Weight loss during 12 week's ad libitum carbohydrate-rich diet in overweight and normal-weight subjects at a Danish work site

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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
Using twelve weeks' intensive instruction to achieve and maintain an ad libitum carbohydrate-rich diet in overweight and normal-weight subjects.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Free-living, normal-weight and overweight employees at a work-site.

Setting
Work-site. The economic study was carried out in Denmark.

Dates to which data relate
No dates were reported.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
It was not clearly stated whether the costing was undertaken on the same patient sample as that used in the effectiveness analysis.

Study sample
No power calculations were reported. From an eligible total of 2,500 individuals, 3.44% were willing to participate (86 individuals). Of these, 59 formed the intervention group, with 17 forming the control.

Study design
This was a nonrandomised study with concurrent controls conducted in a single work-site. The duration of follow-up was until 52 weeks after the start of the intervention. The individuals joined each group according to their own choice. Moreover, there was a 27.5% drop-out rate during the 12-week intervention period in the intervention group, and 5.9%
in the control group, giving a total of 23.2%. The intervention group was subclassified into normal-weigh group (BMI < 25kg/M2, n=18) and over-weight group (BMI > 25kg/M2, n=32).

Analysis of effectiveness
The analysis was based on treatment completers only. The primary health outcome used in the analysis was body weight, fat mass and lean body mass loss. A two-way ANOVA was used to analyse the differences between groups by adjusting for type of patient (overweight/normal weight).

Effectiveness results
At 12 weeks follow-up, the change in BMI was -1.5kg/M2 (+/-0.1), fat mass -4.4kg (+/- 0.6); fat mass -3.9% (+/- 0.3): all these changes had values of p<0.05 with respect to the control group. The corresponding figures for the control group were as follows: BMI -0.3 kg/M2 (+/- 0.2); fat mass -0.9kg (+/- 0.6); fat mass -0.9% (+/- 0.5). At 24 and 52-week follow-up, the subjects in the intervention group did not regain the weight loss. The over-weight subjects in the intervention group experienced significantly better health outcomes (p<0.05) than their normal-weight counterparts in the same group. Only the mean reductions experienced by the intervention group had a p<0.05. Questionnaire data on macronutrient and energy intake during the intervention was available for only 44 patients in the intervention group and 15 in the control. The authors reported that the subgroup of six patients who completed the intervention and, for whom, these data were missing, did not differ from the remainder of the group in terms of age, weight, fat mass, lean body mass, history of dieting before the intervention or exercise habits. The authors reported that, according to the questionnaire, there were no changes in the level of physical activity or smoking behaviour after 12 weeks relative to baseline with p values <0.05.

Clinical conclusions
The ad libitum intake of a carbohydrate-rich and low-fat diet under free-living conditions results in a significant weight loss in overweight and normal weight subjects. Furthermore, overweight subjects lost more body weight and fat mass than normal weight subjects, and none of the normal weight subjects became underweight. Finally, the weight loss was not regained up to a year after the end of the intervention period.

Measure of benefits used in the economic analysis
Loss in body weight and fat mass at 12 weeks after the start of the intervention were the main benefit measures.

Direct costs
No quantities of resource use were reported. Research, administration, material, and dietary costs were measured. The boundary adopted was that of the programme and the patient. Although the estimate of costs for the 12-week intervention period was based on actual data, no more details were provided regarding the methods used. It was not specified from whose point of view the cost analysis was performed. The price date was not stated.

Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.
Estimated benefits used in the economic analysis
At 12 weeks, the changes achieved with the intervention were: BMI -1.2kg/M2, fat mass -3.5kg and fat mass -3.0%.

Cost results
Not reported.

Synthesis of costs and benefits
The cost of losing 1 kg body weight was $14.7 per person, while the cost of a 1% reduction in percentage over-weight was $11.9 per person. The cost of a gram change in daily carbohydrate intake was $1.6 per person.

Authors' conclusions
The study showed that the ad libitum dietary principle was successfully applied at a work site with low cost and relatively high effectiveness.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was clear.

Validity of estimate of measure of benefit
The estimate of benefit is likely to be subject to bias associated with self-selection, the treatment-completers principle used in the analysis, the high dropout rate (25%) and the small control group.

Validity of estimate of costs
No quantities of resource use were reported, and insufficient details of the costing methodology used in the study were provided, thus, it is not clear whether all relevant cost items were included in the analysis.

Other issues
Given the lack of randomisation, sensitivity analysis, and statistical analysis of the costs, the results need to be treated with some caution. The conclusions reached by the authors were not fully justified given the uncertainties in the data. The issue of generalisability of results to other settings/countries was not addressed.

Implications of the study
As the authors themselves noted, further studies are necessary to make a valid estimation of the changes in macronutrient intake (for which data was incomplete in the present study) during the weight loss period. However, the additional problem of valid results in terms of cost-effectiveness in the setting in question also needs to be addressed, preferably by a randomized, double-blind controlled trial, with a long-term follow-up, and adequate resource use data collection.

Source of funding
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