Skills for weight loss and Maintenance (SkiM): The feasibility of an intervention to support weight loss maintenance, and of a trial to evaluate it

STUDY PROTOCOL

Version: 9

Study Sponsor:	University of Exeter
Chief Investigator:	Professor Colin Greaves (University of Exeter Medical School)
Funding:	NIHR Career Development Fellowship (CDF-2012-05-259)
REC Reference:	15/SW/0126

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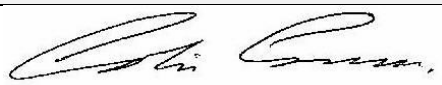
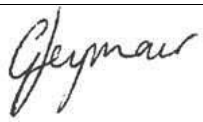
1 SIGNATURES

Role	Name	Signature	Date
Chief Investigator	Assoc Prof Colin Greaves		15/07/16
Study Manager	Dr Leon Poltawski		15/07/16
Sponsor's representative	Gail Seymour		15/07/16

2 KEY CONTACT DETAILS

Chief Investigator: **Prof Colin Greaves**
Associate Professor in Psychology Applied to Health
Exeter Medical School - Smeall Building
St Luke's Campus, Heavitree Road
Exeter
Devon
EX1 2LU
Telephone: 0798 9895165
Email: c.j.greaves@exeter.ac.uk

Statistical Advisor: **Prof Rod Taylor**
Professor in Health Services Research
Exeter Medical School - Veysey Building
Salmon Pool Lane
Exeter
Devon
EX2 4SG
Telephone: 01872 255167
Email: r.taylor@exeter.ac.uk

Principal Investigator /Study Manager: **Dr Leon Poltawski**
Research Fellow
Exeter Medical School - Smeall Building
St Luke's Campus, Heavitree Road
Exeter
Devon
EX1 2LU
Telephone: 01392 725406
Email: L.Poltawski@exeter.ac.uk

Co-investigator: **Lucy O'Loughlin**
Health Improvement Manager
Devon County Council
Rm 255 County Hall
Exeter
EX2 4QL
United Kingdom
Telephone: 01392 386384
Email: Lucy.oLoughlin@devon.gov.uk

Sponsor Representative: **Gail Seymour**
Research & Knowledge Transfer, Innovation Centre
University of Exeter
Rennes Drive,
Exeter
EX4 4RN
Telephone: 01392 726621
Email: g.m.seymour@exeter.ac.uk

Co -investigator: **Dr Richard Merrifield**
Richard Merrifield
Health Improvement Specialist- Obesity
Health Promotion Devon
Old Forde House
Brunel Road
Newton Abbot
Devon, TQ12 4XX
Telephone: 01626 882574
Email: richard.merrifield@nhs.net

PenCTU Senior Data Manager: **Laura Cocking**
Peninsula Clinical Trials Unit
N14, ITTC Building 1
Tamar Science Park
Derriford
PL6 8BX
Telephone: 01752 439828
Email: laura.cocking@plymouth.ac.uk

PenCTU Assistant Data Programmer: **Elliot Carter**
Peninsula Clinical Trials Unit
N14, ITTC Building 1
Tamar Science Park
Derriford
PL6 8BX
Telephone: 01752 439829
Email: elliot.carter@plymouth.ac.uk

3 LIST OF ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
BP	Blood pressure
CI	Chief Investigator
ConSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CRN	Clinical Research Network
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
GP	General Practitioner
HR	Heart rate
ICER	Incremental cost-effectiveness ratio
ICH GCP	International Conference on Harmonisation of Good Clinical Practice
NIHR	National Institute of Health Research
NRES	National Research Ethics Service
CRN	Clinical Research Network
PenCTU	Peninsula Clinical Trials Unit
PMG	Project Management Group
PPI	Participant and Public Involvement
QALY	Quality Adjusted Life Year
R&D	Research and development
RCT	Randomised controlled trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SkiM	Skills for weight loss Maintenance
SUSAR	Suspected Unexpected Serious Adverse Reaction
TSC	Trial Steering Committee

4 STUDY SUMMARY

Study Title	Skills for weight loss Maintenance (SkiM): Developing an intervention to support maintenance of weight loss and a trial to evaluate it.
Study Setting	Two community-based health service providers in Devon, UK. - Westbank Healthy Living Centre, Exminster. - Torbay and Southern Devon Health and Care NHS Trust
Study Design	Action research feasibility design including before-and-after evaluation of two iterations of a weight management intervention, delivered in two different formats.
Study Aims and Objectives	Aims 1. To develop a weight management intervention that specifically addresses weight loss maintenance 2. To inform development of a trial that will be used to evaluate the intervention Objectives 1. To assess the feasibility and acceptability of incorporating the SkiM intervention into existing community-based weight loss programmes. 2. To refine the SkiM intervention, so as to optimise its potential effectiveness and feasibility for incorporation into existing community-based weight management programmes. 3. To assess the feasibility and acceptability to study participants of recruitment, assessment and process evaluation strategies that may be used in a future trial of the SkiM intervention. 4. To determine rates of participant recruitment, retention and outcomes completion at 12 months, and identify influences on these variables. 5. To estimate the resources needed for the planned future trial. 6. To develop and select process and outcomes measures for use in a future trial. 7. To develop the framework for economic evaluation in a future trial, including estimation of intervention costs.
Study Participants	• People who have agreed to take part in an existing Tier 2 community-based weight loss programme delivered by one of the identified Service Provider organisations. • People recruited specifically for this study by other routes. • Programme provider staff (who will deliver the intervention).
Inclusion Criteria (participants)	• Meets eligibility criteria for existing weight management programme, with which SkiM will be combined. • Adults (aged ≥18 years) • Body mass index (BMI) ≥30 kg/m^2 (white European) or ≥27.5kg/m^2 (South Asian and black African/Caribbean heritage populations) • Provision of informed consent to participate
Exclusion Criteria	• Excluded by eligibility criteria of existing programmes, with which Skim

<table>
<tr><td>(participants)</td><td>intervention will be combined
• Currently pregnant, planning to be pregnant in next year, or childbirth in last 6 months
• BMI≥50kg/m^2
• Clinically diagnosed eating disorder
• Medical condition (e.g. terminal illness, uncontrolled thyroid disease, dementia, psychosis) judged by medical practitioner to seriously limit capacity to manage weight.
• Concurrent participation in other weight management programmes (e.g. commercial weight loss programmes)
• Unable to understand the study information, read the study manual or complete outcome questionnaires.
• Unable to make own arrangements to travel to intervention venue
• Participating in concurrent interventional research which may over-burden the participant or confound data collection.</td></tr>
<tr><td>Entry criteria (Intervention staff)</td><td>• Existing providers of selected Tier 2 weight management services in Devon to which NHS clinicians may make referrals
• Completion of the SkiM intervention training course
• Provision of informed consent to provide study data.</td></tr>
<tr><td>Target sample size</td><td>• 110 programme participants (up to 55 at each site)
• Up to 6 intervention staff to deliver the intervention (2-3 delivering the programme at each site)</td></tr>
<tr><td>Intervention</td><td>A programme in which the SkiM intervention is integrated with the existing weight loss intervention, and delivered over six months in a group format. Data gathered during the first presentation in each format will be used to refine the intervention, which will then be evaluated in a second iteration.</td></tr>
<tr><td>Study duration</td><td>Total duration: 26 months (1st March 2015 to 31st May 2018)
<table>
<tr><td>Mar-Jul 2015</td><td>Intervention development</td></tr>
<tr><td>Aug-Oct 2015</td><td>Training of intervention providers
Recruitment for first iteration</td></tr>
<tr><td>Oct 2015-Apr 2016</td><td>First iteration</td></tr>
<tr><td>May-Aug 2016</td><td>Data analysis & refining intervention</td></tr>
<tr><td>Jul-Sep 2016</td><td>Recruitment for second iteration</td></tr>
<tr><td>Sep 2016-Mar 2017</td><td>Second iteration of intervention
12-month follow-up assessment of Phase 1</td></tr>
<tr><td>Aug -Sep 2017</td><td>12-month follow up assessment of Phase 2</td></tr>
<tr><td>Feb-Mar 2018</td><td>18-month follow up assessment of Phase 2</td></tr>
<tr><td>Feb-May 2018</td><td>Data analysis, reporting and trial planning</td></tr>
</table></td></tr>
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5 BACKGROUND AND RATIONALE

This study forms part of a programme of work on the identification and evaluation of interventions to support the *maintenance* of weight loss through lifestyle change (changes in diet and physical activity). In particular the study aims to pilot the intervention and trial procedures for a future full-scale trial to assess the cost-effectiveness of alternative strategies for supporting weight loss maintenance that have different resource requirements. The information produced by the larger, full-scale trial will help inform the commissioning of weight loss services for implementing new NICE guidance on diabetes prevention[1] and for managing obesity in the NHS.

1: *Impact of obesity:* Obesity is associated with a reduction in life expectancy of up to 14 years,[2] primarily due to an increase in cardiovascular disease (CVD) risk. Because excess fat causes impaired glucose regulation (IGR), obesity also substantially increases the risk of developing type 2 diabetes.[3] People with a BMI of 35-40kg/m^2 have a relative risk of type 2 diabetes 8 to 11 times higher than people of normal weight.[3] Obesity is also associated with an increased likelihood of developing kidney disease, fatty liver disease, osteoarthritis, several cancers, hypertension, dementia, depression and sleep apnoea.[4] Based on current trend in obesity prevalence (currently 23% in adults), the combined cost to the NHS and to UK society will reach £49.9 billion/year by 2050.[5]

2. Benefits of weight reduction: Evidence from systematic reviews shows that, in people with increased cardiovascular risk, relatively modest reductions in weight (2-5kg) reduce key cardiovascular risk factors (e.g. lipid profiles, blood pressure) to a clinically meaningful extent.[6, 7] Weight loss also reduces insulin resistance and can prevent progression to type 2 diabetes.[8, 9] In the Finnish Diabetes Prevention Study, a mean 3.4kg of weight loss in people with IGR, reduced the incidence of type 2 diabetes at 4 years of follow-up by 58%.[9]

3. *Why focus on maintenance?* Although lifestyle interventions are increasingly successful in promoting *initial* weight loss (after 3-6 months)[7, 10, 11] gradual weight regain is common, with weight typically returning to baseline levels over 5-6 years.[11] The cost-effectiveness of using lifestyle interventions to prevent type 2 diabetes is strongly dependent on assumptions about the maintenance of weight loss: Two central assumptions of the current NICE economic model for diabetes prevention are that the prevention effect (a relative risk reduction of 16% per kg of weight loss[12]) lasts only as long as weight loss is sustained and that weight loss regresses to zero over 5-6 years.[4] The economic case for the national (England) NHS Health Checks programme is also strongly driven by the assumed cost-savings from prevention of diabetes and cardiovascular disease following "intensive lifestyle intervention" to support changes in diet and /or physical activity. These benefits account for around 40% of the estimated savings attributed to NHS Health Checks.[13] Hence, if the major health economic benefits of intervention to reduce diabetes risk and cardiovascular risk through weight loss are to be realised, then sustaining weight loss is a crucial issue.

4) What new research is needed? More research is needed to establish effective strategies for maintenance of weight loss following initial intervention. Recent reviews of weight loss maintenance (at 1 to 4 years of follow up)[14, 15] found that most trials had substantial methodological limitations. However, the data suggests that weight loss maintenance may be associated with the use of a) peer or social support b) frequent continued professional support c) specific 'self-regulatory' methods like goal setting, problem solving, relapse prevention, self-monitoring, and daily self-weighing.[16, 17] Further

systematic reviews show that targeting both diet and physical activity also generates more weight loss at one year compared with either diet or physical activity alone.[4, 18, 19] Intervention effectiveness also increases with the intensity or amount of intervention delivered (total contact time or number of contacts).[19-21] However, the reviews conclude that more experimental research on the relationship between intervention intensity and effectiveness is needed.[19, 21]

Intervention cost is a major constraint for NHS delivery /commissioning of obesity management services in the current economic climate. The intensive lifestyle interventions that are used in research settings are often not practical for commissioning on a large scale.[22, 23] Hence, there is clear need to develop strategies that are realistic and affordable for future commissioners of NHS services. There have been repeated calls for experimental research to identify cost-effective methods for supporting the long-term maintenance of diet, physical activity and weight loss in government reports,[2] evidence-based guidelines[4, 24, 25] and numerous systematic reviews.[7, 11, 14, 19] The need for more research on health behaviour maintenance was also identified as one of the main recommendations of the recent House of Lords Select Committee on behaviour change.[26]

Interim summary: People who lose weight often put it back on within a few years. The existing literature suggests some potentially useful intervention strategies. However, there is a pressing need for research to increase our understanding of longer-term maintenance of the lifestyle changes (i.e. changes in diet and physical activity) needed to achieve weight loss, and in particular to identify intervention strategies that are practical and cost-effective for use in UK healthcare settings.

Prior work to develop the SkiM intervention: Our intervention approach is informed by extensive needs assessment activities, including consultation with service users, service providers and commissioners of weight management services,[27] reviews of quantitative (trial) evidence,[14, 15, 28] a review of theoretical ideas[29] and a synthesis of qualitative research studies on weight loss maintenance[30]. Using MRC guidelines for developing complex interventions[31] and rigorous intervention development techniques (intervention mapping and process mapping)[32 33, 34] we have developed intervention materials and training materials to support weight loss maintenance. Rather than offering and evaluating these as a standalone intervention, we have incorporated them into several existing weight management programmes. This will ensure that principles and skills for behavioural sustainability are attended to from an early stage in weight management efforts.

6 AIMS AND OBJECTIVES

6.1 Aims

1. To inform the development of a weight management intervention that specifically addresses weight loss maintenance
2. To inform development of a trial that will be used to evaluate the intervention

6.2 Objectives

1. To assess the feasibility and acceptability of incorporating the SkiM intervention into existing community-based weight loss programmes.
2. To refine the SkiM intervention, including its content and delivery modes, and associated training materials, so as to optimise its individual tailoring, potential effectiveness and feasibility for incorporation into existing community-based weight management programmes.
3. To assess the feasibility and acceptability to study participants of recruitment, assessment and process evaluation strategies that may be used in a future trial of the SkiM intervention.
4. To determine rates of, and influences on, outcome measure completion, as well as intervention and study participant retention and attrition.
5. To estimate the resources needed for the planned future trial.
6. To select process and outcomes measures for use in a future trial.
7. To develop the framework for economic evaluation in a future trial.

7 STUDY DESIGN

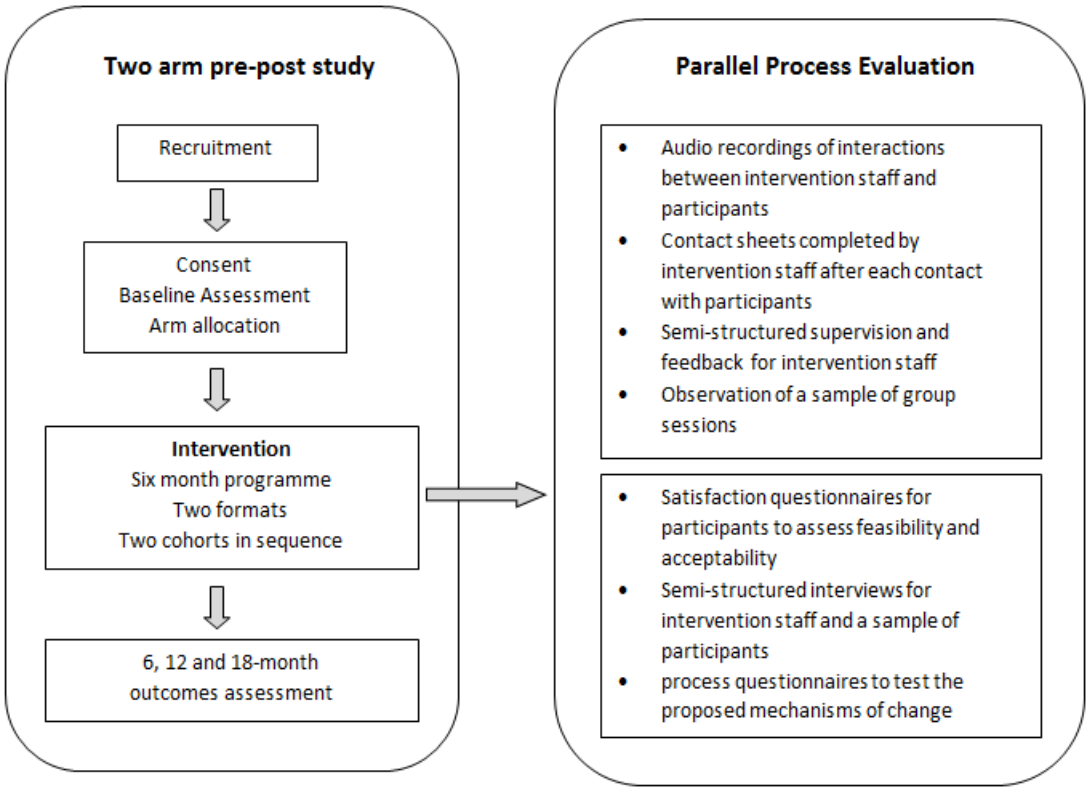
7.1 Summary of the study design

An action research approach [35] will be used, in which the SkiM intervention is tested and developed in an iterative cycle, involving stakeholders (particularly the service users themselves) in all stages of the process. The cycle involves three iterations of the intervention: an initial version has been developed with the involvement of service users, providers and commissioners as well as academics in the field of health behaviour change; this will be subject to mixed methods evaluation including pre-post testing, the results of which will be used to develop a second iteration of the intervention, which will also be evaluated. A third version of the intervention will then be developed for formal testing in a randomised control trial. This iterative approach involving multiple stakeholders and a pre-post test design, will enable investigation of the feasibility of integrating the SkiM intervention into existing programmes, as well as issues of acceptability, demand and implementation [36]. It also facilitates the evaluation and further development of recruitment, assessment and retention methods to be used within a subsequent trial. It is expected that in a trial, the control group would receive best-practice

usual care, which would be an existing weight loss programme. Hence all participants would receive an active intervention, and the need for a control arm is less pressing in a feasibility study.

The intervention period is six months, with outcomes assessment at baseline, and at 6, 12 and 18 months post-baseline. Eighty participants will be allocated equally to one of two study arms with different programme formats: both will be group-based, but they will differ in the number of sessions and supplementary support available. The study will be staged into two cohorts of approximately 40 participants. These will be run sequentially and separated by a period of four months, during which process data collected from the first stage will be used to refine the intervention for delivery in the second phase. This design is illustrated in Figure 1.

Figure 1: Study design



STUDY PARTICIPANTS

7.2 Participants

Participants will be adults who have agreed to take part in existing weight loss programmes delivered by one of our collaborating Service Provider organisations, or who have been recruited via other routes specifically to take part in this study.

7.2.1 Inclusion criteria

- Adults (aged ≥18 years)
- Body mass index (BMI) ≥30 kg/m^2 (white European) or ≥27.5kg/m^2 (South Asian and black African/Caribbean heritage populations)
- Eligible for inclusion in commissioned Tier 2 weight management services in Devon (See Appendix 4 for details)

7.2.2 Exclusion Criteria

- Concurrent participation in other weight management programmes (e.g. commercial weight loss programmes)
- Pregnancy or planned pregnancy during the study, or childbirth in last six months
- BMI ≥50kg/m^2
- Diagnosed eating disorder (anorexia nervosa, bulimia, binge eating)
- Medical condition (e.g. terminal illness, uncontrolled thyroid disease, dementia, psychosis) judged by medical practitioner to seriously limit capacity to manage weight.
- Unable to understand the study information, read the study manual or complete outcome questionnaires (in opinion of Researcher conducting initial screening)
- Unable to make own arrangements to travel to intervention venue
- Participating in concurrent interventional research which may over-burden the participant or confound data collection.

7.3 Intervention staff

Intervention providers will be three current providers of Tier 2 weight management services in Devon. They are the Westbank League of Friends (a voluntary sector organisation) and Fitness in Torbay, an organisation within Torbay and Southern Devon Health and Care NHS Trust. Up to six existing staff members in will be selected by the providers to deliver the interventions. All will receive a 2 day training course provided by the research team (CG, LP) to facilitate their delivery of the intervention and their assistance with some study procedures (e.g. recording of consultations, completing end-of-session checklists), as well as bi-monthly debrief meetings, where formative feedback will be provided by the research team.

Each intervention provider will deliver a different format of intervention, based upon their existing weight management service provision.

8 PARTICIPANT IDENTIFICATION

8.1 Method 1: Recruitment via the existing routes used by Intervention Providers

Recruitment to existing Tier 2 weight management services in Devon is through referral by a GP or other NHS health professional. In South Devon and Torbay, referrals are channelled to the Community Fitness Team (CFT) who provide a 12 week group-based weight management programme. In areas around Exeter, referrals are directed to Health Promotion Devon (HPD), a lifestyle hub that helps individuals select a programme from a number that have been commissioned, including group and one-to-one programmes. Trained staff from CFT or HPD staff speak with referred individuals by telephone for screening, information provision and direction to a weight management programme. During these calls, those people who have selected one of the programmes offered by our providers will be asked, using a standard script, if they would be interested in taking part in an extended version of the programme as part of a research study concerned with maintenance of weight loss. Those expressing an interest will be asked to consent to their contact details being given to the research team so that further information about the study can be supplied to them.

8.2 Method 2 (via GP practice lists)

With help from the Peninsula Clinical Research Network's primary care research network, we have identified research-ready General Practices that are within the catchment area of our intervention providers and represent a diverse demography. The practices will identify patients meeting the study inclusion criteria according to their medical records and send a study invitation letter to a total of 80 potentially eligible people in the first instance. Depending on recruitment rates, letters may be send to further tranches of patients. The letter will be signed by a representative of the Practice and the study manager, and will be accompanied by a leaflet describing the study, a reply slip and a reply-paid envelope addressed to the study team.

8.3 Recruitment feasibility data collection

For each of the recruitment routes, anonymised data on the age, gender, BMI of the total eligible sample will be recorded where possible, to allow assessment of the representativeness of the recruited sample. Where possible, ethnicity data and postcode (from which socio-economic status may be derived) will also be collected. The total numbers of potentially eligible people from each route, and the numbers approached and reaching each stage in the recruitment process, will be recorded to enable investigation of recruitment feasibility for a full trial.

9 RECRUITMENT PROCEDURES

9.1 Participant Invitation

Potentially eligible people who have expressed an interest via either of the routes described in Section 8 will be sent a study information pack, which will include a letter from the study team, the Participant Information Sheet, a reply slip and reply-paid envelope. Different information leaflets will be used

according to whether the individual came through the Torbay hub or the Exeter-based routes, to reflect the programme format available in each area.

Within 7-10 days of sending the information pack, the Study Manager will contact the individual by telephone to check if they are still interested in participation, provide more detailed information about what is involved, and discuss any questions they may have about the study. If they want to participate, they will progress immediately to telephone screening (see below). If they do not, they will be asked if they are willing to say why they chose not to, which will aid the feasibility aim of the study. However it will be made clear that that they are not obliged in any way to disclose reasons. If they agree to give reasons, a brief questionnaire will be used at that point, or sent to the individual with a reply paid envelope if they prefer. Individuals approached through Method 1 (see Section 8) and who decline participation will be referred back to the appropriate hub so they may still participate in their standard weight management programme. Individuals approached through method 2 (see Section 8) and who decline participation will be informed of the possibility of referral to standard weight management programmes, in case they should wish to consider them.

9.2 Telephone screening and first study appointment for baseline assessment

During the telephone call, for those who have confirmed their interest in participating in the study, the researcher will use a brief series of questions to assess eligibility, and will also request contact details for the person's GP, in case any medical exclusion criteria need to be checked. Potential participants will be asked if they have any medical condition (such as a stroke) that might affect their ability to participate in the study (which might involve changes to their diet or physical activity levels), and advised to seek guidance from their GP if necessary.

For individuals who meet the study eligibility criteria and give oral consent to participate in the study, a date for obtaining written consent and baseline assessment will be set. This will be arranged to take place in their home or at the University of Exeter, according to their preference. With the individual's agreement, the Informed Consent Form and the baseline questionnaire pack will be posted to the participant at least week before the baseline assessment meeting so that they can be read and the questionnaires completed beforehand (the researcher will not ask for the completed questionnaires until after written consent is obtained). The baseline assessment will be delayed until it is clear there will be sufficient **(10-15)** people to form a group.

If the person is not eligible to take part in the study, the researcher will explain why and thank them for their time. If the person declines to participate, they will be invited to give reasons to help our feasibility assessment (but it will be made clear that they are not obliged in any way to disclose reasons). If they agree to give reasons, a brief questionnaire will be used at that point, or sent to the individual with a reply paid envelope if they prefer. Individuals approached through Method 1 (see Section 8) and who decline participation will be referred back to the appropriate hub so they may still participate in their standard weight management programme. Individuals approached through methods 2 and 3 (see Section 8) and who decline participation will be informed of the possibility of referral to standard weight management programmes, in case they should wish to consider them.

9.3 Intervention facilitator recruitment

Each of the three provider partner organisations will be asked to identify up to 3 practitioners to deliver the three SkiM interventions ('the facilitator'). The recruitment process will specify that the facilitator will be required to take part in the process evaluation. This includes having consultations digitally-recorded, taking part in a qualitative interview, and completion of data forms providing other information requested by the research team (see process evaluation - Section 15). Informed consent will be obtained from the intervention facilitators for these data collection procedures.

10 PROCEDURES FOR BASELINE MEETING

Overview: At the baseline meeting, the study researcher will first recap information about study, answer any questions that the potential participant has, and take written consent. The baseline questionnaires that were sent to the participant for completion ahead of the meeting will then be checked for completeness and any queries and a short series of qualitative questions on any previous weight management experiences will be asked. Objective body measurements will be taken, and the participant will be given an accelerometer and instructed in its use, so that they wear it over the following 7 days and send it to the CTU using a rely-paid envelope. Participants will be informed of the arrangements and timing for the programme in which they will take part. Travel expenses will be paid for attending the assessment, if needed, and those without transport or convenient public transport will be reimbursed for use of a taxi to and from the assessment venue.

10.1 Informed Consent

Following an opportunity to discuss and questions or concerns about the study, potential participants will be invited to provide written consent. This will be obtained by the PI or authorised delegate, prior to any baseline assessment data being collected. Participants will be informed that they may, at any time, withdraw their consent to participate in the study without giving a reason, and without it affecting their relationship with their clinical team, and/or their future treatment and care. It will also be stated that, although they are under no obligation to provide a reason for withdrawing from the study, it would be helpful information when assessing the success of the future main trial. Hence, if the person declines to participate during this meeting, they will also be invited (but not obliged) to provide reasons.

10.2 Baseline data collection

After written informed consent has been obtained; the researcher (the PI or authorised delegate) will collect demographic and medical history information from participants. Participants will then be asked to:

- Complete the study baseline questionnaire pack or to hand in the completed form for checking (if they agreed at the telephone meeting to complete it in advance – see section 9.2). This will include a health and social care service receipt inventory.
- Provide responses to a short series of qualitative questions about any previous experience of trying to manage their weight.

- Wear an accelerometer (a wrist-worn electronic device to record physical activity) for seven days. This will be fitted by the researcher along with instructions on its use. Accelerometers will be returned to the CTU by post after being worn for 7 days, using reply-paid recorded delivery envelopes which the researcher will provide.
- Be measured for height, weight and waist circumference.

More detailed information on the measures are provided section 14.

10.3 Programme allocation

Completion of each successful screening/baseline visit will be communicated by the PI (or authorised delegate) to the central study management team and to the appropriate intervention provider. The provider will contact the individual regarding start date and practical arrangements. Depending on practitioner and participant availability, participants should commence their programme within 6 weeks of the assessment.

10.4 Incentive vouchers

We will offer £30 in shopping vouchers for a choice of popular local stores as an incentive to complete the study: £10 vouchers will be provided after completion of each of the follow-up assessments and return of accelerometers.

10.5 Information provided to GPs

Following successful completion of the screening/baseline visit, the researcher will ensure that the participant's GP is informed, so that participation in the study is recorded in the participant's medical record as appropriate.

10.6 Expected recruitment rate

The study requires that 40 participants are recruited over a two-month period for each cohort (This figure maybe revised depending on experiences of programme and study attrition with the first cohort.) Preliminary feasibility work has established that recruitment for the study will require both the standard referral route and additional recruitment from local research-ready General Practice lists. Recruitment will be phased, with invitations sent initially to 80 people across several Practices, with subsequent mailings dependent on response and uptake rates. Assuming a 25% uptake rate, the standard referral routes are expected to produce 20 people per cohort and the Practice route will deliver 20 people per cohort. Experience in recruitment of the first cohort will determine the number of practices and patients to be approached in the second cohort.

11 INTERVENTION

11.1 Principles of the SkiM intervention

Depending on the commissioning body, Tier 2 weight management programmes are typically of 12 weeks' duration and may be provided in group or 1:1 format. Programmes focus on weight loss, usually through dietary restriction but in some cases also through increasing physical activity, and may teach behaviour change skills such as self-monitoring. Programmes augmented with the SkiM intervention will be longer, emphasise personally sustainable weight management practices and lifestyle modifications, and focus on optimising self-management through the development of behaviour change and maintenance skills and personal attributes.

The SkiM intervention involves a considerable element of exploration and addressing of individual needs. In particular, the internal and external influences on obesogenic behaviours are identified, and way of managing these influences are developed. Building on ongoing personal assessments, SkiM encourages a personalised skills-development approach which is tested and adapted through experience over an extended period, during which the individual encounters and learns to manage the various influences on their weight-related behaviours.

The key principles of the SkiM intervention, which will be incorporated into existing programmes, are

1. Personal assessment of internal and external influences on weight-related behaviours. These include
    a. Psychological and emotional needs
    b. Habits
    c. Personal and social identity
    d. Knowledge of energy balance principles and practical recommendations
    e. Attitudes and behaviours of family, friends, peers and work colleagues
    f. Physical environment including food availability and opportunities for physical activity

2. Managing personal and external influences on weight-related behaviours, including
    a. Self-monitoring of weight-related behaviours and outcomes
    b. Developing vigilance for high risk-of-lapse situations
    c. Setting limits to acceptable weight regain and triggers for compensatory action
    d. Identifying and developing strategies to deal with risk-of-lapse situations, such as eating for emotional regulation, hedonistic impulses, and social pressure
    e. Constructively managing cognitive and emotional responses to lapses
    f. Breaking obesogenic cognitive and behavioural habits
    g. Habituating cognitive and behavioural strategies for weight management
    h. Reviewing and modifying management strategies

3. Developing congruence between weight management behaviours and self-identity, including
    a. Reinforcing elements of self-concept that are supportive of weight management, including positive body-image, positive social identity (including family and social relationships), emotional resilience and self-esteem, as well as competence and autonomy in weight management behaviours

b. Identifying and resolving conflicts between identity beliefs and weight management goals and behaviours. This includes finding non-obesogenic ways of meeting personal needs, including pressures to overeat that stem from social or hedonic (pleasure-fulfilment) needs and challenging unhelpful beliefs, thoughts and feelings relating to weight and weight management

These intervention components will be combined with the existing programmes in ways that preserve and build upon their original aims and content. However, group sessions will be structured consistently, with an initial period of education on a weight management issue, followed by identification of specific types of challenge in weight management and group generation of solutions, plus individual, pair or small group work focussing on individual assessment, planning and practice of strategies. In both programmes, facilitators will discourage dependence and encourage autonomous (self-driven and self-directed) self-management.

Further details of the intervention, and the logic model underpinning it, are provided in Appendix 5.

11.2 Delivery of the intervention

Both providers have existing weight management programmes, delivered primarily through group-based contacts over a 3-month period. They include elements addressing dietary restriction and increased physical activity, but differ in their specific content, the practitioners leading them (e.g. health trainers and dieticians), and the types of supplementary support offered, for example as supervised gym sessions, walking groups or cookery classes.

The augmented programmes will be adapted so that they are spread over a 6-month period, with up to 4 additional meetings in the programme schedules to ensure sufficient opportunity to address weight loss maintenance issues.

Both programmes will be supplemented by additional Skim-specific forms of support

1. A self-help manual, written by the research team and addressing the key elements of the Skim intervention
2. An automated telephone text service, in which personalised texts will be sent regularly to each participants, reminding them to self-monitor by measurement of their weight. The service will enable the individual to reply with their most recent weight measurement and this data will be recorded automatically and made available to the practitioner leading their programme.

11.3 Organisation of the intervention

After the baseline assessment the study team will pass contact details of participants on to the appropriate provider, who will contact the individual to let them know practical arrangements.

Recruitment will be organised so that the intervention can be run twice in succession, with a four-month break between. The first cohort will have 40 participants divided into four groups; depending on experience with this cohort, the second cohort may have up to 60 participants, divided into four groups, two being delivered by each provider. This process will provide the maximum experience of

delivering the intervention in different contexts and groups, and the 4-month break will allow process evaluation data to be analysed and the intervention refined before it is run a second time. Figure 2 illustrates how this will occur.

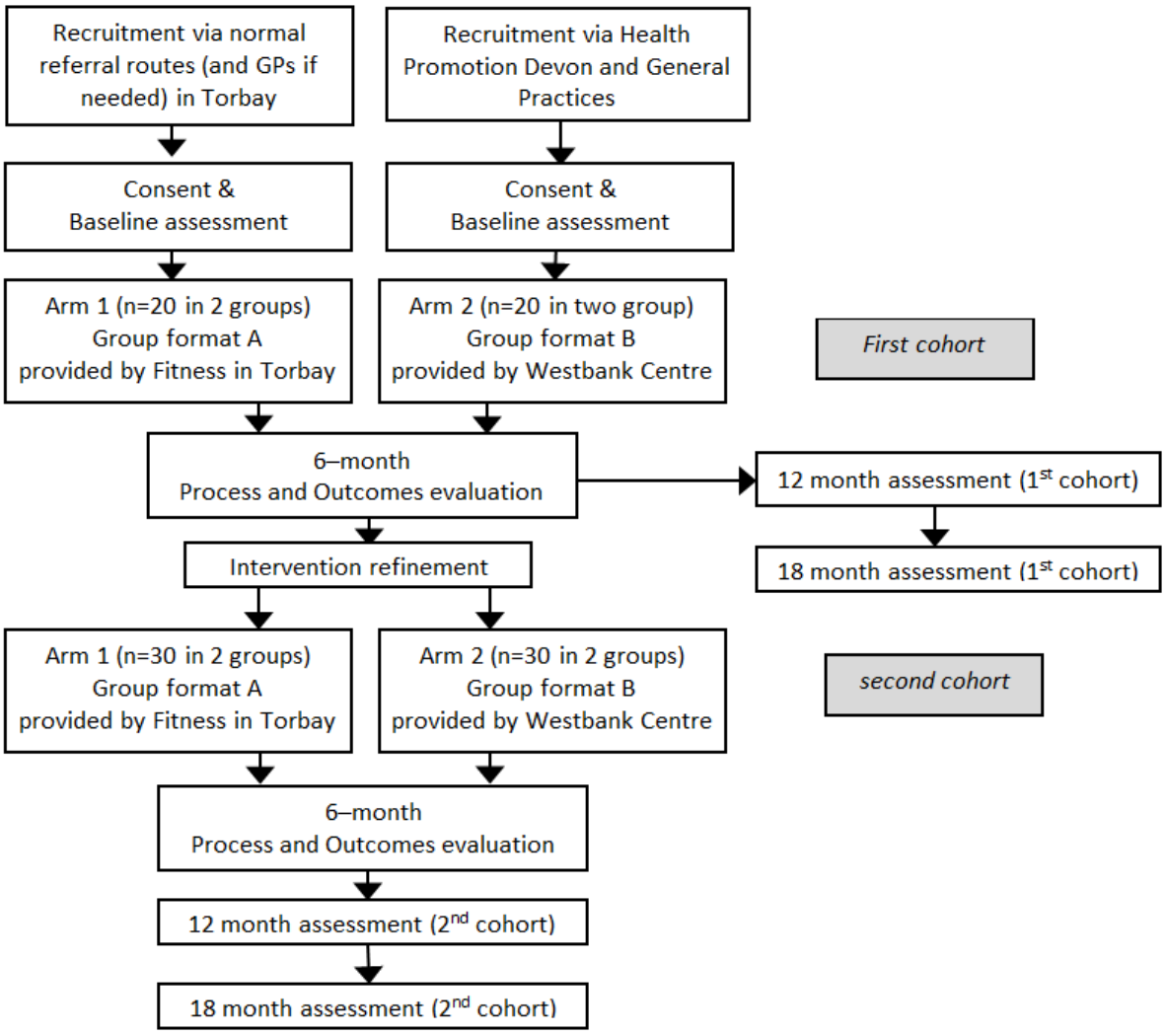


Figure 2: Organisation of intervention arms

Intervention providers will inform the research team when programmes commence, so that process evaluation and follow up data collection can be scheduled appropriately.

12 FOLLOW-UP DATA COLLECTION (AT 6, 12 AND 18 MONTHS)

Two weeks prior to follow-up visits at 6 and 12 months post baseline, questionnaires and accelerometers will be posted to participants by CTU with instructions for their use and a request to complete the questionnaires and wear the accelerometer for 7 days before the visit. At the meeting the researcher will

- Go through the questionnaire booklet to ensure all questions have been answered

- Check information provided by the participant regarding healthcare service utilisation over the preceding period
- Collect the accelerometer.

In addition, participants will be asked to identify any newly diagnosed conditions or new medications started during the intervention delivery periods, as well as any other management services or interventions used (including commercial weight loss programmes) and any smoking cessation attempts (which can cause substantial weight gain).

At the 18-month assessment, the only quantitative measurements will be weight and waist circumference . See Appendix 2 for the full schedule of quantitative measurements.

Participant travel expenses will be paid for attending, if needed, and those without transport or convenient public transport will be reimbursed for use of a taxi to and from the meeting venue.

13 DURATION OF PARTICIPANT INVOLVEMENT

Each recruited participant is expected to be involved in the study for 18-20 months between the baseline visit and the second follow-up visit.

14 STUDY MEASURES AND DATA COLLECTION

14.1 Trial feasibility measures

To assess the feasibility of a trial of the SkiM intervention, the following measures will be used:

- Recruitment rate (the proportions of participants sent an invitation letter who are enrolled)
- Study completion rate (the proportion of those starting the study who provide data at 18 months). Reasons for dropout or loss to follow-up will be recorded where possible.
- Outcomes completion rates (proportions of participants who complete each measure at each time point)
- Intervention attendance (the proportion attending ≥ 66% of maintenance intervention sessions).

14.2 Demographic and health data

At baseline assessment, we will collect the following data on participant characteristics:

- Age
- Gender
- Education level
- Occupational status
- Multiple Deprivation index (derived from postcode and national census data)[37]

- Ethnicity
- Weight loss history (experience of weight-cycling, use of weight loss programmes, weight loss medications, bariatric surgery)
- Smoking status
- Depression (using the 8-item Patient Health Questionnaire [38])
- Co-morbidities including diabetes and other metabolic disorders, cardiovascular or respiratory disorders, arthritis and other joint disorders, any other conditions that might influence diet or physical activity levels.

These variables have been selected because they may moderate the effects of the intervention.

14.3 Intervention outcome measures

Potential outcome measures for a trial will be used in this study to test processes for collection, their acceptability /feasibility, and to assess outcome completion rates. We will also assess assessment burden using a Study Process Questionnaire which will be completed by participants during the **6 month follow-up visit**.

14.3.1 Outcome measures

The primary outcome in a trial of weight loss maintenance strategies will be change in body weight (kg) between 6 month and 18 or 24 month follow ups, i.e. after a period of weight loss.

Proposed secondary outcome measures for a trial are:

- Changes in minutes of moderate activity per week and total energy expenditure (assessed by accelerometer)
- Body Mass Index (BMI)
- Waist circumference
- Self-reported quality of life (EQ-5D-5L [39])

In addition, data will be collected on any newly diagnosed medical conditions or changes in medication during the study period, as well as any other weight management services or interventions used (co-interventions), and smoking cessation attempts (which can cause substantial weight gain).

14.3.2 Economic evaluation

Proposed economic evaluation measures for a trial are

- Cost-effectiveness of the SkiM intervention (using an NHS / Payer perspective)
- Resource use for intervention delivery (the costs and time requirements of training facilitators and delivering the intervention)
- Costs for health and social care utilisation (primary and secondary care contacts, social care contacts and medication usage) over study period, using a bespoke Service Use Inventory.

All participant outcomes will be assessed at baseline (0 months) and at 6 and 12 months. Outcome questionnaires will be self-completed but checked for completeness by a researcher during assessment visits, and body measurements will be taken by the researcher. See Appendix 2 for the full schedule of quantitative measurements.

15 PROCESS EVALUATION

15.1 Design

Aims: In line with the recommendations of the MRC Framework and guidelines for development and evaluation of complex interventions[31, 40] we will conduct a process evaluation with the following aims:

a) To elicit experiences of engaging with the intervention approaches, including identification of processes of lifestyle behaviour change and maintenance that work well or badly

b) To identify other potential processes that may influence the success of the maintenance component of the interventions

c) To identify possible barriers to engagement with the intervention programmes and ways in which the interventions could be improved

d) To examine the fidelity of intervention delivery and receipt

15.2 Participant interviews and session recordings

We will explore the research aims above using individual semi-structured interviews at baseline and at 6 and 18 months after baseline. A short interview will be conducted with all participants at baseline. A more in-depth interview will be used at follow-up, with 12-15 participants from each intervention arm (6-8 interviews per arm per cohort), interviewing the same participants at both time points where possible and using a mixture of face-to-face and telephone interviews depending on location /availability of participants. A topic guide will be developed in consultation with our service user advisory group. In the follow-up interviews, we will purposively sample to achieve diversity in age, gender and success or failure in maintaining weight loss. 'In-vivo' recordings will also be made of all intervention contacts (with permission from participants and intervention providers), using digital recording equipment operated by the facilitator. Recordings of group sessions will be audio-visual, but any 1:1 contact recordings will be audio-recorded only. This will allow assessment of intervention fidelity and provide a basis for providing formative feedback to our facilitators, as well as providing anonymised examples of good practice for future provider training. The session recordings will also be a source of 'triangulation' data to add depth to the narratives derived from the individual interviews (the use of session recording data has been found in prior studies to add substantial depth to participant interview data[41]). Consent to take part in the study (for both participants and facilitators) will include consent for these recordings to be made.

15.3 Process measures

Self-report questionnaires will be used to measure several intervention processes (i.e. to see whether the theoretical change processes which the intervention is designed to deliver are working as planned). These will be developed by the research team, but may include the following:

- Self-report Habit Index (automaticity subscale)
- Engagement in self-regulation activities (including frequency of self-weighing, use of goal-setting and problem-solving strategies taught in the intervention)
- Self-efficacy for lapse management (prevention and recovery)
- Self-efficacy for managing external influences on weight-related behaviours
- Perceived tension /difficulty maintaining weight (scale to be constructed by the research team based on their synthesis of qualitative research in weight loss maintenance)
- Resilience in weight management (scale to be constructed by the research team based on their synthesis of qualitative research in weight loss maintenance)
- Weight-related identity beliefs (scale to be constructed by the research team based on their synthesis of qualitative research in weight loss maintenance)

15.4 Intervention fidelity assessment

The primary data to assess intervention fidelity will be the session recordings (see section 15.224). Following procedures used in previous trials of complex interventions by the research team[42, 43], an intervention fidelity measure will be developed and applied. The procedure involves a) identifying the behavioural techniques and delivery processes that are associated with the intervention (as defined by the intervention development work conducted prior to this study) and b) using the Dreyfus skill acquisition scale[44] to rate the competence of providers in delivering the targeted techniques and delivery processes. This produces a score of 0 to 6 for each targeted element of the intervention process. The scale is anchored such that a score of 3 is considered acceptable, 0 is non-existent and 6 is perfect performance (which is unusual). Two experts in behaviour change intervention will listen to the set of recordings for each participant (or group). They will apply the fidelity measure to rate competence in each element of intervention in each contact and across the whole set of recordings. They will mark sections of the recording that may be useful for informing feedback to the facilitators (examples of good or poor practice, or which illustrate the intended intervention processes) by noting the timestamp of the digital recording and keywords to reflect the content. This will allow the construction of formative feedback and prompts for discussion for each facilitator. These sections may also be transcribed (and anonymised) so that they can be used to inform future training. Where processes are consistently difficult to deliver and performance does not improve with feedback, or if the facilitators strongly feel that part of the intervention is not working/not workable, this may suggest changes to the intervention or to the delivery procedures. We will not be able to reprint the intervention materials until the end of this study, but we can adapt the delivery procedures and elements of programme content, giving the facilitators a chance to develop their skills over the course of the study.

Recordings of group sessions will be augmented by two field visits per programme presentation, in which a Researcher observes the session. This will enable aspects of group interactions and dynamics to be observed that would be difficult to capture through an audio-visual recording. The researcher

will make notes during and after each visit, based upon a checklist of criteria relating to fidelity and to other issues that may impact upon intervention effectiveness.

15.5 Intervention receipt

We will assess receipt /enactment of the targeted intervention processes by:

a) coding participant engagement as part of our fidelity checklist approach described in section 15.4 (both from session recordings and as part of our session observation checklist);

b) self-report questionnaires assessing changes in each individual participants' weight management skills or behaviours (see Section 15.3);

c) session attendance (the proportion of offered sessions that are attended);

d) coding participant engagement in planned activities /intervention processes (such as goal-setting) as part of any session-observations;

e) a 'progress tracker' in the self-help manual where planning and self-monitoring activities will be recorded by the participant – this data may also be coded and summarised.

15.6 Supervision and Feedback sessions

A semi-structured supervision session for the intervention facilitators will be provided twice during each delivery period (see Gantt chart in Appendix 1). This will be an opportunity to share ideas/good practice, problem-solve, and provide and discuss formative feedback based on the above reviewing of recorded sessions. The supervision sessions will be conducted by teleconference to pool learning across intervention providers, and these sessions will also be recorded.

15.7 Satisfaction questionnaires

Questionnaires for participants to assess feasibility, satisfaction and ideas for improvement will be given a) after each participant-provider contact and b) at 6 months (end of intervention). We will give a similar questionnaire to the intervention facilitators as part of the 'contact sheet' described below. The questionnaires will contain mainly open-ended questions and a single satisfaction/overall feasibility question with a Likert response scale.

15.8 Facilitator contact sheet

A facilitator contact sheet will be completed following each participant interaction. This will record attendance, contact type (e.g. face-to-face, telephone) and duration and will also ask the facilitator to make notes about what was covered, what went well in the session; what worked less well; what s/he could have done differently and what we could improve about the intervention materials or the delivery process. The importance of completing these sheets will be reinforced in the training and at supervision sessions.

15.9 Facilitator interviews

Brief semi-structured interviews either by telephone or face-to-face will be conducted with all the intervention facilitators about their experiences of delivering the intervention at the end of each intervention period. Topic guides will be developed in consultation with the intervention development team and the co-applicants. A schedule of events for the Intervention Delivery and Process Evaluation is detailed in Appendix 3.

16 DATA ANALYSIS AND SAMPLE SIZE CONSIDERATIONS

16.1 Quantitative Analysis

Colin Greaves will lead the analysis of outcomes, under supervision from Prof Rod Taylor. Recruitment, intervention concordance, measures-completion and attrition rates will be calculated using descriptive statistics with 95% confidence intervals. Accelerometer data analysis will use bespoke analysis algorithms to extract physical activity variables, and data will be processed with advice from Prof Melvyn Hillsdon (School for Sports and Health Science, University of Exeter) using 'R' statistical software. The variance in continuous outcomes at each time point will also be reported using descriptive statistics. Given the feasibility nature of this study we do not propose to formally test for differences in outcomes and costs between study arms. However, we will report the mean and standard deviation or confidence intervals outcomes at baseline and for changes in scores between baseline and follow up time points.

Participant flow through the study will be summarised using the CONSORT diagram (adapted for complex non-pharmacological interventions)[45] and will include the number of recruitment letters sent, numbers consenting, numbers participating , number undertaking intervention, and number of completed outcomes. Any differences between the recruited sample and the wider eligible sample will also be reported descriptively.

16.2 Sample size considerations

The sample size is calculated to provide realistic estimates (and confidence intervals (CIs)) for the recruitment and study completion rates. The resulting sample size will also allow realistic estimates of the intervention concordance rate and provide an ample pool of participants for qualitative sampling. From recent UK-based trials of interventions to support dietary /physical activity change, it is estimated that 25-30% of those contacted will take part and 70-80% of these will complete measures at 24 months[46, 47]With a 30% recruitment rate, in order to estimate the recruitment rate with 95% CIs of +/-8% at each site, we would need to approach 133 people at each site (and this would recruit around 40 people per site). If recruitment rates vary between 20 and 50%, the CIs on the estimated recruitment rate would still be acceptable (between +/-6.8 and +/-8.5%). The total sample size requirement for two sites is therefore 80.

This sample size will also allow realistic estimates of the intervention concordance and study completion rates (+/-9 or 10%, assuming 70-80% completion) and provide an ample pool of participants for qualitative sampling (to get feedback on the intervention) in both phases of

intervention development (we would have 2 groups of 10 people receiving the intervention in each phase at each site).

Each of our provider partners will supply 2-3 intervention facilitators (5-6 in total) to deliver the study interventions. It is considered that experience of providing 2-4 complete programmes for 10-20 participants each would give the facilitators sufficient exposure to the intervention to be able to comment on its feasibility and acceptability

If intervention concordance /attendance is lower than expected, we will recruit a higher number (up to 50% more) in the second round to ensure that: a) sufficient people get exposure to the intervention to allow us to get collect a meaningful amount of data on process issues such as acceptability and possible improvements to the programme; b) the facilitators get experience of running several groups; and c) the group size does not become too low to function effectively (if this does still occur, we will consider merging groups to keep the group size above 5 if possible).

16.2.1 Stopping conditions

We will consider not continuing on to a trial if a) any serious adverse events are reported or are revealed by the qualitative data that are attributable to the intervention or the study procedures and are deemed by the ethics committee and our independent clinical advisors to constitute an unacceptable risk for further research b) the recruitment rate is less than 15% of those approached c) loss to follow-up rates are greater than 15% per year (this would affect generalisability for a large trial) d) intervention attendance is less than 50% of offered contacts being taken up. These criteria will be developed further by the Project Management Group prior to analysis.

16.3 Analysis of process data

The analysis of qualitative process evaluation data (interviews with participants and facilitators and recordings of participant-provider contacts) will be led by Dr Leon Poltawski. The data will be analysed using thematic analysis techniques[48] to elicit individual narratives and common themes relating to the qualitative research aims of the study (in particular to assess the feasibility and acceptability of the interventions and barriers to participation). Techniques to enhance objectivity and depth of analysis will include second coding of a sample of interviews (10%), negative case seeking /analysis, participant feedback and triangulation (both within the data and against other data from the study (e.g. outcomes data, other process measures).[49] Discussion with our service user advisory group will help to ensure the relevance, credibility and trustworthiness of emergent themes. Data from facilitator contact sheets will be thematically summarised in the final study report and used to inform the refinements to the intervention and to the facilitator training materials. Qualitative analysis software (N-VIVO version 10 or above) will be used to organise and code the data. See Section 22.4 for details of data protection and confidentiality.

Satisfaction questionnaires will be scored and summarised using descriptive statistics (means, 95% confidence intervals). Intervention fidelity scores will be summarised in the same way and collated both in total and by facilitator. Where items are scored low for some or all facilitators, this will identify areas where change is needed (either via formative feedback and a training update or via changes to the intervention materials). The checklist scores and notes taken about good practice and learning needs during the review of the recordings will provide ideas for individualised formative feedback to

each facilitator (in written form). Examples of good practice will be flagged, transcribed and extracted as audio or audio-visual clips (with the facilitator's permission) to inform future training. The methodology has been used successfully before in previous complex intervention trials undertaken by the applicants[42, 43].

16.4 Revising the intervention and training materials

The results of the satisfaction questionnaires and contact report forms, as well as intervention fidelity checking and qualitative analyses will be used to revise the SkiM intervention and training materials. This work will be conducted after each cohort has completed the intervention. A four-month period between cohorts will allow data to be analysed, the intervention to be refined, documentary changes to be made and facilitators to be briefed so that the amended intervention can be assessed in the second cohort. Any further refinements will be made after the second cohort, so that a final version is available to be taken forward to a trial if appropriate.

17 ECONOMIC EVALUATION AND ANALYSES

The health economic evaluation is advised by Professor Colin Green, University of Exeter Medical School. A future fully-powered randomised controlled trial will include an economic evaluation, the aim of which will be to estimate the incremental cost-effectiveness of the SkiM intervention plus usual care vs. usual care alone, from an NHS and personal social services perspective (with other perspectives to be considered in sensitivity analyses). In such future analyses, cost-effectiveness will be assessed through the calculation of incremental cost-effectiveness ratios (ICER), estimating the incremental cost per unit of outcome, including health-related quality of life (i.e. cost per quality-adjusted life-years). Such analyses are not appropriate within this feasibility study, but we will assess

(i) the feasibility and acceptability of collecting data on participant NHS, social services and related resource use via a self-report form,

(ii) the feasibility and acceptability of collecting health outcome data relevant for the economic endpoints,

(iii) the collection of resource data and estimation of related costs associated with delivery of the SkiM intervention (e.g. through facilitator contact sheets and interviewing management staff).

As part of the study, we will also develop the framework for the estimation of cost-effectiveness in analyses alongside any future full RCT, including plans for within-trial analyses and plans to extrapolate beyond trial outcomes using evidence synthesis and economic modelling methods to predict future outcomes (e.g. health events avoided due to any potential improvements in weight management /status).

18 END OF STUDY

The study will end on completion of data collection for the last participant for whom data is collected at the 18 month follow up.

19 DISSEMINATION

We will write up and publish the results of the study in a series of articles in peer-reviewed journals, aiming to place at least the main study report in an open access journal, in line with NIHR Open Access policy.

Over time, we aim to construct a web-based repository of weight loss maintenance intervention evidence, intervention materials, training materials and delivery strategies. We hope that this will be hosted by an authoritative national body (e.g. Association for the Study of Obesity, or the NHS Health Checks Resources website). Other dissemination activities will include conferences, publications and seminars for NHS staff /trainers involved in implementing NHS Health Checks or NICE guidance on diabetes prevention.

20 DISCONTINUATION / WITHDRAWAL

Participants are free to withdraw from the study at any time, and this will be emphasised during the consent process. If a participant chooses to withdraw he /she will be invited to provide reasons, which will be noted. To minimise dropout due to perceived measurement or intervention-attendance burden, they will be asked if they are willing to provide minimal data (weight-only) at follow-up, even if they do not wish to be involved in other study activities. Participants do not have to provide a reason for withdrawal and this will be reiterated by the PI (or authorised delegate) in the event that a participant withdraws. Anonymised data collected on participants prior to withdrawal will be retained for analysis unless the participant requests otherwise (and this will be stated on the consent form).

21 SAFETY REPORTING

The risks of harm associated with study procedures and the intervention are considered to be very low. Nevertheless, procedures are in place in case any should occur.

21.1 Definitions

Adverse Event (AE)

Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons **whether or not related to any research procedures or to the intervention.**

Non-serious adverse events (see definition below) which are not related to study procedures or to the intervention will **not** be reported in this study.

Adverse Reaction (AR)

An adverse event judged as having a reasonable causal relationship to the intervention or to study procedures will be considered an Adverse Reaction (AR). The existence of a 'reasonable causal relationship' will be judged by the researcher reporting the event. Any evidence or argument to suggest a causal relationship will also be reported.

In this study, adverse reactions will be reported, regardless of seriousness.

Seriousness

Any adverse event or adverse reaction will be regarded as serious if it:

i. results in death;
ii. is life threatening;
iii. requires hospitalisation or prolongation of existing hospitalisation;
iv. results in persistent or significant disability or incapacity
v. results in a congenital anomaly or birth defect; or
vi. results in any other condition, judged to be significant by a clinician.

An adverse event meeting any one of these criteria will be a **Serious Adverse Event (SAE)**. An adverse reaction meeting any one of these criteria will be a **Serious Adverse Reaction (SAR).**

In this study, all serious events will be reported whether they are related to the administration of the research procedures or not. A tabulated summary of reportable events is given in

Table 1:

Table 1: Reporting of Adverse Events

Event type	Reported by	Reported to	Timeframe
Adverse Reaction	CI or authorised delegate	Chief investigator (CI), Sponsor	Within 3 days*
Serious Adverse Event (SAE)	CI or authorised delegate	CI, Sponsor	Within 24 hours*
Serious Adverse Reaction (SAR)	CI or authorised delegate	CI, Sponsor	Within 24 hours*

**of the CI (or authorised delegate) becoming aware of the event*

Non-serious, unrelated AEs will not be recorded

21.2 Reporting adverse events to Investigator and Sponsor

Non-serious adverse events which are unrelated to the intervention or study procedures will not be recorded or reported. Adverse events which are serious and/or related to study procedures or the SkiM intervention, from the point that informed consent is obtained until the end of the study, will be recorded in the case report form (CRF) and reported as described below.

The method for collecting adverse event information will be a) via the data collection visits at follow-up assessments, and b) direct contact from participants or intervention facilitators.

21.2.1 Reporting non-serious events

The CI (or authorised delegate) will question participants about adverse events at the 6 and 12 month data collection visits and will be responsible for adjudging relationship to the intervention and study

procedures. Related adverse events will be documented in the purpose-designed CRF. Multiple symptoms will be recorded as separate events. The events will be reported to the CI and Sponsor on a designated report form which will capture the relatedness of the event to study procedures/the intervention, in the opinion of the PI (or authorised delegate).

21.2.2 Reporting serious adverse events

Serious adverse events will be recorded and sent for subsequent adjudication by two clinical advisors (Dr Philip Evans of St Leonards Practice and Dr Chris Clark of Witheridge Medical Centre). If one advisor is not available, Prof John Campbell (academic GP and head of the primary care research group at UEMS) will be consulted instead. The role of the adjudicators will be to judge whether the event is likely to be due to participation in the study.

Onward reporting: Reporting of all SAEs will follow a study-specific SOP (Standard Operating Procedure) for Adverse Event Reporting. Briefly, all SAEs that are related to the study or intervention procedures will be reported to NHS Research Ethics Committee using the non-CTIMP Safety Report Form within 15 days of the CI becoming aware of the event.

If incomplete information is available to the CI (or authorised delegate) at the time of when s/he becomes aware of a reportable event, all information available at that time should be reported onward as soon as possible. The CI will coordinate adverse event information, including generating requests for missing/additional information as required. Any documentation will be anonymised before passing on for adjudication /reporting purposes.

All reportable events will be followed until resolution where possible or until the end of the data collection period.

21.3 Processing safety information

Safety information in the form of designated adverse event report forms, with any relevant documents, will be sent to the clinical advisors for adjudication of whether they might be related to study participation or not. Summary reports listing all reportable adverse events and adjudication about relatedness (and the rationale for these decisions) will be compiled by the CI and sent to the Sponsor on a case by case basis. Events which are both serious and related to the SkiM intervention or study procedures will be communicated immediately to the CI who will be required to decide if such an event is unexpected.

If unexpected, the event will be regarded as an Unexpected Serious Adverse Reaction and will be reported to the Research Ethics Committee by the CI within **15 days** of the CI (or authorised delegate) becoming aware of the event, using the SAE report form for research other than clinical trials of investigational medicinal products (non-CTIMPs) published on the NRES website. The report will be copied to the Sponsor.

22 DATA MANAGEMENT

22.1 Study Numbering

Each participant will be allocated a unique study number on consenting to the study and will be identified in all study-related documentation by their study number and initials.

22.2 Data Collection

Data will be recorded on study specific data collection forms (CRFs) by the research team. All persons authorised to collect and record study data will be listed on the study delegation log, signed by the CI. Source data will include all data recorded directly into the CRF, accelerometer data and any participant completed questionnaire booklets.

Digitally recorded data will be collected by the intervention facilitators and the SkiM research team and transcriptions will be made by a University of Exeter approved transcribing contractor.

22.3 Data entry

Completed CRFs will be checked and signed by a member of the research team before being sent to the CTU. Original CRF pages and questionnaire booklets will be posted to the CTU at agreed timepoints for double-data entry on to a password-protected database, with copies retained at the relevant study site if applicable. Accelerometers will be returned to the CTU for data transfer, preparation for re-use and posting to study participants when required. All data will be transferred to the research team in Exeter for subsequent analysis. All forms and data will be tracked using a web-based trial management system. Double-entered data will be compared for discrepancies using a stored procedure. Discrepant data will be verified using the original paper data sheets.

22.4 Data Confidentiality

Participant names and addresses will be collected for the purpose of managing questionnaires and process evaluation interviews. Investigators will ensure that the participants' anonymity is maintained on all other documents. Within the CTU, anonymised and identifiable study data will be stored separately, to prevent the identification of participants from research records, in locked filing cabinets within a locked office. Electronic records will be stored by the CTU in a SQL server database, housed on a restricted access, secure server maintained by the University of Plymouth. Data in the database will be backed up daily by the University of Plymouth web team and will be accessible for up to 6 months. The website will be encrypted using SSL. Data will be collected and stored in accordance with the Data Protection Act 1998. Direct access to study data will be restricted to members of the research team and the CTU, with access granted to the Sponsor on request. Access to the database will be overseen by the CTU data manager. Copies of original study data retained at study sites will be securely stored for the duration of the study prior to archiving. Digital recordings and participant names and addresses will be stored on a restricted access, secure servers at the University of Exeter. Access will be password protected and limited to the SkiM research team.

22.4.1 Archiving

Following completion of study data analysis, the Sponsor will be responsible for archiving the study data and essential documentation in a secure location for a period of 5 years after the end of the study. No study-related records will be destroyed unless or until the Sponsor gives authorisation to do so.

23 DATA MONITORING AND QUALITY ASSURANCE

The Study Manager will check completed case report forms for missing data or obvious errors before the forms are sent to the CTU. Data will be monitored centrally for quality and completeness by the CTU and every effort will be made to recover data from incomplete forms where possible. The CTU data manager will oversee data tracking and data entry and initiate processes to resolve data queries where necessary.

Participating sites will be required to permit the Study Manager, or representative of the sponsor, to undertake study-related monitoring to ensure compliance with the approved study protocol and applicable SOPs, providing direct access to source data and documents as requested.

All study procedures will be conducted in compliance with the protocol and according to the principles of the International Conference on Harmonisation Good Clinical Practice (ICH GCP). Procedures specifically conducted by the CTU team (e.g. data management) will be conducted in compliance with CTU standard operating procedures (SOPs).

24 STUDY ORGANISATIONAL STRUCTURE

Responsibility for the study is assumed by the CI (Prof Colin Greaves) and the Study Manager (Dr Leon Poltawski) who will ensure its timely completion and will be responsible for managing the clinical aspects of the study, participant recruitment and data collection, and ensure compliance with applicable Clinical Trial Regulations.

The UKCRC-accredited PenCTU will allocate at least one Data Manager to the study to oversee data management in the study. They will attend, on request, Project Management Group meetings and ensure that all parties involved are fully apprised of progress.

24.1 Project Management Group (PMG)

A PMG including the CI, CTU data manager (on request), statistician, health economist, Study Manager, and specialist advisors (service provider and service commissioning representatives) will meet regularly throughout the duration of the study to monitor progress, resolve day-to-day problems, oversee development of documentation and forms, monitor participant recruitment and follow-up, review the budget, discuss analysis, results, draft reports and dissemination. The PMG will meet at least every quarter.

24.2 Events Adjudication Advisory Group

An Events Adjudication Advisory Group comprising two general practitioners who are not involved in the study will assess all serious adverse events involving participants during the study (see Section 21 regarding adverse event reporting).

25 DIRECT ACCESS TO SOURCE DATA AND DOCUMENTS

The CI and the Sponsor will permit study-related monitoring, audits, regulatory inspections and REC review by providing appropriate bodies (e.g. PenCTU, REC etc.) direct access to (anonymised) source data.

26 RESEARCH GOVERNANCE

26.1 Sponsor

The study Sponsor is the University of Exeter.

26.2 Ethics and NHS approvals

The study will be conducted in accordance with the Research Governance Framework for Health and Social Care, Second edition (2005). The study will be supported by the UKCRC-registered PenCTU (Registration Number 31), University of Exeter and approved by a recognised NHS REC, and the Royal Devon & Exeter NHS Foundation Trust Research and Development (R&D) Department. The study will be adopted by the NIHR Clinical Research Network (CRN).

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP. Any amendments to the protocol will be submitted for REC approval as appropriate.

On request, the Chief Investigator will make available relevant study-related documents for monitoring and audit by the Sponsor, and the relevant Research Ethics Committee.

Annual progress reports will also be submitted to the REC using the recognised National Research Ethics Service (NRES) template. An end-of-study declaration will be provided to the REC within 90 days of study conclusion or within 15 days of termination in the event the study is prematurely terminated.

The Sponsor will draw up an agreement with the PenCTU regarding study responsibilities, which will be agreed and signed by the authorised representatives of each party.

27 STUDY PARTICIPANTS COMPLAINTS PROCEDURE

If programme participants are unhappy about any aspect of their participation in the intervention, which cannot be resolved by discussion with the programme Facilitator, they will be invited to contact the study CI. If a programme participant or Facilitator is unhappy about any aspect of their participation in the study, they are invited to contact the CI. In either case, if the CI cannot resolve the

issue, the matter will be raised with the Project Management Group. If they cannot resolve the issue they will determine whether it requires referral to the Programme provider organisation for resolution by their own complaints procedure, or to the University of Exeter's Research Complaints Procedure via the Study Sponsor, who is responsible for Study Governance. At each stage of the procedure, an acknowledgement of the complaint will be made within 24 hours, and the issue will be addressed within 5 days. The CI will ensure regular and positive communication with the complainant until the issue is resolved, and will report its outcome to the Project Management Group, and to the Sponsor and other bodies as recommended by GCP guidance.

28 STATEMENT OF INDEMNITY

This is a University-sponsored research study. If an individual suffers negligent harm as a result of participating in the study, University indemnity covers University staff and those people responsible for conducting the study who have honorary contracts with the University.

29 PUBLICATION POLICY

A publication plan will be developed outlining any publications and manuscripts that will be developed for peer reviewed journals. Study outputs may be presented at national and international conferences including the annual meetings of the UK Society for Behavioural Medicine, The Association for the Study of Obesity and the International Society for Behavioral Nutrition and Physical Activity.

30 FINANCE

The SkiM study is funded by the NIHR as part of a Career Development Fellowship awarded to Colin Greaves (Grant Number CDF-2012-05-259).

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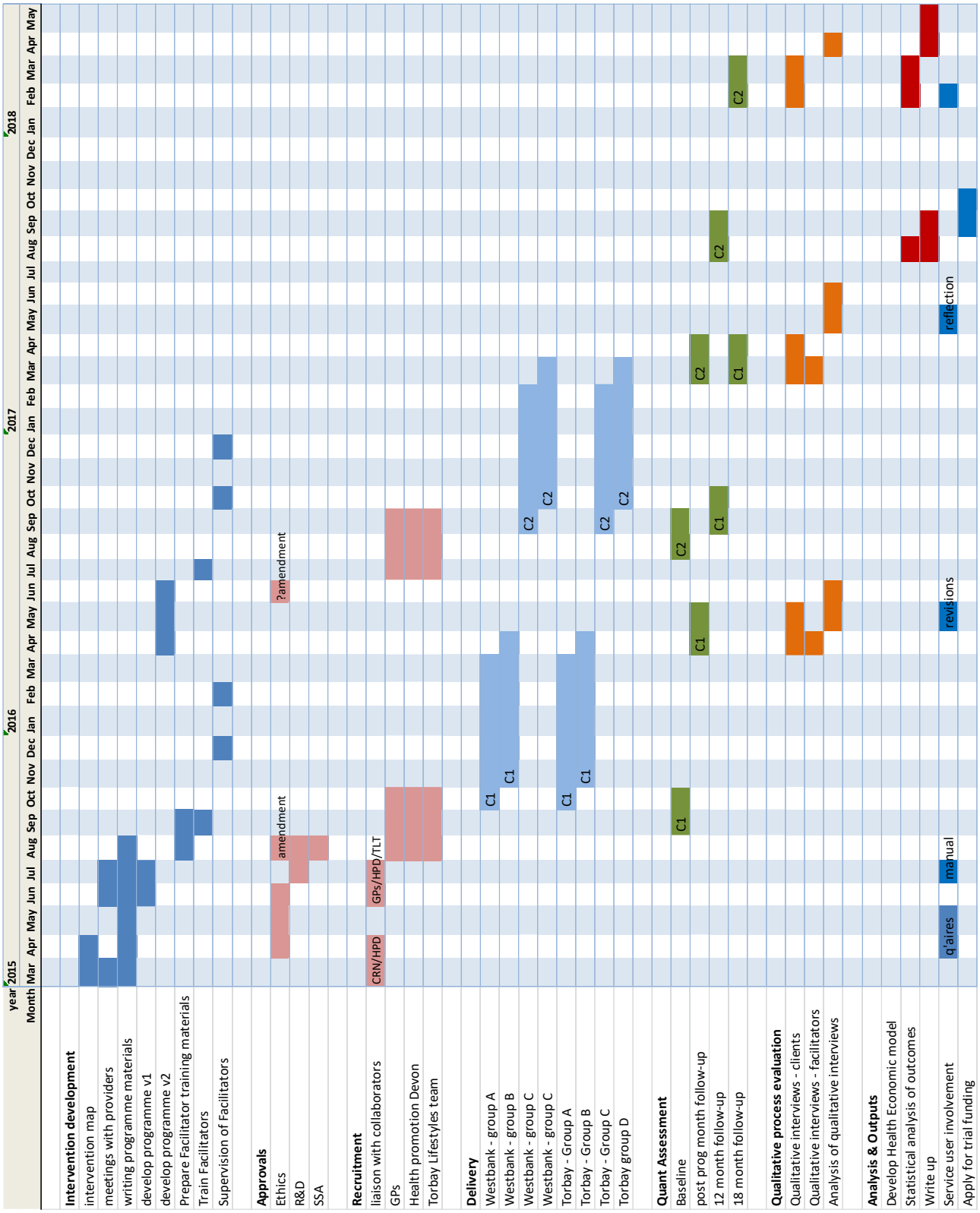
32 APPENDICES

Appendix 1 – Study Gantt Chart



Appendix 2 – Schedule of measurements

	Assessment visit 1 (Baseline*)	Assessment visit 2 (6 months)	Assessment visit 3 (12 months)	Assessment visit 4 (18 months)
Demographics (incl. age, sex, socio-economic status)	X			
Medical history (incl weight changes and management, and co-morbidities)	X			
Changes in health status		X	X	X
Depression & Anxiety (screening questions then Hospital Anxiety & Depression Scale if indicated)	X			
Body measurements (Weight, height, waist circumference)	X			
Body measurements (Weight, waist circumference)		X	X	X
Physical activity levels (7 day accelerometry)	X	X	X	
EQ5D-5L	X	X	X	
Health & Social Care Use Inventory (including medication)	X	X	X	X
Self-reported Habit Index (Automaticity)	X	X	X	
Self-efficacy (Lapse management)	X	X	X	
Self-efficacy (Managing external influences)	X	X	X	
Perceived maintenance tension	X	X	X	
Maintenance resilience questionnaire	X	X	X	
Weight-related identity beliefs	X	X	X	
Adverse events		X	X	

Appendix 3 – Schedule of Intervention Delivery and Process Evaluation

Instrument	Each session	Baseline	Post-programme	Assessment visit 3 (12 months)	Assessment visit 4 (18 months)
Audio-visual recording of session	X				
Satisfaction questionnaire (client)	X		X		
Facilitator records (facilitator) Including self-assessment of each session, contact and non-contact time)	X				
Client logs (e.g. goals, boundaries, weight, physical activity)	X				
Qualitative interview (client)		X	X		X
Qualitative interview (facilitator)			X		
Study Process Questionnaire			X		

Appendix 4 – Eligibility Criteria of Existing Weight Management Programmes

Torbay

Inclusion criteria

- aged 16 years and above
- having a BMI >=30 (those who are 16-17 years commencing the weight management programme will also be automatically referred to the dietetics team for specific review).
- Assessed by clinician as ready for change
- willing and able to participate in a group education programme that includes an exercise element.

Exclusion criteria

- already attended a weight management programme within the preceding 12 month period and did not complete the programme
- assessed by clinician as not showing commitment or readiness for change
- assessed by clinician as having psychological / emotional issues regarding eating (e.g. binge eating disorder) and who would need more specific advice.
- assessed by clinician as not having appropriate fitness levels or who would not be able to participate in the exercise component.
- not completing consent form.

Exeter area

Eligibility

- Age ≥ 16y
- BMI 35-50 (32.5-50 for Black/Asian populations) WITHOUT co-morbidities
- BMI 30-50 (27.5-50) WITH co-morbidities
- Considered ready to change by health professional

Co-morbidities are

- Type 2 diabetes or previous gestational Diabetes
- Uncontrolled hypertension (≥140/90)
- Patients whose Hyperlipidaemia is uncorrected by maximum tolerated doses of Statins (total C.5.2mmol/l or Total C:HDL ratio 6.0mmol/l
- Sleep apnoea
- Severe Osteoarthritis eg: requiring listing for joint replacement or in severe pain uncontrollable with analgesics.
- For those with co-morbidities, a risk assessment algorithm is used to determine whether or not the individual should be offered a programme including supervised physical exercise

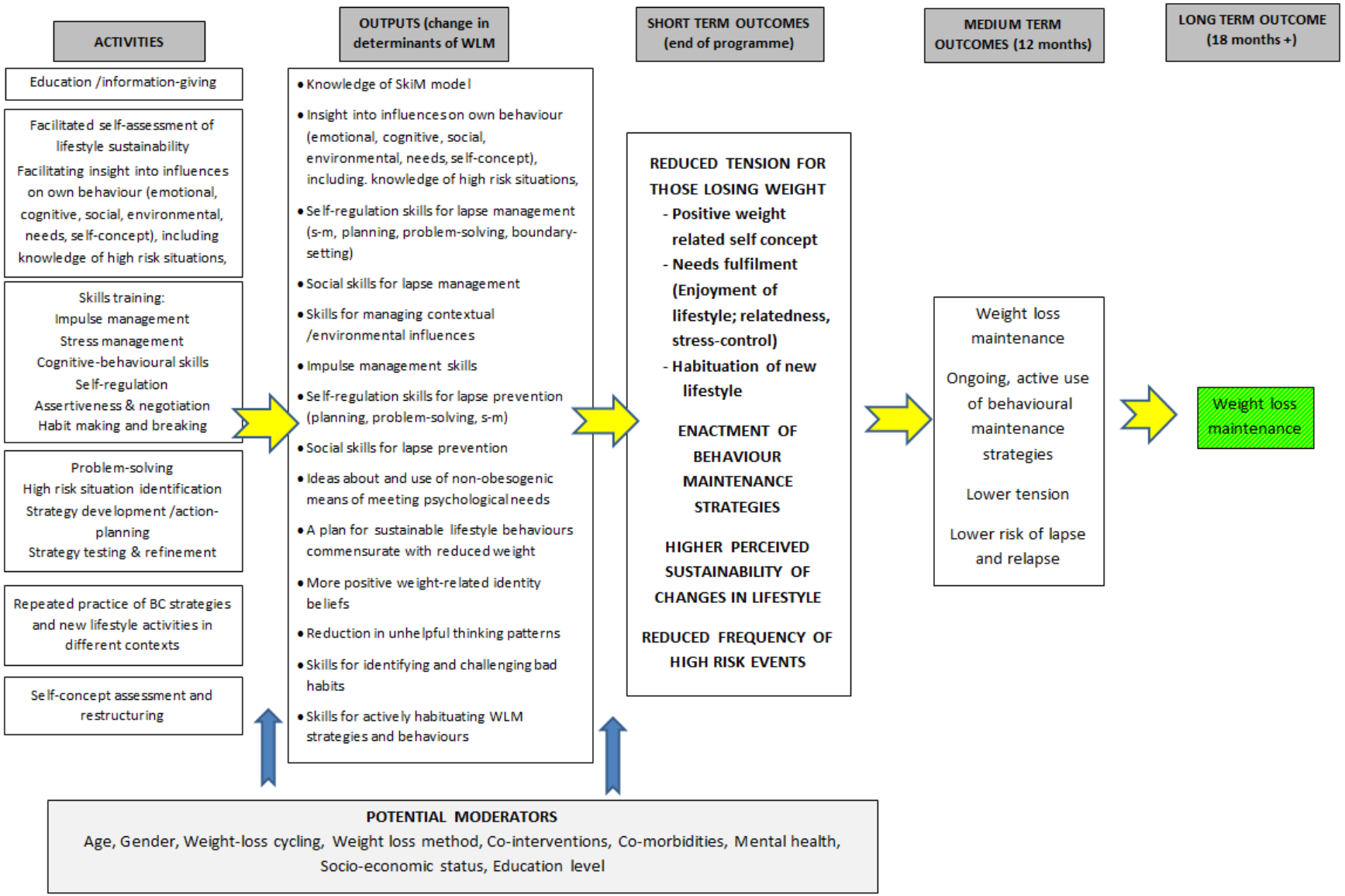
Appendix 5 – Overview of the SkiM Intervention

The Skim intervention comprises a programme of training in a set of skills and strategies that can be used by individuals to support sustainable change in weight-related behaviours. It includes:

(i) Materials to support the delivery of the training programme. This includes plans for activities of 5 to 20 minutes that can be incorporated into existing weight management programmes, as well as handouts and other learning resources for use in sessions.
(ii) A self-help manual, called "Keeping it Off" for use by programme participants. It provides written information about how weight loss (and weight regain) works, what is involved in weight loss maintenance, its challenges and ways to deal with them, tips for managing weight in the long term and a set of interactive tools to assist personalised self-assessment, planning, monitoring of progress and problem-solving.
(iii) A training package for the Facilitators who will deliver the intervention as part of a broader weight management programme.

The logical model underpinning the intervention is provided overleaf, and this is followed by indicative contents of the self-help manual and examples of the intervention materials. The purpose of the proposed research is to develop and refine the materials through a) discussion with the intervention providers and with our service user group and b) feedback received during the proposed study. Hence, the materials presented here must be seen as indicative and subject to change.

The Skim Intervention Logic Model



Example Sections from the Self-help manual

Keeping it Off

A guide for long-term weight management

CONTENTS

Part 4: The new you: Identity and weight management

4.1 Ira's story (a case study)

4.2 Weight loss and You. How do you relate to your weight? How does losing weight affect your sense of who you are and how you relate to the world?)

- Managing unhelpful thoughts and feelings (identity beliefs)
- Staying motivated
- Finding a healthy and enjoyable lifestyle that suits you

Part 5: Other Information

Information sources for healthy eating (Eat Well plate /NHS Choices), recipes, "mindful eating" exercises, local opportunities for physical activity and other local service information.

2.2.3 Managing food cravings (snacks and portion-control)

What's the problem?

Life is full of temptations! Everywhere you look there are snacks and treats and people offering you tempting foods. Often, our attempts to eat healthily are undermined by in-the-moment urges to snack on something that we know isn't really healthy. Indeed research has shown that the "pleasure-reward centres" in our brains respond especially strongly to combinations of fat and sugar. Even worse, because this combination (fat with sugar) doesn't usually exist in nature, our appetite-control systems (the hormones and nerve signals that tell our brains we are full) are not well set up to manage our intake of this type of food. So we can easily end up eating much more than we need of this type of food (and the food industry has not hesitated to take advantage of this fact). Yes, we are talking about doughnuts, cream cakes, biscuits, ice cream, chocolate bars – the more tempting it is, the more likely it is to be a fat-sugar combination!

Food cravings are strong impulses to eat that are triggered by tempting foods, moods, and situations. They exist because we have in the past associated pleasure or reward with eating the food item (or eating a certain type of food in a certain situation). Food cravings become stronger and more frequent when they are acted on - because we get a big, positive reward from the fat and sugar involved. So, unhealthy snacking can easily become a habit. The eating often tends to happen automatically, without too much effort or thought – we know we are doing it, but we don't think about it too much (like being on auto-pilot when driving on a familiar route). Trying to resist the craving on the other hand, may require considerable effort.

Two other common situations where automatic eating or food cravings can sometimes be a problem are 1) deciding how much food to put on your plate and 2) stopping eating once you are full (as opposed to automatically emptying your plate) – stopping eating once you have started can be particularly difficult.

What can I do about it?

So what can you do to manage the urge to snack or to over-fill your plate or to eat too much once you have started? The SkiM programme offers you a clear, three-step plan for identifying and learning to manage food cravings. It may be difficult to do at first, but the more you practice these techniques, the easier it will become – as the old unhealthy habit is suppressed and replaced with alternative ways of thinking or eating.

1) Learn to recognise the craving and when it happens, put up a mental STOP sign so that you can take a moment to make a clear decision 2) try out different strategies to reduce or resist the craving 3) learn from experience what works for you.

1. First, put up the STOP sign!

When you experience a craving, imagine shouting ‘hang on’ or ‘stop’ (imagine a big red STOP sign like the one above!). Give yourself a bit of time to check the situation and make sure that you are making a clear, conscious decision (and not working on automatic pilot). It may be useful to bring to mind the main reason why you are trying to manage your diet or lose weight, or to design your own bit of “self-talk” for use in these moments. An example might be “Hold on! let’s just check my options here.” – of course, you will have your own ideas about what makes sense for you.

You may still decide to have a snack and of course, it is fine to have treats and enjoyment in your life. The other important thing is that YOU are challenging your ‘automatic pilot’ and bringing these decisions under your conscious control. Even if you only succeed in overcoming the craving one time in three, you will have a better chance of keeping a healthy overall energy balance.

2. Try out some different strategies

The following may be helpful ...

Put it off: Often food cravings only last a few minutes, so if you put off the decision you may find that the craving goes away – try saying to yourself "I'll leave it for now and see if I want one later"

Distract yourself: Find something else to do – maybe say to yourself "I might have one later after I have (for example) watched Eastenders", or after I have been for a walk". **Physical activity** is often a good distraction tactic as it releases chemicals (endorphins) that stimulate the pleasure centres of the brain. This can often help the craving to go away. So maybe try doing a few stretches or muscle-strength exercises whilst watching the telly, instead of having a snack.

Substitution: Choose a healthy alternative, or go for a smaller portion of the thing that is tempting you (for example cut it in half).

Enjoy it more!: Savour the experience so that you can get more satisfaction from a smaller quantity (see the section at the end of this piece about 'being mindful' about your lifestyle). An example of this is if you are watching TV at the same time as snacking, you are unlikely to really enjoy the snack and it is easy to eat a lot without realising it. If you put a big bowl of nuts or crisps in front of you, they will go! So think about the amount you serve up and try to avoid eating in front of the TV.

Use your social support: Involve others in the decision, or get your spouse, partner or friend to support your decision (for example, you might say out loud "Hmm, what is a healthy option here?"). Once you have made your intention public, that is a powerful motivator to follow it through.

Surf that urge: The urge-surfing technique (below) encourages you to accept and observe the craving experience, rather than trying to resist it. This technique is also designed to reduce stress. Instructions for doing this are provided below.

Chill out!: Boredom and stress can be causes of food cravings (this is often a cause of "comfort eating"), so if you think this is appropriate for you, you might try using one of our recommended relaxation techniques (urge surfing, or breathing focus), which are described below.

3. Learn from experience

It is possible to control cravings if you are prepared to engage in a bit of trial and error. It doesn't always work and it doesn't always work first time, However, the more times you try, the more you will learn about what works or doesn't work for you. Keeping track of your progress is a good way to encourage learning, so ask yourself the following questions each time you get a food craving during the next couple of weeks. Be aware of what happens and try out different strategies to help figure out what works best for you:

1. What were you craving for?

_____

_____

2. How did you try to deal with the situation?

_____

_____

3. How well did you control the craving?

_____

_____

4. What did you learn from this experience to help manage future cravings?

_____

_____

It can also be worth thinking about what are the main situations when cravings occur (for example "when I am watching TV later in the evening") and thinking in advance about what strategies you might try to use (making an IF-THEN plan). Later sections of this manual deal with identifying high risk situations and making IF-THEN plans.

Urge Surfing

Urge surfing is a "mindfulness" technique that has been shown to reduce the intensity and frequency of food cravings. It also makes it much less likely that you will give in to them.

Next time you have a craving or an urge to eat ...

1. Sit back and relax, focus on your feelings. Think to yourself, what am I feeling? Do you feel any tightness anywhere? Are your hands clammy?
2. Imagine the urge or craving to be like a wave. It arrives naturally, will build up, and eventually subside.
3. Pay attention to your breath. Notice any drifting thoughts, and slowly bring your focus back to your breathing.
4. Instead of fighting the craving, simply focus your attention on it. Let it wash around you, like a wave that you are floating on. Focus on observing the urge and just floating on the wave.

You may notice that your cravings change over time as you learn to use this technique. You can't stop the waves, but you can learn how to surf!

Further information about using mindfulness techniques to manage your eating (e.g. a video and a mindful eating exercise to use whilst eating) is provided in the Information section in Part 4 of the manual.

Smart-phone support: The ImpulsePal® app

For people with smart-phones, working with Samantha Van Beurden and other colleagues at University of Exeter, we have developed an “app” which is designed to help you manage food cravings. Unfortunately, this is only currently available for the Android operating system, but if it is found to be useful, we will make it more widely available. Instructions for accessing the app will be given to you by the research team.

2.3.3 Getting Support

Who could provide support for you? For healthy eating? For being more active? What could they do to help? Here are some ideas to help you:

Ways to help me eat healthy & be more active:

- Buy and cook healthy food
- Go for a walk with me. Or do other physical activities with me
- Plan social events around being active
- Don't tempt me with problem foods as a reward or gift
- Compromise when my plan for being physically active conflicts with their schedule.
- Clear the table and put food away as soon as the meal is over
- Praise my efforts when I do my planned activity.
- Help with cooking, shopping, or cleaning up after meals
- Don't offer me second helpings
- Set up a regular date with me to be active
- Encourage me to cook or try new foods
- Encourage me to go out for a walk when I'm wondering whether or not to go
- Praise my efforts to eat healthier foods.
- Try to achieve and maintain my goals with me.

3.1 Learning from experience (progress tracker introduction)

As we have seen, there are many things which you can do to help manage your weight and move towards a lifestyle that is both healthy and enjoyable. Other people can help, but the most important person in managing your weight is you. In the SkiM programme you have learned a number of skills including:

- Skills for managing unhelpful thoughts, feelings and beliefs which might previously have triggered over-eating or low levels of activity
- Skills for managing other influences on your eating and physical activity
- Identifying high risk situations and making plans about how to avoid and manage them
- Skills for managing food cravings and unhelpful habits
- Skills for building new healthy habits
- How to assess your diet and physical activity to see if it is sustainable and plan changes to increase sustainability

However, as with all skills, to really master them requires practice, practice, practice! We all know from experience that ideas and plans for managing your weight don't always work first time. Because everyone is different, the things that might get in the way of success or help you to succeed are also different for each person. The best way to figure out what works for you is by trial and error - you need to try out your new skills and learn from the experience. The Keeping Track booklet will help you to monitor your progress over time and help you to figure out what works best for you. If you keep it up for the course of the programme, it should also help to make the things you need to do to manage you weight part of your daily routine.

The booklet has been designed to help you:

- Monitor your weight and your eating patterns
- Keep track of your physical activity
- Monitor any unhelpful thoughts or feelings or situations that get in the way of eating healthily and getting enough physical activity
- Learn what things help you to manage your lifestyle and reduce the "tension" of weight management
- Identify any concerns that you may want to discuss with your weight management advisor.

4.5 A “mindful eating” exercise

‘Mindfulness’ is an idea that may be useful in managing food cravings. When your mind is not focused on what you are currently experiencing it can be described as being on ‘auto-pilot’. That is, you are not really in touch with the ‘here and now’. In this state, many of your behaviours and day-to-day choices are based on existing habits and tend to become automatic, rather than being clearly thought about. In this state, we tend to follow the path of least resistance and may be inclined towards less healthy choices, which offer a ‘quick fix’ or ‘instant gratification’.

When trying to overcome old habits and adopt new behaviours, the first step is to be ‘mindful’ or aware of exactly what is that you are doing, when you are doing it. This way you are better placed to break free of or not ‘buy into’ unhelpful habits, or thoughts or feelings that are getting in the way of positive action.

For example: when you eat your dinner whilst watching television, your mind may be far away from the food you’re putting in your mouth. You don’t even notice the taste or pleasure and only stop eating when the plate is empty. You may even still feel hungry.

Instead: take the time to sit down at the table and really focus on the food that you are eating: what does it taste like, what texture does it have, is it hot or cold? Savour the flavours and maximise your enjoyment of each mouthful. Be aware of the food going down into your stomach and how full your stomach is feeling.

By doing this you may find: firstly that you enjoy your meal much more! Secondly, you may notice that you feel full before you’ve finished all the food on your plate and you may be able to stop eating earlier. Indeed, another way to practice ‘mindfulness’ is to deliberately slow down the pace at which you eat – take mini-breaks in eating and allow your conscious mind to exert a bit of control over your hunger. By practising this technique, you may find that your relationship with food changes gradually to one where you are more able to eat what you choose when you choose, rather than being in a situation where your eating is driven by the ‘force of habit’. You should become more in control of your appetite, rather than it being in control of you.

Often the ‘automatic cue’ for stopping eating is just the fact that your plate is empty, so you may also be able to exert some control over this automatic process by putting a bit less food on it in the first place.

Programme Session plans

The session plans revolve around facilitating the development of the skills for weight loss maintenance that are described in the Keeping it Off book. These will be integrated alongside the delivery of existing weight management intervention sessions, delivered by our provider organisation partners.

Session 1 (25 mins): The challenge of weight loss maintenance

- Why is it difficult to stop weight going back on? (The SkiM model)
- How can I increase my chances of succeeding?
- A plan for long term weight management (Understand the problem, Learn the skills, Learn from experience)

Session 2.1.i (20 mins): Where do I stand? Current weight management skills

- Self-assessment of Current skills /resilience
- Start making an individually tailored 'training' plan (skills to learn for WLM)

Session 2.1.ii (5 mins): Assess sustainability of lifestyle changes

- Sustainability questions to be integrated with instructions for (and text of) action planning for healthy eating /changes to diet
- To be integrated with instructions for (and text of) action planning for increasing physical activity

Session 2.1 (iii-v) (30 mins): Food for thought: The role of thoughts, feelings and beliefs

- Assess personal needs /drivers of overeating (social approval, pleasure-reward, stress-control). Thinking about alternative (non-obesogenic) strategies
- Unhelpful and helpful thoughts and feelings, motivations
- Self concept (identity) and eating – an introduction

Session 2.2 (25 mins): Breaking bad habits

- Identifying unhelpful patterns of behaviour (eating and PA) and the context (social, emotional, physical) in which they occur. Identifying food cravings and the context in which they occur
- Learning to challenge habits and cravings
- Brainstorm for alternative strategies (including managing unhealthy eating impulses)
- Refer to the 'Managing Cravings' section in the manual

Session 2.2 (ii) (25 mins): Making new habits

- Identifying helpful patterns of behaviour (eating and PA) and the context (social, emotional, physical situations) in which they need to occur.
- Prompting practicing – reminders, cues, rewards

- Spreading habits to different contexts /situations

- Making habits of weight management practices (self-weighing, reviewing progress, problem-solving, setting (and re-setting) goals and boundaries)

2.3 Managing influences (45 mins)
- Identifying high risk situations

- Developing strategies for managing them, including getting social support

- Managing Conflict with other life goals (being too busy)

2.4 Managing thoughts and feelings (45 mins)
- Eating in response to stress boredom and tiredness

- Managing unhelpful thoughts and feelings (**list from iMap)

- Managing Conflict with other life goals (other priorities)

Part3: Developing your skills

3.1 Learning from experience (30 mins): Introduction Session
- Keeping track of progress and problem-solving: present rationale for and use of the 'Keeping Track' booklet

- Setting limits and making plans for slips and lapses

- Keeping track of your skills and what is working for you

- Managing lapses: Avoid them, deal with them, or make up for it

3.1b Learning from experience (20 mins x 5): Follow-up Sessions
- Reviewing progress and problem-solving: review 'Keeping Track' records

- Reviewing limits and plans for slips and lapses (to address practical strategies, as well as cognitive, emotional and social strategies)

- Reviewing skills and what is working for you

4.2 Weight loss and You (60 mins):
- How do you relate to your weight? How does losing weight affect your sense of who you are and how you relate to the world?

- Managing unhelpful thoughts and feelings (identity beliefs)

- Developing and reinforcing positive /helpful thoughts and feelings /staying motivated

- Working towards a healthy and enjoyable lifestyle that suits you

Key Facilitator delivery skills

1) **Empathy building:** Using a person-centred guiding style; Open-ended questions; Affirmation; Reflective Listening; Rolling with Resistance;

2) **Assessment:** Facilitating use of the diet-sustainability, PA-sustainability and Skills for weight loss Maintenance (SkiM) self-assessment tools

3) **Exchanging information:** Ask-Tell-Discuss

4) **Exploring motivation and barriers to change:** (Importance plus Confidence): Exploration of possible futures; Confidence Ruler and OE questions to explore barriers and high-risk situations

5) **Planning:** SMART-ER goals. Coping and social support plans.

6) **Self-regulation techniques** (Learning from experience): Using feedback; Self-monitoring; Re-framing failure; Problem-solving

7) **Managing emotional processes:** Encouraging enjoyment of lifestyle; managing food cravings and stress-related eating

8) **Cognitive restructuring and behavioural experiments:** Identifying and addressing helpful and unhelpful thoughts and beliefs.

Example SkiM Intervention material

A "mindful eating" exercise

'Mindfulness' is an idea that may be useful in managing food cravings. When your mind is not focused on what you are currently experiencing it can be described as being on 'auto-pilot'. That is, you are not really in touch with the 'here and now'. In this state, many of your behaviours and day-to-day choices are based on existing habits and tend to become automatic, rather than being clearly thought about. In this state, we tend to follow the path of least resistance and may be inclined towards less healthy choices, which offer a 'quick fix' or 'instant gratification'.

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