

# Supported Adherence to Medication Study

<b>Submission date</b> 10/05/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 31/08/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/02/2016	<b>Condition category</b> 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  
Robinson Way  
Cambridge  
United Kingdom  
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## Additional identifiers

**Protocol serial number**  
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](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

**Primary study design**  
Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Treatment

**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(s)**

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).

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**Institute of Public Health**

Cambridge

United Kingdom

CB2 2SR

**Sponsor information**

**Organisation**

University of Cambridge (UK)

**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, Medical Research Committee and Advisory 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****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				

<a href="#">Results article</a>		05/04/2012	Yes	No
<a href="#">Results article</a>	results	05/06/2014	Yes	No
<a href="#">Results article</a>	results	01/12/2014	Yes	No
<a href="#">Protocol article</a>	protocol	11/04/2008	Yes	No