Technical skills for weight loss: preliminary data from a randomized trial
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The health technology examined in the study was a skill-based intervention (SBI) developed to provide skills for overweight and obese subjects. The intervention consisted of two 90-minute didactic sessions delivered to groups of about 20 people at a time, followed by skill-based sessions over a 4-month period. The contents of the intervention were described in detail.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women between 30 and 65 years of age; obese or overweight, as defined by a body mass index (BMI) greater than 25; and being the primary person in the household who purchases groceries and prepares meals. Women were excluded if they had an unstable medical condition affecting their ability to participate fully in the study protocol; were participating in another weight reduction programme; had pharmacologically treated diabetes; or were using medications known to affect weight loss or gain.

Setting
The setting was not reported. The economic study was conducted in Connecticut, USA.

Dates to which data relate
No dates for effectiveness or resource use data collection were reported. The price year was not given.

Source of effectiveness data
The effectiveness evidence came from a single study.

Link between effectiveness and cost data
The costing was conducted prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
The authors noted that their study was powered at 80% to detect an absolute between-group difference of 30% in the rate of weight loss maintenance at 2 years, with a higher rate of weight loss maintenance in the SBI group hypothesised. Of the initial sample of 272 women who responded to the study advertisement, 136 were considered eligible and 99 agreed to participate. However, 4 women were subsequently considered ineligible and 15 declined to participate.
Therefore, 80 subjects were allocated to the SBI (n=40; mean age: 48 +/- 9 years) and CBI (n=40; mean age: 51 +/- 11 years) groups. However, 4 women dropped out immediately after group allocation and one died. Therefore, the final study sample comprised 75 women: 37 in the SBI group and 38 in the CBI group.

**Study design**
This was a prospective, randomised, clinical trial, which was conducted in Connecticut, USA. Randomisation was carried out using a computer procedure by an analyst who had no contact with study subjects. The length of follow-up was 6 months. Forty-nine women (24 in the SBI group and 25 in the CBI group) were available for final outcome assessment. A research assistant, blinded to all subject treatment assignments, carried out all outcome assessment. Subjects in the SBI group had telephone and e-mail access to the dietitian for one year.

**Analysis of effectiveness**
The analysis of the clinical study was based on intention to treat. The health outcomes used in the analysis were proportion of women with a 5% decrease or more in body weight; absolute weight difference; proportion of subjects with a weight loss of greater than or equal to 10 lb; absolute change in body mass index. Women in the SBI group had significantly higher systolic blood pressure and were more likely to be married. The two groups were comparable at baseline with respect to other characteristics. No significant differences were found between those who were lost to follow-up and those who were available for final assessment. Multivariate regression was carried out to assess the association of demographic and clinical variables on weight loss at 6 months.

**Effectiveness results**
The proportion of women with a 5% decrease or more in body weight was 40% in CBI patients and 16.8% in SBI patients, (p=0.07).

After 6 months, both groups had mean declines in absolute weight compared to baseline: the SBI group lost an average of 3.8 lb, (p=0.01), and the CBI group lost an average of 8.8 lb, (p=0.0001).

BMI also decreased in the CBI group and there was no statistically significant difference in BMI in the SBI group.

The CBI group had a greater change in absolute weight compared with SBI from baseline to follow-up.

The absolute change in BMI was also statistically significant in the CBI group.

Multiregression analysis showed that predictors of weight loss, namely baseline weight, group, and medication use, accounted for 50% of the variation in weight loss.

The analysis also revealed that subjects with higher initial BMIs had greater weight loss at 6 months.

The proportion of subjects with a weight loss of greater or equal to 10 lb was 40% in CBI patients and 25% in SBI patients, (p=0.27).

**Clinical conclusions**
The effectiveness study showed that the standard individualised counselling approach was more effective in producing weight loss than the innovative skill-based intervention.

**Measure of benefits used in the economic analysis**
The summary benefit measure was the weight lost, which was derived directly from the effectiveness study.

**Direct costs**
Discounting was not relevant since costs were incurred over a period of 6 months. The economic evaluation considered...
only the cost of dietitian time. The unit cost was provided separately from quantities of resources used. The cost/resource boundary of the study was not reported. The source of cost data was not given. Resource use was based on actual data derived from the sample of patients considered in the clinical study. The price year was not reported.

**Statistical analysis of costs**
Costs were treated deterministically.

**Indirect Costs**
Indirect costs were not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analyses were conducted.

**Estimated benefits used in the economic analysis**
Please refer to the effectiveness results reported above.

**Cost results**
The cost per participant was $140 with CBI and $117.25 with SBI.

**Synthesis of costs and benefits**
Average cost-effectiveness ratios were calculated to combine costs and benefits of the two interventions under evaluation. The average cost per lb lost was $21 (range: $12 - $205) with CBI and $46 (range: $18 - $516) with SBI.

**Authors’ conclusions**
The authors concluded that the innovative skill-based intervention, delivered in group sessions, was not as effective as the standard individualised approach for weight loss in obese and overweight women in the short-term. The skill-based intervention also led to an increase in treatment costs.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. CBI was selected as it represented a traditional treatment approach for overweight and obese subjects. You should decide whether this is a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence was based on a randomised trial, which was appropriate for the study question. Randomisation was carried out by an independent investigator and blinding was applied for outcome assessment. The length of follow-up was limited to 6 months but a longer time frame would have been interesting. Power calculations were conducted to justify the sample size. The internal validity of the analysis was further enhanced by the use of intention to treat as the basis of the clinical analysis. However, only a subgroup of patients initially identified participated in the study, and a substantial loss to follow-up was observed. Multiregression analysis was carried out to test the impact of potential confounding factors, which were likely to have an impact due to the baseline differences between the groups. Finally, the study sample comprised volunteers, and may therefore not have been representative of the actual study population.
Validity of estimate of measure of benefit
The summary benefit measure was derived from the effectiveness study and represented an intermediate measure, which would be difficult to compare with the benefits of other health care interventions. The use of a more generalisable measure would have been helpful.

Validity of estimate of costs
The authors did not state which perspective was adopted in the study and only dietitian costs were considered in the study. The unit cost was provided separately from quantities of resources used, making the replication of the study in other settings easier. However, the source of cost data and the price year were not reported. Furthermore, costs were treated deterministically and no sensitivity analyses were conducted. As a result, the estimates were specific to the study setting.

Other issues
The authors compared their findings with those from other studies, which confirmed the advantages of individualised counselling. The issue of the generalisability of the study results to other settings was not addressed and no sensitivity analyses were conducted. Therefore, the external validity of the analysis was low. The authors highlighted some limitations of their study, such as the fact that only women were enrolled, and the inclusion of participants who were predominantly non-Hispanic white. The use of incremental rather than average cost-effectiveness ratios would have been useful.

Implications of the study
The authors noted that long-term follow-up studies should be carried out better to compare the cost-effectiveness of alternative management programmes for weight loss. Future research should be conducted to evaluate reasons for recidivism among subjects, due to the high level of attrition observed during the study. A more detailed definition of the contents and objectives of the skill-based intervention would have been useful.

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