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

Submission date
25/04/2013

Recruitment status
No longer recruiting

Registration date
15/07/2013

Overall study status
Completed

Last Edited
16/10/2015

Condition category
Nervous System Diseases

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

Plain English summary of protocol

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?
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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
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 objectives
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

Health condition(s) or problem(s) studied
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

Completion date
28/02/2014

Eligibility

Key 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

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

Date of first enrolment

01/04/2013

Date of final enrolment
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
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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