CHAPTER 5

EFFORTS TO REDUCE TYPE 2 DIABETES AND CARDIOVASCULAR DISEASE RISK IN REAL LIFE - RESULTS OF THE HOORN PREVENTION STUDY

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ABSTRACT

Objectives
To investigate the effectiveness of a lifestyle intervention to decrease the estimated risk of developing T2DM and for CVD mortality, and to improve healthy lifestyle behaviours in a primary care environment.

Design and participants
The Hoorn Prevention Study is a randomised controlled trial in which 622 adults with ≥10% estimated risk of T2DM and/or CVD mortality were enrolled and monitored over a period of 12 months (between December 2007 and September 2009).

Intervention and setting
A theory-based lifestyle intervention provided by trained practice nurses in 12 general practices. In a maximum of 6 individual counselling sessions, followed by 3-monthly telephone sessions, the participants participated in a cognitive behaviour programme based on an innovative combination of motivational interviewing and problem solving treatment.

Main outcome measures
Estimated risk of developing T2DM and for CVD mortality, calculated according to the ARIC and the SCORE formulae, respectively. Secondary outcomes included lifestyle behaviour (diet, physical activity and smoking).

Results
536 (86%) of the 622 participants (age 43.5 years (SD 5.3)) completed the 6-month follow-up, and 502 (81%) completed the 12-month follow-up. The mean baseline estimated T2DM risk was 19% (SD 8.2) and the mean estimated CVD mortality risk was 4% (SD 3.0). The intervention group participated in a median of 2 sessions. After six months the intention-to-treat analyses showed beta’s for between group differences of 0.3 (95% confidence interval -0.6 to 1.2; p=0.28) on the ARIC, and 0.0 (-0.3 to 0.2; p=0.96) on the SCORE. After 12 months this was 0.3 (-0.6 to 1.2; p=0.52) on the ARIC and -0.2 (-0.7 to 0.4; p=0.58) on the SCORE.
Conclusions

After 6 and 12 months the lifestyle intervention was found to be not more effective than providing health brochures in improving the estimated risk scores for T2DM and CVD or lifestyle behaviour in an at-risk population.
INTRODUCTION

Overweight, smoking, low levels of physical activity and an unhealthy diet are major risk factors for chronic diseases such as type 2 diabetes (T2DM) and cardiovascular diseases (CVD),\(^1\)-\(^3\) and the high prevalence of these risk factors has become a major public health problem. More and more public health policymakers expect health care providers to identify at-risk groups and to provide effective interventions to reverse this trend. It has been proven that intensive lifestyle interventions can lower the incidence of T2DM in individuals with impaired glucose metabolism, but the question remains as to whether the positive results observed in these well-controlled settings can be achieved in primary health care settings.\(^4\),\(^5\) Barriers in translating intensive interventions to a ‘real life’ setting include lengthy diagnostic testing procedures to identify pre-diabetes, the cost of highly educated personnel to provide the intervention, the possible cost of incentives to motivate participants, and offering the intervention in locations such as single medical centers.\(^6\)

Consequently, intensive lifestyle interventions exceed both the available resources and training facilities in primary health care.\(^7\) So far, randomised controlled trials evaluating the effectiveness of programmes that target lifestyle behaviour(s) to prevent T2DM or CVD in primary health care settings have had various different results, and if they were effective, the effects were small and unsustainable.\(^8\)-\(^12\)

We developed and implemented a feasible lifestyle intervention for the primary prevention of T2DM and CVD, tailored to the available resources and infrastructure for national primary health care services in the Netherlands. These kind of pragmatic trials have the potential to be an important source of information to guide clinical practice and health care delivery.\(^13\) The intervention consisted of a cognitive behaviour programme, based on the theory of planned behaviour, performed in a primary health care setting. An innovative and key element of this trial was that the participants were supported in their motivation and self-empowerment to make sustainable changes in lifestyle behaviour by means of a combination of practical, evidence-based tools (i.e. motivational interviewing and problem-solving treatment).
The aim of this study was to investigate the effectiveness of a theory-based lifestyle intervention on the estimated risk of developing T2DM and CVD mortality in at-risk adults, compared to the provision of written information only. A further aim was to assess the effects of the intervention on actual lifestyle behaviour (physical activity, dietary behaviour and smoking).

**METHODS**

**Study design and participants**

The methods and theory underlying the Hoorn Prevention Study have already been reported in detail elsewhere. Between December, 2007 and April, 2008, a total of 8,193 men and women, 30-50 years of age living in various municipalities in the semi-rural region of West-Friesland in the Netherlands, were invited to participate in a selective screening procedure. The choice for the age group of 30-50 years was motivated by estimates of Dutch diabetes incidence rates based on the number of newly diagnosed patients by the general practitioner (GP) in five GP records. Those estimates clearly mark the age-period in which incidence-rates start to rise (i.e. from 30 years onwards). The target group was approached after the identification of date of birth and absence of diabetes or known CVD from the computerised databases of the participating general practices (n=12). The invitation included a tape measure for the measurement of waist circumference according to detailed instructions. Of the 3,587 respondents (44%), 2,401 responded positively, 921 of whom were eligible with regard to the pre-set cut-off score of the self-administered waist-circumference (≥101 cm for men and ≥87 cm for women). Of these eligible respondents, 772 visited the Diabetes Research Center for baseline measurements, gave written informed consent, and participated in the trial (Figure 1).

T2DM and CVD risk scores were estimated according to the formulae described in the Atherosclerosis Risk In Communities (ARIC) Study and the Systematic COronary Risk Evaluation (SCORE) project. For both scores, and for each participant, age was extrapolated to 60 years to address the problem of a high relative but low absolute risk in younger persons. This made it possible to identify a potentially high risk at the age of 60. All respondents with at least a 10% T2DM risk and/or CVD mortality risk and no known prevalent T2DM or CVD were randomly assigned to either the intervention group or the control group. Before ran-
domisation, we excluded 150 individuals, 140 of whom had a less than 10% risk, and 10 who had undiagnosed T2DM (Figure 1).

The study protocol was approved by the Medical Ethics Committee of the VU University Medical Center in Amsterdam, and all participants gave written informed consent.

**Outcome measures**

The primary outcome measures were the estimated risk of developing T2DM and the estimated risk of CVD mortality.

The 9-year risk of developing T2DM was estimated with the risk formula derived from data from the ARIC Study,\(^\text{16}\) based on ethnicity, parental history of diabetes, systolic blood pressure, waist circumference, and height.

The 10-year risk of CVD mortality was estimated with the formula developed by the SCORE project,\(^\text{17}\) which includes sex, smoking status, total cholesterol, and systolic blood pressure.

Secondary outcome measures included self-reported physical activity (metabolic equivalent of task (MET)- minutes per day light, moderate and vigorous activity), and number and proportion of participants who met the national recommendations for physical activity (≥30 minutes moderate-intensity physical activity such as brisk walking, on at least five days of the week). Physical activity was measured with a validated questionnaire.\(^\text{18}\) Fruit (pieces per day, and number and proportion of participants who met the national recommendation of at least 2 pieces of fruit per day) and vegetable intake (grams per day, and number and proportion of participants who met the national recommendation of at least 200 grams of vegetable consumption per day) was assessed according to an extended and modified version of the 8-item Food Frequency Questionnaire.\(^\text{19}\) Smoking behaviour (smoking every day/occasionally/never smoked) was assessed with validated questions recommended by the WHO for the assessment of smoking status.\(^\text{20}\)

Height was measured to the nearest 0.1 cm without shoes, and weight was measured to the nearest 0.5 kg, wearing light clothes and no shoes. The standard scales that were used (SECA; London, UK) were calibrated regularly. Waist circumference was measured midway between the lowest rib margin and the iliac crest. Two measurements to the nearest 0.5 cm were recorded; if the difference be-
tween the measurements was greater than 1 cm, a third measurement was made and the mean of the two closest measurements was calculated. Systolic and diastolic blood pressure were measured after 10 minutes of rest, in a seated position, with a Colin Press BP 8800p Non-Invasive Blood Pressure Monitor (Colin Medical Technology Corporation, USA). Fasting plasma glucose was measured according to the enzymatic reference method with hexokinase, HbA1c determination was based on the turbidimetric inhibition immunoassay for haemolysed whole blood, and total and HDL cholesterol and triglycerides were measured with the enzymatic colorimetric method. All laboratory tests were performed using the Cobas Integra system (Roche diagnostics, Basel, Switzerland).

Randomisation
A randomisation schedule was drawn up with a computerised random number generator. If more than one member of the same family participated, consecutive members of that family were randomised to the same group as the first member, to avoid contamination. To ensure concealment of the treatment allocation, an independent administrative assistant from the Diabetes Research Center, who had no information at all about the participants, performed the randomisation. Members of the trial staff who were responsible for the measurements and data-entry were unaware of the groups to which the participants were assigned. Blinding of the participants and the practice nurses for the intervention was not feasible, but the research assistants, the principal investigator and the general practitioners remained blinded during the entire intervention period. This was achieved by instructing the participants not to communicate about the intervention with their general practitioner or the medical assistants.

Intervention
The programme integrated and combined several components of previous interventions that have shown to be effective, including: 1) the use of cognitive-behavioural approach;\textsuperscript{21,22} 2) involving an at risk population as opposed to a general, healthy population;\textsuperscript{23–27} 3) the use of a solid theoretical framework.\textsuperscript{28}

The lifestyle intervention was based on the theory of planned behaviour, and was provided by specifically trained practice nurses in the participating general practices. In up to six face-to-face 30-minute counselling sessions, followed by 3-monthly telephone sessions, Motivational interviewing\textsuperscript{29} (MI) and problem solv-
Motivational Interviewing

The aim of MI was to reinforce the participants’ attitude and their intention to change their lifestyle. It also aimed to induce a discrepancy between a personal goal and the actual situation. MI was originally developed and used extensively for psychological disorders and the treatment of addiction to smoking and alcohol. In the Hoorn Prevention Study, one of the techniques that was used during MI is reflective listening. The practice nurses were taught to apply this throughout the whole counselling process. A ‘gap’ between the participant’s actual behaviour and the broader goals was emphasised, cultivating motivation for lifestyle change. Theoretically, when the participant recognises such discrepancies, a certain level of discontent arises that makes change more likely to occur. Discrepancies were emphasised after exploring the participant’s views on their actual and future behaviours. ‘Rolling with resistance’ was used to invite the participant to consider a new perspective, instead of having it imposed. Finally, self-efficacy, or the confidence to change a specific behaviour under difficult circumstances, was supported whenever possible because it is one of the best predictors of treatment outcome. Ideally, after the MI counselling the participant were willing to change and ready to strengthen the commitment to a plan for lifestyle change using PST.

Problem Solving Treatment

PST was used to support participants in finding solutions to overcome this discrepancy, to strengthen their perceived control, and to provide tools to overcome barriers that hinder changes in lifestyle behaviour. The nurse practitioner, together with the participant, made an implementation plan concerning where, when and how the behaviour changes would take place. This was done in the following series of stages: 1) explanation of the intervention and its rationale; 2) definition and breaking down of the problem; 3) establishing SMART goals for problem-solving (Specific, Measurable, Achievable, Relevant, Timed); 4) generating multiple possible solutions; 5) evaluating and choosing the solution; 6) implementing the
preferred solution; and 7) evaluating the outcome.\textsuperscript{30}

**Training of practice nurses**
The counselling programme was provided by eight female practice nurses. Prior to the intervention, all practice nurses received 12 hours of training MI and 6 hours of training PST from experienced psychologists. A treatment manual was used during the training and counselling. Coaching on the job was provided halfway through the intervention, consisting of one hour individual coaching. In addition, a peer supervision meeting was arranged with all practice nurses to provide on-going feedback and to increase uniformity of the counselling style.

The counselling sessions were initially given on a weekly base, but after a few sessions the time between the sessions is extended to 2/3 weeks, followed by 3-monthly counselling sessions by phone, to act as a reminder for the participants, to reinforce what they have learned, and to give them support and feedback.

A random selection of sessions per practice nurse, taped on a digital voice recorder, was used during the coaching. A peer supervision meeting was also arranged to provide on-going feedback and to increase uniformity of the counselling style among the practice nurses.

The last counselling session was brought to an end by reviewing the content of the counselling sessions undergone, with emphasis on the successes achieved by the participant and implementation of behavioural changes in the future, independent of the nurse practitioner.

**Control group**
Participants in the control group received existing brochures containing health guidelines regarding physical activity and a healthy diet, obtained from the Dutch Heart Foundation. Smokers received an additional brochure on how to stop smoking from the Dutch Anti-Smoking Foundation (STIVORO). An independent administrative assistant sent the brochures to the participants.

**Sample size calculation**
For the sample size calculation we used data from a Dutch working population of overweight people (body mass index ≥25), in which the standard deviation (SD) of
the ARIC score was 8.11.\textsuperscript{32} For a two-sided detection of a 5% between-group difference in ARIC risk score (i.e. representing a difference in waist circumference of 1.5 cm or a difference in systolic blood pressure of 4 mmHg), with an alpha of 0.05 and a power of 90% in the present study, 120 participants per group were needed. However, in order to perform stratified analyses, and to take loss to follow-up into account, more participants were needed (i.e. 300 per group).

**Data-entry**
In order to ensure a high level of data accuracy, 10% of the manually entered data was entered twice, and each second entry was checked against the first. A maximum discrepancy level of 1.5% was accepted.

**Statistical methods**
Descriptive statistics (means ± SD, or median and interquartile ranges, as appropriate) were used to describe the study sample with regard to demographics, physical characteristics and baseline laboratory values. Linear and logistic regression analysis was applied to examine the between-group differences in each outcome measure, adjusted for baseline values.

We examined effect modification by individual-level factors, including sex, age, level of education, and T2DM and CVD risk at baseline. Stratified analyses were performed for effect modifiers if their interaction term was considered to be significant (p<0.1 in this case). All primary analyses were performed according to the intention-to-treat principle: participants were analysed in the groups to which they were originally randomly assigned, regardless of whether or not they actually received the intervention. Only participants for whom data were available were included in the analyses. In the analyses of smoking behaviour we only included data of those who reported being a smoker at baseline. Participants with a fasting glucose >7.0 mmol/L (confirmed with a second fasting blood sample) were referred to their general practitioner and then excluded from consecutive measurements because of the anticipated extra medical attention they might receive. Women who became pregnant during follow-up were also excluded because of potential bias in weight and waist circumference measurements. A per-protocol analysis included participants in the intervention group who attended at least 4 counselling sessions. All analyses were performed in SPSS 15.0 (SPSS Inc., Chicago, IL, USA).
RESULTS

Figure 1 presents the trial's flow chart. 622 participants were randomly assigned to receive either the lifestyle intervention (n=314) or health brochures only (n=308). After 6 months, 536 participants (86%) attended the first follow-up measurement, 533 (86%) of whom provided complete data and could be included in the analysis. 502 participants (81%) attended the second follow-up measurement. A dropout analysis showed no significant differences in baseline values of the outcome measures between participants who completed the study and those who dropped out (data not shown).

The baseline characteristics of the participants in the two groups were similar (Table 1). The mean age at baseline was 43.5 years (SD 5.3) and 363 participants were female (58%). Of 49 participants we also included the partner, who we assigned to the same group as the first-included. At baseline, the mean estimated 9-year risk of developing T2DM was 19% (SD 8.2) and the mean estimated 10-year CVD mortality risk was 4% (SD 3.0). Participants in the intervention group received a median of 2 (interquartile range 1-3) counselling sessions. The baseline and follow-up values and the differences between groups in risk scores and lifestyle behaviour are shown in Table 2.
Table 1. Baseline characteristics of randomised participants in the Hoorn Prevention Study

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>CONTROL GROUP (N=308)</th>
<th>INTERVENTION GROUP (N=314)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NO. (%)</td>
<td>NO. (%)</td>
</tr>
<tr>
<td><strong>SEX</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>185 (60.1)</td>
<td>178 (56.7)</td>
</tr>
<tr>
<td><strong>AGE (YRS), MEAN (SD)</strong></td>
<td>43.4 (5.5)</td>
<td>43.6 (5.1)</td>
</tr>
<tr>
<td><strong>LEVEL OF EDUCATION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;Primary</td>
<td>103 (33.6)</td>
<td>101 (32.5)</td>
</tr>
<tr>
<td>Secondary</td>
<td>145 (47.1)</td>
<td>141 (44.9)</td>
</tr>
<tr>
<td>College, university</td>
<td>59 (19.2)</td>
<td>69 (22.0)</td>
</tr>
<tr>
<td><strong>FAMILY HISTORY OF DIABETES</strong></td>
<td>77 (25.0)</td>
<td>94 (29.9)</td>
</tr>
<tr>
<td><strong>ANTHROPOMETRICS MEAN (SD)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>90.7 (15.4)</td>
<td>90.2 (15.5)</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>96.7 (9.7)</td>
<td>96.7 (9.8)</td>
</tr>
<tr>
<td><strong>BLOOD PRESSURE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic (mmHg)</td>
<td>129.3 (13.3)</td>
<td>128.7 (13.2)</td>
</tr>
<tr>
<td>Diastolic (mmHg)</td>
<td>73.8 (9.0)</td>
<td>73.0 (9.9)</td>
</tr>
</tbody>
</table>
Figure 1: Flow chart of the Hoorn Prevention Study

8,193 adults invited, aged 30-50 years

3,587 responded (44%)

772 eligible according to self-reported waist circumference and attended measurement visit

622 high risk according to ARIC and SCORE, randomly assigned

140 low risk
10 diagnosed T2DM

308 allocated to control group

Loss to follow-up (n=39)
29 unable to attend
5 withdraw consent
3 became pregnant
2 unable to contact

Follow-up 1 (6 months) n=269

Loss to follow-up (n=18)
8 unable to attend
3 withdraw consent
3 unable to contact
1 became pregnant
1 died of CVD

Follow-up 2 (12 months) n=253

Loss to follow-up (n=47)
38 unable to attend
8 withdraw consent
1 became pregnant

314 allocated to intervention group

Loss to follow-up (n=18)
9 unable to attend
4 withdraw consent
1 unable to contact
4 had diagnosed T2DM at follow-up 1

Follow-up 1 (6 months) n=267

Follow-up 2 (12 months) n=249
T2DM and CVD risk scores
There were no significant between-group differences in either of the estimated risk scores between the intervention and the control group at either follow-up (Table 2).

Lifestyle behaviour
An increase in fruit intake of 0.2 pieces of fruit per day in the control group was found to be a significantly difference after 6 months, but not after 12 months. We found no significant difference between the groups with regard to changes in physical activity, vegetable intake or smoking behaviour over the 6 and 12 month follow-up period.

Secondary analyses (per protocol, sub-group)
Per protocol analyses (n=360) did not affect the findings described above. Stratified analyses revealed that participants with a lower level of education in the control group were responsible for the increase in fruit intake. In this sub-group analysis the control group (n=308) consumed, on average, a fourth of a piece of fruit per day more than the intervention group (n=53) after 6 and 12 months. Stratified analyses of groups separated by the mean baseline ARIC or mean SCORE risk showed no change in the results.

DISCUSSION
In the current study we evaluated the effectiveness of an innovative, theory-based lifestyle intervention carried out in a primary health care setting. To our knowledge, we are the first to report on the effects of a lifestyle intervention to reduce the estimated risk of developing T2DM and CVD mortality. The cognitive behaviour programme was provided in the participants’ own general practice, by practice nurses instead of researchers in the study. In contrast to the procedure in former lifestyle interventions, the participants in our study were encouraged to find solutions instead of being told how to change their behaviour, and they were also taught how to implement these solutions into their life. However, our findings show that the lifestyle intervention was not more effective than health brochures, and it therefore offers no adequate solution for the growing public health problem caused by T2DM and CVD.
Table 2. Baseline and follow-up values and group differences in risk scores and lifestyle behaviour adjusted for baseline (95% CI)

<table>
<thead>
<tr>
<th>RISK SCORES</th>
<th>CONTROL GROUP</th>
<th>INTERVENTION GROUP</th>
<th>GROUP DIFFERENCES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Follow-up 1 (6 months)</td>
<td>Follow-up 2 (12 months)</td>
</tr>
<tr>
<td>ARIC</td>
<td>18.8 (8.5)</td>
<td>18.0 (7.6)</td>
<td>17.8 (9.2)</td>
</tr>
<tr>
<td>SCORE</td>
<td>3.8 (2.9)</td>
<td>3.7 (3.0)</td>
<td>3.7 (4.6)</td>
</tr>
</tbody>
</table>

| PHYSICAL ACTIVITY | | | | | | |
| light activities | | | | | | |
| moderate activities | | | | | | |
| vigorous activities | | | | | | |
| meeting recommendations n(%) | | | | | | |
| pieces of fruit per day | | | | | | |
| meeting recommendations fruit intake n(%) | | | | | | |
| vegetable intake (grams per day) | | | | | | |
| meeting recommendations veg. intake n(%) | | | | | | |
| SMOKING BEHAVIOUR | | | | | | |
| smokers n(%) | | | | | | |

Data are mean (standard deviation) unless otherwise specified.
ARIC = Atherosclerosis Risk In Communities formula based on: ethnicity (black yes/no), parental history of diabetes, systolic blood pressure, waist circumference and height; SCORE = formula developed by the Systematic COronary Risk Evaluation project based on sex, smoking status (smoking yes/no), total cholesterol and systolic blood pressure.
1 Based on the Short Questionnaire to ASsess Health enhancing physical activity (SQUASH). Values are median (Q1;Q3) Metabolic Equivalent of Task (MET) - minutes per day, representing the time engaged in specified physical activities multiplied by the metabolic equivalent value of each activity. Light activities are rated as 2.0 to <4.0 METs, moderate activities are rated as ≥4.0 to <6.5 METs, vigorous activities are rated as ≥6.5 METs
2 Meeting national recommendations on physical activity (≥30 minutes moderate -intensity physical activity such as brisk walking, on at least five days of the week)
3 Meeting national recommendations on fruit intake (at least 2 pieces a day)
4 Meeting national recommendations on vegetable intake (at least 200 grams a day)
CI= confidence interval
Earlier research in controlled settings has demonstrated that, separately, MI and PST are more effective than attention alone,\textsuperscript{33,34} and there is evidence to support the efficacy of MI in a number of programmes promoting change in lifestyle behaviour.\textsuperscript{31} Although it has been convincingly demonstrated that T2DM can be delayed or prevented in high risk individuals, it is still a considerable challenge to provide evidence-based lifestyle programmes for high risk populations in ‘real life’ settings. The results of previous studies in primary care have to be interpreted with caution, because most of these studies had insufficient power, used single-group designs, and/or had high rates of attrition.\textsuperscript{35,36} These methodological limitations were addressed in the Hoorn Prevention Study: we had sufficient power, randomisation was performed at individual level, and relatively few participants were lost to follow-up.

Compared to the participants in previous trials of highly effective lifestyle interventions, the participants in our study were, on average, younger, had a lower absolute risk of developing T2DM, did not receive financial incentives, and were recruited from the general population. Whereas the latter two arguments may be considered as strengths of the present study, they may also be associated with the lack of effectiveness of the intervention. The chosen age group may have influenced our findings as well. A relatively young, working population may differ from older (retired) individuals who perhaps have more time or may perceive their health as more important. We standardised the age of all participants to 60 years in our risk score calculations, which resulted in a ‘projected’ risk score that was useful to accentuate absolute risk. The true absolute risk, the absolute risk reduction and the corresponding number needed to treat (NNT) were not calculated since we found the intervention to be ineffective.

In addition, the rather low attendance rate may have contributed to the lack of an intervention effect, since a median number of 2 counselling sessions were attended. On the other hand, after per protocol analyses (which only included participants who had attended at least 4 counselling sessions) there was no change in the results. Six or less face-to-face sessions as we provided may not have been enough to induce a sustainable lifestyle behavioural change, given that previous effective lifestyle interventions provided at least 12 sessions.\textsuperscript{37-39} However, since our participants were not even motivated enough to attend 6 sessions, it is unlikely that they would be willing to attend more.
With regard to the external validity we like to point out that the study sample was not culturally diverse. Although our population (predominantly from a Western European culture) was representative for the study region in the Netherlands, this may affect the generalizability of findings. Furthermore, non-respondents are a potential threat to the external validity of the results. Efforts were made to reduce barriers for participation to a minimum, and we chose to approach potential participants via correspondence at multiple moments, as described by Dillman et al. Other efforts to reduce non-participation included the choice to provide the intervention in general practices (which are near to the homes of the participants), as well as to minimise the burden of the measurements by using short questionnaires, and to refrain from using unpleasant measurement methods such as 2-hour oral glucose tolerance tests. Nonetheless, the recruitment rate was 44%, and further participants dropped out before the intervention.

Some limitations must be noted with regard to the outcome measures used. We used the version of the ARIC formula that includes only non-invasive methods to assess participants’ T2DM risk. Although this version has the advantage that the potential applicability in primary care is high, it has a lower responsiveness in comparison with versions that include laboratory measures. Furthermore, the outcomes of the lifestyle behaviours are based on self-reported data and are therefore subject to recall bias. In a recent review of physical activity questionnaires it was concluded that the SQUASH survey had sufficient content validity (i.e. it covers all relevant settings of physical activity), but its responsiveness has never been assessed. In addition, the assessment of the impact of the intervention on dietary behaviour was limited to fruit and vegetable intake in order to minimise the intervention effect that might emanate from using intensive and more complex research methods for assessing broader patterns of dietary intake.

After 6 and 12 months the lifestyle intervention was not more effective than providing health brochures in improving estimated risk scores for T2DM and CVD or lifestyle behaviour in an at-risk population. Hence we conclude that providing this type of primary prevention intervention is not effective in a ‘real life’ primary care setting.
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