

Supported Adherence to Medication Study

Submission date 10/05/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 31/08/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/02/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Diabetes is a lifelong condition that causes a person's blood sugar (glucose) level to become too high. Previous studies have shown that up to half of the tablets for type 2 diabetes may not be taken as prescribed. If we could help support patients in taking their medicines as prescribed, then the benefits of these drugs in reducing diabetes complications might be more widely realised. Previous studies to help patients with taking their medications regularly have used educational approaches or relied on use of prompts and reminders. We have been guided in our approach to this research by work from psychologists about how people might become motivated to take medicines regularly and how taking medicines can become a habit. The aim of this study is to measure the effectiveness of an intervention to support people with type 2 diabetes to take their medication.

Who can participate?

Patients aged 18 or over with type 2 diabetes, currently taking any oral glucose-lowering medication, whose control of their diabetes could benefit from improvement.

What does the study involve?

Participants are randomly allocated into two groups. In the intervention group patients receive additional support from their practice nurse to help them take their medicines more regularly; the other group receive standard treatment. We also collect blood samples and look at the relationships between taking tablets and levels of active drugs in the bloodstream.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

12 general practices from Oxfordshire, Buckinghamshire, Huntingdon, Suffolk and Essex (UK)

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

March 2006 to December 2008

Who is funding the study?

Medical Research Council (MRC) (UK)

Who is the main contact?
Prof Ann Louise Kinmonth

Contact information

Type(s)
Scientific

Contact name
Prof Ann Louise Kinmonth

Contact details
Institute of Public Health
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CB2 2SR

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0500267/73444

Study information

Scientific Title
Supported Adherence to Medication Study

Acronym
SAMS

Study objectives
The principal aim of the study is to measure the potential efficacy of an intervention to support hypoglycaemic medication among people with type 2 diabetes.

More details can be found at:
http://www.medschl.cam.ac.uk/gppcru/index.php?option=com_content&view=article&id=332:sams-supported-adherence-to-medication-study&catid=12:project-profiles&Itemid=59

Ethics approval required
Old ethics approval format

Ethics approval(s)

London Multicentre Research Ethics Committee, 30/03/2006, ref: 06/MRE02/3
Local approval was given by the following: Huntingdon Research Ethics Committee (REC),
Oxfordshire REC C and A, Suffolk Local Research Ethics Committee

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Type 2 diabetes

Interventions

Two stage randomisation trial. Initially a 1:1 randomisation to use of TrackCap measure of adherence; followed at eight weeks by a further randomisation 2:3 between standard care and use of motivational and volitional interventions to support medication adherence.

Standard care:

Participants will be asked to complete measures of belief, habit and intention to take medication regularly as prescribed.

Intervention group:

In addition to procedures for the standard care group, participants' beliefs about benefits and harms, views of important others and issues of control over taking their medication regularly, will be elicited. Participants will also be asked to make action plans for taking medication regularly as prescribed. Information for this group will include the advantages and disadvantages of taking medication regularly and advice about monitoring and reviewing action plans and maintaining motivation.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The proportion of days on which the prescribed doses of main hypoglycaemic medication was correctly taken will be measured with an electronic medication monitor (TrackCap).

Secondary outcome measures

Secondary outcomes include HbA1c and well-being. Serum drug levels, self-reported measures of medication adherence, and information from dispensing records will also be collected to complement the electronic measure.

Overall study start date

01/03/2006

Completion date

01/12/2008

Eligibility

Key inclusion criteria

1. Individuals with type two diabetes of at least three month duration
2. Diagnosed aged 18 years or above
3. Currently taking any oral glucose-lowering agent
4. HbA1c equal to or above 7.5%

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

250

Key exclusion criteria

1. Those deemed by their General Practitioner unable to give informed consent on the basis of documented memory impairment or psychological or psychiatric illness that would make participation inappropriate
2. Those for whom tight glycaemic control would be inappropriate

Date of first enrolment

01/03/2006

Date of final enrolment

01/12/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Institute of Public Health

Cambridge

United Kingdom

CB2 2SR

Sponsor information

Organisation

University of Cambridge (UK)

Sponsor details

16 Mill Lane

Cambridge

England

United Kingdom

CB2 1SB

Sponsor type

University/education

ROR

<https://ror.org/013meh722>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (UK) (ref: G73444)

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

Funder Name

NHS Support for Science Funding (UK)

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	11/04/2008		Yes	No
Results article	results	05/04/2012		Yes	No
Results article	results	05/06/2014		Yes	No
Results article	results	01/12/2014		Yes	No