Lifestyle Counseling for Type 2 Diabetes Risk Reduction in Dutch Primary Care

Results of the APHRODITE study after 0.5 and 1.5 years

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OBJECTIVE—To study the overall effect of the Active Prevention in High-Risk Individuals of Diabetes Type 2 in and Around Eindhoven (APHRODITE) lifestyle intervention on type 2 diabetes risk reduction in Dutch primary care after 0.5 and 1.5 years and to evaluate the variability between general practices.

RESEARCH DESIGN AND METHODS—Individuals at high risk for type 2 diabetes (Finnish Diabetes Risk Score ≥13) were randomly assigned into an intervention group (n = 479) or a usual-care group (n = 446). Comparisons were made between study groups and between general practices regarding changes in clinical and lifestyle measures over 1.5 years. Participant, general practitioner, and nurse practitioner characteristics were compared between individuals who lost weight or maintained a stable weight and individuals who gained weight.

RESULTS—Both groups showed modest changes in glucose values, weight measures, physical activity, energy intake, and fiber intake. Differences between groups were significant only for total physical activity, saturated fat intake, and fiber intake. Differences between general practices were significant for BMI and 2-h glucose but not for energy intake and physical activity. In the intervention group, the nurse practitioners’ mean years of work experience was significantly longer in individuals who were successful at losing weight or maintaining a stable weight compared with unsuccessful individuals. Furthermore, successful individuals more often had a partner.

CONCLUSIONS—Risk factors for type 2 diabetes could be significantly reduced by lifestyle counseling in Dutch primary care. The small differences in changes over time between the two study groups suggest that additional intervention effects are modest. In particular, the level of experience of the nurse practitioner and the availability of partner support seem to facilitate intervention success (NTR1082).

With a global prevalence of 285 million diagnosed individuals (1), type 2 diabetes poses a major public health concern. Moreover, the prevalence of the disease is estimated to rise to 438 million in 20 years (1). Several studies in experimental settings have shown that type 2 diabetes incidence and risk can be significantly reduced by lifestyle intervention in high-risk individuals (2). Furthermore, the beneficial effect of behavioral change can be sustained long after counseling is stopped (3,4).

In daily-life settings, less resources for program implementation and delivery may be available than in experimental settings, which may influence results (5,6). Individual dietary counseling or extensive exercise programs, for example, may be too expensive. Nevertheless, significant reductions in type 2 diabetes risk were found in recent studies in the community and in primary and occupational health care (7–12). However, in most of these studies in daily-life settings, usual-care comparison groups were lacking, and therefore, the additional effectiveness of the interventions could not be determined (5). Furthermore, differences between health care institutions were not reported.

The Active Prevention in High-Risk Individuals of Diabetes Type 2 in and Around Eindhoven (APHRODITE) study investigates the effectiveness and feasibility of type 2 diabetes prevention by lifestyle intervention in Dutch general practice. In this article, we report the overall effect of the APHRODITE lifestyle intervention on type 2 diabetes risk reduction in Dutch primary care after 0.5 and 1.5 years. Furthermore, we evaluate differences in risk-factor reduction between practices and investigate the characteristics of participants and health care providers that may facilitate success.

RESEARCH DESIGN AND METHODS—Participants were recruited in January 2008 by 48 general practitioners from a cooperation of 14 primary care practices in Eindhoven and five surrounding villages. A Dutch translation of the Finnish Diabetes Risk Score (FINDRISC) (13) was sent to general practitioner patients aged ≥40 and ≤70 years (n = 16,032). All individuals with a score of ≥13 points were invited to participate in the program. Random assignment was performed on the level of the individual, by assigning every second individual contacting the general practitioner assistant to schedule an admission interview to the usual-care group. Details of the recruitment phase were described previously (14).

Theoretical framework and objectives

The APHRODITE intervention was based on the stages-of-change model by Prochaska and DiClemente (15). For the APHRODITE intervention, five objectives of behavioral change were specified as
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follows: a weight reduction of ≥5% if overweight; physical exercise of moderate or high intensity for at least 30 min at least 5 days a week; intake of dietary fat <30% of total energy intake; intake of saturated fat <10% of total energy intake; and intake of dietary fiber of at least 3.4 g per millijoule (MJ).

Planning and intensity of the intervention

After the admission interview with the general practitioner (details have been described previously [14]), 11 consultations of 20 min over 2.5 years were scheduled alternately with the nurse practitioner and the general practitioner. Each participant in the intervention group, therefore, had encounters with both professionals. Although the general practitioners oversaw guarding the participants’ progress, nurse practitioners intensively guided the behavioral-change process. Before the start of the project, all nurse practitioners underwent a 5-evening course in motivational interviewing (16).

Individual consultations were supported by five group meetings to give more detailed information on diet and exercise. These 1-h meetings were conducted by trained dietitians (meetings 1, 2, 4, and 5) and physiotherapists (meeting 3). In addition, all individuals in the intervention group were invited for a 1-h personal consultation with the dietitian. During this consultation, dietary intake according to a 3-day food record was discussed, and suggestions were given for improvement.

Usual-care group

During the admission interview with the general practitioner, participants in the usual-care group received oral and written information about type 2 diabetes, their risk for developing the disease, and the benefits of exercise and a healthy diet. After this first meeting, the participants visited the nurse practitioner only for measurements at baseline and after 6 and 18 months (10 min). Apart from the admission interview, participants did not have study-related encounters with the general practitioner.

Outcome measures

Measurements were performed at baseline and after 6 and 18 months. Primary outcome measures were fasting and 2-h plasma glucose values, waist circumference, and BMI. Oral glucose tolerance tests were taken according to internationally accepted standards (17). Diagnosis of type 2 diabetes was based on one oral glucose tolerance test according to the 2006 World Health Organization diagnostic criteria (18). Individuals with glucose values in the diabetic range were excluded from the study and were referred to the general practitioner for a second blood test to confirm the diagnosis and for additional care. Measurements of height, weight, and waist circumference were performed by the nurse practitioner in accordance with the standards of the Dutch Society of General Practitioners. Details of the anthropometrical measurement taking were described previously (14).

Secondary outcome measures were physical activity, physical activity of moderate to high intensity, and intakes of energy, total fat, saturated fat, and dietary fiber. Activity measures were estimated from the Short Questionnaire to Assess Health-Enhancing Physical Activity (SQUASH) (19). Dietary intakes of the previous 4 weeks, as a proxy for usual intake, were estimated from a validated food-frequency questionnaire (20). Before data entry, all filled out food questionnaires were checked by trained dietitians for missing information and for inconsistencies. When abnormalities were found, the participant was contacted by the dietitian for clarification.

Statistical analysis

Differences in baseline characteristics between the two study groups and differences between participants who were successful or unsuccessful in losing weight or keeping a stable weight over 1.5 years were evaluated with either an independent-samples t test or a χ² test. As for this group, weight loss was not an objective, and individuals with a healthy weight at baseline (BMI <25 kg/m²) were excluded from the analysis of successful versus unsuccessful participants (n = 80, 17.4% in the intervention group; n = 81, 19.4% in the usual-care group). Differences between practices were evaluated using ANCOVA adjusted for baseline differences.

Differences over time between and within the study groups were evaluated using multilevel analysis (level 1 = time point; level 2 = participant; level 3 = nurse practitioner). For the between-group analyses, mixed models were estimated for each outcome variable, with study group, sex, age, smoking, time point, and group × time point as fixed variables. In the within-group analyses, sex, age, smoking, and time point were entered as fixed variables. The random part of both between-group and within-group models consisted of an adjustment for repeated measurements with an unstructured covariance matrix (also accounting for baseline differences in outcome variables between subjects) and an adjustment for nurse practitioner by allowing a random intercept on level 3.

All analyses were performed without data from dropouts (n = 46, 9.6% in the intervention group; n = 36, 8.1% in the usual-care group) and patients with diabetes (n = 32, 6.8% in the intervention group; n = 32, 7.3% in the usual-care group). Multilevel models were estimated using SAS version 9.2. All other analyses were performed using SPSS version 18.0. A P value <0.05 was considered to be significant.

RESULTS—Table 1 shows baseline characteristics and mean changes in clinical measures, physical activity pattern, and diet after 0.5 and 1.5 years of all participants who completed the intervention period. At baseline, weight was higher in the intervention group than in the usual-care group (P = 0.03). For all clinical measures, changes over time were modest in both groups. Fasting plasma glucose significantly decreased by −0.10 mmol/L in the intervention group and by −0.08 mmol/L in the usual-care group. Improvements in fasting plasma glucose were comparable between the two study groups (P = 0.77). In both groups, 2-h plasma glucose improved over the first half-year (−0.05 mmol/L in the intervention group; −0.15 mmol/L in the usual-care group) but increased to levels higher than at baseline in the next year (0.13 mmol/L in the intervention group; 0.18 mmol/L in the usual-care group). Changes over time were significant within the usual-care group but not within the intervention group (P = 0.09) or between groups (P = 0.49).

Both groups showed significant reductions in BMI that were less pronounced after 1.5 years than after 0.5 years. However, improvements after 1.5 years were comparable between groups (−0.2 kg/m² in the intervention group; −0.1 kg/m² in the usual-care group; P = 0.66). Waist circumference decreased by −0.4 cm in the intervention group (P = 0.008) but nonsignificantly increased by 0.3 cm in the usual-care group (P = 0.26). Changes in waist circumference also were not significant between groups (P = 0.35) (Table 1).
### Table 1—Changes in clinical measures, physical activity patterns, and diet after 0.5 and 1.5 years within and between study groups of participants who completed the intervention.

| Group                  | BMI changes (kg/m²) | Waist circumference changes (cm) | Physical activity (min/week) | Energy intake (Kcal) | Fat intake (g/MJ) | Carbohydrate intake (g/1000 Kcal) | Protein intake (g/1000 Kcal) |
|------------------------|---------------------|---------------------------------|-----------------------------|---------------------|------------------|------------------------------------|-----------------------------|
| Usual-care group       | -0.33 ± 0.66, P = 0.001 | -0.18 ± 0.36, P = 0.008 | 236 ± 120, P = 0.001 | -22, P = 0.001 | 3.8 ± 0.5, P = 0.001 | 0.5 ± 0.1, P = 0.001 | 0.8 ± 0.1, P = 0.001 |
| Intervention group     | -0.62 ± 0.33, P < 0.001 | -0.31 ± 0.18, P < 0.001 | 290 ± 110, P < 0.001 | -27, P < 0.001 | 3.2 ± 0.3, P < 0.001 | 0.6 ± 0.1, P < 0.001 | 0.9 ± 0.1, P < 0.001 |

Compared with baseline participants in both groups, total physical activity at 0.5 years was significantly lower in the usual-care group (−84 minutes/week in the usual-care group vs. −55 minutes/week in the intervention group, P < 0.001). In both groups, overall total physical activity decreased by about 10% over time, although the decrease was more pronounced in the usual-care group (−12% vs. −6%, P < 0.001). Total energy intake decreased by 27 kcal/day in the usual-care group and by 23 kcal/day in the intervention group (P < 0.001). Fat intake decreased by 0.7 g/MJ in the usual-care group and by 0.5 g/MJ in the intervention group (P < 0.001). Carbohydrate intake increased by 0.5 g/1000 Kcal in the usual-care group and by 0.8 g/1000 Kcal in the intervention group (P < 0.001). Protein intake decreased by 0.1 g/1000 Kcal in the usual-care group and by 0.1 g/1000 Kcal in the intervention group (P < 0.001).
1.5 years. The outcome variable weight was chosen because of the significant interpractice variation in BMI. In the intervention group, successful individuals more often were married or were in a stable relationship ($P = 0.02$). Furthermore, in this group the mean work experience of nurse practitioners was more than in the unsuccessful individuals ($P = 0.04$). In the usual-care group, unsuccessful individuals more often had normal instead of prediabetic baseline glucose values ($P = 0.03$).

**CONCLUSIONS**—In this article, we reported the overall effectiveness of the APHRODITE intervention program. Risk factors for type 2 diabetes could significantly be reduced by lifestyle counseling in Dutch primary care. However, differences in changes over time between the two study groups were small and mostly not significant. Differences between general practices were significant for clinical measures investigated but not for lifestyle measures. Differences in the characteristics of both health care providers and participants may underlie this interpractice variation.

**Changes in clinical measures**

For all clinical measures, changes over time were modest, a pattern that also was found...
in other diabetes-prevention studies in daily-life settings (7,11,12). Three other studies in the “real world” showed larger effects on risk factors for type 2 diabetes (8–10). However, in these studies the intensity of the interventions was higher than in our study. Only in the Greater Green Triangle Study (10) was risk reduction larger despite relatively low program intensity.

Risk-factor reduction also may have been larger in these three studies because of the less favorable initial risk profile of the participants. Mean baseline BMI, for example, ranged between 31.4 and 33.5 kg/m² (8–10) in these studies compared with 28.7 kg/m² in our study. A less favorable initial profile leaves more room for improvement and may, moreover, increase participant motivation (5,11). However, in other studies results were comparable despite a higher initial BMI and FINDRISC score (7,11,12).

Risk-factor profile in our study may seem more favorable than in previous studies because of the exclusion of individuals who developed type 2 diabetes. In the APHRODITE study, participation and follow-up were ended when blood glucose values in the diabetic range were measured, reflecting a real-life situation. In our study, mean FINDRISC score indeed was nearly one point higher in participants who developed diabetes within 1.5 years than in other participants.

Changes in lifestyle measures

Although results were modest, changes over time were more pronounced in the intervention group than in the usual-care group for all lifestyle measures. Intervention group levels of total physical activity were lower after 1.5 years than at baseline despite project recommendations. Comparable with the Finnish Diabetes Prevention Study (DPS) (21), improvements in leisure-time physical activity over time were not significant within or between groups (intervention group mean = 34 min/week; P = 0.50; usual-care group mean = 13 min/week; P = 0.82; P between groups = 0.96).

Dietary fiber intake also was reduced in the intervention group despite project recommendations. This pattern differed from that in the DPS (21) and the Dutch SLIM studies (22), where dietary fiber intake was modestly increased over time. With the exception of total energy intake in the DPS study, improvements in total energy intake, total fat intake, and saturated fat intake were much larger in the DPS and the SLIM studies than in our study. However, both of these studies were performed in an experimental setting, and extensive individual dietary counseling was offered to each participant.

It must be noted that the self-reported dietary and activity measures in our study may have been subject to a differential Hawthorne effect because participants in the intervention group may have been more aware of the rationale and objectives of the study than participants in the usual-care group. Furthermore, in both the food-frequency questionnaire and the SQUASH individuals were asked about their lifestyle during the previous 4 weeks. This 1-month reference period may not be representative for the usual activity pattern or dietary intake. In addition, correct quantification of behavioral change using questionnaires relies on the memory of the participants. Individuals may have had difficulties recalling their eating and activity patterns. However, despite these constraints validity and reliability of both questionnaires were reasonable (19,20). Moreover, using questionnaires may be unavoidable when measuring lifestyle change in large populations.

Intervention effectiveness

Although except for fasting and 2-h plasma glucose effects were more pronounced in the intervention group, the usual-care group showed significant improvements for several measures as well. Furthermore, differences between the two study groups in changes over time were small and were significant only for total physical activity and fiber intake. These observations suggest that the additional effect of the APHRODITE intervention program above the effect attributable to usual preventive care in Dutch general practice is modest.

Table 2—Differences between participants who were overweight at baseline and who were either successful or unsuccessful in losing weight or maintaining a stable weight over 1.5 years in both study groups

| Intervention group (n = 330) | Usual-care group (n = 305) |
|-----------------------------|---------------------------|
| Successful                  | Unsuccessful              | Successful                  | Unsuccessful              |
| n (%)*                      |                           | n (%)*                      |                           |
| Age (years)                 | 59.5 ± 7.1                | 60.1 ± 7.2                 | 59.0 ± 7.1                | 57.9 ± 6.5                |
| Sex (%) Male                | 41.7                      | 41.8                       | 40.5                      | 38.8                      |
| FINDRISC score (points)     | 14.4 ± 2.0                | 14.9 ± 2.2                 | 14.9 ± 2.0                | 14.7 ± 1.9                |
| Smoked (%)                  | 16.4                      | 15.4                       | 12.3                      | 14.3                      |
| Smoked in the past (%)      | 46.8                      | 55.8                       | 53.1                      | 53.6                      |
| Low education (%)           | 52.3                      | 53.8                       | 48.5                      | 57.7                      |
| Average education (%)       | 25.6                      | 26.9                       | 25.4                      | 27.0                      |
| Normal glucose values (%)   | 70.3                      | 71.2                       | 67.2                      | 79.3†                     |
| Married/stable relationship (%) | 88.3                      | 76.9†                      | 86.9                      | 83.9                      |
| Sex of general practitioner (%) Male | 74.3                      | 73.9                       | 73.3                      | 69.0                      |
| Age of general practitioner (years) | 51.2 ± 7.7                | 51.1 ± 8.5                 | 49.1 ± 8.7                | 49.3 ± 8.6                |
| Experience as general practitioner (years) | 20.7 ± 8.4                | 20.5 ± 9.4                 | 19.0 ± 9.0                | 19.0 ± 9.2                |
| Employment of general practitioner (hours/week) | 40.9 ± 9.8                | 41.3 ± 8.5                 | 42.0 ± 10.0               | 40.2 ± 9.8                |
| Age of nurse practitioner (years) | 41.6 ± 10.1               | 42.2 ± 10.0                | 41.3 ± 9.6                | 40.1 ± 10.2               |
| Experience as nurse practitioner (years) | 5.3 ± 2.7                 | 4.6 ± 2.7†                | 4.1 ± 2.6                 | 4.2 ± 2.7                 |
| Employment of nurse practitioner (hours/week) | 24.8 ± 6.1                | 25.7 ± 6.3                 | 22.2 ± 6.4                | 23.2 ± 7.1                |

Data are means ± SD, unless otherwise indicated. *Participants with a healthy weight at baseline (BMI <25 kg/m²) were excluded from the analysis. †Significant differences between groups as tested by either ANOVA or χ² tests.
The beneficial changes in the usual-care group may be explained by several factors. First, the prospect of the annual check-up with the nurse practitioner and annual blood sampling may have motivated individuals to lose weight, eat healthier, and exercise more. Second, as a part of daily general-practice care, participants may have been enrolled in other behavioral-change programs as well, for example, for high blood pressure or cardiovascular disease. Third, during the study several campaigns were held by the government and by the Dutch Nutrition Council to promote a healthy lifestyle.

Variability between practices
In the APHRODITE study, general practices significantly differed in change in BMI and 2-h plasma glucose in intervention-group participants completing the 1.5-year period. Differences between practices were not significant for energy intake and physical activity. However, as discussed above, difficulties quantifying behavioral change may have influenced accuracy of lifestyle measurements.

Variability between general practices may be partly caused by differences in characteristics of both the patient populations and the health care providers in the practices (5,6). Although in the intervention group mean work experience of nurse practitioners was higher for the successful individuals than for the unsuccessful individuals, there was no difference in work experience of general practitioners. This could first be explained by the different roles of the nurse practitioners and general practitioners in the APHRODITE intervention program. Although the nurse practitioners intensively guided the behavioral-change process, the general practitioners oversaw guarding the participants’ progress. Second, nearly all general practitioners already were working in a practice for over 10 years and may therefore all be considered “experienced.”

It is important to note that the mean experience of nurse practitioners was lower in the usual-care group (4.1 years) than in the intervention group (5.2 years) ($P = 0.001$). This difference in nurse practitioner experience may be caused by a differential drop-out rate between study groups, which may have influenced the results of the between-group analyses of risk-factor reductions over time. However, although the mean experience of nurse practitioners indeed was larger in dropouts in the usual-care group (4.5 years) compared with dropouts in the intervention group (4.0 years), this result was not significant ($P = 0.523$). The relatively low amount of dropouts in both groups ($n = 29$ in the intervention group and $n = 19$ in the usual-care group) may, however, have led to a lack of statistical power to detect the differential drop-out rates.

In our study, individuals who were successful in losing weight more often were married or were in a stable relationship. This result suggests that partner support is an important factor for successful behavioral change. For example, partners may be considerate of participants while shopping or preparing dinner. In addition, they may contribute to the action or coping self-efficacy necessary to change. In line with this hypothesis, lack of family support was found to be a barrier for both achieving (6) and maintaining (23) behavioral change in interventions for type 2 diabetes prevention. Furthermore, the use of social support was found to increase the effectiveness of weight-loss interventions at 1 year of follow-up (24).

In the usual-care group, unsuccessful individuals more often had normal baseline glucose values. Knowing that glucose values still are within the normal range may limit motivation to change unhealthy behavior. However, in the intervention group, the proportion of individuals with normal glucose values was similar between successful and unsuccessful participants. This may be explained by the efforts of the general practitioner and/or nurse practitioner in the intervention group to convince individuals of the importance of weight maintenance or loss despite normal glucose values.

In conclusion, although low-intensity and low-cost interventions like the APHRODITE program are particularly suitable for implementation in real-life settings, they may come with the price of lower intervention effectiveness (5,7,11). In our study, the additional effect of the APHRODITE intervention above the effect attributable to usual preventive efforts in Dutch general practice was modest. The effectiveness of type 2 diabetes prevention in primary care therefore requires additional research. Furthermore, it may prove useful to health policymakers to investigate the conditions under which interventions are most likely to be successful (5). In our study, the level of nurse practitioner experience and the availability of direct social support particularly seemed to facilitate intervention success. Program effectiveness may furthermore be increased by inclusion of participants with a higher initial risk and/or a higher motivation to change behavior (5,11) or by quality-based financial incentives (25). In addition to studying effectiveness, process evaluations are needed to identify organizational or motivational barriers to the implementation of diabetes prevention initiatives in the real world.

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