ISRCTN99175498 https://doi.org/10.1186/ISRCTN99175498

Does adding facilitated behaviour change improve outcomes for people with recently diagnosed diabetes?

Submission date
02/05/2001

Recruitment status
No longer recruiting

Registration date
02/05/2001

Overall study status
Completed

Last Edited
08/01/2016

Condition category
Nutritional, Metabolic, Endocrine

[X] 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). There is good evidence that risk of cardiovascular disease is lower for patients who make changes in health behaviours such as diet, physical activity, smoking, drinking alcohol and taking medication, compared to those who make few changes. Making and maintaining changes in these behaviours is not easy. There is certainly scope for improvements in the frequency of health-promoting behaviours among people with diabetes. Developing effective approaches to help people with behaviour change to prevent progression of the disease is therefore an important part of tackling the growing public health burden of type 2 diabetes. This study aims to assess the effectiveness of adding a new behaviour change intervention to the treatment of type 2 diabetes patients. The study results will inform guidelines concerning the management of patients early in the course of diabetes. Findings will also improve our understanding of the factors that influence health behaviours and how health behaviours are associated with the complications of diabetes, in particular cardiovascular disease.

Who can participate?
Participants were aged between 40-69 and identified as having diabetes through the previous ADDITION study (ISRCTN86769081) or diagnosed during the previous three years in participating GP surgeries.

What does the study involve?
Participants taking part in the study were randomly allocated to one of two groups: a control group and an intervention group. Participants in the study did not know which group they were in. Participants in the control group received intensive treatment of risk factors by their GP and practice nurse. Participants in the intervention group received the same intensive treatment plus individually tailored support from a facilitator. Facilitators taught participants key skills to enable change and maintenance of key behaviours (physical activity, dietary change, medication adherence and smoking), including goal setting, action planning, self-monitoring and building habits. All participants were invited to a clinic appointment at the start of the study. This

involved collection of information on overall health (such as blood pressure, weight and medication) and completion of questionnaires on lifestyle (such as diet and physical activity). 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 participants in the two study groups. It also allowed us to see how changes in behaviours were associated with risk factors for cardiovascular disease. We now plan to do a 10-year follow up. This time, in order to reduce the burden to participants and the costs of the study, instead of inviting people to clinic, we will collect the same information again but from the participants' medical records and by sending individuals a questionnaire in the post. We will also collect information concerning whether or not participants have developed cardiovascular disease.

What are the possible benefits and risks of participating?
All participants enrolled in the study received a check up from the study team after one and five years of taking part in the study. This included blood tests, such as blood glucose measurement and a liver function test, and measurement of weight and blood pressure. These results were sent to participants' GPs. There were limited risks to taking part in the study as all participants continued to receive standard care from their GPs. Risks remain low as there is no active intervention or invasive measurement. If participants agree to return postal questionnaires, these will take around 90 minutes to complete.

Where is the study run from?
The MRC Epidemiology Unit in Cambridge (UK).

When is the study starting and how long is it expected to run for?
October 2001 to December 2016.

Who is funding the study?
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?
Richard Salisbury
richard.salisbury@mrc-epid.cam.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Simon Griffin

Contact details
Institute of Public Health
University of Cambridge
University Forvie Site
Robinson Way
Cambridge
United Kingdom
CB2 2SR

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0001164

Study information

Scientific Title
Does adding a facilitated behaviour change intervention improve outcomes among people with recently diagnosed type 2 diabetes receiving intensive treatment in General Practice?

Acronym
The AdditionPlus study

Study objectives
1. Can an approach, based on theory and evidence from psychology, to increase and maintain health-promoting behaviours (physical activity, dietary change, taking medication and smoking cessation) achieve clinically important and measurable change in these behaviours when offered to people with screen-detected diabetes?
2. What is the effect on modelled cardiovascular risk and the cost (economic and psychological) of a behavioural intervention for people aged 40 to 69 years with screen-detected diabetes?
3. What are the added benefits and costs of facilitation of healthy behaviours among people aged 40 to 69 years with diabetes detected by screening and intensively treated?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Eastern MREC, 02/5/24
2. 5 Year Follow Up: Hertfordshire REC, 09/H0311/65
3. 10 Year Follow Up: Berkshire B, 15/SC/0341

Study design
Single-blind multipractice randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes

Interventions
Recruited practices have been randomised to screening for diabetes followed by Routine Care (RC) according to national guidelines or screening followed by Intensive multifactorial intervention (I). We hope to achieve this intensive treatment through the addition of the following features to the existing diabetes care within the practice:
1. Additional NHS R&D Support for Science funding to facilitate more frequent contact between patients and practitioners and to facilitate dietician referrals for all newly diagnosed patients
2. Three practice-based education sessions with the local diabetologist. Patient education materials providing a shared framework on the causes, consequences and treatment of diabetes
3. Management algorithms specifying prescription of an angiotensin converting enzyme inhibitor (ACE) and aspirin, followed by stepwise target-led treatment to reduce hyperglycaemia, blood pressure, hyperlipidaemia and microalbuminuria
4. Provision of glucometers for patients and any necessary training in their use for practitioners

Patients in the intervention arm (I) are randomly allocated to receive the additional behavioural intervention (I1) or not (I2). The behavioural intervention is delivered by trained facilitators during six consultations in the surgery and by telephone follow-up. It is designed to strengthen both motivation to increase physical activity, adopt a healthier diet, take prescribed medication, stop smoking if relevant and to teach self-management skills to achieve and maintain these changes, using a person-centered approach. Following detailed protocols, the facilitator helps patients define achievable goals for behaviour change by exploring the beliefs and attitudes underlying their motivation and confidence to change specific behaviours. Over the first three sessions patients learn how to define specific action plans and to implement these using self-monitoring, reinforcement and relapse prevention techniques. The second three sessions focus on maintaining change by continued use of these skills and their generalisation to other domains, goal setting and review, and motivation-enhancing skills. Over time patients practice these skills in relation to physical activity, dietary intake, taking medication and smoking cessation if relevant. Each session begins with a review of progress, and skills acquired and applied, before moving on to the introduction of new skills on their application to new domains.

Following the funded extension the same intervention is provided to half of the patients with diabetes diagnosed within the last 3 years, allocated at random.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The principal comparisons between I1 and I2 include changes in weight, self-reported physical activity (IPAQ, EPAQ2), diet (Food Frequency Questionnaire), medication adherence (MARS), smoking status and differences at 1 year in objectively measured physical activity (PAR, CSA

[accelerometer]), diet (plasma vitamin C) and medication adherence (plasma drug levels). A cross domain measure of behaviour change at 1 year is under development. Modelled 5-year risk of cardiovascular events, incorporating glycaemia, blood pressure and lipid levels, represents the main outcome for the trial of intensive treatment (RC vs I). In addition, we propose to assess at all levels along our causal pathway psychological measures (illness perceptions, attitudes and intentions towards targeted healthy behaviours), anthropometric variables (weight, body fat distribution and waist circumference) and biochemical parameters (HbA1c, cholesterol and albumin/creatinine ratio).

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2001

Completion date
31/12/2016

Eligibility

Key inclusion criteria
Patients aged 40-69 with a diabetes risk score more than or equal to 0.17 (representing the top 25% of risk distribution) are invited for a random capillary screening test for diabetes. Patients are eligible to take part if the diagnosis of diabetes is confirmed by subsequent fasting capillary test and oral glucose tolerance test.

Following the funded extension, inclusion criteria extended to include patients aged 40 to 69 years with type 2 diabetes diagnosed within the last 3 years.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1000 for risk factor calculation; 400 for behaviour intervention

Key exclusion criteria
Potential participants are excluded if they are pregnant or lactating, have a psychotic illness or have an illness with a likely prognosis of less than 1 year.

Date of first enrolment
01/10/2001

Date of final enrolment
01/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Cambridge
Cambridge
United Kingdom
CB2 2SR

Sponsor information

Organisation
University of Cambridge (UK)

Sponsor details
c/o Dr Joanne Martindale
Research Operations Office
School of Clinical Medicine, Box 111
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0SP

Sponsor type
Research organisation

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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

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 in: patients' experiences of screening	08/09/2007		Yes	No
Results article	results in: psychological impact of screening	08/09/2007		Yes	No
Results article	results	07/10/2008		Yes	No
Results article	results	30/11/2009		Yes	No
Protocol article	protocol	04/04/2011		Yes	No
Results article	results	01/01/2014		Yes	No
Results article	results	01/02/2015		Yes	No
Results article	results	06/01/2016		Yes	No
Results article	results	01/09/2016		Yes	No
HRA research summary			28/06/2023	No	No