ISRCTN38274953 https://doi.org/10.1186/ISRCTN38274953

# Improving Adherence to Medication in Stroke Survivors

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| **Submission date**<br>03/12/2009 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>18/01/2010 | **Overall study status**<br>Completed | |
| **Last Edited**<br>27/06/2014 | **Condition category**<br>Circulatory System | |

**Plain English summary of protocol**
Not provided at time of registration

**Study website**
http://www.psychology.stir.ac.uk/research/IAMSS

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Ronan O'Carroll

**Contact details**
University of Stirling
Stirling
United Kingdom
FK9 4LA
reo1@stir.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
CZH/4/569

# Study information

## Scientific Title
Improving Adherence to Medication in Stroke Survivors: a single centre randomised controlled pilot study

## Acronym
IAMSS

## Study objectives
This project will pilot the feasibility of a brief intervention in stroke and transient ischaemic attack (TIA) patients exhibiting sub-optimal adherence to medication with the aim of:
1. Establishing a better medication taking routine using an implementation intentions intervention, and
2. Eliciting and modifying any emergent erroneous beliefs regarding the patient's medication and their stroke

We will test whether medication routines and beliefs are changeable, and if the results are promising, this will pave the way for a larger randomised controlled trial (RCT) to determine whether adherence is improved, physiological risk is changed (e.g. via reduction in blood pressure) and rate of recurrent vascular events is reduced.

The research questions addressed by this study are:
1. Is the brief intervention feasible, understandable and acceptable (e.g. uptake/attrition)?
2. Does the intervention improve adherence?
3. Is improvement in adherence mediated by:
3.1. Changes in illness and medication beliefs, and/or
3.2. Reduced forgetting?
4. What effect size is observed to inform the power calculation for a larger, more definitive study?

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Lothian NHS Board, South East Scotland Research Ethics Committee 02, 30/10/2009, ref: 09/S1102/36

## Study design
Single centre randomised controlled pilot study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Stroke/transient ischaemic attack

## Interventions
Intervention group:
Two brief sessions, two weeks apart with a trained RA, lasting approximately 30 - 45 minutes each. Session 1 will focus on helping each patient draw up a specific plan, so as to establish a better medication-taking routine using an implementation intentions approach. Patients will be helped to complete an individualised worksheet plan for each scheduled daily dose of antihypertensive medication. The participant and RA will both keep a copy of the plan. After completing the implementation intention worksheet in session 1, participants will then complete the Brief Illness Perceptions Questionnaire (BIPQ), and the Beliefs about Medications Questionnaire (BMQ). The participants' responses on these measures will be used as the basis for eliciting and challenging dysfunctional illness and medication beliefs in Session 2. Baseline blood pressure readings will be taken during Session 1. At Session 2, the effectiveness of the implementation intentions plan and any barriers/difficulties in following the plan will be reviewed, with appropriate coping strategies/plans developed collaboratively. This session will also focus on eliciting and, if appropriate, challenging patients' beliefs regarding their medication, e.g. beliefs regarding toxicity, dependence, fears regarding medications interacting harmfully, etc. The aim here will be to correct any misperceptions and provide evidence so that participants' medication necessity beliefs come to outweigh their medication concerns beliefs. Modification of erroneous beliefs about stroke will be based on the model of Petrie, who elicited and modified patients' dysfunctional beliefs regarding their recent myocardial infarction. This resulted in faster return to work and lower angina symptoms at 3 months. If the RA is unable to answer any specific questions regarding the patient's stroke or medication, then immediately following the interview, the RA will email the query to one of the stroke consultant experts on the research team, and the RA will then telephone the patient with the information within 7 days of the interview. At the end of session 2, the RA will fill each participant's MEMS medication bottle with the following month's supply of antihypertensive medication. We propose using the patients existing supply of antihypertensive medication. A check will be taken at session 1, and if supplies are running low, participants will be asked to obtain their repeat prescription in advance of session 2. For each of the next three months, the RA will repeat this process, and also take an electronic reading from the MEMS cap, downloading the data on to a laptop PC for later analysis. At the final visit, the outcome measures will be administered.

Treatment as Usual (TAU) control condition:
Participants in the control group will receive the same number of RA visits, and will also complete the MARS, BMQ, BIPQ, MEMS recordings, and BP recordings at baseline and at three month follow up. During the first 2 sessions, the RA will also engage the TAU participants in non-medication related conversation, e.g. how they are feeling, how they are spending their time, etc., in an attempt to provide some control for non-specific effects of attention/social contact. All interviews will be timed and digitally audio-recorded and transcribed for supervision feedback and check on treatment fidelity.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Medication adherence recorded using MEMS (Medication Event Monitoring System, MEMS® Aardex Ltd, Switzerland) pill containers which electronically record openings. We shall use the following main outcomes, counting each opening as a presumptive dose:
1. Percentage of doses taken
2. Percentage of days on which the correct number of doses was taken
3. Percentage of doses taken on schedule

### Secondary outcome measures
1. MARS self-reported adherence of all secondary preventative medication
2. Systolic and diastolic blood pressure

Recorded at baseline and 3-month follow-up.

### Overall study start date
01/12/2009

### Completion date
30/06/2012

## Eligibility

### Key inclusion criteria
1. Male and female patients who have suffered first-time stroke (ischaemic and haemorrhagic) or transient ischaemic attack (TIA)
2. Age range 18 + years (no upper age range)
3. Discharged from the Edinburgh Western General Hospital stroke units and clinics
4. Prescribed secondary antihypertensive medication on discharge
5. Exhibiting sub-optimal adherence on the Medication Adherence Report Scale (score of 24 or less)
6. Living at home
7. Responsible for own medication

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
We aim to recruit 60 people into the trial (30 in each arm)

### Key exclusion criteria
1. Age below 18 years
2. Marked cognitive impairment (Mini-Mental State Examination [MMSE] less than 23)
3. Significant dysphasia (Frenchay screen greater than 13/20)
4. Already using Dosette boxes (or similar) to improve their medication adherence
5. Participants who are not responsible for their own medication

### Date of first enrolment
01/12/2009

### Date of final enrolment
30/06/2012

## Locations

### Countries of recruitment
Scotland

United Kingdom

### Study participating centre
**University of Stirling**
Stirling
United Kingdom
FK9 4LA

## Sponsor information

### Organisation
University of Stirling (UK)

### Sponsor details
-
Stirling
Scotland
United Kingdom
FK9 4LA
jill.dykes@stir.ac.uk

### Sponsor type
University/education

### Website
http://www.external.stir.ac.uk/

### ROR
https://ror.org/045wgfr59

## Funder(s)

### Funder type
Government

### Funder Name
Chief Scientist Office of the Scottish Executive Health Department (UK) (ref: CZH/4/569)

## 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 | 24/02/2010 | | Yes | No |
| Results article | results | 01/12/2013 | | Yes | No |