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A study of an Electronic Medicine Management Assistant (EMMA®) system

Submission date
04/07/2011

Recruitment status
Stopped

Registration date
19/07/2011

Overall study status
Stopped

Last Edited
27/08/2013

Condition category
Circulatory System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Many people who take prescribed medicines find it difficult to remember to take them as their doctor has recommended (i.e. taking the medicines in the right amount and at the right time). This is especially true for people who have to take several different medicines every day. If medicines are not taken as intended by the doctor this might mean that the medicines do not work as well as they should. Therefore various devices have been developed to help people to take their medicines at the correct time and in the correct way.

One such device is an Electronic Medicine Management System known as EMMA®, already used in the USA. EMMA® is a computer aided medicine storage unit that alerts people (noises and on-screen displays) when medicines are supposed to be taken and supplies (dispenses) the medicines to a person at those times in their own home. It also keeps a record of when medicines have been supplied so that the patients GP will know this and be better informed when reviewing the patients medicines.

In this study, we want to find out if people in the UK find EMMA® a useful way to help them manage their medicines. We will see if people having their medicines supplied in an EMMA® unit find it easier to take their medicines as directed by the doctor, and how they feel in general, compared to a group of people continuing to receive their medicines in the usual packaging.

Who can take part?
You are eligible for participation
1. If you use the participating community pharmacies
2. Have difficulty remembering to take your medication(s) and
3. Take four or more different medicines each day or
4. Take a specific medicine usually used to treat heart failure, called furosemide

What does the study involve?
GPs will be asked to confirm if you are eligible to take part. If you have a carer who helps you with your medicines they will also be invited to take part. A researcher will come to your home to confirm if you are suitable to take part in the study i.e. if you would benefit from a device, are able to operate the device and have room to house it. At this visit you will also be asked to

complete a questionnaire. You will then be assigned by chance to either intervention group, receiving medications from the EMMA® device, or to the usual care group, receiving medicines as usual. If you are assigned to the EMMA® group, you will receive another visit to setup the device and you will be taught how to operate it.

At the start of the study, any medicines that you have in your possession will be noted and stored in a tamper proof pack. A new prescription of all your medicines will be ready for you when the study starts. If you are assigned to the EMMA® group, your medicines will be delivered with the EMMA® unit and you will then use the unit for the next four months. If you are in the usual care group, you will get your prescription dispensed as usual in the pharmacy and continue to take your medicines as usual for the next four months.

After four months all patients, both EMMA® and usual care groups, will be visited again by a researcher who will ask them to complete a follow-up questionnaire. The medicines in the tamper proof pack will be checked against the most recent prescription to ensure they are still relevant and handed back to you. Some patients might be asked to take part in an interview about their experiences of using the EMMA® unit.

What are the possible benefits and risks of participating?
Benefits:
The EMMA® unit is a new solution for managing your medicines. If you have trouble remembering how and when to take your medicines the EMMA® unit could help you by:
1. Reminding you when to take your medicines
2. Releasing the correct dose at the correct time
3. Overall, this may mean you rely less on others

Risks:
1. If you are in the usual care group there are no risks associated with taking part
2. If you are in the EMMA group there are some minor problems which could arise:
2.1. If you need to take a dose of medicine at a time other than scheduled this is possible by manually asking for it from the EMMA® unit but this action will be recorded
2.2. If there is a failure with EMMA® and the medicine is not provided, you or your caregiver should immediately contact the service center
2.3. If there is loss of mains power to EMMA®, the EMMA® unit has an automatic battery backup that provides immediate power to the device for up to two hours. If nearly two hours have passed since power was lost, the labelled packs of medicines are automatically released from the EMMA® unit and can then be taken in the usual manner
2.4. You will also be given an emergency pack by the pharmacist containing a two day supply of essential medicines according to your prescription. Therefore, there is no risk that you would be without your medicines because of loss of power to the EMMA® unit

Where is the study run from?
The study is taking place in Grampian, Scotland.

When is the study starting and how long is it expected to run for?
Recruitment of patients will start in August 2011 and follow-up of patients will end in April 2012.

Who is funding the study?
The study is funded by the manufacturers of EMMA®, INRange Systems, Inc.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of an Electronic Medication Management Assistant (EMMA®) in improving patient adherence to medicines compared to usual care

Acronym
EMMA

Study objectives
The overall aim is to evaluate, in a population of primary care based, domiciliary patients on either polypharmacy regimes or with heart failure, whether use of a remotely controlled point-of-care medication administration system (EMMA®) leads to improved patient medication adherence, compared to patients self-administering medication following usual procedures.

The hypothesis is that patients who are reminded to take a medication at the exact time prescribed and provided with the correct dose will be more adherent to the prescription than those self administering alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committees North of Scotland, Committee 1 approved on 16/06/2011 (REC ref.: 11/AL /0153)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

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
Heart failure and polypharmacy

Interventions
This is a randomized controlled trial; the Intervention Group will use the EMMA® device and the Control Group will receive and administer their medicines according to current usual practice.

Patients randomised to the intervention arm will use the EMMA® device for four months. All medication will be dispensed for the patient packaged in blister cards designed for the EMMA® unit. Patients or their carers will load the blister cards into the EMMA® unit and the EMMA® unit will administer the patients medications based upon the programmed instructions. Medications not suitable for a blister pack will be supplied in standard containers, but EMMA® will still be programmed to prompt their administration at the appropriate times.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Medication adherence will be assessed using the Morisky Scale and/or the Medication Adherence Rating Scale (MARS).

Assessments are carried out at baseline (pre-randomisation) and follow-up is carried out at four months after randomisation.

Secondary outcome measures
1. SF-12
2. Hospital Anxiety and Depression Scale (HADS)
3. Medication Understanding and Use Self-Efficacy Scale (MUSE) - the Taking Medication Sub-scale
4. The Caregiver Assessment of Difficulties index (CADI) and the Caregiver Assessment of Satisfaction Index (CASI)
5. Health service utilisation cost
6. Medication administration errors
7. In the intervention group only, the experiences of users, and acceptability of the EMMA® system to users (patients, carers, professionals (pharmacists and prescribers)

Assessments are carried out at baseline (pre-randomisation) and follow-up is carried out at four months after randomisation.

Overall study start date
01/08/2011

Completion date
31/03/2012

Eligibility

Key inclusion criteria
Detailed inclusion criteria are that patients must use participating pharmacies and:
1. Be at least 18 years of age
2. Be alert and oriented to person, place, and time
3. Primarily use English language for written and oral communication
4. Be on a regular prescription for furosemide or be taking four or more (but less than 20) different prescription medications
5. Have a self-reported history of inconsistent patient self-medication management
6. Be living in the study area
7. Achieve a score of >24 on the Mini-Mental State Exam (Folstein, Folstein and McHugh 1975)
8. Have dexterity and visual acuity to open the individual unit dose medicine packages used in EMMA®
9. Have the facility in their home to permit EMMA® to communicate with its server either utilising an internet connection or utilising the EMMA® devices built-in cellular modem

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Patients: N = 156; Carers: N = 156

Key exclusion criteria
1. Have disabilities preventing safe use of the EMMA® Device (e.g. blindness, amputation, paralysis)
2. Have an anticipated life expectancy of less than three months
3. Are, in the opinion of either the responsible general practitioners (GP) or the pharmacist, unsuitable for the trial e.g. severe mental illness; other family circumstances
4. Are known to be intentionally non-adherent to their medication regimen
5. Are already receiving their medication in an MDS (monitored dosage system)

Date of first enrolment
01/08/2011

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Academic Primary Care
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
INRange (USA)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
INRange (USA)

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