ISRCTN10386209 https://doi.org/10.1186/ISRCTN10386209

Nurse-led medication monitoring and adverse events

Submission date	Recruitment status	[_] Prospectively registered
30/11/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/04/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/01/2015	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sue Jordan

Contact details
School of Human and Health Sciences
Swansea University
Singleton Park
Swansea
United Kingdom
SA2 8PP

Additional identifiers

Protocol serial number
NA

Study information

Scientific Title
Nurse-led medication monitoring and adverse events in a respiratory medicine outpatient department. A single site parallel group pragmatic randomised controlled trial (RCT) of the West Wales Adverse Drug Reaction (WWADR) Profile for Respiratory Medicine

Acronym
WWADR 2

Study objectives
Concurrent and formal monitoring of respiratory medication Adverse Drug Reactions (ADRs) using the WWADR Profile for Respiratory Medicine in addition to 'usual' care will increase the number of problems detected and actioned by nurses compared to 'usual' nursing care alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The South West Wales Research Ethics Committee approved on the 10th of February 2010 (ref: 09/WMW02/60)

Study design
Single centre pragmatic randomised controlled parallel group trial with stratified random allocation to groups

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic respiratory disease

Interventions
Patients with chronic respiratory disease attending the nurse-led respiratory clinics will be allocated to one of two groups. Allocation by concealment, stratified randomisation by West Wales Organisation for Rigorous Trials in Health and Social Care (WWORTH).

1. WWADR Profile for Respiratory Medicine in addition to usual nursing care:
A five sectioned profile that records medication used by patient, vital signs, and asks a series of questions about their medication and several observations along with checking when laboratory tests were last done.
2. Usual nursing care alone

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Number of problems detected in rounds one and two identified using the WWADR profile

Key secondary outcome(s))
1. Number of problems actioned by the nurse in rounds one and two
2. Action taken is recorded descriptively and identified using the WWADR profile

Completion date
01/06/2012

Eligibility

Key inclusion criteria
1. Patients attending the outpatient respiratory clinics in Singleton Hospital, Swansea, Wales
2. Existing chronic respiratory condition
3. Currently prescribed and receiving at least one of:
3.1. Bronchodilators
3.2. Corticosteroids
3.3. Theophylline
3.4. Leukotriene receptor antagonists

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Aged 16 or under
2. Lack of fluency in English or Welsh
3. Patients will be screened by trained physicians and/or nurses to ensure they are well enough to participate in this project, and will be excluded as necessary by their clinicians:
3.1. Patients considered lacking the capacity to consent
3.2. Patients experiencing undue stress or vulnerability

Date of first enrolment
05/01/2011

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
School of Human and Health Sciences
Swansea
United Kingdom
SA2 8PP

Sponsor information

Organisation
Swansea University (UK)

ROR
https://ror.org/053fq8t95

Funder(s)

Funder type
Research organisation

Funder Name
Research Capacity Building Collaboration (RCBC) Wales (UK)

Alternative Name(s)
RCBC

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	05/05/2014		Yes	No