Impact of communicating familial risk of diabetes using a web-based tailored advice on preventive behaviour.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23302

Source
NTR

Brief title
PreDiCT

Health condition

Effectiveness of a preventive web-based advice for people at (familial) risk for type 2 diabetes.

Sponsors and support

Primary sponsor: EMGO institute for Health and Care Research, VU University Medical Center, Amsterdam, the Netherlands
Source(s) of monetary or material Support: Centre for Society and Genomics (CSG) in the framework of the Netherlands Genomics Initiative (NGI)

Intervention

Outcome measures

Primary outcome

1. Mean physical activity level will be measured by the self-administered short version of the International Physical Activity Questionnaire (IPAQ). Time points: Baseline, 3 months;

2. Mean saturated fat intake using a validated short food frequency questionnaire, the short Fat list. Time points: Baseline, 3 months;

3. Testing for diabetes: the percentage of people who test for diabetes after the risk information and attitudes towards taking a yearly or regular test for diabetes. Time points: Baseline, 3 months.

Secondary outcome

1. Body measures: Self-reported waist circumference, BMI (self-reported body weight and length). Time points: Baseline, 3 months;

2. Threat appraisal: people's perception about the severity of diabetes. Baseline, 1 week and 3 months;

3. Coping appraisal: Self-efficacy, response efficacy for fat intake and physical activity. Time points: Baseline, 1 week and 3 months;

4. Illness representations: Causal beliefs, and perceived personal control adapted from the revised form of the Illness Perception Questionnaire. Time points: Baseline, 1 week and 3 months;

5. Risk perception: perceived susceptibility. Time points: Baseline, 1 week and 3 months;

6. False reassurance: causal beliefs and risk perception will be used to assess false reassurance;

7. Intentions: Intentions to engage in behavioural activities (fat intake, physical activity). Time point: 1 week;

8. Psychological impact: diabetes risk worry. Time points: Baseline, 1 week and 3 months;

9. Perceived implications: perceived impact on autonomy, freedom of choice, responsibility, feelings of stigmatisation and discrimination, worries about confidentiality of the information, impact on family relationships, medicalisation, and practical aspects. Time point: 3 months.

Study description

Background summary

Family history is an important and independent risk factor for many common chronic diseases, reflecting the consequences of genetic predisposition, shared environment, and common behaviour. It is seen as a useful tool for disease prevention in public health and preventive medicine, and may be used for tailoring behavioural messages. Internet is seen as an effective way to improve health and disseminate information among the public, even when people do not perceive themselves at risk for disease. In this study type 2 diabetes is taken as an example. The main objective of this study is to investigate how the collection of a diabetes family history, interpretation and communication of familial risk information using a web-based tool affects health behaviour, and to explore the possible negative implications for individuals and their families.

Research questions are:

1. What is the impact of the collection of a family history of diabetes and communicating familial risk information of diabetes in a web-based tailored intervention on preventive behaviour?

A. What is the effect on health behaviour change (saturated fat intake, physical activity, test for diabetes)?

B. To what extent does the information affect causal beliefs, personal control, and perceived susceptibility?

C. Are people without a positive family history falsely reassured about their risk for diabetes, when the emphasis in the diabetes risk communication is on familial risk?

2. What are possible implications for the individual¡¯s freedom of choice, feelings of stigmatisation and discrimination, worries about confidentiality of the information, and impact on family relationships?

Study objective

The main objective of this study is to investigate how the collection of a diabetes family history, interpretation and communication of familial risk information using a web-based tool affects health behaviour, and to explore the possible negative implications for individuals and their families.

Study design

Baseline, 1week and 3 months.

Intervention

The (web-based) intervention consists of:

1. Familial risk assessment, in addition to diabetes risk based on general risk factors, personal risk communication containing familial risk information and lifestyle

recommendations (intervention group);

2. Diabetes risk assessment based on general risk factors, personal risk communication and lifestyle recommendations (control group).

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Eligibility criteria

Inclusion criteria

Healthy people from the general population aged 35-65 years will be recruited. Inclusion criteria:

1. 35 to 65 years;

2. Body Mass Index (kg/m2) ¡Ý 25;

3. People with or without a postive (at least 1 first degree relative) family history of diabetes;

4. Access to a computer and internet.

Exclusion criteria

Exclusion criteria (assessed when people are invited for the study):

1. People with diagnosed diabetes type 1 or 2;

2. People unable to read and complete questionnaires in Dutch;

3. Hindus, Turks, Creoles and Moroccans, since these populations require a specific diabetes risk intervention, due to their higher than avarage risk of getting diabetes.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2009
Enrollment:	1110
Type:	Actual

Ethics review

Positive opinion

Date:	07-08-2009
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	NL1828
NTR-old	NTR1938
Other	Scientific Committee of the EMGO Institute for Health and Care Research. : WC2008-011
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A