ISRCTN20442834 https://doi.org/10.1186/ISRCTN20442834

Using family history as a tool to increase risk awareness and to motivate preventive behaviour of individuals at risk for diabetes type two

Submission date	Recruitment status	[_] Prospectively registered
22/11/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/11/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/04/2009	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR761

Study information

Scientific Title

Study objectives
As a result of the intervention we hypothesise that:

1. Due to a tailored consultation provided by a counsellor, containing information on the causes and consequences of Diabetes Mellitus type Two (DM2) (with emphasis on familial risk) (intervention group compared to control group):
1.1. Perceived risk will increase due to an improved perception of the nature and height of the risk
1.2. Peoples perceptions of the causes and consequences of DM2 will be more accurate
1.3. Perceived severity of DM2 will increase due to more insight into the consequences of DM2
1.4. A higher protection motivation is expected
2. Due to risk reduction information (information on preventive options) (both groups) perceived controllability (or response efficacy) will increase because of increased understanding that the risk can be reduced due to behaviour change

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised single-blind active-controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes mellitus type two (DM type II)

Interventions

The intervention consists of tailored information (risk communication) on the causes and consequences of DM2 such as cardiovascular disease (with emphasis on familial risk). It will be emphasised that it is even more important to change behaviour, because of a positive family history (which cannot be changed). The consultation is based on a counselling model and is presented by a trained counsellor. Our group has gained extensive experiences in the field of genetic counselling for e.g. familial risk of breast cancer, cystic fibrosis.

The underlying goal of the intervention is to change people's perceptions of risk, and perceived causes and consequences of DM2 to increase their motivation to change behaviour. In addition, all participants receive information on preventive options to help them see how they can cope with their risk (increase controllability).

To analyse the effect of the intervention, subjects are randomly allocated to the intervention or control group:
1. Information on the causes and consequences of DM2 (with emphasis on familial risk) and intensive risk reduction information (intervention group)
2. General risk information and intensive risk reduction information (control group)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Protection motivation: Intention to engage in DM2 risk-reducing behaviour. Three core behavioural intentions will be assessed:
1. Increasing physical activity
2. Restricting calories by eating low fat foods
3. Follow subsequent advice to screening for diabetes

Stopping smoking and reducing alcohol intake will also be assessed when relevant. For each participant, intentions towards the three core behaviours will be measured and combined to assess overall motivation to reduce risk.

Secondary outcome measures
1. Illness representations
2. Perceived severity of diabetes
3. Perceived risk of getting diabetes
4. Coping appraisal: self-efficacy
5. Self-reported health behaviour
6. Psychological well-being: Positive And Negative Affect Scale (PANAS).

Overall study start date
01/11/2006

Completion date
01/06/2007

Eligibility

Key inclusion criteria
1. Positive family history
2. Symptom Risk Questionnaire Scores more than ten (highest expected effects from the intervention)
3. Aged less than 75 years (born after 01/01/1931)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90

Key exclusion criteria
1. People with diagnosed DM2
2. People unable to complete questionnaires in Dutch

Date of first enrolment
01/11/2006

Date of final enrolment
01/06/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Vu Medical Center
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (Netherlands)

Sponsor details

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Research organisation

Funder Name
Societal Aspects of Genomics at the Centre for Medical Systems Biology (Maatschappelijke Aspecten van Genomics van het Centre for Medical Systems Biology [MAGCMSB]) (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?
Results article	results	01/04/2009		Yes	No