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Effect evaluation of a Motivational Interviewing based counselling strategy in diabetes care

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ABSTRACT

Aim: The present study assessed the effects of a Motivational Interviewing (MI) based counselling training for nurses on clinical, behavioural and process outcomes among diabetes type 2 patients.

Methods: The study is an RCT with follow-up measurements after 12 and 24 months. Thirty-three nurses and 584 patients participated. Nurses in the experimental condition received the training; control group nurses were trained after the study. The training consisted of two training sessions, two follow-up meetings, written feedback and three direct feedback sessions. Basic MI-principles and techniques and an MI-based counselling protocol were addressed.

Results: Results indicated disadvantageous effects on fat intake and HDL and advantageous effects on chance locus of control and knowledge. No effects were found on vegetable or fruit intake, physical activity, HbA1c, weight, blood pressure, total cholesterol, LDL, triglycerides, health care climate, quality of life or on self-efficacy.

Conclusions: As in other MI studies, mixed results were found. It would be premature to recommend dissemination of MI in diabetes care. More studies are needed in real-world settings with health care professionals of the field instead of intensively trained MI interventionists. Knowledge should be gained about adequate training and factors contributing to the implementation of MI in daily practice.

1. Introduction

The incidence of diabetes type 2 (DM2) worldwide increases rapidly due to changing lifestyles and increased longevity [1,2]. In addition to physical and psychological burden to the patient, the increase in diabetes causes a financial burden to society [3]. Besides pharmacological treatment, lifestyle modification (such as adjustment of diet and physical activity) is a crucial element in treatment to prevent or delay the onset of complications [4–6]. Because of their daily responsibility for a large number of behavioural choices and activities, patients play a central role in their own treatment. Patients experience difficulties with self-management during daily life, contributing to frequent suboptimal control of risk factors [7–10]. To limit the consequences of the increase of patients with DM2, effective ways of patient counselling are urgently needed.

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A promising counselling strategy in the treatment of lifestyle problems and disease is 'Motivational Interviewing' (MI). MI is defined as 'a client-centred, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence' (p. 25) [11]. In contrast to traditional, more paternalistic, counselling styles, MI gives the patients' knowledge and experiences a central role in finding the best behaviour change strategies. The motivation to change should originate from the patient instead of being imposed by the health care professional.

MI was originally developed in the addiction field, but this relatively new counselling style is increasingly being advocated in other health areas such as diet, exercise, and diabetes [12–14]. Nevertheless, consistent evidence for the effectiveness of MI in these areas is still limited and additional research is indicated [14–16]. MI in chronic disease care may require a different approach than in addictive behaviours and the health care providers are different [14]. However, as summarized by Martins and colleagues [17], MI shows potential for diabetes care. In some of the nine studies reviewed by Martins and colleagues [17], beneficial effects on glucose levels, physical activity, weight and engagement in dietary changes were found. In all studies the intervention consisted of separate (additional) MI-sessions aimed at behaviour change instead of MI embedded in usual care.

In conclusion, MI seems promising for diabetes care but its effectiveness when incorporated in daily practice and not as a separate intervention in addition to usual care is still unclear. Therefore, the present study determined the effects of an MI-based counselling training to nurses on clinical, behavioural and process outcomes in DM2 patients. Nurses were supposed to use the counselling style during usual care.

2. Methods

2.1. Study design and procedures

In The Netherlands, diabetes care is provided mainly in primary care. In most practices patients are seen annually by their general practitioner and quarterly by a ''practice'' nurse, whose main tasks are monitoring the disease, providing education and lifestyle counselling. These nurses specialize in the care in chronic diseases such as diabetes and COPD, and are supervised by the general practitioner.

General practices were recruited in the southern parts of The Netherlands. In total 33 nurses participated. Nurses were asked to list all eligible patients within their practice(s): DM2 for $\leq$5 years and an age between 40 and 70 years. Patients were excluded if they had severe co-morbidity or insufficient command of the Dutch language. All patients were invited by letter to participate in the study. Of the 1517 patients approached, 618 patients (41%) signed informed consent. Based on the in- and exclusion criteria, 584 patients were included.

This study is a cluster randomized controlled trial. Nurses within a district frequently contact each other and have shared training sessions. To avoid contamination, cluster randomization was chosen. With a computerized randomizer, two districts (18 nurses) were assigned to the experimental condition and two districts (15 nurses) were assigned to the usual care condition. Nurses could not be blinded but assessment of outcomes was done by an independent observer.

The intervention started in autumn 2006, when nurses of the experimental condition were trained. The effects of the intervention were measured among patients. Besides a pre-test before the start of the intervention, post-tests were conducted after 12 and 24 months (autumns of 2007 and 2008).

The medical ethics committee of the academic hospital Maastricht and Maastricht University approved the study.

2.2. Intervention

Nurses in the experimental condition received an MI-based counselling training after baseline measurements. Nurses were supposed to apply the new counselling style during standard quarterly consultations with their patients. Patients of control group nurses received usual care: quarterly consultations with a nurse who did not attend the MI-based training.

During the two years of study, nurses and patients from the experimental and control group had access to a web-based education programme (www.diep.info) that was developed to support self-management by patients. This programme does not only provide information, but also offers tools to support self-reflection, goal setting, problem solving, and active patient participation. The development and content of this programme is described in detail elsewhere [18].

2.2.1. Training

Two 5-h sessions were organized to train nurses in an adapted form of MI and the use of the education tool. The MI part was given by a certified trainer. The training consisted of presentations, demonstrations, role-playing and discussions. Nurses received a project folder with information about the study, training material (e.g. cases for role-playing), background information about MI including examples of dialogues between health care professionals and patients, and information about the education tool and how to use it. Furthermore, nurses received instruction charts specifying counselling techniques to support them during consultations. In the week between the two sessions, nurses were asked to read all the MI background information and the information about the education programme (diep.info). Three months after the training, nurses received written feedback on two audio-taped consultations. Besides, nurses were visited three times during their work for direct feedback (3 h per visit), approximately 6, 9 and 11 months after the training. The first time this was done by the MI-trained researcher, while the second and third visits were done by the MI-trained teaching nurse. Additionally, nurses had two opportunities to assemble an afternoon to share experiences and practice together; 8 months and 18 months after the training. In total, approximately 21.5 h counselling training was given, and 5 h optional group meetings.

2.2.2. Adapted Motivational Interviewing

The counselling intervention was based on MI [11] and health behaviour change counselling [19] and was designed to fit to

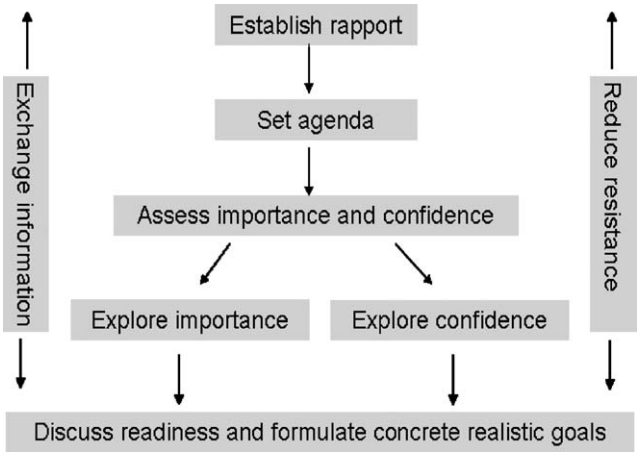

Fig. 1 – Counselling protocol.

diabetes care consultations (approximately 20 min per consultation).

During the first day of training, basic principles and techniques of Motivational Interviewing were addressed: expressing empathy, developing discrepancy, rolling with resistance, supporting self-efficacy, getting permission for actions, avoiding the provision of unsolicited advice and/or information, using open-ended questions instead of closed questions, using reflections and using summaries [11,19].

The second day focused on a MI-based counselling protocol, see Fig. 1, and the use of the education programme. The protocol consisted of the following steps: establish rapport, set agenda together with patients, assess importance and confidence, explore importance and confidence, summarize positive and negative issues of behaviour change, discuss a plan with patients, set concrete and realistic goals with a patient if the patient is ready for change and there is a need for goals, summarize the plan and ask if the patient agrees, and finish the consultation appropriately. Strategies that were learned to explore importance and confidence were the 0–10 strategy, the matrix of pros and cons, and brainstorming about solutions [11,19]. Counselling skills targeting behaviour change, for example exploring confidence, only had to be used when there was a reason to, like declining medical outcomes. Other skills such as basic principles and techniques should always be used.

2.3. *Outcome measures*

Measurements took place at baseline, after 12 months and after 24 months. Patients completed a self-administered, written questionnaire with mainly validated scales on self-management behaviours and process-outcomes, supplemented with a question about the use of www.diep.info and background variables. The latter included age, sex, ethnicity, educational level, time since diagnosis and living situation (alone or together). Nurses recorded several clinical parameters.

2.3.1. *Self-management behaviours*

Fat, fruit and vegetable intakes were measured using validated food frequency questionnaires (FFQ) [20,21]. The fat FFQ assessed the frequency and amount of 19 products or product groups contributing most to saturated fat intake. Instead of grams fat, a fat score (range 0–80) is calculated because the FFQ does not cover all sources of saturated fat [20]. The FFQ for fruit and vegetable intake assessed the frequency and quantity of fruit, fruit juice and raw or cooked vegetables. Average fruit and vegetable intake in grams per day were calculated [21].

Two items of the Summary of Diabetes Self-Care Activities scale (SDSCA) were used to assess smoking (smoked during the past seven days; yes/no) and to assess whether the physical activity (PA) standard of $\geq$30 min on at least 5 days a week was met (PA-norm) [22].

Additionally, to have a measure of the amount of PA and time spent sedentarily, the Dutch short form of the 'International Physical Activity Questionnaire' (IPAQ) was used [23,24]. This 'last 7 days recall form' assessed walking, moderate-intensity activities, vigorous-intensity activities and sedentary time. For PA, a MET-min/week sum score was used as outcome measure (PA-score).

2.3.2. *Clinical parameters*

Nurses recorded the following clinical parameters up to 12 weeks old or late at baseline and up to 6 weeks old or late at follow-up: height and weight (for body mass index calculation), blood pressure (BP), glycated haemoglobin (HbA1c), fasting cholesterol (total, LDL, HDL) and triglycerides.

2.3.3. *Process outcomes*

According to the Self Determination Theory [25] increased perceived competence is influenced by perceived autonomy support and improves patient outcomes [26,27]. To asses the patient's perception of the degree to which the nurse supported autonomy, the Health Care Climate Questionnaire (HCCQ) was used (15 items, Cronbach's $\alpha = 0.95$) [28]. It includes items such as "I feel that my physician has provided me with choices and options". Answers were given on a 1 (strongly disagree) to 7 (strongly agree) scale. Also, perceived competence was assessed by the Diabetes Management Self-Efficacy Scale for people with DM2 (DMSES) (18 items, Cronbach's $\alpha = 0.81$) [29]. It includes items such as "I think I am able to overcome high blood glucose levels". The answering options range from 1 (no, certainly not) to 5 (yes, certainly).

Health Locus of Control (HLOC) was measured with the Dutch version of the diabetes specific health locus of control scale for diabetes patients [30]. Three loci of control were distinguished [31–33]: Internal, Powerful others and Chance HLOC referring to the beliefs that health outcomes are dependent on one's own behaviour (IHLOC, Cronbach's $\alpha = 0.85$) [33], on the health care provider (PHLOC, Cronbach's $\alpha = 0.75$) [33], or that health outcomes are random occurrences (CHLOC, Cronbach's $\alpha = 0.72$) [33]. Each sub-scale consisted of six items with a Likert-scale ranging from 'fully agree' (1) to 'fully disagree' (6). Subscale scores were sum scores of all six items (range 6–36).

Diabetes specific quality of life (DSQoL) was measured with the Problem Areas in Diabetes Scale (PAID) (20 items, Cronbach's $\alpha = 0.95$) [34]. This is a self-report measure of diabetes-related distress. Respondents indicate the extent to

which a specific aspect of diabetes management is a problem, on a 5-point Likert scale ranging from 'no problem' (0) to 'a serious problem' (4). For example, ''Feel discouraged about your treatment''.

Additionally, diabetes knowledge was measured by a multiple choice questionnaire (50 items), with a minimum of 0 (zero correct answers) and a maximum score of 50 (all 50 questions correct). To our knowledge there was no validated Dutch knowledge questionnaire, therefore we developed our own. The questionnaire addressed questions about diet (e.g. Does milk contain carbohydrates?), PA (e.g. Through regular exercise, blood glucose levels can increase), causes and consequences of diabetes (e.g. Diabetes can cause cardiovascular diseases), and overweight and diabetes (e.g. In patients with diabetes who are overweight, insulin works better than in patients with a healthy weight).

2.4. *Analyses*

Prior to our study, a power analysis (using Health Locus of Control as criterion variable) led to an initial sample size needed of 120 patients per cell ($p < .05$, power = .09); because of expected drop-out we increased the sample size to the final 584 (also because sampling actually was done on the level of the nurses, not the patients).

Data analyses included descriptive statistics of the demographic variables and outcome parameters. Missing data on items of (sub)scales were replaced by the mean score of the individual on the other items of that (sub)scale, but only when no more than 20% of the values were missing. Scores on the DSQoL-scale and the PA-score were not distributed normally and therefore log-transformed. In the case of the HCCQ-score, which was also not normally distributed, transformation did not help. Therefore, next to the continuous HCCQ-outcome, a binary outcome measure based on the median (below or at the median versus above median) was computed. The same was done for the SDSCA-variable which measured the number of days an individual is physically active for at least 30 min a day. This variable was transformed into a binary variable for the analysis; 'A minimum of 30 min PA on at least 5 days a week: yes/no'.

Since we had multiple measurements and patients were nested within practices, multilevel analyses were conducted to test differences between the experimental and control group at baseline and at follow-up measurements regarding behavioural, clinical and process outcomes, correcting if necessary for influences of time since diagnosis, age, sex, educational level and living situation. Within some practices there was more than one nurse. Patients were not seen solely by one of them and it was impossible to trace which patient was seen by which nurse at all consultations. Therefore it was decided to omit nurses as a level from the analysis. Continuous outcome measures were analyzed with *linear* mixed regression in SPSS and binary outcome measures with *logistic* mixed regression in MLwiN [35]. In the multilevel approach available cases are included instead of only complete cases [36], thus enabling an intention-to-treat analysis. An analysis on available cases results in more statistical power. Furthermore, the multilevel approach assumes that missings are at random (MAR), that is, they may depend on variables included in the model. This is more flexible than assuming that missings are *completely* at random (MCAR), in which case they are not allowed to depend on any variable, an assumption made when performing the analyses only on complete cases.

Random slopes and random intercepts were tested first, followed by the fixed effects according to a top-down procedure. The least and non-significant components were deleted step-by-step from the model with a significance level of 0.10. In the most reduced model, the intervention effects were examined with a 0.05 significance cut-off point. First an overall intervention effect across both follow-up measurements was tested. Only when the overall effect was significant, short and long term effects of the intervention were examined separately. In all analyses, a correction for baseline scores was made.

3. Results

3.1. *Descriptives*

From a total of 36 general practices, 584 patients started in our study of which 537 (92%) filled out the baseline questionnaire, 447 (77%) filled out the questionnaire at twelve months follow up and finally 423 (72%) filled out the questionnaire at 24 months. Of all patients, 389 (67%) filled out all three questionnaires and 32 (5%) filled out none.

Concerning clinical parameters, 570 (98%) patients had at least one valid value at baseline, 498 (85%) at 12 months follow up and 462 (79%) at 24 months.

The average age of the patients was 59 years (SD = 5.27) and somewhat less than half of them were female (44.9%). Most patients had lower education (61.7%), 23.6% had a medium level of education and 14.7% had a high educational level. Approximately one quarter (26.4%) of the patients was diagnosed with diabetes $\leq$1 year, 47.0% between 2 and 3 years and 26.6% 4 and 5 years. During the 2-year follow up, 138 (29.1%) patients visited the educational programme (diep.info) at least once. In the control group, 79% of the patients never visited the website and another 10% only visited the website once. For the experimental group these percentages are 73% and 13% respectively. At baseline, 77.3% had an HbA1c level below 7% (norm score); approximately 41.3% had a (Body Mass Index) BMI below 28 and 42.2% had a BMI above 30.

Tables 1a and 1b show baseline scores and the results of the comparison between experimental and control group. No significant differences between the experimental and control group were found in patient characteristics or outcome measures, except for smoking status, physical activity and fat intake. Patients of the experimental group had a lower fat intake (−1.5 points), a lower PA-score (−110 MET-min/week), and smoked more often (+8.8%).

3.2. *Intervention effects*

Table 2 shows the corrected effect estimates for self-management behaviours (vegetable, fruit and fat intake, physical activity, sedentary time and smoking) after 12 months and after

Table 1a – Baseline continuous outcome scores and differences between experimental and control group.

	Experimental group		Control group		C – E[a]
	N	Mean (SD)	N	Mean (SD)	
Behavioural outcomes					
Vegetable intake (grams a day)	273	191.11 (84.65)	258	198.74 (81.94)	7.63
Fruit intake (grams a day)	273	335.76 (218.73)	258	345.54 (201.39)	9.78
Fat intake (points, score 0–95)	275	15.91 (6.09)	262	17.44 (5.62)	1.53**
PA-score (MET-minutes per week)	153	3675.62 (4796.12)	139	3785.61 (3985.86)	109.99*
Sedentary time (minutes a day)	151	368.18 (200.88)	148	329.59 (178.15)	−38.59
Clinical outcomes					
HbA1c (%)	287	6.49 (0.85)	272	6.51 (0.74)	0.02
Weight (kg)	280	88.77 (17.39)	268	88.23 (17.19)	−0.54
Systolic BP (mmHG)	280	138.63 (15.88)	270	137.15 (15.96)	−1.48
Diastolic BP (mmHG)	280	81.95 (7.91)	270	81.01 (8.68)	−0.94
Total cholesterol (mmol/l)	267	4.64 (0.98)	249	4.62 (0.88)	−0.02
LDL (mmol/l)	267	2.60 (0.92)	251	2.65 (0.79)	0.05
HDL (mmol/l)	267	1.22 (0.32)	249	1.17 (0.30)	−0.05
Triglycerides (mmol/l)	267	1.76 (1.01)	252	1.69 (0.85)	−0.07
Process outcomes					
HCCQ-score (score 1–7)	273	6.00 (1.11)	260	6.21 (0.91)	0.21
IHLOC (score 6–36)	270	28.27 (4.75)	256	28.59 (4.43)	0.32
PHLOC (score 6–36)	271	25.78 (5.67)	256	26.40 (5.40)	0.62
CHLOC (score 6–36)	270	15.60 (5.70)	256	14.76 (5.17)	−0.84
DSQoL (score 0–80)	274	16.83 (13.32)	259	16.98 (13.92)	0.15
DMSES (score 18–90)	268	73.16 (9.42)	259	72.26 (9.46)	−0.90
Knowledge (score 0–50)	270	31.93 (7.76)	251	33.04 (6.27)	1.11

[a] Control group mean minus experimental group mean.
* $p < .05$.
** $p < .01$.

24 months follow-up. No significant differences between experimental and control group were found except for fat intake in favour of the control group. Correcting for baseline scores, patients of the experimental group had a higher fat intake both at 12 months follow-up and at 24 months follow-up ($p < 0.05$) when compared to the control group.

Concerning clinical parameters, at 12 months follow-up no intervention effects were found, see Table 3. At 24 months follow-up there is a significant difference between groups for HDL-cholesterol in favour of the control group. Compared to the control group, HDL-cholesterol was significantly lower in the experimental group at 24 months follow-up ($p < 0.01$).

The only significant intervention effects in favour of the experimental group were found on process outcomes, as shown in Table 2. On both follow-up measurements, 12 and 24 months, scores on the chance HLOC of the experimental group were significantly lower ($p < 0.01$) and their knowledge-scores were significantly higher (12 months; $p < 0.01$, 24 months; $p < 0.05$) compared to the control group.

4. Discussion

The present study was an evaluation of an MI-based counselling strategy embedded in usual diabetes care. Results

Table 1b – Baseline binary outcome scores and differences between experimental and control group.

	Experimental group: N (%)	Control group: N (%)	C – E[a]
Behavioural outcomes			
PA-norm:			0.01
Meets norm	165 (61.1%)	154 (59.7%)	
Does not meet norm	105 (38.9%)	104 (40.3%)	
Smoking:			0.10*
Yes	73 (26.5%)	45 (17.3%)	
No	202 (73.5%)	215 (82.7%)	
Process outcomes			
HCCQ:			0.02
≤Median	137 (50.2%)	126 (48.5%)	
>Median	136 (49.8%)	134 (51.5%)	

[a] Differences in proportions between experimental and control group.
* $p < .05$; **$p < .01$.

Table 2 – Results from the multilevel analyses of behavioural and process measures comparing experimental with control group.

	p-value overall intervention effect	Corrected effects[a] at 12 months follow-up Exp. versus contr. group (95% CI)	Corrected effects[a] at 24 months follow-up Exp. versus contr. group (95% CI)
Continuous			
Behavioural			
Vegetable intake (grams a day)	0.34	−6.42 (−18.41 to 5.57)	−8.66 (−20.88 to 3.56)
Fruit intake (grams a day)	0.28	4.52 (−27.09 to 36.14)	26.79 (−0.84 to 62.00)
Fat intake (points, score 0–95)	0.04	0.92* (0.13–1.72)	0.84* (0.03–1.66)
PA-score[b] (MET-minutes per week)	0.73	0.01 (−0.10 to 0.12)	−0.04 (−0.15 to 0.08)
Sedentary time (minutes a day)	0.16	−44.64 (−91.89 to 2.61)	−10.07 (−57.63 to 37.49)
Process			
HCCQ-score (score 1–7)	0.12	0.09 (−0.11 to 0.28)	0.21 (0.01–0.41)
IHLOC (score 6–36)	0.19	0.71 (−0.09 to 1.52)	0.12 (−0.70 to 0.94)
PHLOC (score 6–36)	0.47	0.29 (−0.64 to 1.22)	0.59 (−0.36 to 1.54)
CHLOC (score 6–36)	0.00	−1.56** (−2.39 to −0.73)	−1.33** (−2.18 to −0.48)
DSQoL[b]	0.35	−0.04 (−0.10 to 0.02)	−0.05 (−0.12 to 0.02)
DMSES (score 18–90)	0.69	0.35 (−0.89 to 1.60)	0.58 (−0.77 to 1.94)
Knowledge (score 0–50)	0.01	1.33** (0.42–2.24)	1.27* (0.31–2.24)

		Corrected odds ratios[a] at 12 months follow-up Exp. versus contr. group (95% CI)	Corrected odds ratios[a] at 24 months follow-up Exp. versus contr. group (95% CI)
Binary			
Behavioural			
PA-norm	0.50	0.76 (0.41–1.38)	0.71 (0.38–1.32)
Smoking	0.65	0.79 (0.33–1.86)	0.66 (0.28–1.59)
Process			
HCCQ (score 0–1)	0.92	1.12 (0.59–2.15)	1.00 (0.52–1.93)

[a] Corrected for baseline differences on the outcome variable and covariates.
[b] Log-transformed scores.
* $p < .05$.
** $p < .01$.

indicate no major intervention effects on outcome measures, although minor differences between groups were found at follow-up measurements for fat intake, HDL-cholesterol, chance health locus of control and knowledge.

Concerning fat intake and HDL-cholesterol an adverse effect was found. At baseline, the control group had a higher fat intake compared to the experimental group and a possible explanation for the decrease in fat intake in the control group could be that the subjects with a higher fat intake at baseline became more aware of their unhealthy behaviour as a result of filling out the baseline questionnaire. Alternatively, the differences at posttests might be a

Table 3 – Results from the multilevel analyses of clinical measures comparing experimental with control group.

	p-value overall intervention effect	Corrected effects[a] at 12 months follow-up Exp. versus contr. group (95% CI)	Corrected effects[a] at 24 months follow-up Exp. versus contr. group (95% CI)
HbA1c (%)	0.44	0.02 (−0.10 to 0.14)	0.09 (−0.05 to 0.23)
Weight (kg)	0.66	−0.03 (−0.79 to 0.73)	0.33 (−0.57 to 1.23)
Systolic BP (mmHG)	0.63	−1.09 (−3.91 to 1.72)	−1.29 (−4.17 to 1.59)
Diastolic BP (mmHG)	0.26	0.24 (−1.31 to 1.80)	1.27 (−0.32 to 2.86)
Total cholesterol (mmol/l)	0.25	0.06 (−0.09 to 0.22)	−0.08 (−0.56 to 0.10)
LDL (mmol/l)	0.77	0.05 (−0.08 to 0.18)	0.03 (−0.13 to 0.19)
HDL (mmol/l)	0.01	−0.02 (−0.06 to 0.01)	−0.07** (−0.12 to −0.03)
Triglycerides (mmol/l)	0.97	−0.02 (−0.16 to 0.13)	−0.02 (−0.17 to 0.14)

[a] Corrected for baseline differences on the outcome variable and covariates.
* $p < .05$.
** $p < .01$.

simple case of regression to the mean. Although an intervention effect was found on HDL-cholesterol, no effects were found on total or LDL-cholesterol. Besides, the corrected effect of -0.07 mmol/l is so small that it might be seen as clinically irrelevant.

Advantageous effects were found on chance HLOC (CHLOC) and knowledge. The effect on CHLOC indicates that people in the experimental group were less inclined than the control group to relate their diabetes control to chance factors. Empowered patients are considered to perceive more control over their diabetes, which has been associated with better self-management outcomes [37,38]. However, we found a decrease in CHLOC, but we did not find an increase in internal HLOC nor did we find a change in powerful others HLOC. Concluding that our intervention contributed to patient empowerment would therefore be premature and also inconsistent with the lack of effect on self-management outcomes. Concerning knowledge, due to the intervention patients might have had a more active role during consultations. As a result, patients possibly felt more confident to ask questions and this might have improved knowledge. However, the corrected effects of 1.33 and 1.27 mean a difference of <1.5 points on a scale of 0–50: a rather modest effect in terms of absolute magnitude.

All in all, based on our study we cannot conclude that our MI-based counselling strategy offers advantages over usual care. Previous research of MI in diabetes care is limited and has shown mixed effects. In two studies where MI-sessions given by a MI-trained psychologist were added to a weight loss intervention for female DM2 patients, effects of MI were found on glucose control [39,40], on blood glucose monitoring [39] and on weight [40]. In another study where three individual MI sessions and three follow-up telephone calls were added to usual DM care, no effects were found on glucose control or BMI, and inconsistent results were found for self-management behaviours [41,42]. Ismail and colleagues [43] evaluated four MI-sessions given by a diabetes nurse and added to usual care. They did not find any effect on glucose control, BMI, QoL or on self-management behaviours [43].

There are several factors in our study that might have influenced the outcomes. First of all: the interventionist. One of the differences between our study and previous studies is that our intervention was delivered by trained nurses instead of a psychologist. Although Rubak and colleagues [44] concluded that effectiveness was not related to the counsellor's educational background as medical doctor or psychologist, they did find that only 5 out of 11 studies that involved other health workers as MI-counsellors (e.g. nurses) were effective [44]. Perhaps we would have found better results when patients consulted a trained psychologist instead of a trained nurse. However, we aimed to embed MI in usual care, by usual health professionals.

A second factor that might have influenced the outcomes is that the counselling strategy had to be applied during regular consultations instead of separate MI-sessions in addition to usual care. This is especially difficult due to the different agendas of patients and nurses. Nurses' agendas may be influenced by treatment protocols and/or by reimbursement systems [45]. In usual diabetes care, not all consultations are dedicated to self-management. Self-management (including lifestyle changes) is only one topic besides other topics such as discussing side effects of medication, insurance issues, and eye examinations. In a study where MI was embedded in diabetes care, outcomes of consultations with a MI-trained dietician were compared to outcomes of consultations with a non-MI-trained dietician. As in our study, limited intervention effects were found. No effects were found on HbA1c, BMI, fruit and vegetable consumption except on fat consumption [46]. Accordingly, more studies are needed to know what the implications are of MI embedded in diabetes care delivered by patients' usual care givers.

A third study characteristic that might have influenced the outcomes is the intervention delivery dose [14]. If nurses were unable to adequately implement the strategy, there is a risk of a type III error [47]. This possible risk should be taken into account when interpreting the findings of our study. Training nurses to change their behaviour might be as challenging as helping patients to change [48]. Perhaps the nurses should have been trained more intensively to practice the MI-based counselling strategy in daily work. We offered two training sessions, two follow-up meetings, written feedback once and three direct feedback sessions during daily work which is more than what is done in other studies where courses often have a workshop format without any kind of follow-up [49]. The question is how realistic it is to demand even more training time than what we did. A possible solution to this would be to incorporate training in MI counselling strategies during regular courses for students. Training intensity is only one aspect of the delivery dose. Also the total time spent on self-management changes during our intervention period may have been too limited. In accordance with the Dutch diabetes care guidelines, the patients in our study had 3–4 consultations per year in which all aspects of diabetes treatment had to be addressed. Previous MI studies in diabetes care offer specific MI sessions to patients which automatically results in more exposure time [17]. Review studies have shown that even small doses of MI (<15 min) can be effective [44] but that higher treatment doses (>60 min) tend to increase the effectiveness [15,44]. Our intervention should be considered as low intensity MI and perhaps more consultations including MI-counselling were needed to be effective. Additional research is needed in this area as the effect of delivery dose is still inconclusive [17].

Fourth, the intervention content might have played an important role. We did not implement MI as it was originally developed in the field of substance use. We created an adapted form (AMI) suitable to quarterly consultations in DM care. However, a previous review and a meta-analysis specifically aimed at AMI-interventions showed beneficial effects [15,16]. Of course, our adaptation may have been suboptimal although we based it on earlier experiences.

A final study characteristic that might have been of importance is our patient population. We did not specifically aim to include people with suboptimal outcomes and looking at the clinical outcomes and some behavioural outcomes our populations seems relatively healthy. Approximately three quarters had a baseline HbA1c of <7%, the average systolic blood pressure was below 140 mmHG and lipid profiles were near normal as well. Furthermore, self-reported vegetable and fruit intake were sufficient at baseline and 60% of the population reported to meet the physical activity norm. Also,

the average baseline score on the measure for autonomy support was 6.1 on a scale of 1–7. According to the self-determination theory, autonomy supportive health care providers can influence a patient's autonomous motivation and thereby improve health outcomes [27]. However, at baseline patients already perceived their health care provider as autonomy supportive, indicating little improvement to expect. These data show a possible ceiling effect; little improvement may be expected from the intervention. On the other hand, more than 50% had a baseline BMI > 28, and 40% did not meet the PA-norm, leaving ample room for improvement. Also, improvement of health locus of control dimensions, quality of life and self-efficacy could be made. Additional analyses to test the effects of baseline Hba1c and BMI on outcomes did not show significant interactions between intervention effects and baseline values. The apparent healthy baseline outcomes may be influenced by medication effects on clinical outcomes, which we unfortunately did not measure, and social desirability effects on dietary intake and PA. For example, it is known that fruit and vegetable intake is insufficient among Dutch adults [50]. Although a ceiling effect should be taken into consideration when interpreting our findings, it cannot fully explain the lack of effectiveness. Another population characteristic is our sample size but a lack of power seems unlikely when we compare our sample size to other studies [17,51].

Our results indicate a need for further research towards MI-based counselling embedded in usual care and assessment of factors influencing the use of such counselling strategies for a better understanding of the applicability of MI-interventions in diabetes care. Evaluations addressing these issues and a description of training methods are often lacking [16,48,52]. We gave a comprehensive description of the training and intervention. In addition to the current study, we evaluated tape-recorded consultations. These tapes show that some skills were implemented (e.g. agenda setting and assessing importance and confidence) but others were not (e.g. reflective listening and exploring importance and confidence). The implementation study also showed the importance of direct feedback on nurses' performances in daily practice and this study will be reported in the near future.

The present study had its limitations. There are no data available of patients or nurses who refused to participate. Therefore, we may have had a selection of nurses who have a special interest in new counselling techniques, which would limit external validity. However, with less motivated nurses it would have been even harder to find intervention effects. Furthermore, to avoid contamination we randomized on district level rather than on practice or patient level. Therefore, we corrected for possibly relevant baseline differences in all analyses. Additionally, we were not in control over counselling behaviours of control group nurses. For example, nurses were allowed to use the web-based education programme, but this limitation is inherent in the practice-based character of our study. Finally, behavioural outcomes were mostly measured by self-report questionnaires, which may have caused bias [53], but analyses of more objective clinical outcomes resulted in similar conclusions.

In sum, based on our study and what is known from other studies so far, it would be premature to recommend dissemination of MI in daily practice of diabetes care. More studies are needed in real-world settings with health care professionals of the field instead of intensively trained MI interventionists. Knowledge should be gained about adequate training and skill levels of health care professionals as well as about factors contributing to the implementation level in daily practice, such as characteristics of the general practices, patient populations, MI, and the health professionals themselves.

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Conflict of interest

There are no conflicts of interest.

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