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RUNNING HEAD: Behaviour change for obesity: Open pilot

Optimising acceptability and feasibility of an evidence-based behavioural intervention
for **obese adults with obesity-related co-morbidities or additional risk factors for co-
morbidities**: An open pilot **intervention** study in secondary care

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ABSTRACT

Objective: To test and optimise the feasibility and acceptability of a physical activity (PA) and healthy eating behaviour change intervention for obese adults with **obesity-related co-morbidities or additional risk factors for co-morbidities**.

Methods: Open-pilot **intervention** study using an uncontrolled pre and post design with ongoing measures on intervention acceptability and feasibility. Participants received 5 weekly nurse-led one-hour **long** group sessions. Acceptability and feasibility were assessed throughout. PA, dietary behaviour and weight were measured before and after the intervention.

Results: Of 74 consenting participants 60 (81%) received and 47 (64%) completed the intervention. Average ratings of intervention materials and components were 4.1-4.9 out of 5. Average facilitator satisfaction rating was 90% ($SD=14.8$, range 75 – 100%). The intervention delivery was feasible for participants and facilitator, indicated by comments and ratings. Participants lost -0.86kg of weight $t(45)=3.84$, $p=0.0001$, and increased PA by an additional 1.6 ($SD=2.7$) sessions/week, $t(31)=-3.3$, $p=0.002$, but no significant dietary differences were found.

Conclusion: The intervention was acceptable to the facilitator and participants and feasible for delivery by a trained nurse. Several aspects of the intervention were further optimised.

Practice Implications:

The current study outlines a PA and dietary behaviour change pilot intervention coupled with a systematic and transparent process of intervention optimisation.

Key words: behaviour change, open pilot, obesity, intervention development

1. INTRODUCTION

The prevalence of overweight and obesity is increasing worldwide [1] primarily resulting from changes in energy balance-related behaviours physical activity (PA) and dietary intake [2]. There is compelling evidence linking obesity to increased risk of cardiovascular disease [3], diabetes [4] cancer [5] and further secondary conditions [6]. Research effort needs to focus on developing and refining effective and efficacious **behaviour change** interventions **for obesity** [7]. **Successful behaviour change** is especially **relevant in** obese adults **with obesity-related co-morbidities (e.g. type 2 diabetes) or additional risk factors for co-morbidities (e.g. impaired glucose tolerance)** as it has the potential to **significantly reduce both risk factors and secondary disease** [8, 9].

The development of behaviour change interventions should be based on the most up-to-date evidence [10]. **However, unsystematic reporting within** published intervention studies [11] **and** the pooling of average intervention effect sizes **within systematic literature reviews** in light of significant between-study heterogeneity fails to identify components that are specific **enough** and pragmatically **relevant** for the intervention development process [12]. **The current** development of a taxonomy to reliably identify intervention content (i.e. behaviour change techniques, BCTs) from written reports **provides a tool** to maximise the information from the available literature [13, 14]. A recent systematic review has used this taxonomy to identify which BCTs and modes of intervention delivery (MODs) might be associated with more successful interventions in **obese adults presenting obesity-related risk factors or co-morbidity** [15]. Subsequently, a **pilot intervention** was developed based on the obtained **review** evidence combining BCTs and MODs associated with more successful interventions. However, developing **pilot** interventions based on **taxonomy informed** systematic review evidence still requires testing and optimising of acceptability and feasibility – **a vital** step in the **intervention development and implementation** process

[16, 17]. The current **study therefore** aimed to test and optimise intervention acceptability and feasibility of an evidence-based **behaviour change pilot intervention for obese adults with obesity-related co-morbidities or additional risk factors for co-morbidities** in a secondary care context.

2. METHODS

2.1 Design

This open-pilot **intervention** study used an uncontrolled pre and post design with ongoing measures on intervention acceptability and feasibility [18]. We investigated and integrated feedback provided on intervention content and delivery for further optimisation. The refinement process consisted of three dynamic steps undertaken sequentially throughout the intervention period: intervention delivery, collecting feedback, and intervention refinement using feedback. The study received ethical approval from the North of Scotland Research Ethics Committee.

2.2 Participants

We recruited obese women and men registered for secondary care treatment relating to weight issues at a nutrition clinic in **North-East** Scotland. The clinic referral criterion was typically a BMI of ≥ 35 . The vast majority of patients registered for this nutrition clinic are referred due to additional risk factors [19]. **All participants registered at the nutrition clinic were eligible for inclusion. Recruitment included postal invitations from the clinic practitioner. Participants providing written consent were referred to the research team to schedule session attendance.**

2.3 Intervention Description

2.3.1 Intervention content

The manual-based intervention targeted dietary and PA behaviour change for weight loss and was developed based on a systematic review of the evidence base [15]¹. The intervention was built from BCTs found to be associated with intervention effectiveness (Table 1). These techniques are in line with self-regulation theory [20] ; Social Cognitive Theory [21]; Social Comparison Theory [22], and the Relapse Prevention model [23].

----- Table 1 -----

The intervention content followed a logical sequence informed by and coherent with theories that map onto used BCTs [13]. For example, intention formation and self-monitoring were presented in the initial sessions followed by the introduction of BCTs such as specific goal setting and barrier identification concluding with relapse prevention (Table 1).

2.3.2 Intervention Delivery

A female research nurse (Endocrine Nurse Specialist) with 15 years of clinical experience facilitated the intervention, which consisted of five weekly one-hour long face-to-face group sessions. The nurse was trained for 1.5 days in the delivery of the manual-based intervention. Up to 10 participants could be scheduled per group. Sessions were delivered **at the nutrition clinic site** - a central **hospital** location. Travel expenses were reimbursed and those participants missing a session were sent materials and details of the next meeting.

2.4 Outcomes

2.4.1 Demographics

Demographics including gender, age, marital status, job, height and weight loss medication were assessed by self-report questionnaires posted before the first sessions.

2.4.2 Acceptability

¹ The full manual for the intervention is available from the first, second or last author.

Acceptability was assessed qualitatively and quantitatively from participants and facilitator. Participant feedback was obtained for individual sessions (following sessions 1-4) and for the intervention overall (following session 5). Facilitator feedback was obtained after each individual session (following sessions 1-5). Rating methods were based on previous studies that assessed the acceptability of behaviour change interventions [24-26]

2.4.3 Participant feedback

Following sessions 1-4 participants rated their satisfaction (“*On a scale from 0 [not satisfied at all] to 100 [completely satisfied] how satisfied were you with today’s session?*”) and provided written feedback on the ‘best bits’ (“*What did you like best about today’s session?*”), ‘room for improvement’ (“*Is there anything that could be improved in today’s session?*”) and ‘other comments’ (“*Do you have any additional comments?*”).

After the final session, participants rated overall intervention satisfaction (“*On a scale from 0 [not satisfied at all] to 100 [completely satisfied] how satisfied were you with the overall programme?*”). Additional ratings were made on overall sessions, overall materials, and specific materials (see Table 3 for details). Free space was provided for participants to elaborate on any of these categories. In addition, suggested intervention improvement options were rated to Yes/No response items (see Figure 2 for details). Final comments could be made to the two items “*Please list below any other suggestions for programme improvement*” and “*Do you have any additional comments?*”.

2.4.4 Facilitator feedback

Following each session, the facilitator rated satisfaction and provided written feedback to the same questions as participants. In addition, the facilitator was given the opportunity to comment on materials used within the session, responding to the item “*Please list any comments that you have on specific intervention materials?*” and a list of materials.

2.4.5 Feasibility

Feasibility was assessed through running the intervention in a nutrition clinic setting, focusing on participant recruitment (i.e. getting individuals to consent for participation), **attendance (i.e. getting participants to turn up to sessions)**, participant retention (i.e. getting **participants** to complete the intervention), and session length. **Recruitment was assessed by responses to study invitations. Attendance, retention and session length were recorded by the intervention facilitator following each session.**

2.4.6 Before-and-after changes

Weight was assessed using a Tanita scale (**participant removed any outdoor clothing i.e. coats, jackets, heavy outerwear, shoes/boots**), at first and final session, PA was assessed using a validated self-report measure assessing how often individuals participated in physical activities for at least 30 min per session in their free time during the previous week [27], and diet was assessed using a 63-item validated food frequency instrument [28]. **Questionnaires were posted before and after the pilot intervention.**

2.4.7 Optimisation

Sources of feedback for intervention optimisation included the research team, participants, the facilitator, as well as indirect feedback such as evaluation of completed intervention materials (e.g. weekly booklet). All comments indicating ‘room for improvement’ were taken into consideration for informing intervention optimisation. If possible (i.e. the suggested change was feasible and evidence congruent) changes were made to the intervention. Any other suggestions were noted to potentially inform future research.

2.5 Analysis

Quantitative data was analysed using SPSS 17.0. **Descriptive statistics were computed as means and standard deviations or ranges for continuous variables and frequency counts and percentages for categorical variables. Between-group differences were assessed using independent t-tests. Before and after differences over time within participants**

were assessed using paired samples t-tests. Differences in categorical variables were assessed using chi-square tests, and correlations were examined using Pearson's product moment correlation coefficient. Qualitative data was categorised into three categories corresponding to the complex intervention components being assessed: (a) 'intervention content' (including BCTs), (b) 'mode of delivery (MOD)' (including intervention setting, intervention procedures, facilitator, style of delivery, materials), and (c) 'other comments' (e.g. intervention overall, elaboration on intervention effects, general positive statements).

3. RESULTS

3.1 Participants

Twelve intervention groups were assembled and the full intervention was delivered between November 2008 and August 2009 including a total of 74 participants (Table 2, Figure 1), with an average of 6 (*SD* 3.3) initial members per group (range 3-10). Participants were mainly female ($n=63$, 85.1%), married (76%) and white-collar workers (49%). The average age was 54.4 (**range: 24-75 years**), and participants were on average extremely obese ($M_{\text{BMI}}=42.2$, **range: 26-64**). Most participants reported taking no weight loss medication (73%). There were no differences in medication status for age, weight and years spent in full time education ($ps>0.05$).

-----Table 2-----

-----Figure 1-----

3.2 Acceptability

3.2.1 *Intervention satisfaction ratings*

Mean satisfaction ranged from 86.4–92% across sessions and from 83-100% across groups. **Overall mean program satisfaction (session 1-5) was 94.5 (range: 83.3-100%).**

The average facilitator satisfaction rating across sessions was 90% (range 75–100%). **No differences in satisfaction between sessions emerged for participants and facilitator respectively.**

3.2.2 *Intervention characteristic and improvement ratings*

Ratings on the intervention characteristics and materials are displayed in Table 3. Scores (**out of 5**) on the intervention overall ranged from 4.4–4.7. Detailed ratings on helpfulness of specific materials revealed scores ranging from 4.1 for the ‘barrier memory card’ to 4.9 for the pedometer. Overall ratings on materials received scores ranging from 4.5–4.7.

-----Table 3-----

Ratings on intervention improvement options (see Figure 2) showed the majority of participants favouring follow-up classes (86%, $n=37$) and additional contact (77%, $n=30$) after the main part of the intervention. Opinions of *opportunities* for additional contact during (56.1%, $n=23$) or after the intervention (51.3%, $n=20$), *actual* additional contact during the intervention (51.3%, $n=20$), and longer classes (47.6%, $n=20$) were divided between participants. The majority of participants indicated that more (69.4%, $n=25$) or **different** materials (70.4%, $n=24$) were not necessary.

-----Figure 2-----

3.2.3 *Comments on sessions and intervention overall*

Participants

Overall 176 forms were collected across groups following sessions 1–4. Comments on the ‘best bits’ of the intervention focused on intervention content (BCTs referred to were social comparison [$n=67$], provision of information [$n=15$], goal setting [$n=14$], barrier identification [$n=12$], provision of feedback [$n=10$], contingent rewards [$n=8$], general

encouragement [$n=5$], and review of behavioural goals [$n=3$]) and the MOD (including group setting [$n=39$], the style of delivery [$n=16$], the facilitator [$n=4$] and materials [$n=2$]). Any additional comments were grouped as introspection on the effects that the intervention had on participants ($n=17$), overall positive ($n=13$) critical ($n=3$) or neutral statements ($n=2$).

Comments on ‘room for improvement’ focused on BCTs (overall content [$n=2$] and contingent rewards [$n=1$]), MOD (procedural aspects of the intervention [$n=15$], materials [$n=5$], group dynamics [$n=5$] and intervention setting [$n=5$]) or were categorised as ‘other comments’ (positive [$n=13$] and neutral comment [$n=2$]). Out of 176 individual responses, 141 (80%) either indicated no room for improvement ($n=100$, 57%) or provided no detail ($n=41$, 23%).

‘Other comments’ included remarks on BCTs (social comparison [$n=4$], self-monitoring [$n=2$], barrier identification [$n=2$], goal setting [$n=2$], feedback [$n=1$]), MOD (procedures [$n=20$], facilitator [$n=2$], materials [$n=1$], setting [$n=1$]) positive statements on the intervention ($n=22$), as well as neutral ($n=4$) and critical ($n=2$) comments.

Facilitator

Feedback on ‘best bits’ of the intervention focused on ‘intervention content’ (BCTs referred to were ‘goal setting’ [$n=8$], ‘contingent rewards’ [$n=5$], ‘review of goals’ [$n=4$], ‘self-monitoring’ [$n=4$], ‘barrier identification’ [$n=2$], and ‘provision of feedback’ [$n=1$]), the MOD (group setting [$n=10$]), and ‘other’ ($n=14$), including comments on impressions on facilitator and participants, and intervention effects.

Responses indicating ‘room for improvement’ all regarded the MOD (including procedures [$n=9$], materials [$n=3$], intervention content [$n=1$] and delivery style [$n=1$]) and ‘additional comments’ focused on MOD (intervention procedures [$n=8$] materials [$n=3$]) and ‘other’ (challenges [$n=5$], positives [$n=5$], effects [$n=3$], and concern in relation to the intervention [$n=2$]).

3.3 Feasibility

3.3.1 Recruitment

Of 214 invites 93 replies were received (43%), with 74 (34%) patients consenting to participate. **Several challenges of integrating the study within the nutrition clinic were encountered.** Firstly, **identification of potential participants from the clinic registers** was slower than planned. Altogether 214 invitations were sent out, but in small and interspersed chunks. Considering the intervention group delivery, this complicated the scheduling of sessions **as not all participants could attend sessions at similar times.** Secondly, the intervention setting underwent restructuring leaving clinic staff and clients unsure regarding future obesity services. These factors added further complexity and potentially influenced recruitment, as well as retention, attendance and adherence (reported below).

3.3.2 Adherence and Retention

Forty-seven (78%) participants that attended at least one session completed the study. Completers attended an average of 4.6 sessions, with 64% ($n=30$) attending all sessions. Sessions lasted on average 68 minutes (range 45 – 95), with an average 4 participants attending, ranging from 1-7.

Of 74 consenting participants 13 (18%) failed to attend any scheduled sessions. Of those participants starting the intervention, 5 (7%) attended 1 session, 4 (5%) attended two sessions, 7 (9%) attended three sessions, 16 (20%) attended 4 sessions and 30 (41%) attended all 5 sessions (materials for missed sessions were sent by post). There was no significant differences on the number of sessions attended **in terms of gender, job category or marital status ($ps<0.05$), and session attendance was not associated with age or BMI ($ps<0.05$).** Of the 60 (82%) participants attending any of the offered sessions the average number of sessions attended was 4.02 ($SD=1.3$). Reasons given for not attending sessions included: health issues, personal issues, limited availability, and lack of parking at venue.

3.4 Before and after changes

3.4.1 Weight

On average, participants completing the intervention **follow-up assessment (n=46)** lost 0.86kg ($SD=1.5$) over the 5 weeks between pre ($M= 118.2\text{kg}$, $SD=23.4$) and post intervention ($M=117.3\text{kg}$, $SD=23.1$), $t(45)=3.84$, $p=0.0001$. Weight change between pre and post intervention ranged from -5.3 to +2.7kg, with 67% of intervention completes displaying at least some weight loss, with a modal decrease of 1kg. **There was no difference in weight loss between women and men ($p=0.6$), and weight loss was not associated with age or BMI ($ps<.05$).**

3.4.2 Physical Activity

The average change in physical activity (PA) behaviour pre and post intervention was an additional 1.6 ($SD=2.7$) PA sessions for at least 30 minutes per session during the last week increasing from 2.06 ($SD=1.9$) at pre test to 3.6 ($SD=2.4$) after the intervention, $t(31)=-3.3$, $p=0.002$. PA behaviour changes ranged from -4 to +7, with a modal increase of two more PA sessions a week across the intervention. **The difference in increased activity between men and women approached significant (1.3 vs. 4.3 sessions respectively, $p=.06$), however the number of men was small ($n=3$). PA increases were not associated with age or BMI ($ps<.05$).**

3.4.3 Dietary behaviours

No significant changes were found between pre and post intervention on calorie, fat, carbohydrate, protein, sugar, starch and fibre consumption. The only decrease that approached significance was observed on starch consumption ($M_1=74.7$ $SD_1=40.9$; $M_2=65.2$ $SD_2=38.5$; $t(35)=1.76$, $p=0.087$).

3.5 Intervention Optimisation

Despite high acceptability ratings of the intervention various potential change avenues were reported (Table 4). Changes were made throughout the study, with the majority of these following an in-depth analysis of feedback and materials from **the first 4 groups**. Overall, out of 37 identified opportunities for change, 7 full and 11 minor changes were made, with 18 improvement suggestions either deemed to be not feasible (**i.e. not possible within the current study context**) or advisable (**i.e. not evidence congruent**). Various improvements relevant for future interventions were identified (Table 4). No significant increases in acceptability could be detected over time, potentially due to the high initial acceptability ratings on all measures

----- Table 4 -----

4 DISCUSSION AND CONCLUSION

4.1. Discussion

Advances in the evidence synthesis [15, 29, 30] and reporting [31] of behaviour change interventions have yet to lead to the systematic development of **health** behaviour change interventions based on the newly established definitions [13]. The current **pilot intervention study is one of the first to fully apply current advances by testing and optimising acceptability and feasibility of a systematically developed technique-based behaviour change intervention for obese adults with obesity-related co-morbidities or additional risk factors for co-morbidities.**

4.1.1 Intervention Acceptability

Intervention content, procedures and materials were found to be acceptable to participants completing the pilot **underlining the potential of a systematic technique-based behaviour change intervention development approach.**

The main suggestion for intervention improvement was a desire for a longer intervention period, or follow-up classes beyond the core part of the intervention. Given time

restrictions the primary aim of the current study was to test and optimise acceptability and feasibility of the intervention, **but future adaptation of this or similar interventions might need to include follow-up periods. The current intervention is relatively brief in comparison to intervention in this area [12, 32]. It was developed condensing BCTs found to be effective [15] into a brief and scalable intervention module for the secondary care context. Having established acceptability for the core part of the intervention, the level and intensity of additional contact needed needs to be determined.**

High scores on aspects of the overall materials and sessions, as well as helpfulness ratings of specific materials were obtained, **particularly for** pedometers (4.9/5). Previous studies have evidenced feasibility [33] and high levels of satisfaction [34] in relation to using a pedometer to increase PA behaviour. In addition, pedometers seems to have a positive effect on attrition; a study with older women showed that a self-regulation intervention with pedometer was not more effective than the same intervention without pedometer, but participants in the condition including pedometers were more likely to complete the intervention [35]. Importantly, systematic review evidence suggests that pedometers are associated with significant increases in walking and subsequently improvements in health such as reductions in weight and blood pressure, especially when used in conjunction with specific goal setting [36], **as was the case in the current intervention pilot.**

The current intervention **seems to be** acceptable from a delivery perspective as **indicated by high** satisfaction ratings **of the delivering facilitator**. Facilitator feedback extensively reflected on the majority of intervention elements, providing an insight into perceptions of the intervention delivery (e.g. *“They have been totally motivated from beginning. Not only have they all lost weight but they all look and feel better. They have better self-esteem and improved confidence.”*). The two constructs most regularly referred to were motivation and self-efficacy [21]. **Despite the usefulness of such reflective accounts**

in establishing acceptability, future studies need to intervention fidelity **in a more formalised manner** [37]. For example, tape recording and transcribing session content could confirm content fidelity (effectively intervention delivery) and process fidelity (intervention delivery in the specified manner) [38].

4.1.2 Intervention Feasibility

Evidence for the feasibility of intervention delivery was varied with recruitment and attendance rates suggesting significant challenges **and reinforcing the importance and purpose of conducting a pilot/feasibility study such as this one**. Despite best efforts of the research team, identification of potential participants was lengthy and slow preventing the formation of larger groups (i.e. ten participants) as originally anticipated. Moreover, challenges in terms of retaining individuals for the duration of the study emerged. However, when participants attended sessions, the feasibility of delivering the intervention was high.

A number of contributing factors for less than optimal response and retention rates can be identified. First, recruitment and retention could have been affected by an unforeseen redesign of obesity management services during the study period. This did not affect the intervention per se, but uncertainty of future care might have impacted on participation and retention. Second, attending a behaviour change group intervention targeting a long-standing problem can be as a stressful experience as overtly indicated by some participant (e.g. “[...] *I was very nervous about coming*”) and the facilitator comments (e.g. “*Participants all seem quite anxious until they start talking and realise that they are not the only person with problem*”). Some participants might initially prefer individual as opposed to group treatment. Such preference has been demonstrated in the mental health literature such as panic disorder and agoraphobia **where individual treatment is typically preferred** [39]. However, even in this clinical population group cognitive-behavioural treatment has been evidenced as being feasible [40] and comparable to individual treatment effectiveness [41]. Group treatment can

thus be applied to a range of personally challenging problems in a feasible and effective manner. Whilst being economical, effective, and popular, it should be noted that barriers such as emotions (e.g. nervousness) or self-regulation failure (e.g. forgetting to attend) [42] might lead to participants' failure to sign up, attend or return to an intervention, **as might be the case in the current pilot intervention**. Future research might focus on examining these barriers [43] and ways of addressing these prior and during (group-based) behaviour change interventions. Efforts to normalise the feeling of emotions prior to the initial engagement (e.g. through sending participant vignettes) and the sending of reminders and might be potential strategies to decrease the number of drop-outs.

4.1.3 Optimisation of Intervention Procedures

Various changes were made to the intervention following assessment of the feedback. These changes did not lead to any obvious differences in terms of participant feedback, **potentially due to the high initial acceptability ratings. However, it can still be argued that intervention optimisation occurred as none of the changes that were made was subsequently mentioned again by a participant. Future studies might benefit from collecting additional and specific data in relation to implemented changes.** Various suggestions for change were captured through the current intervention that could not be addressed. However, future adaptation of the current study would benefit from taking the systematically gathered feedback into account. Moreover, many of the learning points obtained through the current interventions might provide universal insight for researchers and practitioner in the process systematic behaviour change intervention development. In addition to testing the entire intervention package, further small scale factorial studies could be conducted testing components of the current intervention in isolation and combination in various different conditions [45, 46]. This could be used to further contribute to optimising

the current intervention, which can only be seen as a start for the development of behaviour change treatment for obese adults with additional risk factors.

4.1.4 Limitations

This study has some limitations. First, the study actively involved participants and facilitator by providing reflective feedback. This might have influenced the perceptions towards the intervention, potentially influencing outcomes. Second, despite being evidence-based and theory coherent, the current intervention needs to be firmly integrated within a theoretical framework. In order to keep measurement burden low, the theoretical mechanisms of potential intervention effect mediators were not assessed. Future studies will need to establish the mechanisms through which intervention effects are obtained in addition to the overall intervention effectiveness [44]. **Third, we were unable to detect dietary changes. Fourth, although we have employed mostly measures based on previous research these are self-report. Subjective measures should be employed where possible in the future. In addition, although feedback on the intervention was obtained anonymously there might have been perceived pressure to reflect positively on the intervention, particularly in small groups. Lastly, the findings of this study might have limited generalizability to other obese populations.**

4.2 Conclusions

The current study outlines a PA and dietary behaviour change pilot intervention coupled with a systematic and transparent process of intervention optimisation. The systematically developed pilot intervention has been evidenced as acceptable and deliverable and participants who completed the study lost weight and increased their PA. Various suggestions for intervention improvement have been evidenced, which might add value in a future version of the current intervention, or might inform the development of other behaviour change interventions in different domains.

4.3 Practice Implications

The current study demonstrates how to establish and optimise feasibility and acceptability of a newly developed evidence-based and theory coherent intervention in line with intervention development recommendations [47, 48] using new methods of intervention specification and evidence synthesis [15]. The developed and optimised intervention for obese adults with additional risk factors seems feasible for delivery by a nurse and highly acceptable to facilitator and participants.

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I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story

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Table 1: Brief outline of intervention content for the weekly sessions.

<i>Week & Topic</i>	<i>Techniques</i>	<i>Materials</i>	<i>Summary (use of techniques indicated in text)</i>
Week 1: Rationale of the intervention and the importance of self monitoring	<ul style="list-style-type: none"> • Facilitating social comparison (FSC) • Overall goal setting (OGS) • Providing instructions (PI) • Self-monitoring of behaviour (SMB) 	<ul style="list-style-type: none"> • Group rules sheet • Pedometer instruction sheet • Omron Walking Style I pedometer • Weekly booklets (OGS, SMB) • Handouts 	<p>Before the start of the initial group session (FSC) participants were provided with a pedometer, Omron Walking Style I, which was calibrated by a research assistant for participants' weight and stride length. The first session aimed at familiarising the participants with each other and the intervention (PI). The intervention programme was introduced, including the rational underlying its development and key assumptions such as a lifestyle approach to sustainable weight loss. Differences between this programme and others were established. The main purpose of the first session was for participants to form an intention to change (eating behaviours, physical activity and/or body weight) by setting an overall goal (OGS) that they would like to achieve through attending the programme. Participants were asked to self-monitor their eating and PA behaviour over the next week (SMB).</p>
Week 2: Goal Setting For Dietary Behaviours	<ul style="list-style-type: none"> • Barrier identification (BI) • FSC • Specific goal setting (SGS) • SMB 	<ul style="list-style-type: none"> • Omron Walking Style I pedometer • Weekly booklets (BI, SGS, SMB) • Handouts • Barrier identification sheets (eating) • Barrier memory card 	<p>The second group session (FSC) aimed to bring focus to eating behaviour change and introduced the concepts of specific goal setting and barrier identification. Completed self-monitoring records for eating and drinking from the previous week were discussed. On the basis of these records participants were asked to formulate a specific action plan for at least one eating behaviour (SGS). Possible barriers that might have impeded this specific goal in the past were identified and a plan for overcoming these barriers was devised (BI). Participants were asked to monitor their behaviour as well as their goal attainment over the next week (SMB).</p>
Week 3: Review of Eating Goal and Goal Setting For	<ul style="list-style-type: none"> • BI • FSC • Prompt Practice (PP) • Review of 	<ul style="list-style-type: none"> • Omron Walking Style I pedometer • Weekly booklets (BI, SGS, SMB) 	<p>The third group session (FSC) aimed to review dietary goal attainment from the previous week (RBG). Possible barriers that might have impeded goal attainment were identified and new dietary goals for the forthcoming week were set, taking into account possible barriers (SGS,</p>

<i>Week & Topic</i>	<i>Techniques</i>	<i>Materials</i>	<i>Summary (use of techniques indicated in text)</i>
Physical Activities	<ul style="list-style-type: none"> ● behavioural goals (RBG) ● SGS ● SMB 	<ul style="list-style-type: none"> ● Handouts ● Barrier identification sheets (PA) 	<p>BI). In addition, the third session aimed to introduce the importance of PA and encourages the setting of a specific physical activity goal and coping plans for the forthcoming week. In addition, participants were asked to practice one PA behaviour over the next week, such as going for a walk, a swim, or to the gym (PP). Participants were again be asked to self-monitor their behaviour (SMB).</p>
Week 4: Review of eating and PA goals and plan rewards	<ul style="list-style-type: none"> ● BI ● FSC ● Plan contingent rewards (PCR) ● RBG ● SGS ● SMB 	<ul style="list-style-type: none"> ● Omron Walking Style I pedometer ● Weekly booklets (BI, SGS, SMB, PCR) ● Handouts ● Self-rewards sheet ● Self-rewards example cards 	<p>The fourth group session (FSC) aimed to review behavioural goals (RBG) for both dietary and physical activity behaviours and to formulate new specific plans, including planning action and coping (SGS, BI). Furthermore, this session also focuses on planning rewards for achievements and how to adjust goals and strategies over time to achieve sustainable behaviour change (PCR). Participants were again asked to self-monitor their behaviour (SMB).</p>
Week 5: Reviewing achievements, generalising activities and promoting maintenance	<ul style="list-style-type: none"> ● BI ● FSC ● Relapse prevention (RP) ● RBG ● SGS 	<ul style="list-style-type: none"> ● Omron Walking Style I pedometer ● Weekly booklets (BI, SGS, SMB, PCR, RP) ● Handouts ● Maintenance memory card ● Certificate 	<p>The fifth and final group session (FSC) aimed to review achievements of previous weeks (RBG), highlight all positive changes that have taken place, and set new specific goals (SGS). It was emphasized that the achieved behaviour changes can be generalised to other behaviours. Moreover, relapse issues as part of an ongoing attempt for permanent lifestyle change were discussed (RP). After this session, participants were asked to take charge independently using their newly acquired skills.</p>

Note. BI = Barrier Identification, FSC = Facilitating Social Comparison, OGS= overall goal setting, PCR = Plan Contingent Rewards, PP = Prompting Practice, PI = Providing Instructions, RBG = Review Behavioural Goals, RP = Relapse Prevention, SGS = Specific Goal Setting, SMB = Self-Monitoring of Behaviour.

Table 2: Demographics of total sample (N=74)

Gender (N=74):	
Women	63 (85.1%)
Men	11 (13.6%)
Age (n=62) (Range 24-75 years)	54.4 (10. 3) years
Marital Status (n=60):	
Married	46 (76%)
Single	4 (7%)
Divorced	8 (13%)
Widowed	0 (0%)
Separated	2 (4%)
Job Category (n=47)	
White collar	23 (49%)
Executive position	6 (13%)
Self-employed	1 (2%)
Labourer	17 (36%)
Years spent in full-time education (n=50)	11.8 (3.3) Years
Further education or training (n=60)	41 (68%) Yes 19 (32%) No
Height (n=61)	164 (.08) cm
Weight (n=59)	113.6 (25.3) kg
Body Mass Index (n=59)	42.2 (9.1)
Taking weight loss medication (n=62)	
Yes	14 (27%)
No	45 (73%)

Note. Data for age, years of education, height, weight, body mass index are mean (SD); gender, marital status, job category, further education, and weight loss medication are n (%)

Table 3: Participant end of intervention ratings of perceptions on materials and intervention

Items	Mean (SD)
Response options (1-5)	
<i>Overall, the programme sessions ...</i> ^a	
had a clear structure ²	4.6 (0.6)
taught me new things ¹	4.6 (0.6)
were well styled and complete ¹	4.4 (0.6)
were understandable ²	4.6 (0.6)
were easy to attend ¹	4.5(0.7)
were structured in logical order ⁴	4.5 (0.6)
were interesting ¹	4.7 (0.4)
were attractive ³	4.6 (0.5)
were relevant ¹	4.6 (0.5)
were useful ¹	4.7 (0.4)
were helpful ⁴	4.7 (0.4)
<i>Please rate how helpful you found specific intervention materials.</i> ^b	
Weekly booklets ¹	4.8 (0.4)
Dietary recommendation leaflets ²	4.4 (0.6)
Pedometers ³	4.9 (0.3)
Session handouts ³	4.5 (0.6)
Group norm worksheet ⁶	4.5 (0.6)
Barrier memory cards ⁶	4.1 (0.9)
Barrier worksheets eating ⁵	4.3 (0.9)
Barrier worksheet physical activity ⁴	4.3 (0.8)
Physical activity recommendation sheet ⁵	4.4 (0.6)
Self-treat worksheet ³	4.2 (0.6)
Relapse Prevention memory card ⁶	4.2 (0.8)
<i>Overall, the materials presented in the programme were...</i> ^a	
Understandable ²	4.6 (0.6)
Easy to use ²	4.6 (0.5)
Presented in logical order ²	4.6 (0.6)
Interesting ³	4.6 (0.5)
Attractive ³	4.5 (0.6)
Relevant ³	4.7 (0.4)
Useful ¹	4.7 (0.4)
Helpful ³	4.7 (0.4)
Logical ³	4.6 (0.5)
Added value on top of the classes ⁵	4.7 (0.4)

Note. ¹ n=46; ² n=45; ³ n=44; ⁴ n=43; ⁵ n=42; ⁶ n=40

^a scale from 1 "I totally disagree" to 5 "I totally agree", ^b scale ranging from 1 ("Totally unhelpful") to 5 ("Totally helpful")

Table 4: Details of received feedback and elaboration on changes and implications.

Area	Source(s)	Description	Changes	Elaboration	Future intervention potential
Intervention	Research team	Lack of name/label/logo for the study	No	Study was referred to as "behavioural study" in absence of a more memorable title.	Need to have a memorable and identifiable name for an intervention to increase clarity of communication for participants and the research team. Structure materials clearly.
Materials	Facilitator	Lack of handout clarity	Yes	Handouts changed to include page numbering and space for notes	
Materials	Facilitator	Forgetting barrier memory cards	No	Memory cards not handed out	Integrate all intervention elements into the procedures of intervention delivery to avoid forgetting.
Materials	Facilitator	Barrier sheet bringing up 'mixed feelings'	Yes	Rewording of content (e.g. I am too fat) into less offensive terms (e.g. I am too heavy).	Attention to be paid to language and potential emotional connotations of intervention materials
Materials	Material engagement	Undesired use of goal setting forms	Yes	Participants responding "nobody" or "myself" to question "With whom am I going to do this" section in goal setting section. Switch of focus in goal setting booklet replacing "With whom am I going to do this" for "How am I going to do this" as the latter question can include information elicited by the former. In addition barrier identification pages were slightly reformulated switching the order in "Who/what could help me?" to "What/who could help me" and "Is there somebody or something that can help me stick to my goal" to "Is there something or somebody that can help me stick to my goal".	Careful wording of intervention material prompts needed.
Materials	Material engagement	Incomplete monitoring of behaviours	Yes	Change layout of self-monitoring pages for eating and activity to integrate both behaviours on the same pages in booklet	Attention needing to be paid to layout of monitoring forms.

Area	Source(s)	Description	Changes	Elaboration	Future intervention potential
Materials	Material engagement	Incomplete questionnaire response	Some	If possible, incomplete time1 questionnaires were handed back to participants at initial session for completion.	Layout of questionnaire needs to be improved; data collection can be improved through having everybody fill in questionnaire at the session, as part of the programme. Detailed information necessary for some participants.
Materials	Participants	More information on handouts	Yes	Handouts changed to include more detailed information	
Materials	Participants	Booklet heading unclear	Yes	Self-monitoring booklet sections for the recording of antecedents, behaviours and consequences changed from 'Antecedents' to 'At first'.	Simple and communicative language most desirable for participants.
Materials	Participants	Self-treats perceived as unreasonable	Yes	Change delivery of self-treat concept. Emphasis on choice and fun element involved in rewarding.	Delivery of techniques as increasing participant choice is more important than behavioural prescriptions.
Materials	Participants	More menus	No	Need to balance the provision of information and help to translate information into behaviour.	Back-up recipes for participants that have tried the provided suggestions. Careful to avoid information overload and keep intervention focused.
Procedures	Facilitator	Bigger groups	Some	Every effort was made to recruit at least 10 participants per group.	Intervention recruitment should focus on identifying enough participants to schedule more than 10 participants per session to keep numbers high accounting for non-attendees. Could include optional dietetic sessions to refresh dietetic input.
Procedures	Facilitator	Dietetic input at the sessions	No	All participants received dietetic input prior to the intervention. The intervention focused on translation of input into behaviour	
Procedures	Facilitator	Physical activity opportunities	Some	Participants were prompted to contact relevant physical activity providers to enquire about physical activity opportunities.	Inclusion of detailed local physical activity opportunities.

Area	Source(s)	Description	Changes	Elaboration	Future intervention potential
Procedures	Facilitator	Negative intervention feedback	No	Participants claimed to not have learned anything new, but completed the intervention and claimed to have been satisfied in the end.	Even initially reserved participants can gain benefit from the interventions.
Procedures	Facilitator	Lack of confidence in intervention delivery	No	Facilitator received two training sessions. Confidence improved throughout intervention delivery experience.	Facilitator training should focus on confidence to deliver the intervention components adequately and accurately.
Procedures	Facilitator	Expectations of detailed multisource input	No	Participant expecting to have access to various health care professionals were informed of the pilot nature of the intervention and told about the possibilities of obtaining specialised input.	Communicate clearly how the intervention sits within the current intervention setting.
Procedures	Facilitator	Grasp concept on non-food rewards	Some	Refine the intervention manual to stress the importance of choosing rewards based on one's own preference and coherent with the overall goal of losing weight	Importance of goal congruence with behaviour needs to be taken into account when delivering self-reward concept
Procedures	Material engagement	Lack of questionnaire response	Some	Participants reminded in time 1 session to fill in questionnaires. Facilitator urged to not give post intervention evaluation questionnaires to participants to send it back with the final questionnaire. Reminders sent to provide the questionnaires one week after the intervention finished.	Phone reminders for returning of questionnaires.
Procedures	Participants	Group communication issues	Some	More frequent reinstatement of group rules when appropriate.	Frequent prompting of group rules to remind participants of agreed communication patterns.
Procedures	Participants	Longer sessions.	No	Sessions remained 60 minutes on average as target time due to practical constraints, but length was delivered flexibly.	Session length could be extended to 90 minutes

Area	Source(s)	Description	Changes	Elaboration	Future intervention potential
Procedures	Participants	Weekly participants weighing	Some	Weekly weighing was undertaken with those participants voicing an interest in this information.	Weighing could be offered voluntarily, but justification would need to be made clear.
Procedures	Participants	Send diary before week 1	No	Sending without facilitator input not ideal, potential to further decrease attendance rates.	No future intervention potential
Procedures	Participants	Psychologist sitting in	No	Not feasible as part of the current intervention, not a sustainable model for obesity intervention delivery.	No future intervention potential
Procedures	Participants	Keeping of pedometers	No	Current study not budgeted for letting participants keep pedometers	Could consider giving pedometers away at end of intervention, or making these available for purchase.
Procedures	Participants, Facilitator	Reunion	Some	Participants prompted to exchange contact details to continue support.	Future group meetings past the core intervention should be part of the programme package.
Procedures	Participants, Facilitator	Information density	Some	Increased encouragement of group members to help one another through group discussions.	Information density could be decreased with increased intervention length and/or elimination of 'inactive ingredients'.
Procedures	Participants, Facilitator	PowerPoint slides	No	Not possible in current setting due to facility size.	PowerPoint slides could be used to enhance the sessions and bring a visual element to the intervention.
Procedures	Participants, Facilitator	Regular follow-up classes	No	Not feasible as part of the current intervention	Follow-up classes after the core part of the intervention should be in place.
Procedures	Participants, Facilitator	Concern/ worry about future	No	Participants and facilitator unsure about the future of the treatment provision.	Communicate clearly how the intervention sits within the current intervention setting.
Procedures	Research team	Difficulties contacting consented participants	Some	Flexible contact times to reach participants were utilised including evenings and weekends.	Designated times for contacting participants needed. Statement of preference for contact time and contact number should be included in return slip to intervention invitation.

Area	Source(s)	Description	Changes	Elaboration	Future intervention potential
Recruitment	Research team	Participant identification issues	No	Participant database not setup to easily identify participants.	Close inspection of held records prior to recruitment.
Setting	Participants	Difficult to park	No	Intervention held at a busy inner city hospital site, parking places cannot be reserved for study. Parking issues highlighted in invitation letter.	Provision of tips where to park and how to get to intervention venue from parking places.
Setting	Participants	Provision of water	Some	Participants prompted to bring along own drinks.	Could consider providing catering of drinks and healthy snacks.
Setting	Participants	Provision of table	No	Tables might interfere with the open group set-up. Space restriction made provision of table impractical.	Could consider having designated space for intervention materials,
Setting	Research team	Uncertain intervention environment	No	System changes throughout the pilot gave rise to some level of uncertainty.	Communicate clearly how the intervention sits within the current intervention setting.

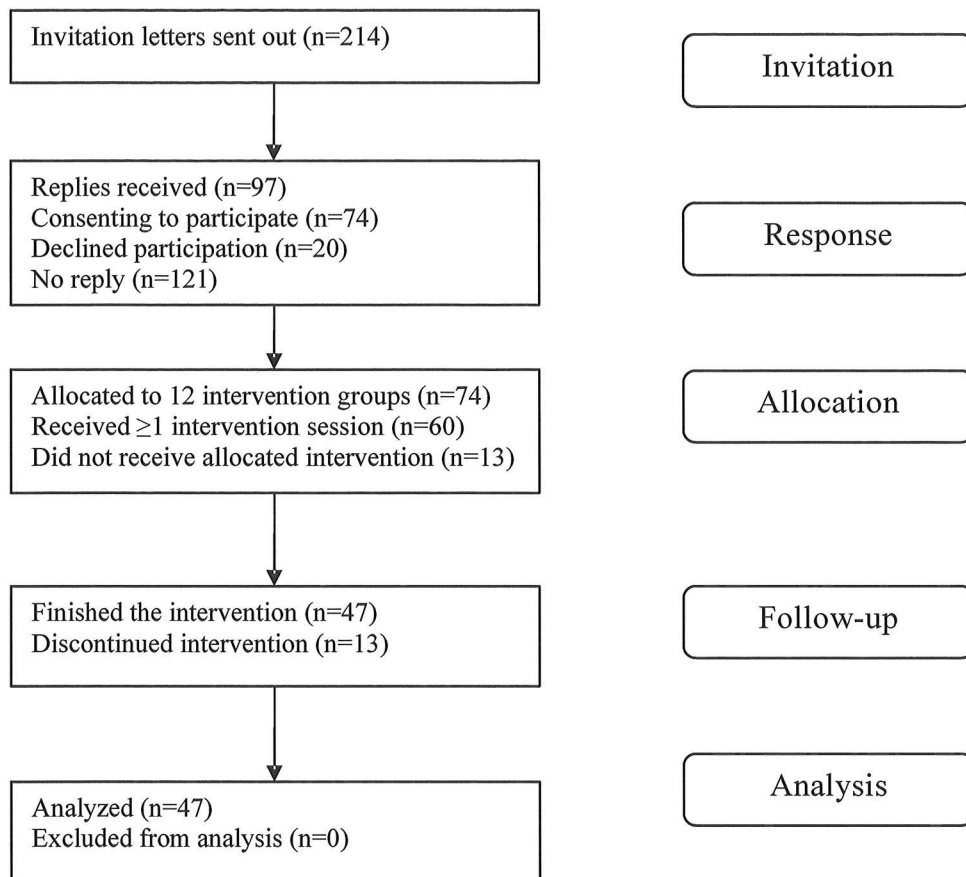


Figure 1: Participant flow diagram.

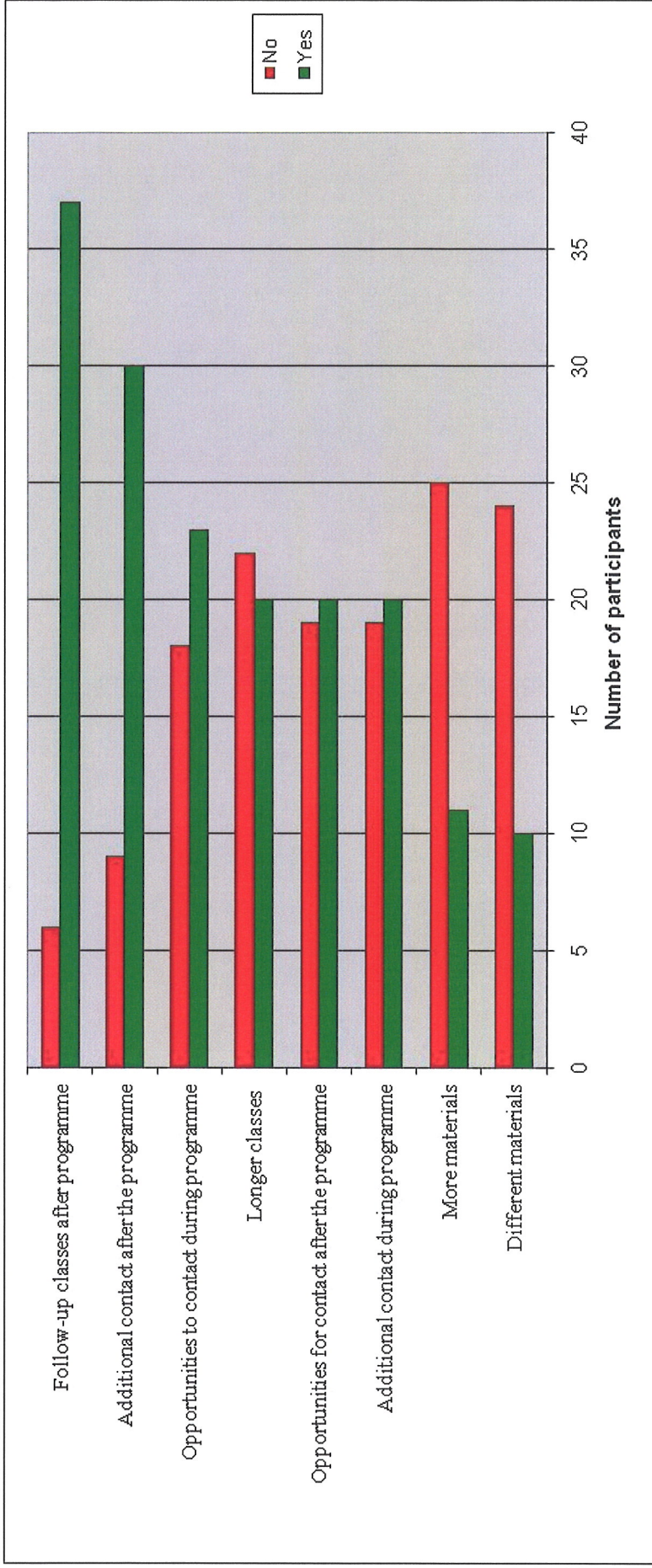


Figure 2: Participant responses to options provided for the item “I think the following elements would improve the programme”.