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

Gepubliceerd: 12-05-2006 Laatst bijgewerkt: 13-12-2022

Adherence to diabetes guideines 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...

Ethische beoordeling Positief advies

Status Werving nog niet gestart

Type aandoening

Onderzoekstype Interventie onderzoek

Samenvatting

ID

NL-OMON21132

Bron

NTR

Verkorte titel

MILD project

Aandoening

type 2 diabetes

Ondersteuning

Primaire sponsor: Radboud University Medical Centre Nijmegen,

Centre for quality of care research(WOK)

Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and

Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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/m2 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.

Doel van het onderzoek

Adherence to diabetes guideines is moderate, especially on educational aspects. Changes in

2 - Motivational interviewing by practice nurses to improve lifestyle adherence in p ... 4-05-2025

lifestyle is a major element of the patient treatment. Studies on motivational Interviewing show promising results among dieticians. There are no primary care studies including practices nurses. Reseach questions: what is the effect of structured diabetes care involving a practice nurse, who has been trained on motivational interviewing and equipped with practial 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?

Onderzoeksproduct en/of interventie

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 groups 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 de control group will receive usual care.

Contactpersonen

Publiek

Afdeling Kwaliteit van Zorg-117, UMC St Radboud, P.O. Box 9101 R.M.E. Jansink Nijmegen 6500 HB The Netherlands +31 (0)24 3619641

Wetenschappelijk

Afdeling Kwaliteit van Zorg-117, UMC St Radboud, P.O. Box 9101 R.M.E. Jansink Nijmegen 6500 HB The Netherlands +31 (0)24 3619641

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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/m2.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel: Parallel

Blindering: Enkelblind

Controle: Geneesmiddel

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-08-2006

Aantal proefpersonen: 700

Type: Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 12-05-2006

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register ID

NTR-new NL624
NTR-old NTR683
Ander register : N/A

ISRCTN ISRCTN68707773

Resultaten

Samenvatting resultaten

N/A