



Evaluation of Living Well, Taking Control

A community-based diabetes prevention and management programme



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Note on Terminology

Living Well, Taking Control is the focus of three evaluation projects. These are explained more fully in the section on the Overview of the Living Well, Taking Control programme. This report refers to these as:

“LWTC evaluation” This is the evaluation led by UWE Bristol that is presented in this report.

“ComPoD trial” This is the evaluation led by University of Exeter Medical School that will be presented in subsequent reports.

“NDPP evaluation” This is the evaluation that includes LWTC activities as part of the roll out of [Healthier You: The NHS Diabetes Prevention Programme](#).

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Living Well, Taking Control Evaluation Summary

Introduction

Type 2 diabetes is a serious, expensive and growing public health challenge. In England, national guidance recommends intensive lifestyle interventions promoting weight loss for people at risk of diabetes and programmes of individualised care, information and advice for those recently diagnosed with type 2 diabetes (NICE, 2012; NICE, 2015). There has been little formal evaluation of ‘real-world’ type 2 diabetes prevention and management programmes in the UK, particularly those delivered by community and voluntary agencies. To inform options for action on type 2 diabetes, there is an urgent need for evidence on the implementation and effectiveness of innovative service models.

Living Well, Taking Control

Living Well, Taking Control (LWTC) is a programme designed to prevent and manage type 2 diabetes in non-clinical, community settings. Between July 2013 and October 2015, LWTC was led by Westbank Community Health and Care, and funded as part of the Big Lottery Fund’s (BLF) Wellbeing Programme. LWTC was delivered through third-sector agencies Westbank based in Devon, and Health Exchange in the West Midlands¹.

LWTC supports adults who have clinically identified Impaired Glucose Regulation (IGR), also commonly known as “pre-diabetes”, to make and maintain lifestyle changes in order to prevent their condition from progressing to type 2 diabetes for as long as possible. The programme also supports individuals who have been recently diagnosed with type 2 diabetes to help them manage their condition and prevent complications. LWTC is a 12-month programme that starts with a GP surgery invitation letter and eligibility check, and is followed by a four-week group course with trained facilitators, follow-on one-to-one contacts, and signposting to selected healthy lifestyle activities.

The programme closely follows NICE guidance for both the prevention and early management of type 2 diabetes – it follows a structured sequence of activities, uses established, well-defined behaviour change techniques, person-centred approaches, and involves frequent engagement with facilitators that is intended to total to 16 hours contact time. The programme has a focus on promoting changes in diet, physical activity, weight loss and mental wellbeing.

Evaluation overview

The research presented in this report is focused on the two main sites of programme delivery – in Devon, led by Westbank, and in the West Midlands, led by Health Exchange. The evaluation study focuses on aspects of LWTC’s delivery processes and outcomes. It is one part of a wider set of research on the programme that has included the fidelity of implementation and social value of the programme. LWTC is also the focus of research led by the University of Exeter Medical School. This comprises a randomised trial with a waiting list control group to evaluate the effectiveness and cost-effectiveness of the diabetes prevention element of the programme.

Evaluation questions

The evaluation sought to address the following research questions:

1. What are the characteristics of the population that the programme attracts?
2. What are the patterns of participation in the programme?
3. How well does the programme perform in terms of the main outcomes of weight loss and change in glycated haemoglobin (HbA1c), and secondary outcomes (e.g. physical activity, diet, mental wellbeing)?
4. What is the association between programme exposure and outcomes?
5. What is the association between practice effects (changes in delivery over time) and outcomes?

¹ As part of the BLF grant, LWTC was also piloted by HealthWORKS (Newcastle) and Pioneering Care Partnership

(Darlington). Evaluation of delivery in these sites is reported separately.

6. How does programme performance vary depending on delivery site?
7. Are programme mechanisms and factors postulated to lead to lifestyle change associated with outcomes?

Evaluation methods

The evaluation is based upon a pre-post assessment of the experiences of programme participants, with additional data derived from programme delivery records. All individuals taking part in LWTC were asked to complete questionnaires and provide biometric measures at the point of enrolment between November 2013 and April 2015. Participants provided follow-up data for a minimum of six months post-enrolment up to the end of October 2015. In addition, all participants who had reached the point of 12 months post-enrolment were asked to provide further follow-up data.

The primary biometric measure was weight. Additional biometric measures were HbA1c, height and weight (and thus body mass index (BMI)), waist circumference and blood pressure. The core baseline and follow-up questionnaire measures included demographic information, co-morbidities, concurrent healthy lifestyle activities, health related quality of life, mental wellbeing, mental ill health, physical activity, dietary behaviour (fat and fibre intake), and motivation to change diet and physical activity behaviour. Validated measures were used where available. At the end of the group course, additional measures covered course satisfaction and social identity. Information on changes in health was collected at six- and 12-month follow-up points.

Programme delivery staff were primarily responsible for collecting the data. The evaluation team trained programme staff in the administration of measures, data entry and regularly reviewed the standards of data collection. The study was given ethical approval through University of the West of England's University Ethics Committee. Individuals taking part in the programme were asked to give written consent to take part in the evaluation after having

been provided with written and verbal information and informed of the right to withdraw.

Results and Discussion

Profile of delivery and participants

We received data from 811 participants (332 in Devon and 479 in the West Midlands) who enrolled onto the programme between November 2013 and April 2015, and who provided at least six-month follow-up data. In the two delivery sites, this figure represents approximately one quarter of those targeted through invitation letters sent out from 17 GP practices.

Of the 722 participants for whom baseline HbA1c results were known, 18.8% were in normal range, 59.6% met criteria for pre-diabetes, and 21.6% for type 2 diabetes. The mean age of participants was 61 years, and 60.5% were female. About 44% of participants were retired, and 58.5% had at least one form of long-term health condition. Participants tended to be from the targeted areas of higher deprivation, with 32.6% of participants resident in the lowest IMD decile. At the Health Exchange site, 64% of participants were from a Black or Minority Ethnic (BME) background. These data indicate that LWTC successfully reached groups that have additional health problems, are less likely to access health information and services, and are likely to experience social barriers to achieving a healthy lifestyle.

Patterns of participation in the programme

The mean attendance at the four initial group sessions was quite high (87.2%) for both programme sites, with an average group size of six participants. In the period following initial group sessions, recorded successful contacts at the Westbank site were consistently higher at each stage of the programme than at the Health Exchange site – for example, at Month 12 follow-up, 47.4% of participants were contacted by Westbank compared with 20.5% of participants at Health Exchange. It is possible that records of Month 12 contacts represent a conservative figure for later entrants, given that programme staff had not stopped seeking to make contact with later entrants at the point at which we finished

collecting data. The overall pattern of declining contacts over time is similar to that experienced by some other community-based healthy lifestyle programmes. There was little evidence that certain demographic groups were less likely to engage with the programme over time. We do not have complete records on the reasons why individuals dropped out of the programme, or did not respond to contact attempts.

Weight loss and change in lifestyle behaviours

Participants enrolled in LWTC achieved statistically significant improvements in weight and most associated measures (BMI, waist circumference), for those with pre-diabetes and diabetes, at six-month and 12-month measurement points.

Of those participants who provided data, 2kg weight loss was achieved by 41.9% (n=156/372) at Month 6 and 44.2% (n=73/165) at Month 12. The 2kg weight loss was achieved by more participants with pre-diabetes than those with diabetes, with 42.9% (n=115/268) and 39.4% (n=41/104), respectively at Month 6.

The results for HbA1c appeared to be very positive. Participants with mean HbA1c in the range for a diabetes diagnosis at baseline (48mmol/mol or over) dropped to the pre-diabetes range (42-47mmol/mol) at follow-ups: 52.36mmol/mol at enrolment to 45.52mmol/mol at Month 6 and 45.00mmol/mol at Month 12. Participants with mean HbA1c in the pre-diabetes range dropped to within the normal range (below 42mmol/mol) at follow-ups: with mean falls from 42.92mmol/mol at enrolment to 41.46mmol/mol at Month 6 and 39.80mmol/mol at Month 12. However potential measurement issues mean that these results should be interpreted with caution.

Weight loss and HbA1c were, in the main, closely paralleled by changes in the secondary outcome measures. Overall, there were statistically significant positive changes in general health state, overall life satisfaction, mental wellbeing, anxiety and depression, and self-reported diet at both Months 6 and 12. However, changes in self-reported physical activity were not statistically significant at either measurement point.

Programme exposure and outcomes

NICE Guidance advises that participants attending intensive lifestyle interventions for diabetes should have at least 16 hours contact time over an 18 month period. The format of LWTC involves 13.5 hours of direct group and one-to-one contact times, plus five or more hours contact with add-on services, sometimes delivered by partner agencies. Over the course of the 12 months, an overall mean of 9.1 hours contact time was recorded. This figure is likely to be an underestimate given that project records had incomplete documentation on the five hours of supplementary contacts. Bearing in mind this incomplete picture, we sought to analyse the relationship between LWTC group and one-to-one total recorded contact time and programme outcomes. When comparing participants with 8-12 contacts hours and those with more than 12 contact hours, there were no statistically significant differences in outcomes at six- and 12-month points (although see the finding based on modelling below).

Practice effects and outcomes

Within the evaluation time frame, there was evidence that the programme delivered similar results over the course of time. Earlier entrants – those who started the programme in the first eight months of the evaluation period – were just as likely to achieve 2kg weight loss (at Month 6) than those who started in the last eight months. Programme teams improved their performance over time, in terms of rate of recruitment and throughput, suggesting that LWTC became increasingly streamlined and integrated in its delivery with other local services. The findings are consistent with the ‘test-and-learn’ used in the LWTC approach to enhance delivery.

Programme performance and delivery site

Participants at the Westbank site were more likely to obtain 2kg weight loss at Months 6 and 12, compared to those at Health Exchange (47.4-50% vs. 33.1-36.7%). The pattern was similar for other changes including in diet and psychological measures. A number of reasons are likely to account for these differences. It may be that the intervention worked less well at the West Midlands site (due to differences in delivery or differences in

responsiveness in this population). Alternatively, the intervention may have worked equally well at both sites, but the underlying trajectory of weight gain was different for the West Midlands population. The demographic profile of Health Exchange participants included greater proportions of participants from areas of higher multiple deprivation and BME backgrounds. Both of these are indicators of lower socio-economic position and inequalities in health, although the links between BME status and health inequalities are increasingly complex with changing demographic patterns in the UK's urban centres.

There was no direct evidence of differences in the acceptability of the programme at the two sites. Participant satisfaction with the group elements of the programme was highly positive, and equally so, at both delivery sites. However, recorded contact time with the programme was higher at Westbank and, as discussed below, this was associated with more positive outcomes.

Modelling influences of weight at six months

We sought to assess the role of potential key factors on weight loss at Month 6. Stepwise multiple regression found that ethnicity was the single best demographic predictor of weight change. None of the other demographic factors predicted weight change. Subsequent modelling found that delivery site and ethnicity acted as very similar measures in this study, with both acting as significant predictors of weight change. After ethnicity and delivery site, programme contact time was the next best predictor of the main outcome. Three other factors – practice effects, co-morbidities, and concurrent lifestyle activities, were not predictors of weight change. The final stage of analysis, using stepwise multiple regression, found that 'White' participants were twice as likely to lose at least 2kg of weight compared to 'BME' participants. Participants who had more contact time throughout the programme were 1.16 times more likely to achieve at least 2kg weight loss.

Strengths and limitations of the evaluation

This was an evaluation of a 'real-world' initiative that drew upon a large volume of data collected with the support of the programme teams. The evaluation was able to assess the implementation and outcomes of LWTC in different settings, and obtained 12-month follow-up data within a short period of data collection. There were some gaps in the comprehensiveness of the data available. We do not have a clear picture of the outcomes for participants not in contact at the six- and 12-month stages of the programme. The study design cannot determine what changes would have occurred in the absence of the programme.

Conclusions and recommendations

The evaluation findings suggest potential positive effects of LWTC on diabetes risk and the early stage management of diabetes. The LWTC programme model offers a number of features that are important for scaling up and embedding action on type 2 diabetes. LWTC incorporates key elements of NICE guidance on both the prevention and management of type 2 diabetes. It has developed successful methods for recruitment in partnership with primary care agencies. The programme builds upon the local expertise and capacity of third sector providers, trained community facilitators and local partner agencies.

There are a number of opportunities to enhance the programme. These include refining systems for recording participant contacts across the programme lifecycle. This work would help inform real-time information on engagement – and actions to improve retention – and ongoing evidence of programme performance. Information on influences, contact time, can be used to refine the focus of the behavioural techniques used by LWTC practitioners. Efforts put into further developing the programme design and support materials will enable delivery agencies to test the transferability of the scheme to other contexts.

1. Introduction

Between 2006 and 2011, the number of people diagnosed with diabetes in England increased by over 25%, from 1.9 to 2.5 million (Diabetes UK, 2015). If trends continue, this number will rise to four million people by 2025. Spending on diabetes accounts for approximately 10% of the NHS budget (ibid.). Both nationally and locally, diabetes is therefore a serious, expensive, and growing public health problem. If we are to curb this growing health crisis and reduce deaths from diabetes and its complications, awareness, early identification, prevention and early management of diabetes must be prioritised (NICE, 2012).

Type 2 diabetes is characterised by substantial loss in life expectancy, and a high risk of developing complications (Laakso & Lehto, 1997). Type 2 diabetes is also one of the fastest growing chronic diseases worldwide together with obesity, and up to 50% of individuals suffering from type 2 diabetes are unaware they have the condition (Glumer *et al.*, 2003). The national NHS Health Checks programme in England is identifying tens of thousands of people each year at high risk of developing type 2 diabetes. Impaired Glucose Regulation (IGR), also known as “pre-diabetes”, or non-diabetic hyperglycaemia is a state of chronically raised blood glucose which confers a high risk of progression to diabetes (>50% increased risk over six years). It is estimated to affect 9.6% of adults in England (Diabetes UK, 2015).

NICE guidance advises that the early detection and treatment of type 2 diabetes is beneficial and that intensive lifestyle programmes have an important role as one form of action (NICE, 2012). A subsequent modelling study estimating the impact of diabetes prevention on public health found that screening for type 2 diabetes followed by lifestyle education for high risk individuals is particularly cost-saving and gives the largest health gains compared to other leading intervention options (Brennan *et al.*, 2014). Type 2 diabetes is strongly preventable through moderate changes in weight and physical activity (Lindstrom *et al.*, 2006), with one kilogram of weight loss being associated with a reduction in diabetes incidence of 16% (Knowler *et al.*, 2002). It is important that cost-effective structured diabetes prevention and management programmes are developed, evaluated, and sustainably implemented in target communities that are usually hard to reach. Lifestyle factors targeted by diabetes prevention programmes are also common risk factors for other long-term conditions. For example, a wealth of evidence from randomised controlled trials shows that relatively modest changes in weight (2-3kg) or physical activity (30-60 mins/week of moderate intensity) modify key cardiovascular risk factors to a clinically meaningful extent (Aucott *et al.*, 2004; Avenell *et al.*, 2004; Bo *et al.*, 2007; Esposito *et al.*, 2004; Laaksonen *et al.*, 2005).

Hence, there is a clear need to evaluate such real-world programmes for diabetes prevention and management in UK communities. Indeed, the NICE guidance on diabetes prevention (NICE, 2012) identified a need for “evidence on both the short- and long-term effectiveness and cost-effectiveness of translating prevention trials into UK practice” as well as “a lack of evidence on the barriers to, and facilitators for, implementing intensive lifestyle-change programmes”. There is also a need to conduct pragmatic evaluations comparing the outcomes of real-world diabetes prevention interventions with the benchmarks provided by large scale clinical effectiveness studies (e.g. the Finnish Diabetes Prevention Study achieved 4.2kg of weight loss at 12 months of follow-up, and this translated into a relative reduction in diabetes incidence of 58% at a median 3.4 years of follow-up; Knowler *et al.*, 2002).

2. Living Well, Taking Control: Overview

Living Well, Taking Control is a programme designed to prevent and manage type 2 diabetes in non-clinical, community settings. Living Well, Taking Control (LWTC) aims to support individuals who have clinically identified “pre-diabetes”, to make and maintain life changes in order to prevent their condition from progressing to type 2 diabetes for as long as possible. The programme also aims to support individuals who have been recently diagnosed (i.e. in the last 12 months) with type 2 diabetes, to help them manage their condition and prevent complications.

The focus of this evaluation is on the phase of the programme running from July 2013 to October 2015. In this period, LWTC was led by Westbank and was funded as part of a £1.2 million programme by the Big Lottery; it was delivered through four community and voluntary sector partner agencies:

1. Westbank Community Health and Care (Devon) <http://www.westbank.org.uk/>
2. Health Exchange (West Midlands) www.healthexchange.org.uk
3. HealthWORKS (Newcastle) www.healthworksnewcastle.org.uk
4. Pioneering Care Partnership (Darlington) www.pcp.uk.net

Well UK (www.welluk.org), an agency that works closely with Westbank and Diabetes UK (www.diabetes.org.uk), have also been involved in supporting the delivery of the programme. LWTC is part of a wider portfolio called “A Healthier Way to Live”, also led by Westbank under the Big Lottery Fund’s (BLF) Wellbeing Phase 2 programme focused on the promotion of wellbeing for people with long-term conditions or vulnerable to ill health. The University of the West of England (UWE), Bristol, has undertaken the overall evaluation of A Healthier Way to Live, with an emphasis on outcomes linked to health and wellbeing, and social value of the initiative (see reports at westbank.org).

The partner agencies worked together, with the support of academic colleagues at UWE and the University of Exeter Medical School (UEMS), to co-develop tailored packages to support lifestyle changes in participants. The partner agencies drew on their experience and knowledge from existing lifestyle interventions for cardiovascular disease as a starting point, in particular from Health Exchange.

3. Aims of the programme

The aim of Living Well, Taking Control is to promote positive health and wellbeing for participants who have a raised HbA1c level that would indicate they either have pre-diabetes or diabetes. The programme encourages weight loss through positive behaviour changes and provides participants with the information, resources, and support required to reduce their blood glucose level and to prevent type 2 diabetes from being diagnosed (for those with pre-diabetes), or allow them to successfully manage their condition (for those with diagnosed type 2 diabetes). The overall programme approach is to focus on five healthy lifestyle issues:

1. Understanding your body and your condition
2. Healthy diet
3. Regular physical activity
4. Positive mental health and wellbeing
5. Achieve and maintain a healthy weight

The programme service objectives are to:

- Increase the number of people identified with a high risk of developing (or recently diagnosed with) type 2 diabetes who receive comprehensive lifestyle advice.
- Establish the feasibility of delivering a lifestyle intervention to people with pre-diabetes and type 2 diabetes through voluntary sector led community-based delivery.
- Assess the performance of the programme in terms of a) weight loss, b) HbA1c, and c) other measures (e.g. physical activity, healthy eating behaviours), and compare this with evidence from other “real-world” diabetes prevention programmes.

4. Programme origins and theory base

The Living Well, Taking Control programme was developed by Westbank based on a programme originally devised by Health Exchange, as part of its range of healthy lifestyle initiatives directed at preventing and managing long-term conditions. Over the course of its evolution, Westbank has adapted the programme by incorporating a number of behaviour change theoretical elements and techniques. The main focus of the programme has been on educating participants about type 2 diabetes, healthy eating, physical activity, and positive mental health and wellbeing in ways that are relevant to the participants' lifestyles. The programme also works with participants to identify the barriers associated with changing their diet and activity behaviours, and providing participants with examples of how they can overcome such barriers. Goal setting plays a large role in the programme, where participants are encouraged to set goals at each of the four weekly group sessions and review their progress with the goals at following group sessions and follow-up sessions.

The programme targets factors identified by various social cognitive models, for instance the Theory of Planned Behaviour, as being important in motivating people to change their behaviour (e.g., risk perceptions, pros and cons of behaviour change, self-efficacy). The programme also adopts motivational approaches from Self-determination Theory (Deci & Ryan, 2000), such as supporting intrinsic motivation, engaging social support/encouraging connectedness and building competence. The core intervention is based around use of behaviour change processes and techniques that derive from self-regulation theories, such as the Social Cognitive Theory (Bandura, 1985) and Control Theory (Carver *et al.*, 2000). These include goal setting, action planning, self-monitoring, feedback on progress, problem solving, and reviewing goals, which are suggested to be important in translating motivations into action, and supporting longer-term maintenance of behaviour change (e.g. Michie & Johnson, 2012). The intervention providers have been trained to use patient-centred counselling approaches (e.g., motivational interviewing) in the delivery of these techniques, which appear to enhance weight loss in overweight and obese participants (Armstrong *et al.*, 2011).

Living Well, Taking Control acts at a local institutional or community level. In this sense the programme is one part of a wider group of agencies, programmes and social practices that may impact on diabetes prevention and management. The role of the programme in contributing to a partnership and strategic agenda can be understood through policy and social change theory such as the Socio-Ecological Model (Glanz *et al.*, 2008).

5. Structure of the programme

5.1 Core elements

The programme includes a number of elements delivered over a 12-month period. In line with NICE guidance (NICE, 2012), these are intended to add up to at least 16 hours of contact through 8 hours of group sessions, 3.5 hours of one-to-one contacts, and at least 5 hours of add-on healthy lifestyle activities. The core elements that are common to all sites are:

- GP surgery-based identification and referral system
- A group-based education programme to create a diabetes-friendly community
- Use of trained facilitators to deliver group sessions
- Individually-tailored lifestyle advice, enhanced through peer support, and evidence-informed behaviour change techniques
- Specialist nutrition, healthy eating, and physical activity advice
- Support for promoting wellbeing and managing stress, anxiety and depression
- Signposting to local community activities that help embed longer-term behaviour change

5.2 GP surgery-based identification and referral

Programme teams work with local GP surgeries to identify eligible participants and obtain referrals to the programme. Programme facilitators (community health trainers) engage with the GP surgeries in order to build a relationship with GPs and encourage referrals. GPs can refer individuals as they present at the surgery for a health check and are subsequently diagnosed with either pre-diabetes or type 2 diabetes (via HbA1c blood tests). Alternatively, GPs refer individuals that have recently been diagnosed with pre-diabetes or type 2 diabetes (via database searches of patient records). At the point of referral, the GP provides the programme facilitator with contact details for the individual, and any relevant health information (e.g., weight, HbA1c etc.). The programme facilitator contacts the individual via phone and/or letter, and invites them to participate in the programme.

5.3 Eligibility criteria

LWTC aims to recruit people who are:

- Aged 18 years and over
- Considered on the basis of recent blood glucose tests to be at high risk for type 2 diabetes according to the criteria in the recent NICE diabetes prevention guidance (Fasting Plasma Glucose level 6.1-6.9mmol/L, or HbA1c 42-47mmol/mol recorded within the last year), or have recently been diagnosed with type 2 diabetes (≥ 48 mmol/mol)
- Resident in specified programme area postcodes
- A BMI of at least 25kg/m² (or 23kg/m² for certain ethnic minority populations) and less than 45kg/m²

The programme applies exclusion criteria for people who have a terminal illness. There are no other criteria for exclusion, given that the programme caters for people with low literacy, in need of translation services, or with mental health problems, learning or physical disabilities, and supports consenting and collecting data from these groups.

5.4 Group sessions

The core component of the programme comprises **four weekly group sessions**. These sessions are usually delivered in an education room at the participants' GP surgery or local community centre. Ideally, each group consists of 10-12 participants, although these numbers may vary over time depending on GP referrals and recruitment.

Each of the four group sessions covers a different topic:

1. Pre-diabetes/type 2 diabetes and a healthy lifestyle
2. Healthy eating
3. Physical activity
4. Positive mental health and wellbeing

As well as improving participants' understanding of type 2 diabetes, healthy eating, physical activity, and positive mental health and wellbeing, these sessions allow participants the opportunity to ask questions, review their current behaviours, discuss the benefits and barriers to changing behaviour, and set goals. If required, participants will be signposted to a relevant Health Care Professional.

5.5 Follow-on support and signposting

Following the four weekly group sessions, the participants are offered a follow-up service that comprises:

- One-to-one follow-ons for review and support
- 5 hours of one-to-one or group support through healthy lifestyle activities delivered by local community services

The follow-on sessions can be delivered within the context of a group session, or via text, email, or phone calls. These sessions consist of:

- Reviewing goals
- Exploring health behaviour changes made
- Reviewing methods for managing long-term conditions (e.g., diabetes)
- Review of clinical metrics (e.g., HbA1c, BMI, blood pressure, waist circumference)
- Any additional support required
- Referral onto required services

The 5 hours of one-to-one or group **healthy lifestyle activities** are provided by existing community services and tailored to individual participant needs, consisting of a selection of sessions including:

- Smoking cessation support
- Physical exercise classes
- Learning to cook using raw foods
- Active walking groups
- Mental health and wellbeing sessions
- Health trainer contacts
- Relaxation courses
- Dealing with comfort eating

Staff may also provide information and support for participants through their respective websites.

5.6 Programme delivery structure and timescale

LWTC runs over a 12-month period. A weekly group course is followed by one-to-one and group follow-ups, and signposting to other community activities.

Weeks -4 to 0	Eligibility and enrolment <i>Eligibility assessment and consents</i>	
Week 1	Group course start <i>Group sessions: baseline measures, questionnaire, biometrics</i>	
Week 4	Group course completion <i>Interim measures: satisfaction, social identity</i> <i>Signposting to healthy lifestyle activities</i>	
Month 2	Interim follow-up <i>Usually telephone contact</i>	Healthy lifestyle activities delivered by community agencies
Month 3	Interim follow-up <i>Face-to-face or telephone contact</i>	
Month 6	Group follow-up <i>Repeat measures – questionnaire, biometrics</i>	
Month 9	Interim follow-up <i>Face-to-face or telephone contact</i>	
Month 12	Group follow-up <i>Repeat measures – questionnaire, biometrics</i>	

5.7 Mapping LWTC to international guidelines

Dunkley *et al.*'s (2014) meta-analysis of pragmatic lifestyle interventions found evidence suggesting diabetes prevention programmes are effective, but effectiveness varies substantially between programmes. They also concluded that “adherence to international guidelines on intervention content and delivery explained much of the variance in effectiveness.” The authors advised that diabetes prevention could be more effective if guideline adherence was maximised. Drawing upon this study, the table below maps LWTC against two combined sets of guidelines: (1) the IMAGE project (Development and Implementation of a European Guideline and Training Standards for Diabetes Prevention; Paulweber, 2010), and (2) NICE (2012). This exercise suggests that LWTC adheres, at least in part, to all the key guideline areas. UWE’s fidelity of implementation study found high levels of adherence and competence with respect to the Westbank delivery of the group session component of the programme (Kok, 2015). It should be noted that the mapping only assesses the correspondence to guidelines for diabetes prevention programmes, although there are similarities to type 2 diabetes management guidance with respect to individualised care, patient information and dietary advice (NICE, 2015).

Living Well, Taking Control intervention content mapped against IMAGE project and NICE guidelines (adapted from Dunkley *et al.*, 2014). See also mapping exercise for ComPoD trial protocol.

1	Aim to promote changes in both diet and physical activity	Both physical activity and diet are core components of the group course and follow-on sessions. They are optional components of the add-on healthy lifestyle activities. These include, for example, walking groups, other exercise classes, and cooking classes.
2	Use established, well-defined, behaviour change techniques (e.g. specific goal-setting)	Use of behaviour change techniques repeatedly across the core sessions, including motivational interviewing, individual tailoring, time management. Additional techniques (e.g. reducing negative emotions, instruction on how to perform a behaviour, behavioural substitution) are used in specific sessions, and in the follow up activities and services from which participants choose (e.g. behavioural practice/rehearsal are present in walking, exercise and cooking classes). All core intervention providers have received training in the basics of these techniques.
3	Work with participants to engage social support for the planned behaviour change (i.e. engage important others such as family, friends, and colleagues)	Social support provided through group format of core sessions. Family and friends can attend group sessions. Role of friends and family reviewed in follow-on sessions.
4	Maximise the frequency or number of contacts with participants (within the resources available)	Face-to-face contacts central to group session and follow-on sessions. This is supported through telephone, text and personal email communications up to Month 12.
5	Use a coherent set of ‘self-regulatory’ intervention techniques (e.g. coping planning aka ‘relapse prevention’; prompting self-monitoring; providing feedback on performance; problem-solving)	Specific, individualised goal-setting and planning, use of self-monitoring tools (e.g. pedometers), reviewing and providing feedback on performance of behaviours and outcomes, planning for and addressing problems, and reviewing progress and goals are central to the structure of the group sessions and follow-on contacts.
6	Use a group size of 10-15 (with a maximum of 15). This recommendation is designed to	Group sessions planned for 10-15 (max.). However, attendance was lower (6-12) for groups due to booking, scheduling and appointment requirements.

	balance cost and effectiveness, rather than to be an exact specified range.	
7	Provide at least 16 hours of contact time over the first 18 months	Total 16.5 hours planned over first 12 months. 8 hours planned for group sessions in Weeks 1-4. 3.5 hours planned for follow-on contacts in Months 2-12. 5 hours minimum planned for add-on healthy lifestyle activities in Months 2-12.
8	Ensure programmes adopt a person-centred empathy-building approach	Clearly stated as a central approach in the programme for trained staff. Includes motivational interviewing techniques.
9	Allow time between sessions, spreading them over a period of 9-18 months	Contacts distributed across the course of the programme Months 1-12. However, there was little time between the first four sessions to allow for learning from experience.
10	Information provision: to raise awareness of the benefits of and types of lifestyle changes needed	Standardised information (verbal and written) on lifestyle changes provided during group and one-to-one sessions
11	Exploration and reinforcement of participants' reasons for wanting to change and their confidence about making changes	Group session reviews and follow-on reviews include focus on motivation (i.e. importance and confidence)
12	Gradual building of confidence (self-efficacy) by starting with achievable and sustainable short-term goals and setting of graded tasks	Goal-setting established at the outset and revisited over the duration of the programme Months 1-12.
13	Use a logical sequence of intervention methods (e.g. motivation, action-planning, maintenance)	Designed into the group sessions and revisited with follow-on contacts.
14	Intervention fidelity checking	Intervention fidelity was assessed by external evaluators (Kok, 2015) for group sessions delivered by Westbank in 2015. This study found high levels of adherence to programme protocol and facilitator competence.

In addition to drawing attention to the importance of adherence to guidelines, Dunkley *et al.*'s (2014) review raises issues that are important for the LWTC evaluation with regard to the processes and mechanisms that are likely to support long-term lifestyle modification, the role of demographic factors, programme performance issues, and options for maximising cost-effectiveness.

6. Evaluation: Overview

6.1 The present study and wider evaluation activity

The research presented in this report is part of a wider set of evaluation activity focussed on the Living Well, Taking Control programme. **This report covers the process and before-after outcome evaluation of the programme.** Other UWE-led evaluation work has focused on (1) a Fidelity of Implementation analysis of LWTC

(Kok, 2015), (2) Social Return on Investment analysis of LWTC (Clifford *et al.*, 2015), and (3) a series of short evaluation data reports on each of the four programme delivery sites.

In addition to the UWE-led evaluation, LWTC is the focus of the Community-based Prevention of Diabetes (ComPoD) randomised trial with a waiting list control group to evaluate the effectiveness and cost-effectiveness of the diabetes prevention element of the programme. This study, led by Jane Smith and Colin Greaves at University of Exeter Medical School, developed out of the initial evaluation work and is funded under NIHR's School for Public Health Research Public Health Practice Evaluation Scheme. The research runs from July 2014 to December 2016 (ISRCTN70221670).

More recently in April 2016, Westbank and Health Exchange successfully bid to deliver diabetes prevention work under the NHS National Diabetes Prevention Programme (NDPP). Aspects of this work incorporate LWTC and are to be evaluated under the NDPP.

6.2 Evaluation setting

The research presented in **this report is focused on the two main sites of programme delivery – in Devon, led by Westbank, and the West Midlands, led by Health Exchange²**. At these sites, prevalence rates for type 2 diabetes were 5.5% (Devon), and 7.1% (West Midlands) in 2012 (APHO, 2013). Devon and the West Midlands represent both rural and urban areas. The West Midlands also covers large South Asian and African/Caribbean populations. The West Midlands programme catchment area includes wards in the highest decile for multiple deprivation. The Devon programme operates in a more rural context that includes smaller pockets of social deprivation and poor access to health, social care, and community services.

As part of the BLF funding plan, between July 2013 and July 2015, programme delivery focused on the postcodes of EX1-6 and EX-16 for Devon, and postcodes B1-21 in the West Midlands. Overall, the agencies combined aimed to involve approximately 500 people in activities that promoted (a) healthy eating, (b) physical activity, and/or (c) wellbeing. The programme monitoring data for July 2015 reported that agencies involved 409 individuals in Devon and 468 individuals in the West Midlands. These figures suggest that the agencies had clearly met their planned targets. It should be noted that the data presented in this report only reflects an analysis of participants enrolled in the shorter period of November 2013 to April 2015.

6.3 Research questions

In this report, the focus of the evaluation is framed in relation to the following research questions:

1. What are the characteristics of the population that the programme attracts?
2. What are the patterns of participation in the programme?
3. How well does the programme perform in terms of the main outcomes of weight loss and change in glycated haemoglobin (HbA1c), and secondary outcomes (e.g. physical activity, diet, mental wellbeing)?
4. What is the association between programme exposure and outcomes?
5. What is the association between practice effects (changes in delivery over time) and outcomes?

² This report does not include an evaluation of the programme at the Darlington and Newcastle sites. The Darlington based programme experienced delays in delivery and consequently low data returns over the evaluation period. The Newcastle based programme adopted a format that recruited and brought together individuals at risk of a range of conditions, not just with respect to type 2 diabetes. This format diverged considerably from core elements of the LWTC programme design. Evaluation data reports to Westbank, delivery agencies and BLF were produced separately for these two delivery sites.

6. How does programme performance vary depending on delivery site?
7. Are programme mechanisms and factors postulated to lead to lifestyle change associated with outcomes?

7. Evaluation Methods

7.1 Overview

This element of the evaluation of LWTC is based upon a pre-post assessment of the experiences of programme participants, with additional data derived from programme delivery records. All individuals taking part in LWTC were asked to complete a questionnaire and provide biometric measures at the point of enrolment, then at six and 12 months following enrolment. Participants also completed a different questionnaire on completion of the four-week group session element of the programme. The programme team supplied additional data on recruitment following initial invitation letters from GP surgeries, and on attendance and contact time.

7.2 Pre-post outcome data collection

Recruitment

Participants for the study were sought from the two project delivery sites in Devon and the West Midlands. Project teams worked with GP surgeries to identify patients that met the inclusion criteria. These were then sent invitation letters through the GP surgeries, with the request to respond to a contact in the LWTC programme team. A member of the programme team provided all prospective participants with written and verbal information about the study, and asked for active consent to take part in the evaluation from all individuals who were referred onto the programme. The GP referral included contact information for the individual, most recent HbA1c score³, and usually (but not always) other clinical measures (e.g., weight, height, and blood pressure). The evaluation period for requesting participation for newly enrolled individuals was from November 2013 to April 2015.

Baseline measures

Participants completed a questionnaire prior to participation in the core four-week group sessions, either in an individual session in the week prior to the four-week programme commencing or on arrival at the first group session. All participants were asked to provide demographic information (date of birth, gender, 'race'/ethnicity (here on: ethnicity), employment, education, disability), co-morbidities, and concurrent participation in other healthy lifestyle activities.

The questionnaire also covered the following areas:

- Health related quality of life (EQ-5D, EuroQol Group, 1990)
- Overall life satisfaction (Life Satisfaction Scale, Abdallah *et al.*, 2008)
- Mental wellbeing (SWEMBS – Short Warwick Edinburgh Mental Wellbeing Scale, Tennant *et al.*, 2007)
- Mental ill health (CESD-7: depression, Radloff, 1977; EQ-5D sub-section: anxiety)

³ The programme delivery team reported occasional difficulties with old or anomalous HbA1c results appearing on patient records. We have not systematically assessed the correspondence between patient record HbA1c results and those obtained at programme enrolment.

- Physical activity (IPAQ, Craig *et al.*, 2003 revised to NZPAQ, McLean & Tobias, 2004)
- Dietary behaviour (Fat and Fibre Questionnaire, adapted from Shannon *et al.*, 1997)
- Motivation to change diet and physical activity behaviour (adapted from Miller & Johnson, 2008)

Biometric measures of height and weight (and thus BMI), waist circumference, and blood pressure were assessed by programme facilitators at baseline (either in an individual session or on arrival at the first group session). HbA1c was recorded from the GP referral information, and was not usually taken by programme facilitators at baseline, unless the most recent GP test was more than 4 months prior to participants entering the programme, in which case facilitators measured HbA1c at the initial session using the Alere Afinion™ HbA1c point of care test cartridge.

An objective measure of physical activity behaviour via accelerometers was originally sought for a subsample of participants. Data collection with accelerometers was slow to implement and was subsequently incorporated as part of the ComPoD trial rather than as a core element of the LWTC evaluation.

Follow-up measures

On week four of the group sessions, participants were asked to complete the following:

- Course Satisfaction Questionnaire (including Friends & Family Test, NHS England, 2013). See Appendix 2.
- Social Identity Questionnaire (Tarrant, 2014) (Westbank only). See Appendix 3. Although this work has yet to be published, reliability analysis of the scales used for each of the three sections of the questionnaire suggest that they have good internal consistency with this study sample, with the following Cronbach alpha coefficient values:
 - Section 1 – Social support : 0.89
 - Section 2 – Social identification with LWTC : 0.91
 - Section 3 – Other group memberships or social identities : 0.96

Programme facilitators assessed weight, height, waist circumference, and blood pressure (Westbank only).

During the follow-up sessions at 6 months and 12 months, participants were asked to complete the same questionnaire as used at baseline, and HbA1c, weight, height, waist circumference, and blood pressure were assessed by the programme facilitator (or ComPoD researcher, for those also included in the trial). In addition to repeating the baseline questionnaire, participants also completed a 'Changes in Health' questionnaire to assess whether any major life-changing event, new medications, or operations occurred in the previous six months (see Appendix 4). These questions aid discovery of whether any changes in physical measures and/or behaviour were affected by forces external to the programme (e.g., medications, bereavement, etc.) either in a positive or negative fashion.

Data collection

The programme facilitators (and/or ComPoD researchers) were responsible for the administration of the baseline and follow-up biometric and questionnaire measures. The programme facilitators were trained to adopt a standardised approach to the administration of the tools and the electronic entry of data. A calibrated scale was used to take weight measures.

Data analysis

Biometric, questionnaire and programme records data were analysed in the statistical software package SPSS v22. Data from the two programme delivery teams were integrated into one dataset, with adjustments needed to accommodate different conventions for recording contact time and other measures of programme delivery. The programme and evaluation teams checked the quality of data recording on a quarterly basis through

reviewing correspondence between paper and electronic records and the identification of late entry, missing, or anomalous data. For missing data, where at least half the items of an instrument scale were present, the technique of person mean substitution (where the imputed value for a variable with missing data is derived from the non-missing items for that person) was adopted to impute data (Hawthorne & Elliott, 2005).

The primary outcome of interest was pre-post weight change, with the minimal clinically important difference (MCID) set at 2kg weight loss. The other main outcome was pre-post changes in HbA1c. Secondary outcomes included BMI, waist circumference, and questionnaire measures. Descriptive statistics were generated for particular sub-groups, and pre-post outcome changes were analysed using repeated measures t-tests or non-parametric equivalents (e.g., Wilcoxon) if data were not normally distributed. Logistic regression was used to explore the influence of baseline characteristics and programme processes on the percentage of participants achieving 2kg weight loss.

7.3 Governance, ethical issues and data protection

The study was conducted in accordance with the 2005 Research Governance Framework for Health and Social Care and the 1998 Data Protection Act. Following an initial period of consultation and development, ethical approval for the evaluation study was obtained through UWE's University Ethics Committee (Ref: HAS/14/03/49) in March 2014. Subsequently ethical approval was obtained for the ComPoD trial (North West Lancaster National Research Ethics Committee ref: 14/NW/1113; 16/7/16). Programme delivery agencies were responsible for implementing most aspects of the evaluation governance. Invitation letters were sent through the GP surgeries. Interested individuals responded directly to their local programme team and signed a consent form after having received written and verbal information about the research from a member of the team. This included information on the handling of data and rights of withdrawal. All data on participants was collected by the programme teams at enrolment and subsequent points; ComPoD researchers were involved for participants also included in the trial. This was held in paper and electronic format in secure environments at the two programme offices. Records were inputted onto locally managed, password protected programme databases. The UWE evaluation team received extracts from the databases with unique ID codes, but excluding names, addresses (apart from postcodes), or any other personally identifiable information. These data are held in a password protected environment at the university.

8. Findings

8.1 Description of the study sample – Attendance and contact

This section reports on patterns of participant attendance and contact with the programme. The term 'attendance' refers to occasions where participants are recorded as taking part in group (or one-to-one) activities. 'Contact' refers to periods in which participants have some form of actual engagement with programme practitioners; this includes any face-to-face, telephone or email correspondence.

a) Recruitment to the programme

Letters of invitation to participate in the programme were sent out from a total of 17 GP practices at the two delivery sites. Approximately one quarter of those targeted responded and enrolled with the programme⁴.

b) Patterns of attendance at group sessions

At Westbank, the average group size at baseline was six participants per group (not including any partners or family members present). Group IDs were not recorded in Health Exchange's database, therefore, the average group size could not be ascertained.

⁴ More detailed information is not available at the point of production of this report.

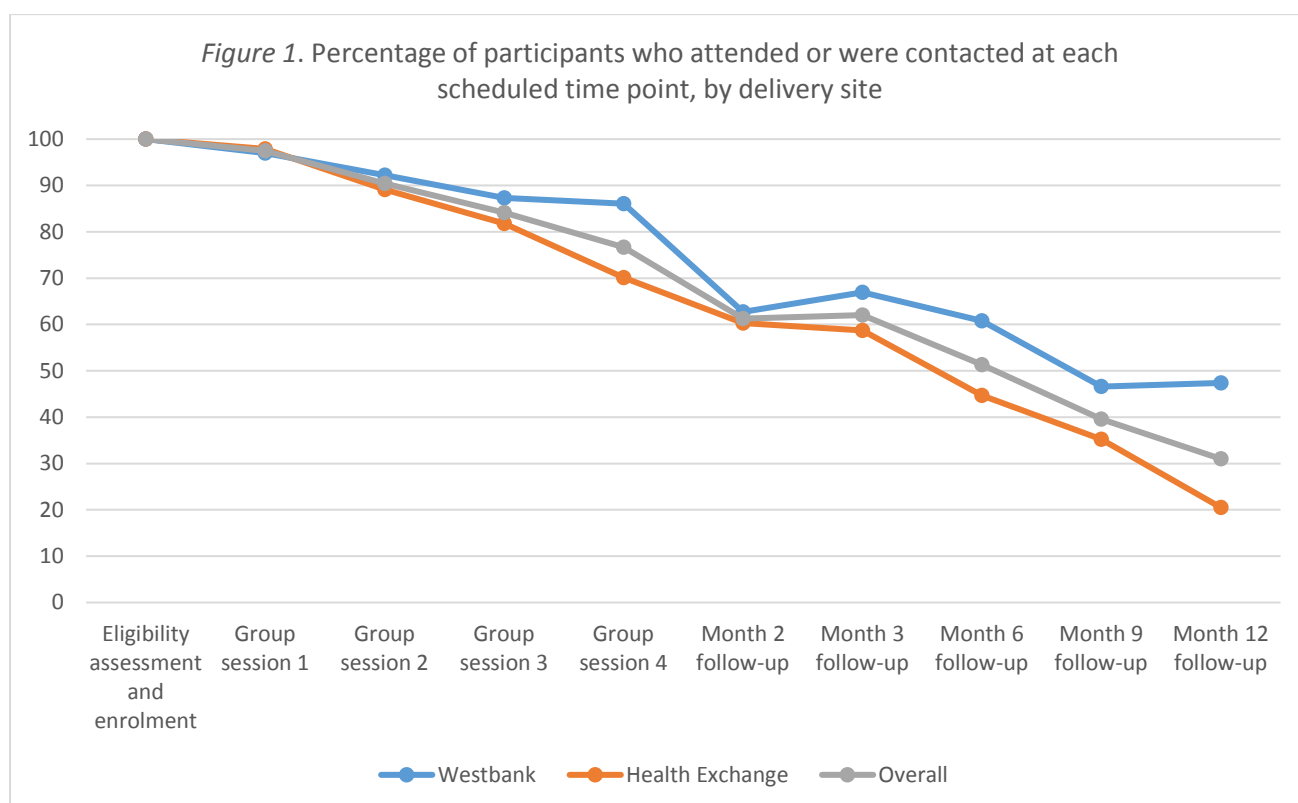
c) Programme contacts with participants

	Number (%) of attendance/contact		
	Westbank	Health Exchange	Overall
Eligibility assessment and enrolment	332 (100.0)	479 (100.0)	811 (100.0)
Group session 1	322 (97.0)	469 (97.9)	791 (97.5)
Group session 2	306 (92.2)	427 (89.1)	733 (90.4)
Group session 3	290 (87.3)	392 (81.8)	682 (84.1)
Group session 4	286 (86.1)	336 (70.1)	622 (76.7)
<i>Mean attendance across all group sessions</i>	301 (90.7)	406 (84.8)	707 (87.2)
Month 2 follow-up	208 (62.7)	289 (60.3)	497 (61.3)
Month 3 follow-up	222 (66.9)	281 (58.7)	503 (62.0)
Month 6 follow-up	202 (60.8)	214 (44.7)	416 (51.3)
Month 9 follow-up*	122 (46.6)	144 (35.2)	266 (39.6)
Month 12 follow-up [§]	100 (47.4)	67 (20.5)	167 (31.0)
<i>Mean contact across all follow-ups</i>	171 (56.9)	199 (43.9)	370 (49.0)
<i>Mean programme attendance/contact</i>	236 (73.8)	303 (64.4)	539 (68.1)

Figures reported for Month 9 and Month 12 follow-ups have been adjusted to take into account the cut-off date of April 2015, and that not all participants would have reached those follow-up time points. This has also been considered in the calculations of mean contact across all follow-ups and mean programme attendance/contact.

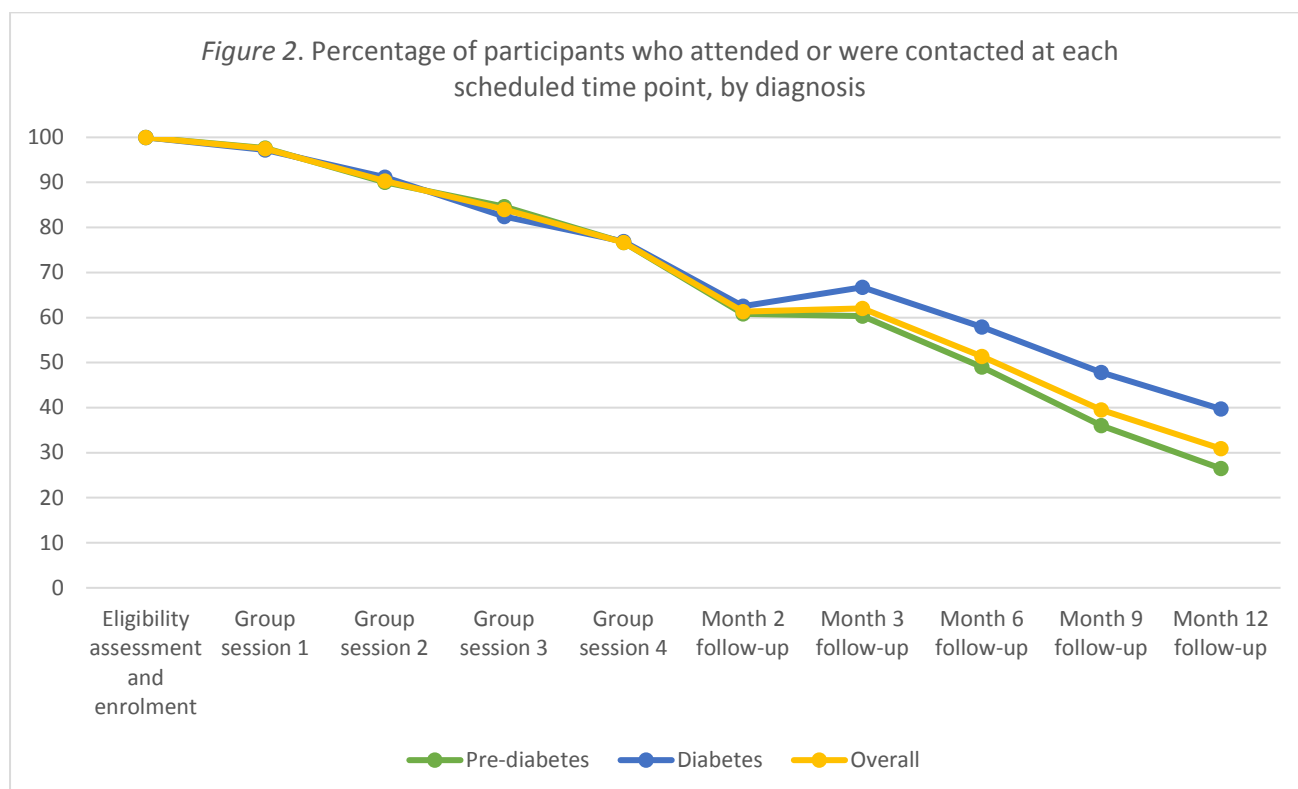
*No. of participants who reached the nine-month time point = 671 (262 from Westbank, 409 from Health Exchange)

[§]No. of participants who reached the 12-month time point = 538 (211 from Westbank, 327 from Health Exchange)



Note: Percentages for Month 9 and Month 12 follow-ups have been adjusted to take into account the cut-off date of April 2015, and that not all participants would have reached those follow-up time points.

Overall, Westbank recorded better programme attendance and contact than Health Exchange. By the fourth group session, Westbank recorded an attendance of about 86% of participants who initially enrolled onto the programme, compared to 70% at Health Exchange. However, both partner agencies were able to contact similar proportion of participants at Month 2 follow-up, as shown in Figure 1. Westbank seemed to continue to do better than Health Exchange after Month 2 follow-up, recording nearly 27% more contact with participants at Month 12 follow-up.



Note: Percentages for Month 9 and Month 12 follow-ups have been adjusted to take into account the cut-off date of April 2015, and that not all participants would have reached those follow-up time points.

The difference in patterns of attendance and contact with the programme between participants with pre-diabetes or diabetes was not evident until after the two-month time point. As Figure 2 suggests, participants with pre-diabetes had less contact with the programme post Month 2 follow-up compared to participants with diabetes. At Month 12 follow-up, 26.5% of participants with pre-diabetes had some form of contact, compared to 39.7% of participants with diabetes.

d) Contact time at group education sessions

Four structured group education sessions were delivered over four weeks. Session 1 is delivered at Westbank as a 90-minute session, while Health Exchange delivers this as a two-hour session. Sessions 2, 3 and 4 last approximately two hours each at both programme delivery sites. Data was provided for 811 participants in total: 332 from Westbank, and 479 from Health Exchange.

Contact time at group education sessions (hours)	Number (%) of Westbank participants
1.5	17 (5.1)
3.5	19 (5.7)
5.5	25 (7.5)
6.0	2* (0.6)
7.5	269 (81.0)

*These two participants are likely to have missed Session 1

Contact time at group education sessions (hours)	Number (%) of Health Exchange participants
2	42 (8.8)
4	28 (5.8)
6	110 (23.0)
8	299 (62.4)

The overall mean contact time at group sessions across both delivery sites was 6.8 hours. Westbank had 18.6% more participants than Health Exchange, who completed all four group sessions.

e) Uptake of additional services offered after completion of group education sessions

LWTC participants were offered at least five hours of add-on healthy lifestyle activities after completion of group education sessions. For example, Westbank asked participants to choose from a list of 25 different activities offered 'in-house', which focused on healthy eating, physical activity, or wellbeing. The duration of each activity was typically an hour, except for 'Healthy Come Dine with Me', the healthy cooking session, and table tennis, which were 2 hours per session. Health Exchange's database did not record uptake or contact at these add-on activities, which were run by external agencies. Westbank undertook some recording: the table below shows data recorded for 33 participants, all of whom had reached at least the nine-month follow-up time point from the cut-off date of April 2015 (27 of these went on to reach the 12-month follow-up time point). However, we are aware that this under-records the full extent of participation in these add-on healthy lifestyle sessions.

Contact time at add-on healthy lifestyle activities (hours)	Uptake of add-on healthy lifestyle activities, n (%)
0	5 (15.2)
1	14 (42.4)
2	3 (9.1)
3	7 (21.2)
4	2 (6.1)
6	1 (3.0)
8	1 (3.0)

f) Total recorded contact time with the programme

This section groups participants into contact time categories over the course of the whole programme. Data was provided for 811 participants in total: 332 from Westbank, and 479 from Health Exchange. Participants are assumed to have been able to achieve more than 12 hours contact time only if they remained on the programme beyond six months. Analysis involving Month 9 and Month 12 follow-ups have been adjusted to take into account the cut-off date of April 2015, and that not all participants would have reached those follow-up time points.

Contact time throughout programme (hours)	Number (%) of participants		
	Westbank	Health Exchange	Overall
Contact hours < 8	81 (24.4)	135 (28.2)	216 (26.6)
8 ≥ Contact hours ≤ 12	166 (50.0)	298 (62.2)	464 (57.2)
12 ≥ Contact hours ≤ 14	71 (21.1)	46 (9.6)	117 (14.4)
Contact hours > 14	14 (4.2)	0	14 (1.7)

	Contact time throughout programme (hours)		
	Westbank	Health Exchange	Overall
Minimum	1.5	2.0	1.5
Maximum	20.0	13.5	20.0
Mean	9.7	8.7	9.1
Std. deviation	3.49	3.03	3.27

Results suggest that at Month 12, four participants at Westbank (1.2%) achieved the NICE recommendation of at least 16 hours contact time, and none of the Health Exchange participants achieved this. It should be noted that these contact time findings do not fully capture all forms of contact. Both project teams reported other forms of ad hoc or un-scheduled contacts with service users that were not comprehensively recorded on the project contact database.

8.2 LWTC programme participant demographics

a) Demographic profile by delivery site

Data was provided for 811 participants in total: 332 from Westbank, and 479 from Health Exchange. The following table shows differences in demographic characteristics by delivery site. The mean age of participants was 65 years at Westbank, and 59 years at Health Exchange (61 years overall). Participants at Health Exchange were more likely to be from a 'BME' (Black and Minority Ethnic) background (63.9%), to be unemployed (22.7% vs. 2.2% at Westbank), to have lower educational attainment (45.9% progressed beyond secondary school, up to 16 years), to be from areas of higher socio-economic deprivation (50.7%), and to be less engaged with any other healthy lifestyle activities (13.9%).

		Westbank, n (%)	Health Exchange, n (%)	Overall, n (%)
Diagnosis	Pre-diabetes	232 (70.5)	360 (75.2)	592 (73.3)
	Diabetes	97 (29.5)	119 (24.8)	216 (26.7)
Age	< 40 years	8 (2.5)	46 (9.6)	54 (6.7)
	40 – 75 years	278 (85.3)	367 (76.6)	645 (80.1)
	> 75 years	40 (12.3)	66 (13.8)	106 (13.2)
Gender	Male	134 (40.4)	186 (38.8)	320 (39.5)
	Female	198 (59.6)	293 (61.2)	491 (60.5)
Ethnicity	White	299 (95.5)	172 (36.1)	471 (59.6)
	Asian or Asian British	4 (1.3)	221 (46.3)	225 (28.5)
	Black or Black British	2 (0.6)	58 (12.2)	60 (7.6)
	Mixed	-	17 (3.6)	17 (2.2)
	Other	8 (2.6)	9 (1.9)	17 (2.2)
BMI categories	Normal weight	35 (10.6)	95 (20.0)	130 (16.1)
	Overweight	119 (36.0)	168 (35.3)	287 (35.6)
	Obese	177 (53.5)	213 (44.7)	390 (48.3)
Employment category	Retired	166 (53.2)	155 (37.0)	321 (43.9)
	Employed	83 (26.6)	86 (20.5)	169 (23.1)
	Self-employed	28 (9.0)	22 (5.3)	50 (6.8)
	Unemployed	7 (2.2)	95 (22.7)	102 (14.0)
	Long-term sick or disabled	10 (3.2)	40 (9.5)	50 (6.8)
	Students, carers or other	18 (5.8)	21 (5.0)	39 (5.3)

Education level	Postgraduate university	17 (6.7)	8 (3.7)	25 (5.3)
	Undergraduate university	37 (14.6)	30 (14.0)	67 (14.3)
	Some additional training	87 (34.3)	35 (16.4)	122 (26.1)
	Completed secondary school (up to 18 years)	17 (6.7)	25 (11.7)	42 (9.0)
	Completed secondary school (up to 16 years)	86 (33.9)	66 (30.8)	152 (32.5)
	Primary school or some secondary school	10 (3.9)	50 (23.3)	60 (12.8)
IMD decile*	1	3 (1.1)	238 (50.7)	241 (32.6)
	2	15 (5.5)	59 (12.6)	74 (10.0)
	3	23 (8.5)	36 (7.7)	59 (8.0)
	4	39 (14.4)	38 (8.1)	77 (10.4)
	5	22 (8.1)	38 (8.1)	60 (8.1)
	6	26 (9.6)	12 (2.6)	38 (5.1)
	7	44 (16.2)	19 (4.1)	63 (8.5)
	8	43 (15.9)	11 (2.3)	54 (7.3)
	9	43 (15.9)	6 (1.3)	49 (6.6)
	10	13 (4.8)	12 (2.6)	25 (3.4)
Co-morbidities	High blood pressure	112 (34.9)	177 (42.2)	289 (39.1)
	High cholesterol	59 (19.7)	144 (30.4)	203 (26.3)
	Arthritis	61 (20.3)	101 (21.4)	162 (21.0)
	Coronary heart disease	20 (6.7)	38 (8.0)	58 (7.5)
	Mobility problems	35 (11.7)	49 (10.4)	84 (10.9)
	Depression	27 (11.1)	27 (5.7)	54 (7.5)
	Stroke	9 (3.0)	14 (3.0)	23 (3.0)
	Chronic kidney disease	5 (1.7)	15 (3.2)	20 (2.6)
	Other co-morbidities	65 (21.6)	98 (20.7)	163 (21.1)
Any co-morbidity	145 (59.7)	274 (57.9)	419 (58.5)	
Prior and/or concurrent engagement with healthy lifestyle activities external to LWTC	Exercise groups	26 (9.7)	22 (4.6)	48 (6.5)
	Swimming groups	10 (3.7)	10 (2.1)	20 (2.7)
	Weight management groups	11 (4.1)	4 (0.8)	15 (2.0)
	Team sports	8 (3.0)	1 (0.2)	9 (1.2)
	Yoga/relaxation groups	3 (1.1)	5 (1.1)	8 (1.1)
	Cooking groups	1 (0.4)	5 (1.1)	6 (0.8)
	Mental health support groups	3 (1.1)	2 (0.4)	5 (0.7)
	Other activities	37 (13.6)	25 (5.3)	62 (8.3)
Any activity	76 (28.5)	66 (13.9)	142 (19.1)	
Smokers	24 (7.6)	39 (12.1)	63 (9.9)	
Disabled	58 (18.7)	63 (13.5)	121 (15.6)	

* IMD decile is from 1 (most deprived area in England) to 10 (least deprived area in England)

Source: English indices of deprivation 2015, Department of Communities and Local Government. Generated from postcode lookup at <http://imd-by-postcode.opendatacommunities.org/>

Note: There is missing data in all categories, except gender.

b) Demographic profile by diagnosis

Data was provided for 592 participants with pre-diabetes (232 from Westbank, and 360 from Health Exchange), and 216 with diabetes (97 from Westbank, and 119 from Health Exchange); diagnosis for three participants was not recorded or not available. The mean age of participants was 61 years for participants with pre-diabetes, and 63 years for participants with diabetes. The table below shows a similar demographic profile regardless of diagnosis.

		Pre-diabetes, n (%)	Diabetes, n (%)
Age	< 40 years	40 (6.8)	14 (6.5)
	40 – 75 years	474 (80.6)	169 (79.0)
	> 75 years	74 (12.6)	31 (14.5)
Gender	Male	218 (36.8)	101 (46.8)
	Female	374 (63.2)	115 (53.2)
Ethnicity	White	344 (59.9)	124 (58.2)
	Asian or Asian British	170 (29.6)	55 (25.8)
	Black or Black British	41 (7.1)	19 (8.9)
	Mixed	10 (1.7)	7 (3.3)
	Other	9 (1.6)	8 (3.8)
BMI categories	Normal weight	104 (17.6)	25 (11.7)
	Overweight	216 (36.6)	71 (33.2)
	Obese	270 (45.8)	118 (55.1)
Employment category	Retired	226 (43.1)	92 (45.1)
	Employed	124 (23.7)	45 (22.1)
	Self-employed	37 (7.1)	13 (6.4)
	Unemployed	69 (13.2)	33 (16.2)
	Long-term sick or disabled	41 (7.8)	9 (4.4)
	Students, carers or other	27 (5.1)	12 (6.0)
Education level	Postgraduate university	21 (5.9)	4 (3.7)
	Undergraduate university	52 (14.5)	15 (14.0)
	Some additional training	90 (25.1)	30 (28.0)
	Completed secondary school (up to 18 years)	29 (8.1)	13 (12.1)
	Completed secondary school (up to 16 years)	121 (33.8)	31 (29.0)
	Primary school or some secondary school	45 (12.6)	14 (13.1)
IMD decile	1	173 (33.0)	68 (31.9)
	2	51 (9.7)	23 (10.8)
	3	37 (7.1)	22 (10.3)
	4	51 (9.7)	26 (12.2)
	5	50 (9.5)	9 (4.2)
	6	26 (5.0)	12 (5.6)
	7	40 (7.6)	22 (10.3)
	8	30 (5.7)	23 (10.8)

	9	44 (8.4)	5 (2.3)
	10	22 (4.2)	3 (1.4)
Co-morbidities	High blood pressure	219 (40.6)	70 (35.2)
	High cholesterol	133 (23.5)	68 (33.2)
	Arthritis	121 (21.4)	39 (19.0)
	Coronary heart disease	41 (7.3)	17 (8.3)
	Mobility problems	67 (11.9)	16 (7.8)
	Depression	36 (6.7)	17 (9.5)
	Stroke	14 (2.5)	9 (4.4)
	Chronic kidney disease	13 (2.3)	7 (3.4)
	Other co-morbidities	120 (21.2)	42 (20.5)
	Any co-morbidity	305 (57.1)	111 (62.0)
Prior and/or concurrent engagement with healthy lifestyle activities external to LWTC	Exercise groups	40 (7.4)	8 (4.0)
	Swimming groups	13 (2.4)	7 (3.5)
	Weight management groups	12 (2.2)	3 (1.5)
	Team sports	7 (1.3)	2 (1.0)
	Yoga/relaxation groups	7 (1.3)	1 (0.5)
	Cooking groups	5 (0.9)	1 (0.5)
	Mental health support groups	5 (0.9)	0
	Other activities	46 (8.5)	15 (7.4)
Smokers		47 (10.4)	16 (8.8)
Disabled		88 (15.6)	32 (15.4)
<i>Note: There is missing data in all categories, except gender.</i>			

c) Demographic profile by attendance at six- and twelve-month follow-ups

There are no obvious differences between the demographic profiles of those who did or did not attend either follow-up time points.

		Attended Month 6 follow-up, n (%)	Did not attend Month 6 follow-up, n (%)	Attended Month 12 follow-up, n (%)	Did not attend Month 12 follow-up, n (%)
Diagnosis	Pre-diabetes	290 (69.9)	302 (76.8)	95 (57.2)	263 (70.9)
	Diabetes	125 (30.1)	91 (23.2)	71 (42.8)	108 (29.1)
Age*	< 40 years	19 (4.6)	35 (8.9)	5 (3.0)	35 (9.5)
	40 – 75 years	337 (81.6)	308 (78.6)	142 (85.0)	285 (77.0)
	> 75 years	57 (13.8)	49 (12.5)	20 (12.0)	50 (13.5)
Gender	Male	152 (36.5)	168 (42.5)	63 (37.7)	148 (39.9)
	Female	264 (63.5)	227 (57.5)	104 (62.3)	223 (60.1)
Ethnicity	‘White’	255 (63.0)	216 (56.1)	113 (68.9)	171 (46.8)
	‘BME’	150 (37.0)	169 (43.9)	51 (31.1)	194 (53.2)
Body Mass Index (BMI)	Normal weight	59 (14.2)	71 (18.1)	23 (13.9)	70 (18.9)
	Overweight	151 (36.4)	136 (34.7)	55 (33.3)	137 (37.0)
	Obese	205 (49.4)	185 (47.2)	87 (52.7)	163 (44.1)
	Employed	123 (32.6)	125 (35.3)	44 (28.9)	121 (36.8)

Employment category [§]	Unemployed	248 (65.8)	225 (63.6)	104 (68.4)	206 (62.6)
Education level [‡]	Low	94 (41.0)	118 (49.4)	34 (51.5)	79 (45.7)
	Intermediate	80 (34.9)	84 (35.1)	22 (33.3)	55 (31.8)
	High	55 (24.0)	37 (15.5)	10 (15.2)	39 (22.5)
IMD decile	1-3	182 (46.2)	192 (55.5)	74 (45.7)	219 (60.3)
	4-7	133 (33.8)	105 (30.3)	53 (32.7)	96 (26.4)
	8-10	79 (20.1)	49 (14.2)	35 (21.6)	48 (13.2)
Co-morbidities	Yes	211 (60.8)	208 (56.4)	78 (68.4)	192 (55.2)
	No	136 (39.2)	161 (43.6)	36 (31.6)	156 (44.8)
Smokers		23 (7.0)	40 (13.0)	4 (2.8)	33 (12.1)
Disabled		64 (16.2)	57 (15.0)	23 (15.0)	59 (16.4)

* Mean age – Attendees at Month 6: 63 years; non-attendees at Month 6: 60 years

Attendees at Month 12: 64 years; non-attendees at Month 12: 59 years

[§] The 'employed' category consists of those who were employed, self-employed, students and carers; the 'unemployed' category consists of those who were unemployed, retired, had long-term sickness or were disabled. Those who selected 'other' in the questionnaire are not included in either category and not presented in the table.

[‡] Education is classified into low (primary school or some secondary school; completed secondary school up to 16 years), intermediate (completed secondary school up to 18 years; had some additional training), and high (undergraduate or postgraduate university).

Note: Analysis for Month 12 follow-up have been adjusted to take into account the cut-off date of April 2015, and that not all participants would have reached that follow-up time point.

8.3 Participant feedback on the programme group sessions

Participants provided feedback on their experience of the programme at the point of completing the group sessions. The following tables show that, overall participants were very positive about the programme at both delivery sites and with respect to their diagnostic group. We sought to examine whether there were any differences on the basis of demographic differences. The results showed no significant variation on the basis of gender, age band, ethnicity, BMI category, employment category, education level, co-morbidity, disability, and smoking status (see Appendix 5).

a) Course satisfaction

<i>Differences between delivery sites</i>	Westbank	Health Exchange	Overall
Did the course benefit you? <i>No. (%) of participants who responded 'yes'</i>	232 (98.7%) Total n = 235	280 (99.3%) Total n = 282	512 (99.0%) Total n = 517
On a scale from 1-10, how much did you enjoy the course? [1: Not at all - 10: Very]	Mean = 8.84 Range 1-10 Total n = 237	Mean = 9.18 Range 4-10 Total n = 270	Mean = 9.02 Range 1-10 Total n = 507
Did the course meet your specific needs? <i>No. (%) of participants who responded 'yes'</i>	213 (97.7%) Total n = 218	273 (99.3%) Total n = 275	486 (98.6%) Total n = 493
On a scale from 1-10, how much would you recommend this course to friends or family? [1:Extremely unlikely - 10: Extremely likely]	Mean = 9.13 Range 2-10 Total n = 184	[Data unavailable]	Mean = 9.13 Range 2-10 Total n = 184

<i>Differences by diagnosis</i>	Pre-diabetes	Diabetes
Did the course benefit you? <i>No. (%) of participants who responded 'yes'</i>	361 (98.9%) Total n = 365	150 (99.3%) Total n = 151
On a scale from 1-10, how much did you enjoy the course? [1: Not at all - 10: Very]	Mean = 8.99 Range 1-10 Total n = 362	Mean = 9.10 Range 4-10 Total n = 144
Did the course meet your specific needs? <i>No. (%) of participants who responded 'yes'</i>	344 (98.3%) Total n = 350	141 (99.3%) Total n = 142
On a scale from 1-10, how much would you recommend this course to friends or family? [1:Extremely unlikely - 10: Extremely likely]	Mean = 9.01 Range 2-10 Total n = 135	Mean = 9.44 Range 5-10 Total n = 48

b) Social identity

Only Westbank provided data for the social identity questionnaire. The questionnaire is made up of three sections – Section 1 looks at social support, Section 2 at social identification with LWTC, and Section 3 at other group memberships/social identities (outside of LWTC). Participants were required to score each item on a seven-point scale – 1: Very strongly disagree – 7: Very strongly agree.

The number of participants responding to each item (at four weeks) ranged from 169 to 184, i.e. 50.9% - 55.4% of the total number of Westbank participants. This is due to this questionnaire being introduced into the programme at a later date. Therefore, only groups after a certain time point completed it, but not the earlier groups. The following table shows the overall mean scores for each section (see Appendix 6 for the item-by-item findings).

Social identity measures	N	Mean	Std. Deviation
Social support	184	4.96	1.06
Social identification (with LWTC)	185	5.30	1.00
Other group memberships/social identities	173	4.25	1.67

Results suggest that participants felt somewhat socially supported, had modest social identification with their LWTC group, and had a small social network outside of the programme.

8.4 Six-month follow-up results

a) Changes in means, from baseline (T0) to 6-month follow-up (T1)

		Westbank	Health Exchange	Pre-diabetes	Diabetes	Overall
Weight (kg)	No. of participants, n	194	178	268	104	372
	Baseline mean (SD)	86.09 (17.89)	81.15 (16.23)	83.15 (17.77)	85.20 (15.91)	83.72 (17.27)
	6-month mean (SD)	83.90 (18.18)	80.02 (16.54)	81.41 (17.91)	83.67 (16.34)	82.04 (17.50)
	Mean difference	2.19***	1.13***	1.74***	1.53***	1.68***
	Std. deviation diff.	3.86	4.28	4.15	3.95	4.09
	95% CI of difference	1.64, 2.74	0.50, 1.76	1.24, 2.24	0.76, 2.30	1.27, 2.10
BMI (kg/m²)	No. of participants, n	190	178	265	103	368

	Baseline mean (SD)	31.09 (5.65)	30.38 (5.23)	30.66 (5.34)	30.97 (5.77)	30.75 (5.46)
	6-month mean (SD)	30.20 (5.82)	29.97 (5.40)	30.04 (5.39)	30.22 (6.19)	30.09 (5.61)
	Mean difference	0.89***	0.40***	0.62***	0.74***	0.65***
	Std. deviation diff.	1.96	1.46	1.61	2.07	1.75
	95% CI of difference	0.61, 1.17	0.19, 0.62	0.42, 0.81	0.34, 1.15	0.47, 0.83
Waist circumference (cm)	No. of participants, n	190	115	220	85	305
	Baseline mean (SD)	103.44 (14.79)	96.81 (19.83)	99.93 (18.66)	103.57 (12.05)	100.94 (17.14)
	6-month mean (SD)	99.02 (14.91)	95.14 (16.07)	96.56 (16.26)	100.14 (12.83)	97.56 (15.45)
	Mean difference	4.42***	1.67	3.37**	3.43***	3.38***
	Std. deviation diff.	5.45	21.64	15.98	6.59	14.00
	95% CI of difference	3.64, 5.20	-2.32, 5.67	1.24, 5.49	2.01, 4.85	1.81, 4.96
HbA1c (mmol/mol)	No. of participants, n	170	129	210	89	299
	Baseline mean (SD)	45.41 (8.42)	46.15 (7.27)	42.92 (3.51)	52.36 (10.98)	45.73 (7.94)
	6-month mean (SD)	41.15 (6.04)	44.67 (6.20)	41.46 (5.43)	45.52 (7.38)	42.67 (6.34)
	Mean difference	4.26***	1.48***	1.46***	6.84***	3.06***
	Std. deviation diff.	8.67	4.55	4.99	10.07	7.31
	95% CI of difference	2.95, 5.58	0.68, 2.27	0.78, 2.14	4.72, 8.96	2.23, 3.89
*p<0.05; **p<0.01; ***p<0.001						

As shown in the table above, there were significant improvements for all measures across sub-groups, with the exception of the reduction in waist circumference observed at Health Exchange ($p>0.05$). Westbank participants did better than Health Exchange participants for all measures. Apart from weight loss, participants with diabetes showed more improvements than participants with pre-diabetes. A post-hoc/exploratory analysis using independent-samples t-tests confirmed that reductions in weight and HbA1c observed at Westbank were significantly greater than those observed at Health Exchange ($p<0.05$ and $p<0.001$, respectively).

b) Number and percentage of participants who achieved the MCID at T1 compared to T0

		Number (%) who achieved at least 2kg weight loss at Month 6
Westbank	All participants (n = 194)	97 (50.0)
	Excluding BMI<25 (n = 175)	87 (49.7)
Health Exchange	All participants (n = 178)	59 (33.1)
	Excluding BMI<25 (n = 152)	52 (34.2)
Pre-diabetes	All participants (n = 268)	115 (42.9)
	Excluding BMI<25 (n = 237)	105 (44.3)
Diabetes	All participants (n = 104)	41 (39.4)
	Excluding BMI<25 (n = 90)	34 (37.8)
Overall	All participants (n = 372)	156 (41.9)
	Excluding BMI<25 (n = 327)	139 (42.5)

Overall, about 42% of participants achieved the MCID of 2kg weight loss – Westbank participants and participants who had pre-diabetes did better to achieve this target than their respective comparator groups. Assessments excluding those with a BMI less than 25 had little impact on the percentages achieving this target.

c) Number and percentage of participants who achieved weight reductions of at least 3%, 5% and 10% at T1 compared to T0

In addition to calculating the number and percentage of those achieving 2kg weight loss, we also assessed the number and percentage of participants that had achieved a minimum percentage weight loss using thresholds widely adopted in weight loss programmes.

		Number (%) who achieved weight reductions at Month 6		
		≥3% weight loss	≥5% weight loss	≥10% weight loss
Westbank	All participants (n = 194)	85 (43.8)	50 (25.8)	8 (4.1)
	Excluding BMI<25 (n = 175)	75 (42.9)	45 (25.7)	8 (4.6)
Health Exchange	All participants (n = 178)	52 (29.2)	28 (15.7)	9 (5.1)
	Excluding BMI<25 (n = 152)	45 (29.6)	23 (15.1)	6 (3.9)
Pre-diabetes	All participants (n =268)	101 (37.7)	57 (21.3)	11 (4.1)
	Excluding BMI<25 (n =237)	91 (38.4)	51 (21.5)	9 (3.8)
Diabetes	All participants (n = 104)	36 (34.6)	21 (20.2)	6 (5.8)
	Excluding BMI<25 (n =90)	29 (32.2)	17 (18.9)	5 (5.6)
Overall	All participants (n = 372)	137 (36.8)	78 (21.0)	17 (4.6)
	Excluding BMI<25 (n = 327)	120 (36.7)	68 (20.8)	14 (4.3)

Approximately one third of total programme participants achieved at least 3% weight loss, a fifth achieved at least 5% weight loss, and very small numbers achieved at least 10% weight loss at T1. A greater proportion of Westbank participants achieved at least 3% and 5% weight loss compared to Health Exchange participants, although a comparison by diagnosis did not yield much difference between participants with pre-diabetes and those with diabetes. Assessments excluding those with a BMI less than 25 had little impact on the percentages achieving these thresholds.

d) Changes in physical activity measures, from T0 to T1

This section is concerned with:

- The number and percentage of participants that meet the recommended guidelines (i.e. at least 150 minutes/week of moderate-to-vigorous physical activity) from T0 to T1 follow-up.
- The mean number of minutes/week of moderate-to-vigorous physical activity.

		Pre-diabetes	Diabetes	Overall
Proportion of participants meeting recommended guidelines	No. of participants, n	130	45	176
	Baseline mean (SD)	0.35 (0.48)	0.42 (0.50)	0.37 (0.48)
	6-month mean (SD)	0.45 (0.50)	0.27 (0.45)	0.41 (0.49)
	Mean difference	-0.11	0.16	-0.04
	Std. deviation diff.	0.53	0.60	0.56
	95% CI of difference	-0.20, -0.02	-0.03, 0.34	-0.12, 0.04
	p-value	p<0.05	p=0.09	p=0.35
Mean no. of minutes/week	No. of participants, n	130	45	176
	Baseline mean (SD)	212.81 (363.66)	181.56 (262.76)	210.77 (348.37)

of moderate-to-vigorous physical activity	6-month mean (SD)	261.51 (355.61)	126.33 (182.35)	229.55 (326.27)
	Mean difference	-48.70	55.22	-18.78
	Std. deviation diff.	370.92	278.90	353.32
	95% CI of difference	-113.07, 15.67	-28.57, 139.01	-71.35, 33.78
	p-value	p=0.14	p=0.19	p=0.48
*p<0.05; **p<0.01; ***p≤0.001				

Comparison of the above measures for each delivery site did not yield any significant differences ($p>0.05$). The only significant difference observed was an increase in the proportion of participants with pre-diabetes who met the recommended guidelines at T1 compared to T0 ($p<0.05$).

e) Changes in diet measures, from T0 to T1

Overall and sub-categories for diet		Westbank	Health Exchange	Pre-diabetes	Diabetes	Overall
Overall reported dietary behaviours	No. of participants, n	187	99	208	77	286
	Baseline mean (SD)	49.50 (8.29)	51.98 (9.85)	50.70 (8.99)	49.47 (8.79)	50.36 (8.92)
	6-month mean (SD)	47.20 (8.42)	50.37 (9.36)	47.89 (8.76)	49.48 (9.14)	48.30 (8.87)
	Mean difference	2.29***	1.61*	2.82***	-0.01	2.06***
	Std. deviation diff.	7.12	8.06	7.70	6.41	7.45
	95% CI of difference	1.27, 3.32	0.01, 3.22	1.76, 3.87	-1.47, 1.44	1.19, 2.93
Substituting specifically manufactured low fat foods (max. possible score = 18)	No. of participants, n	183	94	201	75	277
	Baseline mean (SD)	11.03 (2.90)	11.99 (3.26)	11.44 (2.99)	11.15 (3.24)	11.36 (3.06)
	6-month mean (SD)	10.49 (2.87)	11.39 (3.24)	10.61 (2.97)	11.29 (3.18)	10.79 (3.03)
	Mean difference	0.54*	0.60	0.83***	-0.14	0.56**
	Std. deviation diff.	3.10	3.24	3.25	2.76	3.14
	95% CI of difference	0.09, 0.99	-0.06, 1.27	0.37, 1.28	-0.78, 0.49	0.19, 0.93
Avoiding fat as a flavouring (max. possible score = 9)	No. of participants, n	181	92	198	74	273
	Baseline mean (SD)	5.78 (1.70)	5.99 (1.68)	5.89 (1.71)	5.73 (1.65)	5.85 (1.69)
	6-month mean (SD)	5.44 (1.60)	6.19 (1.86)	5.66 (1.68)	5.78 (1.87)	5.69 (1.73)
	Mean difference	0.34*	-0.20	0.23	-0.05	0.16
	Std. deviation diff.	1.81	1.89	1.81	1.96	1.85
	95% CI of difference	0.08, 0.61	-0.59, 0.19	-0.02, 0.49	-0.50, 0.41	-0.06, 0.38
Modifying meats to be low in fat (max. possible score = 15)	No. of participants, n	182	92	199	74	274
	Baseline mean (SD)	7.58 (2.35)	7.66 (2.00)	7.57 (2.31)	7.64 (2.01)	7.60 (2.24)
	6-month mean (SD)	7.14 (2.04)	7.24 (2.13)	7.08 (2.12)	7.43 (1.93)	7.18 (2.07)
	Mean difference	0.43**	0.41*	0.50***	0.20	0.43***
	Std. deviation diff.	1.76	1.95	1.80	1.87	1.82
	95% CI of difference	0.18, 0.69	0.01, 0.82	0.24, 0.75	-0.23, 0.64	0.21, 0.64
Replacing high fat meats with low fat alternatives (max. possible score = 9)	No. of participants, n	157	92	188	61	249
	Baseline mean (SD)	6.52 (1.44)	6.04 (1.59)	6.45 (1.47)	6.00 (1.59)	6.34 (1.51)
	6-month mean (SD)	6.25 (1.48)	5.87 (1.59)	6.01 (1.57)	6.43 (1.34)	6.11 (1.53)
	Mean difference	0.27*	0.17	0.45***	-0.43*	0.23*

	Std. deviation diff.	1.47	1.61	1.51	1.36	1.52
	95% CI of difference	0.04, 0.50	-0.17, 0.50	0.23, 0.66	-0.78, -0.09	0.04, 0.42
Eating fruit and vegetables (max. possible score = 15)	No. of participants, n	184	95	203	75	279
	Baseline mean (SD)	7.97 (2.04)	8.78 (2.49)	8.31 (2.25)	8.10 (2.19)	8.25 (2.23)
	6-month mean (SD)	7.69 (2.00)	8.50 (2.58)	7.93 (2.21)	8.09 (2.35)	7.97 (2.24)
	Mean difference	0.28*	0.28	0.38*	0.01	0.28*
	Std. deviation diff.	1.75	2.40	2.06	1.77	1.99
	95% CI of difference	0.02, 0.53	-0.21, 0.77	0.09, 0.66	-0.40, 0.42	0.04, 0.51
Choosing high-fibre foods (max. possible score = 15) [§]	No. of participants, n	186	94	204	75	280
	Baseline mean (SD)	10.71 (2.97)	11.36 (3.37)	11.02 (3.04)	10.73 (3.31)	10.93 (3.12)
	6-month mean (SD)	9.95 (2.99)	11.36 (3.20)	10.42 (3.19)	10.48 (2.99)	10.42 (3.13)
	Mean difference	0.76***	0.00	0.60**	0.25	0.50**
	Std. deviation diff.	2.82	2.91	2.81	3.04	2.87
	95% CI of difference	0.35, 1.16	-0.60, 0.60	0.22, 0.99	-0.45, 0.95	0.17, 0.84

*p<0.05; **p<0.01; ***p≤0.001
[§]Merges sub-categories of 'cereals and grains' and 'substitute low-fibre foods for high-fibre foods'

For diet measures, a lower score indicates healthier diet choices reported. Results show that, overall, there were significant changes across all but one sub-category in self-reported dietary behaviour for participants at T1. Dietary changes in all sub-categories were more consistent for Westbank than Health Exchange participants. Participants with pre-diabetes made significant dietary improvements in all sub-categories, except for 'avoiding fat as a flavouring'. Participants with diabetes did not appear to make any significant positive dietary changes.

f) Changes in general health, mental health, and mental wellbeing measures, from T0 to T1

This section draws upon the following measures:

- General Health State
- Overall Life Satisfaction
- Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)
- Anxiety, EQ-5D
- Depression, CESD-7

		Westbank	Health Exchange	Pre-diabetes	Diabetes	Overall
General health state (on a scale of 0-100)	No. of participants, n	166	114	201	78	280
	Baseline mean (SD)	71.77 (20.80)	72.30 (21.43)	71.86 (21.73)	72.14 (19.30)	71.99 (21.02)
	6-month mean (SD)	74.04 (18.86)	75.75 (21.77)	74.71 (19.82)	74.55 (20.86)	74.74 (20.08)
	Mean difference	-2.27	-3.46	-2.86*	-2.41	-2.75*
	Std. deviation diff.	17.57	19.67	19.33	16.09	18.43
	95% CI of difference	-4.96, 0.43	-7.11, 0.19	-5.54, -0.16	-6.04, 1.22	-4.92, -0.58
Overall life satisfaction	No. of participants, n	175	120	211	83	295 (2.05)
	Baseline mean (SD)	7.60 (1.95)	7.69	7.74 (1.90)	7.36 (2.39)	7.64 (3.13)
	6-month mean (SD)	8.03 (3.72)	8.13	8.17 (3.47)	7.78 (2.03)	8.07

(on a scale of 0-10)	Mean difference	-0.43	0.43**	-0.43	-0.42*	-0.43*
	Std. deviation diff.	3.57	1.67	3.28	1.89	2.95
	95% CI of difference	-0.96, 0.10	-0.74, -0.13	-0.88, 0.01	-0.84, -0.01	-0.77, -0.09
SWEMWBS (max. possible score = 35)	No. of participants, n	179	142	230	90	321
	Baseline mean (SD)	26.86 (5.10)	27.43 (5.53)	27.48 (5.15)	26.22 (5.58)	27.11 (5.29)
	6-month mean (SD)	27.32 (4.94)	28.15 (5.81)	27.89 (5.11)	27.13 (5.94)	27.69 (5.35)
	Mean difference	-0.46	-0.72	-0.41	-0.91	-0.58*
	Std. deviation diff.	3.59	5.55	3.96	5.80	4.56
	95% CI of difference	-0.99, 0.07	-1.64, 0.20	-0.93, 0.10	-2.12, 0.30	-1.08, -0.08
Anxiety (score of 0 or 1)	No. of participants, n	184	135	221	97	319
	Baseline mean (SD)	0.29 (0.46)	0.24 (0.43)	0.26 (0.44)	0.31 (0.47)	0.27 (0.45)
	6-month mean (SD)	0.27 (0.44)	0.17 (0.38)	0.21 (0.41)	0.26 (0.44)	0.23 (0.42)
	Mean difference	0.03	0.07	0.05	0.05	0.05*
	Std. deviation diff.	0.38	0.47	0.41	0.44	0.42
	95% CI of difference	-0.03, 0.08	-0.01, 0.15	-0.01, 0.10	-0.04, 0.14	0.00, 0.09
Depression (max. possible score = 30)	No. of participants, n	179	138	227	89	317
	Baseline mean (SD)	14.44 (4.79)	14.23 (4.41)	14.16 (4.77)	14.86 (4.22)	14.35 (4.62)
	6-month mean (SD)	13.97 (4.62)	13.46 (4.28)	13.48 (4.49)	14.43 (4.40)	13.75 (4.47)
	Mean difference	0.47	0.77*	0.68**	0.43	0.60**
	Std. deviation diff.	3.76	3.76	3.74	3.84	3.76
	95% CI of difference	-0.08, 1.03	0.13, 1.40	0.20, 1.17	-0.38, 1.24	0.19, 1.02

*p<0.05; **p<0.01; ***p<0.001

For self-reported measures of general health state, overall life satisfaction, and mental wellbeing (SWEMWBS), the desired outcome is a higher score, whereas for measures of anxiety and depression, the desired outcome is a lower score. Results show that, at T1, there were significant positive changes for all the above measures for the overall LWTC programme participant population. However, comparisons across sub-groups of delivery site and diagnosis suggest that the programme did not significantly improve wellbeing or anxiety ($p>0.05$).

Westbank participants did not show any significant changes across all measures ($p>0.05$). Health Exchange participants had significant improvements in overall life satisfaction and depression scores at T1 ($p<0.01$ and $p<0.05$, respectively). Participants with pre-diabetes had significant improvements in general health state and depression scores at 6 months ($p<0.05$ and $p<0.01$, respectively), while participants with diabetes had a significant improvement in overall life satisfaction ($p<0.05$). There were no significant differences between T0 and T1 for mobility problems, self-care problems, problems with usual activities, and pain or discomfort assessed using the EQ5D, for the overall participant population and across sub-groups ($p>0.05$), and are therefore not reported in the table above.

8.5 Twelve-month follow-up results

The total number of participants expected to have completed the 12-month follow-up by October 2015 was 538. The breakdown of numbers is shown below:

- By delivery site: 211 from Westbank, and 327 from Health Exchange
- By diagnosis: 358 with pre-diabetes, and 179 with diabetes (data missing for one participant)

a) Changes in means, from baseline (T0) to 12-month follow-up (T2)

		Westbank	Health Exchange	Pre-diabetes	Diabetes	Overall
Weight (kg)	No. of participants, n	116	49	100	65	165
	Baseline mean (SD)	82.76 (18.08)	81.64 (15.02)	81.64 (18.28)	83.64 (15.42)	82.43 (17.19)
	12-month mean (SD)	80.63 (18.88)	81.27 (15.13)	80.05 (19.14)	82.01 (15.60)	80.82 (17.80)
	Mean difference	2.13***	0.37	1.59***	1.63**	1.61***
	Std. deviation diff.	4.19	4.02	4.12	4.38	4.21
	95% CI of difference	1.36, 2.90	-0.78, 1.53	0.78, 2.41	0.54, 2.71	0.96, 2.25
BMI (kg/m²)	No. of participants, n	111	49	98	62	160
	Baseline mean (SD)	30.32 (5.81)	30.36 (5.86)	30.30 (5.83)	30.38 (5.82)	30.33 (5.81)
	12-month mean (SD)	29.51 (6.10)	30.23 (5.86)	29.66 (6.10)	29.84 (5.93)	29.73 (6.02)
	Mean difference	0.81***	0.13	0.64***	0.54*	0.60***
	Std. deviation diff.	1.61	1.50	1.60	1.61	1.60
	95% CI of difference	0.51, 1.11	-0.30, 0.56	0.32, 0.96	0.13, 0.95	0.35, 0.85
Waist circumference (cm)	No. of participants, n	115	25	88	52	140
	Baseline mean (SD)	100.52 (15.83)	99.57 (9.86)	99.60 (16.77)	101.63 (11.14)	100.35 (14.91)
	12-month mean (SD)	95.66 (15.46)	96.95 (9.77)	95.26 (15.93)	96.96 (12.06)	95.89 (14.59)
	Mean difference	4.86***	2.62*	4.34***	4.67***	4.46***
	Std. deviation diff.	5.58	5.14	5.55	5.61	5.55
	95% CI of difference	3.83, 5.89	0.50, 4.75	3.17, 5.52	3.10, 6.23	3.53, 5.39
HbA1c (mmol/mol)	No. of participants, n	107	43	89	61	150
	Baseline mean (SD)	46.51 (9.16)	47.77 (8.24)	42.93 (2.91)	52.62 (11.29)	46.87 (8.90)
	12-month mean (SD)	40.87 (4.45)	44.52 (5.46)	39.80 (3.56)	45.00 (5.27)	41.91 (5.03)
	Mean difference	5.64***	3.25*	3.13***	7.62***	4.96***
	Std. deviation diff.	8.21	8.19	3.40	11.83	8.25
	95% CI of difference	4.07, 7.22	0.73, 5.77	2.42, 3.85	4.59, 10.65	3.63, 6.23

*p<0.05; **p<0.01; ***p<0.001

As shown in the table above, there were significant improvements for all measures across sub-groups, with the exception of weight loss and BMI reduction observed at Health Exchange (p>0.05). Similar to findings at T1, Westbank participants did better than Health Exchange participants for all measures. Apart from BMI reduction, participants with diabetes showed more improvements than participants with pre-diabetes. A post-hoc/exploratory analysis for the outcomes of weight loss and HbA1c reduction using independent-samples t-tests found that the differences observed between delivery sites were statistically significant for weight loss (p<0.05), but not for HbA1c reduction (p>0.05); there were no significant differences observed between diagnosis sub-groups

b) Number and percentage of participants who achieved the MCID at T2 compared to T0

		Number (%) who achieved at least 2kg weight loss at Month 12
Westbank	All participants (n = 116)	55 (47.4)
	Excluding BMI<25 (n = 98)	47 (48.0)
Health Exchange	All participants (n = 49)	18 (36.7)
	Excluding BMI<25 (n = 38)	15 (39.5)
Pre-diabetes	All participants (n = 100)	45 (45.0)
	Excluding BMI<25 (n = 83)	36 (43.4)
Diabetes	All participants (n = 65)	28 (43.1)
	Excluding BMI<25 (n = 53)	26 (49.1)
Overall	All participants (n = 165)	73 (44.2)
	Excluding BMI<25 (n = 136)	62 (45.6)

Overall, about 44.2% of participants achieved the MCID of 2kg weight loss at T2. Similar to observations at T1, Westbank participants and participants who had pre-diabetes did better to achieve this target than their respective comparator groups. Assessments excluding those with a BMI less than 25 had little impact on the percentages achieving this target.

c) Number and percentage of participants who achieved weight reduction thresholds at T2

		Number (%) who achieved weight reductions at Month 12		
		≥3% weight loss	≥5% weight loss	≥10% weight loss
Westbank	All participants (n = 116)	50 (43.1)	29 (25.0)	10 (8.6)
	Excluding BMI<25 (n = 98)	42 (42.9)	27 (27.6)	10 (10.2)
Health Exchange	All participants (n = 49)	12 (24.5)	8 (16.3)	1 (2.0)
	Excluding BMI<25 (n = 38)	9 (23.7)	5 (13.2)	1 (2.6)
Pre-diabetes	All participants (n = 100)	40 (40.0)	23 (23.0)	5 (5.0)
	Excluding BMI<25 (n = 83)	31 (37.3)	19 (22.9)	5 (6.0)
Diabetes	All participants (n = 65)	22 (33.8)	14 (21.5)	6 (9.2)
	Excluding BMI<25 (n = 53)	20 (37.7)	13 (24.5)	6 (11.3)
Overall	All participants (n = 165)	62 (37.6)	37 (22.4)	11 (6.7)
	Excluding BMI<25 (n = 136)	51 (37.5)	32 (23.5)	11 (8.1)

Results for the number and percentage of participants that had achieved thresholds widely adopted in weight loss programmes at T2 were similar to results at T1 – approximately one third of total programme participants achieved at least 3% weight loss, a fifth achieved at least 5% weight loss, and very small numbers achieved at least 10% weight loss. A greater proportion of Westbank participants achieved at least 3% and 5% weight loss compared to Health Exchange participants, although a comparison by diagnosis did not yield much difference between participants with pre-diabetes and those with diabetes. Assessments excluding those with a BMI less than 25 had little impact on the percentages achieving these thresholds.

d) Changes in physical activity measures, from T0 to T2

		Proportion of participants meeting recommended guidelines*	Mean no. of minutes/week of moderate-to-vigorous physical activity
Overall	No. of participants, n	76	76
	Baseline mean (SD)	0.43 (0.50)	268.75
	12-month mean (SD)	0.47 (0.50)	312.22
	Mean difference	-0.04	-43.47
	Std. deviation diff.	0.60	489.21
	95% CI of difference	-0.18, 0.10	-155.26, 68.32
	p-value	p>0.05	p>0.05

*Recommended guidelines: at least 150 minutes/week of moderate-to-vigorous physical activity

Comparison of physical activity measures for Westbank (n=73) did not yield any significant differences (p>0.05). There were only three matched pairs for Health Exchange; therefore a comparison could not be made. Comparison of physical activity measures by diagnosis also did not yield any significant differences (p>0.05).

e) Changes in diet measures, from T0 to T2

Overall and sub-categories for diet		Westbank	Health Exchange	Pre-diabetes	Diabetes	Overall
Overall reported dietary behaviours	No. of participants, n	110	23	84	48	133
	Baseline mean (SD)	48.97 (8.50)	52.42 (10.00)	50.01 (8.11)	48.86 (10.09)	49.57 (8.83)
	6-month mean (SD)	46.77 (7.69)	50.72 (9.60)	46.85 (7.84)	48.43 (8.72)	47.46 (8.15)
	Mean difference	2.20***	1.70	3.16***	0.43	2.11***
	Std. deviation diff.	6.87	8.27	6.79	7.36	7.10
	95% CI of difference	0.90, 3.50	-1.88, 5.28	1.69, 4.64	-1.71, 2.56	0.90, 3.33
Substituting specifically manufactured low fat foods (max. possible score = 18)	No. of participants, n	108	23	84	46	131
	Baseline mean (SD)	11.01 (2.87)	12.28 (2.99)	11.62 (2.65)	10.56 (3.31)	11.24 (2.92)
	6-month mean (SD)	10.43 (2.74)	11.74 (3.51)	10.60 (2.76)	10.72 (3.25)	10.66 (2.92)
	Mean difference	0.59*	0.54	1.02***	-0.16	0.58*
	Std. deviation diff.	2.62	3.33	2.71	2.67	2.74
	95% CI of difference	0.09, 1.09	-0.90, 1.98	0.43, 1.60	-0.95, 0.63	0.11, 1.05
Avoiding fat as a flavouring (max. possible score = 9)	No. of participants, n	107	21	82	45	128
	Baseline mean (SD)	5.78 (1.69)	5.81 (1.72)	5.73 (1.60)	5.86 (1.88)	5.78 (1.69)
	6-month mean (SD)	5.64 (1.69)	5.57 (1.44)	5.56 (1.63)	5.73 (1.69)	5.63 (1.64)
	Mean difference	0.14	0.24	0.16	0.12	0.16
	Std. deviation diff.	1.76	2.07	1.82	1.82	1.81
	95% CI of difference	-0.20, 0.48	-0.70, 1.18	-0.24, 0.57	-0.42, 0.67	-0.16, 0.47
Modifying meats to be low in fat	No. of participants, n	107	19	80	45	126
	Baseline mean (SD)	7.57 (2.56)	7.55 (1.95)	7.55 (2.56)	7.53 (2.30)	7.57 (2.47)
	6-month mean (SD)	7.13 (2.00)	7.68 (2.38)	7.19 (2.23)	7.20 (1.73)	7.21 (2.06)

(max. possible score = 15)	Mean difference	0.44*	-0.13	0.36	0.34	0.36*
	Std. deviation diff.	1.84	1.81	1.85	1.86	1.84
	95% CI of difference	0.09, 0.80	-1.00, 0.74	-0.05, 0.77	-0.22, 0.89	0.03, 0.68
Replacing high fat meats with low fat alternatives (max. possible score = 9)	No. of participants, n	81	20	67	34	101
	Baseline mean (SD)	6.48 (1.40)	5.55 (1.62)	6.45 (1.35)	5.99 (1.70)	6.29 (1.49)
	6-month mean (SD)	6.27 (1.17)	6.15 (1.53)	6.23 (1.28)	6.26 (1.19)	6.24 (1.24)
	Mean difference	0.21	-0.60	0.22	-0.28	0.05
	Std. deviation diff.	1.29	1.68	1.50	1.17	1.41
	95% CI of difference	-0.08, 0.50	-1.39, 0.19	-0.15, 0.58	-0.69, 0.13	-0.23, 0.33
Eating fruit and vegetables (max. possible score = 15)	No. of participants, n	109	22	83	47	131
	Baseline mean (SD)	7.85 (1.87)	9.41 (2.36)	8.10 (2.08)	8.16 (2.01)	8.11 (2.04)
	6-month mean (SD)	7.59 (1.73)	8.92 (2.68)	7.68 (2.00)	8.08 (1.93)	7.81 (1.97)
	Mean difference	0.26	0.49	0.42*	0.08	0.30
	Std. deviation diff.	1.82	2.21	1.86	1.93	1.88
	95% CI of difference	-0.08, 0.61	-0.49, 1.47	0.01, 0.82	-0.48, 0.65	-0.02, 0.63
Choosing high-fibre foods (max. possible score = 15) [§]	No. of participants, n	109	20	82	46	129
	Baseline mean (SD)	10.62 (2.94)	11.54 (3.04)	11.03 (2.75)	10.39 (3.26)	10.76 (2.96)
	6-month mean (SD)	9.62 (2.85)	11.18 (2.36)	9.60 (2.65)	10.34 (3.12)	9.86 (2.83)
	Mean difference	1.01***	0.38	1.43***	0.04	0.91***
	Std. deviation diff.	3.01	2.55	2.47	3.48	2.94
	95% CI of difference	0.43, 1.58	-0.83, 1.56	0.89, 1.98	-0.99, 1.08	0.39, 1.42

*p<0.05; **p<0.01; ***p≤0.001

[§]Merges sub-categories of 'cereals and grains' and 'substitute low-fibre foods for high-fibre foods'

For diet measures, a lower score indicates healthier diet choices reported. Changes in overall self-reported dietary behaviour at T2 were only significant for Westbank participants and for participants with pre-diabetes. Sub-categories that did not show any significant improvements overall and across sub-groups were 'avoiding fat as a flavouring' and 'replacing high fat meats with low fat alternatives'. Only participants with pre-diabetes made a significant improvement in the 'eating fruit and vegetables' sub-category.

f) Changes in general health, mental health, and mental wellbeing, from T0 to T2

This section draws upon the following measures:

- General Health State
- Overall Life Satisfaction
- Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)
- Anxiety, EQ-5D
- Depression, CESD-7

		Westbank	Health Exchange	Pre-diabetes	Diabetes	Overall
General health state (on a scale of 0-100)	No. of participants, n	95	37	87	44	132
	Baseline mean (SD)	74.67 (18.80)	70.46 (22.68)	73.59 (20.19)	73.02 (19.89)	73.49 (19.97)
	6-month mean (SD)	77.71 (17.88)	77.70 (22.45)	78.99 (17.63)	74.77 (21.93)	77.70 (19.19)
	Mean difference	-3.03	-7.24*	-5.40**	-1.75	-4.21**

	Std. deviation diff.	17.69	16.88	18.55	15.35	17.51
	95% CI of difference	-6.64, 0.57	-12.87, -1.61	-9.36, -1.45	-6.42, 2.92	-7.23, -1.20
SWEMWBS (max. possible score = 35)	No. of participants, n	106	42	93	54	148
	Baseline mean (SD)	26.94 (4.85)	27.30 (6.44)	27.73 (4.76)	25.94 (6.08)	27.04 (5.33)
	6-month mean (SD)	28.01 (4.53)	29.01 (6.47)	28.45 (4.80)	28.02 (5.79)	28.29 (5.15)
	Mean difference	-1.07**	-1.71	-0.73	-2.08*	-1.25**
	Std. deviation diff.	3.73	7.83	4.33	6.42	5.21
	95% CI of difference	-1.79, -0.35	-4.15, 0.73	-1.62, 0.17	-3.84, -0.33	-2.10, -0.40
Pain or discomfort (score of 0 or 1)	No. of participants, n	111	43	95	58	154
	Baseline mean (SD)	0.48 (0.50)	0.53 (0.51)	0.45 (0.50)	0.55 (0.50)	0.49 (0.50)
	6-month mean (SD)	0.39 (0.49)	0.35 (0.48)	0.38 (0.49)	0.38 (0.49)	0.38 (0.49)
	Mean difference	0.09*	0.19**	0.07	0.17**	0.12***
	Std. deviation diff.	0.42	0.45	0.42	0.43	0.43
	95% CI of difference	0.01, 0.17	0.05, 0.33	-0.01, 0.16	0.06, 0.28	0.05, 0.19
Anxiety (score of 0 or 1)	No. of participants, n	112	43	93	61	155
	Baseline mean (SD)	0.32 (0.47)	0.28 (0.45)	0.27 (0.45)	0.38 (0.49)	0.31 (0.46)
	6-month mean (SD)	0.27 (0.45)	0.16 (0.37)	0.20 (0.41)	0.30 (0.46)	0.24 (0.43)
	Mean difference	0.05	0.12	0.07	0.08	0.07*
	Std. deviation diff.	0.42	0.39	0.36	0.49	0.41
	95% CI of difference	-0.03, 0.13	-0.004, 0.24	-0.01, 0.14	-0.04, 0.21	0.01, 0.14
Depression (max. possible score = 30)	No. of participants, n	107	40	93	53	147
	Baseline mean (SD)	14.21 (4.78)	14.75 (4.57)	14.04 (4.64)	14.98 (4.85)	14.36 (4.72)
	6-month mean (SD)	13.24 (4.31)	13.39 (4.43)	13.15 (4.36)	13.43 (4.31)	13.28 (4.33)
	Mean difference	0.97**	1.36*	0.89*	1.54**	1.08***
	Std. deviation diff.	3.77	4.05	3.68	4.02	3.84
	95% CI of difference	0.25, 1.69	0.07, 2.66	0.13, 1.65	0.43, 2.65	0.45, 1.70
*p<0.05; **p<0.01; ***p<0.001						

For self-reported measures of general health state, and mental wellbeing (SWEMWBS), the desired outcome is a higher score, whereas for measures of pain or discomfort, anxiety and depression, the desired outcome is a lower score. Results show that, at T2, there were significant positive changes for all the above measures for the overall LWTC programme participant population. Comparisons across sub-groups of delivery site and diagnosis suggest that although the programme significantly improved depression, it did not significantly improve anxiety ($p>0.05$).

Both delivery sites showed significant reductions in pain or discomfort. Westbank had a significant improvement in wellbeing ($p<0.01$) compared to Health Exchange ($p>0.05$), while the reverse was observed for general health state ($p>0.05$ and $p<0.05$, respectively). Participants with pre-diabetes had a significant improvement in general health state ($p<0.01$), while participants with diabetes had significant improvements in wellbeing, and pain or discomfort ($p<0.05$ and $p<0.01$, respectively). There were no significant differences between T0 and T2 for overall life satisfaction, mobility problems, self-care problems, and problems with usual activities, for the overall participant population and across sub-groups ($p>0.05$), and are therefore not reported in the table above.

8.6 Association between demographics and changes in mean weight and HbA1c, at T1 and T2

This section reports on the relationship between the demographic characteristics of participants and the programme outcome measures of changes in mean weight and HbA1c.

a) Gender

		Baseline to Month 6		Baseline to Month 12	
		Weight (kg)	HbA1c (mmol/mol)	Weight (kg)	HbA1c (mmol/mol)
Male	No. of participants, n	135	114	62	57
	Baseline mean (SD)	90.33 (17.17)	45.65 (5.94)	89.67 (17.41)	46.69 (7.13)
	Follow-up mean (SD)	88.85 (17.29)	42.74 (6.99)	88.68 (18.32)	41.78 (5.18)
	Mean difference	1.48***	2.91***	0.98*	4.92***
	Std. deviation diff.	4.54	7.32	3.37	7.11
	95% CI of difference	0.71, 2.26	1.55, 4.27	0.13, 1.84	3.03, 6.80
Female	No. of participants, n	237	185	103	93
	Baseline mean (SD)	79.96 (16.20)	45.78 (8.97)	78.07 (15.59)	46.98 (9.86)
	Follow-up mean (SD)	78.16 (16.43)	42.62 (5.93)	76.09 (15.77)	42.00 (4.95)
	Mean difference	1.80***	3.16***	1.98***	4.98***
	Std. deviation diff.	3.82	7.32	4.62	8.91
	95% CI of difference	1.31, 2.29	2.09, 4.22	1.08, 2.88	3.15, 6.82

*p<0.05; **p≤0.01; ***p≤0.001

Although the table above suggests that women had greater reductions in mean weight and HbA1c than men, independent-samples t-tests found that the differences observed between genders were not statistically significant at T1 and T2 (p>0.05).

b) Ethnicity

		Baseline to Month 6		Baseline to Month 12	
		Weight (kg)	HbA1c (mmol/mol)	Weight (kg)	HbA1c (mmol/mol)
'White'	No. of participants, n	250	201	119	109
	Baseline mean (SD)	84.67 (17.64)	45.54 (45.54)	82.53 (18.12)	46.69 (8.95)
	Follow-up mean (SD)	82.58 (17.82)	41.67 (41.67)	80.57 (18.69)	41.00 (4.40)
	Mean difference	2.09***	3.87***	1.96***	5.69***
	Std. deviation diff.	3.84	8.11	4.18	8.11
	95% CI of difference	1.62, 2.57	2.74, 5.00	1.20, 2.72	4.15, 7.23
'BME'	No. of participants, n	113	92	40	36
	Baseline mean (SD)	82.34 (16.56)	46.38 (8.21)	82.76 (14.99)	48.09 (9.15)
	Follow-up mean (SD)	81.70 (16.94)	44.85 (7.02)	82.35 (15.64)	44.89 (5.87)
	Mean difference	0.64	1.43**	0.40	3.21*
	Std. deviation diff.	4.52	5.06	4.37	8.78
	95% CI of difference	-0.21, 1.48	0.39, 2.48	-1.00, 1.80	0.23, 6.18

*p<0.05; **p≤0.01; ***p≤0.001

The table above shows that 'White' participants had greater reductions in mean weight and HbA1c than 'BME' participants. Independent-samples t-tests found that the differences in weight loss between ethnicities were statistically significant at both T1 ($p < 0.01$) and T2 ($p < 0.05$). However, the differences in HbA1c reduction between ethnicities were only statistically significant at T1 ($p < 0.01$).

c) Employment category

		Baseline to Month 6		Baseline to Month 12	
		Weight (kg)	HbA1c (mmol/mol)	Weight (kg)	HbA1c (mmol/mol)
Employed	No. of participants, n	98	84	52	49
	Baseline mean (SD)	89.32 (18.77)	45.47 (8.65)	86.54 (18.67)	46.66 (9.69)
	Follow-up mean (SD)	88.04 (19.24)	41.71 (4.61)	84.99 (20.57)	41.55 (4.64)
	Mean difference	1.28**	3.76***	1.54**	5.10***
	Std. deviation diff.	4.18	7.06	4.09	8.57
	95% CI of difference	0.45, 2.12	2.23, 5.29	0.40, 2.68	2.64, 7.56
Unemployed	No. of participants, n	238	185	96	88
	Baseline mean (SD)	82.28 (16.71)	46.03 (8.14)	81.71 (16.84)	47.07 (8.19)
	Follow-up mean (SD)	80.41 (16.52)	43.01 (7.19)	80.07 (16.58)	42.32 (5.35)
	Mean difference	1.86***	3.03***	1.64***	4.75***
	Std. deviation diff.	3.97	7.82	4.51	7.92
	95% CI of difference	1.36, 2.37	1.89, 4.16	0.73, 2.56	3.07, 6.43

* $p < 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$

The differences in weight and HbA1c reductions observed between employed and unemployed participants were not statistically significant ($p > 0.05$) at T1 and T2.

d) Education level

		Baseline to Month 6		Baseline to Month 12	
		Weight (kg)	HbA1c (mmol/mol)	Weight (kg)	HbA1c (mmol/mol)
Low-to-intermediate	No. of participants, n	175	134	63	56
	Baseline mean (SD)	85.62 (16.48)	44.96 (8.16)	83.31 (17.55)	46.17 (1.34)
	Follow-up mean (SD)	83.80 (16.39)	41.85 (4.79)	80.68 (17.89)	41.61 (5.11)
	Mean difference	1.82***	3.11***	2.63***	4.56***
	Std. deviation diff.	3.87	7.25	4.23	9.41
	95% CI of difference	1.24, 2.39	1.87, 4.35	1.56, 3.69	2.04, 7.08
High	No. of participants, n	45	36	19	18
	Baseline mean (SD)	81.82 (18.30)	44.34 (4.44)	81.52 (14.74)	44.80 (5.57)
	Follow-up mean (SD)	80.14 (18.70)	43.38 (10.12)	80.12 (16.85)	41.28 (4.00)
	Mean difference	1.68*	0.97	1.40	3.52**
	Std. deviation diff.	5.05	10.15	4.10	4.59
	95% CI of difference	0.17, 3.20	-2.47, 4.40	-0.58, 3.38	1.24, 5.80

* $p < 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$

The differences in weight and HbA1c reductions observed between participants with low-to-intermediate levels of education and participants with a high level of education were not statistically significant ($p>0.05$) at T1 and T2.

e) Index of Multiple Deprivation (IMD)

		Baseline to Month 6		Baseline to Month 12	
		Weight (kg)	HbA1c (mmol/mol)	Weight (kg)	HbA1c (mmol/mol)
IMD deciles 1-5 (high deprivation)	No. of participants, n	213	165	87	82
	Baseline mean (SD)	83.68 (17.10)	46.59 (8.34)	83.60 (15.80)	47.01 (8.85)
	Follow-up mean (SD)	82.48 (17.24)	43.40 (6.34)	82.80 (16.32)	42.59 (5.18)
	Mean difference	1.21***	3.19***	0.80	4.42***
	Std. deviation diff.	3.51	6.95	3.98	8.66
95% CI of difference		0.73, 1.68	2.12, 4.26	-0.05, 1.65	2.52, 6.33
IMD deciles 6-10 (low deprivation)	No. of participants, n	117	98	71	62
	Baseline mean (SD)	81.90 (17.10)	46.11 (7.59)	80.77 (18.00)	46.76 (9.20)
	Follow-up mean (SD)	79.60 (17.20)	41.71 (3.88)	78.24 (18.63)	41.23 (4.73)
	Mean difference	2.30***	4.40***	2.54***	5.53***
	Std. deviation diff.	3.88	6.46	4.43	8.02
95% CI of difference		1.59, 3.01	3.10, 5.69	1.49, 3.59	3.50, 7.57

* $p<0.05$; ** $p\leq 0.01$; *** $p\leq 0.001$

Results show that participants from less deprived areas had greater weight loss compared to participants from more deprived areas, at both time points. Independent-samples t-tests found that the differences in weight loss between participants from areas of high and low deprivation were statistically significant at both T1 ($p=0.01$) and T2 ($p<0.05$). However, the differences in HbA1c reduction between the two groups were not statistically significant at either time point ($p>0.05$).

8.7 Association between contact time and programme outcomes, at T1 and T2

This section examines the association between contact time and the following programme outcomes, at T1 and T2:

- Changes in mean weight and HbA1c measures at six and 12 months
- Changes in physical activity measures
- Changes in diet measures
- Changes in selected psychological measures

Contact time was used as a measure of exposure to the programme (or ‘programme dose’). All participants were expected to have had a minimum of six months follow-up post-enrolment, which is estimated to be equivalent to at least eight hours and up to 12 hours of contact time. Participants who continued on the programme beyond six months are estimated to have had more than 12 hours contact time – adjustments have been made to take into account the cut-off date of April 2015, and that not all participants would have been able to reach the 12-month time point.

Effect size statistics was interpreted using guidelines proposed by Cohen (1988, pp. 284-7):

0.01 = small effect

0.06 = moderate effect

0.14 = large effect

a) Changes in mean weight and HbA1c

Contact time throughout programme (hours)		Baseline to Month 6		Baseline to Month 12	
		Weight (kg)	HbA1c (mmol/mol)	Weight (kg)	HbA1c (mmol/mol)
8 ≥ contact hours ≤ 12	No. of participants, n	240	179	56	49
	Baseline mean (SD)	83.67 (16.93)	45.50 (6.96)	82.15 (17.16)	45.49 (4.76)
	Follow-up mean (SD)	82.00 (17.26)	43.50 (7.51)	81.18 (17.82)	42.20 (4.22)
	Mean difference	1.67***	2.00***	0.97	3.29***
	Std. deviation diff.	4.06	5.98	3.98	4.23
	95% CI of difference	1.15, 2.18	1.12, 2.88	-0.10, 2.03	2.07, 4.50
> 12 contact hours	No. of participants, n	109	102	100	93
	Baseline mean (SD)	83.83 (17.54)	47.20 (9.49)	82.66 (17.58)	47.41 (9.86)
	Follow-up mean (SD)	81.61 (17.50)	41.65 (3.81)	80.75 (18.15)	41.77 (5.31)
	Mean difference	2.22***	5.55***	1.91***	5.64***
	Std. deviation diff.	3.58	9.15	4.40	9.33
	95% CI of difference	1.54, 2.90	3.75, 7.34	1.03, 2.78	3.72, 7.57

*p<0.05; **p≤0.01; ***p≤0.001

A post-hoc/exploratory analysis for the outcome of weight loss using independent-samples t-tests found that the differences observed between participants with 8-12 contact hours and those with more than 12 contact hours were not statistically significant at T1 and T2 ($p > 0.05$). The difference between the two groups for HbA1c reduction at T2 was also not significant ($p > 0.05$). The only significant difference was for HbA1c reduction at T1 ($p = 0.001$), whereby participants with more than 12 contact hours lost a mean of 3.55mmol/mol (95% CI: 1.55, 5.54) more than participants who had 8-12 contact hours. The magnitude of this difference was small (eta squared = 0.042).

b) Changes in physical activity measures

Independent-samples t-tests were conducted to compare the number of minutes per week of moderate-to-vigorous physical activity (MVPA) for participants with 8-12 contact hours and those with more than 12 contact hours. There were no significant differences in mean number of minutes per week of MVPA for the two groups at both T1 ($t(155) = 0.82, p = 0.41$), and T2 ($t(70) = 1.20, p = 0.23$).

c) Changes in diet measures

For diet measures, a lower score indicates healthier diet choices reported. Independent-samples t-tests were conducted to compare the overall reported diet behaviour scores for participants with 8-12 contact hours and those with more than 12 contact hours. There was a significant difference in T1 mean scores for participants with 8-12 contact hours ($n = 178, M = 3.00, SD = 7.65$) and those with more than 12 contact hours ($n = 85, M = -0.17, SD = 7.16; t(261) = 3.21, p = 0.001$), but the magnitude of the difference (mean difference = 3.17, 95% CI: 1.23, 5.12) was small (eta squared = 0.038). There was no significant difference in mean scores for the two groups at T2 ($p > 0.05$).

Subsequently, independent-samples t-tests were conducted to compare the scores for sub-categories of diet, for the two groups. There were significant differences in mean scores between participants with 8-12 contact hours and those with more than 12 contact hours at T1, but not at T2. The significant differences at T1 were in the following sub-categories:

- **Modifying meats to be low in fat**
Participants with 8-12 contact hours (n = 171, M = 0.65, SD = 1.82) compared to those with more than 12 contact hours (n = 80, M = -0.07, SD = 1.94; t (249) = 2.86, p <0.01); effect size is small (mean difference = 0.72, 95% CI: 0.22, 1.22, eta squared = 0.032)
- **Eating fruit and vegetables**
Participants with 8-12 contact hours (n = 174, M = 0.46, SD = 2.17) compared to those with more than 12 contact hours (n = 82, M = -0.02, SD = 1.54; t (215.57) = 2.01, p <0.05); effect size is very small (mean difference = 0.48, 95% CI: 0.01, 0.94, eta squared = 0.012)

For the three diet measures described above, where significant differences were observed, participants with 8-12 contact hours scored lower at T1 compared to T0, indicating healthier diet choices. By contrast, participants with more than 12 contact hours scored slightly higher at T1 compared to T0, indicating less healthy diet choices, although the number of participants in this group was approximately half the number in the comparator group – thus, results should be interpreted with caution.

d) Changes in selected psychological measures

Independent-samples t-tests were conducted to compare between participants with 8-12 contact hours and those with more than 12 contact hours, for changes in the following psychological measures:

- General health state
- Overall life satisfaction
- Mental wellbeing (SWEMWBS)
- Anxiety, EQ-5D
- Depression, CESD-7

There were no significant differences in scores for the two groups for all the above measures, at both T1 and T2 (p>0.05).

8.8 Association between participant motivations and programme outcomes, at T1 and T2

Participants’ motivations to change behaviour in terms of physical activity and diet choices were assessed based on two measures – importance and confidence. Participants who scored 0-5 were categorised as having ‘low’ motivation, while those who scored 6-10 were categorised as having ‘high’ motivation.

Participant motivations		Baseline	Month 6	Month 12
Importance	No. of participants, n	478	320	154
	% in ‘high’ category	93.9	94.7	96.8
	Mean score (SD)	8.24 (1.62)	8.31 (1.54)	8.39 (1.36)
Confidence	No. of participants, n	464	313	152
	% in ‘high’ category	81.3	83.4	85.5
	Mean score (SD)	7.15 (2.06)	7.22 (1.80)	7.43 (1.93)

Results show that at baseline, 93.9% of participants placed a high importance on behaviour change, while 81.3% had high confidence to make changes. Findings at T1 and T2 were similar. Due to the ceiling effect, comparisons could not be made to assess the association between participant motivations and programme outcomes.

8.9 Association between social identity and programme outcomes, at T1 and T2

Participants who responded to the social identity questionnaire were split into two groups – those who had a negative experience and those who had a positive experience; participants who gave a ‘neutral’ response were not included in the analysis. Results show that 85.8% of participants had a positive experience of social support, while 91.8% had a positive experience of social identification within the LWTC programme. Due to the ceiling effect, comparisons could not be made to assess the association between social support and social identification with programme outcomes.

The split in the proportion of participants with positive versus negative experiences of social networks outside of LWTC was more balanced – 57.8% vs 42.2%, respectively. However, analysis using independent-samples t-tests found that the differences observed between these two groups for weight loss and HbA1c reduction were not statistically significant at T1 and T2 ($p>0.05$).

8.10 Association between practice effects and changes in mean weight and HbA1c, at T1

Participants were split into two groups – those who entered the programme approximately in the first eight months (28 November 2013 to 7 August 2014) were considered ‘early entrants’ (baseline, $n = 408$), while those who entered the programme in the last eight months (9 August 2014 to 7 April 2015) were considered ‘late entrants’ (baseline, $n = 403$). Practice effects were not tested for changes at T2 since data was only available for 20 matched pairs of late entrants.

		Early entrants	Late entrants
Weight (kg)	No. of participants, n	196	176
	Baseline mean (SD)	83.04 (18.30)	84.49 (16.07)
	6-month mean (SD)	81.56 (18.49)	82.58 (16.35)
	Mean difference	1.48***	1.91***
	Std. deviation diff.	3.60	4.58
	95% CI of difference	0.98, 1.99	1.23, 2.59
HbA1c (mmol/mol)	No. of participants, n	172	127
	Baseline mean (SD)	46.79 (9.16)	44.29 (5.62)
	6-month mean (SD)	42.30 (6.18)	43.16 (6.54)
	Mean difference	4.49***	1.13*
	Std. deviation diff.	7.66	6.36
	95% CI of difference	3.34, 5.64	0.01, 2.25
* $p<0.05$; ** $p\leq 0.01$; *** $p\leq 0.001$			

A post-hoc/exploratory analysis using independent-samples t-tests found that the difference observed between early and late entrants for HbA1c reduction was statistically significant at T1 ($t(297) = 4.03$, $p<0.001$). The magnitude of the difference (mean difference = 3.36, 95% CI: 1.72, 5.00) was small (eta squared = 0.052). This might be a reflection of a change in HbA1c measurement methods – early entrants relied on GP records, whilst late entrants were measured via point of care testing machines. The difference observed between early and late entrants for weight loss was not statistically significant ($p>0.05$).

8.11 Modelling moderators of weight at T1

Stepwise multiple regression was used to assess the ability of demographic factors to predict weight change at T1. The independent demographic variables entered were age, gender, ethnicity, employment status, level

of education, and IMD for area lived in. Results show that ethnicity was the single best predictor of weight change at T1, accounting for 2.7% of the variance, $F(1, 218) = 6.05, p < 0.05$. None of the other demographic factors predicted weight change.

Backward stepwise regression was then used to assess the ability of two control measures – ethnicity and delivery site, to predict weight change at T1. Step 1 had both variables, while Step 2 had only ethnicity. Results show that the difference in the R-square between Step 1 and Step 2 was small ($= 0.002$), which is expected since ethnicity and delivery site were very similar measures in this study – 95.5% of Westbank participants were ‘White’, while 63.9% of Health Exchange participants were ‘BME’. Both control measures were significant predictors of weight change ($F(2, 360) = 5.29, p < 0.01$), with Step 1 explaining an additional 0.2% of the variance in weight change compared to Step 2.

Subsequently, stepwise multiple regression was used to assess the ability of the following factors to predict weight change at T1: ethnicity, delivery site, programme contact time, practice effects, co-morbidities, and prior and/or concurrent engagement with other healthy lifestyle activities. Results (see tables below), again, show that ethnicity was the single best predictor of weight change at T1, accounting for 2.7% of the variance, $F(1, 308) = 8.55, p < 0.01$. Programme contact time was the next best predictor – along with ethnicity, it explained an additional 1.7% of the variance in weight change ($F(2, 307) = 6.99, p = 0.001$). The other four factors were not predictors of weight change.

Multiple regression model summary^c

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	0.164 ^a	0.027	0.024	4.04583	0.027	8.549	1	308	.004
2	0.209 ^b	0.044	0.037	4.01776	0.017	5.319	1	307	.022

a. Predictors: (Constant), Ethnicity

b. Predictors: (Constant), Ethnicity, Programme contact time

c. Dependent Variable: Weight change at T1

ANOVA^a

Model		Sum of Squares	df	Mean Square	F	p-value
1	Regression	139.943	1	139.943	8.549	0.004 ^b
	Residual	5041.576	308	16.369		
	Total	5181.520	309			
2	Regression	225.806	2	112.903	6.994	0.001 ^c
	Residual	4955.714	307	16.142		
	Total	5181.520	309			

a. Dependent Variable: 6 month weight minus baseline weight

b. Predictors: (Constant), Race - White or BME

c. Predictors: (Constant), Race - White or BME, Total contact time in hours

The final modelling procedure was a direct logistic regression to assess the impact of ethnicity and programme contact time on the likelihood that participants would achieve the MCID of 2kg weight loss at T1. These two control measures were chosen based on the outcome of the preceding stepwise multiple regression analysis. The full logistic regression model containing both predictors was statistically significant, $\chi^2(2, N=363) = 17.35, p < 0.001$. The model as a whole explained between 4.7% (Cox and Snell R square) and 6.3% (Nagelkerke R squared) of the variance in achieving the MCID weight loss. As shown in the table below, both variables made a uniquely statistically significant contribution to the model. As expected, the strongest predictor of achieving

the MCID weight loss was ethnicity, recording an inverted odds ratio of 2.03 ($p < 0.01$), suggesting that, at T1, 'White' participants were twice as likely to lose at least 2kg of weight compared to 'BME' participants. The odds ratio of 1.16 for programme contact time suggests that participants who had more contact time throughout the programme were 1.16 times more likely to achieve at least 2kg weight loss at T1.

Logistic regression predicting the likelihood of achieving the MCID weight loss

		B	S.E.	Wald	df	p-value	Odds Ratio	95% C.I. for Odds Ratio	
								Lower	Upper
Step 1 ^a	Ethnicity	-0.709	0.243	8.514	1	0.004	0.492	0.305	0.792
	Programme contact time	0.146	0.053	7.653	1	0.006	1.158	1.044	1.284
	Constant	-1.751	0.603	8.421	1	0.004	0.174		

a. Variable(s) entered on step 1: Ethnicity, Programme contact time

9. Discussion

9.1 Overview

This study sought to develop an understanding of the impact of participation in Living Well, Taking Control on diabetes risk reduction and management, and the role of potential mechanisms and other factors that might lead to change. The evaluation drew upon a set of measures developed for the evaluation of diabetes prevention and management programmes along with additional measures previously used in community-based lifestyle change programmes. Data collection was largely managed by the programme delivery teams, with support from the evaluation team. The evaluation relied on pre-post data collection from participants, with additional single point measures and programme contact records providing supplementary evidence on the process of programme delivery.

9.1.1 The characteristics of the programme population

We received data from a total of 811 participants over a period between November 2013 and October 2015 from two programme delivery sites in Devon and the West Midlands. Approximately a quarter of people who received GP practice invitation letters were eligible and interested in taking up the programme. The use of GP patient records systems appears to be a successful method for targeting and recruiting people that met the programme criteria for eligibility. Given the continuum between diabetes and high risk of diabetes, and that individuals may move in and out of these groups over time, LWTC's recruitment process represents a pragmatic approach to case identification at a population level. Reliance on GP records did have some difficulties, including old and anomalous HbA1c records and the inconsistent take-up of Health Check-based data collection at GP surgeries. Overall, the high number of eligible patients identified through GP records re-affirms the scale of the problem of diabetes and diabetes risk.

The mean age of participants was 61 years. Females were more likely than males to enrol on the programme: 60.5% were female, which is similar to the mean found in Dunkley *et al.*'s (2014) meta-analysis of 'real-world' diabetes prevention programmes. Over 43% of the participants were retired. Fifty eight per cent had at least one form of other long-term health condition. Participants tended to be from areas of higher deprivation, with almost one third (32.6%) of participants resident in the highest IMD decile. About four in five participants did not have a higher education degree. Notably at the Health Exchange site, 64% of participants were from a Black and Minority Ethnic background, most of whom defined themselves as (South) Asian/Asian British. These data indicate that the LWTC programme successfully reached groups that have health problems (additional to IGR), are less likely to access health information and services, and are likely to experience social barriers to achieving a healthy lifestyle.

9.12 Patterns of participation in the programme

The mean attendance at the four group sessions was quite high (87.2%) for both programme sites. Participants reported a high level of satisfaction with group sessions, with 99% stating that they had benefited, and 98.6% stating that it had met their needs. Contacts dropped off in the period following the group sessions until Month 12. Recorded contacts at the Westbank site were consistently higher at each stage of the programme than at the Health Exchange site so, for example, at Month 12 follow-up, successful contacts were made with 47.4% of participants by Westbank and 20.5% by Health Exchange. It is possible that records of Month 12 contacts represent a conservative figure for later entrants, given that programme staff had not stopped seeking to make contact at the point at which we finished collecting the data from projects, and also that there may have been delays in updating participant records.

The overall pattern of declining contacts over time is similar to that experienced by other community-based healthy lifestyle programmes (e.g. Jones *et al.*, 2014). It might also reflect the high allocation of programme resources to initial recruitment and the delivery of group sessions – as opposed to the follow-up period between months 2 and 12. There was little evidence that certain demographic groups were less likely to engage with the programme over time. There were differences in contacts based upon diabetes diagnostic status: at Month 12 follow-up, 26.5% of participants with pre-diabetes had some form of contact, compared to 39.7% of participants with diabetes. We do not have complete records on the reasons why individuals dropped out of the programme or, more precisely, did not respond to contact attempts. However, practitioner notes indicate that there was a mixture of circumstances, including cases where individuals withdrew after having met their personal goals, and cases where others withdrew having *not* met their goals.

9.13 Programme performance in terms of weight loss, and change in lifestyle behaviours

For weight loss and most associated measures (BMI, waist circumference) LWTC participants regardless of diagnosis achieved statistically significant improvements at six-month and 12-month measurement points.

At Month 6 about 42% of respondents had lost 2kg in weight. Expressed as thresholds, approximately one third of total programme participants achieved at least 3% weight loss, a fifth achieved at least 5% weight loss, and very small numbers achieved at least 10% weight loss. This pattern was similar at Month 12, for example, with about 44% of respondents losing 2kg in weight, although we have no basis for assessing changes for the higher number of non-respondents at this point.

The results for measures of HbA1c appeared to be very positive. Participants with an HbA1c diabetes diagnosis at baseline dropped to the pre-diabetes range at follow-ups: from 52.36mmol/mol at enrolment to 45.52mmol/mol at Month 6, and 45.00mmol/mol at Month 12. Participants with an HbA1c pre-diabetes diagnosis dropped to within the normal range at follow-ups: from 42.92mmol/mol at enrolment to 41.46mmol/mol at Month 6, and 39.80mmol/mol at Month 12. However, it is important to interpret these figures with some caution. There are potential issues with the validity and reliability of the HbA1c measurements that are being explored further in the ComPoD trial. Furthermore, the larger drop in mean HbA1c readings for participants with diabetes is likely to be attributed to natural variation rather than the programme.

Weight loss and HbA1c reductions were, in the main, closely paralleled by changes in the secondary outcome measures. Overall, there were statistically significant positive changes in general health state, overall life satisfaction, mental wellbeing, anxiety and depression, and self-reported diet at both Month 6 and Month 12. However changes in self-reported physical activity were not statistically significant at either measurement point.

9.14 Programme exposure and outcomes

NICE Guidance advises that participants attending diabetes intensive lifestyle interventions should have at least 16 hours contact time. The format of LWTC involves 13.5 hours of group and one-to-one contact times, plus five or more hours contact with services delivered by partner agencies. Over the course of the whole programme, LWTC recorded a mean of 9.1 hours contact time. This figure is likely to be an underestimate given that project records had incomplete feedback on the take-up of services (the five hours of supplementary contact) delivered by partner agencies. Bearing in mind this incomplete picture, we sought to analyse the relationship between LWTC group and one-to-one recorded contact time and programme outcomes.

An analysis for the outcome of weight loss found that the differences observed between participants with 8-12 contact hours and those with more than 12 contact hours were not statistically significant at both six- and 12-month points. Similarly, the difference between the two groups for HbA1c reduction at Month 12 was also not significant. Programme 'dose' did not significantly influence physical activity levels, dietary behaviour, or psychological state. This is supported by the lack of influence of 'dose' on participant motivations towards increasing physical activity and healthier diet choices. We did not test the relationship between low contact time (under 8 hours) and outcomes at Months 6 and 12.

9.15 Practice effects and outcomes

One element of the evaluation was to examine the outcomes of the programme over time. Previously such 'practice effects' have not been widely tested elsewhere in evaluations of healthy lifestyle interventions. Within the evaluation time frame, there was no evidence that the programme obtained better results over the course of time. From the point of programme start-up, the rate of recruitment increased over an 18-month period. Later entrants – in other words those starting the programme in the last eight months of the evaluation period – were not more likely to lose weight or have a reduced HbA1C level, than those starting in the first eight months. Whilst we do not have a full picture, these findings indicate that the programme delivered similar outcome results over the course of the delivery period. The increased rate of throughput suggests that LWTC became increasingly streamlined and integrated alongside other local services.

9.16 Programme performance and delivery site

Participants at the Westbank site were more likely to obtain 2kg weight loss at Months 6 and 12 compared to those at Health Exchange. Westbank participants achieved a mean weight loss of 2.19kg at Month 6 and 2.13 at Month 12, whereas Health Exchange participants achieved 1.13kg weight loss at Month 6 and 0.37kg at Month 12. The pattern was similar for other behavioural changes including diet and psychological measures. A number of reasons are likely to account for these differences. The demographic profile of Health Exchange participants included greater proportions of participants from areas of higher multiple deprivation and BME backgrounds. Both of these are indicators of lower socio-economic position and inequalities in health, although the links between BME status and health inequalities are increasingly complex with changing demographic patterns in the UK's urban centres.

There was no direct evidence of differences in the acceptability of the programme at the two sites. Participant satisfaction feedback on the group elements of the programme was highly positive, and equally so, at both delivery sites. However, recorded contact time with the programme was higher at Westbank and, as discussed below, this was associated with more positive outcomes.

9.17 Modelling moderators of weight at six months

We sought to assess the role of potential key factors on weight loss at Month 6. Stepwise multiple regression found that ethnicity was the single best demographic predictor of weight change. None of the other demographic factors predicted weight change. Subsequent modelling found that delivery site and ethnicity acted as very similar measures in this study, with both acting as significant predictors of weight change. After

ethnicity and delivery site, programme contact time was the next best predictor of the main outcome. Three other factors – practice effects, co-morbidities, and concurrent lifestyle activities, were not predictors of weight change. The final stage of analysis, using stepwise multiple regression, found that ‘White’ participants were twice as likely to lose at least 2kg of weight compared to ‘BME’ participants. Participants who had more contact time throughout the programme were 1.16 times more likely to achieve at least 2kg weight loss.

9.2 Strengths and limitations of the study

9.21 Strengths

A major strength of this study is that it has developed as a close coordination between the routine recording, monitoring and evaluation activities of the programme team, and the evaluation contributions of external researchers with specialisms in public health, primary care, community engagement, behaviour change, and diabetes prevention and management. This enabled us to develop a practical and pragmatic approach to the evaluation process that made good use of available resources and sought to connect closely to service development and commissioning priorities. The evaluation was embedded into routine part of the programme to such an extent that the measurements and associated procedures were unlikely to influence outcomes.

An important aspect of the evaluation has been to make a contribution to research on real-world lifestyle interventions (Dunkley *et al.*, 2014). LWTC developed from a combination of local best practice and national guidance and, as such, was well placed to host a structured evaluation from the outset. The evaluation is based upon a real-world programme developed in response to local needs by third sector organisations. Few programmes of this type appear to be delivered outside the formal health sector. The evaluation has provided the opportunity to test out LWTC’s implementation in both rural and urban contexts, and in contexts of high social deprivation and ethnic diversity. The evaluation built upon standardised measurement tools and procedures, and a large dataset that tracked participant engagement with the programme. This provided a good platform from which to investigate several key research questions that are important both specifically to the programme teams and to those interested in improving community-based healthy lifestyle initiatives more widely. Finally, the evaluation sought to include all participants, rather than only a sub-set, involved in the programme over the study period.

9.22 Limitations

Within the constraints of the evaluation resources and the timing of the programme’s evolution, the evaluation was centred on a baseline and follow-up data collection from participants. This places limits on the learning to be derived from the research. It is not possible, for example, to determine what changes would occur for participants in the absence of the intervention. This is a key issue examined in the ComPoD trial on the LWTC programme.

Some further specific limitations are concerned with the comprehensiveness and quality of the data. We were able to standardise, support and check the collection of most data as part of a process led by the delivery teams. However, there are a number of instances of gaps and under-recording of data. The duration of the data collection period meant that we had quite a limited body of 12 months post-enrolment data, and this placed constraints on the scope of the analyses. High loss to follow-up at six- and 12-month data collection points means that caution is needed in the interpretation of the findings. However, similarities in the demographic profiles of baseline and follow-up groups suggest that the programme did not have problems keeping specific groups engaged. Higher retention and follow-up data returns make the interpretation of the findings more straightforward for the Devon site compared to those of the West Midlands site.

To date, it has been beyond the scope of the evaluation to fully analyse the full range of data collected. Some areas currently outstanding include the EQ-5D data that might underpin further cost-effectiveness analysis

(beyond that already undertaken as part of the SROI analysis), but which is planned for the ComPoD trial. We also have an incomplete understanding of the influence of co-morbidities, adverse health events, and health service usage on programme outcomes. Finally, we have not fully analysed the relationship between prior or concurrent participation in healthy lifestyle activities and the LWTC programme.

10. Conclusions and recommendations

10.1 Conclusions

The results presented in the current study suggest that participants who maintain contact and engagement with the LWTC programme are likely to achieve significant reductions in weight and other outcomes linked to reduced risk of Type 2 diabetes or improved management of Type 2 diabetes. Whilst factors such as demographic differences, motivational disposition and programme delivery characteristics are linked to the scale of effects, the findings suggest that the programme is associated with positive outcomes for diverse groups in a range of context. The group component, in particular, of the programme is well received by participants. LWTC offers innovative aspects that are of note to service developers, commissioners and policy makers. These include the twin track delivery of prevention and management services and partnership with other agencies delivering healthy lifestyle activities. These features present pragmatic opportunities to deliver modestly costed services that integrate well with other community and primary care services.

This evaluation forms one component in a programme of research and evaluation of diabetes prevention and management programme activity delivered by Westbank and Health Exchange. As further research evidence becomes available LWTC delivery agencies are in an excellent position to refine and enhance the programme. This is particularly the case given the important position that LWTC now holds with involvement that Westbank and Health Exchange in the delivery of the NDPP initiative.

10.2 Recommendations

There are a number of recommendations arising from this study. Some of those listed below incorporate learning from other aspects of the evaluation of the LWTC programme.

1. A recording system would be useful to allow LWTC practitioners to log non-responses to GP invitation letters and non-eligibility following assessment.
2. Given evidence of the importance of the role of motivations in positive outcomes, the programme might be re-designed to place greater emphasis on work with participants in this area.
3. A recording system would be useful to ensure that LWTC practitioners can use a consistent typology for logging attendance and reasons for non-contact with participants. This will help build a clearer picture of the causes for programme drop out and inform actions to support retention.
4. Given that contact is linked to outcomes, programme staff should be supported to engage participants especially in cases of missed sessions. Short informal communications may have a useful role in this respect.
5. With approximately 40% male engagement, LWTC performs well compared to other healthy lifestyle programmes in terms gender balance. However male engagement is an important area to continue as a focus for programme development, particularly because fewer males appear to achieve the programme outcomes.
6. The programme team should explore the role of session 4 on wellbeing as part of the wider programme. At one of the delivery sites, this session had a drop off in attendance.

7. The programme team might explore opportunities to space out the initial sessions over a period longer than four weeks in order to allow participants more time to absorb and rehearse learning.
8. LWTC would benefit from having better evidence regarding the role of additional community-based sessions. Take up of these sessions was under-recorded, in part due to the need for additional resources to track participation and maintain contacts with participants and delivery agencies.
9. Meanwhile, providers offering additional community-based sessions might review their services to more closely align with the goals of LWTC and those of similar programmes. This will support better partnerships between third sector/civil society activities and formal health services.
10. Adults not recorded as being at risk of diabetes, but with other long-term conditions, are likely to benefit from participation in LWTC through support to make healthy lifestyle changes. It would be useful to examine the potential of LWTC to have a generic core of relevance to a wider range of people with - or at risk of- long-term conditions (such as cardiovascular disease or overweight), alongside more specialist diabetes prevention and management components.
11. It would be useful to collect better records of participants' use of health services and medication. This would help external health stakeholders obtain a better understanding of the role of the programme in supporting their own service goals. This is an area that will be further addressed through the ComPoD trial.
12. The common measurement framework could be simplified to exclude measures that have been found to be unlikely to yield useful information. An example of a measure that could be removed is EuroQol EQ5D, because it is insufficiently sensitive to capture change for this relatively healthy population.
13. Westbank and Health Exchange have clearly developed a programme package that might be adopted or commissioned in other areas. To achieve these ends it is essential that lead agencies are supported to develop the programme materials and test their transferability to other contexts.

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Appendix 1. Common measurement framework

This section provides details of the core evaluation measures used at baseline (T0) and follow-up points (T1, T2). It includes notes on coding and methods for scoring where applicable.

Biometric information

Has the participant been diagnosed with diabetes or pre-diabetes?	(Diabetes =1, Pre-diabetes =2)
Date of diagnosis - diabetes or pre-diabetes (DD/MM/YYYY)	
Is the participant on insulin? (Yes / No)	(Yes = 1, No = 2)
Weight (Kg)	
Height (cm)	
Waist (cm)	
BMI (kg/m ²)	
Blood pressure (mmHg)	
HbA1c (mmol/mol or %) Date of HbA1c measurement (DD/MM/YYYY)	

Participant information

Title	
First name	
Family name	
Name known as	
Gender (please circle)	Male(1) / Female(2)
Date of birth (DD/MM/YYYY)	
Address	

Postcode	
Contact number	
Email	
Signature regarding consent statement	"I am happy for the information that I have given in this questionnaire to be used to evaluate and improve the activity [course or other term as appropriate]. I understand that any information I provide will be stored securely and kept confidential in line with the Data Protection Act 1998."
Date (DD/MM/YYYY)	
Race /Ethnicity (please circle) Please state on database whether you used short version (SV) or long version (LV).	<p>Short version: White(1) / Black or Black British(2) / Asian or Asian British(3) / Other (4) [please state] (Enter in separate column – free text)</p> <p>Long version: White – British(1) White – Irish(2) Any other White background(3) Mixed – White and Black Caribbean(4) Mixed – White and Black African(5) Mixed – White and Asian(6) Any other Mixed background(7) Asian or Asian British – Indian(8) Asian or Asian British – Pakistani(9) Asian or Asian British – Bangladeshi(10) Any other Asian background(11) Black or Black British – Caribbean(12) Black or Black British – African(13) Any other Black background(14) Chinese(15) Any other ethnic group(16) [please state] (Enter in separate column – free text)</p>
Employment status (please tick)	Employed(1) / Carer(2) / Retired(3) / Self-employed(4) / Student(5) / Unemployed(6) / Long-term sick or disabled(7) / Other(8) [please state] (Enter in separate column – free text) / Not disclosed(99)
What is the <u>highest</u> level of education that you have completed? (please tick the <u>highest level</u> you have completed)	Primary school(1) Some secondary school(2) Completed secondary school up to 16 years(3) Completed secondary school up to 18 years(4) Some additional training (apprenticeship, BTEC courses etc.)(5) Undergraduate university (degree)(6) Postgraduate university (masters degree or PhD)(7)
Long-term condition (please tick any that apply) Use separate columns for each long-term condition, with coding 1 for 'yes', 2 for 'no'	Chronic kidney disease(1) / Stroke(2) / Diabetes(3) / Pre-diabetes(4) / Coronary Heart Disease(5) / High Cholesterol(6) / Arthritis(7) / Mobility issues(8) / Other(9) [please state] (Enter in separate column – free text)

Do you smoke? (please tick) If yes, how many per day?	Yes(1) No(2) (Enter in separate column – number)
Do you have any disabilities? (please tick) If yes, please state.	Yes(1) No(2) (Enter in separate column – free text)
Are you taking part in any OTHER activity groups to support your health? (please tick any that apply) Do not include this project.	Exercise group(1) / weight management group(2)/ cooking group(3) / swimming group(4) / team sport(5) / yoga or relaxation group(6) / mental health support group(7) / Other(8) [please state] (Enter in separate column – free text) Use separate columns for each activity, with coding 1 for 'yes', 2 for 'no'.

Health

By placing a tick in each group below, please indicate which statements best describe your own health state today.

a) Mobility	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
I have no problems in walking about	(1)
I have some problems in walking about	(2)
b) Self care	<input checked="" type="checkbox"/>
I have no problems with self care	(1)
I have some problems washing or dressing myself	(2)
I am unable to wash or dress myself	(3)
c) Usual activities (e.g., work, study, housework, family, or leisure activities)	<input checked="" type="checkbox"/>
I have no problems with performing my usual activities	(1)
I have some problems with performing my usual activities	(2)
I am unable to perform my usual activities	(3)
d) Pain/discomfort	<input checked="" type="checkbox"/>
I have no pain or discomfort	(1)
I have moderate pain or discomfort	(2)

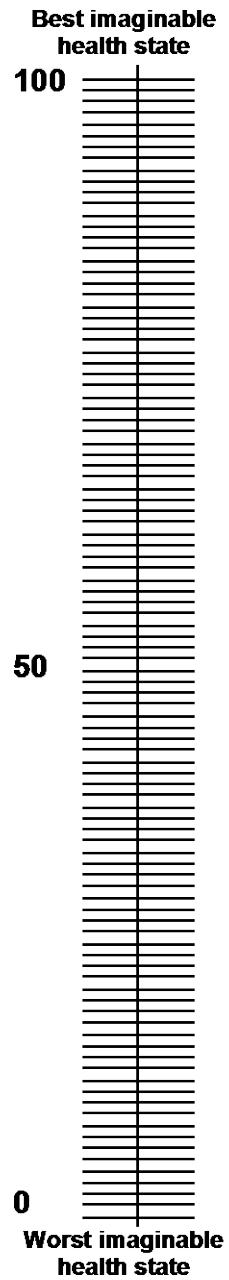
I have extreme pain or discomfort	(3)
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e) Anxiety/depression	✓
I am not anxious or depressed	(1)
I am moderately anxious or depressed	(2)
I am extremely anxious or depressed	(3)

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your own opinion.

Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.



(Enter number from 0-100)

Overall life satisfaction

All things considered, how satisfied are you with your life as a whole nowadays? Please tick the box that best describes your current overall life satisfaction.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely Dissatisfied	(0)	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	10	Extremely Satisfied

Physical activity

The following questions ask you about the time you spent being physically active in the last 7 days. By ‘active’ we mean doing anything using your muscles. Think about activities at work, school or home, getting from place to place, and any activities you did for exercise, sport, recreation, or leisure. You will be asked separately about brisk walking, moderate activities, and vigorous activities.

Walking

a) During the last 7 days, on how many days did you **walk at a brisk pace** – a brisk pace is a pace at which you are breathing harder than normal? This includes walking at work, while getting from place to place, at home and at any activities that you did solely for recreation, sport, exercise, or leisure.

Think only about brisk walking done for at least 10 minutes at a time.

Write in, put ‘0’ if none

Days (per week)

(0-7)

b) How much time did you typically spend walking at a brisk pace on each of those days?



Write in

(0-24)

hours

(0-60)

minutes

Moderate physical activity

a) During the last 7 days, on how many days did you do moderate physical activities? ‘Moderate’ activities make you breathe harder than normal, but only a little – like carrying light loads, bicycling at a regular pace, or other activities like swimming or social tennis. Do not include walking of any kind. Think only about those physical activities done for at least 10 minutes at a time.

Write in, put ‘0’ if none

Days (per week)

(0-7)

b) How much time did you typically spend on each of those days doing moderate physical activities?



Write in

(0-24)

hours

(0-60)

minutes

Vigorous physical activity

a) During the last 7 days, on how many days did you do vigorous physical activities? 'Vigorous' activities make you breathe a lot harder than normal ('huff and puff') – like heavy lifting, digging, fast bicycling, or other activities like running or playing football. Think only about those physical activities done for at least 10 minutes at a time.

Write in, put '0' if none

Days (per week)

b) How much time did you typically spend on each of those days doing vigorous physical activities?



Write in

hours

minutes

Frequency of activity

Thinking about all your activities over the last 7 days (including brisk walking), on how many days did you engage in:

- At least 30 minutes of moderate activity (including brisk walking) that made you breathe a little harder than normal, **OR**
- At least 15 minutes of vigorous activity that made you breathe a lot harder than normal ('huff and puff')?

Write in, put '0' if none

Days (per week)

Physical activity motivations

The following statements are about motivation to be physically active on a scale from zero (not at all) to ten (very). Please circle the number that best describes how you feel on each line.

	<div style="display: flex; justify-content: space-between; padding: 5px;"> Not at all Very </div>										
	0	1	2	3	4	5	6	7	8	9	10
I am trying to do more physical activity	0	1	2	3	4	5	6	7	8	9	10
It is important for me to be physically active	0	1	2	3	4	5	6	7	8	9	10
I could do more physical activity if I wanted to	0	1	2	3	4	5	6	7	8	9	10

Diet

The following is a list of ways to reduce the amount of fat or increase the amount of fibre in your diet. Please tick the box that best describes how often you do the following. If you do not include the foods listed below in your normal diet, please tick 'not applicable'.

Substitute specifically manufactured low fat foods	Usually or always	Sometimes	Rarely or Never	Not applicable
1. Eat frozen yogurt or low-sugar sorbet instead of ice cream?	(1)	(2)	(3)	(4)
2. Use low-calorie or low-fat salad dressing instead of regular?	(1)	(2)	(3)	(4)
3. Use yogurt instead of cream?	(1)	(2)	(3)	(4)
4. Eat low-fat cheese instead of regular cheese?	(1)	(2)	(3)	(4)
5. Drink semi skimmed, skimmed, or 1% milk instead of whole milk?	(1)	(2)	(3)	(4)
6. Use spray oil instead of oil, margarine or butter?	(1)	(2)	(3)	(4)

Avoid fat as a flavouring	Usually or always	Sometimes	Rarely or Never	Not applicable
7. Eat potatoes without oil, butter or margarine?	(1)	(2)	(3)	(4)
8. Eat bread or toast without butter or margarine?	(1)	(2)	(3)	(4)
9. Avoid adding butter, oil, or margarine to vegetables?	(1)	(2)	(3)	(4)

Modify meats to be low in fat	Usually or always	Sometimes	Rarely or Never	Not applicable
10. Take the skin off chicken?	(1)	(2)	(3)	(4)
11. Eat grilled meat, rather than fried?	(1)	(2)	(3)	(4)
12. Trim the visible fat from your meat?	(1)	(2)	(3)	(4)
13. Eat small portions of meat?	(1)	(2)	(3)	(4)
14. Eat baked, grilled or steamed fish, rather than fried?	(1)	(2)	(3)	(4)

Replace high fat meats with low fat alternatives	Usually or always	Sometimes	Rarely or Never	Not applicable
15. Eat beans (e.g., kidney beans, chickpeas) and/or pulses (e.g., lentils) instead of meat?	(1)	(2)	(3)	(4)
16. Eat egg whites and/or low-fat cottage cheese instead of meat?	(1)	(2)	(3)	(4)
17. Eat fish, chicken or turkey instead of red meat?	(1)	(2)	(3)	(4)

Fruits and vegetables	Usually or always	Sometimes	Rarely or Never	Not applicable
18. Eat raw vegetables or fruit as part of a snack?	(1)	(2)	(3)	(4)
19. Eat fruit as part of your breakfast?	(1)	(2)	(3)	(4)
20. Eat a vegetable or fruit as part of your lunch?	(1)	(2)	(3)	(4)
21. Eat two or more vegetables as part of your dinner?	(1)	(2)	(3)	(4)
22. Eat fruit for dessert?	(1)	(2)	(3)	(4)

Cereals and grains	Usually or always	Sometimes	Rarely or Never	Not applicable
23. Eat high-fibre cereals (e.g., All Bran, Bran Flakes, Quaker Oats, Shredded Wheat, Weetabix, Oatmeal) instead of low-fibre cereals (e.g., Cornflakes, Rice Krispies)?	(1)	(2)	(3)	(4)
24. Eat whole-grain crackers (e.g., Ryvita whole-grain crackers) or whole-grain bread (e.g., wholemeal, granary, brown) instead of white bread or regular crackers?	(1)	(2)	(3)	(4)

Substitute low-fibre foods for high-fibre foods	Usually or always	Sometimes	Rarely or Never	Not applicable
25. Eat whole-wheat pasta (brown) instead of regular pasta?	(1)	(2)	(3)	(4)
26. Eat brown rice instead of white rice?	(1)	(2)	(3)	(4)
27. Eat the skin on potatoes?	(1)	(2)	(3)	(4)

Healthy eating motivations

The following statements are about motivations to eat more healthily on a scale from zero (not at all) to ten (very). Please circle the number that best describes your feelings on each line.

Not at all											Very
-------------------	--	--	--	--	--	--	--	--	--	--	-------------

I am trying to eat healthier 0 1 2 3 4 5 6 7 8 9 10

It is important for me to eat healthier 0 1 2 3 4 5 6 7 8 9 10

I could eat healthier if I wanted to 0 1 2 3 4 5 6 7 8 9 10

Below are some statements about feelings and thoughts. Please tick the box that best describes your experiences of each over the last two weeks.

	None of the time	Rarely	Some of the time	Often	All of the time
a) I've been feeling optimistic about the future	(1)	(2)	(3)	(4)	(5)
b) I've been feeling useful	(1)	(2)	(3)	(4)	(5)
c) I've been feeling relaxed	(1)	(2)	(3)	(4)	(5)
d) I've been dealing with problems well	(1)	(2)	(3)	(4)	(5)
e) I've been thinking clearly	(1)	(2)	(3)	(4)	(5)
f) I've been feeling close to other people	(1)	(2)	(3)	(4)	(5)
g) I've been able to make up my own mind about things	(1)	(2)	(3)	(4)	(5)
h) I've been feeling happy or contented	(1)	(2)	(3)	(4)	(5)
i) I've been feeling engaged or focused in what I've been doing	(1)	(2)	(3)	(4)	(5)
j) I've been feeling energised or lively	(1)	(2)	(3)	(4)	(5)
k) I've been feeling lonely	(1)	(2)	(3)	(4)	(5)
l) I've been feeling everything I do is an effort	(1)	(2)	(3)	(4)	(5)
m) My sleep has been restless	(1)	(2)	(3)	(4)	(5)

Appendix 2. Course Satisfaction Questionnaire

Course Satisfaction (end of 4-week course only)

Did the course benefit you? (Please circle) Yes(1) / No(2)

On a scale from 1-10, how much did you enjoy the course?

Not at all	Very
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Please circle the number that best describes how much you enjoyed the course

1 2 3 4 5 6 7 8 9 10

What did you like the most? (Please comment in the box provided)

What did you like the least? (Please comment in the box provided)

Did the course meet your specific needs? (Please circle) Yes(1) / No(2)*

*If no, please tell us why. (Please comment in the box provided)

On a scale from 0 to 10, with 0 being the worst score and 10 being the best, how likely is it that you would recommend the Living Well, Taking Control programme to a family member or friend?

Please tick the box that best describes how likely it is that you would recommend the programme.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely Unlikely												Extremely Likely

Appendix 3. Social Identity Questionnaire

Being part of a group

The following statements are about your experiences with being part of a group during the 'Living Well Taking Control' (LWTC) programme. Read each statement carefully, and indicate **how you feel** about each one by ticking the box that most accurately represents how you feel.

The following statements are about your experiences <u>with other members in the group meetings as part of the 'Living Well, Taking Control' (LWTC) programme.</u>							
	Very strongly disagree	Strongly disagree	Mildly disagree	Neutral	Mildly agree	Strongly agree	Very strongly agree
a) Other members in the group meetings at LWTC really try to help me.							
b) I can count on other members in the group meetings at LWTC when things go wrong.							
c) There are other members in the group meetings at LWTC with whom I can share my joys and sorrows.							
d) I can talk about my problems with other members in the group meetings at LWTC.							

The following statements concern how you feel about <u>being a member of your group as part of the 'Living Well, Taking Control' (LWTC) programme.</u>							
	Very strongly disagree	Strongly disagree	Mildly disagree	Neutral	Mildly agree	Strongly agree	Very strongly agree
e) I identify with other members in my group at LWTC.							
f) I see myself as a LWTC group member.							
g) I am glad to be a member of my group at LWTC.							
h) I feel strong ties with other members in my group at LWTC.							

The following statements are about your membership of different groups outside of the 'Living Well, Taking Control' (LWTC) programme (e.g., groups may be charity, sports, community groups, etc.). <u>Any group other than the Living Well, Taking Control programme may be included.</u>							
	Very strongly disagree	Strongly disagree	Mildly disagree	Neutral	Mildly agree	Strongly agree	Very strongly agree
i) I belong to lots of different groups outside of LWTC.							

j) I join in the activities of lots of different groups outside of LWTC.							
k) I have friends who are members of lots of different groups.							
l) I have strong ties with lots of different groups outside of LWTC.							

Appendix 4. 'Changes in Health' Questionnaire

In the last six months, have you experienced a major life-changing event? Examples of major life-changing events include: being diagnosed with a serious illness, experiencing a loss, getting married, changing occupation)? (Please circle)

Yes / No. If yes, could you please tell us what this was?

In the last six months, were you prescribed any **new** repeat medications? (Please circle)

Yes / No. If yes, could you please tell us what these were?

In the last six months, did you have any operations? (Please circle)

Yes/ No, If yes, could you please tell us what these were?

Appendix 5. Course Satisfaction Results by Demographic Status

<i>Differences between genders</i>	Male	Female
Did the course benefit you? <i>No. (%) of participants who responded 'yes'</i>	195 (99.0%) Total n = 197	317 (99.1%) Total n = 320
On a scale from 1-10, how much did you enjoy the course? [1: Not at all - 10: Very]	Mean = 8.91 Range 4-10 Total n = 197	Mean = 9.09 Range 1-10 Total n = 310
Did the course meet your specific needs? <i>No. (%) of participants who responded 'yes'</i>	187 (98.9%) Total n = 189	299 (98.4%) Total n = 304
On a scale from 1-10, how much would you recommend this course to friends or family? [1:Extremely unlikely - 10: Extremely likely]	Mean = 8.99 Range 2-10 Total n = 69	Mean = 9.22 Range 3-10 Total n = 115

<i>Differences between age bands</i>	< 40 years	40 – 75 years	> 75 years	Overall
Did the course benefit you? <i>No. (%) of participants who responded 'yes'</i>	29 (96.7%) Total n = 30	411 (99%) Total n = 415	67 (100%) Total n = 67	507 (99%) Total n = 512
On a scale from 1-10, how much did you enjoy the course? [1: Not at all - 10: Very]	Mean = 9.27 Range 6-10 Total n = 30	Mean = 9.00 Range 1-10 Total n = 408	Mean = 9.02 Range 5-10 Total n = 64	
Did the course meet your specific needs? <i>No. (%) of participants who responded 'yes'</i>	25 (100%) Total n = 25	397 (98.3%) Total n = 404	59 (100%) Total n = 59	481 (98.6%) Total n = 488
On a scale from 1-10, how much would you recommend this course to friends or family? [1:Extremely unlikely - 10: Extremely likely]	Mean = 8.00 Range 7-10 Total n = 3	Mean = 9.13 Range 2-10 Total n = 158	Mean = 9.16 Range 6-10 Total n = 19	

<i>Differences between BMI categories</i>	Normal	Overweight	Obese	Overall
Did the course benefit you? <i>No. (%) of participants who responded 'yes'</i>	81 (100%) Total n = 81	184 (98.9%) Total n = 186	245 (99.2%) Total n = 247	510 (99.2%) Total n = 514
On a scale from 1-10, how much did you enjoy the course? [1: Not at all - 10: Very]	Mean = 8.94 Range 4-10 Total n = 77	Mean = 8.96 Range 5-10 Total n = 185	Mean = 9.10 Range 1-10 Total n = 242	
Did the course meet your specific needs? <i>No. (%) of participants who responded 'yes'</i>	71 (98.6%) Total n = 72	179 (98.4%) Total n = 182	234 (98.7%) Total n = 237	484 (98.6%) Total n = 491
On a scale from 1-10, how much would you recommend this course to friends or family? [1:Extremely unlikely - 10: Extremely likely]	Mean = 9.09 Range 7-10 Total n = 23	Mean = 9.15 Range 3-10 Total n = 62	Mean = 9.13 Range 2-10 Total n = 99	

<i>Differences between employment categories</i>	Employed	Unemployed	Overall
Did the course benefit you? <i>No. (%) of participants who responded 'yes'</i>	141 (98.6%) Total n = 143	309 (99.4%) Total n = 311	456 (99.1%) Total n = 460
On a scale from 1-10, how much did you enjoy the course? [1: Not at all - 10: Very]	Mean = 8.94 Range 1-10 Total n = 144	Mean = 9.08 Range 4-10 Total n = 307	
Did the course meet your specific needs? <i>No. (%) of participants who responded 'yes'</i>	130 (98.5%) Total n = 132	306 (98.7%) Total n = 310	442 (98.7%) Total n = 448
On a scale from 1-10, how much would you recommend this course to friends or family? [1:Extremely unlikely - 10: Extremely likely]	Mean = 8.95 Range 2-10 Total n = 62	Mean = 9.30 Range 5-10 Total n = 108	

<i>Differences between education levels</i>	Low	Intermediate	High	Overall
Did the course benefit you? <i>No. (%) of participants who responded 'yes'</i>	127 (100%) Total n = 127	106 (99.1%) Total n = 107	59 (96.7%) Total n = 61	292 (99.0%) Total n = 295
On a scale from 1-10, how much did you enjoy the course? [1: Not at all - 10: Very]	Mean = 9.11 Range 1-10 Total n = 123	Mean = 9.02 Range 6-10 Total n = 107	Mean = 8.77 Range 3-10 Total n = 61	
Did the course meet your specific needs? <i>No. (%) of participants who responded 'yes'</i>	119 (99.2%) Total n = 120	103 (99.0%) Total n = 104	54 (96.4%) Total n = 56	276 (98.6%) Total n = 280
On a scale from 1-10, how much would you recommend this course to friends or family? [1:Extremely unlikely - 10: Extremely likely]	Mean = 9.39 Range 6-10 Total n = 57	Mean = 9.11 Range 2-10 Total n = 81	Mean = 8.97 Range 3-10 Total n = 36	

<i>Differences by presence or absence of co-morbidities</i>	Present	Absent	Overall
Did the course benefit you? <i>No. (%) of participants who responded 'yes'</i>	264 (99.2%) Total n = 266	188 (99.5%) Total n = 189	452 (99.3%) Total n = 455
On a scale from 1-10, how much did you enjoy the course? [1: Not at all - 10: Very]	Mean = 9.11 Range 1-10 Total n = 264	Mean = 9.07 Range 4-10 Total n = 181	
Did the course meet your specific needs? <i>No. (%) of participants who responded 'yes'</i>	259 (98.5%) Total n = 263	171 (99.4%) Total n = 172	430 (98.9%) Total n = 435
On a scale from 1-10, how much would you recommend this course to friends or family? [1:Extremely unlikely - 10: Extremely likely]	Mean = 9.23 Range 3-10 Total n = 97	Mean = 9.08 Range 2-10 Total n = 71	

<i>Differences by presence or absence of disability</i>	Disabled	Not disabled	Overall
Did the course benefit you? <i>No. (%) of participants who responded 'yes'</i>	70 (100%) Total n = 70	421 (99.1%) Total n = 425	491 (99.2%) Total n = 495
On a scale from 1-10, how much did you enjoy the course? [1: Not at all - 10: Very]	Mean = 9.10 Range 6-10 Total n = 67	Mean = 9.05 Range 1-10 Total n = 416	
Did the course meet your specific needs? <i>No. (%) of participants who responded 'yes'</i>	70 (95.9%) Total n = 73	393 (99.2%) Total n = 396	463 (98.7%) Total n = 469
On a scale from 1-10, how much would you recommend this course to friends or family? [1:Extremely unlikely - 10: Extremely likely]	Mean = 9.10 Range 5-10 Total n = 29	Mean = 9.20 Range 2-10 Total n = 143	

<i>Differences between smokers and non-smokers</i>	Smokers	Non-smokers	Overall
Did the course benefit you? <i>No. (%) of participants who responded 'yes'</i>	31 (100%) Total n = 31	371 (99.2%) Total n = 374	402 (99.3%) Total n = 405
On a scale from 1-10, how much did you enjoy the course? [1: Not at all - 10: Very]	Mean = 9.27 Range 6-10 Total n = 33	Mean = 8.96 Range 1-10 Total n = 369	
Did the course meet your specific needs? <i>No. (%) of participants who responded 'yes'</i>	32 (100%) Total n = 32	352 (98.3%) Total n = 358	384 (98.5%) Total n = 390
On a scale from 1-10, how much would you recommend this course to friends or family? [1:Extremely unlikely - 10: Extremely likely]	Mean = 9.23 Range 5-10 Total n = 13	Mean = 9.17 Range 2-10 Total n = 163	

<i>Differences between ethnicities</i>	'White'	'BME'	Overall
Did the course benefit you? <i>No. (%) of participants who responded 'yes'</i>	307 (99%) Total n = 310	193 (99.5%) Total n = 194	500 (99.2%) Total n = 504
On a scale from 1-10, how much did you enjoy the course? [1: Not at all - 10: Very]	Mean = 8.94 Range 1-10 Total n = 304	Mean = 9.18 Range 4-10 Total n = 191	
Did the course meet your specific needs? <i>No. (%) of participants who responded 'yes'</i>	292 (98.3%) Total n = 297	182 (99.5%) Total n = 183	474 (98.8%) Total n = 480
On a scale from 1-10, how much would you recommend this course to friends or family? [1:Extremely unlikely - 10: Extremely likely]	Mean = 9.17 Range 2-10 Total n = 167	<i>[Data only available for 8 participants]</i>	

Appendix 6. Social Identity Results

Section 1: Social support			
The following statements are about participants' experiences <u>with other members in the group meetings as part of the LWTC programme</u>			
	Disagree, n (%)	Neutral, n (%)	Agree, n (%)
a) Other members in the group meetings at LWTC really try to help me	6 (3.3)	40 (21.9)	137 (74.9)
b) I can count on other members in the group meetings at LWTC when things go wrong	16 (9.1)	74 (42.0)	86 (48.9)
c) There are other members in the group meetings at LWTC with whom I can share my joys and sorrows	14 (7.8)	54 (30.2)	111 (62.0)
d) I can talk about my problems with other members in the group meetings at LWTC	18 (10.3)	39 (22.3)	118 (67.4)

Section 2: Social identification			
The following statements concern how participants' felt about being a member of their group as part of the LWTC programme			
	Disagree, n (%)	Neutral, n (%)	Agree, n (%)
e) I identify with other members in my group at LWTC	8 (4.4)	23 (12.6)	152 (83.1)
f) I see myself as a LWTC group member	9 (4.9)	24 (13.2)	149 (81.9)
g) I am glad to be a member of my group at LWTC	5 (2.7)	18 (9.8)	161 (87.5)
h) I feel strong ties with other members in my group at LWTC	22 (12.0)	54 (29.5)	107 (58.5)
Section 3: Other group memberships/social identities			
The following statements are about participants' membership of different groups outside of the LWTC programme (e.g., groups may be charity, sports, community groups, etc.). Any group other than the LWTC programme may be included.			
	Disagree, n (%)	Neutral, n (%)	Agree, n (%)
i) I belong to lots of different groups outside of LWTC	56 (32.6)	33 (19.2)	83 (48.3)
j) I join in the activities of lots of different groups outside of LWTC	58 (34.1)	32 (18.8)	80 (47.1)
k) I have friends who are members of lots of different groups	40 (23.4)	28 (16.4)	103 (60.2)
l) I have strong ties with lots of different groups outside of LWTC	56 (33.1)	33 (19.5)	80 (47.3)

Appendix 7. Number and percentage of participants who achieved specific weight loss thresholds, by demographic status

		Number (%) of participants achieving weight reductions at Month 6		
		≥3% weight loss	≥5% weight loss	≥10% weight loss
Male	All participants (n = 135)	49 (36.30)	28 (20.74)	4 (2.96)
	Excluding BMI<25 (n = 118)	42 (35.59)	24 (20.34)	3 (2.54)
Female	All participants (n = 237)	88 (37.13)	50 (21.10)	13 (5.49)
	Excluding BMI<25 (n = 209)	78 (37.32)	44 (21.05)	11 (5.26)
		Number (%) of participants achieving weight reductions at Month 12		
		≥3% weight loss	≥5% weight loss	≥10% weight loss
Male	All participants (n = 62)	17 (27.42)	11 (17.74)	1 (1.61)
	Excluding BMI<25 (n = 52)	13 (25.00)	8 (15.38)	1 (1.92)

Female	All participants (n = 103)	45 (43.69)	26 (25.24)	10 (9.71)
	Excluding BMI<25 (n = 84)	38 (45.24)	24 (28.57)	10 (11.90)

		Number (%) of participants achieving weight reductions at Month 6		
		≥3% weight loss	≥5% weight loss	≥10% weight loss
'White'	All participants (n = 250)	102 (40.80)	62 (24.80)	11 (4.40)
	Excluding BMI<25 (n = 222)	92 (41.44)	57 (25.68)	11 (4.95)
'BME'	All participants (n = 113)	30 (26.55)	12 (10.62)	5 (4.42)
	Excluding BMI<25 (n = 97)	24 (24.74)	8 (8.25)	2 (2.06)
		Number (%) of participants achieving weight reductions at Month 12		
		≥3% weight loss	≥5% weight loss	≥10% weight loss
'White'	All participants (n = 119)	51 (42.86)	30 (25.21)	9 (7.56)
	Excluding BMI<25 (n = 99)	43 (43.43)	28 (28.28)	9 (9.09)
'BME'	All participants (n = 40)	9 (22.50)	6 (15.00)	2 (5.00)
	Excluding BMI<25 (n = 32)	6 (18.75)	3 (9.38)	2 (6.25)

		Number (%) of participants achieving weight reductions at Month 6		
		≥3% weight loss	≥5% weight loss	≥10% weight loss
Employed	All participants (n = 98)	33 (33.67)	19 (19.39)	1 (1.02)
	Excluding BMI<25 (n = 89)	27 (30.34)	16 (17.98)	1 (1.12)
Unemployed	All participants (n = 238)	91 (38.24)	52 (21.85)	13 (5.46)
	Excluding BMI<25 (n = 207)	83 (40.10)	47 (22.71)	11 (5.31)
		Number (%) of participants achieving weight reductions at Month 12		
		≥3% weight loss	≥5% weight loss	≥10% weight loss
Employed	All participants (n = 52)	18 (34.62)	14 (26.92)	3 (5.77)
	Excluding BMI<25 (n = 42)	13 (30.95)	10 (23.81)	3 (7.14)
Unemployed	All participants (n = 96)	37 (38.54)	21 (21.88)	7 (7.29)
	Excluding BMI<25 (n = 80)	34 (42.50)	20 (25.00)	7 (8.75)

		Number (%) of participants achieving weight reductions at Month 6		
		≥3% weight loss	≥5% weight loss	≥10% weight loss
Low	All participants (n = 93)	35 (37.63)	19 (20.43)	3 (3.23)
	Excluding BMI<25 (n = 81)	32 (39.51)	17 (20.99)	3 (3.70)
Intermediate	All participants (n = 82)	31 (37.80)	19 (23.17)	4 (4.88)
	Excluding BMI<25 (n = 76)	30 (39.47)	19 (25.00)	4 (5.26)
High	All participants (n = 45)	18 (40.00)	9 (20.00)	3 (6.67)
	Excluding BMI<25 (n = 40)	17 (42.50)	8 (20.00)	3 (7.50)

		Number (%) of participants achieving weight reductions at Month 12		
		≥3% weight loss	≥5% weight loss	≥10% weight loss
Low	All participants (n = 34)	17 (50.00)	10 (29.41)	3 (8.82)
	Excluding BMI<25 (n = 27)	13 (48.15)	8 (29.63)	3 (11.11)
Intermediate	All participants (n = 29)	8 (27.59)	7 (24.14)	3 (10.34)
	Excluding BMI<25 (n = 25)	7 (28.00)	6 (24.00)	3 (12.00)
High	All participants (n = 19)	9 (47.37)	4 (21.05)	1 (5.26)
	Excluding BMI<25 (n = 16)	7 (43.75)	3 (18.75)	1 (6.25)

		Number (%) of participants achieving weight reductions at Month 6		
		≥3% weight loss	≥5% weight loss	≥10% weight loss
IMD deciles 1-3	All participants (n = 140)	42 (30.00)	18 (12.86)	4 (2.86)
	Excluding BMI<25 (n = 122)	36 (29.51)	14 (11.48)	1 (0.82)
IMD deciles 4-7	All participants (n = 124)	51 (41.13)	30 (24.19)	5 (4.03)
	Excluding BMI<25 (n = 110)	46 (41.82)	28 (25.45)	5 (4.55)
IMD deciles 8-10	All participants (n = 66)	27 (40.91)	18 (27.27)	4 (6.06)
	Excluding BMI<25 (n = 55)	22 (40.00)	14 (25.45)	4 (7.27)
		Number (%) of participants achieving weight reductions at Month 12		
		≥3% weight loss	≥5% weight loss	≥10% weight loss
IMD deciles 1-3	All participants (n = 55)	15 (27.27)	10 (18.18)	1 (1.82)
	Excluding BMI<25 (n = 46)	12 (26.09)	7 (15.22)	1 (2.17)
IMD deciles 4-7	All participants (n = 63)	25 (39.68)	17 (26.98)	7 (11.11)
	Excluding BMI<25 (n = 53)	23 (43.40)	16 (30.19)	7 (13.21)
IMD deciles 8-10	All participants (n = 40)	19 (47.50)	8 (20.00)	3 (7.50)
	Excluding BMI<25 (n = 33)	14 (42.42)	7 (21.21)	3 (9.09)