ISRCTN30522359 https://doi.org/10.1186/ISRCTN30522359

Supported Adherence to Medication Study

Submission date	Recruitment status	[_] Prospectively registered
10/05/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/08/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/02/2016	Nutritional, Metabolic, Endocrine	

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
Robinson Way
Cambridge
United Kingdom
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
Ramdomised 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