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The project DiPS: Exceeding the cutoff value for blood glucose - what does that mean to you? Issue, offering and evaluation of an evidence based patient information about blood glucose testing and primary prevention of diabetes mellitus type 2

Submission date
15/08/2008

Recruitment status
No longer recruiting

Registration date
12/09/2008

Overall study status
Completed

Last Edited
18/10/2012

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Andrea Icks

Contact details
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Leibniz Centre for Diabetes Research
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Aufm Hennekamp 65
Duesseldorf
Germany
40225

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01EL0706

Study information

Scientific Title
Blood glucose testing and primary prevention of diabetes mellitus type 2 - evaluation of the effect of evidence based patient information: a parallel-group, cluster-randomised controlled interventional study

Acronym
DIPS (Diabetes-Präventions-Check/Diabetes Prevention Check)

Study objectives
Current hypothesis as of 16/10/2009:
The purpose of this study is a web-based evaluation of how evidence-based consumer information compared to standard information on elevated blood glucose levels screening and diabetes mellitus type 2 - prevention affects the quality of decision, defined by adequate knowledge and consistent with ones attitudes and intention. The measure is based on:
1. Knowledge about elevated blood glucose levels, metabolic testing, options of primary prevention of diabetes (primary outcome)
2. Attitudes to metabolic testing
3. Intention to undergo metabolic testing
4. Decision conflict about testing
Furthermore:
5. Satisfaction with the information

An evidence-based consumer information about elevated blood glucose levels is not available yet and developed within this project.

Null Hypothesis: There is no statistical significant difference in knowledge between participants achieving evidence-based consumer information or standard information about elevated blood glucose levels.

Initial hypothesis at time of registration:
The purpose of this study is to determine how evidence based consumer information compared to standard information on pre-diabetes screening and diabetes prevention affects:
1. The uptake of pre-diabetes screening, and
2. The satisfaction with information delivery
An evidence-based consumer information about pre-diabetes is not available yet.

Null hypothesis:
There is no statistical significant difference between participants achieving evidence-based consumer information or standard information about pre-diabetes.

A power calculation was performed, considering participations of 30% (control group) and 50% (intervention group), yielding 16 companies and 1800 employees to be included.

Please note as of 16/10/2009 this record has been substantially amended due to problems with recruitment and a subsequent change to the original protocol. All amendments can be found under the relevant section with the above update date. Please also note that at this time, the following fields have also been amended:
1. The titles of the trial were amended and an acronym added; the initial titles of this trial at the time of registration were:
Initial public title: Efficacy of evidence-based consumer information on pre-diabetes screening: a randomised controlled trial
Initial scientific title: Metabolic test for primary prevention of type 2 diabetes in elderly employees as part of workplace health promotion: evaluation of effects of evidence based patient information
2. The target number of participants field was updated; the initial target number of participants was "3696"
3. The study design was slightly amended; the initial study design was "a multicentre, parallel-group, cluster-randomised controlled interventional study"
4. The disease/condition/study domain field was slightly amended; the initial disease/condition /study design field was "Pre-diabetes in elderly employees"
5. The anticipated end date was slightly amended; the initial anticipated end date was 31/05 /2010

As of 22/03/2012, the target number of participants have been updated from 2000 to 1054.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was received from the Ethics Committee of the University of Düsseldorf on the 28th February 2008. Amendments to the protocol were approved on the 7th August 2009 (ref: 3020)

Study design
Parallel-group cluster-randomised controlled interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Elevated blood glucose levels in the elderly population

Interventions
Current information as of 16/10/2009:
Evidence-based consumer information compared to standard information, both provided as online information. Individual data are collected during an online session. Data of the primary and partly of the secondary endpoints are collected during the first online session. Two weeks later at a second individual online session, further secondary endpoint data are collected.

Initial interventions at the time of registration:
Evidence-based consumer information brochure/counselling compared to standard brochure /counselling. The intervention in each company will be about one month, depending of the size of the company. All companies will be contacted again in the end of the study at approximately 15 months after the first intervention.

Added 21/10/2009:
Contact details for cooperating partner of trial:
Scientific Institute for Benefit and Efficiency in Health Care (WINEG)
Habichtstrasse 30
22305 Hamburg
Germany

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current information as of 16/10/2009:
Knowledge about elevated blood glucose levels and metabolic testing, collected during the first online session.

Initial primary outcomes at the time of registration:
Participation at a metabolic test in fasting blood glucose testing. Outcomes will be measured in the end of the intervention in each company.

Secondary outcome measures
Current information as of 16/10/2009:
1. Attitudes to metabolic testing
2. Intention to undergo metabolic testing
3. Decision conflict about testing
4. Satisfaction with information delivery
Collected during the first online session and again two weeks later at a second online session.

Initial secondary outcomes at the time of registration:
Satisfaction with the information. Outcomes will be measured in the end of the intervention in each company.

Overall study start date
01/12/2007

Completion date
30/06/2010

Eligibility

Key inclusion criteria
Current inclusion criteria as of 22/03/2012
Aged 40 - 70 years, either sex

Previous inclusion criteria as of 16/10/2009:
Aged 50 - 70 years, either sex

Initial inclusion criteria at the time of registration:
1. Employees of participating companies
2. Aged 50 or older, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1054

Key exclusion criteria
Current exclusion criteria as of 22/03/2012
1. Known to have diabetes mellitus
2. Aged younger than 40 years

Previous exclusion criteria as of 16/10/2009:
1. Known to have diabetes mellitus
2. Aged younger than 50 years

Initial exclusion criteria at the time of registration:
1. Employees of participating companies known to have diabetes mellitus
2. Aged younger than 50
3. Have no German language ability

Date of first enrolment
01/12/2007

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
Germany

Study participating centre
German Diabetes Centre
Duesseldorf
Germany
40225

Sponsor information

Organisation
German Diabetes Centre (Germany)

Sponsor details
Institute of Biometrics and Epidemiology
Aufm Hennekamp 65
Duesseldorf
Germany
40225

Sponsor type
Hospital/treatment centre

Website
http://www.ddz.uni-duesseldorf.de/

ROR
https://ror.org/04ews3245

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium fuer Bildung und Forschung [BMBF]) (Germany)

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	protocol	14/01/2010		Yes	No
Results article	results	01/08/2012		Yes	No