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Addressing the psychology of weight loss and maintenance: A feasibility study of the Skills for weight loss and Maintenance weight management programme

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Abstract

Objectives: Building on prior theory, we aimed to evaluate the feasibility and acceptability of integrating novel, weight loss maintenance strategies into existing weight management programmes. We also piloted recruitment and data collection procedures for future research.

Design: Two phases of action research nested within a single-arm feasibility study. The intervention was refined between phases using feedback from intervention fidelity analysis and qualitative exploration of patient and provider experiences. Changes in outcomes were assessed up to 18 months post-baseline.

Methods: One hundred adults with a mean body mass index of 37 kg/m² were offered the Skills for weight loss and Maintenance (SkiM) intervention. This included existing weight management programme content and additional weight loss maintenance techniques delivered fortnightly for 6 months in local community centres to groups of 11–15 people.

Results: Of the 100 participants, 65%, 58% and 56% provided data at 7, 12 and 18 months. Across both phases, the mean initial weight loss was 4.2 kg (95% CI: 2.4–5.9) and 3.1 kg at 18 months (95% CI: .8–5.5). In Phase 2, we observed better weight loss maintenance (.5 kg [13.2%] regain from 7 to 18 months, vs. 1.7 kg [36.2%] in Phase 1). Variation in outcomes, high early dropout rates and qualitative

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feedback indicated that, although delivery of the intervention and trial procedures was feasible and acceptable, there was scope to refine the intervention to engage a wider range of participants. Intervention fidelity was acceptable, particularly in Phase 2.

Conclusions: The SkiM intervention seems promising, but more research is needed to improve recruitment and retention prior to further evaluation.

KEYWORDS

behaviour change, feasibility study, intervention, maintenance, weight loss

Statement of Contribution

What is already known?

- Gradual weight regain is common following weight loss interventions, with weight typically returning to baseline levels over 3–6 years.
- Recent theory suggests that following weight loss, people are ‘pulled back’ to obesogenic behaviours because fundamental personal (physical, psychological or social) needs that were previously being addressed with over-eating (or being sedentary) are not satisfactorily met by their new healthier lifestyle.
- Few interventions have been developed to sustain weight loss by addressing the psychological tensions (above).

What does this study add?

- An intervention to address psychological tensions alongside existing weight management programmes was developed.
- Delivery of intervention and trial procedures was feasible, with good weight loss and maintenance for completers.
- However, drop-out was high, indicating that further refinements are needed to engage a wider range of participants.

BACKGROUND

Around 64% of UK adults are overweight, with 28% being affected by obesity (having a body mass index of 30 kg/m² or more; NHS Digital, 2020). Living with obesity is associated with reduced life expectancy (Jebb, 2004) and the development of cardiovascular disease, diabetes, osteoarthritis and several forms of cancer (Must et al., 1999; National Institute for Health and Clinical Excellence, 2006). Based on current trends, the combined cost to the UK's National Health Service (NHS) and to UK society will reach £49.9 billion/year by 2050 (Butland et al., 2007), if not earlier (Wang et al., 2011).

Systematic reviews have shown that, in at-risk populations, relatively modest reductions in weight (2–5 kg) reduce key cardiovascular risk factors (e.g. lipid profiles, blood pressure) to a clinically meaningful extent (Avenell et al., 2004; Espeland et al., 2007). Weight loss also reduces insulin resistance and can prevent progression to type 2 diabetes (Knowler et al., 2002; Tuomilehto et al., 2001). For example, in the Norfolk Diabetes Prevention Study, a mean of 1.8 kg of weight loss in people with impaired glucose regulation, sustained for 24-months, reduced the subsequent incidence of type 2 diabetes by over 40% (Sampson et al., 2020).

However, the long-term benefits of lifestyle interventions for preventing illnesses are strongly dependent on assumptions about the maintenance of weight loss (Department of Health, 2008). Hence, if meaningful health economic benefits from interventions to reduce diabetes risk and cardiovascular risk through weight loss are to be realized, then sustaining weight loss is a crucial issue. Unfortunately, gradual weight regain is common following weight loss interventions, with weight typically returning to baseline levels over 3–6 years (Dansinger et al., 2007). More research is therefore needed to establish effective strategies for maintenance of weight loss.

A recent review of interventions for weight loss maintenance (at 1–4 years of follow-up) found a mean reduction in weight regain at 12 months of follow-up of 1.56 kg (95% CI: 2.27 to .86) compared with controls (Dombrowski et al., 2014). These data, along with other reviews, suggest that weight loss maintenance is associated with the use of (a) peer support, (b) frequent continued professional support and (c) specific ‘self-regulatory’ methods like goal setting, problem solving, relapse prevention, self-monitoring, and daily self-weighing (Simpson et al., 2011; Svetkey et al., 2008; Wing et al., 2006). However, until recently most approaches to maintenance intervention have consisted of attempts to extend behavioural self-regulation (self-monitoring of behaviours and/or outcomes, review of progress, problem-solving of setbacks, revision of action plans) and engaging social support (Dombrowski et al., 2014).

Recent theoretical advances suggest that it may be possible to use more psychological approaches to address fundamental influences, persistent beliefs and emotional processes that drive lifestyle behaviour changes (Greaves et al., 2017; Kwasnicka et al., 2016). These include ‘third wave’ cognitive behavioural approaches such as acceptance and commitment therapy, dialectical behaviour therapy and mindfulness-based cognitive behavioural therapy (Lawlor et al., 2020). A recent synthesis of qualitative studies of weight loss maintenance (Greaves et al., 2017) suggests that a wider-ranging needs-based approach, based on addressing fundamental psychological, social and physical needs that drive overeating (and sedentary behaviour) might also be appropriate. This synthesis suggests that following weight loss, people are pulled back to obesogenic behaviours because fundamental personal (physical, psychological or social) needs that were previously being addressed with over-eating (or being sedentary) are not satisfactorily met by their new healthier lifestyle. The psychological tension generated by this situation then drives a return to the previous obesogenic behaviours. Drawing on the insights from this ‘Tension Theory’ gave rise to the development of the Skills for weight loss and Maintenance (SkiM) intervention, which is designed to promote weight management in a way that does not conflict with personal needs, thereby resulting in more sustainable lifestyle behaviour change.

The purpose of the current study was to assess the feasibility and acceptability of the SkiM intervention and of the research procedures needed to conduct a future full-scale randomized controlled trial. The specific objectives of the study were to:

1. Assess the feasibility and acceptability to study participants of recruitment and assessment procedures.
2. Assess the feasibility and acceptability of incorporating the SkiM intervention into existing community-based weight loss programmes, as evidenced by attendance and retention rates, as well as data on weight loss/maintenance (indicating participant engagement with response to the intervention).
3. Estimate the intervention costs and resources needed for a future trial.

METHODS

Design

We conducted a single-arm feasibility study with two phases of nested action research. Outcomes were measured pre- and post-intervention during both phases. The study was conducted between August 2015 (start of recruitment) and May 2018 (last data collection) and the protocol was retrospectively registered on an international trials database (ISRCTN ID: 45134679) in October 2022.

Stopping conditions

We specified in advance that we would consider not continuing on to a full-scale trial if (a) any serious adverse events attributed to the intervention or the study procedures constituted an unacceptable risk, (b) the recruitment rate was less than 15% of those approached, (c) loss to follow-up rates were greater than 15% per year and (d) intervention attendance was less than 50% of offered contacts.

Participants and setting

Participants were adults (aged at least 18), with body mass index (BMI) of 30–50 kg/m², or 27.5–50 kg/m² for South Asian or African-Caribbean ethnic groups. People were excluded if they were pregnant (or planned pregnancy during the study period); had a current, diagnosed eating disorder; had any medical conditions considered by the participant's general practitioner (GP) to seriously limit capacity to engage in the programme; were already participating in a weight management programme; or were not able to read or write sufficiently in English to engage with the intervention materials.

Informed consent and outcome measurement took place at the University of Exeter or, if preferred, in the participant's home. The intervention was delivered by two already-active community-based weight management service providers in Devon: A NHS-based Healthy Lifestyles Team and a not-for-profit community organization.

Participants were identified and recruited through two routes: Firstly, two general practices searched their patient databases for people meeting the study eligibility criteria. Following the GP screening of potential participants for exclusion criteria, the practice sent an invitation letter to a random sample. Secondly, staff in two NHS Healthy Lifestyle referral hubs verbally provided information about the study to potentially eligible people who had been referred to the hubs by NHS staff for weight management.

Intervention

An overview of the intervention content and facilitator training is provided in File S1. The intervention was developed using Intervention Mapping (Bartholomew Eldredge et al., 2016) and was informed by consultation with service users, service providers and commissioners of weight management services (Poltawski & Greaves, 2014), reviews of theory (Kwasnicka et al., 2016) and reviews of quantitative (Dombrowski et al., 2012, 2014; Simpson et al., 2011) and qualitative (Greaves et al., 2017) evidence on weight loss maintenance.

Rather than developing a stand-alone maintenance programme, we decided to integrate techniques and strategies for weight loss maintenance into existing weight loss programmes. The resulting, combined programme was called Skills for weight loss and Maintenance (SkiM).

Intervention delivery and training

We delivered the SkiM intervention in two phases, with substantial edits being made to the intervention content and structure between Phase 1 and Phase 2, based on feedback from Phase 1: In both phases, each provider organization delivered the SkiM programme to two groups of 11–15 participants using two programme facilitators. The backgrounds of the facilitators varied but included qualifications in health training, counselling, nutrition and fitness instruction, and employment in healthcare, education and the fitness industry. At least one member of each team had several years of experience in delivering group-based weight loss or physical activity programmes.

All facilitators received around 30 hours of face-to-face training (delivered by Author 1, Author 2) across the two phases of the study, addressing both the content of the programme and the intended delivery

approach (Box 1). The training included group meetings during delivery to address emerging issues and refresh learning. In addition, members of the research team (LP, CG) communicated regularly with the facilitators by phone and email to enhance their confidence and skills in delivering the intervention.

The SkiM programme was delivered over 6 months through a series of 90-minute meetings in local community venues, including a church hall and the community organization's own premises, with a choice of day or evening sessions. In Phase 1, Provider A (NHS) delivered 14 fortnightly group sessions, and Provider B (Community Organization) offered eight group sessions plus 1:1 meetings at the beginning, mid-point and end of the programme. In Phase 2, both providers offered 13 fortnightly group sessions and Provider B also offered a 1:1 individual assessment at the start of the programme. The structure and content of the sessions for Phase 2 are outlined in Figure 1.

Theoretical underpinnings

The fundamental principle of SkiM is that successful weight loss and maintenance requires attention to the underlying personal needs and other influences on behaviour that originally led to excess weight. The needs which drive obesogenic behaviours can be physical (e.g. having energy, avoiding joint pain), psychological (e.g. managing mood, being consistent with core identity beliefs), or social (e.g. the need to be approved of by/to please others; Greaves et al., 2017). If these driving influences/needs are not attended to, behaviour changes are likely to induce a psychological conflict or 'tension' due to the needs no longer being met. This tension makes maintenance of weight loss very challenging and is likely to lead to relapse (Greaves et al., 2017). Based on these principles, the SkiM approach aims to (a) enhance the individual's awareness of these influencing factors in their own life, (b) develop knowledge, skills and strategies to address needs differently and (c) identify circumstances that increase the 'tension' of weight-management and make plans to cope 'in the moment', in circumstances when tension is particularly high. The intervention information presented in File S1 and the content description in Figure 1 illustrates how the SkiM programme attempted to do this. The use of techniques to engage positive peer support, make action plans, self-monitor behaviours (and outcomes) and problem-solve (including relapse prevention), which have previously been associated with increased effectiveness in weight loss interventions were also incorporated as potential ways to help prevent, manage or resolve tension (Greaves et al., 2017).

BOX 1 Principles of SkiM programme facilitation/delivery

Managing group dynamics

- Recognizing typical group dynamics and adapting facilitation accordingly
- Handling difficult individual and group behaviours
- Co-facilitation roles

Client-centred counselling (using motivational interviewing techniques)

- Making and taking opportunities for individual discussions in sessions
- Help individuals identify personal drivers of unhealthy eating and sedentary behaviour and facilitators of behaviour change
- Problem-solving personal barriers

Teaching approach

- Use of open questions, affirmation, reflective listening, summary reflection strategic summarizing
- Didactic where appropriate (knowledge-based elements)

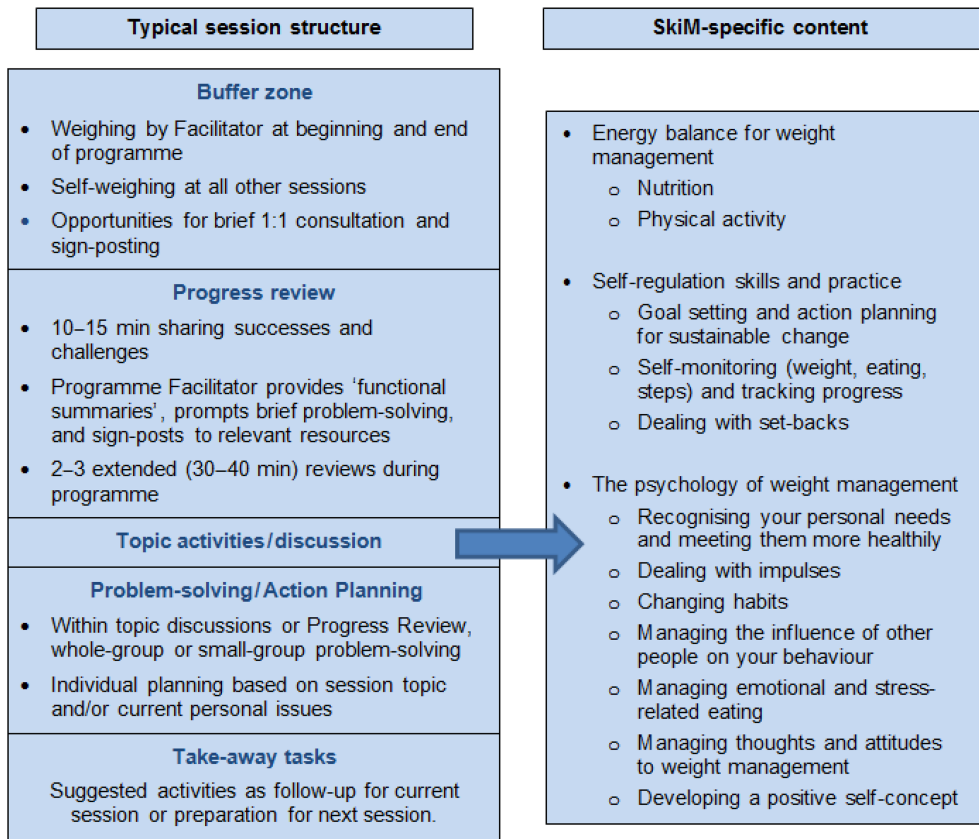


FIGURE 1 SkiM Programme (Phase 2) session structure and content.

Measures

Measures were collected at the baseline visit (between September 2015 and November 2016), post-programme (median 7 months post-baseline) and 12 and 18 months post-baseline. Process questionnaire data were collected at baseline, post-programme and 12 months. The assessment schedule is provided in File S2 (Tables S2.1 and S2.2).

Demographic data

At baseline we recorded age, gender, ethnicity, education, employment status and area deprivation (multiple deprivation index derived from postcode [Department for Communities and Local Government, 2015]), smoking status and comorbidities or treatments potentially affecting weight.

Outcomes

The outcomes measured were weight (the envisaged primary outcome measure for a future trial), minutes of moderate-to-vigorous activity assessed by 7-day wear of the wrist-worn (GENEActiv accelerometer, model GATV02), body mass index (BMI), waist circumference, depression score (Personal Health Questionnaire Depression Scale [PHQ8]) and health-related quality of life (EQ-5D-5L [Herdman et al., 2011]).

Adverse events

Participants were asked at follow-up about any adverse events they attributed to the intervention. These were followed up using a standardized adverse event management protocol (File S2).

Assessment of intervention costs

Intervention costs were assessed using data on resource use and time sheets completed by all facilitators to record contact and non-contact hours associated with intervention delivery. A questionnaire recorded participants' health and social service use over the preceding 6 months.

Process evaluation

A mixed-method process evaluation was conducted and the qualitative findings on behaviour change processes are reported elsewhere (Poltawski et al., 2020). The elements that relate to the feasibility and acceptability of the intervention and research processes are presented below.

At the post-programme assessment (7 months post-baseline), a questionnaire (File S2) asked participants to rate the supportiveness of the facilitators (4 items), satisfaction with the research procedures (13 items) and elements of the programme they found most useful.

We also conducted a series of face-to-face semi-structured interviews. At baseline, all 100 participants were briefly interviewed about their expectations of the intervention. After the programme (at a median of 7 months), a sample of 36 participants were interviewed. Within each research phase, they were purposively selected to provide diversity in weight loss achieved, gender, age and provider. This interview and a follow-up interview at 18 months with the same sub-sample provided feedback on programme acceptability. The interview topic guides (File S3) were developed by the intervention designers (Author 1, Author 2) and refined after the first few interviews. Interviews were conducted by two researchers with relevant experience and training (Author 2, Author 3). We also attempted to contact any participant who dropped out of the intervention to briefly ascertain reasons for disengagement.

The SkiM Facilitators were consulted in audio-recorded telephone consultations and group meetings during and after each delivery phase to discuss their experiences of delivering the intervention and ideas for improvement. These discussions were semi-structured around 'what went well, what did not go well and how could things be improved'. The same structure was used in a report form that all facilitators were asked to complete at the end of each intervention session to record their immediate impressions and summarizing, with reasons, any deviations from the intended session plan and session attendance.

Fidelity assessment

To assess the fidelity of intervention delivery (Borrelli, 2011), all weight management sessions were audio-recorded (and video-recorded in Phase 2). Two researchers (Author 1, Author 2) listened to the recordings and used a checklist to rate delivery fidelity on three key dimensions:

1. Adherence to content for each intended component of each session, based on descriptions of essential content in the intervention manual. Rating was on a percentage scale from zero (no planned content evident) to 100% (delivered completely as planned).
2. Quality of delivery of each intended component, using a 7-point scale based on the Dreyfus system for skills acquisition (Dreyfus, 1989), with 0 corresponding to none-delivery or minimal quality, and 6 corresponding to expert delivery.

3. Quality of group facilitation for each session, using the same 7-point Dreyfus scale, applied to facilitation criteria identified by the intervention designers.

File S4 provides a detailed description of the intervention components rated, and the rating scales. Prior to scoring, we defined 'adequate delivery' as a delivery quality rating of 3 or more and 'adherence to intervention content' as delivering at least 60% of the intended content for each component.

Procedures

People expressing interest in the study were sent detailed study information and screened via telephone to confirm eligibility. Questionnaires were posted for completion prior to meeting a study researcher at the University of Exeter or (if preferred) their home. Following written consent, biometric measures were taken by the researcher, who asked the participant to wear the accelerometer for the next 7 days. Completion of each assessment was incentivized with a £10 shopping voucher. Participants were assigned to a SkiM intervention group, taking preference for location and timing into consideration. Programmes commenced as soon as possible following the recruitment of 11–15 participants.

Analysis

Recruitment, and retention rates at each time point were calculated using descriptive statistics with 95% confidence intervals. Given the feasibility nature of this study, we did not formally assess effect sizes for study outcomes. However, to explore the variance and the likely range of changes within the intervention group, we calculated the mean, standard deviation and 95% confidence intervals for changes in outcomes between baseline and follow-up time points. Data were reported for completers only. Data are presented for both providers combined.

Accelerometer data were downloaded using GENEActiv PC software (version 3.0 Activinsights Ltd) and analysed in R using package GGIR version 1.5-12 (van Hees et al., 2013). GGIR performed auto-calibration and checked for abnormally high values prior to analysis (van Hees et al., 2014). Non-wear time was detected using 60-min windows in moving 15-min increments (and defined as three axes with a value range < 50 mg and standard deviation < 13 mg [da Silva et al., 2014]). Data were analysed in 5-s epochs from the first to the last midnight of data collection using Eslinger thresholds (Eslinger & Tremblay, 2007), with sedentary time defined as an activity with raw acceleration values ≤ 45.2 mg between 6 am and 11 pm (Eslinger & Tremblay, 2007). Participants were included in analyses if they had a minimum of 16 h of wear for at least 4 days (including 1 weekend day).

Qualitative interviews were transcribed verbatim and analysed thematically in relation to the aims of the study. Two researchers independently coded different transcripts using NVivo software. They second-coded 10% of each other's transcripts and met at intervals to agree coding definitions. The results of the interview analysis were synthesized with other qualitative data (free text responses in post-programme questionnaires, withdrawal surveys, facilitator session reports, notes from the intervention designers' meetings with facilitators and service managers, researcher field notes, and notes from coding of intervention fidelity), using a protocol for triangulating multiple sources of data (Farmer et al., 2006; O'Cathain et al., 2010).

Sample size

The sample size was calculated to provide realistic estimates for the recruitment and study completion rates. Assuming that 30% of those contacted would take part and 70%–80% of these would complete measures at 18 months (Greaves et al., 2008; Kinmonth et al., 2008), to estimate the recruitment rate with 95% confidence intervals of $\pm 8\%$ at each site, we needed to approach 133 people (and recruit

around 40 people) per site. The total sample size requirement was therefore 80. This also provided an ample pool of participants for qualitative sampling within each phase.

Ethics approval and consent

The study procedures were approved by the National Health Service Research Ethics Service (NRES) Committee South West – Exeter (Reference: 15/SW/0126). Written consent was obtained from all participants (both patients and service providers).

RESULTS

Aim 1: Feasibility of the research methods

Recruitment and retention

Figures 2 and 3 show the data on recruitment and retention. Participant recruitment and retention patterns for each referral route are provided in Table 1. As recruitment and retention rates did not vary substantially between providers, the data are not segregated by provider. Of the 100 participants, 65%, 58% and 56% provided data at 7, 12 and 18 months.

A total of 100 participants were enrolled in the study (47 in Phase 1 and 53 in Phase 2). Where it was possible to calculate recruitment rates (we could not collect data on the numbers of people invited by the

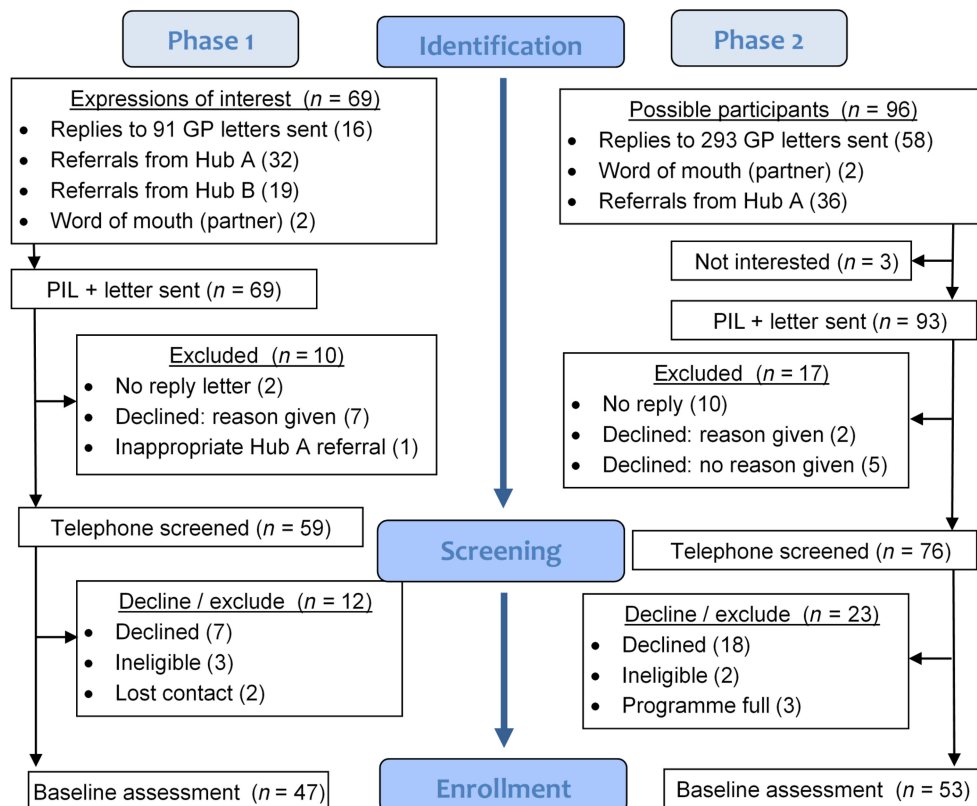


FIGURE 2 CONSORT (Eldridge et al., 2016) Diagram showing participant flow from identification to allocation.

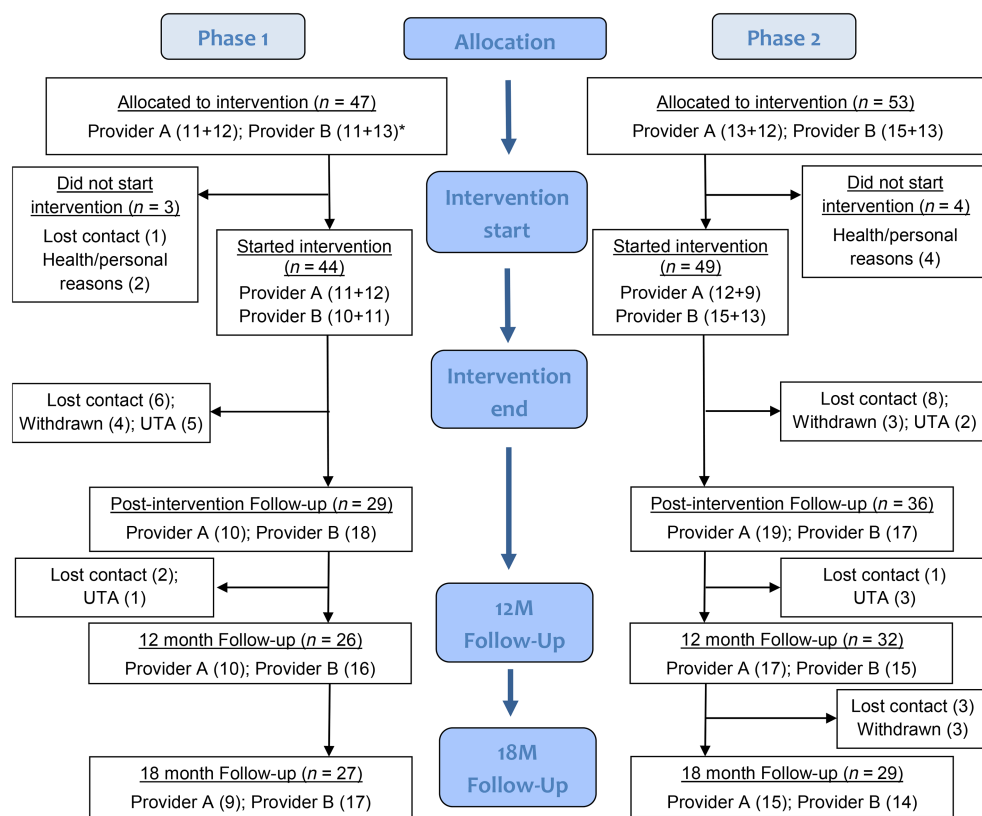


FIGURE 3 CONSORT Diagram showing participant flow from allocation to final follow-up. *Figures in brackets indicate numbers in each intervention group. UTA, unable to attend.

TABLE 1 Study recruitment and retention numbers for each recruitment route.

	Phase 1		Phase 2	
	Hub	GP	Hub	GP
Invitations	NR	91	NR	293
Interest declared (% of those invited)	51	18 (20%)	36	60 (20%)
Enrolled (% of those invited)	37	10 (11.0%)	25	28 (9.6%)
Attended >70% of intervention (% of enrolled)	12 (32%)	5 (50%)	12 (48%)	12 (43%)
Completed post-intervention assessment (% of enrolled)	22 (59%)	7 (70%)	19 (76%)	17 (61%)
Completed 12 months follow-up assessment (% of enrolled)	19 (51%)	7 (70%)	17 (68%)	15 (54%)
Completed 18 months follow-up assessment (% of enrolled)	19 (51%)	7 (70%)	15 (60%)	14 (50%)

Abbreviations: GP, General practitioner; NR, not recorded.

referral hubs), the recruitment rate (via GP surgery invites) was 9.9% (95% CI: 6.9–12.9). The retention rate (proportion of participants with weight data available at 18 months of follow-up) was 56% (95% CI: 46–66). Recruitment and retention rates did not vary substantially between the two phases (Table 1). The mean time between study enrolment and first intervention contact was 11 days in Phase 1 and 17 days in Phase 2.

Sample characteristics

The characteristics of the whole sample and for Phase 1 and Phase 2 are shown in Table 2. In the overall sample, participants had a mean BMI of 36.8 kg/m², a mean age of 56 years and were predominantly female (71%). Almost all of the sample (96%) were White British. There was a good representation for all quintiles of area deprivation, with 41% of the sample recruited in the top two quintiles of area deprivation. The sample characteristics were broadly similar between Phase 1 and Phase 2, although more men were recruited in Phase 2 (36%) than in Phase 1 (21%) and the sample had higher area deprivation in Phase 1 than in Phase 2 (49% vs. 34% in the two most deprived quintiles).

The recruited sample (overall and in both phases) was broadly representative of the population referred for weight management services in Torbay and Devon in 2014–2016 (Table S6.1), although we recruited a higher proportion of men (29% vs. 16%).

In the overall sample (Phases 1 and 2 combined), there were no substantial differences in baseline age, BMI, gender, physical activity or area deprivation between completers at 7 and 18 months and the baseline sample (Table S6.1). Depression scores (PHQ8) were slightly lower in the 18-month sample (Table S6.2), suggesting that those with higher depression scores at baseline were more likely to drop out of the study. The picture was broadly similar within each phase.

TABLE 2 Sample characteristics.

Characteristic	Whole sample ^a , N=100	Phase 1, N=47	Phase 2, N=53
BMI (kg/m ²)	36.8 (4.4)	36.3 (4.5)	37.1 (4.3)
Waist circumference (cm)	116.8 (12.4)	116.9 (12.2)	116.7 (12.7)
MVPA (min/week) in bouts ≥10 min	21.2 (47.9)	19.1 (49.6)	23.2 (46.7)
EQ-5D overall health (0–100 ‘thermometer’ scale)	61.4 (21.0)	61.2 (21.4)	61.5 (21.0)
Age (years)	55.7 (13.1)	56.6 (13.4)	54.9 (13.0)
PHQ8 Depression score	8.3 (6.3)	9.7 (6.8)	7.1 (5.7)
IMD score ^b	22.3 (14.3)	26.1 (16.2)	18.9 (11.6)
IMD quintiles			
1 (high deprivation)	23 (23.0%)	13 (27.7%)	10 (18.9%)
2	18 (18.0%)	10 (21.3%)	8 (15.1%)
3	30 (30.0%)	13 (27.7%)	17 (32.1%)
4	19 (19.0%)	8 (17.0%)	11 (20.8%)
5 (low deprivation)	10 (10.0%)	3 (6.4%)	7 (13.2%)
Gender: N (%) male	29 (29%)	10 (21.3%)	19 (35.8%)
Ethnicity			
White British	96 (97.0%)	45 (97.8%)	51 (96.2%)
Other	3 (3.0%)	1 (2.2%)	2 (3.8%)
Education			
Up to age 16 (or less)	21 (21.6%)	8 (18.2%)	13 (24.5%)
Up to age 18	6 (6.2%)	1 (2.3%)	5 (9.4%)
Some additional	44 (45.4%)	25 (56.8%)	19 (35.8%)
Undergrad or higher	26 (26.8%)	10 (22.7%)	16 (30.2%)
Smoking	10 (10.1%)	8 (17.4%)	2 (3.8%)

Abbreviations: EQ-5D, European Quality of Life-5 Dimensions (questionnaire name); IMD, Index of multiple deprivation; MVPA, Moderate-to-vigorous physical activity; PHQ8, Personal Health Questionnaire Depression Scale.

^aFigures are mean (SD) for continuous data, or N (%) for categorical data.

^bHigher MDI score represents increased area deprivation.

Exploratory analysis of outcomes

Table 3 shows changes in weight from baseline to each follow-up time point for the whole sample and for the two phases separately. Secondary outcomes are reported for the whole sample only.

For the whole sample, the mean weight loss (for those providing data) was 4.2 kg post-intervention (95% CI: 2.4–5.9), 4.4 kg at 12 months (95% CI: 2.2–6.5) and 3.1 kg at 18 months (95% CI: .8 to 5.5). The initial weight loss for Phase 1 was 4.7 kg and for Phase 2 it was 3.8 kg. The amount of weight regain from the end of the intervention to the 18-month data-collection was 1.7 kg (36.2%) in Phase 1 and .5 kg (13.2%) in Phase 2.

For the whole sample, physical activity of (non-bouted) moderate intensity increased by around 20% (Mean Diff: 49.0 min/week, 95% CI: 17.9–80.2) from baseline to the end of the intervention. However, this increase in activity was not sustained at the one-year follow-up (Mean Diff: 1.2 min/week, 95% CI: –37.6 to 39.9).

In the whole sample, participants who attended 60% or more of the intervention session (high attenders) constituted 73.8% of participants providing data at 7 months. The mean weight loss of high and low attenders was 5.0 and 1.8 kg respectively at 7 months.

Qualitative feedback on research procedures

Some participants were frustrated by the length of time between the initial contact with the researcher and the start of the intervention, which was partly due to the need to recruit a viable group. The measurement process (including session recordings) was acceptable and the capacity of the research team to conduct home-based assessments may have prevented some study dropouts. However, some questionnaire items were reported to be difficult to understand or inapplicable. Data collection by facilitators, which included completion of session report forms and time-sheets (for the health economic costing), and participation in review meetings, was time consuming and could be better incentivized in future studies.

Questionnaire feedback on research procedures

Questionnaire responses (combined for both phases) showed that 79% (Taylor et al., 2018) of participants felt they had received enough information about the study prior to taking part, but some felt they could have done with ‘a bit more’ or ‘a lot more’ information (20%; 11/56). Almost all (98%; 60/61) said they had been given the opportunity to ask the team questions about the study and had received clear answers to any questions (98%; 48/49). The majority felt their dealings with the university research team were satisfactory or very satisfactory (92%; 56/61). Only one participant (2%) reported having major problems with being weighed (as opposed to ‘minor’ or ‘no’ problems). Similarly, 92% (55/60) had no problem completing the questionnaires with the remaining 8% reporting only minor problems.

Aim 2: Feasibility of the intervention

Intervention attendance

Figure 4 shows the attendance rates for each provider in each phase of intervention delivery. Of the participants recruited, 44.7% attended at least 60% of the sessions in Phase 1 and this increased to 52.8% in Phase 2. Changes made between Phase 1 and Phase 2 that might explain the improved attendance in Phase 2 are outlined in **Box 2**.

TABLE 3 Changes in weight and secondary outcomes.

Outcome	Change from baseline to post-intervention ^b (mean, 95% CI)	N	Change from 0 to 12 months (mean, 95% CI)	N	Change from 0 to 18 months (mean, 95% CI)	N
Weight loss (kg) for whole sample	4.2 (2.4 to 5.9)	65	4.4 (2.2 to 6.5)	58	3.1 (.8 to 5.5)	56
Weight loss (kg) in Phase 1	4.7 (1.7 to 7.6)	29	4.2 (.3 to 8.1)	26	3.0 (-1.2 to 7.3)	26
Weight loss (kg) in Phase 2	3.8 (1.7 to 5.9)	36	4.5 (2.0 to 6.9)	32	3.3 (.6 to 5.9)	30
MVPA ^a (min/week)	49.0 (17.9 to 80.2)	64	1.2 (-37.6 to 39.9)	58	-	-
MVPA in bouts \geq 10 min/week	10.5 (-1.9 to 22.9)	64	3.7 (-10.5 to 17.9)	58	-	-
Light physical activity (min/week)	101.0 (25.3 to 176.7)	64	-7.5 (-80.3 to 65.4)	58	-	-
Sedentary time (min/week)	-143.5 (-232.5 to -54.6)	64	-9.1 (-107.8 to 89.7)	58	-	-
BMI (kg/m ²)	-1.49 (-2.10 to -.88)	65	-1.56 (-2.34 to -.78)	58	-1.08 (-1.94 to -.22)	56
Waist circumference (cm)	-3.44 (-5.05 to -1.84)	65	-3.52 (-5.49 to -1.55)	58	-3.37 (-5.59 to -1.15)	55
EQ-5D overall health (0-100 thermometer ^c scale)	6.63 (2.13 to 11.12)	62	7.12 (3.03 to 11.21)	58	-	-

Abbreviations: EQ-5D, European Quality of Life-5 Dimensions (questionnaire name); MVPA, Moderate-to-vigorous physical activity.

^aModerate to Vigorous Physical Activity.

^bMean follow-up time 7.0 months.

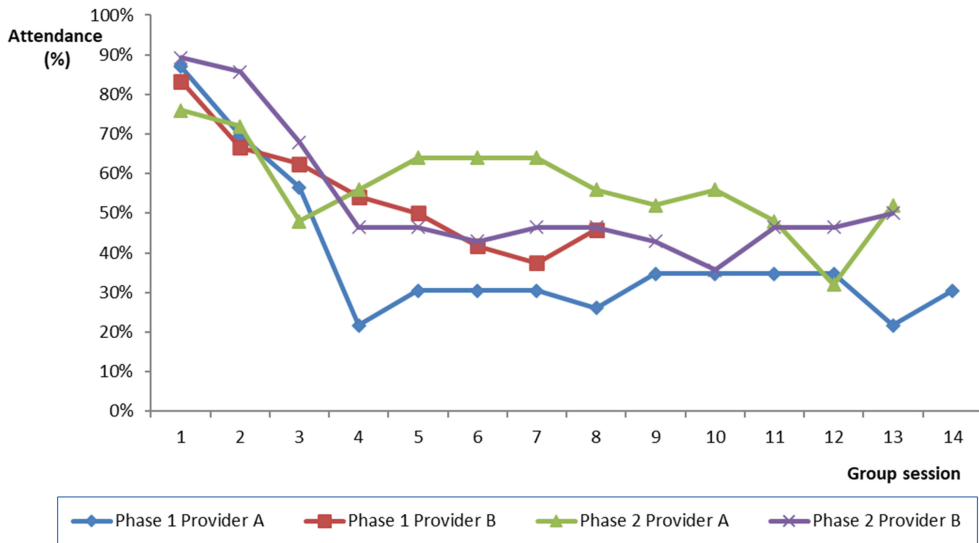


FIGURE 4 Skim enrolment and group session attendance.

BOX 2 Changes made to the SkiM programme following feedback from Phase 1

Changes to intervention materials/content

- Integration of the two weight loss programmes, into 13 × 90-min sessions at each site (plus a one-to-one initial assessment process for Provider B).
- We provided ‘menus’ of possible changes for use with action plans.
- We introduced a ‘before/during/after’ format to some tension-related action plans and problem-solving activities.
- We front-loaded the first two sessions with weight loss content, to encourage more of a ‘quick start’.
- We made some sessions more interactive, for example, assertiveness skills.
- We edited supporting materials to use simpler language and make them more visually engaging and simplified the presentation on habit-forming/breaking.
- In Phase 2, we asked for a commitment to attend at least half of the sessions as part of the recruitment process.

Changes to training:

- We provided further training on introducing and supporting action planning, personalizing the application of the SkiM model, progress tracking, problem-solving, impulse management, dealing with lapses, managing thoughts and feelings, and encouraging/reinforcing positive changes in self-concept.
- We encouraged more use of summaries of key points after each section.
- We increased the emphasis on nurturing a positive group dynamic and provided additional training on handling difficult group/individual dynamics.

Across both phases, attendance tended to drop most markedly within the first four sessions and then stabilize. Eight people (8%) failed to attend any sessions and 26 (26%) attended only one or two sessions. [Table S6.3](#) shows the reasons given by 40 participants who dropped out of the intervention (defined as attending less than 30% of sessions).

Intervention fidelity

File S4 provides a detailed description of the intervention components rated and the scores for each intervention fidelity component. Table 4 provides summary fidelity scores for each Provider in each Phase of the study. Provider A delivered with good overall adherence, delivery quality and group facilitation in both phases. Provider B improved from a lower level in Phase 1 to match the scores of provider A in Phase 2.

It is worth noting that these aggregated scores (Table 4) mask substantial variations between different intervention components, with adherence scores between zero and 100%, and quality scores in the range 0–5.5 (out of 6).

The analysis of fidelity in Phase 1 identified several areas where changes to the intervention content and training were needed to enhance intervention fidelity, as shown in Box 2. In Phase 2, fidelity had improved across many of these components (see Tables S4.1 and S4.2), but there was still a need for improvement in several areas, particularly in identifying needs served by unhealthy eating, supporting habit formation, personalized application of the SkiM model, and encouraging/reinforcing positive changes in self-concept. We also identified areas where facilitator performance could be improved in terms of facilitating planning, setting homework, introducing themes and ‘functionally summarizing’ discussions.

Video recording of sessions greatly helped the fidelity assessment process, enabling many activities and interactions of facilitators and participants to be observed that would not be apparent on audio recordings. For example, we could observe levels of participant engagement in discussion activities, whether and how facilitators were interacting with small groups and individuals, co-facilitator behaviours, and the use of resources like slides and materials.

Questionnaire feedback on the SkiM programme

At the end-of-intervention assessment, 88% (Goldstein et al., 2020) of participants who responded felt the SkiM Programme benefited them and 76% (Taylor et al., 2018) felt that the course met their specific needs. The facilitator-rating questionnaire demonstrated very good scale reliability (Cronbach's alpha .94), with a moderately skewed distribution (skewness -1.37) and some evidence of a ceiling effect (19% scored the maximum of 7 for all items). The mean score (across all 4 items) was 5.7 (SD 1.3; 5.5 in Phase 1 and 5.9 in Phase 2), indicating a positive overall rating of facilitator support (6 indicates ‘Agree’), improving from Phase 1 to Phase 2.

Adverse events

There were no serious adverse events in either phase. Several musculoskeletal problems were reported following increases in physical activity, but all were resolved without hospitalization. One diabetic participant sought medical advice due to concern about lower blood sugar levels due to dietary changes. Several participants reported skin irritation during accelerometer wear, despite rigorous adherence to the strap-cleaning protocol.

TABLE 4 Intervention fidelity, quality and group facilitation scores averaged across all rated sections.

	Provider A		Provider B	
	Phase 1	Phase 2	Phase 1	Phase 2
Adherence (%)	74	79	61	76
Delivery quality (0–6)	4.2	4.1	3.2	4.0
Group facilitation (0–6)	4.4	4.3	3.4	4.2

Qualitative feedback on the SkiM intervention

Feedback from both participants and facilitators from Phase 1 was used to make changes to the intervention materials and programme content (as outlined in [Box 2](#)).

The findings (see [Table S5.1](#) for themes and supporting quotes) indicated that the SkiM programme was well-regarded by many participants. Its primary value was seen to be the combination of content on nutrition, physical activity, self-regulation and psychological issues, in the context of a supportive and well-facilitated group process.

Participants valued the support provided by other group members, as well as by the facilitators, although some felt alienated by differences in age, background, or concerns of other group members. Participants identified text reminders and the 'stop sign' technique as being particularly useful elements of the programme. The facilitators noted the impact of differences in personal barriers and motivation, and in-group dynamics, on levels of engagement. For example, some groups developed an unhelpful culture, characterized by a continued focus on problems and resistance to planning or making changes. The facilitators found the training useful, but some would have liked more training on group facilitation, including a wider range of interactive methods to engage and energize participants. The facilitators observed that the action-planning process was repetitive and became less engaging over time.

The feedback from Phase 2 is reported in detail in [File S5](#). The participants liked the weight loss strategies and ideas for changing diet and physical activity that was presented, the non-directive approach, the small group format and the 'spread out' (fortnightly over 6 months) timing of the intervention. However, some would have liked more structured physical activity to have been built into the programme and some individuals said they would have preferred more direction/a specific diet to follow. They also valued the strategies to help manage eating impulses and for managing both social and emotional influences/stress-related eating. However, specific issues with some of the content were reported such as (a) insufficient time being available to develop important skills including stress management and negotiating with others and (b) repetitiveness of some elements (e.g. action-planning). Moreover, opinions differed substantially between participants: Some found different topics more or less personally relevant, some did not engage well with written tasks and some felt they required more individual-level support. A significant minority were demotivated by an unhelpful group culture that developed in some groups. This was characterized by a preference to focus on problems rather than solutions, and/or a resistance to change-talk. Interactive technological elements such as SMS (Short Messaging Service) text reminders to self-weigh, the use of pedometers and advice on smartphone apps were highly valued by many, although the more 'static' SkiM study website and support materials/information placed there were rarely accessed. Similarly, the written workbook support materials were only used by a few participants, although some found these materials useful.

The facilitators concurred with much of the participant feedback and felt they were more confident in delivery and better at managing group dynamics in Phase 2. However, dealing with negativity within the group was reported to be very difficult by all the facilitators. They also noted that, although improved, sustained engagement of participants with action planning was still difficult. To address this, they recommended more unstructured time in later sessions to allow participants to define the priorities and content more.

Aim 3: Intervention costs (Phase 2 only) and feasibility of economic assessment

We calculated the cost of delivering the intervention in this study, and then made assumptions to estimate the cost of the intervention as it might be rolled out in practice (the figures reported below). The return rate of timesheets was 100% for one provider, but only 42% for the other, so some imputation was required. A detailed account of the methods, data, assumptions and calculations used is available on request from the corresponding author.

Assuming that each team of 2 facilitators led ten groups of 15 participants over 2 years, using 2017 health service costing data from the Personal Social Services Research Unit (Curtis & Netten, 2018), we estimated that the cost of the intervention per participant would be between £233 (Provider B) and £297 (Provider A) per participant. Costs varied due to differences in facilitator pay grades and time spent in preparation. If the programme used only one facilitator, the cost per participant would be reduced by around £70.

DISCUSSION

Summary of findings and relation to other literature

The data on acceptability and feasibility for the SkiM intervention and the proposed trial procedures were somewhat mixed: In terms of meeting the conditions needed to continue to a full-scale trial that was agreed prior to data analysis. No serious adverse events were attributable to the intervention or the study procedures. The recruitment rate (via GP surgery invites) was 9.9%, somewhat below the 15% specified. However, on reflection, the targeted recruitment rate may have been a little over-optimistic, given that recruitment rates of around 10% are common in weight loss trials (Befort et al., 2020; Glasgow et al., 2007; Jolly et al., 2011). Loss to follow-up rates was 29.3% per year. This was greater than the desired level of 15% per year and the rates typically seen in other trials (Stubbs et al., 2015). Intervention attendance was 51% overall and 55% in Phase 2. This was above the 50% required and similar to attendance rates seen in other weight loss trials (albeit a little on the low side).

The fidelity analysis indicated adequate intervention delivery quality, with improved fidelity in Phase 2. This indicates, that with suitable training and practice, it is feasible to deliver the SkiM programme in real-world community settings/with existing service providers. However, there were considerable individual variations in weight loss and high early drop-out rates, indicating that the intervention did not suit all participants. This is an important feasibility issue as engagement is a prerequisite for effectiveness (Yardley et al., 2015).

We observed good levels of initial weight loss in people who provided outcome data, with a mean weight loss of 4.2 kg at the end of the intervention. This compares well with other community-based programmes: For example, completers in the English national diabetes prevention programme achieve 3.7 kg (Taylor et al., 2018) and commercial weight loss programmes achieve 4–5 kg (Jolly et al., 2011) at the end of the intervention period. However, it would also be of interest to see whether the SkiM approach could work alongside more intensive initial weight loss programmes, such as meal replacement (Lean et al., 2019), or bariatric surgery, as a way to support ‘transition’ to sustainable behaviour change, following such interventions. Indeed, addressing emotion regulation (one element of SkiM) may be particularly important for people attempting total diet replacement, as stress and negative mood are reported as particular drivers of weight regain in this context (Thom et al., 2021).

In the second phase, the maintenance profile appeared to represent an improvement over Phase 1 (5 kg [13.2%] regain from the end of the intervention to 18 months, vs. 1.7 kg [36.2%] in Phase 1). However, no statistical comparison can be drawn due to the low numbers involved and no claims about the effectiveness of the intervention can be made from this feasibility data.

Strengths and limitations

This is the first study to apply Tension Theory (Greaves et al., 2017) to try to enhance maintenance in weight loss programmes. The intervention has a strong theoretical grounding and was rigorously developed, with strong service user and service provider input into the design of both the intervention and the study. We used objective measures of weight loss and physical activity and multiple methods to address the feasibility and acceptability aims of the study. Several participants who had dropped out of the

intervention still provided qualitative feedback, which gave valuable insights into reasons for disengagement. We recruited well amongst people with high area deprivation (23% in the most deprived quintile) and a range of education levels and ages. A further strength of the study was the use of multiple rounds of development and feedback, which seemed to elicit tangible improvements in participant engagement and programme outcomes (including weight loss maintenance) from Phase 1 to Phase 2. This use of a 'feasibility study with nested action research' research design is therefore recommended for future intervention development studies.

However, the study had several limitations that need to be acknowledged. Only 29% of our recruited sample were men. Although this is higher than the 5% who typically attend commercial weight management programmes (Stubbs et al., 2015), similar numbers of men and women live with obesity. Hence, more efforts are needed to engage and retain men in the intervention. Due to the small sample size and lack of a control group, as well as a lower-than-expected uptake rate and high levels of loss to follow-up, the changes observed in outcomes, as well as claims about the feasibility of a future trial must be treated with caution.

A further potential limitation is the validity of the underpinning theoretical basis for the intervention, which has not been previously operationalized and tested. A summary of the qualitative feedback on the intervention content is provided in the Supporting Information (Table S5.1). In addition, the qualitative data collected longitudinally here has been analysed to specifically identify implications for refining the theory and content of the SkiM intervention, by contrasting the accounts of those who were more and less successful in terms of longer-term weight loss. This analysis is published elsewhere (Poltawski et al., 2020), but broadly speaking, the findings support Tension Theory, as well as the inclusion of self-regulation, particularly self-regulation that is focused on managing 'high-risk' situations where contextual factors (including psychological status and social context) can increase the likelihood of engaging in obesogenic behaviours. Furthermore, theories and interventions for weight loss and maintenance need to consider multifactorial influences and the possibility of intervention at multiple levels to address physiological (e.g. pharmaceutical or surgical approaches), psychological, social and societal level influences.

Implications/future research directions

The study suggests several implications for the future delivery of this novel, psychologically focused weight loss and maintenance intervention: Some kind of advance selection would be beneficial as the SkiM approach does not appeal to everyone. Predicting who will engage or disengage with weight loss programmes is notoriously difficult, with most evidence in the field being based on retrospective analysis of demographic information in relation to adherence (Burgess et al., 2017; Teixeira et al., 2004). However, the SkiM study has collected a wide range of process data/questionnaires on theoretical predictors of weight loss, which may be helpful in profiling people who may be well suited to this type of intervention (this data will be presented elsewhere).

The feedback that the intervention tries to cover too much ground and may therefore fail to fully deal with important issues, suggests that, even for those who do engage with the programme, a more tailored approach (to identify and address individual needs/concerns) might be more effective. This may also help to keep people engaged in the process. An individual, one-to-one approach might therefore be more suited for people with more complex needs, at least for some elements of the programme. A stepped care (increasing the level or types of support if needed, based on weight change) or a triaging approach (assigning participants to elements of the programme that match their needs) might also be appropriate. Mobile or machine-learning approaches could also be employed to assist in matching content to individual needs (Goldstein et al., 2020).

Training is a key issue for the effective delivery of weight management programmes, as is the pragmatic issue of time commitment for busy NHS (or non-NHS) staff who might deliver programmes like SkiM in the future. Such training should include formative opportunities to practice delivery of key

components and opportunities to share and discuss their experiences over time, possibly including an element of asynchronous/online support to facilitate this.

Our finding that intervention fidelity (and retention and outcomes) improved over time (from Phase 1 to Phase 2) implies an important methodological issue for weight management research: Developers of weight management programmes, as well as other complex, provider-dependent health interventions, should allow time for multiple cycles of development prior to evaluation.

More research is needed to further develop and evaluate the SkiM intervention for delivery in NHS and community settings: The approach seems promising, particularly in terms of the maintenance profile achieved. However, prior to a full-scale trial, the feasibility of recruitment to and retention of participants in an adapted service model need to be established. In a future trial, subject to positive trial findings at 12 months, an extended follow-up period would be useful to establish the 5-year maintenance profile.

In the UK health context, given the costs/relative intensity of the SkiM intervention and the lack of funding for preventative weight management in the current system, the SkiM programme may be best suited for use in hospital-based weight management services or in services for higher risk populations, such as the English national diabetes prevention programme (Barron et al., 2018), or in weight loss programmes targeting diabetes remission (Lean et al., 2018). Further development of the underpinning 'Tension Theory' and of novel behaviour change techniques and strategies designed to specifically address tension processes is also needed.

CONCLUSION

The SkiM weight loss and maintenance intervention seem promising for some people, but further refinements are needed to engage a wider range of participants. Future directions may include matching participants to intervention components depending on individual assessment of support needs. More research is needed to adapt the SkiM intervention for delivery in health service and community settings and to improve recruitment and retention rates prior to a full-scale trial.

AUTHOR CONTRIBUTIONS

Colin J. Greaves: Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; supervision; writing – original draft; writing – review and editing. **Leon Poltawski:** Conceptualization; formal analysis; investigation; methodology; project administration; supervision; writing – original draft; writing – review and editing. **Samantha B. van Beurden:** Formal analysis; investigation; writing – review and editing. **Lisa Price:** Formal analysis; methodology; writing – review and editing. **Rodney S. Taylor:** Conceptualization; writing – review and editing. **Richard Merrifield:** Methodology; resources; writing – review and editing. **Lucy O'Loughlin:** Methodology; resources; writing – review and editing.

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CONFLICT OF INTEREST STATEMENT

CG has been paid for consultancy work with a commercial weight loss company within the last 5 years. The remaining authors declare no competing interests.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy (GPRD) or ethical restrictions.

CONSENT FOR PUBLICATION

Not applicable.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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