

# Nurse-led medication monitoring and adverse events

<b>Submission date</b> 30/11/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/04/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/01/2015	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**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**

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 measure**

Number of problems detected in rounds one and two identified using the WWADR profile

### **Secondary outcome measures**

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

### **Overall study start date**

05/01/2011

### **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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

50

### **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)

**Sponsor details**

c/o Ceri Jones

Singleton Park.

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**Sponsor type**

University/education

**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

**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?
<a href="#">Results article</a>	results	05/05/2014		Yes	No