

# Motivational interviewing by practice nurses to improve lifestyle adherence in patients with type 2 diabetes.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21132

### Source

NTR

### Brief title

MILD project

### Health condition

type 2 diabetes

## Sponsors and support

**Primary sponsor:** Radboud University Medical Centre Nijmegen,  
Centre for quality of care research(WOK)

**Source(s) of monetary or material Support:** ZON-MW, The Netherlands Organization for  
Health Research and Development

## Intervention

## Outcome measures

### Primary outcome

Primary outcome measure will be HbA1c, but main proces indicators will consist of changes in

exercise as measured by validated actometer and questionnaires; and diet measured by validated self report forms before and after the intervention.

## **Secondary outcome**

Besides the actual participation in dieting and exercise programmes we will determine the intentions of the patients according to the ASE-model. The quality of life of the patients will be measured by EQ-5D. We also determine the degree of adherence to all other recommendations in the diabetes guideline by process indicators and measurements of the blood pressure and the lipids, because the focus on diet and exercise should not drop the adherence to the other recommendations. In the process evaluation the feasibility of the strategy will be discussed with all involved parties; and for the practice nurses we will have to explore how well they were capable in performing the counseling technique MI.

## **Study description**

### **Background summary**

Objective: Improving Type 2 diabetes guideline adherence focussing on lifestyle changes by structuring the organisation of care and using the patient-oriented motivational interviewing (MI) technique.

Design: Randomized controlled trial.

Study population: Type 2 diabetes patients with HbA1c above 7.0% and BMI above 25 kg/m<sup>2</sup> in general practice. Data will be obtained from medical files, and patient and providers questionnaires.

Intervention and implementation strategy: Diabetes care according to the guidelines focussing on diet and exercise will be implemented using a patient-oriented strategy embedded in structured daily routine. The team has to make a schedule to plan the necessary activities into daily routine. The practice nurse trained in MI has to activate the patient in diet and exercise.

Outcome and process measures: Primary outcome measurement is HbA1c. Main process indicator is lifestyle counselling measured by the patient's involvement in diet and exercise. Other measures are blood pressure, lipids and process indicators based on the guideline recommendations (all elements of diabetes care have to stay covered).

Power/data-analysis: Multilevel logistic regression analysis will be used to explain differences in outcomes in 70 general practice (35 intervention practices) among 700 patients (10 per practice). This

calculation is based on the primary outcome HbA1c (success: number of patients with HbA1c above 7.0% reduced by 50%) as well as dieting and exercise process (tripling its effectiveness).

Economic evaluation: Cost of the implementation strategy will be counted, such as changes in the diabetes organisation, training the professionals in motivational interviewing and extra contacts by telephone with the patients as well as the major patient-related costs items (number and type of visit and

treatment). The cost will be balanced against the effect measures in a standardized model approach.

## **Study objective**

Adherence to diabetes guidelines is moderate, especially on educational aspects. Changes in lifestyle is a major element of the patient treatment. Studies on motivational interviewing show promising results among dietitians. There are no primary care studies including practice nurses. Research questions: what is the effect of structured diabetes care involving a practice nurse, who has been trained on motivational interviewing and equipped with practical tools on diet and exercise programmes compared to usual care on a) HbA1c, b) diet and exercise and c) other patient's clinical outcomes and professionals' adherence to process indicators based on the diabetes guidelines?

2) What is the incremental cost-effectiveness ratio of our implementation strategy compared to usual care?

## **Intervention**

Diabetes care according to the guidelines focussing on diet and exercise will be implemented using a patient-oriented strategy embedded in structured daily routine. The intervention practices have to make a schedule on how diabetes care is planned into the daily routine. The nurse trained in MI had to activate the patient in diet and exercise. The nurse will get a 2 day course and follow-up meetings within a supervision group twice during the first year. The 2 day course will include an introduction on MI followed by group discussions and training the technique by role-plays on specific skills as empowerment, use of the ambivalence, the decision balance schedule, stage of change and reflective listening.

The inclusion of the patients will start at the regular 3 monthly control. The practice nurse and patient have to come up with arrangements for the diet and exercise program by making use of MI. The patients will be equipped with a questionnaire and actometer for clinical parameter and short term targets on diet and/ or exercise. The patient should be educated on the interpretation of this information by the practice nurse.

The patients in the control group will receive usual care.

## **Contacts**

### **Public**

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## Eligibility criteria

### Inclusion criteria

The trial will be held among general practices and their patients with type 2 diabetes, younger than 80 years. Patients will be included with HbA1c levels above 7% and BMI above 25 kg/m<sup>2</sup>.

### Exclusion criteria

Type 2 diabetes patients who are very ill and patients that are primarily managed in secondary care (e.g. by internist).

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2006
Enrollment:	700

Type: Anticipated

## Ethics review

Positive opinion

Date: 12-05-2006

Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL624
NTR-old	NTR683
Other	: N/A
ISRCTN	ISRCTN68707773

## Study results

### Summary results

N/A