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A feasibility study of the effectiveness and cost effectiveness of Medication Organisation DeviceS (MODS)

Submission date
18/04/2012

Recruitment status
No longer recruiting

Registration date
23/04/2012

Overall study status
Completed

Last Edited
08/07/2016

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is important that medicines are taken as prescribed in order to obtain maximum health gain. However, we know that taking medicines exactly as prescribed can be very difficult. We also know that there are many factors that can affect the way that people take their medicines. For example, some people may be forgetful, others may have difficulty getting pills out of their packaging and others may simply not want to take their pills. It would be beneficial in both health and economic terms if medicines were taken exactly as prescribed. Pill boxes which are sectioned into days of the week and times of the day are tools that may help some people to take their medicines as prescribed. Medication is usually received from the pharmacy every month but pill boxes are usually provided every week. At the moment we do not know whether pill boxes are helpful or whether receiving medication weekly compared with monthly makes a difference to whether medicines are taken correctly.

Who can participate?
The greatest difficulty in taking medicines correctly occurs where people regularly take several different kinds of medicine and this most often happens with older people. We will ask people who are 75 years or older and who take at least three different types of pills to take part in our study.

What does the study involve?
Our aim is to carry out a small study that will eventually lead to a much bigger study to confirm whether pill boxes and weekly medication supply help people to take their medicines correctly. We will test two different ways of inviting patients to be involved in the study: by letter and in person. People participating in the study will be randomly allocated to get their medication supplied in the usual packaging either weekly or monthly or in a pill box supplied either weekly or monthly. We will measure whether medicines are taken correctly during the study using an electronic film which will be stuck to the medication packaging of pill box. Every time a patient removes a tablet from its packaging or pill box, this information will be recorded in the film. When the medication packaging or pill box is returned to the pharmacy, an electronic reader can be used to obtain information about how often medication was removed from the packaging or

pill box. At the end of the study we will invite a selection of patients to attend a group discussion to obtain their thoughts and experiences of being involved in the study. This information will help us to make any necessary changes to improve the design of a larger study.

What are the possible benefits and risks of participating?
Study involvement poses no risks to patients but may be inconvenient because there will be questionnaires to complete, home visits from researchers and a change of routine if their method of medication supply is changed from monthly to weekly or usual packaging to a pill box.

Where is the study run from?
The study will be run by researchers at the University of East Anglia and Aberdeen University. Six medical practices and community pharmacies based in Norfolk will help with running the study. Researchers will visit participants in their own homes.

When is the study starting and how long is it expected to run for?
July 2012 to March 2013

Who is funding the project?
National Institute for Health Research Health Technology Assessment programme.

Who is the main contact?
Mrs Clare Aldus

Contact information

Type(s)
Scientific

Contact name
Mrs Clare Aldus

Contact details
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Additional identifiers

Protocol serial number
HTA 09/34/03

Study information

Scientific Title

A feasibility study to determine the effectiveness and cost effectiveness of medication organisation devices in facilitating health benefit and medication adherence in a population aged 75 years and over and taking three or more solid oral dose form medications compared to usual care which will inform future trial design.

Acronym
MODS

Study objectives
This study will inform the design of a full scale RCT to determine the effectiveness and cost effectiveness of medication organisation devices. There are many complex factors that affect medicine taking behaviours. This study aims to elucidate key factors important in medication-taking behaviour and experimental design that will allow clear elucidation of the effectiveness and cost effectiveness of multi-compartment medication devices by enabling informed design of a future full-scale RCT.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/093403
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0011/54389/PRO-09-34-03.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 2x2 factorial feasibility study of 3 months duration

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Older people

Interventions
Intentional non-adherence will be ascertained by questionnaire and intentionally non-adherent participants will be excluded from the randomised controlled trial (RCT). Full adherence will be measured by pill counts in a 3-week pre-trial observational study. Fully adherent participants will be excluded from the RCT. Neither intentionally non-adherent nor fully adherent participants will provide optimal data for the RCT. The proportion of intentionally non-adherent or fully adherent participants determined will also be used to inform future study design.

RCT participants will be assessed for manual dexterity, cognitive ability and visual acuity.

RCT participants (unintentionally non-adherent) will be allocated to receive either a medication organisation device weekly, a medication organisation device 4-weekly, usual medication supply

weekly, or usual medication supply 4-weekly. All participants will have solid oral dose form medications monitored electronically using proprietary films printed with an electronic circuit which records the time at which the circuit is broken by a pack-opening event.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Medication taking events will be measured using proprietary electronic films and results compared for pill boxes and usual supply and weekly and 4-weekly medication supply.

Key secondary outcome(s))
Unintentionally non-adherent RCT trial participants will be characterised using tests of visual acuity, finger dexterity and cognitive ability. These aspects are likely to be particularly important in the study population and results will be compared for medication organisation devices and usual packaging for monthly or weekly supply to ascertain differences.

Participant satisfaction with their method of medication supply, participant perceived autonomy, quality of life data and carers' views on the effects of the medication supply on them and their caring routines will be measured using questionnaire-based tools. Health care utilisation during the period of the study will be assessed using Healthcare Episode Statistics and GP-provided data. Where applicable, results will be compared for pill boxes and usual packaging for monthly or weekly supply to ascertain differences. Information pertaining to health economics (quality of life and healthcare utilisation) will be used to determine cost effectiveness. In addition, views on acceptability, patient autonomy and quality of life in the study population and cost effectiveness will also be used to inform future study design.

Completion date
30/03/2013

Eligibility

Key inclusion criteria
1. Aged 75 years or over
2. Are prescribed three or more solid oral dose form medications for the management of a chronic condition
3. Have a life expectancy equal to or in excess of one year
4. Are capable of providing informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Participants in receipt of a prescribed medication organisation device or with a history of having received amedication organisation device
2. Are resident in a care home
3. Are currently or have recently been involved in medication intervention trials
4. Have been diagnosed with Parkinson's disease
5. Have a severe mental health disorder such as schizophrenia or other clinical contraindications which in the opinion of the healthcare team renders the patient inappropriate for trial participation

Date of first enrolment
02/07/2012

Date of final enrolment
30/03/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of East Anglia
Norwich
United Kingdom
NR7 7TJ

Sponsor information

Organisation
University of East Anglia (UK)

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type

Government

Funder Name
NIHR Health Technology Assessment programme - HTA (UK) ref: 09/34/03

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 article	results	01/07/2016		Yes	No