

Motivational interview by practice nurses to improve lifestyle adherence in patients with type 2 diabetes

Submission date 29/06/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 29/06/2006	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 09/01/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr R.M.E. Jansink

Contact details
Afdeling Kwaliteit van Zorg-117
UMC St Radboud
P.O. Box 9101
Nijmegen
Netherlands
6500 HB
+31 (0)24 3619641
R.Jansink@kwazo.umcn.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Acronym

MILD

Study objectives

Adherence level 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 dieticians. There are no primary care studies involving practice nurses.

Research questions:

1. What is the effect of structured diabetes care involving a practice nurse, that 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
- 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?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Diabetes mellitus type 2 (DM type II)

Interventions

Diabetes care according to guidelines focussing on diet and exercise will be implemented using patient-oriented strategy embedded in a structured daily routine. The intervention practitioners have to decide on a schedule on how diabetes care is incorporated into the daily routine. The nurse trained in motivational interviewing (MI) has to activate the commencement of the patient to diet and exercise. The nurse will get a two-day course and follow-up meetings within a supervisory group twice during the first year. The two-day course will include an introduction on MI followed by group discussions and training in the technique using role-play on specific skills including: empowerment, ambivalence, decision balance schedule, stage of change and reflective listening. 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 parameters 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

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Primary outcome measure will be HbA1c, but main process indicators will consist of changes in exercise as measured by validated actometer and questionnaires as well as diet, as measured by validated self-report forms before and after the intervention

Secondary outcome measures

Besides the actual participation in dieting and exercise programmes, we will determine the intentions of the patients according to the self efficacy (ASE) model. The quality of life of the patients will be measured by EQ-5D. We will also determine the degree of adherence to all other recommendations in the diabetes guidelines by process indicators and measurements of parameters such as, blood pressure and lipids. The focus on diet and exercise should not reduce adherence to 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 capable they were in administering MI.

Overall study start date

01/08/2006

Completion date

01/02/2008

Eligibility**Key inclusion criteria**

The trial will be held in general practices and all patients with type 2 diabetes, that are <80 years will be included. Patients with HbA1c levels above 8% and body mass index (BMI) above 25 kg /m² will also be included.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

700

Key exclusion criteria

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

Date of first enrolment

01/08/2006

Date of final enrolment

01/02/2008

Locations**Countries of recruitment**

Netherlands

Study participating centre

Afdeling Kwaliteit van Zorg-117

Nijmegen

Netherlands

6500 HB

Sponsor information**Organisation**

University Medical Center St Radboud, Center for Quality of Care Research (WOK) (The Netherlands)

Sponsor details

117 Kwazo
P.O. Box 9101
Nijmegen
Netherlands
6500 HB

Sponsor type

University/education

ROR

<https://ror.org/05wg1m734>

Funder(s)

Funder type

Research organisation

Funder Name

ZonMw (The Netherlands Organization for Health Research and Development)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/01/2009		Yes	No
Results article	results	28/03/2013		Yes	No
Results article	results	01/06/2013		Yes	No