

Nurse-led medication monitoring for patients with dementia and adverse events

Submission date 25/04/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/07/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/10/2015	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English Summary

Background and study aims

It is important to improve the quality of care for people with dementia through person-centred care and reduction in inappropriate use of medications. Most side effects to long-term medicines could be improved by regularly looking for it in patients. We suggest to introduce this using the West Wales Adverse Drug Reaction (ADR) Profile for Mental Health medicines. This comprises of a checklist of questions, and observations (including weight and blood pressure), based on the known side effects of mental health medicines. The first section can be passed to the prescriber, with problems highlighted, while the health promotion section is passed to nurses or carers with suggestions for actions. Guidelines are supplied. The aim if this study is to find out if observing the medications given, improves clinical outcome. The ADR Profile is already available in the public domain, will be used in the care home as an education package

Who can participate?

This study aims to recruit 50 patients with dementia, or a dementia subtype, living in care homes. At enrolment, participants must be taking at least one of antipsychotic, antidepressant or anti-epileptic medicines.

What does the study involve?

Five care homes will use the West Wales (ADR) profile with 10 patients each at different intervals. Care home staff will complete the ADR profile during usual care. This will involve observing or questioning patients and seeking information from medical records. Care home staff will complete short assessments at each interval. Information will be taken from the patients notes for evidence of medication monitoring, problems identified, actions taken, and outcomes. Staff will be asked to provide some feedback at the end of the project during short interviews.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part. However, there should be benefits to future service users with dementia receiving at least one of the targeted medications. We foresee no physical or emotional risks to participants.

Where is the study run from?

The study has been set up by Swansea University in collaboration with West Wales Organisation for Rigorous Trials in Health and Social Care, UK.

When is the study starting and how long is it expected to run for?

Recruitment of participants starts in April 2013. Participants will be enrolled on the study for a period of up to seven months.

Who is funding the study?

Funding has been provided by Wales School for Primary Care Research (WSPCR), Cardiff, UK.

Who is the main contact?

Dr Susan Jordan, s.e.jordan@swansea.ac.uk

Dr Marie Gabe, m.gabe@swansea.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Susan Jordan

Contact details

College of Human and Health Sciences

Swansea University

Singleton Park

Swansea

United Kingdom

SA2 8PP

+44 1792 518541

s.e.jordan@swansea.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Nurse-led medication monitoring using the West Wales Adverse Drug Reaction (WWADR) for patients with dementia in care homes in South West Wales: a feasibility study for a stepped wedge trial

Acronym

WWADR

Study hypothesis

We hypothesise that structured nurse-led medication monitoring using the West Wales Adverse Drug Reaction (ADR) for mental health, alongside usual care, will help detect previously unsuspected ADR-related problems for residents in care homes. Jordan S., Knight J., Pointon D. 2004 Monitoring Adverse Drug Reactions: Scales, Profiles and Checklists. International Nursing Review. 51, 208-221

Ethics approval required

Old ethics approval format

Ethics approval(s)

The South West Wales Research Ethics Committee, 10 April 2013, ref: 13/WA/0067

Study design

Stepped-wedge cluster RCT of nurse-led medication monitoring in 5 care homes at monthly intervals. Randomisation performed by West Wales Organisation for Rigorous Trials in Health and Social Care

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

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

Condition

Dementia, including dementia subtypes

Interventions

Staff in the care home, who are responsible for patient care, will use the West Wales Adverse Drug Reaction Profile for mental health between 1-5 times for each participant. Supporting scales will be completed at the discretion of the clinical staff.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Problems found and actions taken at each step in the trial. Each step is separated by one month and data will be collected using the ADR profile and case note review.

Secondary outcome measures

This project will be used to develop a feasibility study to assess:

1. Rates of recruitment, retention, compliance and cross-over
2. Feasibility of reporting changes in documentation for:
 - 2.1. Amelioration of problems found using the profile
 - 2.2. Problems found and actions taken using the profile
 - 2.3. Medication review or changes
 - 2.4. Patients with different severity of illness
3. Develop clinical endpoints for a full trial, such as measures to capture changes in patients functioning
4. Calculate intra-cluster correlation coefficient (ICC), and any time delay to patient benefits
5. Explore the basis for cost-effectiveness analysis
6. Report views of care home staff on the WWADR profile for mental health medicines

Overall study start date

01/04/2013

Overall study end date

28/02/2014

Eligibility**Participant inclusion criteria**

1. Resident at the care home
2. Diagnosed with dementia or dementia subtypes
3. Currently taking at least one of: antipsychotic or anti-epileptic or antidepressant medicine
4. Willing and be able to give informed, signed consent themselves, or if capacity is lacking, guardian or representative willing to give consent to access the patient records

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

50

Participant exclusion criteria

1. Not be well enough to participate, as screened by their nurses
2. Those aged 18 or under

Recruitment start date

01/04/2013

Recruitment end date

28/02/2014

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

College of Human and Health Sciences

Swansea

United Kingdom

SA2 8PP

Sponsor information

Organisation

Swansea University (UK)

Sponsor details

c/o Ceri Jones

Department of Research and Innovation,

Singleton Park

Swansea

Wales

United Kingdom

SA2 8PP

Sponsor type

University/education

ROR

<https://ror.org/053fq8t95>

Funder(s)

Funder type

Research organisation

Funder Name

Wales School for Primary Care Research (WSPCR), Cardiff (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?
Results article	results	13/10/2015		Yes	No
HRA research summary			28/06/2023	No	No