibility related to the natural variation in weight throughout the course of any given day.

Included within the weight chart were brief prompts to support participants in limiting their weight gain. The weight chart included in the intervention sheet is available in Appendix 6. The 10TT were slightly adapted for seasonal appropriateness and included within the intervention sheet and entitled 'Ten Top Tips'. The PACE information was also included within the participant intervention sheet. The information specified the physical activity equivalent information of festive foods and drinks grouped into the following categories: the components of a Christmas dinner; beverages (alcoholic and non-alcoholic); party/buffet foods; and snack items. The calorie information was taken from the composition of foods integrated data set (CoFIDS) [161] where possible. The physical activity calorie equivalents were calculated from the British Heart Foundations' online exercise calculator [162] and based on the default option of a 55 year old male. Slow running (6 mph) and medium paced walking (3-5 mph) were selected as the activity equivalents, as these are the most pragmatic and acceptable types of activity for the general population [162]. To improve replicability of the intervention, it was assessed according to the Template for Intervention Description and Replication (TIDieR) checklist [163], which provides a systematic way of describing complex interventions. The completed checklist is available in Table 4.

Table 4: TIDieR Checklist

Item No	Item
Brief name 1	Provide the name or a phrase that describes the intervention The Winter Weight Watch study.
Why 2	Describe any rationale, theory, or goal of the elements essential to the intervention The multi-component intervention was informed by self-regulation theory [160] and the habit formation model [118] and aimed to promote restraint of energy consumption. The explicit behavioural goal of the intervention was for participants to gain no more than 0.5 kg (~1lb) of their baseline weight (i.e. to prevent weight gain).
What 3	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL) Participants allocated to the intervention group received a four-page A4 leaflet containing an explanation of why people typically gain weight over Christmas, how much weight people typically gain over Christmas and the health implications of excess weight, by means of an introduction to the rationale of the study. The three components of the intervention were also included within this sheet; self-weighing record chart; PACE information; and the 10TT. The participant intervention sheet is available in Appendix 6.
4	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities For the self-weighing intervention component, participants were instructed by the researcher to weigh themselves regularly during the study period, ideally daily but at least twice a week, and record their weights on the chart provided in the intervention sheet. Participants were advised that the goal was to not allow their weight to go above their maximum weight, which was 0.5kg above baseline weight.
Who provided 5	For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given Trained researchers with experience in intervention studies delivered the intervention to participants and provided them with the intervention materials. Participants could contact the research team if they had any questions.
How 6	Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group After baseline data collection, randomisation was undertaken, and participants allocated to the intervention arm were provided with intervention materials and self-weighing instructions.
Where	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features

Item No	Item
7	Participants were provided with intervention materials in either their homes, a community venue or the university where the researchers were based.
When and How Much 8	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose The intervention specified for participants to weigh themselves at least twice a week ideally daily. It was suggested that participants weigh themselves at the same time of day wearing similar amounts of or no clothing. PACE and 10TT intervention components were provided as information participants may find useful during the Christmas period.
Tailoring 9	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how The intervention provided some flexibility around the frequency of self-weighing with participants self-weighing daily or at least twice a week. The PACE information and 10TT were provided for participants to use them in the way most suitable for them.
Modifications 10*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how) No changes to intervention.
How well 11	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them Process measures.
12*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned

4.2.8 Comparator group

This study was focused on whether a multi component intervention was effective in preventing weight gain over the Christmas holiday period, therefore, rather than providing no information as the comparator to the intervention, participants allocated to this group received a brief leaflet with detail about leading a healthy lifestyle adapted from general public health information [164]. This contained no specific dietary or physical activity advice (see Appendix 7). General health information was considered an appropriate comparator as the provision of information alone is not effective for weight management [165].

4.2.9 Behavioural change techniques

Complex behavioural interventions often comprise of several behaviour change techniques, which are the functional constituents of interventions. Describing these techniques in a consistent manner is important to help the translation of research into practice [157]. In accordance with this, the behaviour change techniques used as part of the Winter Weight Watch study intervention and comparator were mapped against the CALO-RE taxonomy which is specifically for use with where interventions target dietary and physical activity behavioural change [157]. Table 3, in Chapter 3 sets out all of the behavioural change techniques used in the study.

4.2.10 Primary and secondary outcomes

The primary outcome was the difference in weight between randomisation groups at follow up, adjusted for baseline weight and attendance at a commercial weight loss programme. The following secondary outcomes were compared between the trial groups at follow up: 1) proportion of participants gaining ≤0.5kg; 2) self-reported frequency of self-weighing (at least twice per week versus less than twice per week); 3) percentage body fat; 4) cognitive restraint of eating score; 5) emotional eating score; and 6) uncontrolled eating score.

Baseline measures were taken pre-Christmas, between 20th November and 15th December in 2016 and 2017. Follow up measures were taken post-Christmas, between 3rd January and 10th February 2017 and 2018. Anthropometric measures were undertaken by trained researchers using standardised protocols. The training manual on the procedures for data collection for researchers undertaking measurements is shown in Appendix 8. Body weight was measured to the nearest 0.1 kg, with participants clothed without shoes or socks, using calibrated automated digital scales (TANITA T6360, Tanita Co., Tokyo, Japan). Percentage body fat was measured simultaneously with body weight using the same scale. Height was measured to the nearest centimetre at baseline using Seca 213, a portable stadiometer. Cognitive restraint, emotional eating, and uncontrolled eating were measured by the Three Factor Eating Questionnaire (TFEQ), and a score was derived for each of these outcomes [167]. The TFEQ measures eating behaviour according to each of the three factors. It was originally devised as a 51-item questionnaire, however in this study we used the revised and validated 18-item questionnaire (TFEQ-R18) [167]. The TFEQ-R18 is included in Appendix 9.

Measuring the intermediate outcomes of energy intake and expenditure was considered and rejected for the following reasons: firstly, this study was evaluating a very brief intervention with short follow up. The assessment of diet and physical activity is onerous for participants and expensive to measure accurately. Secondly, according to the energy balance equation [168], energy intake and energy expenditure must be equivalent. Therefore, for participants to prevent weight gain, this must be the case thus there is no need to measure energy intake and expenditure.

4.2.11 Process measures

Data relating to specific process measures were also collected to ascertain the mechanisms by which the intervention produced its effects. Guidance issued by the Medical Research Council (MRC) suggests that process evaluation should be included in the reporting of RCTs of complex interventions as it can help to understand intervention fidelity and clarify causal mechanisms [14]. Both quantitative and qualitative methods were used for the process evaluation within this trial. Both methods contribute to the understanding of intervention implementation, acceptability and causal mechanisms. Aspects of process evaluation captured by this quantitative study are causal mechanisms and acceptability. The qualitative study presented in Chapter 5, captured implementation and acceptability aspects of process evaluation, enabling the integration of findings. At follow up, in the intervention group, the self-reported habit index (SRHI) was used to assess automaticity of self-weighing [169]. The SRHI is the most frequently used measure of habit strength. It measures three key areas of habit as related to the behaviour: automaticity, repetition and frequency. In this study, seven questions from the SRHI were included to assess the automaticity, repetition and frequency of self-weighing. Participants rated their responses on a 5-point scale with 0 (strongly disagree) to 4 (strongly agree). To evaluate the processes within self-regulation, self-weighing (self-

monitoring) was assessed by participants recording their frequency of weighing. For participants in the intervention group, the follow up questionnaire also contained questions relating to their perceptions of self-weighing. Perceptions of self-weighing were also measured using another validated questionnaire [170]. The perceptions of self-weighing questions were based on previous work on self-weighing in weight gain prevention and weight loss [171] [172]. This portion of the follow up questionnaire required participants to provide responses to eight questions pertaining to self-weighing on an 8-point scale with 8 being most favourable and 1 most unfavourable.

4.2.12 Statistical justification for sample size

The relationship between overweight and mortality is linear (30% increase per 5 kg/m^2) [173], therefore the prevention of even small amounts of weight gain, that are sustained over the lifetime, has important health benefits [165]. We proposed a sample size based on an effect size of 0.75kg difference in weight between the groups at follow up. We chose this pragmatically as an effect size that we could realistically expect to achieve from a brief intervention over a short time period. In addition, previous weight gain prevention studies have demonstrated similar effect sizes (0.6kg and 1.3kg) [174, 175]. A total of 226 participants provided 80% power to detect 0.75 kg (SD=2.0) difference in weight at follow up between the groups with 5% significance. This particular SD was based on the results of a similar low intensity, brief intervention [152]. With allowance for 20% loss to follow up, the required sample size was 284.

4.2.13 Randomisation and masking

Eligible participants who had provided written informed consent, subsequently had their baseline measurements taken. Participants were then randomised following collection of baseline data and allocation was concealed using opaque, sequentially numbered, sealed envelopes. The random allocation sequence was generated by an independent statistician with random block sizes of 4, 6 and 8 using STATA software (version 14.2, StataCorp LP, College Station, TX, USA). An independent researcher checked the allocation sequence weekly.

Randomisation was stratified by participant attendance at baseline at a commercial weight loss programme. This was chosen as a stratification variable as commercial weight loss programmes have been shown to be effective interventions for weight loss [176]. Data on attendance at these programmes were collected at baseline

4.2.14 Blinding of participants to the study purpose

Participants were not informed of their group allocation (intervention or control) until they had completed follow up, but as this was a behavioural intervention, it is possible that participants made an assumption about the arm they were randomised to.

4.2.15 Blinding of study personnel at follow up

During follow up appointments, researchers were blinded to group allocation and baseline weight as this was kept in a sealed envelope until participants' follow up weights had been measured. Participants were requested not to reveal the information given to them at baseline as this could reveal group allocation to the researcher.

4.3 Analyses

A pre-specified statistical analysis plan (SAP) was prepared by myself with input from the PhD supervisors and the trial statisticians, and was made publicly available prior to analyses (http://www.isrctn.com/ISRCTN15071781; the full SAP appended on 15/05/18).

4.3.1 Descriptive analysis

Participant characteristics for the intervention and comparator groups were summarised using the STATA software programme (version 14.2, StataCorp LP, College Station, TX, USA). Categorical data were summarised by numbers and percentage and continuous data were summarised by mean and standard deviation or median and interquartile range if data were skewed. Participants were summarised by randomisation group according to the following variables: route of recruitment; age; gender; ethnicity; deprivation quartile (IMD score); weight (kg), BMI category; employment status; marital status; education status; number of children living at home; celebrating religious and/or social occasions i.e., Christmas; attending commercial weight management programme during study; ever tried to lose weight; sitting time per day; know anyone else in study; alcohol consumption in the last week; weekly physical activity; frequency of self-weighing at baseline; cigarettes smoked per day; weight management intentions; following a weight loss diet; taking prescribed medication to control weight; cognitive restraint score. The time participants were enrolled in the study was also analysed and presented by group as a mean and SD.

4.3.2 Analysis of primary outcome

An intention to treat (ITT) analysis was planned which was determined by the loss to follow up threshold, which was agreed and published prior to analyses. The loss to follow up threshold (5%), determined whether a full ITT approach would be used with imputation of missing data, or a modified ITT approach would be used, including only those who provided data at follow up. If <5% of participants were missing the primary outcome (weight) they were excluded from the analysis and no imputation conducted. If loss to follow up was ≥ 5%, multiple imputation was planned for the primary model based on the following variables: sex, BMI, age, ethnicity and socio-economic status (IMD score). Self-reported weight was to be used in the analyses if objective weights were not available. In this case, the primary analysis was by modified intention to treat (ITT), which included all randomly assigned patients for whom data on the primary endpoint were available.

The primary outcome was assessed using linear regression modelling with weight at follow up as the outcome variable, trial arm as the explanatory variable of interest, and baseline weight and the stratification variable (attendance at a weight loss programme) as covariates. The difference in weight between the intervention and comparator group is presented as an adjusted mean with corresponding 95% confidence interval and p value. The unadjusted change in weight between baseline and follow up for both groups is also presented.

The primary outcome analysis was repeated with additional covariates (BMI and time (days) between baseline and follow up). Other continuous outcomes (percentage body fat, cognitive restraint of eating, emotional eating and uncontrolled eating) were analysed in the same way as the primary outcome (adjusted for baseline measures and the stratification variable) and repeated with the additional covariates.

4.3.3 Analyses of secondary outcomes

To estimate the odds ratio (comparing intervention and comparator groups) for gaining ≤0.5 kg of their baseline weight at follow up and frequency of self-weighing (at least twice per week), logistic regression models were used, firstly adjusting for only the stratification variable (and baseline for the self-weighing outcome) and then including the additional covariates. These results are presented as adjusted odds ratios, 95% confidence intervals with associated p values.

4.3.4 Analyses of subgroups

Exploratory predefined subgroup analyses were performed as some subgroup differences were considered possible. There is evidence to suggest that people in a higher BMI category gain more weight at high risk times [64]. Secondly, there is evidence to suggest that intervention adherence is positively associated with weight outcomes so it is possible that people who adhere to the intervention would benefit more than those who do not. Therefore, subgroups according to BMI (measured at baseline) and adherence to the intervention (as measured by the weight record card) were conducted. Two definitions of assessing intervention adherence were used: minimum and high adherence. Minimum adherers were defined as participants who weighed themselves and recorded their weight on the record card at least twice a week for 75% of weeks prior to their follow up. High adherers were defined as participants who weighed themselves and recorded their weight on the record card at least five times a week for 75% of weeks prior to their follow up. These levels of adherence were chosen based on the instruction to participants to self-weigh at least twice a week, but ideally daily.

Differences in the effect of the intervention on the primary outcome in the pre-defined subgroups were explored by including interaction terms (Intervention: BMI at baseline; Intervention: minimal adherence; Intervention: maximum adherence) in the modelling.

4.3.5 Analyses of process outcomes

In the intervention group, association between frequency of self-weighing during the intervention period (from the weight record card data) and cognitive restraint of eating at follow up was explored using linear regression analysis (adjusting for cognitive restraint baseline score). The association between index of habit strength scores and weight at follow up in the intervention group was explored using linear regression analysis (adjusting for baseline weight and attending a commercial weight management programme).

Additional analysis to examine the relationship between cognitive restraint score and weight was explored using linear regression analysis with cognitive restraint as the explanatory variable and weight as the outcome variable (adjusting for baseline weight and attendance at a commercial weight management programme).

4.4 Patient and public involvement

Prior to commencement of the trial, patient and public involvement (PPI) representatives provided feedback on the research question, study design and study concept. Seven questions were sent to 125 members of the PPI group. The questions were as follows: 1. Do you ever try to control your weight over Christmas? 2. Do you think it is a good idea to control your weight over Christmas? 3. How difficult do you find it to control your weight over Christmas? 4. Would you consider taking part in a study like this? 5. Would you want to weigh yourself every three days over Christmas and keep a record of your weight? 6. If you decided to take part in a study like this, would you want others in your household to take part? 7. Please let us

know any comments you may have and any suggestions about the way we should design the study. In total, 22 responses were received. These responses were used to refine and inform specific elements of the trial. In particular, the responses were positive towards idea of managing weight during the Christmas period, and a simple, non-intensive trial was preferred.

4.5 Results

The study was conducted between 21st November and 13th February in 2017 and 2018. In total, 311 interested participants contacted the trial team between 1st November 2016 and 10th December 2017 and were screened for eligibility. In total, 272 participants were eligible and agreed to the two research visits. A total of 272 adults were randomised (n=93 in 2016 and n=179 in 2017). Figure 5 shows the flow of participants through the study. Only six participants did not provide follow up data for the primary outcome (2.2%). Two participants self-reported their follow-up weight. Table 5 shows the baseline characteristics of participants who were predominantly female (78%) and of White ethnicity (78%). The mean age was 43.9 years and 24.1% of participants were from areas of higher deprivation. Mean length of time in the study was 45.3 days (SD=5.7). Participant characteristics across groups were generally well balanced.

Figure 5: CONSORT flow diagram for the Winter Weight Watch study

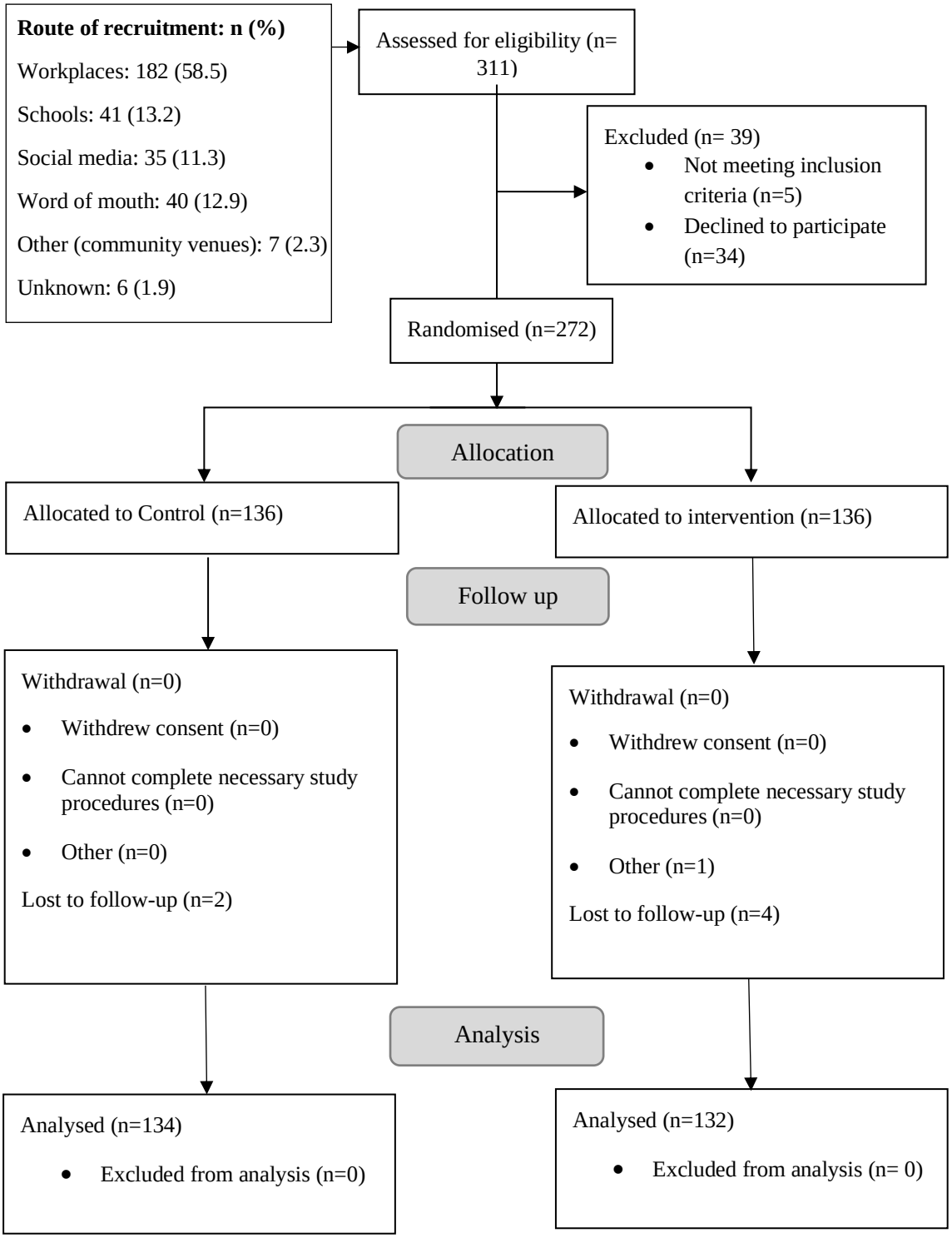


Table 5: Baseline characteristics of participants and time in the study according to randomisation group.

	All participants (n=272)	**Comparator group (n=136)**	**Intervention group (n=136)**
Demographics			
Route of recruitment: n (%)			
Workplaces	158 (58.1)	85 (62.5)	73 (53.6)
Schools	33 (12.1)	18 (13.2)	15 (11.1)
Social media	31 (11.4)	10 (7.4)	21 (15.4)
Word of mouth	37 (13.6)	18 (13.2)	19 (13.9)
Other (community venues)	13 (4.8)	5 (3.7)	8 (6.2)
Unknown	2 (0.7)	2 (1.5)	0 (0)
Age, years: mean (SD)	43.9 (11.7)	43.4 (11.9)	44.4 (11.6)
Gender			
Female: n (%)	213 (78.3)	106 (77.9)	107 (78.7)
Ethnicity: n (%)			
White	206 (78.3)	101 (77.7)	105 (79)
South Asian	34 (12.8)	17 (13.1)	17 (12.8)
Black Caribbean	10 (3.8)	5 (3.9)	5 (3.8)
Black African	1 (0.4)	1 (0.8)	0 (0)
Mixed	8 (3)	4 (3.1)	4 (3)
Other Asian	4 (1.5)	2 (1.5)	2 (1.5)
Deprivation quartile (IMD score): n (%)			
1 (most deprived)	67 (24.6)	31 (22.8)	36 (26.5)
2	62 (22.8)	34 (25)	28 (20.6)
3	52 (19.1)	23 (17)	29 (21.3)
4 (least deprived)	91 (33.5)	48 (35.3)	43 (31.6)
Weight, kg: mean (SD)	79.9 (19)	79.8 (19)	80.1 (19.2)
Weight, kg: median (IQR)	75.6 (65.9-88.6)	75.6 (67.5-86.9)	76.1 (65-90.5)
BMI category: n (%)			
20-24.9	87 (32)	44 (32.4)	43 (31.6)
25-29.9	100 (36.8)	52 (38.2)	48 (35.3)
30-34.9	43 (15.8)	20 (14.7)	23 (16.9)
35-39.9	23 (8.5)	11 (8.1)	12 (8.8)
40+	19 (7)	9 (6.6)	10 (7.4)
BMI, kg/m^2: mean (SD)	28.8 (6.6)	28.7 (6.7)	28.8 (6.5)
BMI, kg/m^2: median (IQR)	27.1 (24.2-31.4)	27 (24.3-30.8)	27.4 (24.2-32.4)
Marital status: n (%)			
Married	147 (55.9)	70 (53.9)	77 (57.9)
Single	116 (44.1)	60 (46.2)	56 (42.1)
Education status			
Never went to school	0 (0)	0 (0)	0 (0)
Went to primary school only	1 (0.4)	1 (0.7)	0 (0)
Went to secondary school but left at the minimum leaving age	28 (10.3)	11 (8.1)	17 (12.5)
Went to secondary school and stayed on past the minimum leaving age	6 (2.2)	3 (2.2)	3 (2.2)
Went to a college of further education	82 (30.1)	47 (34.6)	35 (25.7)

Went to university	146 (53.7)	68 (50)	78 (57.3)
Not known	9 (3.3)	3 (2.2)	6 (4.4)
Employment status			
In paid employment	207 (76.1)	104 (76.5)	103 (75.7)
Self-employed / freelance	20 (7.4)	9 (6.6)	11 (8.1)
Unemployed	2 (0.7)	1 (0.7)	1 (0.7)
Retired from paid work	17 (6.3)	7 (5.1)	10 (7.4)
Student	5 (1.8)	2 (1.5)	3 (2.2)
Looking after the home/family	9 (3.3)	4 (2.9)	5 (3.7)
Sick / disabled	3 (1.1)	3 (2.2)	0 (0)
Not known	9 (3.3)	6 (4.4)	3 (2.2)
Celebrating religious and/or social occasions i.e., Christmas: n (%)			
Yes	258 (94.9)	128 (94.1)	130 (95.6)
Attending commercial weight management programme during study: n (%)			
Yes	25 (9.2)	12 (8.8)	13 (9.6)
Ever tried to lose weight			
Yes	244 (89.7)	124 (91.2)	120 (88.2)
Sitting time per day (hours)			
1-2	11 (4)	7 (5.1)	4 (2.9)
3-4	42 (15.4)	18 (13.2)	24 (17.6)
5-6	67 (24.6)	33 (24.3)	34 (25)
7-8	93 (34.2)	48 (35.3)	45 (33.1)
9-10	36 (13.2)	17 (12.5)	19 (13.9)
11 or more	21 (7.7)	13 (9.6)	8 (5.9)
Not known	2 (0.7)	0 (0)	2 (1.5)
Know anyone else in study			
Yes	130 (47.8)	67 (49.3)	63 (46.3)
Alcohol consumption in the last week: n (%)			
Yes	170 (65.6)	90 (70.3)	80 (61.1)
Weekly physical activity: n (%)			
None	44 (16.9)	19 (14.8)	25 (18.9)
Once per week	59 (22.7)	29 (22.7)	30 (22.7)
2-3 times per week	98 (37.7)	53 (41.4)	45 (34.1)
4-5 times per week	35 (13.5)	16 (12.5)	19 (14.4)
6+ times per week	24 (9.2)	11 (8.6)	13 (9.9)
Frequency of self-weighing: n (%)			
Daily	25 (9.2)	13 (9.6)	12 (8.8)
6 times a week	3 (1.1)	1 (0.7)	2 (1.5)
5 times a week	3 (1.1)	1 (0.7)	2 (1.5)
4 times a week	11 (4)	3 (2.2)	8 (5.9)
3 times a week	5 (1.8)	3 (2.2)	2 (1.5)
Twice a week	20 (7.4)	9 (6.6)	11 (8.1)
Once a week	77 (28.3)	41 (30.2)	36 (26.5)
Less than once a week	70 (25.7)	37 (27.2)	33 (24.3)
Never	47 (18)	22 (16.9)	25 (19.1)
Cigarettes smoked per day: n (%)			
None	251 (95.8)	124 (96.1)	127 (95.5)
≤5	4 (1.5)	2 (1.6)	2 (1.5)

≥6	7 (2.7)	3 (2.3)	4 (3)
Weight management intentions: n (%)			
Lose weight	173 (66.8)	89 (69)	84 (64.6)
Maintain weight	64 (24.7)	33 (25.6)	31 (23.8)
Not trying to lose or gain	22 (8.5)	7 (5.4)	15 (11.5)
Following a weight loss diet: n (%)			
Yes	49 (18.6)	24 (18.5)	25 (18.8)
Taking prescribed medication to control weight: n (%)			
Yes	1 (0.4)	0 (0)	1 (0.8)
Cognitive restraint score: mean (SD)	13.5 (3.14)	14 (3.16)	13.1 (3.05)
Emotional eating score: mean (SD)	7.75 (2.59)	7.54 (2.67)	7.94 (2.99)
Uncontrolled eating score: mean (SD)	20.21 (5.68)	19.83 (5.12)	20.46 (5.90)
Time in study, days: mean (SD)*	45.3 (5.7)	45.9 (5.8)	44.7 (5.6)

* Assessed at follow up.

4.5.1 Primary outcome

The unadjusted mean weight change between baseline and follow up was -0.13kg (95% CI: -0.4 to +0.15) in the intervention group and +0.37kg (95% CI: +0.12 to +0.62) in the comparator group. The mean difference in follow up weight between groups, adjusted for baseline weight and the stratification variable of attendance at a weight loss programme, was -0.49kg (95% CI: -0.85 to -0.13, p=0.008), meaning follow up weight was lower in the intervention group than the comparator group. The result was similar when further adjusting for baseline BMI and the time participants were involved in the study (-0.48; 95% CI: -0.84 to -0.12; p=0.01; Table 6).

Table 6: Adjusted differences in primary and secondary outcomes between intervention and comparator groups at follow up.

	Baseline				**Follow up**				**Primary model[1]**			**Further adjusted model[2]**		
	Comparator		**Intervention**		**Comparator**		**Intervention**							
Outcome	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**N**	**Mean (SD)**	**Mean difference**	**95% CI**	**p**	**Mean difference**	**95% CI**	**p**
Primary outcome														
Weight at follow up	136	79.72 (19.01)	136	80.29 (19.45)	134	80.16 (18.77)	132	79.95 (18.96)	-0.49	(-0.85 to -0.13)	0.008	-0.48	(-0.84 to -0.12)	0.010
Secondary outcomes														
Percentage body fat	136	33.99 (8.78)	134	34.23 (9.42)	133	34.14 (8.99)	128	34.37 (9.17)	-0.02	(-0.51 to 0.48)	0.945	-0.03	(-0.53 to 0.47)	0.910
Cognitive restraint	129	14.01 (3.16)	131	13.05 (3.05)	124	14.10 (2.92)	121	14.22 (2.98)	0.64	(0.08 to 1.20)	0.026	0.62	(0.06 to 1.19)	0.030
Emotional eating	129	7.54 (2.67)	133	7.94 (2.99)	126	7.56 (2.66)	128	7.63 (2.82)	-0.06	(-0.43 to 0.30)	0.733	-0.05	(-0.42 to 0.32)	0.795
Uncontrolled eating	128	19.83 (5.12)	128	20.46 (5.90)	124	19.91 (5.03)	122	19.84 (5.09)	-0.49	(-1.25 to 0.26)	0.199	-0.42	(-1.18 to 0.34)	0.278
	n	**No. (%)**	**n**	**No. (%)**	**Total**	**No. (%)**	**Total**	**No. (%)**	**Odds ratio**	**95% CI**	**p**	**Odds ratio**	**95% CI**	**p**
Gaining no more than 0.5kg	-	-	-	-	134	79 (58.96)	132	84 (63.64)	1.22	(0.74 to 2.00)	0.443	1.23	(0.75 to 2.04)	0.412
Self-weighing at least twice per week	130	30 (23.08)	131	37 (28.24)	126	25 (19.84)	128	109 (85.16)	55.93	(22.15 to 141.24)	<0.001	64.96	(24.48 to 172.39)	<0.001

[1] Adjusted for baseline value of the outcome variable and attendance at a commercial weight loss programme (stratification variable) [2] Model further adjusted for baseline BMI and time of follow up

4.5.2 Secondary outcomes

The estimated reduction in percentage body fat in the intervention group compared with the comparator group was small and not statistically significant (-0.02%, 95% CI: -0.51 to 0.48, p=0.95, primary model). The model further adjusted for baseline BMI and time of follow up provided a similar result. The odds of gaining no more than 0.5kg was higher for those in the intervention group compared with the comparator group but this was not statistically significant (OR 1.22, 95% CI: 0.74 to 2.00, p=0.44, primary model). Those in the intervention group had increased odds of self-weighing at least twice per week (OR 55.93, 95% CI: 22.15 to 141.24, p<0.001, primary model). Again, similar results were shown in the further adjusted model.

There was a significant increase in cognitive restraint scores for the intervention group compared with the comparator group at follow up (mean difference in primary model: 0.64, 95% CI: 0.08 to 1.20, p=0.026). Differences in emotional eating and uncontrolled eating scores were small and not statistically significant (Table 6).

4.5.3 Subgroup analyses

In the subgroup analyses the interaction between baseline BMI and randomisation group estimated an increase of 0.03kg in follow up weight for every one unit increase in baseline BMI for those in the intervention group, but this was not statistically significant (coefficient=0.03, 95% CI: -0.02, 0.09; p=0.265). When assessing adherence to self-weighing, participants in the intervention group who achieved minimal adherence (i.e. self-weighing at least twice but less than five times per week, n=45) had no real difference in follow up weight compared with those not meeting minimal adherence (n=27, -0.01kg (95% CI: -0.67, 0.65; p=0.982)). The estimated difference in follow up weight between those achieving high

adherence (i.e. self-weighing at least five times per week, n=47), and those not meeting minimum adherence in the intervention group was -0.30kg (95% CI: -0.94, 0.33; p=0.347), although this was not statistically significant. See Table 7.

Table 7: Adjusted differences for subgroup analyses between intervention and comparator for weight at follow up. Interaction terms: Intervention: BMI at baseline; Intervention: minimal adherence; Intervention: maximum adherence).

Subgroup	Explanatory variable	Coefficient	95% CI	p
BMI	Intervention	-1.41	(-3.06 to 0.25)	0.095
	BMI	-0.01	(-0.08 to 0.05)	0.698
	Attending a weight loss programme	0.26	(-0.40 to 0.93)	0.432
	Baseline weight	0.98	(0.96 to 1.00)	<0.001
	Intervention: BMI	0.03	(-0.02 to 0.09)	0.265
Adherence	Intervention	-0.38	(-0.91 to 0.16)	0.171
	Attending a weight loss programme	0.26	(-0.12 to 0.64)	0.185
	Baseline weight	0.98	(0.97 to 0.99)	<0.001
	Intervention: minimum adherence	-0.01	(-0.67 to 0.65)	0.982
	Intervention: maximum adherence	-0.30	(-0.94 to 0.33)	0.347

4.5.4 Process measures

In the intervention group, there was no significant association between frequency of self-weighing during the intervention period (from the weight record card data) and cognitive restraint of eating at follow up (-0.47, 95% CI -2.03, 1.09, p=0.551).

There was an association between greater automaticity of self-weighing (habit strength of self-weighing) and weight gain prevention in the intervention group. Other characteristics of habit strength, namely frequency and relevance, were assessed and no significant associations were found. Relative to a score of zero, a high automaticity score was associated with lower weight at follow up (mean weight at follow up was 1.10kg less for those scoring 4 compared with those scoring zero (95% CI: -2.20 to 0.005, p=0.051)). See Table 8.

Additional analysis explored the mediatory effect of cognitive restraint and weight at follow up. Comparing the effect of cognitive restraint by intervention group, demonstrated a one unit increase in cognitive restraint score was associated with a 0.03kg lower weight at follow up in the control group and 0.02kg lower weight at follow up in the intervention group. However, neither association was statistically significant (p=0.57, p=0.71) and the difference between the two values was not statistically significant.

Table 8: Multivariate linear regression analysis of relationship between habit strength and weight at follow up [x]

Measure of habit strength	Coefficient	95% CI	p	Participants (n)
Automaticity				
0				13
1	-0.656	(-1.729 to 0.418)	0.229	25
2	-0.440	(-1.566 to 0.685)	0.440	20
3	-0.650	(-1.644 to 0.343)	0.197	46
4	-1.098	(-2.201 to 0.005)	0.051	22
Frequency				
0				15
1	-0.282	(-1.268 to 0.704)	0.57	33
2	-0.411	(-1.50 to 0.678)	0.456	21
3	-0.148	(-1.127 to 0.831)	0.765	36
4	-0.898	(-2.014 to 0.218)	0.114	18
Relevance				
0				15
1	-0.655	(-1.588 to 0.278)	0.167	40
2	-1.103	(-2.070 to -0.135)	0.026	32
3	-0.989	(-2.012 to 0.322)	0.058	23
4	-0.929	(-2.070 to 0.272)	0.110	14

[x]Adjusting for baseline weight and attending a commercial weight management programme. Reference category for all habit strength scores is zero. Participants in the intervention group answered one question for automaticity, one for relevance and one for frequency.

4.6 Discussion

A brief intervention that encouraged participants to weigh themselves regularly, provided information about the physical activity calorie equivalents (PACE) of popular festive food and drinks and offered advice for good weight management, prevented weight gain over the Christmas period in adults. The observed difference in weight between intervention and comparator groups was marginally smaller than the estimate of effect size used in our sample size calculation. However, this is still important given the relationship between weight and mortality is linear and any weight gain prevented will have a positive impact on health outcomes. The secondary outcome of reducing the proportion of participants gaining 0.5kg was not significant but the trial was not powered to detect a difference in this dichotomous outcome. The null finding for percentage body fat may be due to the difficulty in detecting small changes in adiposity using bioelectrical impedance [177]. In line with the aims of the intervention, the intervention group were more likely to weigh themselves at least twice a week than comparators. The proposed logic model (see Figure 4, Chapter 3) hypothesised that the intervention would promote the cognitive restraint of energy intake through each of the intervention components, which would ultimately result in participants preventing weight gain during the period. Results from the analysis of the conscious restraint of energy intake scores have provided evidence that this occurred in the intervention group, who demonstrated significantly higher cognitive restraint of eating scores post intervention, than comparators.

4.6.1 Comparison with existing literature

Very few trials have tested weight gain prevention interventions in adults. One systematic review reported that only nine RCTs in ten years have been published [94]. Furthermore, there are no trials testing very brief (<10 weeks) weight gain prevention interventions. Most studies

included in the systematic review have reported interventions that result in small to modest differences in weight between groups at follow up. Furthermore, several studies included in the review have reported a significant difference in weight between intervention and comparator of 1.0kg and 3.5kg [178-183]. All successful interventions were multifactorial and intensive consisting of dietary, behavioural and physical activity elements with regular contact and support. Interventions varied in duration (ranging from 10 weeks to 5 years) and the substantial heterogeneity of interventions made them difficult to compare. The review authors concluded that the less intensive interventions incorporating self-monitoring of weight, in addition to general dietary advice, physical activity recommendations and behaviour change components, could be more successful at preventing the small gains in weight observed in populations over time and that studies to test this were required. In line with this previous evidence, this trial has found that a brief intervention of between four and eight weeks that prompted participants to demonstrate restraint in their eating/drinking, during a high-risk period for weight gain (Christmas holidays), can be effective.

While this intervention was successful in preventing weight gain, it consisted of multiple components and it is therefore not possible to determine the effectiveness of the individual components, although the intervention group were more likely to weigh themselves at least twice per week than comparators. There is evidence from other studies to suggest that each of the individual intervention components can be effective in facilitating weight management, discussed in Chapter 3 of this thesis [103, 150, 152]. Previous prevention trials which included self-weighing, reported associations between frequent self-weighing and weight change [94]. Additionally, a recently published weight gain prevention trial demonstrated success with daily self-weighing during the holiday period of Thanksgiving to New Year [103]. Conversely, one study included in the review, found self-weighing not to be associated with weight

change [179] which could have been the result of the low level of adherence to self-weighing in the study, which was not the case in this trial as 92 participants met either minimal or high adherence to self-weighing.

Chapter 3 set out the theoretical basis of the intervention: the intervention was underpinned by self-regulation theory with the habit formation model as an additional theoretical framework supporting participants to sustain behavioural changes. The encouragement of regular self-weighing was hypothesised to develop habit formation. Previous literature has suggested that automaticity is the 'active ingredient' of habit formation [184] and that achieving automaticity should be the ultimate aim of habit formation. In this study, analysis of the association between the indicators of habit formation and self-weighing demonstrated that higher automaticity was associated with lower weight at follow up. This is important given that habit formation can take 66 days [153]. No significant associations were found between lower weight at follow up and other indicators of habit formation: behavioural frequency (repetition) and identity (relevance). Results from this study add further support for the role of habit formation (specifically automaticity) cultivated through self-weighing, in supporting behaviour change.

In addition to offering participants tips for good weight management, highlighting the energy content and demands of popular food and drinks to participants was an important consideration. This is because studies have shown that the public frequently underestimate the calories contained in foods [144, 145] and/or do not understand the amount of physical activity required to expend the energy dense foods [146], which are consumed more frequently at Christmas [68]. By highlighting this information to participants, the logic model proposed that they would demonstrate eating and drinking restraint and to a lesser extent, increase their physical activity. Previous studies have shown the provision of physical activity calorie equivalent (PACE) information to be useful in reducing the number of calories chosen from

menus or consumed at meals times by the public whilst also encouraging them to be more physically active and to achieve energy balance [148, 149]. Chapter 5 explores the mechanisms of action stimulated by the PACE information in more detail, through the descriptions offered by participants, to determine how well and the mechanisms by which the intervention components worked.

4.6.2 Strengths and limitations

This is the first RCT to examine the effectiveness of a weight gain prevention intervention focusing specifically on the Christmas period. The intervention was designed to be simple so that it could be easily implemented if effective. Loss to follow up was very low at 2.2% reducing the potential for attrition bias. With this low dropout rate, it was possible to detect a smaller effect than we had initially intended according to the sample size calculation for the trial. The high follow up rate of ~98% could be because participants engaged well with the study or because the follow up period was short. Nevertheless, a strength of this study is that we implemented several strategies to ensure low loss to follow up. Specifically, participants were reimbursed for their time when they completed follow up (£10 high street voucher) and follow up visits were conducted in participants' homes at a time convenient to them. Additionally, participants were blinded to the specific purpose of the study and the researchers who collected outcome data at follow up were also blinded to group allocation until after weight had been measured.

Another strength of this study is that a broad range of people were recruited from a range of ethnic groups with varied BMI and deprivation status, which increases the generalisability of the findings. This also highlights that the intervention has the potential to be appealing across the population thereby having the potential to reduce health inequalities. The PACE

information on Christmas foods and drinks used in the study was tailored to the local cultural context, but could easily be adapted for use in different settings by including the foods and drinks that are typically consumed during the festive period in particular cultural settings or countries.

We recorded that 83.1% (n=230) of participants had access to scales at home. This supports the ease with which the intervention could be implemented with the public. Furthermore, while men can be difficult to recruit to weight management trials, [185] this trial recruited a reasonable proportion (22%).

There are, however, some limitations to this research. A longer period of follow up would have been useful to determine if the weight gain prevented persisted over time. The amount of weight gain prevented by the intervention might be considered relatively small (~0.5kg) but the intervention was brief and at a population health level this amount of weight prevention would be important if it was not regained [165]. Additionally, energy consumption (food and alcohol) and levels of physical activity were not objectively assessed. Although the qualitative study described in Chapter 5 adds valuable insights, these further measures would have provided auxiliary information on the mechanisms of action of the intervention. Furthermore, as alcohol can contribute considerably to energy intake, weight gain prevention interventions at Christmas could be enhanced by having an increased focus on reducing the consumption of alcoholic drinks.

While we blinded participants to the main outcome of the study and did not explicitly state its intention, our recruitment materials requested volunteers for a study to stop gaining weight during winter. It is possible those who were more health conscious and therefore more engaged with weight management were recruited for the trial which provided a more positive

result. However, we were able to recruit people with a range of BMI statuses, not just those in the healthy BMI category. This could also be true for the comparator participants, who may have made changes to their behaviour due to being measured as part of the trial. This could have resulted in less weight gain than they would typically experience at Christmas time, had they not had been part of the trial.

Some of the key characteristics of participants in this study may differ to those of the general population. These may include gender (22% Male WWW RCT vs 50.4% Male general population), proportion of previous weight loss attempts (89.7% WWW RCT vs. 61.3% Europe/Central Asia), proportion of those attempting to lose weight (66.8% WWW RCT vs. 28% UK) the proportion of those who self-weighed on a daily basis (9.2% WWW RCT). Whilst these differences do not affect the validity of the findings, the implications are important to consider for the wider implementation of the intervention as 66.8% of the study population were already trying to lose weight whereas the general population may not have the same weight loss intentions.

4.7 Conclusions and policy implications

This brief, multicomponent intervention, consisting of encouragement to regularly self-weigh, tips for weight management and PACE information prevented weight gain over the Christmas period in adults. The conscious restraint of energy intake was significantly increased in the intervention group, suggesting that this is an important process by which participants prevented weight gain. Whilst these results provide a promising, potential solution to preventing weight gain during high risk occasions, understanding more about the mechanisms of the intervention and the processes required of individuals to prevent weight gain, and whether effects are sustained, will add valuable insights, important for implementation. These

results should be considered for implementation at scale by health policy makers to prevent weight gain in the population during high risk periods such as holidays.

CHAPTER 5

5.0 LEARNINGS FROM THE WINTER WEIGHT WATCH STUDY INTERVENTION: RESULTS FROM A NESTED QUALITATIVE STUDY

This chapter presents results from the nested qualitative study undertaken to gain a deeper understanding of the participants' views and experiences of the intervention, and to explore the specific processes that led to participants preventing weight gain during the intervention. This chapter also explores how the qualitative data supports the hypothesised mechanisms of action presented in the logic model in Chapter 3.

5.1 Qualitative research methods

Quantitative research methods enable researchers to test hypotheses and establish relationships between variables across different settings and contexts. In contrast, qualitative methods enable researchers to engage in exploratory research, providing in depth insights into individual views, beliefs and experiences [186]. Qualitative research centres on understanding the realities of individuals. This is enabled through their own descriptions of behaviour, attitudes and feelings. The role of the researcher is to appreciate that there is no single reality, and that this is subjective [187]. The strengths of qualitative research are that researchers are able to explore issues in such depth to uncover subtleties and complexities that may be missed by other positivist research methods such as quantitative research.

Qualitative research is guided by a range of beliefs known as research paradigms. Whilst the term ‘qualitative research’ is frequently used in studies, it is important to acknowledge that it encompasses a wide range of paradigms. Characterising different methods which reflect the complexity of how individuals view the world and acquire knowledge, allows for deeper justifications of findings in health research. Paradigms have been defined as basic belief

systems which relate to ontological, epistemological and methodological assumptions [188]. No one single paradigm is superior to another, but this is often debated, and they are used interchangeably to answer research questions. Ontology relates to how the researcher approaches reality and its existence [189-191] and determines the approach to the nature of the world and reality. There are two overarching positions in ontology: realism and idealism. The realist position asserts than an external reality does exist and that this is independent in nature whereas the idealist position believes there is no reality that exists independently from one's own beliefs and understanding. The variants of each of these overarching approaches are listed in Table 9. The approach to the theory of knowledge is known as epistemology. Epistemological assumptions are based on an individual's view and knowledge of the world and how these are constructed [190, 191], i.e. how we come to know what we know. These approaches enable the researcher to set out a position on how knowledge was gained and how it is presented. Methodology is how knowledge is discovered using systematic processes. Methodology is guided by the researcher's ontological position and epistemological approaches.

Table 9: Ontological philosophical positions

Ontology		
Overarching position	**Name**	**Description**
Realism: an external reality exists beyond beliefs and understanding.	Naïve realism [192]	Reality can be both directly and accurately observed.
	Cautious realism [193]	Reality may not be known accurately, only approximately.
	Depth realism [193]	There are different levels of reality: what is experienced through the senses; where observation is irrelevant to reality; and where the underlying mechanisms and processes are considered.
	Subtle realism [193, 194]	Where perceptions and observations are subjective.
	Materialism	Where only material features determine reality.
Idealism: No external reality exists beyond constructed beliefs and understanding.	Subtle idealism [195]	The social world constructs representations, based on specific contexts, which are shared by people.
	Relativism [195]	Shared social reality does not exist, only individual constructs.

5.1.1 Ontological position

Subtle realism best characterises the ontological position for this work [194]. Subtle realism asserts that perceptions and observations are subjective and that different methods will uncover different aspects of the underlying reality. It aims to represent and individuals' subjective reality rather than attain the absolute truth. This is appropriate for this work as here the aims are to explore reality through participants' perspectives of it through the rational descriptions and discernments provided by individuals [196].

5.1.2 Epistemological position

Whilst ontology relates to the view of reality, epistemology related to views about knowledge: how it is acquired; how we can learn about reality; and what constitutes the basis of knowledge. There are two main epistemological approaches for researchers to consider: positivist and interpretivist. The positivist approach asserts that the researcher's role does not impact on knowledge acquisition; that objective inquiry is possible; and that through observation knowledge may be gained. In contrast, the interpretivist approach asserts that: the researcher's role is significant and impacts on knowledge acquisition; the researcher has the ability to view the experiences of others in differing contexts to obtain knowledge; and that knowledge is subjective and not objective in any way.

5.1.3 Post positivism

Quantitative research methods are associated with a positivist approach whereas qualitative research methods are associated with an interpretivist approach. A further approach is known as the post positivist approach. Post positivism is considered as a more moderate form of positivism in that it values objectivity but alongside the belief that the researcher's role is important and significant and could impact on observations. This is unlike positivism, as post

positivism acknowledges the role of the researcher and attempts to moderate this. Mixed methods research is often within a post positivist approach as the methodology in post positivism incorporates both quantitative and qualitative research methods due to the belief that knowledge exists in a social context that can be best uncovered using both experimental and interpretative methods. This work therefore is associated with a post positivist epistemological position.

5.1.4 Qualitative research within RCTs

In accordance with a realist, post positivist approach, an understanding of reality can be best achieved through the combination of experimental and interpretative methods. In health research, qualitative inquiry is often undertaken alongside trials as it enables researchers to enrich and add context to quantitative findings and facilitates an appreciation of the complexity of interventions. Used alongside RCTs, qualitative research often seeks to explore: the experiences and views of participants; the mechanisms of action of an intervention; and contextual information which may influence how the intervention is delivered and engaged with in practice. These data help researchers to explain trial outcomes and predict how interventions may work when not under experimental conditions, in line with a realist approach.

In the MRC's framework for the development and evaluation of complex interventions [14, 106], it is highlighted that the use of qualitative research (along with other methods) would add a valuable component to the evaluation of these interventions. In health research in general, the benefits of using both qualitative and quantitative research methods in trials are increasingly reported [197-199]. A systematic mapping review reported the use of qualitative research within RCTs [199]. The review aimed to identify and categorise the main aspects of RCTs assessed

using qualitative research methods. The review identified 296 articles which were published in peer reviewed journals between 2008 and September 2010. Analyses of the articles provided five broad categories for aspects of the trial the qualitative research focused on: intervention content and delivery; trial design, conduct and processes; outcomes; measures of process and outcomes; and the target condition. The review also identified areas where qualitative research added value to the trials: i) the potential value added by facilitating the transferability of findings by exploring the social contexts that may affect the implementation of the intervention outside of experimental conditions; ii) identifying the mechanisms of action impacting on the intervention providing a successful outcome; and iii) improving external validity through the identification of barriers.

5.1.5 Assessing quality in qualitative research

Debate exists around the how the quality of qualitative research should be assessed [200]. Some researchers argue that qualitative research should be assessed using the same criteria as quantitative whilst others hold the opposing view [201]. The reason for these opposing views relates to the differing ontological and epistemological standpoints held by researchers; realist or interpretivist. The majority of theoretical orientations state that there is no single, true, definitive reality to be accessed, documented and reported. Therefore, qualitative research should set out a number of justifications for the research to help define quality. Subtle realism, the ontological position of this research, enables researchers to assess and compare the differing perspectives provided by the different methodologies, and assess quality against criteria common to both research methods such as validity and relevance [193, 194]. However, it is important to note that the specific aims of the qualitative research should be considered and if appropriate, amended during this assessment process.

5.1.6 Validity

The integrity of qualitative research can be evaluated by assessing the validity of the research through the following means: triangulation; respondent validation; clear description of data collection; methods and analyses; reflexivity; attention to negative cases and fair dealing. Table 10 describes each of these techniques.

5.1.7 Relevance

Assessing the relevance of research is another element of the subtle realism ontological position. Relevance can increase knowledge, add to existing knowledge and enhance generalisability. To explore relevance, research should be reported in a sufficiently detailed manner to facilitate interpretation by the reader. The extent to which researchers provide compelling reasons to accept their interpretations is a key part of assessing quality.

Table 10: Techniques used in qualitative research to improve validity

Technique	**Description**
Triangulation	Involves more than one method of data collection on the same topic. The aim of triangulation is to capture different dimensions of the same phenomena by comparing these results. Allows for corroboration of overall interpretation. Assumes that one method compensates for any weaknesses of the other so possibly not a true measure of validity rather a measure of completeness and facilitating reflexivity.
Respondent validation (member checking)	Involves research participants responding to initial data, checking for accuracy or interpretative claims. Participants can check the accuracy or add to initial data following reflection on the research question. Respondent validation is considered to be a strong validity check [202]. This method helps to reduce errors and enable further interpretation.
Clear description of methods of data collection and analysis	Requires a clear description of methods and analyses to enable the reader to judge the interpretation of data.
Reflexivity	A consideration of the role of the researcher and research process in the collection of data. Personal characteristics of the researcher should be considered with regards to the effects on the data collected. The relationship with the researcher and the research should also be examined and reported.
Attention to negative cases	Involves the presentation and discussion of alternate or negative cases (deviant cases) which may contradict the findings. Including deviant cases helps to refine analysis and add to the validity of findings.
Fair dealing	Includes a wide range of responses and viewpoints to represent a range of realities or truths.

5.2 The Winter Weight Watch study RCT

As the Winter Weight Watch study was a complex behavioural intervention, it is important to know more about participants' experiences to facilitate a deeper understanding of how the intervention as a whole and its different components influence individuals. Qualitative methodologies are a highly appropriate means of eliciting information about beliefs, attitudes, experiences and knowledge, and the ways that individuals justify their decision-making [203]. The intention of this nested qualitative study was to enhance the interpretation of the findings of the RCT by exploring how the intervention exerted effects found in the outcome RCT analyses. Moreover, exploring the acceptability of the intervention was also an important objective for this research, particularly as a behavioural intervention during the Christmas period was targeted, which is typically a time of celebration and enjoyment. This study utilised a pragmatic, objectives driven approach [204, 205] which aimed to gain a deeper understanding of participants' views and experiences of the intervention and the individual components and of participant's perspectives regarding how they engaged with the different parts of the weight prevention intervention.

5.2.1 Qualitative study objectives

The specific aims of the research were:

1. Given the topic of the study was novel, participant thoughts and views towards weight gain prevention at Christmas was explored in depth to understand whether this time period is an acceptable target for weight gain prevention.
2. To explore participants' views and experiences of the intervention as a whole, as well as each intervention component.
3. To explore participants' suggestions for enhancements and improvements.

4. To explore and understand in more depth the mechanisms of action of the intervention according to participants and comparing these to the proposed causal pathways in the logic model.

5.3 Methods

5.3.1 Participants

Participants were recruited from those allocated to the intervention group of the Winter Weight Watch study RCT. As participants were recruited to the trial over two consecutive Christmas periods (2016 and 2017) a sample of participants from each year were included in this qualitative study to ensure a representation across both recruitment phases. Participants who completed the intervention, were contacted to arrange a convenient time for the interview to take place. Completion of the intervention was defined as having attended a follow up appointment and providing an end weight measurement.

5.3.2 Sampling

To ensure a broad representation of the views of participants, purposive sampling was undertaken based on the following attributes: gender; BMI at baseline; weight change during study; and adherence to self-weighing (defined as low: less than once per week, 75% of available weeks; minimal: once a week, 75% of available weeks; and high: daily, 75% of available weeks). Participants with these characteristics were identified by searching the study database. Weight change during the study was targeted first, in order to gather views from participants who had gained, prevented weight gain or lost weight during the study. The characteristics of participants were continuously checked during sampling and to ensure characteristics were not underrepresented.

5.3.3 Recruitment

Participants in the WWW study provided informed consent to taking part in interviews during consent procedures for the RCT. Following completion of the data collection for the RCT and purposive sampling by the research team, potential interview participants were contacted by telephone and provided with additional detail on the qualitative element of the study. Participants were asked to confirm their agreement to take part and an appointment was scheduled for a telephone interview.

5.3.4 Interviews

Interviews were semi-structured, using open-ended questions allowing participants to freely express their opinions in their own terms without being guided or steered by the interviewer in any way [206]. Interviews followed a topic guide (Appendix 10) which was developed according to the specific objectives of the study. The topic guide was developed with input from the study team and with consideration of previous literature on weight gain prevention, including questions deemed to be relevant and according to the specific aims of the study.

After the first three interviews, the topic guide was reviewed and amended based on the data generated by the interviews to ensure study objectives were met. Each participant was interviewed once, and all interviews were audio-recorded and transcribed intelligent verbatim in preparation for analysis. I completed transcription of twelve interviews with the remainder transcribed by a transcription company. During interviews, emergent themes were noted down and reviewed following the conclusion of each interview. Once no new themes emerged, following review of interviews and discussion with the study team, it was agreed to cease data collection. Interviews covered the following broad areas:

- The overall experience of the intervention
- Self-weighing
- PACE
- 10TT
- Weight gain prevention at Christmas

5.3.5 Credibility

To improve trustworthiness and credibility of this study, interviews followed broad topic areas based on previous literature and the study objectives, and respondents were encouraged to discuss their perceptions and experiences freely.

Reflexivity was a key part of the data collection process. During each interview, the researchers' own role in the formulation of the following elements of the study was carefully examined and considered to facilitate a reflexive approach to the research. Reflexivity focused primarily on the following areas:

- Formulation of the interview questions
- Data collection, particularly with regards to recruitment and choice of location
- Researchers' relationship with participants

To adopt and ensure a reflexive approach, I kept a research journal during data collection in which I recorded notes relating to the areas described above. Specifically, notes were recorded relating to my own values and beliefs; methodological considerations and decisions (and justifications for these); and any preconceptions and assumptions I held during the research process. I reviewed the journal throughout the data collection and analysis phase and

compared these to my interpretations to establish whether there was any impact of these on the findings of the study. During the process of data collection, I considered the potential influence of my own position as the primary researcher for this study and attempted to limit confirmatory and leading questions during interviews.

Participants were asked if they would like to receive a summary of the anonymised results at the conclusion of the interview.

5.3.6 Framework analysis

Each transcript was independently analysed by the researcher following the framework approach which is based on thematic analysis The framework method used in qualitative data management and analysis was introduced by Ritchie and Lewis in the 1980's [186]. The framework approach enables the analysis of the associations between different themes, and uncovering patterns based on participant characteristics [207]. The method is positioned within thematic analysis [208] and enables researchers to analyse qualitative data case by case (participant) across codes using a matrix, which is its distinguishing feature. This enables researchers to identify themes whilst retaining the context of each individual's view and experience. A key strength of the framework approach is that it easily facilitates the comparison of data and eases the contrasting process, which is essential for qualitative research [209]. The method is most commonly used when semi-structured interviews have been conducted [210]. The approach has clear steps to guide researchers along the process. These are set out in Table 11. The framework method is not aligned to a particular epistemological or theoretical standpoint and therefore can facilitate a deductive or inductive analysis approach [186]. The framework method is an appropriate approach for this study as both deductive and inductive analysis will be required to investigate predefined, specific elements of the

intervention as well as exploring the mechanisms of action of the intervention and comparing these to those hypothesised in the logic model.

5.3.7 Data analysis

Analysis was carried out by reading the interview transcripts and identifying emerging themes and categories. Analysis by participant attribute was also undertaken and any differences across attributes are described in the results [208].

All transcripts were read and checked for accuracy. Immersion in the transcripts and audio recordings enabled familiarisation with the data. Two researchers independently coded four transcripts to develop an initial coding framework (FM & AF). A high-level deductive approach was taken in which codes identified *a priori*, (which related to the study objectives and topic guide areas), were applied, and within these high-level codes, inductive, thematic coding was undertaken. After discussion between the two researchers and the wider study team, the coding structure was refined. This coding structure was then entered into the NVivo programme (NVivo qualitative data analysis software; QSR International Pty Ltd. Version 12, 2018) and all remaining interviews were coded against the coding framework which continued to be developed in an iterative manner to produce a set of themes and subthemes. The framework matrices were then produced using the NVivo software. Charting was completed by summarising the data included in each cell of the matrix. I carried out interpretation of the data where it was compared assessing relationships, content and similarities and differences by participant attribute.

Understanding more about the mechanisms of action of the intervention is a key part of this qualitative study. The logic model developed during the intervention development phase and described in Chapter 3, set out a hypothesis for how the intervention may work, through

proposed mechanisms of action and the identification of a theoretical basis. Participants described some of their actions during the intervention in detail which were mapped against and used to test the hypothesised processes and theories within the logic model. This process involved using the inductively identified codes and mapping to the mechanisms of action and theoretical underpinnings of the logic model. A code book was developed to describe the content of each code in the final coding framework and is available in Appendix 11.

Table 11: Procedural stages used sequentially in the framework method

Stage	Procedure
1: Transcription	Interview transcriptions should be verbatim or intelligent verbatim (transcriptions where 'fillers' (i.e., um, erm) are omitted).
2: Familiarisation	The researcher should familiarise themselves with each interview by listening to the audio recordings and reading and annotating transcriptions with reflections and early analytical thoughts.
3: Coding	A code is a summarised reflection of what is being said. Codes may be predefined (deductive) and based on specific areas of interest or testing. Inductive coding is where the data drives the codes and they are not predefined. The researcher should code these summaries whilst reading transcripts. Two researchers should independently code a sample of transcripts then compare coding.
4: Developing the framework	Following independent coding, researchers should meet to discuss the coding framework or structure to apply to all transcripts. This framework is not necessarily set, and codes may be added during the coding process.
5: Application of the framework	The coding framework is then applied. This process may involve the use of a computer programme such as NVivo.
6: Charting	Charting involved summarising the data in each cell of the matrix by reducing large amounts of text thus easing analysis.
7: Interpretation	Interpretation involves comparing data, assessing similarities and differences by participant attribute, exploring theoretical constructs and relationships and creating typologies.

5.4 Results

5.4.1 Participants

In total, 24 participants took part in the study: 19 in 2017 and 5 in 2018. Each interview lasted around 30 minutes. The age of participants ranged from 28 to 69 years (mean age 46.6) and 80% (n=20) were women. The mean BMI was 28 kg/m^2 (SD=5.4). 29% of participants were within the healthy weight category; 46% in the overweight category; and 25% were in the obese BMI category. The number of participants with high adherence to self-weighing was 12 (50%), 4 had low adherence to self-weighing (17%) and 8 (33%) were minimal adherers to self-weighing. Table 12 shows the participant characteristics.

Table 12: Characteristics of participants in the WWW qualitative study.

Characteristic	**All participants (n=24)**
Age, years: mean (SD)	46.6 (11.3)
Gender: n (%)	
Male	4 (20)
Female	20 (80)
BMI, kg/m^2: mean (SD)	28 (5.4)
BMI category: n (%)	
Healthy weight	7 (29)
Overweight	11 (46)
Obese	6 (25)
Adherence to Self-weighing: n (%)	
High	12 (50)
Low	4 (17)
Minimal	8 (33)

5.4.2 Themes

Five high-level, objective-driven deductive themes were applied to the data and are presented below: Christmas; experiences and acceptability of the intervention and its components (10TT, PACE and self-weighing); suggested improvements and enhancements; mechanisms of action: testing the logic model. Inductively interpreted sub-themes within the mechanisms of action theme are also presented and include reflection; conscious restraint of energy intake; physical activity; and habit formation. Illustrative quotations are provided, and the attributes of each participant are provided after each illustrative quotation, displayed in parentheses. Interviewee details displayed are the participants' attributes used for purposive sampling: gender, weight change during the study, BMI at baseline and adherence to self-weighing (defined as; low: less than once a week; 75% of available weeks; minimal: once a week, 75% of available weeks; and high: daily, 75% of available weeks).

5.4.3 Christmas

Normal changes in weight over the Christmas period

Exploring perceptions of weight changes during this period resulted in a general sense of experiencing weight gain during the Christmas period. Generally, participants perceived that they routinely gain weight during Christmas, although participants described tending not to weigh themselves during this time. Participants described weighing themselves after Christmas and assessing their weight gain at that point in time. They described reasons for their weight gain over Christmas, which included overconsumption, increased sedentary behaviour and the increased availability of foods.

> *"It goes up and you know it's going up because you're over-eating and you are indulging; you're being gluttonous." (Female, ID 20031, gained weight, healthy BMI, high adherence to self-weighing).*

> *"Ok well I guess previously I've over-indulged so I've probably looked at it as being an excuse to drink more, eat more, eat the wrong things at the wrong time, generally just, I suppose pig out really."(Male, ID 120011, lost weight, obese, high adherence to self-weighing).*

> *"I'm definitely somebody who historically has put on weight over Christmas and New Year. It's when I'm most sedentary. It's when no exercise is happening, and I eat the most." (Female, ID 40006, lost weight, overweight, minimal adherence to self-weighing).*

Not all participants felt that they routinely gained weight during this period however, and some described weight control as a simple and easy process for them.

> *"I don't think a huge amount happens because I am aware of my weight. I'm not one of these people whose weight goes up and down a lot, or very quickly; it doesn't vary hugely." (Male, ID 0018, gained weight, healthy weight, high adherence to self-weighing).*

The notion of weight gain prevention at Christmas

On the whole, participants were generally positive and open towards the notion of weight gain prevention at Christmas. This could be because they felt they routinely gained weight during the Christmas period which provided a clear rationale for this approach.

> *"I wanted, I suppose I wanted to get involved. I wasn't worried about it being over Christmas. I just though oh, here's something different to try. Could it help me get control of my weight? So, the fact that it was over Christmas wasn't a deterrent." (Female, ID 20071, lost weight, obese, high adherence to self-weighing).*

> *"I thought it was a good thing as rather than it being an excuse to ignore it, I decided to do it because I thought I could do without another 5 pounds on that I'd need to try and do something about in January, so if there was something I could do that would make me think about it, that was a good thing." (Female, ID 20022, lost weight, overweight, low adherence to self-weighing).*

Conversely, one participant felt that weight gain prevention during the Christmas period was too challenging a time to attempt to control weight due to more social occasions and the increased availability of food.

"IV: Because it was done [the intervention] in the festive time there was too much temptation on the market. And in the house. And if I didn't buy it my partner would buy it so [yeah] and the kids would come around and friends would come around and we'd go out for meals and things like that so…..

I: Yeah. So, can you think of anything that might help at Christmas time? That might make the study better?

IV: Not doing it at Christmas time." (Female, ID 20030, prevented weight gain, obese, minimal adherence to self-weighing).

Impact on the enjoyment of Christmas

The effect the study had on people's experiences of the Christmas period was explored with participants. Participants generally expressed that they experienced no real difference when compared to their 'normal' Christmas experience, with the exception of the attempt to avoid over consumption. Significantly, overall, despite being part of the study and using the intervention strategies as an attempt to control their level of weight gain over Christmas, many reported no impact on their enjoyment of the festive period.

"It was no different, it was the same although I did always have, in the back of my mind, the fact that I shouldn't overeat, so I was a little more careful." (Female, ID 00117, prevented weight gain, healthy BMI, high adherence to self-weighing).

"It [Christmas] was absolutely the same so I did the same things. I didn't stop myself from like going out and meeting friends or… I honestly didn't." (Female, ID 20025, prevented weight gain, healthy BMI, min adherence to self-weighing).

"I don't think the actual joy of Christmas and the feelings that I have around Christmas of happiness and the positivity and optimism went away." (Female, ID 40006, lost weight, overweight, minimal adherence to self-weighing).

"There weren't that many differences. We had the same sorts of food, I did have a Christmas dinner, did have a little bit of pudding…" but a much smaller piece than everybody else and a bit smaller than I would have done on previous years and I was quite happy with that, I felt quite okay about that." (Female, ID 20071, lost weight, obese, high adherence to self-weighing).

5.4.4 Acceptability and experience of the intervention and its components

Overall acceptability of the intervention

Overall acceptability of the intervention was high. Some participants articulated potential barriers to adherence to the intervention as a whole; these related to being away from home, eating out, illness and a change in routine.

"The only difficulty I found was when we were away from home." (Female, ID 20018, prevented weight gain, healthy BMI, high adherence to self-weighing).

"I: Did you find that the intervention was difficult to adhere to considering that it was Christmas time?

IV: Well, I suppose it was really, because obviously, I was conscious that I was going out to eat more than I would do normally, as I said before. So, parties, functions, etc." (Female, ID 20031, gained weight, healthy BMI, high adherence to self-weighing).

"I: So, would you say that the intervention was difficult to adhere to considering it was Christmas time?

IV: I think it was and it wasn't in a sense…unfortunately for me…I actually wasn't well at all over Christmas and New Year into January with this sort of, well I think a lot of people had it. It was like a chest problem for a good number of weeks [yeah]. So, I actually felt very lethargic, so I wasn't really energetic enough to look for good food options. So of course, or go shopping even for fresh food very often. So, what I was doing was finishing off all of the easy stuff which you know were the nuts, the crisps, the chocolate. So, it was a bit of a strange, I'm afraid situation for me. I wasn't motivated because I wasn't well [yeah] to actually stick to you know the smoothie recipes that I know give me a balance, vitamins and whatever else. I just hadn't got the physical energy to do that [yes], unfortunately." (Female, ID 20024, gained weight, overweight, low adherence to self-weighing).

Self-weighing

Participants described a generally positive response to the self-weighing component of the intervention. When asked to describe their initial reaction to being asked to weigh themselves regularly during the study, responses ranged from acceptance to interest to displeasure.

> *"Fine, yeah. I didn't feel that was a problem." (Female, ID 20024, gained weight, overweight, low adherence to self-weighing).*

> *"A little anxious to think, 'Oh my gosh. How much is the weight going to change and fluctuate?' But I was interested to see how it does fluctuate…" (Female, ID 20031, gained weight, healthy BMI, high adherence to self-weighing).*

> *"I wasn't really best pleased. To me, I didn't think it would benefit me. I couldn't see the point in weighing myself every day. I didn't think it was going to make much of a difference. So, to weigh myself every single day…" (Female, ID 20028, gained weight, overweight, high adherence to self-weighing).*

In general, participants reported that self-weighing during the Christmas period was easy to do, unless access to scales was hindered for reasons such as being away from home. The ease of self-weighing was described by some participants as due to establishing a routine.

> *"So, I just as soon as I get up in the morning, so I was always doing it at the same time. I'd just hop on the scales before I got in the shower so it's quite easy because I've got easy access to scales. Had I not then it would have been a lot more difficult if say it was only at the gym or only at somebody else's house [yeah]. So, when I haven't got access to them like when I was on holiday then I felt like I didn't know what was going on which I didn't like."(Female, ID 20018, prevented weight gain, healthy BMI, high adherence to self-weighing).*

"We've got weighing scales in the bathroom and I established getting a routine by weighing myself at the same time of day in the morning around about 11 00 or 12 o'clock in the morning. Just occasionally, I was outside this, but as I say, it's about establishing a routine." (Male, ID 00117, prevented weight gain, healthy BMI, high adherence to self-weighing).

The weight goal, to gain no more than 0.5kg during the study period, resulted in feelings of trepidation for some participants whilst others found it to be acceptable and motivating. The specific amount was found by most participants achievable with many describing it as 'easy'.

"I thought to myself straight away, I can easily do it, when I've first seen it. That was not going to be a problem." (Female, ID 20028, gained weight, overweight, high adherence to self-weighing).

"Realistic. [Yeah?] Yeah, yeah." (Male, ID 40007, prevented weight gain, overweight, minimal adherence to self-weighing).

"I: What were your thoughts on that amount?

IV: That was quite good actually…From like it kind of, it encouraged me to be a bit more careful.

I: Okay and the specific amount. Any thoughts on that? Was that reasonable or?

IV: Yeah that was fine. Yeah it was reasonable yeah." (Female, ID 10003, prevented weight gain, overweight, high adherence to self-weighing).

"Yeah, well when I first seen it and when I first was explained about it, I thought it was going to be a bigger amount. I thought you know because people are known to put on weight at Christmas, but I thought it was going to be five pound or ten pound. So originally, I was shocked that it was only a pound, but it only gives you more motivation because I wanted to be under that when the survey was finished." (Female, ID 20016, prevented weight gain, obese, high adherence to self-weighing).

However, for some participants, the maximum weight was found to be smaller than expected, and some considered this unreasonable considering the festive period, a known high-risk time for weight gain and therefore challenging for weight control.

"I suppose at Christmas a pound isn't very realistic. But other times maybe…yeah, so I did think a pound isn't much at all." (Female, ID 20010, gained weight, obese, low adherence to self-weighing)

"It was only half a kilo, a pound, wasn't it? It seemed very low and scary and I thought I'd never get there; never to keep to it, especially over Christmas. It could make you feel like giving up before you start." (Female, ID 00118, prevented weight gain, healthy BMI, high adherence to self-weighing).

In general, the acceptability of self-weighing was high. However, for one participant, self-weighing was a negative experience. They described that daily self-weighing led to overconsumption as a result of observing increases in weight. They also described a sense of a loss of control and confusion associated with the fluctuations in weight.

> *"I'll be honest, I was annoyed because A. I couldn't see no benefit, and secondly the weight just kept going up, up, up or down or up and down and then it wasn't a proper weight for me, it wasn't a true character to what I'm used to. So, one day I was up and this day I was down, up down up down and it was a yo-yo. I just couldn't understand if I was coming or going with the weight. It wasn't true. If it was once a week, on the same day but every day it wasn't the correct figure for me. I couldn't work it out." (Female, ID 20028, gained weight, overweight, high adherence to self-weighing).*

Despite this dislike for self-weighing, this participant had high adherence to self-weighing and weighed daily throughout the study period. They reported that the frequency of the self-weighing was the cause of their displeasure.

> *"Because every single day it was the same or it didn't change or it kept going up and when it kept going up, it was shooting up. I didn't see any value, to me it was just pointless. I couldn't understand because I was doing it every day. If it was once a week, I could understand but I couldn't see any benefit. I could see the figure going up, but I couldn't see any proper benefits to me. And the more it kept going up the more I was just thinking, do you know what, I can't be bothered to do this, and I just kept eating and eating. It was weird that was." (Female, ID 20028, gained weight, overweight, high adherence to self-weighing).*

A few participants discussed the potential for the behaviour of self-weighing to become somewhat obsessive. Although this was mentioned by very few participants, the remarks were projections of what could happen, and participants did not describe self-weighing as becoming compulsive for them.

> "*I wonder whether, I don't know if anyone could get obsessed with it [self-weighing]. I don't know whether it's, I found it helpful, but you know if someone was obsessively trying to go, head down as opposed to maintain, but it wasn't an issue for me." (Female, ID 20022, lost weight, overweight, high adherence to self-weighing).*

> *"My anticipation was that weighing myself every day would be possibly a little bit too obsessive a level of weighing, just because your weight does fluctuate naturally over the course of a week. But I really didn't find it too bad, to be honest. It didn't bother me that much." (Female, ID 60007, lost weight, overweight, minimal adherence to self-weighing).*

> *"Good and bad. If I was a neurotic type it could cause me to be neurotic. But I'm not so it was okay." (Female, ID 20014, gained weight, overweight, low adherence to self-weighing).*

PACE

The PACE information strongly resonated with participants. Participants described the information as noteworthy and somewhat striking, and that it provided them with a context for the calories they were consuming during the festive period. Crucially, participants described a level of unfamiliarity with the number of calories contained within foods which seemed to be new information to them, unlike the 10TT. Despite this apparent unfamiliarity associated with the calorie content of foods, some participants declared that they had come across information presented in this way before.

> *"I was amazed that it takes a lot of exercise to burn off only a few calories." (Female, ID 00117, prevented weight gain, healthy BMI, high adherence to self-weighing),*
>
> *"A few of them I wasn't surprised, but a few of them I was definitely surprised. I was surprised about how long you'd have to walk to burn it off. That was specifically what I found shocking." (Female, ID 40006, lost weight, overweight, minimal adherence to self-weighing).*
>
> *"That sort of sticks in my mind about how far I'd have to walk to walk off five Roses." (Female, ID 20030, prevented weight gain, obese, minimal adherence to self-weighing).*
>
> *"So, I was interested in you know, if I feel sort of virtuous having done an hours walk in the evening you know actually how much does that equate to in rubbish consumed. So, you know it helped me realise the two parts [okay] much more visually." (Female, ID 20024, gained weight, overweight, low adherence to self-weighing.*

"Um, it was a bit shocking really, because you think that if you exercise that weight will just drop off you but you don't realise how much exercise you have to do to make a difference." (Female, ID 80018, prevented weight gain, overweight, high adherence to self-weighing).

"I was quite shocked at how many calories are in things… it opened my eyes up to them tips that can help you realise what you're eating and how many calories is in things." (Female, ID 20016, prevented weight gain, obese, high adherence to self-weighing).

"I: Had you ever come across information like that before?

IV: Yeah, I have. Yeah, many times." (Male, ID 40007, prevented weight gain, overweight, minimal adherence to self-weighing).

The 10TT

Broadly, participants reported that they found the 10TT to be familiar advice that they were used to seeing as part of general health information. However, some participants described the 10TT as serving as reminders and prompts to follow the advice as recommended. Comments relating to the 10TT were largely brief, with some participants failing to recall them at all. They did not appear to be a key feature of the intervention according to any of the participants interviewed.

> *"I suppose I thought, 'Well this is stuff that I already know but I don't do or sometimes do'. But yeah, I thought they were quite helpful prompts. Because it's like a little reminder isn't it to do that, you know, especially when you are eating a lot." (Female, ID 20010, gained weight, obese, low adherence to self-weighing).*

> *"They were simple, easy to understand and not difficult to meet. I think I was aware of them anyway so there was nothing new there for me." (Female, ID 00117, prevented weight gain, healthy BMI, high adherence to self-weighing).*

> *"Ok, yeah so they didn't particularly resonate. The point of it and the meaning behind it I remember the explanation, but I don't really remember the tips." (Female, ID 20022, lost weight, overweight, high adherence to self-weighing).*

5.4.5 Suggested improvements and enhancements to the intervention

Few suggestions for improvements and enhancements were offered by participants. The few suggestions centred upon altering the frequency of weighing to avoid daily weighing and incorporating digital means such as an app, to support the intervention.

> *"I failed to remember every day. So maybe if it was, I don't know, three times a week? Rather than a daily basis." (Female, ID 20010, gained weight, obese, low adherence to self-weighing).*

> *"If I was going to do a study like this again, I personally wouldn't ask the person to weigh themselves every day. Once a week but not every day." (Female, ID 20028, gained weight, overweight, high adherence to self-weighing).*

> "*Maybe digital but maybe that's just a fashion I think everybody's getting into." (Female, ID 20024, gained, overweight, low adherence to self-weighing).*

5.4.6 Mechanisms of action: Testing the logic model

From the inductive thematic analyses within the deductive high-level themes, the concepts relating to the logic model that were identified were: reflection; conscious energy restraint; physical activity; and habit formation, each of which is discussed in turn below.

Reflection

Reflection emerged as a key process that participants undertook and appears to be essential in promoting behavioural change and weight gain prevention. Almost all participants described the process of reflection in some way. Reflection occurred as a result of weight fluctuations (observed following self-weighing) and the intervention information, PACE information specifically. Participants described a process of reflection and the conscious planning

strategies such as restraining energy intake or increasing physical activity. This is coherent with self-regulation theory [114]. As described in Chapter 3, in the context of self-weighing, self-regulation theory suggests that behavioural change results from an individual observing their current weight and comparing this to their behavioural goal (self-monitoring). This is combined with the individual being aware of the interaction between awareness, self-observation, recording and self-evaluation (reflection): features which appear to have emerged in this study. The data suggests that the process of reflection is working at multiple points according the descriptions of participants: their reflection on weight change; their reflection on their consumption of food and drinks (both retrospective and prospective); their reflection on their physical activity levels. This process of reflection appears to be an essential part of weight gain prevention.

> "*It's obvious where and when you've gone wrong. For example, the next day you can think about what you shouldn't have eaten and drunk the day before. You can try and reduce it when it's gone up and try to identify what you've done to make it go up." (Female, ID 00117, prevented weight gain, healthy BMI, high adherence to self-weighing).*
>
> *"I found that quite interesting, you know, seeing how it varied and trying to work out in your own mind or trying to think of a reason why it had varied [Yeah] why gained a kilo and a half? Was that something like that? Or it's gone up; it's gone down, because I went out? An hour in the gym, you know, may have helped it, or whatever? So, it made you think, consciously about what you were eating." (Male, ID 00118, prevented weight gain, healthy BMI, high adherence to self-weighing).*

"To show, you know you can have a look at what you've, think about what you've eaten in the day and if you've got a gain you can think, 'Well actually shouldn't have eaten that or shouldn't have eaten that'." (Female, ID 10003, prevented weight gain, overweight, high adherence to self-weighing).

It made me think, "Do I need that? Do I really need that? Some things you can't help, you know, because it's Christmas and you have to have certain things, but you didn't really need them. Do I really need another one? Do I really need to have that every day?" (Female, prevented weight gain, healthy BMI, minimal adherence to self-weighing).

Conscious restraint of energy intake

The theme of conscious energy restraint emerged strongly. Participants described restraining their food and drink intake in relation to each of the intervention components and to the intervention as a whole. Participants appeared to avoid or reduce consuming particular foods or drinks, which was often described as atypical behaviour for them during the Christmas period. Participants described a conscious thought process of reflecting on the intervention (either as a whole or a specific component), taking a moment to decide whether to consume a specific food or drink item, and ultimately consuming less or none of the specific item. This behaviour also appeared to be supplemented with an element of planning, where participants would plan to reduce energy intake in advance of upcoming meal events. According to participants' descriptions, this planning behaviour was associated with self-weighing in particular, where participants would engage in planning because they were going to be weighing themselves.

"I was a bit more considered with the eating I did over Christmas. And probably the drinking. I was more considered with the drinking. I still let myself, treated myself to the food I wanted, I might have just been a little bit more restrained with the drinking I was having."(Female, ID 80014, gained weight, healthy BMI, minimal adherence to self-weighing).

"I was more conscious. And the fact that I knew, you know I was writing it down and logging it and also reading those little pointers that were on there. On the sheet, as well [yes]. So, I'd say yeah, I was definitely more conscious of things more than I would have been [yes] you know in other times when I haven't, you know when it's been Christmas and I'd have just gone all out sort of thing." (Female, ID 20010, gained weight, obese, low adherence to self-weighing).

"Like if I was out one day and then I saw that the weight was so high then next day or maybe a couple of days after I was okay you know, sort it out [laughs]. And then I had all these tips so I could like, walk a bit more, count the steps so I made sure that I done 3000 which was the average. And then made the effort to go to 10,000. Things like that, yeah….But not eating when I wasn't, if I was full I wouldn't eat." (Female, ID 20025, prevented weight gain, healthy BMI, minimal adherence to self-weighing).

"I certainly stayed away from mince pies more than I would have done otherwise." (Female, ID 60007, prevented weight gain, overweight, minimal adherence to self-weighing).

Participants described the intervention overall as making them more conscious of their food and drink intake over the Christmas holiday, despite it being the period when temptation to overconsume high energy foods and drinks is great.

"I: Was there any impact that the study had, in particular?

IV: I think I did watch my eating more than I would have otherwise." (Female, ID 60007, lost weight, overweight, minimal adherence to self-weighing).

"If people brought sweets into the office, I would have one, but then I would stop and just have one or two at a push, whereas before I'd have one every hour or any time anybody offered me a sweet I'd say yes and never say no. Similarly, with my family, I had a little bit of everything on Christmas dinner day, but I didn't have piles of potatoes and piles of chicken and loads of little cocktail sausages. I had just one or… So I didn't feel I missed out that much, if I'm honest. I don't think it felt that different; it was just a little bit - I wouldn't even like to use the word restrained - it was just a little bit more sensible; that's all I would say." Female, ID 40006, lost weight, overweight, minimal adherence to self-weighing).

When exploring the mechanisms of action brought about by each of the intervention components, there were a number of instances where the PACE information and self-weighing were described by participants as promoting restraint. With reference to the PACE information specifically, for some participants, this information led to them restraining their energy intake during the study.

"I quite like a Ferrero Rocher, but I don't like it that many calories. So, I didn't have one Ferrero Rocher over Christmas, I normally eat about three boxes." (Female, ID 20006, lost weight, overweight, high adherence to self-weighing).

Participants described instances of the thought process involved following seeing the PACE information which prompted them to reduce or avoid the consumption of particular foods. Participants did not describe increasing physical activity as a result of seeing the information in general, rather that they chose to reduce or avoid the consumption of particular foods or drinks.

> "*You know it's like hang on, 'Have I got time to do 30 minutes' brisk walk?'. No, I'll just leave the packet of crisps." (Female, ID 20024, gained weight, overweight, low adherence to self-weighing).*

> *"So actually, it gave me much more awareness of how much energy content there is in it and how much it would take to burn off. I think it's quite a useful way to put it together. I suppose you're saying if it's 400 calories, that's an hour on a bike and you think, oh hang on a minute, I'm not going to get to do an hour on a bike so I had better not consume 400 calories." (Female, ID 20022, lost weight, overweight, high adherence to self-weighing).*

> *"It was unbelievable. There was something on there about the sweets that you get in tins and how long it would take you to walk off, or get rid of was it two or three of those? [Yeah] And I couldn't believe it so, I thought, 'Right okay, right I'm not having any of those at all." (Male, ID 20008, lost weight, obese, high adherence to self-weighing).*

One participant provided a particularly interesting insight where she appeared to create a hierarchy based on her desire of particular foods, where the PACE information prompted her to consider and assess her desire for certain foods, altering her consumption. Interestingly, this participant described consuming other, foods (sweets), that she found more desirable, but to a lesser extent.

> *"It did translate into not actually eating it so I didn't eat it and then go and try and exercise, I just thought actually I don't even really like mince pies that much, I'm not going to eat them. I do like sweets, but I'll just eat a couple and not absentmindedly unwrap five things without really thinking about it just because it's there." (Female, ID 20022, lost weight, overweight, high adherence to self-weighing).*

In general, participants described self-weighing as making them more conscious of their energy consumption during the period. In some cases, this was a new experience. Participants described their experiences of the process of self-weighing in detail. Participants reported that self-weighing was followed by their reflection on their own weight changes, with consideration of the previous day's consumption. Participants then described making adjustments to their consumption following the result on the scales, again interpreted as features of self-regulation theory. Regular self-weighing enables individuals to observe changes in their weight and relate these to energy consumption (eating and drinking), physical activity or specific situations. This then promotes individuals to make changes to these behaviours to achieve their goals. Restraint in eating and drinking was frequently reported as an outcome of the process of self-weighing. Interestingly, minimal and high adherers to self-weighing reported this reflection and restraint in response to self-weighing.

"If I saw that it had gone above my - if I was above my initial weight a few days in a row, I thought to myself, 'Okay, tomorrow I really need to keep an eye and not go too crazy on anything.' I would try and keep things under control. I think it did help to remind myself that I needed to watch out that I didn't gain." (Female, ID 60007, lost weight, overweight, minimal adherence to self-weighing).

"I had a bit of as what I describe as morbid curiosity [laughter] to see if it had gone up after I'd eaten all this rubbish. Then, once that had been confirmed a few times, the link obviously was permanently made in my head about what I put in my mouth and my weight and things, and how much of an impact the foods that I was eating would have." (Female, ID 40006, lost weight, overweight, minimal adherence to self-weighing).

"But I was interested to see how it does fluctuate and to think that one night I'll go to the cinema and have a massive bag of popcorn and a big bag of chocolate - does that weight literally go up straight away, or does it take a few days to go on? So, I was a little anxious, but also interested to see, because I never used to weigh myself regularly. It was something new to me." (Female, ID 20031, gained weight, healthy BMI, high adherence to self-weighing).

Although many participants described attempts to consciously restrain energy intake to some extent during the study, some participants described restraint as difficult due to the high temptation during the Christmas period. However, despite their perceived difficulties, participants still recognised the value in conscious restraint of energy intake during the Christmas period.

"I: So, did you find that it was quite difficult to stick to because it was Christmas time?

IV: I did yeah.

I: Yeah and what made it difficult to stick to?

IV: Well because there was so much nice food about. There were things on the market that you never have any other time apart from Christmas. There was you know; I mean the shops are just full of it aren't they. And you see something there and you think, 'Oh yeah, I'll get that', and you only have stuff like that at Christmas." (Female, ID 120029, prevented weight gain, healthy BMI, minimal adherence to self-weighing).

"IV: I would say… definitely more difficult than not difficult, because it did make me think more when I went out, whereas normally I'd be a bit carefree and think, 'Oh, I'll just eat that.' It didn't really stop me eating things, but I maybe chose different things from the menu, to be more conscious of my weight. But I think that's a good thing." (Female, ID 20031, gained weight, healthy BMI, high adherence to self-weighing).

"There were some days that it was difficult, and I still did have a few treats around Christmas but not the way I would usually eat at Christmas. But had it have not been for the study, I would have been eating my normal amount that I would eat [yeah]. So, I do think it was helpful that it was, because Christmas is particularly the time where you eat more than you should do." (Female, ID 20016, prevented weight gain, obese, high adherence to self-weighing).

One participant expressed disappointment at not losing a significant amount of weight during the study, despite feeling that they had significantly reduced their intake of calories.

> *"The only negative is that overall I felt I did deserve to lose more weight than I did because I'm aware that I did cut my calorie intake a fair amount and I am a bit disappointed that I didn't lose more weight easily…" (Female, ID 20071, lost weight, obese, high adherence to self-weighing).*

Physical activity

Participants referred to physical activity frequently during the interviews. Some participants reported increasing their activity levels however, in general, participants largely expressed that the intervention encouraged them to reduce their energy intake as opposed to increasing their physical activity levels. The main driver of this behaviour appeared to be the PACE information, where participants described feelings of 'shock' and 'surprise' at the amount of physical activity required to expend the calories in foods they would typically consume during the Christmas period. As a result of this, participants avoided consuming certain foods.

> "*You had to do a lot of work to get rid of what you eat were my thoughts." (Female, ID 20018, prevented weight gain, healthy BMI, high adherence to self-weighing).*

One participant did report increasing their activity as a result of the PACE information. For this participant, the PACE information enabled them to visualise the energy balance equation, resulting in them increasing their physical activity (in this case walking) to counteract calories consumed.

"...but the one that sticks out for me is the equation of that snack equals that amount of walking [yes]. Possibly because I quite like walking anyway, so I regarded that as a, you know part of my plan to try and manage my weight. So, I was interested in you know, if I feel sort of virtuous having done an hours walk in the evening you know actually how much does that equate to in rubbish consumed. So, you know it helped me realise the two parts [okay] much more visually." (Female, ID 20024, gained weight, overweight, low adherence to self-weighing).

Despite PACE and self-weighing generally not appearing to promote increased physical activity among participants, the 10TT appeared to encourage some participants to engage in physical activity. Although this was described by only a few participants, they found the tips to be acceptable as general and familiar healthy eating and activity advice. Participants did not report high adherence to them, describing no adherence or adherence to only one or two of the tips during the study.

"No, I didn't I'm afraid [adhere to the 10TT] but I don't think I needed reminding about them once I'd read them because I already do most of them. But, I did take more exercise over the holiday because it's something I don't do very often and I know I need to." (Female, ID 00117, prevented weight gain, healthy BMI, high adherence to self-weighing).

"I tried to [adhere to the 10TT]. I tried to get off my bottom and do a little bit more exercise and not be so sedentary and, even at my desk, try not to - and I'll continue to try not to sit about so much - to try and get up and move about more when possible." (Female, ID 20031, gained weight, healthy BMI, high adherence to self-weighing).

Habit formation

Some participants did provide responses indicating that self-weighing was becoming embedded as routine, using words such as ‘automatic’ and ‘routine’.

> *“We’ve got weighing scales in the bathroom and I established getting a routine by weighing myself at the same time of day in the morning around about 11 o’clock” (Male, ID 00118, gained weight, healthy BMI, high adherence to self-weighing).*

However, the emergence of habitual behaviours was not conveyed by participants in general as few participants gave an account indicating that the self-weighing behaviour was becoming habitual.

5.5 Discussion

5.5.1 Main findings

Participants were generally accepting of the notion of weight gain prevention during the Christmas holiday period. Participants considered weight gain at Christmas to be common and mainly driven by overconsumption and lower levels of physical activity. Overall, the intervention seemed not to reduce people’s enjoyment of the Christmas period and did not appear to impact on participants’ perceived ‘usual’ experience of Christmas. On the whole, participants found the intervention acceptable to follow during the Christmas period, with some challenges experienced related to being away from home, illness and social occasions.

With reference to the intervention components, PACE and self-weighing strongly resonated with participants and was information that they were not aware of, which participants ostensibly used to foster reflection and behavioural changes to restrain energy intake. Some

participants found that the 10TT prompted them to adopt advice, which was already well known to them, but many did not find it helpful or did not remember it.

Although the majority of participants found self-weighing to be a useful strategy for the intervention, one participant provided very strong views against its use during the period. This participant felt that the frequency of self-weighing was too high, seemingly having the opposite behavioural effect to the conscious restraint of energy intake and weight gain prevention, actually promoting overconsumption in this case. This deviant case implies that although self-weighing is a good strategy for most, it may not be suitable for everyone.

Participants described the processes they undertook to prevent weight gain during the intervention. Frequently, participants described a process of reflection, either of the intervention information or of their weight trajectory, which led to the conscious restraint of energy intake. Often, participants approached the prevention of weight gain as a choice related to the energy balance equation: either to restrain their energy intake; or to increase their levels of physical activity, with participants often describing choosing to reduce or exclude the consumption of food and/or drinks as opposed to increasing physical activity. This is an interesting finding as participants suggested that increasing physical activity was too much effort or too time consuming to compensate for the intake of certain foods. This is important for future work as it suggests that the restraint of eating is perceived as easier than increasing physical activity levels.

The processes described by participants appeared to support the proposed mechanisms of action in the intervention logic model (described in Chapter 3) with the exception of habit formation. There was no emerging theme to support habit formation during the intervention period from the participant interview data. This may be due to the duration of this trial; habit

formation takes at least 66 days to develop so the establishment of habits in this case would not necessarily be expected. Nevertheless, the data did indicate the early emergence of routine and automaticity.

5.5.2 Comparison with existing literature

Participants expressed a general acceptance of the notion of weight gain prevention at Christmas. According to previous research, holiday periods are high risk times for weight gain in the population [64] with the Christmas period being of particular risk across differing countries [8]. This finding is important as no weight gain prevention intervention set during the Christmas period has previously been tested. Understanding that the public are open to the concept of preventing weight gain during the Christmas holidays is significant and challenges the belief that weight gain during this time is inevitable.

5.5.3 Comparison with existing Qualitative research

The WWW study is the first trial to test an intervention to prevent weight gain specifically during the Christmas period; comparisons with previous qualitative studies to prevent weight gain are therefore difficult. However, it is useful to compare results from qualitative studies on each of the intervention components. One such recently conducted qualitative study [211], assessed the views and experiences of participants who had taken part in a RCT testing the effectiveness of two habit based interventions for weight loss [212], one of which was the 10TT intervention [152]. Participants were invited by email contact to join the qualitative study at the end of the RCT. Participants were sampled based on gender, age, weight change during study and education level. In total, seven participants took part in semi structured interviews to explore their general experiences of the intervention, views on acceptability and whether there was any effect on their lifestyle post intervention. Participants reported positive experiences

of the 10TT overall and that the advice was simple and practical to implement in their everyday lives. Contrary to the qualitative findings from the WWW study, participants described a level of automaticity associated with some of the behaviours, indicating the formation of habits. Although the subjective findings from the Self-Reported Habit Index (SRHI) questionnaire administered during the WWW study RCT demonstrated an association between higher automaticity of self-weighing and lower weight at follow up, results from the qualitative study reported in this chapter did not add any further evidence of automaticity according to participants' accounts. However, the WWW qualitative study did not explicitly ask participants about habit formation, only about their experiences of the intervention. Moreover, this apparent inconclusive evidence supporting the formation of habits could also be explained by the short duration of the intervention. Research suggests that behaviours require an average of 66 days to become habitual [121] and here the intervention period was shorter; a mean of 44.7 days for the intervention group (SD=5.6). This is a possible explanation for the lack of a strong perception of habit formation. As a comparison, the duration of the 10TT intervention (which incorporated daily self-weighing) was 84 days (12 weeks) [152] where results demonstrated that behaviours were establishing as habitual.

5.5.4 Comparison with systematic reviews

A systematic review of qualitative studies assessing the views and beliefs of people using cognitive and behavioural strategies to manage their weight provides a relevant comparison to this study [213]. The review, published in 2018, examined the views and experiences of participants in relation to a range of self-directed behavioural strategies including self-weighing. It presented results on the role self-monitoring in weight management attempts. Qualitative studies conducted with adults in community or primary care settings were included. In the studies included (n=22), participants were all attempting to, or had previously

attempted to lose weight through behaviour change interventions. Quality of the included studies was mixed when assessed using the critical appraisal skills programme tool (CASP) [214]. Analysis used an interpretivist approach from which three main themes emerged: self-perception and emotions; attentive and reactive self-monitoring; and trust and deception. In line with this qualitative study, self-weighing emerged as a useful tool facilitating adherence and analysis (reflection) which in turn supported behavioural change. However, these positive themes were interlinked with the theme of trust and deception. Here, there appeared to be an increased likelihood of abandoning the weight control attempt following a poor result from the weighing scales or mistrust in the measures used i.e., scales. Despite this, self-analysis (reflection) emerged as a key process to mitigating the feelings of shame which lead to abandonment of self-monitoring. The systematic review concluded that facilitating self-analysis or reflection associated with self-monitoring is an important tool for successful weight management. Without this reflection, the authors concluded that abandonment of the behaviour was more likely. Similarly, in the WWW qualitative study, a theme around the reflection on weight trajectory emerged strongly, which is akin to self-analysis described in the systematic review from 2018. Results from the qualitative work presented in this Chapter, shows how participants described the process of reflection as an antecedent to the conscious restraint of energy intake. This process of reflection and analysis appears to be a key constituent of weight gain prevention in this case.

5.5.5 Comparison with PACE literature

Qualitative research examining the views and experiences of PACE labelling is currently limited. There is some evidence from two qualitative studies which suggests that PACE labelling provides a more personalised source of information to people, whereby they may more easily contextualise individual food choices as part of dietary intake [215, 216]. These studies conducted focus groups exploring preferences and views of PACE labelling. Participants were able to understand the labelling and in general, seemed aware of calories as a measure and the physical activity equivalents. However, in the study by Van Kleef et al. [216], participants assessed PACE labelling in comparison to simpler labelling referring only to the amount of calories per 100g of the food item. In this study, participants least preferred the PACE labelling finding it to be overly complex and difficult to understand in comparison to the simpler labelling only depicting calories per 100g. These findings were in contrast to participants' reports from the study by Swartz et al.[215], who described the PACE information as 'personalised', thus encouraging them to apply the information directly to them. Specifically, participants described asking themselves the question "How does this apply to me?" and subsequently answering this based on their own perspective. Findings from the study reported in this chapter demonstrated a strong positive reaction towards the PACE information provided as part of the intervention. Participants described shock and surprise at the physical activity equivalents of festive foods and drinks and reported that they restrained their intake as a result of this information. Furthermore, the calorie content of foods included in the PACE information seemed to influence energy intake behaviour in its own right to a certain extent for some participants. Participants also described a reflective process which may be similar to the one described by Swartz and colleagues, where individuals behave as if the information has been personalised for them. These findings provide important evidence

supporting the use of PACE information to facilitate behaviour change during high risk periods for weight gain.

5.5.6 Strengths and limitations

All participants interviewed had participated in the intervention and provided detailed responses to the open questions posed during the interviews. This enabled the trial to be 'unpicked' and an in-depth analysis of the mechanisms of action of the intervention during the study period to take place. Interviews were conducted until data saturation was achieved. The code book was developed iteratively with independent coding and discussion between two researchers. The use of purposive sampling of participants ensured a broad representation of views [186]. The ontological position of this work, subtle realism, suggests that assessing quality should relate to relevance and validity. Many of the criteria for assessing validity were met by this qualitative work. For instance, reflexivity was actively appraised during data collection and analysis using a reflexive journal to minimise researcher bias. Additionally, attention to negative cases, fair dealing and a clear description of methods support validity and relevance of the findings.

A potential limitation of this qualitative study is generalisability of the findings. As participants in the RCT were volunteers, it is possible that those who were more conscious of weight gain during the winter months and open to weight control during this time were more likely to participate in the trial, possibly providing more positive views. In addition, interviews were conducted by a single researcher who had been involved with the data collection for the RCT. Although reflexivity was actively appraised during the interviews as described in the methods section of this chapter, the potential for researcher bias exists due to their role in the research in particular and that participants may have provided more positive

views of the intervention in an attempt to 'please' the researcher. Additionally, only the views of participants from the intervention group of the trial were sought and not those from the control group. The views of control participants would have enabled the research volunteer effect to be explored further.

5.5.7 Implications

Overall, participants responded positively to the Winter Weight Watch study intervention. Weight gain prevention during the Christmas period elicited generally positive reactions from participants, with many describing it as a helpful strategy for weight control. This finding is significant for public health practice as combined with the evidence of effectiveness from the quantitative study, the qualitative research indicates that the public would largely accept interventions to prevent weight gain during high risk occasions. Whilst this is a promising finding with implications for public health practice, it is worth noting that this group were self-selected, having volunteered to participate in the trial, which suggests that they may be more health focused and open to the prospect of weight control during the winter months. In addition, one participant described a negative experience specifically in relation to self-weighing, indicating that this strategy may not suit everyone, although this view was a deviant case. Overwhelmingly, participants reported that their weight routinely increases during the Christmas period and many believed this was due to the occurrence of a relaxation of weight control behaviours leading to overconsumption and reduced physical activity. This acknowledgement indicates that in general, people are aware of the behaviours that drive weight gain. As reported by participants, this intervention was simple to follow on the whole and did not impact on the enjoyment of the Christmas period. Some challenges related to being away from home and suffering illness during the period were reported so these are important to consider as potential barriers to intervention adherence.

Whilst the intervention tested here targeted the Christmas period specifically, other holiday occasions are worthy of consideration for intervention as these also pose a high risk for potential weight gain amongst the population. Particular population groups may be considered to be at a greater risk of weight gain during specific holiday occasions and the tailoring of this intervention to these groups may warrant further exploration. Moreover, findings from this study regarding participants' suggestions for improvement and enhancement are useful to consider as implications for practice. Overall, there were few suggestions for improvement or enhancement of the intervention, however the suggestion of differing modes of delivery for the intervention information, such as digital means, could be worthy of consideration for delivery of the intervention to the public at scale.

A few participants discussed whether the behaviour of self-weighing had the potential to become compulsive for others. According to the current evidence base, research suggests that regular self-weighing does not adversely affect psychological outcomes or eating behaviour [136, 142, 143]. In this qualitative study, although participants discussed this in the context of others and not in relation to themselves, future work could seek to explore this in more depth with participants to add to the literature around adverse physiological outcomes and self-weighing.

5.6 Conclusions

The findings from this qualitative study suggest that a weight gain prevention intervention delivered during the Christmas period is an acceptable concept. The Winter Weight Watch study's multi component intervention was generally acceptable to participants with barriers to adherence cited as being away from home and illness. PACE information and self-weighing facilitated the conscious restraint of energy intake among participants. The 10TT were not novel to participants and in some cases, not remembered, therefore, overall, this did not

appear to prompt behaviour change. Reflection (in response to self-weighing and PACE information) emerged strongly as an antecedent to conscious restraint of energy intake, which was the more likely change in behaviour to achieve weight gain prevention than increasing physical activity. Some participants did not find self-weighing a useful strategy. Mapping of emergent themes to the proposed logic model suggests that the self-weighing and PACE intervention components prompted participants to use a process of reflection followed by conscious energy restraint to prevent weight gain. Habit formation did not emerge from the interviews as a strong theme, however the duration of the intervention may not have been long enough for new behaviours to have become habitual.

CHAPTER 6

6.0 DISCUSSION, IMPLICATIONS FOR FUTURE PRACTICE AND CONCLUSIONS

6.1 Summary of thesis findings

The prevention of overweight and obesity is a public health concern globally, given their rising prevalence and substantial contribution to morbidity and mortality. The aim of this thesis was to investigate behavioural strategies for preventing weight gain in adults during occasions where the risk for weight gain is high. These periods are a potential target for brief weight gain prevention interventions because weight tracking studies demonstrate that annual weight gain occurs during shorter, discrete periods rather than gradually throughout the year [8]. A complex intervention developed according to guidelines produced by the MRC [14, 106], current evidence and using theoretical underpinning, was developed and evaluated in an RCT and nested qualitative study. Results from the RCT demonstrated that the intervention prevented weight gain during the Christmas period. Results from the qualitative study suggested that the notion of weight gain prevention at Christmas was acceptable to participants. Furthermore, they were more likely to restrain their energy intake than increase their physical activity levels. Reflection (on weight, dietary intake and/or physical activity) emerged as a key process to the restraint of energy intake. This was facilitated by self-weighing and PACE information which both emerged as having substantial influence on restraint of energy intake, according to participants.

In summary, this research has demonstrated that a behavioural intervention underpinned by theory, implemented during a period where the probability of weight gain is high, was successful in preventing weight gain in adults. Furthermore, this work has demonstrated that

the public are receptive to such interventions even if they are implemented during holiday occasions, which are typically challenging for weight management. Participants who were interviewed did not report that the intervention reduced their enjoyment of their Christmas holiday and the intervention appears to be a promising option for weight gain prevention in the population.

6.2 Refined intervention logic model

In accordance with good practice for intervention development, an intervention logic model was developed, setting out the hypothesised mechanisms of action by which this intervention may act to achieve the desired outcome of weight gain prevention (Chapter 3, Figure 4). According to guidelines for intervention development [14], a logic model is useful for process evaluation to test and refine the hypotheses of the intervention. When comparing the descriptions provided by participants of the processes and experiences of the intervention, the proposed logic model appears to be a generally accurate representation of how the intervention components led to the prevention of weight gain in participants. However, there are some parts of the model that require modification and further consideration. A revised intervention logic model has therefore been created based on the findings of this research. The revised logic model is presented in Figure 6. The refined logic model depicts unclear, theoretical relationships and/or mechanisms as dashed lines, arrows or boxes. Refinements as a result of findings from the qualitative study are presented in yellow boxes, and findings from both qualitative and quantitative studies are presented in red boxes. The key points which have informed the refinement of the logic model are summarised below.

6.2.1 Conscious restraint of energy intake

Conscious restraint of energy intake was hypothesised as a key strategy to achieving the intended outcome of preventing weight gain. Results from the RCT demonstrated a significant increase in cognitive restraint scores in the intervention group. Furthermore, through interviews with intervention group participants, the action of restraining energy intake was frequently expressed through the descriptions of instances of consciously reducing intake of particular foods or drinks, for example eating only two sweets rather than five. Participants described a process where reflection on their food and drink intake, weight and/or physical activity, initiated by self-weighing and/or PACE information appeared to act as an antecedent to the individual executing the conscious restraint of energy intake. These findings demonstrate that, as hypothesised in the logic model, promoting the restraint of energy intake seems central to the prevention of weight gain during this period. Therefore, strategies to promote the restraint of energy intake are likely to be integral to the future success of weight gain prevention interventions targeting high risk periods.

6.2.2 Self-weighing

Self-weighing also emerged as a key strategy promoting the process of reflection on weight, energy intake and/or physical activity, and subsequent restraint of energy intake among participants. These findings are similar to the findings from a recent RCT which evaluated the effectiveness of daily self-weighing on weight gain prevention during the holiday season (late September to early April) [103]. The trial included 111 adults and reported that graphical feedback on weight trajectory promoted self-regulation by encouraging individual reflection on weight trends.

The proposed logic model set out that the intervention component of self-weighing would promote the restraint of energy intake and facilitate habit formation to sustain behavioural changes. The habit formation model [118] was proposed as a supplementary theory specifically for the continuation of the behaviour of regular self-weighing. Conversely to this hypothesised process, the development of habits around self-weighing did not emerge through the interviews with participants. However, this intervention was brief (mean 43 days) and habits are likely to take longer to form according to previous research (mean 66 days) [121]. In addition, the formation of habits linked to regular self-weighing may have been limited by the delivery of the intervention as there was no cue specifically linked to the self-weighing behaviour. As higher automaticity was associated with lower weight at follow up in the trial, and some participants described the behaviour of self-weighing as routine, the formation of habits to self-weigh regularly could still be important to the prevention of weight gain. Future work should assess the role, addition of a cue (e.g., advising participants to place scales in a visible place and to self-weigh during morning teeth cleaning) and function of habit formation within weight gain prevention in more detail but in this case, the formation of habits around self-weighing did not have a prominent role in preventing weight gain.

Consideration should also be given to the potential for the promotion of regular self-weighing to cause harms. Current evidence suggests that regular self-weighing does not lead to adverse psychological outcomes or the development of negative eating behaviours such as binge eating [133, 136, 142]. However, some studies have suggested that there may be some adverse effects associated with the behaviour [139-141]. Whilst this study and the available evidence suggests no association between daily weighing and adverse psychological outcomes, a few comments were made by some participants during the interviews reported in this study. More specifically, a comment was made by a participant about the potential for obsessive behaviour

around self-weighing to occur. Another participant commented that self-weighing could cause psychological harm in those with a predisposition. Therefore, this highlights the importance of continuing to assess both the potential benefits and harms of an intervention and how potential harms might feature within intervention logic models.

6.2.3 PACE information

PACE information emerged as another key intervention component for promoting the restraint of energy intake in the interviews. When describing the behavioural processes resulting from the PACE information, participants described restraining their energy intake to varying extents. Significantly, participants appeared to choose to restrain their energy intake rather than increase their physical activity levels as a result of the PACE information. This finding is important as it suggests that restraining eating is perceived to be more achievable than increasing physical activity. Many participants also described surprise at the physical activity equivalents and the number of calories contained within the information on foods given to them. This supports previous research suggesting a lack of awareness and understanding among the public of the calorie content of foods and drinks and how this relates to energy expenditure and physical activity [149, 217].

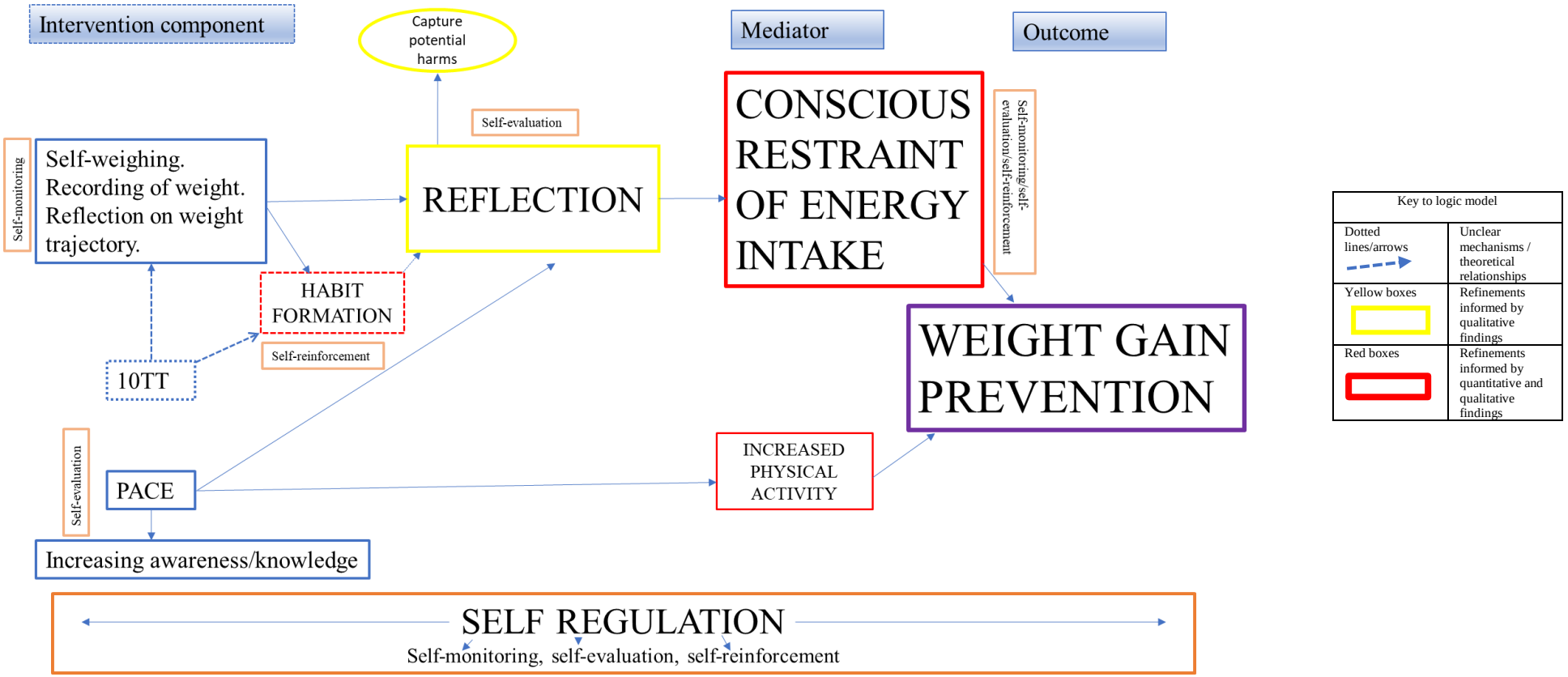
In addition, PACE is a relatively novel component and this work contributes to the current understanding of the concept. Furthermore, other organisations have called for its effectiveness to be tested as a simple public health intervention to educate the public on the energy content of foods and how to achieve energy balance [151]. In this study the intervention participants liked the concept of PACE and thought providing this type of information was valuable.

6.2.4 The 10TT

The logic model proposed that the 10TT would also facilitate the restraint of energy intake, however there was no strong evidence from this work to support this this suggestion. Nevertheless, the 10TT may have a role in the formation of habits to support weight gain prevention as previous research found an association with providing the 10TT and increased automaticity of key weight management behaviours (including self-weighing) [123, 153, 211], which was a key indicator of weight management success. In a revised logic model for this intervention (presented in Figure 6), the 10TT are linked to habit formation as a precursor to the conscious restraint of energy and as supporting the formation of the habit of self-weighing, making the behaviour more likely to be sustained.

In summary, this research has found that weight gain can be prevented during the Christmas period through promoting the restraint of energy intake. Individuals may restrain their energy intake through the process of reflection, where reflecting on their weight, intake of food and drink, and physical activity may be facilitated through self-weighing and PACE information. Both self-weighing and PACE information are key intervention components with the 10TT playing a lesser part. The role of habit formation in weight gain prevention requires further investigation, however, this research suggests that it may have a function in the continuation of the behaviour of self-weighing.

Figure 6: Refined logic model displaying the mechanisms of action for the WWW intervention.



6.3 Strengths and limitations

The detailed strengths and limitations of the studies in this thesis have been described in their respective chapters. This chapter will therefore describe the strengths and limitations pertaining to the overall thesis and research question.

6.3.1 Strengths

A particular strength of this work is its contribution to the existing evidence base. The prevention of weight gain in adults is an under researched area despite it being targeted as a priority area by different health organisations [9, 11]. Few trials have been conducted testing the effectiveness of behavioural interventions on weight gain prevention in adults. The RCT described in Chapter 4 is novel due to the paucity of published trials specifically targeting the Christmas period as an opportune time to prevent weight gain. This is first study to investigate weight gain prevention during the Christmas period.

To answer the research question of establishing strategies to prevent weight gain during high-risk occasions, both quantitative and qualitative research methodologies were utilised. The use of both of these research methodologies is increasingly used in health research [18] and referred to as mixed methods research. The definition of mixed methods research varies and is debated. One definition which is most commonly used is that it is research that 'focuses on collecting, analysing, and mixing both quantitative and qualitative data in a single study or a series of studies' [205]. Mixed methods research is driven by post positivism and pragmatism and its particular strength is that it can help to develop an understanding of the research question facilitated by the collection of differing types of data which provides enhanced insights into health issues [19]. The research presented in this thesis utilised an RCT study design to examine the effectiveness of a behavioural intervention on the prevention of weight

gain during the Christmas period. The RCT quantified the effects of the intervention. The nested qualitative study design provided additional in-depth context to the quantitative findings and enabled me to investigate the processes participants used in the attempt to prevent weight gain during this high-risk time. As the qualitative study was nested, addressing a slightly different research question relating to the processes participants undertook during the trial, this work may not fit all definitions of a pure mixed methods study. Nevertheless, this approach of using both quantitative and qualitative methods was beneficial here as it also allowed the intervention logical model to be refined, which will aid further research in this field.

6.3.2 Limitations

One limitation worth noting is generalisability as the trial likely recruited individuals who were keen to take steps to prevent weight gain. Although **t**he trial demonstrated effectiveness at follow up (5-8 weeks between baseline and follow up) and the qualitative study demonstrated a generally favourable response to the intervention overall and its individual components, longer term benefits and outcomes are unknown. Despite the intervention being set during a brief period within the calendar year, following up participants for longer, for example 6 months, would have provided more information on the sustained effects of the intervention. Additionally, further qualitative work with participants after a longer time period would enable an exploration of how the intervention exerts sustained effects, if indeed it does.

As described earlier in this discussion chapter, this intervention did not include a formal assessment of the potential adverse effects of the intervention (specifically the self-weighing component). Although the qualitative research allowed participants to communicate any

adverse effects as part of the semi-structured interviews, it is a limitation of this work that potential harms or adverse events were not routinely assessed.

A PPI group was used to help inform development and delivery of the intervention (described in Chapter 4). Although the responses were used to inform elements of the trial, the group could have been used more widely, and at other stages of the research process. Specifically, the PPI group could have aided the recruitment process, offering insights into possible routes and methods of recruitment. The group could have also provided insights into future development and implementation which would be particularly useful, as the focus of this research is on one particular holiday period and therefore translating the intervention to other holiday periods is challenging. The effective use of PPI groups can benefit the research process both ethically and pragmatically and may have enhanced the data collection and dissemination of results phases of this trial.

6.4 Implications for weight gain prevention research and future practice

The RCT and qualitative study findings presented in this thesis suggest that this intervention targeting a high-risk period could be an effective strategy for weight gain prevention in adults. This should be considered by public health policy makers as one approach to the prevention of overweight and obesity in adults. The intervention could be implemented at scale, to the general population, as a national awareness campaign during the Christmas period. The campaign could encourage the public to promote restraint of energy intake, through simple methods and information such as regular self-weighing and PACE, to prevent excessive weight gain. Importantly for implementation, 83% of participants reported that they had access to scales suitable for self-weighing suggesting that many of the population would be able to engage with the intervention. However, a consideration for policy makers is the long-

term effects of the intervention, particularly as Christmas and other holidays are reoccurring events in people's lives, not single, isolated events.

Although the positive nature of these outcomes is important, if the intervention were to be implemented then consideration must be given to the cost effectiveness of it. The intervention was deliberately designed to be low cost but whether this resulted in a cost-effective intervention is not known and this would be an important question for future research.

Additional considerations for implementation are to explore the generalisability of this intervention. In particular, the intervention may require adaptations to be culturally appropriate for different groups. Settings for recruitment may also warrant consideration, with workplaces a particular focus as evidence suggests promising results for weight management interventions [218, 219]. The potential acceptability of this intervention also warrants consideration given that the study sample may not have been fully representative of the general population. For instance, this research recruited a high proportion of women and those who were probably more receptive to weight management in general, given they mostly had tried to lose weight previously therefore it is likely that they would be more open to weight management at Christmas, which is a recognised high risk period for weight gain. Exploring the acceptability of weight gain prevention during the Christmas period with the general population could add important insights into the wider implementation of this intervention.

Combined with the effectiveness of the intervention demonstrated by the trial, learning that the public may be open to the idea of weight gain prevention at such a high-risk time as the Christmas period is important. Previous studies have reported that holidays are a commonly perceived weight control challenge. Reasons for holiday weight gain include: a greater availability of energy dense foods [86, 87]; increased alcohol intake [220]; larger portion sizes

[35]; and increased social occasions resulting in relaxed eating with family and friends [88, 89]. Similarly, according to the qualitative work presented in Chapter 5, individuals described that weight gain was a common occurrence experienced during the Christmas period, for which overconsumption and under activity was the cause.

6.5 Personal reflection

The process of this research has been extremely enlightening for me personally. I feel I have both developed new skills and techniques as well as refining my existing skillset. Of particular note is the conduct and management of the trial, where I learnt many new procedures around data collection, mitigating bias and analyses of quantitative and qualitative data and ended the process recognising the tremendous value of participants to research. Preparing a research paper for publication was a great experience for me personally. Through this process, I learned to manage the inputs of several co-authors and stakeholders and found that organisation skills were critical during this time. The process of peer review also provided invaluable experience, which encouraged me to deeply consider issues such as conducting research and interpreting findings from the trial (such as the role of alcohol consumption during the Christmas period, the dissemination (communication) of research findings) that I had not previously acknowledged. Another significant process for me was communicating the research via the media when the research paper was published. The opportunity to take part in a podcast organised by the BMJ journal provided me with a great opportunity where I was able to discuss the research in more detail and from which I learnt a great deal.

Overall, I feel this work has important consequences for public health practice but it would have been beneficial to be able to follow participants up for a slightly longer period, although

the aim of the work was to specifically target the Christmas period. Additionally, I feel that the PPI group were underutilised and that this group could have informed elements of the trial such as input on the recruitment materials, informing the qualitative element and at a later stage inputting into dissemination of the findings. There is a planned cost effectiveness analysis which will also aid policy makers when considering the implementation of the intervention.

6.6 Conclusions

A brief, behavioural, multi-component intervention with theoretical underpinning investigated in this thesis resulted in weight gain prevention amongst adults during the Christmas holiday period. According to participants, the notion of weight gain prevention at Christmas time is an acceptable one and the intervention did not reduce their enjoyment of the Christmas holidays. Engaging in the restraint of energy intake appears to be a predictor of weight gain prevention. The process of reflection on energy intake emerged as a strong premise for the conscious restraint of energy intake, which was significantly increased among participants in the intervention group, relative to comparators during the study period. Reflection was promoted by self-weighing and through the PACE information. Participants were more likely to demonstrate the restraint of energy intake as opposed to increasing their physical activity levels, which was perceived as more difficult and time consuming. Although it is not possible to determine the effectiveness of individual intervention components, self-weighing and PACE information resonated strongly with participants. These results have important implications for future public health interventions, which could target high risk periods for weight gain, using this low intensity, assumed low cost intervention.

APPENDIX 1

Publications arising from this work

Mason F, Farley A, Pallan M, Sitch A, Easter C, Daley AJ. Effectiveness of a brief behavioural intervention to prevent weight gain over the Christmas holiday period: randomised controlled trial. BMJ. 2018; 363:k4867.

Conferences

Mason F, Farley A & Daley AJ. Winter Weight Watch study. Efficacy of a brief, behavioural intervention to prevent weight gain during the Christmas holiday period: a randomised controlled trial and nested qualitative study. 'Rising to the challenge of collaborative research.' A research seminar. Birmingham City Council. December 2017. Poster presentation.

Mason F, Farley A, Pallan M, Sitch A, Easter C, Daley AJ. Jingle all the weigh. A randomised controlled trial to prevent weight gain over the Christmas holidays. UKSBM 2018. Oral presentation.

Mason F, Farley A, Pallan M, Sitch A, Easter C, Daley AJ. Jingle all the weigh. Effectiveness of a randomised controlled trial prevent weight gain over the Christmas holidays. Medical and Dental school's festival of research. April 2019. Poster presentation.

Mason F, Farley A, Pallan M, Sitch A, Easter C, Daley AJ. Jingle all the weigh. Effectiveness of a randomised controlled trial prevent weight gain over the Christmas holidays. Medical and Dental school's festival of research. April 2019. 3-minute thesis presentation.

Mason F, Farley A, Pallan M, Sitch A, Easter C, Daley AJ. Jingle all the weigh. Effectiveness of a randomised controlled trial prevent weight gain over the Christmas holidays. Graduate school research conference. June 2019. Poster presentation.

APPENDIX 2

Scientific justification for the Ten Top Tips (10TT) adapted from:

Lally et. al. Healthy habits: efficacy of simple advice on weight control based on a habit-formation model [221].

Tip	Scientific justification	Estimated calorie deficit
1. Keep to your meal routine. Try to eat at roughly the same times each day, whether this is two or five times a day.	People who succeed at long term weight loss tend to have a regular meal rhythm (avoidance of snacking and nibbling) and show 'flexible' rather than 'rigid' control' of eating [222]. A consistent diet regimen across the week and year also predicts subsequent long-term weight loss maintenance [223].	This tip helps encourage habit development.
2. Go reduced fat Choose reduced fat foods (e.g. dairy foods, spreads, salad dressings) where you can. Use high fat foods (e.g. butter and oils) sparingly, if at all.	There is a great deal of evidence to support the effectiveness of low-fat diets (where 30 % or less of total daily energy is from fat), which produce weight loss by decreasing calorie intake [224]. Following a low-fat diet is also associated with better weight maintenance [93].	- 200 kcal
3. Walk off the weight Walk 10 000 steps (equivalent to 60–90 min moderate activity) each day. You can use a pedometer to help count the steps.	Achieving the UK government recommendation of at least 30 minutes of at least moderate intensity physical activity on 5 or more days a week would increase most people's energy expenditure and contribute to weight management [225]. More activity (45–60 mins) may be required to prevent the transition to overweight and obesity and maximize weight loss [226]. People who have lost weight may need to do 60–90 minutes of activity a day to maintain their weight loss.	- 100 to 200 kcal

	Doing 10,000 steps/day is approximately the equivalent to at least 60 minutes of walking at a brisk pace (4.5 mph) [227].	
4. Pack a healthy snack If you snack, choose a healthy option such as fresh fruit or low-calorie yogurts instead of chocolate or crisps.	Readily available snack foods and drinks are often high in energy and tend to be used to supplement rather than replace meals. Between 1993 and 1998 sales of snacks more than tripled in the UK from £173 million to £541 million. Snack consumption is related to a higher daily energy intake [228].	- 150 kcal
5. Learn the labels Be careful about food claims. Check the fat and sugar content on food labels when shopping and preparing food.	Food labels detailing the caloric and nutritional content of foods provide a basis for making healthy food choices. Inadequate labelling can have a negative impact on nutrition. Providing individuals with simple methods to understand labels will facilitate informed choices [229].	This tip helps people to make informed choices.
6. Caution with your portions Do not heap food on your plate (except vegetables). Think twice before having second helpings.	Portion sizes have increased in the past 30 years [36, 230]. Larger portions contain more calories and can contribute to excess energy intake and weight gain. Eating satisfying portions of low-energy-dense foods can help enhance satiety and control hunger while restricting energy intake for weight management [36].	- 100 kcal
7. Up on your feet Break up your sitting time. Stand up for ten minutes out of every hour.	Inactive people are more likely to be obese than active people [225]. Time spent in sedentary behaviours is related to overweight and obesity, independent of physical activity level [231, 232]. Decreasing sedentary time and increasing light–to-moderate activity may bring substantial health benefits [225, 231].	- 100 kcal
8. Think about your drinks Choose water or sugar-free	Intake of sugar-sweetened soft drinks has increased over the	- 150 kcal

squashes. Unsweetened fruit juice contains natural sugar so limit to one glass a day (200ml/one-third pint). Alcohol is high in calories; limit to one unit a day for women and two for men.	last 30 years; up by 135 % (278 kcal) in 5 years [233]. Higher consumption of sugar-sweetened beverages is associated with greater weight gain [234]. Intake of calorific drinks may lead to excess energy intake that is not compensated for elsewhere in the daily diet [234].	
9. Focus on your food Slow down. Do not eat on the go or while watching TV. Eat at a table if possible.	More TV viewing tends to be associated with a higher calorie intake. Internal cues regulating food intake may not be as effective while distracted by the TV [235].	This tip helps place the focus on current habits avoiding unconscious slips in behaviour.
10. Do not forget your 5 a day Eat at least 5 portions of fruit and vegetables a day (400g in total).	The UK Department of Health recommends 400 g of fruit and vegetables a day. Fruits and vegetables have high nutritional quality and low energy density. Eating the recommended amount produces health benefits including reduction in the risk of cancer and coronary heart disease [236].	This tip is important for health.
Total calorie deficit		800 – 900 kcal

APPENDIX 3

Copy of ethical approval for the trial granted by University of Birmingham's Science, Technology, Engineering and Mathematics ethical review committee (ERN_16-0673).

From: Susan Cottam
Sent: 07 November 2016 10:39
To: Amanda Daley; Amanda Farley (Institute of Applied Health Research)
Subject: Application for amendment ERN_16-0673A

Dear Dr Daley and Dr Farley

Re: "Efficacy of a brief public health intervention to prevent weight gain during the Christmas holiday period: randomised controlled trial and nested qualitative study"
Application for amendment ERN_16-0673A

Thank you for the above application for amendment, which was reviewed by the Science, Technology, Engineering and Mathematics Ethical Review Committee.

On behalf of the Committee, I can confirm that this amendment now has full ethical approval.

I would like to remind you that any substantive changes to the nature of the study as now amended, and/or any adverse events occurring during the study should be promptly bought to the Committee's attention by the Principal Investigator and may necessitate further ethical review. A revised amendment application form is now available at https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Ethical-Review-Forms.aspx . Please ensure this form is submitted for any further amendments.

Please also ensure that the relevant requirements within the University's Code of Practice for Research and the information and guidance provided on the University's ethics webpages (available at https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Links-and-Resources.aspx) are adhered to and referred to in any future applications for ethical review. It is now a requirement on the revised application form (https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Ethical-Review-Forms.aspx) to confirm that this guidance has been consulted and is understood, and that it has been taken into account when completing your application for ethical review.

Please be aware that whilst Health and Safety (H&S) issues may be considered during the ethical review process, you are still required to follow the University's guidance on H&S and to ensure that H&S risk assessments have been carried out as appropriate. For further information about this, please contact your School H&S representative or the University's H&S Unit at healthandsafety@contacts.bham.ac.uk.

If you require a hard copy of this correspondence, please let me know.

Kind regards

Susan Cottam
Research Ethics Officer
Research Support Group

1

APPENDIX 4

Completed CONSORT check list for RCT reporting.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	55
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	55
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	55
	2b	Specific objectives or hypotheses	56
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	56
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	57
	4b	Settings and locations where the data were collected	58
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	59, 60
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	66
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	68
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	68
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	68, 69
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	68, 69
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	69
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	69

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	70, 71
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	71, 72
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	73, 74
	13b	For each group, losses and exclusions after randomisation, together with reasons	74
Recruitment	14a	Dates defining the periods of recruitment and follow-up	73
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	75-77
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	74, 79
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	78, 79
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	79
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	80-84
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	88, 89, 90
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	88
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	85, 86, 87
Other information			
Registration	23	Registration number and name of trial registry	56
Protocol	24	Where the full trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	55

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

APPENDIX 5

Example of recruitment materials, study website and social media pages.

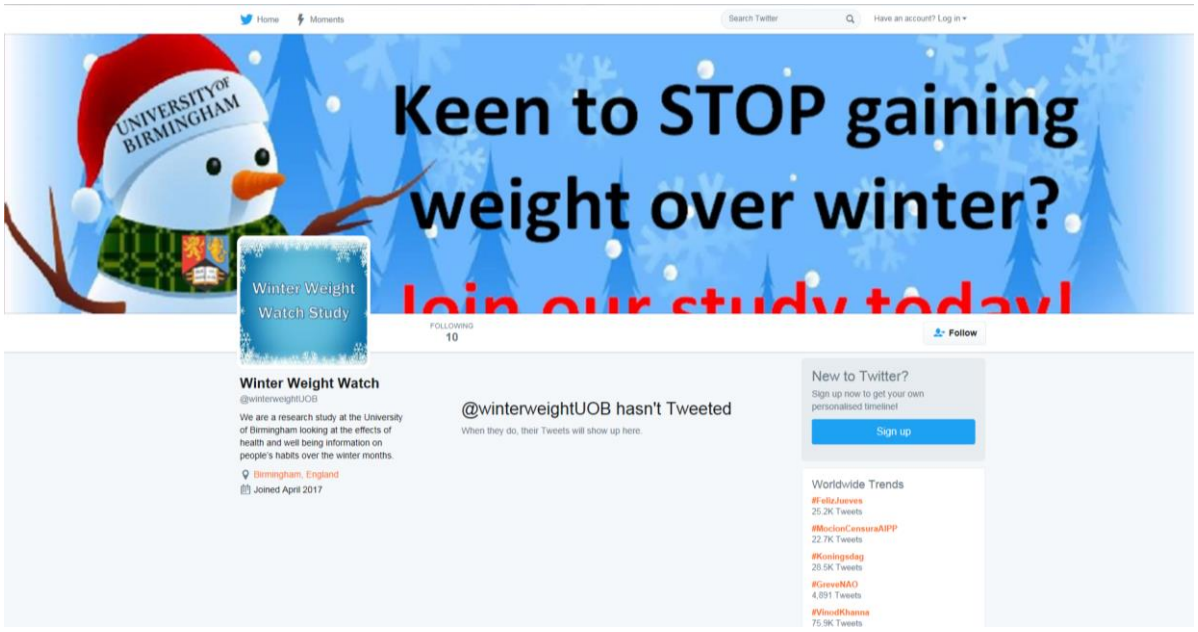
Dear Parents,

The College of Medical and Dental Sciences, University of Birmingham are looking for participants to take part in a research study looking at weight gain during the winter months. Please note, this is a study for adults and ***not children*** therefore the attached poster is for your participation and not for your child. The study is open to anyone aged over 18 years. If you are interested in taking part in the study, please contact the study team directly via the telephone number or email address provided on the poster.

Many thanks,

The Winter Weight Watch study team

University of Birmingham



APPENDIX 6

The Winter Weight Watch study participant intervention sheet.

Participant ID:

Please weigh yourself at least twice a week, ideally every day and record your weights below. You should weigh yourself at the same time of day (e.g. as soon as you wake up) wearing similar amounts of clothing or no clothing.

Current Weight:

Maximum Weight:

Date	Weight	+/- 'Current Weight'
Remember to limit your weight gain to 0.5kg or 1lb		
Has your weight gone up? Take caution with your portions		
Look out for your weight going up. Spot it early and stop!		

Date	Weight	+/- 'Current Weight'
Weight going up? Get up on your feet and walk off the weight!		
Try more reduced fat foods if your weight is going up		
Stick to your meal times to stop gaining weight		

Version 2, 10/08/2016

Winter Weight Watch Study

This study will test whether brief information and encouragement to watch your weight prevents you from gaining weight over Christmas.

Most people in the UK are overweight because they eat too much food and don't do enough physical activity. People also naturally gain weight over time, from one year to the next. Being overweight is not good for your health and it increases your risk of serious chronic diseases including type 2 diabetes, heart disease and cancer. For these reasons it is important that we do all we can to prevent the general public from gaining too much weight.

Weight gain at Christmas time

Studies report that holidays are a very high risk period for weight gain and most of us will gain weight. On average, people will gain between **0.5 to 1.0 kg (1-2 pounds)** over the Christmas holidays that they do not lose afterwards. Over 10 years this amounts to between **5 to 10kgs (11-22lbs)** in weight gain.

Why do people gain weight at Christmas time?

Changes in routine, taking less physical activity, parties, increased alcohol consumption and food temptation leading to over consumption all contribute to a greater risk of weight gain over the Christmas period. Attending more social events also encourage over eating and drinking, with more alcohol, snack foods and larger portions on offer.

What you have to do for the study

1. **Ten Top Tips**

Inside this leaflet are 'Ten Top Tips' which we would like you to follow to limit your weight gain. As examples, this leaflet also gives you information about the amount of walking and running you need to do to burn off calories from popular Christmas food and drinks.

2. **Family and Friends**

We would also like you to tell your family and friends about the study so that they can support you to limit your weight gain.

3. **Weigh**

We would like you to weigh yourself at least twice a week, ideally every day, and record your weight on the back of this leaflet.

We would like you to gain **no more than 0.5 kg (1 lb)** above your weight (as measured today) over Christmas. Your maximum weight is written on the back page of this leaflet in the **Maximum Weight** box.

We hope you have a healthy and happy holiday period and look forward to hearing how you got on in the New Year.

Contact Details: Tel: 0121 414 6422 0121 415 8725
Email: winterweight@contacts.bham.ac.uk

1 Keep to your meal routine:
Try to eat roughly the same time each day, whether this is two or five times a day.

2 Go reduced fat:
Choose reduced fat foods (e.g. dairy foods, spreads, salad dressings) where you can. Use high fat food sparingly (e.g. butter and oils), if at all.

3 Walk off the weight:
Walk 10,000 steps each day (equivalent to 60-90 min moderate activity). You can use a pedometer to help you count the steps. Start by counting your steps, then building up more each day with an ultimate target of 10,000.

4 Pack a healthy snack:
If you snack, chose a healthy option such as fresh fruit or low calorie yogurts instead of chocolate or crisps.

5 Learn the labels:
Be careful about food claims. Check the fat and sugar on food labels when shopping and preparing food. Be aware of what the higher fat and sugar foods are.

6 Caution with your portions:
Do not heap food on your plate (except vegetables). Think twice before having second helpings.

7 Up on your feet:
Break up your sitting time. Stand up for 10 minutes out of every hour.

8 Think about your drinks:
Choose water or sugar free squashes. Unsweetened fruit juice contains natural sugar so limit to one glass a day (200ml: one third of a pint). Alcohol is high in calories so limit to one unit per day for women and two for men. Try diluting your drinks with water, soda or low calorie mixers.

9 Focus on your food:
Slow down. Do not eat on the go or while watching TV. Eat at a table if possible. Enjoy your food.

10 Do not forget your 5 a day:
Eat at least five portions of fruit and vegetables a day (400 g in total). Try something new! Frozen and tinned (in water) count too.

Festive food	Calorie content	Activity needed to burn calories (mins) Walking	Running
1 thick slice roast turkey (60g)	100	16	8
5 pigs in blankets	70	12	6
3 large roast potatoes (100g)	161	27	14
Brussel sprouts (100g)	35	6	3
5 tbsp gravy (125g)	50	8	4
1 small Christmas pudding (450g)	1280	210	110

Festive drink	Calorie content	Activity needed to burn calories (mins) Walking	Running
Small glass of mulled wine	192	33	17
Small glass of sparkling wine	105	17	9
Pint of lager	180	30	16
Pear cider (500ml bottle)	240	39	21
Can of coke (330ml)	140	26	13
Small glass (125ml) of orange juice	50	8	4

Festive food	Calorie content	Activity needed to burn calories (mins) Walking	Running
1 mini sausage roll (15g)	53	9	4
1 slice smoked salmon (30g)	56	9	4
Stilton (100g)	410	67	35
1 slice of pizza	238	39	21
1 vegetable samosa (40g)	87	15	7
2 pieces of garlic bread	182	30	16
1 mini pork pie	370	60	32
1 quarter of a quiche lorraine	113	18	9

Festive food	Calorie content	Activity needed to burn calories (mins) Walking	Running
1 (85g) mince pie	245	40	21
5 roses chocolates	240	39	21
1 slice (60g) Christmas cake	213	35	18
1 large bag (150g) potato crisps	740	122	63
1 bag (100g) dry roasted peanuts	590	97	50
1 Ferrero Rocher	73	12	6
1 box of dates (227g)	672	110	57

APPENDIX 7

Comparator group leaflet.

There are simple things you can do to help you wind down and prepare for bed. Think about setting a bedtime routine where you wind down ready for sleep and go to bed at a set time. Remove distractions, like your TV, computer and phone, from your bedroom. Avoid caffeine, nicotine, and alcohol too close to bedtime as they can keep you awake.

Stress

Lots of things can cause stress, including work, relationships and money problems. Stress can affect how you feel, think, behave and how your body works – ranging from how well you sleep to your immune system. In the short-term that's not really a bad thing, but long-term stress puts your health at risk.

Reducing your stress levels and feeling more in control boosts your mood and means you are more able to cope with life's ups and downs. Getting stress under control supports your immune system and helps prevent serious health problems, such as high blood pressure and heart disease.

There's no quick-fix cure for stress, but there are simple things you can do to help you stress less. These include relaxing, exercising, eating a healthy and balanced diet, and talking to someone.

Source: Public Health England, ONEYOU

Have a Healthy Lifestyle

"Being healthy isn't a fad or a trend, instead it's a lifestyle".

Eating well, taking regular exercise and managing the demands of everyday life will help you to achieve a healthy lifestyle and in turn, enjoy better health.

Eating

What you eat, and how much, is very important. Having a healthy diet will help you to maintain a healthy weight, reduce your risk of developing type 2 diabetes, high blood pressure and high cholesterol and reduce your risk of developing coronary heart disease and some cancers.

What do I need to eat for my health?

A balanced diet is recommended for good health. This means you need to eat a wide variety of foods in the right amounts to give your body what it needs. For a balanced diet you should eat:

- plenty of fruit and vegetables,
- plenty of bread, rice, potatoes, pasta and other starchy foods (choose wholegrain varieties)
- some milk and dairy foods
- some meat, fish, eggs, beans and other non-dairy sources of protein
- just a small amount of food and drink high in fat and/or sugar

Sugar

Too much sugar can lead to the build-up of harmful fat on the inside of our bodies, often around our organs, which is damaging to health. Having a lot of this fat stored in the body can cause serious diseases, such as type 2 diabetes and heart disease. Eating too much sugar can also cause tooth decay.

Version 2, 26/07/2016

Fat

There are different kinds of fat in the food we eat – saturated and unsaturated fat. We need some fat to help our bodies absorb vitamins and stay healthy but we shouldn't have too much, especially of saturated fat as this can raise our cholesterol, leading to serious problems such as a heart attack or stroke.

Salt

Many of us in the UK eat too much salt. Too much salt can raise your blood pressure, which puts you at increased risk of health problems, such as heart disease and stroke. Adults should eat no more than 6g of salt a day – that's around one teaspoon. Children should eat less than this.

Much of the salt we eat isn't added at the table – 75% of the salt we eat is already in everyday foods including bread, breakfast cereal and ready meals.

Smoking

Smoking is the most damaging thing you can do to your health. From the day-to-day effects on your heart and your breathing, to longer-term smoking-related diseases such as heart disease, cancer and stroke, the consequences are severe. Your smoke can also harm your family's health, too.

No matter how long you've smoked for, quitting can help improve your health straight away. Curb those nicotine cravings and improve your chances of quitting with stop smoking aids. Remember, there are plenty of treatments out there and they can give you the extra support you need to kick the habit for good. Many smokers also find e-cigarettes a helpful way to manage their cravings.

Alcohol

Men and women are advised not to drink more than 14 units of alcohol a week. This is the same as 6 pints of average strength beer a week. If you regularly drink above the lower risk guidelines, cutting back on alcohol can help your general wellbeing. From weight gain to increasing your risk of cancer, alcohol can have serious effects on your body. Once you start cutting back, you may quickly find you have more energy and feel less tired during the day as well as seeing improvements to your general health.

Physical Activity

Being active is really good for your body, mind and health. If you aren't very active and spend long periods of time sitting (being sedentary) you increase your risk of developing serious conditions, including heart disease, type 2 diabetes and some cancers.

Sleep

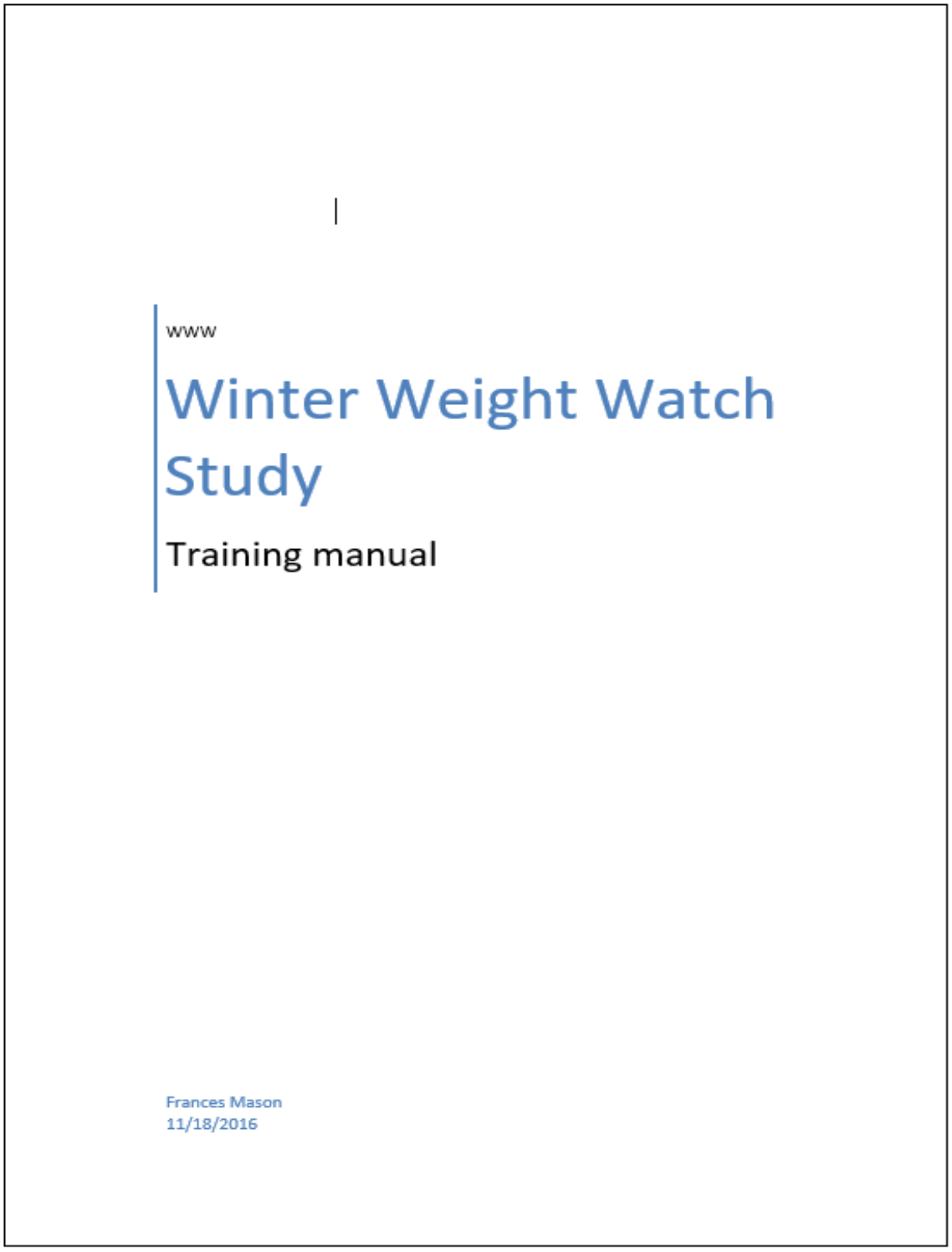
Good-quality sleep is more important than the amount of sleep that you get and it helps to keep you feeling healthy. The odd bad night's sleep can make you feel tired and irritable the next day, but it won't harm your health. However, regular poor-quality sleep can have a huge effect on your health, putting you at risk of developing serious medical conditions and can affect your body, thoughts, emotions and behaviour.

Sleep provides you with a boost to your energy and immune system, helping your body recover from illnesses. While you sleep your body builds and repairs itself by making new tissue. Sleep helps your brain to recover and revive itself, helping it to make sense of the day, storing your memories and creating new ideas. Sleep allows your mind to unwind and de-stress and this allows your mental and emotional wellbeing to be restored.

Version 2, 26/07/2016

APPENDIX 8

Training manual for researchers carrying out data collection for the Winter Weight Watch study.



Contents

Winter Weight Watch – WWW - Training Manual

Introduction and background

The Winter Weight Watch study is looking at the effectiveness of a brief, low cost intervention on the prevention of weight gain during the Christmas period.

Study rationale

There is evidence to suggest that holidays (e.g., Christmas) are a high-risk period for weight gain. The average gain is 0.5-1kg during each holiday period meaning the accumulative gains of multiple holiday events over each year are significant. For example, over a 10-year period, gains of 5-10kg are possible and without compensation gains like this which are driving the obesity epidemic and are responsible for the majority of the annual weight gain in the population. Interventions to address this issue are scant therefore this study will test whether a simple, low cost intervention can prevent the public from gaining weight during holiday periods.

Study design

The study is a randomised controlled trial where participants will be randomly allocated to either the intervention (specific information) group or control (general information) group. Participants will be blinded to their allocated group.

Participants

284 participants (142 per group) will be recruited to take part in the study. Up to 20 of these will take part in a qualitative study at the end of the study period. Participants will be provided with a £10 high street voucher for completing the study.

Recruitment

Participants will be recruited via schools across the Birmingham area (parents) as well as via two employers: Midland Heart and Birmingham City Council. 22 schools have agreed to assist in placing pre-prepared flyers into children's book bags in the first week in November in order to recruit parents (NB: children will not be involved in the study). Schools taking part are recorded on the excel sheet.\School recuitment.xlsx

Participants will also be recruited through Midland Heart, a local large workplace via recruitment email/desk drop.

Screening

Potential participants will contact the research team by phone if they are interested in taking part. Participants will then be asked questions to see if they are eligible for the study. They can only take part if…

Inclusion - aged 18 or above

- BMI of ≥20

Exclusion - Pregnant or intending on becoming pregnant during the study period

- Breastfeeding

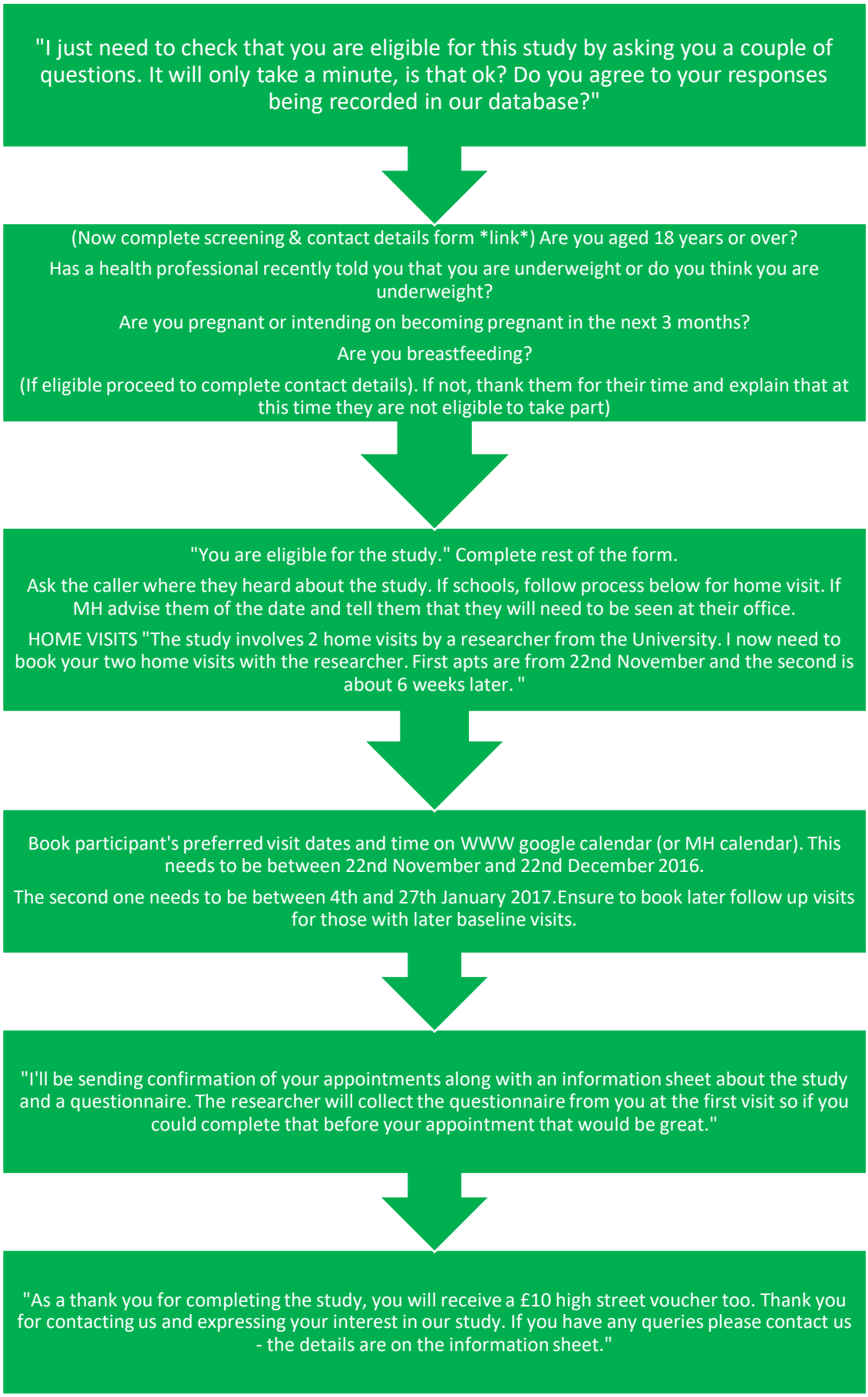
Once a participant contacts the research team, the following script should be followed (taken from.\Study Materials\Process\Screening process.docx). Use the screening form to help complete the process.

The following is a suggested process:

"Hello, thank you for making contact with us to let us know you might be interested in taking part in the Winter Weight Watch Study"

"I'll start by telling you a bit about the study….This study is a research trial by the University of Birmingham. It is looking at the effects of information on health habits over the winter months. The study will compare 2 different types of information to see how useful they are. **The study involves two visits by a researcher to measure your weight, height and % body fat. We will also ask you to complete two questionnaires. These visits normally take around 30 minutes** . Is that ok?"

Get screening & contact details form ready to complete*


"I just need to check that you are eligible for this study by asking you a couple of questions. It will only take a minute, is that ok? Do you agree to your responses being recorded in our database?"
(Now complete screening & contact details form *link*) Are you aged 18 years or over?
Has a health professional recently told you that you are underweight or do you think you are underweight?
Are you pregnant or intending on becoming pregnant in the next 3 months?
Are you breastfeeding?
(If eligible proceed to complete contact details). If not, thank them for their time and explain that at this time they are not eligible to take part)
"You are eligible for the study." Complete rest of the form.
Ask the caller where they heard about the study. If schools, follow process below for home visit. If MH advise them of the date and tell them that they will need to be seen at their office.
HOME VISITS "The study involves 2 home visits by a researcher from the University. I now need to book your two home visits with the researcher. First apts are from 22nd November and the second is about 6 weeks later. "
Book participant's preferred visit dates and time on WWW google calendar (or MH calendar). This needs to be between 22nd November and 22nd December 2016.
The second one needs to be between 4th and 27th January 2017.Ensure to book later follow up visits for those with later baseline visits.
"I'll be sending confirmation of your appointments along with an information sheet about the study and a questionnaire. The researcher will collect the questionnaire from you at the first visit so if you could complete that before your appointment that would be great."
"As a thank you for completing the study, you will receive a £10 high street voucher too. Thank you for contacting us and expressing your interest in our study. If you have any queries please contact us - the details are on the information sheet."

NOTE

If people ask for more information, you can read what is on the participant information sheet.\Study Materials\Patient Information Leaflet\WWW Patient Information Leaflet V2 11072016_tracked changes.docx. If they still need more information, explain that you are unable to give any more detailed information at this point and refer them to Amanda/Frances.

PLEASE AVOID SAYING CHRISTMAS, WEIGHT LOSS OR HOLIDAYS.

Google calendar

To book an appointment, open the Winter Weight Watch google calendar https://calendar.google.com/calendar/render?tab=mc#main_7

User name is

And the password is

Each researchers' availability is entered into the calendar and each researcher has a colour code. When booking a visit, please note the postcode of the previous visits, check the location on the map and attempt to keep those close in proximity together to avoid excessive travel for researchers.

Please attempt to book visits around 6 weeks apart, i.e., if participant is booked for late November, their follow up should be early January.

Confirm the booked dates with the participant and let them know the name of the researcher who will be visiting them.

NOTE:

MH employees will have a separate google calendar as they will be seen at their offices. Open this calendar to book these appointments.

User name is

Password is

Pacemakers

If participants answer 'Yes' to the pacemaker question, please mark this on to the google calendar by adding a 'P' before their screening ID on the appointment itself.

Following the call…

1. Ensure all information has been added to the database (database), Add the screening ID to the screening form and baseline questionnaire (bottom right corner).
2. Add the appointment details to the cover letter, print and post the cover letter *link*, baseline questionnaire and Patient Information Leaflet to the participant.
3. Ensure that booked visits have been added to the google calendar. Please ensure to add the screening ID and the first half of the postcode.
4. For ineligible participants, ensure details are added to database with reasons for non-participation – not meeting inclusion criteria, declined to participate, other.

Procedures for Baseline visit

Pre visit

Tina is responsible for ensuring the online home visit booking calendar is well maintained and up to date. Frances will provide all the information required for the visit (e.g. name, address, ID etc.).

The home visits at follow up will be arranged at the initial screening call. Follow up visits will be confirmed via letter, during baseline visit and via text message over the Christmas period.

NOTE if the participant has a pacemaker fitted this will be denoted by a 'P' on the calendar and visit sheet. For these participants please use only SECA scales and do not measure body fat.

Equipment and materials required for the home visits

Please make sure you have all of the following before you leave to conduct a home visit.

Checklist for baseline home visits

- Folders containing visits sheet, CRF, consent form
- Blue folder containing intervention leaflets
- White folder containing control leaflets
- Randomisation envelopes (brown batch and white batch – further explanation on page 8)
- Tanita weighing & body fat scales
- Seca height meter
- Spare SECA scales in case of pacemaker
- Spare consent forms
- Spare baseline questionnaires
- Spare CRFs
- Pencil case containing black pens, calculator, stapler
- Spare prepaid envelopes
- Mobile phone to call or text in and out of the home you are visiting. Please confirm who you need to text/call prior to leaving the office.

First home visit: Baseline

Step 1: Collect equipment from office

Collect your folders for the day's visits. Each participant has a folder containing a blank CRF and consent form. On the top of the folders will be your visits sheet which contains details for that day's visits.

Identify who you are to be texting in and out that day (this is the responsibility of the researcher).

Step 2: Introductions

Call/text in to the team to let someone know you are entering the home. Show your ID and introduce yourself. Explain the purpose of the visit is to weigh participants, measure their height and then randomise them to one of the study groups; specific information or general information.

Step 3: Eligibility& consent

Explain that you need to check eligibility and obtain the participants' consent to taking part in the study.

Measure participant's height first. Record on CRF.

Weight and height should be measured in light clothing with shoes **and socks/tights** removed (socks must be removed for an accurate body fat result).

Measure weight. **NB., BEFORE the participant steps on the scales, you must ask them if they have a pacemaker fitted. If a participant has a pacemaker, they CANNOT be weighed on the Tanita scales. Please use the SECA scales to record weight.**

Make sure scales are on a flat surface. Follow the flashing lights on the handheld Tanita monitor to guide you. Below is the process:

1. Enter clothes weight: 1kg
2. Ask the participant to step on (shoes and socks removed)
3. Enter body type 'STANDARD'
4. Enter participant's gender MALE/FEMALE
5. Enter participant's height as measured
6. Body fat will be measured
7. Remove the printout and record participant's weight and BMI as displayed on the printout. Retain the printout. If participant asks to keep the printout explain that unfortunately we need to keep this for the study.

If the participants' BMI is 20 or above, obtain consent. Ask the participant to read the consent form carefully and sign and initial each box if they agree. Answer any questions they may have. Retain the white copy and hand the second copy to the participant.

NB. If ineligible, explain that they do not meet the eligibility criteria for this particular study and thank them for their interest. Text out upon departure from the home.

Step 4: Complete baseline data collection on the CRF

Complete the height, weight, BMI and % body fat on the CRF.

Ask the participant the questions as specified on the CRF. Please note the following point below:

- For the 'time spent sitting' question, please work out a rough average in hours per day. E.g., a rough estimate is fine here. We are looking for those who spend more than 8 hours per day sitting as this is high risk. You can ask people to think in terms of categories so in the morning, afternoon and evening. The following is an example of how sitting is assessed from http://www.juststand.org/tabid/866/Default.aspx:

Sitting-Time Calculator

Evaluate how much you sit each day and learn ways to reduce that time for better health.

Calorie-Burn Calculator

See the difference that standing makes!

Select the number of hours you sit when you...

Eat breakfast	0	
Commute to work	0	
Work the morning hours	0	
Eat lunch	0	
Work the afternoon hours	0	
Commute home	0	
Eat the evening meal	0	
Watch TV / gaming	0	
Compute at home	0	
Other	0	

Additional Information

☐ I exercise about 1/2 hour to an hour daily.

Select the longest amount of time (in hours) you sit without interruption

0

Calculate Reset

Step 5: Collect baseline questionnaires

At baseline: Participants have already been sent the questionnaire. Please check all sections have been completed. If it has not been completed, ask them to do so now.

At baseline the questionnaire is the same for both groups (cream coloured). Check the questionnaire has been completed correctly and fully. If participants do not have time to complete the questionnaire at the home visit give them a prepaid envelope but please try to avoid leaving questionnaires as they are normally not returned to us if left.

Step 6: Randomise participants

Participants will be randomly allocated to either the specific (intervention) or general information (control) group. This means the group the participant receives is a result of chance and not pre-determined in any way. Inform participants that they cannot choose which group they receive and the best way to describe this is by saying its *'like tossing a coin*" or "*your group will depend on what's in the envelope"*. Explain that the participant ill not know which group they are in – they will be blinded to this.

Participants will be allocated to the groups according to the number order of the batch of envelopes you are given. It is **VERY** important that each envelope is opened sequentially in number order – **do not** choose an envelope from your batch unless it is the next in the number sequence.

You will be given two batches envelopes: WHITE and BROWN

- If participants indicate they **WILL** be attending a commercial weight loss programme over the duration of the study, then open the next envelope in the **BROWN batch**
- If participants indicate they **WILL NOT** be attending a commercial weight loss programme during the study, then open the next envelope in the **WHITE batch**
- You should open the envelope and take out the randomisation slip. The slip will tell you which group the participant has been allocated to – intervention or control. Follow the instructions on the slip. Screening ID, date of visit and name of researcher and signature should be written on the back of the slip.
- Put the randomisation envelope in the participant's visit envelope and give this back to Tina as soon as you can along with the CRF.
- Tina will then record the group allocation on the database and enter the CRF data on to the database.

*Please note, the randomisation number will become the participant ID. The randomisation number contains the prefix WW. This is the number used to identify the participant. The screening ID is not used to identify a participant.

What do I do and say to each group of participants after randomisation?

What you say will depend on which group they are allocated to; this is outlined below. For each group follow the instructions below.

Intervention group

1. Explain that you will now give them the leaflet that contains information about how to limit weight gain over the Christmas period. Tell participants why we people gain weight at Christmas and why this is important to limit.

2. Give the participant the A4 colour INTERVENTION leaflet. Ask them to read it fully as they will find lots of useful information to help them. Show them the Ten Top Tips and activity and food section. Explain that the goal over the study period is to limit their weight gain to NO MORE THAN 0.5kg or 1lb.

3. Turn to the back page of the intervention leaflet. Tell participants that they are to weigh themselves at least twice per week, ideally every day using their own scales and record this on the back page. Ask the participant to go and get their own scales. (If participants have no access to scales, suggest options such as borrowing scales, using accessible scales at Boots/Gyms/health centres. In some cases, we have a small number of scales which we may be able to lend to participants for the duration of the study. Please contact Frances to discuss on a case-by-case basis.)

4. In the 'CURRENT WEIGHT' box, write the participants' weight using the weight as measured on **participants' own scales** in the units they prefer**.** If the participant has no scales, use the weight from your scales. ***NOTE, THE WEIGHT RECORDED ON THE CRF MUST BE THE WEIGHT FROM THE RESEARCHERS' TANITA SCALES, NOT THE WEIGHT FROM THE PARTICIPANTS' OWN SCALES***

5. Calculate 0.5kg or 1lb above the participants' measured weight according to their scales and write this in the 'MAXIMUM WEIGHT' box. Reiterate to the participant that this is the weight they should not go above.

6. Explain that participants need to record each weight in the table and work out the differences from their 'current weight' each time they weigh themselves and record this in the +/- box. Explain that we are asking them to do this so that they reflect on their weight gains and losses and take action to limit weight gain. Provide an example; "So if your current weight was measured at 11st3lbs and your weight today was 11st4lbs you will need to write **+1lb.**"

7. Thank the participant for taking part in the study, remind them someone will come to visit them on the date booked (specify this date – shown in CRF) to weigh them again and to see how they have got on.

8. Advise participants that they will receive another questionnaire to complete prior to their next visit in the post and that they will receive their £10 voucher at that next visit

Control group

1. Explain that this is a study looking at information to help people follow a healthy lifestyle. Give them the A5 black and white control leaflet 'Have a Healthy Lifestyle' which contains information about having a healthy lifestyle.

2. Explain that once this visit has been completed, they will receive a follow up visit to see how they have got on. Specify the date booked to the participant.

   NB., if the participant tells you that the booked follow up appointment is no longer convenient, access the google calendar to rebook an appointment. If you cannot access remotely, call 0121 414 6422 to rebook with Tina.

3. Advise participants that they will receive another questionnaire to complete prior to their next visit in the post and that they will receive the £10 voucher at that visit

4. Thank participants for taking part

Step 5: Call out

Ring or text the study team to let them know you have left the home.

Upon return from the visit…

- Data from CRF and questionnaires to be entered onto the database.
- Participant ID to be logged on the screening form.
- Text message for appointment reminder to be set up.
- Follow up questionnaire to be prepared with a date to be posted.

Second home visit: Follow up

At the follow up visit, questionnaires need to be collected, along with weight and % body fat measured. Take with you the prepared envelopes containing the participants' CRF for completion.

Checklist for follow up home visits

- Name, address, phone numbers, participant ID and group allocation of participant (visit sheet)
- Tanita body composition & weighing scales
- Participants' CRF that was completed at baseline in a sealed envelope
- Spare follow up questionnaires. Make sure you have the correct one according participants' group allocation

- Pens
- Mobile phone to call in and out of the home you are visiting
- Phone or camera for taking a picture of the weight record card (if not collected in)
- £10 voucher

During the visit

1. Text in
2. Take weight and % body fat.
3. Complete section 6 (follow up) of the CRF. There are a few additional questions that need to be answered on the CRF which should be asked in a relaxed, conversational manner. Please see the following for further explanation:

"The following questions should be asked in a general chat relaxed conversation style. They are simply listed here as prompts to remind you to ask the questions and give you a feel for how they might be asked. Please try and avoid a question and answer style conversation. One of the best ways of doing this is to express an interest in how the participant is getting on, but you should avoid getting into a lengthy detailed conversation about their diet and eating habits etc. Try to encourage the participant to elaborate on their answers; usually open-ended questions are the best approach to achieving this e.g., how have you found weighing yourself regularly?"

4. Questionnaires

At baseline the questionnaire is the same for both groups but at the follow up visits they are different – **intervention group are PINK and control group are BLUE** – please watch out for this.

Participants will have received their appropriate questionnaire by post prior to the follow up visit so it should be completed, ready. If it isn't, please ask the participant to complete it while you wait. If the participant is unwilling to do this, as a last resort, please leave a SAE for them to return it directly to the research team.

5. Thank them for their participation and inform them that they will receive a copy of the findings in the post once they are available
6. Give participant their £10 gift voucher and get them to sign for receipt on the back page of the CRF. NB., participants have the option of donating their voucher to charity – The Birmingham Children's Hospital. If donating, researcher must retain the voucher. If the participant wishes to donate themselves, they need to tick the box to say they have received the voucher
7. Text out

Upon return from the visit…

- Data from CRF and questionnaire should be entered into the database *link*
- File CRF and questionnaires in allocated folder

Appendix

Tanita scales: operating instructions

Weight and height should be measured in light clothing with shoes **and socks/tights** removed (socks must be removed for an accurate body fat result).

Measure weight. **NB., BEFORE the participant steps on the scales, you must ask them if they have a pacemaker fitted. If a participant has a pacemaker, they CANNOT be weighed on the Tanita scales. Please use the SECA scales to record weight.**

Make sure scales are on a flat surface. Follow the flashing lights on the handheld Tanita monitor to guide you. Below is the process:

1. Enter clothes weight: 1kg
2. Ask the participant to step on (shoes and socks removed)
3. Enter body type 'STANDARD'
4. Enter participant's gender MALE/FEMALE
5. Enter participant's height as measured
6. Body fat will be measured
7. Remove the printout and record participant's weight and BMI as displayed on the printout. Retain the printout. If participant asks to keep the printout explain that unfortunately we need to keep this for the study.

APPENDIX 9

TFEQ-R18 used in WWW study

Questions about your eating habits

The following statements ask about your eating habits. Using the scale below, circle the number that best describes how true you feel each of the following statements is for you. Please respond to every item.

		Definitely true	Mostly true	Mostly false	Definitely false
15a.	When I smell a sizzling steak or juicy piece of meat, I find it very difficult to keep from eating, even if I have just finished a meal	4	3	2	1
15b.	I deliberately take small helpings as a means of controlling my weight	4	3	2	1
15c.	When I feel anxious, I find myself eating	4	3	2	1
15d.	Sometimes when I start eating, I just can't seem to stop	4	3	2	1
15e.	Being with someone who is eating often makes me hungry enough to eat also	4	3	2	1
15f.	When I feel down or low, I often overeat	4	3	2	1
15g.	When I see a real delicacy, I often get so hungry that I have to eat right away	4	3	2	1

15h.	I get so hungry that my stomach often seems like a bottomless pit	4	3	2	1
15i.	I am always hungry so it is hard for me to stop eating before I finish the food on my plate	4	3	2	1
15j.	When I feel lonely, I console myself by eating	4	3	2	1
15k.	I consciously hold back at meals in order not to weight gain	4	3	2	1
15l.	I do not eat some foods because they make me fat	4	3	2	1
15m.	I am always hungry enough to eat at any time	4	3	2	1

16.	How often do you feel hungry?	*Only at meal times*	*Sometimes between meals*	*Often between meals*	*Almost always*
17.	How frequently do you avoid “stocking up” on tempting foods?	*Almost never*	*Seldom*	*Usually*	*Almost always*
18.	How likely are you to consciously eat less than you want?	*Unlikely*	*Slightly likely*	*Moderately likely*	*Very likely*

19.	Do you go on eating binges though you are not hungry?	*Never*	*Rarely*	*Sometimes*	*At least once a week*

20. On a scale of 1 to 8, where 1 means no restraint in eating (eating whatever you want, whenever you want it) and 8 means total restraint (constantly limiting food intake and never “giving in”), what number would you give yourself?

Thank you very much for your time.

APPENDIX 10

Topic guide for semi structured participant interviews.

Version 1 03082016

WWW study: Qualitative study interview topic guide
Intervention Group

Introduction

- Thank you for taking part in this extended part of the Winter Weight Watch study
- Your views are really important in helping us to understand in more depth what worked and what did not work during the study.
- Please be honest. If you didn't like something - tell us.
- Everything you say is anonymous
- Recording for transcription purposes

Christmas

- Can you tell me a bit about your routine at Christmas?
- What normally happens in your home at Christmas?
- What normally happens to your weight at Christmas?

The study

- How did you feel about being asked to take part in a study over Christmas?
- Why did you decide to take part?
- Was there anything that you were concerned about prior to the first visit?
- Did you tell friends or family that you were taking part in the trial? If so, what was their reaction? Were they supportive/not supportive?

- Was the intervention difficult to adhere to considering it was Christmas time? What specifically made it difficult/not difficult?
- Did the study make you more conscious about what you were eating over Xmas time? Can you give an example?

Experiences of the study – weight information

- What were your expectations about what information and support would be given?
- How did you find the explanation on the leaflet (first page)?
- Did you relate it to yourself? In what way?

Experiences of the study – Ten Top Tips (10TT)

- What were your first impressions of the Ten Top Tips?
- What was helpful and unhelpful about these TTTs?
- Did you adhere to any of the TTTs? Which ones? Why were those ones the most useful?
- Were any of the TTTs not useful at all? Which ones? Why was this?
- What else would have been helpful to include?
- What did you think of the calorie and time to burn information? Did you respond to this in any way?

Experiences of the study – Self weighing

- When you were asked to weigh yourself regularly, how did you feel about doing that? How did you feel about doing that over Xmas?
- Do you look forward to weighing yourself or do you dread it?
- How does weighing yourself make you feel? - During / after
- How do you think weighing yourself has affected your weight over Christmas?
- Was weighing yourself a new or different experience for you? In what way? What was your past experience of weighing yourself?
- What makes it difficult for you to weigh yourself?
- Are there issues that affect your ability to weigh yourself regularly?
- What helps/motivates you to weigh yourself regularly?
- In your opinion, what was the most helpful element of self-weighing?
- In your opinion, what was the least helpful element of self-weighing?

- What value did you see in recording your weight regularly and writing it down? What specifically?
- How did you find being asked to reflect on the changes in your weight?
- How did you find having a maximum weight to stick to? What were your thoughts on that specific amount?
- How did you find working out the differences in gains/losses? Did you act on any differences?
- How often did you weigh yourself? What was the reason for this?

Final Questions

- How different was this Xmas to your 'normal' Xmas?
- Which elements of the study will you continue with to help you to manage your weight?
- How important is it for you to manage your weight / prevent weight gain?
- Overall, what were the positives of the study?
- Overall, what were the negatives of the study?
- If you were asked to take part in another weight management study at Christmas time, how would you respond to that? What would your feelings be towards that prospect?
- Overall thinking about the study -what do you think we could improve on?
- Is there anything we did particularly well?
- Is there anything else you would like to say?

APPENDIX 11

Code book developed as part of qualitative analyses.

WWW qualitative study: codebook

Pragmatic coding for intervention

Deductive code name	Description
1. Christmas	All mentions of Christmas
a. Normal changes in weight	Typical weight patterns at Christmas, behaviours driving weight changes; experiences of weight changes at Christmas, experiences of weight change post-Christmas.
b. Normal Christmas	Their normal routine at Christmas, descriptions of their typical Christmas.
c. Difference during trial	Descriptions of how the trial impacted on Christmas, al comments relating to a different Christmas, descriptions of the same as usual.
2. Views on weight management	Broad descriptions relating to any views in general on weight management
a. Weight gain prevention at Christmas	Descriptions of thoughts, feelings, views of preventing weight gain at Christmas. References to Christmas time and weight management, trying to prevent weight gain at Christmas, dieting at Christmas, restraining intake at Christmas.
3. Self-weighing (SW) and weight goal (WG)	All references to self-weighing and weight goal
a. Acceptability and engagement	Descriptions of how acceptable SW and the WG were. How they engaged with SW and the WG. Usage of SW and WG. Descriptions of SW & WG in action.
b. Previous exposure	Descriptions of previous use of SW and or a WG.
c. What effect did it have	Descriptions of how SW and WG were used. What participants did re. SW WG. How they used it including descriptions of not using it.
4. 10TT	All references to the 10TT
a. Acceptability and engagement	Descriptions of how acceptable the 10TT were. How they engaged with the 10TT. Usage of the 10TT. Descriptions of the 10TT in action.

Deductive code name	Description
b. Previous exposure	Descriptions of previous use of the 10TT or prior knowledge.
c. What effect did it have	Descriptions of how the 10TTwere used. What participants did re. 10TT. How they used it including descriptions of not using it
5. PACE	All references to PACE
a. Acceptability and engagement	Descriptions of how acceptable PACE was. How they engaged with PACE. Usage of the PACE information. Descriptions of PACE in action.
b. Previous exposure	Descriptions of previous use of PACE information or prior knowledge.
c. What effect did it have	Descriptions of how PACE information was used. What participants did re. PACE. How they used it including descriptions of not using it.
6. Trial	Broad references to the trial in general.
a. Acceptability of trial processes	References to how acceptable or not the trial processes were, i.e., recruitment, communication, booking appointments, researchers, consent procedures, recruitment processes.
b. Continue in the future	References to participant's' plans for future weight management.
c. Expectations	What participant's expectations were of the trial prior to commencement.
d. Family and friends' reaction	Descriptions of how family and friends reacted to their involvement in the trial.
e. General effects	Broad descriptions of the effects of the trial.
f. Recommendations for intervention	Suggestions for improvements, enhancements, refinements, revisions to the intervention.
g. Why take part	Participant's descriptions of why they decided to take part in the trial.

Inductive coding for logic model testing

Deductive code name	Inductive code	Description
1. Self-weighing c. What effect did it have	a. Automaticity	Descriptions relating to the behaviour of SW being automatic. E.g., routine, habit, without thinking, automatic, effortless.
	b. Changed behaviour	Instances of where participants have made behavioural changes in response to SW. Could be related to food or physical activity.
	c. Conscious	Descriptions of conscious thought. Could be around food choices or behaviour linked to SW.
	d. Dread	Descriptions of dread.
	e. Awareness	Remarks relating to awareness fostered by SW. Could be related to calories, food, drinks, physical activity, weight gain, preventing weight gain, weight, Christmas
	f. Obsessive	Any descriptions of obsession, neuroses, linked to SW.
	g. Reflection	Descriptions of instances of reflection on weight, weight gain, weight changes, weight fluctuations, energy intake, energy expenditure, behaviour changes, weight trajectory.
	h. Prevented weight gain	Any references to SW and weight gain prevention.
	i. Frequency	Comments relating to the frequency of weighing.
	j. Positive	All comments relating to SW being a positive/good experience.
	k. Negative	All comments relating to SW being a negative/bad experience.
2. 10TT c. What effect did it have	a. Already doing/familiar	References to the 10TT being familiar information, already familiar, known information, typical information, seen before, already doing, nothing new.
	b. Changed behaviour	Descriptions of when participants have changed behaviour such as food/drink selection, physical activity, sedentary behaviour, read food labels.

Deductive code name	Inductive code	Description
	c. Did not apply/no effect	Reports of no change or no effect.
	d. Awareness	Remarks relating to awareness fostered by 10TT. Could be related to calories, food, drinks, physical activity, weight gain, preventing weight gain, weight, Christmas.
3. PACE c. What effect did it have	a. Changed behaviour	Instances of where participants have made behavioural changes in response to PACE. Could be related to food or physical activity, social behaviour, food and drink selection, planning behaviour.
	b. Awareness	Remarks relating to awareness fostered by PACE. Could be related to calories, food, drinks, physical activity, weight gain, preventing weight gain, weight, Christmas.
	c. Physical activity	Descriptions relating to physical activity. Includes increasing, decreasing, thinking about, planning, considering.
	d. Calories	Descriptions relating to calories. Includes increasing, decreasing, thinking about, planning, considering.
	e. Fear/anxiety	Descriptions of fear, anxiety in response to the PACE information.
	f. Shock/surprise	Descriptions of shock, surprise in response to the PACE information.
	g. Reflection	Descriptions of instances of reflection on calories, physical activity, food, weight, weight gain, weight changes, weight fluctuations, energy intake, energy expenditure, behaviour changes, weight trajectory.

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