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Diabetes in Europe - Prevention using Lifestyle, physical Activity and Nutritional intervention (DE-PLAN) project

Submission date
29/07/2016

Recruitment status
No longer recruiting

Registration date
03/08/2016

Overall study status
Completed

Last Edited
12/09/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). T2DM is linked to a number of severe complications, as well as increasing the risk of heart disease (cardiovascular disease) and cancer. In recent years, greater stress is being put on diabetes prevention, by encouraging people to change their lifestyles to reduce their risk of developing the disease. A number of studies have looked at the benefits of individual counseling, however this can be expensive and isn't always relevant to 'real life'. This study will look at a diabetes prevention program which combines group activities and motivational follow up to encourage healthier lifestyle choices. The aim of this study is to find out if this diabetes prevention program is an effective way of reducing diabetes risk.

Who can participate?
Adults aged 25 years or over who live in Kraków and have a high risk of developing diabetes.

What does the study involve?
Participants are invited to take part in a ten month diabetes prevention course run by a trained nurse. The course involves a combination of group sessions, focusing on changing diet and exercise habits, six motivational telephone sessions, two motivational letters and the opportunity to take part in exercise sessions twice a week. The course stresses the importance of social support and family members or spouses are also able to take part in the sessions. At the start of the study and then after 12 and 36 months, participants have their diabetes risk assessed by having their blood sugar control tested through a series of blood tests, having weight and blood pressure measurements taken, and completing a range of questionnaires. The cost effectiveness of the course is assessed at the end of the study by recording the costs of all activities involved.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved for participants taking part in this study.

Where is the study run from?
The study is coordinated by Jagiellonian University and takes place in nine Primary Health Care Centers in Kraków (Poland)

When is the study starting and how long is it expected to run for?
January 2006 to January 2014

Who is funding the study?
The Commission of the European Communities, Directorate C - Public Health (Belgium)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DEPLAN/PR1.02/2007

Study information

Scientific Title

The feasibility and cost effectiveness of screening and prevention of type 2 diabetes by lifestyle intervention in real life community setting within existing health care systems in Europe: Diabetes in Europe Prevention using Lifestyle, physical Activity and Nutritional intervention (DE-PLAN) project

Acronym
DE-PLAN

Study objectives
Hypothesis:
The translation of the current research evidence about diabetes preventive intervention programmes into clinical settings within existing health care systems in Europe is feasibile and cost-effective.

Study aim:
The aim of this study is to develop and test models of efficient identification and site specific intervention of individuals at high risk of type 2 diabetes in the community.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Commitee of Jagiellonian University, 23/03/2006, ref: KBET/43/L/2006

Study design
Non-randomised interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not longer available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prediabetes, high diabetes risk

Interventions
Patients fulfilling the inclusion criteria are invited to participate in the lifestyle intervention consisting of two parts: an intensive initial phase followed by an ongoing maintenance phase,

based on reinforced behaviour modification focusing on five lifestyle goals: weight loss, reduced intake of total and saturated fats, increased consumption of fruits, vegetables and fibre and increased physical activity.

A trained nurse certified in diabetes prevention delivers the intervention over a period of 10 months. This involves 10 group sessions focusing on diet and physical activity changes, six motivational telephone sessions, two motivational letters and the opportunity to participate twice weekly in physical activity sessions, over a period of 10 months. During each session, printed educational materials related to the topic of the session are distributed. Social support is emphasised in the group setting and participants are also encouraged to involve their own social circle in the lifestyle changes. A spouse or other family member can also participate in the sessions.

Patients are examined at baseline, after 12 and 36 months of initiation of the study. Questionnaires (FINDRISC, clinical and lifestyle and Quality of life) and biochemical tests including fasting and 120'OGTT glucose, serum triglycerides, HDL and total cholesterol, as well as body mass index (BMI), waist circumference, diastolic and systolic blood pressure are measured. Lifestyle changes are explored with the use of self reported questionnaire (consumption of vegetables and fruits, fat and saturated fat, alcohol and physical activity during the past year).

Intervention Type
Behavioural

Primary outcome measure
Type 2 diabetes mellitus risk is measured at baseline, 12 and 36 months using metabolic and anthropometric indices and questionnaires:

Biochemical tests:
1. Fasting glucose mmol/l
2. 120'OGTT glucose mmol/l
3. Serum triglycerides mmol/l
4. HDL cholesterol mmol/l
5. Total cholesterol mmol/l

Anthropometric measurements:
1. Body mass index (BMI), calculated as weight divided by height squared
2. Waist circumference (cm), measured midway between the lowest rib and iliac crest
3. Blood pressure (mmHg), measured while sitting after 10 minutes rest

Questionnaires:
1. Finnish Diabetes Risk Score (FINDRISC) questionnaire
2. Questionnaire measuring lifestyle (specially designed for the purpose of this study)
3. Questionnaire measuring sociodemographic data regarding, education, marital status, working status, smoking (specially designed for the purpose of this study)
4. Questionnaire measuring current health status, history of elevated glucose level, cardiovascular disease, hypertension, hyperlipidemia, depression, other chronic conditions, currently taken medication. family history of diabetes (specially designed for the purpose of this study)

Secondary outcome measures

1. Quality of life is measured using the 15D HRQoL questionnaire at baseline, 12 and 36 months
2. Cost effectiveness is assessed by collecting the costs of screening and intervention activities (i. e. related personnel use, services provided, consumables, media costs, etc.) at 36 months

Overall study start date
01/01/2006

Completion date
01/01/2014

Eligibility

Key inclusion criteria
1. Aged 25 years and over
2. Krakow city inhabitants
3. High diabetes risk (Finnish Diabetes Risk Score (FINDRISC) >14)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Known or oral glucose tolerance test (OGTT) screened diabetes
2. Known chronic disease

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
Poland

Study participating centre
Jagiellonian University
Department of Endocrinology
Medical College

Kopernika 17
Krakow
Poland
31-501

Study participating centre
Niepubliczny Zakład Opieki Medicina
Rogozińskiego 12
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31-559

Study participating centre
Niepubliczny Zakład Opieki Zdrowotnej Praktyka Lekarza Rodzinnego
Inicjatywy lokalnej 5
Kraków
Poland
30-499

Study participating centre
Niepubliczny Zakład Opieki Centrum Medyczne Prokocim Nowy
Teligi 8
Kraków
Poland
30-835

Study participating centre
Niepubliczny Zakład Opieki Centrum Medyczne Nowa-Huta
Ujastek 3
Kraków
Poland
30-969

Study participating centre
Niepubliczny Zakład Opieki Przychodnia Na Wzgórzach
Na Wzgórzach 1
Kraków
Poland
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Study participating centre
Niepubliczny Zakład Opieki Praktyka Grupowa Lekarzy Rodzinnych
Bocheńska 4
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30-500

Study participating centre
Firma Marketingowo - Medyczna, Niepubliczny Zakład Opieki Mark- Med
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Study participating centre
Praktyka Grupowa Lekarzy Rodzinnych
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Study participating centre
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Sponsor information

Organisation
The Commission of the European Communities, Directorate C - Public Health

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Sponsor type
Government

ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type
Government

Funder Name
The Commission of the European Communities, Directorate C - Public Health

Results and Publications

Publication and dissemination plan
Data on the one year results were published in 2011. Data on the 3 year results are planned to be published in 2016.

Intention to publish date
01/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/02/2017		Yes	No
Results article	results	02/01/2018		Yes	No
Dataset			12/09/2023	No	No
Results article		23/03/2018	12/09/2023	Yes	No