Effect of nutritional counselling and nutritional plus exercise counselling in overweight adults: a randomized trial in multidisciplinary primary care practice

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Objective. To compare the effects of nutritional counselling with nutritional plus exercise counselling on body weight and waist circumference in overweight adults in a multidisciplinary primary care setting.

Methods. One hundred and thirty-four overweight adults (body mass index 28–35) were randomly assigned to individual counselling sessions by a dietician (D) or counselling sessions by a dietician plus physiotherapist (D + E) during 6 months with one follow-up session at 12 months. Outcomes were assessed at baseline, 6 and 12 months. Difference in changes of outcome measures between groups were analysed using generalized estimating equations.

Results. Weight reduced from baseline to 6 months in D [–2.2 (–3.1 to –1.4) kg] and D + E [–3.0 (–4.0 to –2.0) kg] and was sustained at 12 months [–2.0 (–3.1 to –1.4) kg and –3.1 (–4.5 to –1.6) kg, respectively]. The reduction in weight did not significantly differ between D and D + E (P = 0.48). In both groups, waist circumference decreased from baseline to 6 months [–2.1 (–3.3 to –0.8) cm for D; –3.7 (–5.1 to –2.3) cm for D + E] and was sustained at 12 months [–2.1 (–3.5 to –0.7) cm and –4.2 (–6.0 to –2.5) cm, respectively]. Participants in D + E tended to decrease their waist circumference more than those in D (P = 0.14).

Discussion. Nutritional counselling by a dietician resulted in modest reductions in weight and waist circumference in overweight adults, which were sustained up to 12 months. Adding exercise counselling by a physiotherapist did not significantly enhance the effect on body weight. Exercise counselling may, however, further improve waist circumference.

Keywords. Counselling, lifestyle, obesity, overweight, primary care.

Introduction

Overweight and obesity pose one of the most serious public health challenges of the 21st century, both in developed and in developing countries. In response to the expanding obesity epidemic, several Western countries have developed evidence-based clinical guidelines for prevention and management of obesity. These guidelines emphasize the role of GPs in identifying and treating obesity. In Australia, Canada and several European countries such as the UK and The Netherlands, GPs are the first to be consulted for health and health care issues and the vast majority of the population is enlisted in a general practice during lifetime. GPs are well positioned to reach a large proportion of the general population and routine consultations provide opportunities to initiate weight management interventions. Given the time-limited nature of primary care visits and lack of GPs’ training in diet and exercise counselling, referral of patients to a multidisciplinary weight management programme hosted in primary care appears to be the most attractive strategy for obesity management in routine primary care.

Data from randomized controlled trials have consistently demonstrated that energy-restricted diets are more effective at facilitating weight loss than...
exercise. In addition, programmes including both diet and exercise produce greater weight loss than diet alone in overweight and obese individuals after 1 year of follow-up. However, the majority of the trials involving lifestyle interventions for the management of obesity were performed in academic medical centres and not incorporated in daily health care. Therefore, the generalizability of the results to routine clinical practice is unknown. Translational studies are needed to determine whether the weight losses achieved in tightly controlled clinical trials can be achieved in real practice settings.

We conducted a 12-month randomized clinical trial in a multidisciplinary primary care setting to evaluate the efficacy of nutritional counselling by a dietician compared with multidisciplinary nutritional plus exercise counselling by a dietician and physiotherapist on weight loss in an adult overweight population. As abdominal obesity is particularly associated with adverse health risks, waist circumference was taken as a secondary outcome. The secondary aim of the study was to compare both interventions with usual care.

Methods

Participants and study design

For the current trial, participants were recruited from the Utrecht Health Project (UHP), an ongoing prospective cohort study, that started in 2000 in Leidsche Rijn, a newly residential area west of the city of Utrecht, The Netherlands. In brief, the UHP is a research infrastructure solidly embedded in primary care that enables answering questions about disease occurrence and its determinants. For the current study, UHP entry data were used to select all men and non-pregnant women aged 18–65 years with a body mass index (BMI) 28–35 kg/m² (n = 877). Subsequently, the GPs were asked to exclude potential participants from the list selected, who were unable to speak Dutch, who were already treated for their overweight by a dietician and/or physiotherapist or who had diagnosed mental health problems or known plans to move out of the residential area shortly. The remaining eligible participants (n = 419) were invited to participate in the trial by a letter from their GP.

Participant recruitment took place between February 2006 and October 2006. Of the 419 invited individuals, 254 declined to participate and 31 did not respond to the invitation letter (Fig. 1). After informed consent was obtained, the UHP research nurses randomly assigned the 134 remaining participants to the nutritional counselling group, further referred to as diet (D) group, or nutritional plus exercise counselling group, further referred to as diet + exercise (D + E) group, using computerized randomization. Measurements started in March 2006 and the follow-up measurements ended in January 2008. The mean follow-up was 13.7 ± 1.1 months.

A third, intentionally untreated control group was selected from new participants of the UHP that fulfilled the above-described inclusion and exclusion criteria of the trial. Of the 103 individuals invited as controls, 23 declined to participate, 6 did not respond to the invitation letter and 4 responded after the recruitment period ended (Fig. 1), resulting in 70 controls.

The trial was approved by the Ethics Committee of the University Medical Center Utrecht, The Netherlands, and all participants provided written informed consent.

Nutritional counselling

All randomized participants were provided with a referral letter from their GP to attend seven individual face-to-face counselling sessions with a dietician during 6 months (with Sessions 4 and 7 fixed at, respectively, 3 and 6 months after the first session) and one follow-up session at 12 months. At the first session, the dietician went through a 3-day food record (2 weekdays and 1 weekend day), which the participants were asked to complete beforehand and bring to the counselling appointment. Participants were informed about the significant health gains that can be achieved with relatively small long-lasting weight loss of ~5 to 10%, and in order to establish realistic expectations, it was emphasized that successful weight loss and maintenance require gradual changes in lifestyle that can be continued over time. In cooperation with the participants, individualized attainable goals for a healthy diet (based on the guidelines from the Health Council of The Netherlands) and effective caloric intake reduction were set and a strategy was developed to gradually achieve a moderate sustainable weight reduction, taking dietary history and habitual diet routines into account. At subsequent sessions, the dietician provided support, dietary advice and encouraged the participants to achieve or maintain their goals. The weight and waist circumference of the participants were measured at each counselling session and additionally at the 6- and 12-month session, a 3-day food record was completed. The duration of the initial session was assumed to be ~40 minutes and later sessions ~20 minutes.

Nutritional plus exercise counselling

Participants randomized to the D + E group were additionally provided with a referral letter from their GP to attend six individual face-to-face counselling sessions with a physiotherapist during 6 months (with Sessions 4 and 6 fixed at, respectively, 3 and 6 months after the first session) and one follow-up session at 12 months. At the first session, the physiotherapist went through a physical activity questionnaire known as the...
SQUASH (Short Questionnaire to ASses Health enhancing physical activity). Under the supervision of the physiotherapist, the participants performed the Astrand submaximal cycle test to determine their maximal oxygen uptake as a measure of cardiorespiratory fitness. In cooperation with the participants individualized, attainable goals for an increase in daily physical activity were set and a strategy was developed to gradually achieve a moderate sustainable weight reduction and improve cardiorespiratory fitness, taking habitual physical activity, fitness and personal preferences into account. The physiotherapist provided advice on exercise and building physical activity into daily life and informed the participants about possibilities for voluntary exercise (swimming, fitness/aerobics and running) at reduced costs as part of the intervention. At subsequent sessions, the physiotherapist provided support, physical activity advice and encouraged the participants to achieve or maintain their goals. At the 6- and 12-month counselling session, the participants were asked to perform another Astrand submaximal cycle test. The duration of the initial counselling session was assumed to be ~45 to 60 minutes and later sessions ~30 minutes.

**Adherence to the intervention**

The dieticians and physiotherapists recorded attendance of the participant at each session and documented all relevant information in an internet-accessible central database.

**Attrition**

Twenty-four participants (18%) did not complete the 6-month intensive intervention period and an additional nine participants (7%) dropped out during the 6-month follow-up period (Fig. 1). Participants dropped out of the study because of personal reasons (n = 14), unmet expectations of the counselling sessions (n = 6), medical reasons (n = 6), unknown reasons (n = 6) or logistic problems (n = 1). Baseline characteristics of participants that completed the study and those who dropped out did not differ, except that completers were older than participants who discontinued the study (44 years, SD = 10 versus 40 years, SD = 8).
Control group
Participants in the control group received usual care and were not invited to receive structured nutritional or exercise counselling by a dietician or physiotherapist.

Outcome measures
Outcome measures were assessed at baseline, 6 months and 12 months by research nurses of the UHP. Height and weight were measured without shoes and heavy clothing to the nearest 0.1 cm and 0.1 kg. BMI was calculated as weight in kilograms divided by height in square metres. Waist circumference was recorded at the midpoint of the lowest rib and the top of the hip-bone (often located at the umbilicus level) to the nearest 0.5 cm.

The UHP intake measurements of the control group served as their baseline measurement of the trial (Fig. 1). Changes in waist circumference were not measured in the control group since this was not part of the UHP routine yet. For reasons of feasibility, outcomes at 6 months were assessed in about half of the participants of the control group (n = 37), while outcomes at 12 months were assessed in the remaining half of the control group (n = 33).

Statistical analysis
Data were analysed using a modified intention-to-treat approach, which included all participants that had at least one follow-up measurement. Continuous variables are presented as means with SDs and categorical variables as percentages. First, crude changes in outcome measures were compared between intervention groups (D + E versus D) using linear regression analysis. Subsequently, generalized estimating equations (GEE) were applied with an autoregressive heterogeneous covariance structure to take the correlation into account between repeated outcome measures within participants. Variables in the GEE models included intervention assignment, time (0, 6 and 12 months) and the interaction between intervention and time. In addition, the proportion of participants who achieved >5% of weight loss at 6 and 12 months were calculated. Differences in proportion of weight loss >5% between the D and D + E group were expressed as relative risks (RR) with corresponding 95% confidence interval (CI). In secondary analyses, we compared changes in weight between intervention and control groups with GEE analysis similarly as described for the two intervention groups. Analyses were conducted using SPSS version 14.0 and R version 2.3.

Results
Overall, 58% of the participants in the intervention groups were men with a mean age of 43 ± 9 years and a mean BMI of 31.0 ± 1.9 kg/m² (Table 1). Baseline characteristics were comparable.

In the control group, 63% were men with a mean age of 41 ± 11 years and a mean BMI of 30.2 ± 1.9 kg/m² (Table 2). The intervention and control group were well matched with regard to the baseline characteristics, except that participants in the intervention groups had a higher BMI.

Adherence to the intervention
Eighty-eight percent of the participants in the D group and 89% of those in the D + E group visited the
dietician (D 4.5 ± 2.1 sessions; D + E 4.1 ± 2.0 sessions). Exclusion of dropouts resulted in a mean number of attended dietician sessions of, respectively, 5.0 ± 1.9 and 4.4 ± 1.9 for the D and D + E group. Eighty-seven percent of the D + E group visited the physiotherapist (5.0 ± 2.1 sessions, without dropouts 5.6 ± 1.9 sessions).

**Difference in outcome measures between intervention groups**

Crude changes in weight are presented in Table 3. Taking into account the correlated observations, weight decreased significantly from baseline to 6 months in D [–2.2 95% CI (–3.1 to –1.4) kg] and D + E [–3.0 (–4.0 to –2.0) kg; Table 4]. The achieved weight loss at 6 months was maintained at 12 months in both intervention groups [–2.0 (–3.1 to –1.4) kg for D; –3.1 (–4.5 to –1.6) kg for D + E]. The reduction of body weight in D + E was slightly higher than that in D at 6 months [–0.8 (–2.1 to 0.6) kg] or 12 months [–1.1 (–2.9 to 0.8) kg], though not statistically significant (overall P-value for interaction in GEE model = 0.48). The interindividual variation in weight change was large (Fig. 2).

Twenty-eight percent (95% CI; 16 to 40) of the participants in the D + E group lost >5% of their baseline weight at 6 months, while the proportion of participants in the D group was 16% (6 to 25%). The corresponding RR of losing >5% weight in D + E versus D was 1.8 (95% CI; 0.9 to 3.8). At 12 months, the

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<th>TABLE 3</th>
<th>Changes in baseline weight and waist circumference for the diet and diet + exercise groups at 6 and 12 monthsa</th>
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<td>Month</td>
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D, diet; D + E, diet + exercise.

a95% CI are estimated with linear regression analysis.
bAdditional effect is defined as change in D group—change in D + E group.
cStatistically significant difference between change in D and D + E group.

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D, diet; D + E, diet + exercise.
a95% CI are estimated with GEE analysis.
bAdditional effect is defined as change in D group—change in D + E group.
cInteraction: time x intervention.

**Figure 2**  Weight of individual participants at baseline and 6 months, and boxplots of change in baseline weight at 6 months, for the diet and diet + exercise groups
proportion of participants who achieved $>5\%$ of weight loss in the D + E and D groups were, respectively, 32\% (19 to 45\%) and 20\% (9 to 31\%), with a corresponding RR of 1.6 (0.8 to 3.2).

Crude changes in waist circumference are presented in Table 3. Taking into account the correlated observations, the waist circumference decreased significantly from baseline to 6 months in both intervention groups $[-2.1 (–3.3 to –0.8) \text{ cm for D; } –3.7 (–5.1 to –2.3) \text{ cm for D + E}]$ and was sustained up to 12 months $[-2.1 (–3.5 to –0.7) \text{ cm and } –4.2 (–6.0 to –2.5) \text{ cm, respectively; Table 4}$. The reduction in waist circumference tended to be larger in participants in the D + E group compared with those in the D group at 6 months $[-1.6 (–3.5 to 0.2) \text{ cm}]$ and 12 months $[-2.2 (–4.4 to 0.06) \text{ cm; overall } P\text{-value for interaction in } \text{GEE model } = 0.14\]$. 

**Difference in outcome measures between intervention and control groups**

Participants in the D and D + E group lost statistically significant more weight than those in the control group at 6 months $[-2.7 (–4.2 to –1.1) \text{ kg and } –3.5 (–5.1 to –1.8) \text{ kg, respectively; Fig. 3}]$. Differences in weight loss from baseline to 12 months were smaller $[-1.3 (–4.0 to 1.4) \text{ kg for D; } –2.4 (–5.2 to 0.5) \text{ kg for D + E}]$.

**Discussion**

In the present randomized clinical trial, conducted in a multidisciplinary primary care setting, we found that adding exercise counselling by a physiotherapist did not significantly enhance the effect on weight, while a small additional beneficial effect on waist circumference may be present.

Strengths of our study include the randomized clinical trial design, performance of the trial in a real primary care setting and the use of few exclusion criteria allowing for translation of the results to everyday clinical practice. Also, the approach was multidisciplinary with tailor-made counselling sessions.

Some limitations of our study deserve to be mentioned. The attrition rate in our study (25\% at 12 months) may potentially bias the results. However, participants who discontinued were evenly distributed among the intervention groups, and the characteristics of those who discontinued and who remained did not differ except that the latter were older. Furthermore, the effect size we found reflects what can be expected when conducting a weight management programme in real life. For completeness, we imputed the missing outcome values multiple times to examine whether the missingness could have introduced bias in our study. Reanalyses on the imputed datasets resulted in somewhat smaller effect estimates with wider CI, i.e. attenuated intervention effects compared with the modified intention-to-treat analyses. The direction of the effect was the same. Furthermore, the scale of the study was relatively small. The number of participants in the control group was in particular limited for logistic reasons. Another limitation is that the control group was not randomly selected. Finally, this trial was carried out in a multidisciplinary primary care setting, which may not be available in all countries.

Participants in our intervention groups lost on average $\sim 2$ kg (diet only group) to 3 kg (diet plus exercise group) of their baseline weight during the 6-month counselling period, which was sustained up to 12 months. This effect is $\sim 2$-fold less than that of meta-analyses by Avenell et al. and Anderson et al. but is of similar magnitude as the result of a recent systematic review on the effectiveness of weight loss interventions for adults with pre-diabetes. The relatively small reductions in weight in our study may be partly explained by the fact that participants did not sought weight loss on their own initiative but were approached by their primary care physicians. Furthermore, the participants did not necessarily have co-morbidities. Therefore, some participants may not have recognized the need and benefits of weight reduction themselves and still have been in the (pre)contemplation stage of change. In addition, no severe energy restrictions or (very) low-calorie diets were prescribed, which often result in greater short-term weight loss but more marked dropout.

When comparing the effects of diet plus exercise with diet alone, the following issues need consideration. As the dieticians also provided advice on enhancing physical activity as part of routine care, a ceiling effect may partly explain the lack of additional benefits in our study. Furthermore, long-term effects might be different. Nutritional plus exercise counselling may be...
superior in the long term. Extensive evidence emphasizes the important role of exercise in long-term weight and waist maintenance.\textsuperscript{20,21} Importantly, our results do not imply that exercise counselling alone is ineffective. We can only conclude that exercise counselling does not add significantly to the beneficial effect of dietary counselling because we did not use a full factorial design. However, our results indicate that exercise counselling may potentially provide additional beneficial effects on waist circumference. Emerging evidence suggests that physical activity is associated with a preferential reduction in abdominal adipose tissue, even with minimal or no changes in body weight.\textsuperscript{22,23} This is important as abdominal obesity in particular conveys an increased health risk.\textsuperscript{10,11}

Further, it is essential to note that increased regular exercise can improve cardiorespiratory fitness, which is associated with reduced morbidity and mortality independent of changes in weight and abdominal adiposity.\textsuperscript{24–26}

We evaluated our tailor-made weight management programme at a group level but we observed substantial differences in efficacy between participants. Therefore, future research should examine predictors of successful treatment to further customize the intervention. Importantly, the cost-effectiveness should also be assessed.

In summary, nutritional counselling by a dietician resulted in modest reductions of weight and waist circumference in overweight adults in a multidisciplinary primary care setting, which were sustained up to 12 months. Adding exercise counselling by a physiotherapist did not significantly enhance the effect but may have additional beneficial clinical effects on waist circumference.

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Contributors: All authors participated in study design, analysis, interpretation of results, drafting of the article and approval of the final draft.

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Declaration

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Ethical approval: Ethics Committee of the University Medical Center Utrecht, The Netherlands.

Conflicts of interest: None.

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