Tackling obesity in areas of high social deprivation: clinical effectiveness and cost-effectiveness of a task-based weight management group programme – a randomised controlled trial and economic evaluation

Hayden McRobbie,[1] Peter Hajek,[1] Sarrah Peerbux,[1]* Brennan C Kahan,[2] Sandra Eldridge,[2] Dominic Trépel,[3] Steve Parrott,[3] Chris Griffiths,[4] Sarah Snuggs[1] and Katie Myers Smith[1]

[1]Health and Lifestyle Research Unit, Wolfson Institute of Preventive Medicine, Queen Mary University of London, London, UK
[2]Pragmatic Clinical Trials Unit, Queen Mary University of London, London, UK
[3]Department of Health Sciences, University of York, York, UK
[4]Centre for Primary Care and Public Health, Blizard Institute, Queen Mary University of London, London, UK

*Corresponding author

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Scientific summary

Obesity in areas of high social deprivation

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Background

An increasing number of people in the UK require help to manage their weight. The NHS currently offers advice in general practice, sometimes accompanied by slimming medications and a referral to the practice nurse or dietitian. Although this is helpful for some patients, more effective approaches are needed that can be disseminated economically on a large scale, possibly in parallel with the successful UK specialist Stop Smoking Service (SSS).

Objective

To assess whether or not a task-based weight management programme [Weight Action Programme (WAP)] has a long-term effect over and above the effect of a 'best practice' weight management intervention provided in primary care by practice nurses.

Methods

Overview

We conducted a randomised controlled trial with 12 months' follow-up between September 2012 and February 2015. The primary outcome measure was weight change at 12 months post randomisation.

Participants

Participants were recruited from six general practitioner (GP) surgeries across the London boroughs of Tower Hamlets and Hackney, both areas with high levels of social deprivation, via GP referrals, mailshots from GP databases and self-referrals facilitated by posters and leaflets. Recruitment was also facilitated by advertisements in the local newspaper, community venues and word of mouth. Those who met the self-reported eligibility criteria assessed during a telephone call were invited to one of two GP surgery sites for the initial screening session.

Participants were eligible if they were aged $\geq$ 18 years, wanted to lose weight and had an objectively measured body mass index (BMI) of $\geq$ 30 kg/m^2 or a BMI of $\geq$ 28 kg/m^2 plus comorbidities. Those who were unable to read/write/understand English, had a BMI of > 45 kg/m^2, had lost > 5% of their body weight in the previous 6 months, were currently pregnant, were taking psychiatric medications, were not registered with a GP in the participating borough areas or were involved in a current research project were excluded.

Following baseline measurements, eligible participants were randomised to the WAP or the nurse arm in a 2 : 1 ratio (WAP to nurse). Treatment in both arms started within 2 weeks of randomisation. All participants were invited to attend 6- and 12-month follow-up appointments to assess outcomes.

Nurse arm

The practice nurse intervention was modelled on a best-practice intervention in primary care, derived from discussions with GPs and practice nurses, and incorporating national guidelines and NHS materials.

Participants received the intervention from a trained study nurse in four one-to-one sessions delivered over 8 weeks. The initial session lasted 20–30 minutes; the follow-up sessions were briefer, as per usual practice. The intervention included advice on diet and physical activity based on NHS 'Change4Life'

material, and motivational support. Participants were encouraged to lose around 1 lb (0.45 kg) per week and were weighed at each session to assess their progress.

Weight Action Programme arm

The WAP is a group-based weight loss programme developed via extensive client feedback and piloting with underprivileged groups since 2002. The WAP aims to provide participants with tools to lose weight and to maintain a long-term healthy lifestyle.

It is delivered over eight weekly group sessions that combine standard cognitive–behavioural interventions, dietary advice and self-monitoring with group-oriented interventions aimed at increasing participant retention, involvement and adherence to weekly tasks. The initial course is followed by 10 monthly maintenance sessions. These maintenance sessions were 'open' groups, with participants at different stages of the intervention attending the same once-a-month session. The target weight loss was 1 lb (0.45 kg) per week. Two advisors (research health psychologists) conducted the WAP sessions in groups of 10–20 participants (one advisor conducted the maintenance sessions).

Both arms, as per standard care, received information about local exercise provision and, where appropriate, participants were given information about orlistat and advised to see their GP if they wished to use it as part of their weight loss programme.

Outcome measurements

Trained study staff assessed weight, waist circumference and blood pressure objectively, following standard protocols. Other secondary outcomes were self-reported: changes in physical activity using the International Physical Activity Questionnaire; changes in healthy eating using the Food Knowledge Assessment questionnaire; and changes in food craving using the Food Craving Questionnaire.

Participants were asked to report adverse events (AEs) at every session. All measurements at 6 and 12 months were collected by a researcher who was blind to treatment allocation.

Sample size

We hypothesised that the WAP would increase annual weight loss by 2.6 kg compared with best usual practice (WAP 3 kg vs. usual care 0.4 kg) for participants available for follow-up at 1 year, and that there would be no difference in weight loss between treatment groups for participants not available for follow-up. Assuming that 50% of participants in both treatment groups were available for follow-up at 1 year, the difference in weight loss between arms would be 1.3 kg (WAP 1.5 kg vs. usual care 0.2 kg). Assuming a standard deviation (SD) of 3 in both arms, and a 5% two-sided significance level, we would require 112 participants in each arm to detect this mean difference with 90% power. To account for potential clustering effects because of group treatment in the WAP arm, assuming a mean cluster size of 18 and an intracluster correlation coefficient of 0.05, a total of 208 individuals were required in the WAP arm. The same power was calculated as achievable with 108 in the nurse arm and 216 in the WAP arm, which was increased to 110 in the nurse arm and 220 in the WAP arm to give an allocation ratio between the two arms (2 : 1), expressed in whole numbers. Thus, we required a total of 330 individuals for the entire study.

Statistical analyses

The main analysis for the primary outcome (change in weight at 12 months) was performed in accordance with the intention-to-treat principle, whereby all participants with at least one recorded weight measurement at either 1, 2, 6 or 12 months were included in the analysis, and were analysed according to the treatment group to which they were randomised. *p*-values were two-sided, with the significance level set at 5%. The primary outcome measure (change in weight) was analysed using a mixed-effects linear regression model, and included a random intercept for cluster, where cluster was defined as the specific nurse delivering care to control arm participants and the WAP group that intervention arm participants belonged to. An unstructured correlation matrix for weight at different follow-up time points (1, 2, 6 and 12 months) was used. The analysis was adjusted for baseline weight, age, sex, ethnicity, smoking status and GP practice.

Two sensitivity analyses were undertaken to assess the robustness of our primary analysis to different assumptions regarding the missing data. These were (1) a complete-case analysis, including only patients with recorded data at 12 months; and (2) an analysis that assumes data missing at 12 months are not missing at random.

Cost-effectiveness analysis

Cost-effectiveness analysis was undertaken to examine whether or not the WAP represents value for money to the NHS.

In order to estimate the cost-effectiveness of the WAP (intervention group) versus nurse-led weight management (representing usual care), a within-trial cost–utility analysis was undertaken. The costs were estimated from the NHS and social services perspectives. To inform the estimation of quality-adjusted life-years (QALYs), participants completed the European Quality of Life-5 Dimensions-5 Levels questionnaire.

The incremental cost-effectiveness ratio (ICER) was calculated. Costs and outcomes were bootstrapped (using 10,000 replications) and the data used to construct cost-effectiveness acceptability curves to show the probability that the WAP is a more cost-effective intervention than routine care.

Base-case analysis makes three key assumptions regarding the cost of the WAP intervention: (1) the prior history of health-care use should not influence results; (2) group sessions are conducted by a band 5 (hospital dietitian); and (3) the cost of the WAP assumes attendance of 15 participants for all sessions. These three assumptions are subject to sensitivity analysis.

Results

Study population

Of 1018 potential participants registering an interest, 389 were ineligible (reasons include use of psychiatric medication, lost > 5% of body weight in the last 6 months, a BMI of < 28 kg/m^2 or < 30 kg/m^2 without comorbidities), 283 declined to participate and 16 could not be randomised because the study sample size target had been reached. The remaining 330 were randomly allocated in a 2 : 1 ratio to the WAP ($n = 221$) and nurse ($n = 109$) arms.

Participants were, on average, in their mid-forties (WAP arm, mean 46.6 years; nurse arm, mean 45.1 years) and weighed, on average, 95.5 kg and 98.3 kg, in the WAP and nurse arms respectively. The majority (72%) were women, and 48% were from black or other ethnic minority communities. Most (59%) were entitled to free prescriptions, reflecting the low income of the population, and 38% had left school before the age of 16 years.

Primary outcome

A total of 291 participants (WAP, $n = 194$; nurse, $n = 97$) were included in the analysis of the primary outcome. Weight loss at 12 months was significantly greater in the WAP arm than in the nurse arm [–4.2 kg vs. –2.3 kg; difference –1.9 kg, 95% confidence interval (CI) –3.7 to –0.1 kg; $p = 0.04$]. In the sensitivity analyses, under the assumption that, on average, the weight of those lost to follow-up showed no change from baseline, the results are unaffected (difference –2.4 kg, 95% CI –4.3 to –0.5 kg). The complete-case analysis showed similar results.

Secondary outcomes

Participants in the WAP arm were significantly more likely than those in the nurse arm to have lost at least 5% of their baseline body weight at 12 months (41% vs. 27%; odds ratio 14.61, 95% CI 2.32 to 91.96; $p = 0.004$).

Reduction in waist circumference at the 12-month follow-up was also greater in the WAP arm ($n = 149$) than in the nurse arm ($n = 83$), although the difference was not significant (–4.0 vs. –2.0 cm; difference –2.0 cm, 95% CI –4.1 to 0.2 cm; $p = 0.07$).

There were no significant differences between groups in changes in blood pressure, physical activity, time spent sitting or knowledge of caloric content of food from baseline to the 12-month follow-up.

Adverse events were reported by 25 (11%) participants in the WAP arm and six (6%) in the nurse arm (odds ratio 2.19, 95% CI 0.86 to 5.58; $p = 0.1$). There were three serious AEs (all in the WAP arm), but none related to study procedures.

Cost-effectiveness

The total cost of providing the WAP intervention (up until the end of maintenance) was £195 per participant, or approximately £10 per session attended. The nurse intervention cost £176 per participant. The mean (SD) unadjusted QALYs gained as a result of the WAP and the nurse intervention was 0.389 (0.072) and 0.404 (0.079), respectively. The cost-effectiveness analysis, which controls for baseline utility and age, shows that the increase in QALYs (WAP vs. nurse) is not statistically significant (0.0104, 95% CI –0.0015 to 0.0224; $p = 0.088$). The ICER for the WAP over and above the best-practice nurse-led intervention is £7742 per QALY, which falls below the nominal threshold of £20,000–30,000 used by the National Institute for Health and Care Excellence.

Conclusions

A WAP delivered in general practice better promotes long-term weight loss than a best usual practice nurse-led weight loss programme.

Implications for health care

A possible model for weight management services along the lines of the SSS.

Recommendations for research

1. We recommend ongoing follow-up of this study cohort, which would enable investigation of whether or not the WAP is able to support weight loss in the long term.
2. The WAP treatment programme is delivered over 8 weeks, with ongoing maintenance sessions. With demands on staff and patient time in addition to financial restraints, research is needed on the added benefit, if any, of longer programmes.
3. Research is needed into factors that would make weight loss programmes more attractive to men.
4. The efficacy of the WAP delivered through electronic media should be investigated.
5. The ICER provides initial evidence that the WAP represents value. However, to address uncertainties in economic evaluations of this health-care programme, future research should conduct a sample size and power calculation for cost-effectiveness analysis.

Trial registration

This trial is registered as ISRCTN45820471.

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Editorial contact: nihredit@southampton.ac.uk

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