CHAPTER 7

PROCESS EVALUATION OF A LIFESTYLE INTERVENTION TO PREVENT DIABETES AND CARDIOVASCULAR DISEASES IN PRIMARY CARE

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Submitted for publication
ABSTRACT

Effective, cost-effective, safe and feasible interventions to improve lifestyle behavior in at-risk populations are needed in primary care. In the Hoorn Prevention Study, we implemented a theory-based lifestyle intervention in which trained practice nurses used an innovative combination of **motivational interviewing** (MI) and **problem solving treatment** (PST). This paper presents the intervention’s reach, effectiveness in terms of process outcomes, adoption, and implementation.

Recruitment strategy and participant flow were documented accurately. The effectiveness in terms of determinants of behavioral change was measured using a validated questionnaire. Questionnaires were also used to assess participant satisfaction and compliance, as well as practice nurses’ confidence in providing the intervention. Counseling sessions were tape recorded to assess MI, PST, and general counseling competence.

The findings indicate that the recruitment strategy was adequate and resulted in a reasonably extensive reach of the target population. Practice nurses were competent and confident in their provision of MI and PST, and participant satisfaction was high. Nevertheless, the number of sessions attended was low, and almost no effects were seen on determinants of behavioral change. We conclude that implementing this type of intervention in primary care is feasible, but more is needed to effectively facilitate changes in determinants of lifestyle behavior in this population.
BACKGROUND

Lifestyle dependent risk factors such being overweight, low levels of physical activity and an unhealthy diet increase the risk of acquiring chronic diseases such as type 2 diabetes (T2DM) and cardiovascular diseases (CVD).\(^1\) More and more, public health policy-makers expect health care providers to identify at-risk groups and to provide effective interventions in an effort to prevent these diseases. In the Hoorn Prevention Study we examined the effectiveness of an innovative lifestyle intervention in at-risk adults, compared to the provision of health brochures only. The intervention consisted of a cognitive behavioural programme based on the Theory of Planned Behaviour (TPB) and was carried out by trained practice nurses in 12 general practices. In a maximum of six individual 30-minute counselling sessions, followed by 3-monthly sessions by phone, an innovative combination of motivational interviewing (MI)\(^4\) and problem solving treatment (PST)\(^5\) were used. Both MI and PST address various components of the TPB. The aim of MI was to reinforce the participants’ attitude and the behavioural intention to make a change in one of three lifestyle behaviours of choice (physical activity, diet or smoking). It also aimed to create a discrepancy between a person’s goal and the actual situation. PST was used to support participants in finding solutions to overcome this discrepancy, to strengthen the perceived control and to provide tools to overcome barriers that hinder lifestyle behavioural changes.\(^5\)

The intervention incorporated components of previously effective interventions, was tailored to the resources and infrastructure available to national health care services in the Netherlands and was pragmatic in design.

In addition to evaluating clinical results of an intervention programme with regard to its effectiveness, it can be as valuable to evaluate the programme’s translatability and feasibility as well as its limitations.

A widely-used evaluation framework for the assessment of interventions which includes multiple process indicators and extends beyond assessing effectiveness has been published.\(^6\) The framework includes the following dimensions: (1) the Reach of the programme; (2) its Effectiveness; (3) its Adoption by intermediaries and users; (4) its Implementation according to plan; and (5) its Maintenance for a long enough time (RE-AIM).\(^6\) In evaluating these dimensions, not only can the strengths of a programme be identified, but also the limitations. These limitations can be improved upon in future research.
This paper describes the evaluation of a primary care based lifestyle intervention programme for adults at risk of diabetes and cardiovascular diseases, based on the RE-AIM framework.

METHODS
The methods and background theory of the Hoorn Prevention Study have been reported in detail previously. The Medical Ethics Committee of the VU University Medical Centre in Amsterdam approved the study protocol and all participants gave written informed consent.

The RE-AIM framework
We systematically assessed the dimensions of the RE-AIM framework as described below. Note that some elements of the framework have been adapted slightly to the intervention under study.

Reach
The recruitment strategy used for participants in the Hoorn Prevention Study out of the target population is evaluated. The participant flow is provided including the reasons for (and percentages of) those who were excluded from the study, those who dropped out during the follow-up, and those who remained.

Effectiveness
The interventions’ effectiveness in terms of affecting determinants of lifestyle behavioural change (according to the TPB) was evaluated. Attitudes, subjective norms, perceived behavioural control, and intentions of lifestyle behavioural change in both groups were measured with the Determinants of Lifestyle Behaviour Questionnaire (DLBQ). This is a valid instrument for measuring substantial determinants of the intention to change diet, physical activity and smoking behaviours in adults at high risk of T2DM and CVD. Confirmatory factor analysis supported the theoretical factor structure of the DLBQ. Attitudes were measured on a 7-point semantic scale ranging from 1 (e.g. unpleasant) to 7 (e.g. pleasant). All other determinants of behavioural change were measured on a 5-point Likert scale ranging from 1 (totally disagree) to 5 (totally agree). Mean scores for behavioural determinants were calculated for each lifestyle behaviour. Theoretically, higher
scores indicate a stronger intention to change lifestyle behaviours and are in favour of behaviour change. Linear regression analyses was used to analyse differences in behavioural determinants between the intervention- and control groups at 6 and 12-months follow-ups (reported as unstandardized B coefficients), with the significance level set at p ≤ 0.05. Analyses were corrected for baseline values to adjust for regression to the mean tendencies, and to take into account the actual changes in behavioural determinants compared to baseline. The analyses were all based on the intention-to-treat principle and were conducted using SPSS 15.0 (SPSS Inc., Chicago, IL, USA). The effectiveness of the intervention lifestyle behaviours and risk of T2DM and CVD has been described elsewhere.9

Adoption

Training of practice nurses

The counselling programme in the Hoorn Prevention Study was provided by eight practice nurses. Prior to the intervention, all practice nurses received 12 hours of training MI and 6 hours of training in PST from experienced psychologists who are specialised in providing CBPs and are qualified to teach CBP techniques. A treatment manual was used during the training and counselling. On-the-job coaching was provided halfway through the intervention, and consisted of one hour individual meetings. 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.

Attitude toward and confidence in providing the intervention

Practice nurses were asked to give their opinion on five statements regarding the perceived effectiveness of MI and PST, and assess their confidence in providing the intervention. Answer categories were 4-point Likert scales ranging from 1 (agree) to 4 (disagree). These assessments were administered twice: just after the end of the training and again when the face-to-face counselling sessions were completed (approximately 6 months later).

Participant satisfaction and compliance

Participant satisfaction and compliance were measured at the first follow-up measurement visit (when most face-to-face counselling sessions were completed); participants randomised to the intervention group were asked to score their
satisfaction with the counselling sessions on a 4-point Likert scale (ranging from completely disagree to completely agree). The proportions of participants who (completely) agreed with the various items on satisfaction were calculated. The number of face-to-face counselling sessions attended was recorded by the practice nurses in order to document participants’ compliance.

**Implementation**

We assessed the extent to which the various intervention components were delivered as intended. We evaluated MI counselling skills and captured dimensions of therapeutic alliance using the third version of the Motivational Interviewing Treatment Integrity rating scale (MITI),\(^{10}\) and components of the Motivational Interviewing Skill Code (MISC).\(^{11}\) Both instruments are specifically designed to evaluate MI and have high reliability and validity.\(^{10,11}\) To assess PST skills we used the modified Problem-Solving Competency Checklist (PSCC) developed by Kendrick et al.\(^{12}\) Please refer to Additional file 1 and 2 for more background information on the MITI 3.0, MISC and PSCC.

The counselling sessions were tape-recorded to allow assessment of the validity of MI and PST provided by the practice nurses. Two tape-recorded sessions of ≥15 minutes from all practice nurses were drawn at random using a computerised randomisation programme and transcripts were made: all final samples were then independently analysed by two researchers. Because not all samples contained sessions in which PST was used, ten extra random sessions have been independently analysed using the PSCC.

**Maintenance**

Because the Hoorn Prevention Study set out to evaluate the effects of the intervention given within a pre-defined timeframe (i.e. two years), this dimension could not be evaluated.
RESULTS

Reach
Between December, 2007 and April, 2008, a total of 8,193 men and women aged 30-50 living in several municipalities in a semi-rural region (West-Friesland) of the Netherlands were invited to participate in a selective screening procedure by mail. The target group was approached after identification of date of birth and absence of diabetes and known CVD from participating general practices (n=12). The invitation letter included a tape measure with detailed instructions on how to measure waist circumference. 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 test (≥101 cm for men and ≥87 cm for women). Of these eligible responders 772 visited the Diabetes Research Centre for baseline measurements, gave written informed consent, and participated in the trial. After this research visit, T2DM and CVD risk scores were calculated according to the formulae of the Atherosclerosis Risk In Communities (ARIC) Study\textsuperscript{13} and the Systematic COronary Risk Evaluation (SCORE) project.\textsuperscript{14} For both scores, age was extrapolated to 60 years for each participant to address the problem of a high relative but low absolute risk in younger persons. In doing so, it was possible to flag individuals with a potential high absolute risk at the age of 60.\textsuperscript{14} All respondents with a minimum risk of 10% of developing T2DM and/or CVD and no known prevalent T2DM or CVD were randomly assigned to either the intervention group or the control group. Before randomisation, we excluded 150 people (140 had a risk lower than 10%, and 10 had undiagnosed T2DM). Of the 622 individuals included in the study, 490 (79%) attended the last follow-up at 24 months. Please refer to Figure 1 for the Hoorn Prevention Study's participant flow and reasons for drop-out. A drop-out 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).

Study population and baseline characteristics
Baseline characteristics of participants of both groups were similar (Table 1). The mean age at baseline was 43.5 years (SD 5.3) and 363 participants were female (58%).
Effectiveness
Baseline and follow-up values and group differences for all TPB determinants of lifestyle behaviours are shown in Table 2 (next page). There were no or very small differences in determinants of lifestyle behaviour between groups at both follow-up. After 6 months, subjective norms with regard to physical activity were significantly lower in the intervention group (B = -0.2; CI -0.4 to 0.0). This difference did not remain after 12 months. The perceived behavioural control of smoking cessation was significantly higher at 12 months follow-up, in favour of the intervention group (B = 0.3; CI 0.1 to 0.6).

Table 1. Baseline characteristics of randomised participants in the Hoorn Prevention study

<table>
<thead>
<tr>
<th></th>
<th>CONTROL GROUP (N=308)</th>
<th>INTERVENTION GROUP (N=314)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex – Female no. (%)</td>
<td>185 (60.1)</td>
<td>178 (56.7)</td>
</tr>
<tr>
<td>Age – yrs, mean (SD)</td>
<td>43.4 (5.5)</td>
<td>43.6 (5.1)</td>
</tr>
<tr>
<td>EDUCATIONAL ATTAINMENT – NO. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤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>Family history of diabetes – no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>77 (25.0)</td>
<td>94 (29.9)</td>
<td></td>
</tr>
<tr>
<td>ANTHROPOMETRICS, MEAN (SD)</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>BLOOD PRESSURE</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
Adoption

Attitude toward and confidence in providing the intervention

The practice nurses considered MI and PST to be effective methods of supporting participants in a behavioural change process, and most were confident in providing the intervention. After the intervention their confidence was unchanged or strengthened (Table 3).

Table 3. Mean scores (SD) of answers on statements regarding practice nurses’ attitudes and confidence towards providing the intervention.

<table>
<thead>
<tr>
<th>Statement</th>
<th>BEFORE THE START OF THE INTERVENTION, BUT AFTER THE TRAINING (N=8)</th>
<th>AFTER THE INTERVENTION (N=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am not (yet) able to guide participants through the counselling sessions</td>
<td>2.8 (1.0)</td>
<td>2.5 (0.9)</td>
</tr>
<tr>
<td>I master the counselling skills sufficiently to use them in practice</td>
<td>2.0 (0.0)</td>
<td>1.9 (0.6)</td>
</tr>
<tr>
<td>I think MI is a suitable part of the counselling sessions</td>
<td>1.2 (0.4)</td>
<td>1.1 (0.2)</td>
</tr>
<tr>
<td>I think PST is a suitable part of the counselling sessions</td>
<td>1.1 (0.2)</td>
<td>1.5 (0.5)</td>
</tr>
<tr>
<td>The combination of MI and PST is valuable for supporting lifestyle behaviour change</td>
<td>1.1 (0.4)</td>
<td>1.2 (0.5)</td>
</tr>
</tbody>
</table>

Scores are Means (SD) on Likert scale ranging from agree (1) to disagree (4). MI motivational interviewing, PST problem solving treatment

Participant satisfaction and compliance

Of the participants who received at least one face-to-face counselling session (n=207) 78% were content with the sessions. Participants in the intervention group received a median of 2 (interquartile range 1-3) of the 6 scheduled counselling sessions.
Table 2. Mean baseline and follow-up values (SD) and between-group differences corrected for baseline (unstandardized B coefficient, 95% CI) of behavioural determinants

| PHYSICAL ACTIVITY |  |
|---|---|---|---|---|---|---|---|
| ATTITUDE | BASELINE (MEAN, SD) | INTERVENTION GROUP | GROUP DIFFERENCES |
| Control Group | Intervention Group | Control Group | Intervention Group | Control Group | Intervention Group | Control Group | Intervention Group |
| BASELINE | 5.6 ± 1.0 | 5.6 ± 1.0 | 5.6 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.6 ± 0.9 | 0.1 (-0.1 to 0.2) | 0.0 (-0.1 to 0.2) | 0.0 (-0.2 to 0.1) |
| 6 MONTHS | 5.7 ± 0.9 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.6 ± 0.9 | 0.1 (-0.1 to 0.2) | 0.0 (-0.1 to 0.2) | 0.0 (-0.2 to 0.1) |
| 12 MONTHS | 5.7 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.6 ± 0.9 | 0.1 (-0.1 to 0.2) | 0.0 (-0.1 to 0.2) | 0.0 (-0.2 to 0.1) |
| 24 MONTHS | 5.7 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.5 ± 1.0 | 5.6 ± 0.9 | 0.1 (-0.1 to 0.2) | 0.0 (-0.1 to 0.2) | 0.0 (-0.2 to 0.1) |
| SUBJECTIVE NORMS | 3.7 ± 1.1 | 2.3 ± 1.1 | 2.2 ± 1.1 | 2.1 ± 1.1 | 2.1 ± 1.1 | 2.1 ± 1.1 | 3.7 ± 1.2 | -0.2 (-0.4 to 0.0)* | -0.1 (-0.2 to 0.1) | 0.0 (-0.2 to 0.2) |
| PBC | 3.1 ± 0.7 | 3.1 ± 0.7 | 3.1 ± 0.7 | 3.0 ± 0.7 | 3.0 ± 0.7 | 3.0 ± 0.6 | 3.1 ± 0.2 | 0.0 (-0.1 to 0.1) | -0.1 (-0.2 to 0.0) | 0.0 (-0.1 to 0.1) |
| INTENTION | 3.2 ± 1.2 | 3.1 ± 1.2 | 3.2 ± 1.1 | 3.0 ± 1.2 | 3.1 ± 1.3 | 2.9 ± 1.3 | 3.0 ± 1.2 | -0.1 (-0.3 to 0.1) | -0.2 (-0.4 to 0.0) | -0.1 (-0.1 to 0.3) |

| DIETARY BEHAVIOUR |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ATTITUDE | BASELINE (MEAN, SD) | INTERVENTION GROUP | GROUP DIFFERENCES |
| Control Group | Intervention Group | Control Group | Intervention Group | Control Group | Intervention Group | Control Group | Intervention Group |
| BASELINE | 5.8 ± 0.9 | 5.8 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.8 ± 0.9 | 0.0 (-0.1 to 0.1) | 0.0 (-0.1 to 0.1) | -0.1 (-0.2 to 0.1) |
| 6 MONTHS | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.8 ± 0.9 | 0.0 (-0.1 to 0.1) | 0.0 (-0.1 to 0.1) | -0.1 (-0.2 to 0.1) |
| 12 MONTHS | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.8 ± 0.9 | 0.0 (-0.1 to 0.1) | 0.0 (-0.1 to 0.1) | -0.1 (-0.2 to 0.1) |
| 24 MONTHS | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.9 ± 0.9 | 5.8 ± 0.9 | 0.0 (-0.1 to 0.1) | 0.0 (-0.1 to 0.1) | -0.1 (-0.2 to 0.1) |
| SUBJECTIVE NORMS | 2.2 ± 1.0 | 2.1 ± 1.0 | 2.0 ± 1.0 | 2.1 ± 1.1 | 2.0 ± 1.0 | 2.0 ± 1.0 | 2.0 ± 1.0 | 0.0 (-0.1 to 0.2) | 0.1 (-0.1 to 0.2) | -0.1 (-0.2 to 0.2) |
| PBC | 3.3 ± 0.8 | 3.4 ± 0.7 | 3.4 ± 0.7 | 3.3 ± 0.7 | 3.4 ± 0.7 | 3.4 ± 0.7 | 3.4 ± 0.7 | 0.0 (-0.1 to 0.1) | 0.0 (-0.2 to 0.1) | 0.0 (-0.1 to 0.1) |
| INTENTION | 3.0 ± 1.1 | 2.9 ± 1.0 | 2.8 ± 1.0 | 3.1 ± 1.2 | 2.7 ± 1.1 | 2.6 ± 1.0 | 2.8 ± 1.1 | -0.1 (-0.3 to 0.0) | 0.1 (-0.1 to 0.3) | 0.2 (-0.1 to 0.3) |

| SMOKING |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ATTITUDE | BASELINE (MEAN, SD) | INTERVENTION GROUP | GROUP DIFFERENCES |
| Control Group | Intervention Group | Control Group | Intervention Group | Control Group | Intervention Group | Control Group | Intervention Group |
| BASELINE | 4.9 ± 1.1 | 4.7 ± 1.0 | 4.7 ± 1.0 | 5.0 ± 0.9 | 4.8 ± 1.2 | 4.7 ± 1.0 | 4.5 ± 1.2 | 4.7 ± 1.2 | 0.3 (-0.1 to 0.8) | -0.1 (-0.8 to 0.5) | -0.3 (-0.7 to 0.1) |
| 6 MONTHS | 4.7 ± 1.0 | 4.7 ± 1.0 | 5.0 ± 0.9 | 4.8 ± 1.2 | 4.7 ± 1.0 | 4.5 ± 1.2 | 4.7 ± 1.2 | 0.3 (-0.1 to 0.8) | -0.1 (-0.8 to 0.5) | -0.3 (-0.7 to 0.1) |
| 12 MONTHS | 4.7 ± 1.0 | 4.7 ± 1.0 | 5.0 ± 0.9 | 4.8 ± 1.2 | 4.7 ± 1.0 | 4.5 ± 1.2 | 4.7 ± 1.2 | 0.3 (-0.1 to 0.8) | -0.1 (-0.8 to 0.5) | -0.3 (-0.7 to 0.1) |
| 24 MONTHS | 4.7 ± 1.0 | 4.7 ± 1.0 | 5.0 ± 0.9 | 4.8 ± 1.2 | 4.7 ± 1.0 | 4.5 ± 1.2 | 4.7 ± 1.2 | 0.3 (-0.1 to 0.8) | -0.1 (-0.8 to 0.5) | -0.3 (-0.7 to 0.1) |
| SUBJECTIVE NORMS | 3.0 ± 1.2 | 3.1 ± 1.1 | 3.0 ± 1.3 | 3.2 ± 1.0 | 3.0 ± 1.3 | 2.8 ± 1.4 | 2.7 ± 1.2 | 2.7 ± 1.2 | -0.1 (-0.4 to 0.3) | 0.1 (-0.4 to 0.5) | -0.3 (-0.7 to 0.2) |
| PBC | 2.8 ± 0.9 | 2.9 ± 0.8 | 2.5 ± 0.8 | 2.9 ± 0.9 | 2.8 ± 1.1 | 2.7 ± 1.0 | 2.9 ± 1.1 | 2.9 ± 0.9 | 0.0 (-0.3 to 0.2) | 0.3 (0.1 to 0.6)* | -0.2 (-0.5 to 0.1) |
| INTENTION | 3.4 ± 1.4 | 3.3 ± 1.3 | 3.3 ± 1.3 | 3.3 ± 1.3 | 3.2 ± 1.4 | 3.2 ± 1.4 | 3.2 ± 1.4 | 3.2 ± 1.4 | 0.1 (-0.5 to 0.4) | 0.1 (-0.4 to 0.6) | -0.1 (-0.7 to 0.4) |

*p < 0.05  SD standard deviation, CI confidence interval, PBC perceived behavioural control
Note: Higher scores are in favour of behavioural change. Positive B for between-group differences are in favour of the intervention group
Implementation
Competence of practice nurses

Mean scores on the MITI, MISC and PSCC for both coders are presented in Table 4. In at least half of the sessions, global ratings (empathy, MI spirit and direction) and percentage MI adherence were judged as sufficient by both coders. Almost all scores were 2 or above except for one session on the sub-score MI-spirit autonomy. Although the reflection-question ratio was not bad, relatively few sessions (37%) met the pre-set level of sufficiency for the reflection-question ratio.

The general therapeutic skills and the problem solving skills of the practice nurses measured with the PSCC were good. The mean scores of part 2 of the PSCC were above the pre-set cut-off score, suggesting a satisfactory implementation of PST skills.

Table 4. Mean scores (range) and inter-coder reliability on the MITI, MISC and PSCC

<table>
<thead>
<tr>
<th></th>
<th>CODER 1</th>
<th>CODER 2</th>
<th>INTER-CODER RELIABILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MITI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reflection question ratio</td>
<td>0.82 (0.35-1.53)</td>
<td>0.82 (0.25-1.78)</td>
<td>NA</td>
</tr>
<tr>
<td>% MI adherence</td>
<td>94.5 (87-100)</td>
<td>93.2 (82.6-8.9)</td>
<td>NA</td>
</tr>
<tr>
<td>Empathy</td>
<td>2.81 (2-3)</td>
<td>2.57 (2-4)</td>
<td>0.43</td>
</tr>
<tr>
<td>MI spirit</td>
<td>2.57 (2-3)</td>
<td>3 (2-4)</td>
<td>0.33</td>
</tr>
<tr>
<td>Direction</td>
<td>4.13 (2-5)</td>
<td>3.71 (2-4)</td>
<td>0.32</td>
</tr>
<tr>
<td><strong>MISC</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% change talk</td>
<td>58.2 (10-83)</td>
<td>74.8 (62-82)</td>
<td>NA</td>
</tr>
<tr>
<td><strong>PSCC</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General therapeutic skills</td>
<td>2.93 (1-4)</td>
<td>3.33 (2-4)</td>
<td>0.31</td>
</tr>
<tr>
<td>Problem solving skills</td>
<td>2.11 (1-4)</td>
<td>2.84 (1-4)</td>
<td>0.51</td>
</tr>
</tbody>
</table>

MITI motivational interviewing treatment integrity
MISC motivational interviewing skill code
PSCC Problem solving competency checklist
aScores are Kappa’s with quadratic weighting between coder 1 and 2
b (total amount of utterance - MI non adherence) / total amount of utterance * 100
c change talk / (change + sustain talk) * 100
NA not applicable
DISCUSSION

The Hoorn Prevention Study set out to evaluate the effectiveness of an innovative lifestyle intervention in at-risk adults, compared to the provision of health brochures only. The aim of the current study was to systematically evaluate the programmes’ reach, effectiveness on intermediate determinants, adoption by the target settings, and its implementation. The findings indicate that the recruitment strategy was adequate and resulted in a reasonably high reach of the target population. Two-third of the eligible individuals participated in the study. The practice nurses were reasonably competent and confident in providing MI and PST, and participant satisfaction was relatively high. Nevertheless, the number of sessions attended was low, and almost no effects on intermediate determinants of behavioural change were observed.

In order to select people who are at risk of T2DM and CVD, self-measured waist circumference was used as a first screening step, which proved to be a simple and feasible method. Relatively few participants were lost to follow-up at 6, 12 and 24 months (n= 86, 34, 22 respectively).

Our intervention addressed several components of the TPB, and made use of effective components and behavioural change strategies identified in the scientific literature (i.e. MI and PST). Apart from a small increase in perceived control regarding smoking at the second follow-up, participants showed no benefit of the intervention in terms of cognitive behavioural determinants. Thus, in spite of the practice nurse’s actual and perceived competence in providing the intervention, it had a very limited effect on changes in determinants of physical activity, dietary- or smoking behaviour in adults at high risk of developing T2DM and/or CVD.

Most participants were content with the face-to-face counselling sessions, but some were not. In particular, at the beginning of the intervention, some practice nurses indicated that various participants expected that they would be told what to do and disliked the directive nature of the counselling. This may have contributed to the rather low attendance rate.

The practice nurses used an innovative combination of MI and PST counselling skills to prompt the participants to find solutions rather than telling participants how to change behaviour, and supported them in implementing these solutions in their lives. It has been demonstrated previously that MI and PST were
significantly more effective than attention alone,\textsuperscript{15,16} and strong evidence exists that supports the efficacy of MI in changing different lifestyle behaviours.\textsuperscript{17} However, the effectiveness of this complex counselling may very well depend on the degree to which they are being mastered. With regard to mastery, this study indicates that the practice nurses were reasonably skilled and confident in using MI and PST in the counselling sessions. Most of the practice nurses indicated after the training that they were capable of providing the intervention, and our assessment using reliable and valid instruments for evaluating the specific counselling skills also indicated that the nurses were indeed quite skilled in using MI and PST. Nevertheless, this study also showed that their performance left room for improvements. Improvement of the counselling techniques may require a longer period of training in MI and PST. From a potential implementation standpoint however, it would not be feasible to provide more training in everyday practice, given the relatively little time for additional education in the practice nurses’ agendas. Furthermore, the daily work of practice nurses requires a different type of professional contact with their patients (e.g. giving advice or explain what needs to be done). Using MI and PST involves a shift in daily practice that may need more time to be implemented fully.

Conclusions
Lifestyle programmes to prevent T2DM and CVD have become increasingly popular during the last decade. Our findings indicate that the recruitment strategy was adequate and resulted in a relatively high reach of the target population. Practice nurses were reasonably competent and confident in providing MI and PST, and participant satisfaction was high. Nevertheless, the number of sessions attended was low, and no effects on determinants of lifestyle behavioural change were seen. We conclude that implementing this type of interventions in primary care is feasible, but more is needed to effectively facilitate changes in determinants of lifestyle behaviours in adults at risk of T2DM and CVD.
REFERENCES


Additional file 1. Description of the MITI 3.0 and MISC

**MITI 3.0**
The MITI 3.0 consists of two components; the global ratings and the counsellor behaviour counts. The global ratings are subdivided in three dimensions: empathy, MI spirit and MI direction. The aim of these dimensions is to evaluate the general impression of the counsellor. These dimensions are measured on a 5-point Likert-type scale, the encoder starting with 3 and going from that point up (good) or down (bad). The counsellor behavioural counts are measures for different expressions given by the counsellor. The expressions are divided in open and closed questions, simple and complex reflections, MI adherent and MI non-adherent. In MI the behavioural count open questions is considered more sufficient than closed question, complex reflections more sufficient than simple and reflections more sufficient than questions. The behavioural count MI adherent is not ‘harmful’, but is facilitating, so MI adherent expressions can be used by one’s own discretion. On the contrary, MI non-adherent is ‘harmful’ and must be avoided.

**MISC**
Three coding passes are included in the MISC. For this study only client change and sustain talk counts of the second pass will be used, because the ratio change versus sustain talk counts are good indications for MI competence. The change talk counts are measures of expressions in favour of change giving by the client while sustain talk count are measures of expressions moving away from change. The reliability and validity was good for this part of the MISC.

Additional file 2. The modified PSCC

*Note:* The original PSCC consists of four general therapeutic skill items, six problem-solving skill items and three overall ratings. In the modified PSCC as used in this study, one item is added to the general therapeutic skill dimension, two items are added to the problem-solving skill dimension and three overall ratings are removed. By adding the two PST items all important stages of PST are represented in the instrument. All items consist of four rating possibilities with scores from 1 to 4. The reliability and validity levels of the PSCC are unknown but the original measurement seems to be good in dividing problem-solving counsellors from generic counsellors.
Part 1: General therapeutic skills

Clarity of communications
1) Counsellor overused jargon and was muddled in his/her presentation of information.
2) Counsellor presented information in a generally coherent fashion but was overly technical.
3) Counsellor presented information in a generally clear way.
4) Counsellor presented information in a clear and well-ordered fashion and checked participants’ understanding.

Pacing and efficient use of time
1) Counsellor made no attempt to structure therapy time. Session seemed aimless.
2) Session had some direction, but the counsellor had significant problems with structuring or pacing (e.g. too little structure, inflexible about structure, too slowly paced, too rapidly paced, unable to deal with over-talkativeness).
3) Counsellor was reasonably successful at using time efficiently. Counsellor maintained appropriate control over flow and aim of discussion and pacing.
4) Counsellor used time very efficiently by pacing the session as rapidly as was appropriate for the participant and draw attention to main subjects.

Facilitates communication
1) No attempt to facilitate participant communication.
2) Some use of facilitating skills but overuse of closed questions with little encouragement for participant to be open about problems.
3) Counsellor made reasonable efforts to facilitate communication.
4) Every effort made to facilitate communication - relaxed, open posture; made facilitative noises while listening; made supportive comments.

Interpersonal effectiveness
1) Counsellor had poor interpersonal skills. Seemed hostile, demeaning, or in some other way destructive to the participant.
2) Counsellor did not seem destructive, but had significant interpersonal problems. At times, counsellor appeared unnecessarily impatient, aloof,
insincere or had difficulty conveying confidence and competence.

3) Counsellor displayed a satisfactory degree of warmth, concern, confidence, genuineness and professionalism. No significant interpersonal problems, but frame of reference differs sometimes.

4) Counsellor displayed optimal levels of warmth, concern, confidence, genuineness and professionalism, appropriate for this particular participant and in this session.

*Success experience and giving compliments*

1) Counsellor did not give compliments, but highlight thing which went wrong.

2) Counsellor did not give compliments, but encouraged participant in some degree.

3) Counsellor gave satisfactory compliments, encouraged the participant and paid attention to the experiences.

4) Counsellor gave compliments, highlighted the success experiences and encouraged participant
Part 2: Application of problem-solving techniques

Explanation and rationale when PST is used for the first time

1) Counsellor used procedures without adequate and explicit rationale.
2) Counsellor tended to give incomplete and/or unclear rationale for procedures used.
4) Counsellor gave complete rationale and established participant comprehension.

Clearly defining the problem

1) No attempt to define problem.
2) Some attempt to clarify problem but problem remains somewhat woolly and definite. Complex problems not broken down.
3) Satisfactory attempt to clarify problem.
4) Excellent definition of problem, participant and counsellor both clear about problem.

Setting achievable goals

1) No goals set.
2) Goals set but by counsellor not participants, or goals not achievable during therapy, or goals remain vague and non-specific.
3) Reasonable attempt to set clear SMART goals.
4) SMART goals set by the participant and participant understands the goals set.

Looking at solutions

1) No attempt made to consider different solutions.
2) Inadequate considerations of alternative solutions, or too many ideas from counsellor.
3) Satisfactory attempt to consider alternative solutions.
4) Good structured approach to consider alternative solutions, involving brainstorming participant’s ideas; deferring judgment until as many solutions as possible considered.
Choosing solution
1) No decision was made.
2) Solution was chosen by counsellor without decision-making guidelines.
3) Decision made.
4) Decision made by participant and clear decision making guidelines spelt out.

Plan of execution
1) No plan of execution is made.
2) Plan is made by counsellor not participant, or no achievable plan is made or plan remains vague and no-specific.
3) Satisfactory attempt to make plan.
4) Excellent plan made by participant.

Homework
1) Counsellor did not set homework.
2) Homework tasks set but not clearly defined.
3) Homework tasks set with satisfactory detail.
4) Clear homework tasks set out in precise terms with times and frequency of activities where appropriate. Participant seems to understand the relevance of tasks set.

Reviewing previously set homework.
1) Counsellor did not review previous homework.
2) Counsellor reviewed previous homework poorly and in a cursory fashion.
3) Counsellor reviewed previous homework competently.
4) Counsellor reviewed previous homework very well, praising success and making helpful positive comments about failure, using homework then as platform for session.