

The effectiveness of adding a cognitive behavioural therapy aimed at changing lifestyle to an optimal diabetes care system

Submission date

12/09/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date

12/09/2005

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

23/09/2021

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NL68 (NTR92)

Study information

Scientific Title

The effectiveness of adding a cognitive behavioural therapy aimed at changing lifestyle to an optimal diabetes care system

Study objectives

A cognitive behaviour intervention is more effective in achieving behavioural changes and therefore changes in lifestyle and cardiovascular risk profile than usual care in patients with type two diabetes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Medical Ethical Committee of the VU University Medical Center Amsterdam.

Study design

Randomised, active controlled, factorial, single blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Diabetes Mellitus type II (DM type II)

Interventions

Intervention group:

A Cognitive Behavioural Therapy (CBT) which consist of a Motivational Interviewing phase and a Problem Solving Treatment phase. The CBT will be performed by dieticians and diabetes nurses and includes six individual sessions of 30 minutes. This sessions will be performed within a period of 16 weeks.

Usual care group:

Usual care by general practitioner/practice nurse and an annual check-up Diabetes Research Centre as is usual in the optimal care system where the study will be performed.

Both groups will be measured at baseline, at six and at 12 months. Measurements include: demographic patient characteristics, patients' history, diabetes care, clinical patients' characteristics (weight, height, waist circumference, foot inspection, blood pressure, fasting plasma glucose, HbA1c, total cholesterol, High Density Lipoprotein [HDL]-cholesterol) and questionnaires.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Differences between intervention and usual care groups in changes in diet, physical activity and smoking behaviour according to the ASE-model, a health behaviour model that assumes that behaviour is determined by attitude (A), social influences (S) and self-efficacy (E)
2. Changes in cardiovascular risk score based on the Oxford Risk Engine (algorithm that includes: age at diagnosis, duration of diabetes, sex, ethnicity, smoking status, systolic blood pressure, HbA1c, total cholesterol, HDL-cholesterol). A risk reduction of 5% is clinical relevant.

Secondary outcome measures

1. Quality of life
2. Patient satisfaction
3. Changes in medication use, adherence to prescribed medication
4. Proportion of patients reaching treatment targets according to the guidelines of the Dutch College of General practitioners
5. Adherence to the 3-monthly visit to the general practitioner

Overall study start date

01/09/2005

Completion date

31/12/2006

Eligibility**Key inclusion criteria**

1. Patients with type two diabetes from general practices with the support of a practice nurse
2. Age 40 to 70 years
3. Written informed consent
4. Capable to fill in questionnaires
5. Understanding of Dutch language
6. HbA1c more than 7.0 % and/or Body Mass Index (BMI) more than 27.0 kg/m² and/or smoking

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

300

Key exclusion criteria

1. Unstable endocrine disorders, with the exception of diabetes
2. Malignant disease
3. Treatment with corticosteroids
4. Serious mental impairment, i.e. preventing to understand the study protocol

Date of first enrolment

01/09/2005

Date of final enrolment

31/12/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

Zernikestraat 29

Eindhoven

Netherlands

5612 HZ

Sponsor information**Organisation**

VU University Medical Centre (The Netherlands)

Sponsor details

EMGO-Institute

Van der Boechorststraat 7

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1081 BT

+31 (0)20 444 8180

emgo@vumc.nl

Sponsor type

University/education

Website

<http://www.emgo.nl/>

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Research council

Funder Name

EMGO Institute (The Netherlands) - internal funding

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	Study protocol	08/05/2007		Yes	No