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A randomised trial of the cost-effectiveness of a program of screening and intensive multifactorial intervention for type 2 diabetes in primary care

Submission date
15/12/2006

Recruitment status
No longer recruiting

Registration date
15/12/2006

Overall study status
Completed

Last Edited
26/10/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes is increasingly common and responsible for significant costs to patients and the health service, mainly through increasing the risk of heart attacks and strokes (cardiovascular disease). At the outset diabetes tends not to cause any symptoms and so people can have the condition for many years without realising it. Indeed, up to half of all people with diabetes remain undiagnosed. One possible strategy to deal with this would be to screen the population with a simple blood test. However, it is only worthwhile screening the population if treatment is effective early in the course of the disease. While there have been many studies among people with longstanding diabetes that have helped to inform treatment guidelines, there have been no previous studies evaluating treatment for people with diabetes detected by screening. The ADDITION study aims to see if helping patients with screen-detected diabetes and general practice teams to intensively treat risk factors for cardiovascular disease (CVD) in the first 5 years after diagnosis will reduce the risk of CVD. The study results will inform guidelines for initial treatment of diabetes and policy decisions about screening.

Who can participate?
This study has now finished recruiting. Participants were aged between 40-64 years at the time of recruitment (2000 to 2006) and identified as having diabetes through the study's screening programme. This involved an initial finger-prick blood sugar (glucose) test in general practice. If this was positive, participants were invited to return fasted for a second finger-prick test, followed if positive by a glucose tolerance test to check that the person did have diabetes.

What does the study involve?
GP practices taking part in the study were randomly allocated to one of two groups: a control group and a treatment group. Participants in the study did not know which group their practice was in. GP practices in the control group were asked to follow routine national guidelines for the treatment of diabetes. GP practices in the treatment group received education and guidelines concerning treatment of diabetes and CVD risk factors. This included treatments such as starting

medications (to lower levels of glucose, cholesterol and blood pressure) or giving lifestyle advice (about diet and physical activity) to patients with screen-detected diabetes. Patients were provided with educational materials. All participants were invited to a baseline clinic appointment (at the point that they were tested for diabetes). This involved collecting information on the participants' overall health (such as blood pressure, weight and taking a history of other medications they were taking) as well as asking them to complete questionnaires on lifestyle (such as their diet and amount of exercise they took). We followed participants up 1 and 5 years later and took all the same measures again. This allowed us to see if there were any health differences between the people who had received routine care and those who had received intensive treatment. We also looked at their medical records to see if they had experienced any CVD events. This included whether they had had a heart attack, stroke or amputation. We now plan to do a 10-year follow-up. This time, instead of inviting people to clinic, we will collect the same information again but from the participant's medical records and by sending individuals a questionnaire in the post.

What are the possible benefits and risks of participating?
All participants enrolled in the study received a test to check if they had diabetes. They also received a check up from the study team after 1 and 5 years of taking part in the study. This included blood tests, such as blood glucose measure and liver function test; weight measurements, and blood pressure. There were limited risks to taking part in the study as all participants continued to receive routine care from their GPs.

Where is the study run from?
The study was run from two centres in the UK: the MRC Epidemiology Unit in Cambridge, and the Leicester Diabetes Centre. We also worked with researchers in the Netherlands and Denmark who were collecting the same information from patients there.

When is the study starting and how long is it expected to run for?
The study started in June 2001 and finished recruiting in March 2006. The study is now about to enter a 10-year follow-up phase which we will be complete in December 2015.

Who is funding the study?
The study has been funded by the Medical Research Council, NIHR Health Technology Assessment Programme, National Health Service R&D, and the National Institute for Health Research (UK).

Who is the main contact?
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Study website
http://www.addition.au.dk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00237549

Secondary identifying numbers
061895

Study information

Scientific Title
A randomised trial of the cost-effectiveness of a program of screening and intensive multifactorial intervention for type 2 diabetes in primary care

Acronym
ADDITION

Study objectives
1. To evaluate the effectiveness and cost (economic and psychological) of a program of screening and intensive multifactorial intervention for type two diabetes in primary care.
2. To measure the effect of a multifactorial intervention for people with screen-detected type two diabetes aged 40 to 69 years on modelled mortality and cardiovascular risk.
3. To assess the psychological and health service costs of screening for type two diabetes.
4. To provide the National Screening Committee with timely evidence to inform the decision on whether screening for type two diabetes should become part of health policy in the United Kingdom.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. ADDITION: Eastern MREC, ref: 02/5/54
2. ADDITION 5 Year: Cambridgeshire 1 REC, ref: 08/H0304/67
3. ADDITION 10 Year: East of England - Cambridge East REC, ref: 14/EE/1129

Study design
Pragmatic randomised parallel-group design

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
In a pragmatic, parallel-group design, general practices recruited to the study in the local area are randomly allocated centrally to control, to screening for type two diabetes followed by routine care of screen-detected cases according to national recommendations, and to screening followed by intensive multifactorial intervention. A minimisation procedure is used to balance the baseline practice variables.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Risk models for mortality and cardiovascular events, specific to people with diabetes, based on age, gender, blood pressure, Body Mass Index (BMI), smoking, previous myocardial infarction, total cholesterol, triglyceride, High Density Lipoprotein (HDL), HbA1c and albuminuria.

Secondary outcome measures
No secondary outcome measures

Overall study start date
21/01/2002

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Aged 40 to 69 years
2. Without known diabetes but with a diabetes risk score in the top 30%

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Recruitment completed on 31/03/2006

Total final enrolment
20184

Key exclusion criteria
1. Already have diabetes
2. Are pregnant or lactating
3. Have a psychotic illness
4. Have an illness with a prognosis of less than one year

Date of first enrolment
01/06/2001

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
Denmark

England

Netherlands

United Kingdom

Study participating centre
MRC Epidemiology Unit
Cambridge
United Kingdom
CB1 8RN

Sponsor information

Organisation
University of Cambridge (UK)

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Sponsor type
Government

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	12/05/2009		Yes	No
Results article	results	17/11/2012		Yes	No
Results article	results	01/08/2016		Yes	No
Results article	results	14/06/2018	11/07/2019	Yes	No
Results article	results	01/08/2019	05/08/2019	Yes	No
Results article		29/03/2021	26/10/2021	Yes	No
HRA research summary			28/06/2023	No	No