An evaluation of an adapted United States model of pharmaceutical care to improve psychoactive prescribing for nursing home residents in Northern Ireland

Submission date	Recruitment status No longer recruiting	Prospectively registered	
21/09/2006		☐ Protocol	
Registration date 17/10/2006	Overall study status Completed Condition category	Statistical analysis plan	
		[X] Results	
Last Edited		Individual participant data	
11/07/2011	Mental and Behavioural Disorders		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Carmel M Hughes

Contact details

School of Pharmacy Medical Biology Centre 97 Lisburn Road Belfast United Kingdom BT7 9BL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Acronym

Fleetwood (N.I.) Project

Study objectives

This project aims to answer the following questions:

- 1. Can an adapted US model of care (the Fleetwood model) improve psychoactive prescribing and reduce falls in nursing home residents in Northern Ireland?
- 2. Does healthcare resource usage (i.e. direct healthcare costs) change as a result of the implementation of the Fleetwood model?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval for the study has been obtained from the Research Ethics Committee 2 of the Office for the Research Ethics Committees, Northern Ireland, date of approval: 15th August 2005 (reference number: 05/NIR02/112).

Study design

Cluster randomised controlled trial (12 month duration)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

This intervention aims to improve the psychoactive prescribing for residents in nursing homes. It is not disease specific.

Interventions

The intervention being tested is an adapted US model of pharmaceutical care - the Fleetwood model. This care model is provided to intervention home residents by pharmacists who have received specialist training in medicines for older people. It consists of monthly visits to nursing

homes and includes the following steps:

- 1. Assessment of residents pharmaceutical care needs
- 2. Medication review
- 3. Preparation of a pharmaceutical care plan that is shared between the relevant healthcare personnel
- 4. Pharmacist intervention and direct communication with the prescriber

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The primary outcomes for this trial will be a change in the prevalence of inappropriate psychoactive drug use and the number of residents who fall in the intervention homes compared to the control sites, over the 12 month study period. At three, six and 12 months, equivalent data as per baseline (excluding patient demographic data) will be collected using documentation provided by the US trial investigators and adapted for use in the present study, in addition to the number and length of pharmacist consultations (intervention group only).

Secondary outcome measures

It has been shown that patients on psychoactive medication are more likely to fall, incurring additional costs to health care systems. Therefore, a secondary outcome of this study will be to examine and quantify the changes in resource usage as a result of the implementation of the modified Fleetwood model. Direct medical (healthcare) costs for both intervention and control patients will be calculated using the framework outlined by Drummond et al. (2000). The evaluation will be performed from the perspective of the payer: direct non-medical, indirect and intangible costs will not be estimated.

Cost estimates will be calculated using data collected at baseline and throughout the intervention period (e.g. hospitalisations, number of consultations), in conjunction with national accounting statistics representative of unit costs surveyed across the United Kingdom. The cost of patient drugs will be obtained from the standard Drug Tariff. Resource use data will be collected for 12 months prior to baseline and for 365 days (to standardise calculation of unit costs) after enrolment or until death. Mean annual cost estimates for each type of resource group will be shown separately (e.g. drug cost, hospitalisations, General Practitioner visits) and compared pre- and post-enrolment and by allocation to control or intervention group.

A secondary outcome to be evaluated in this study will be professional satisfaction of intervention prescribing support pharmacists, GPs and nurses (of intervention residents) with the programme. This will be assessed using postal questionnaires.

Overall study start date

01/04/2006

Completion date

31/08/2007

Eligibility

Key inclusion criteria

Eleven matched pairs of nursing homes were selected at random from all those in Northern Ireland with greater than 30 beds, which consented to participate in the project. Within each home, all residents aged more than 65 years were invited to participate. Where appropriate, their next-of-kin were approached for consent to participate.

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

330

Key exclusion criteria

Residents were excluded if they were terminally ill, in a coma or if no consent was obtained.

Date of first enrolment

01/04/2006

Date of final enrolment

31/08/2007

Locations

Countries of recruitment

Northern Ireland

United Kingdom

Study participating centre School of Pharmacy

Belfast United Kingdom BT7 9BL

Sponsor information

Organisation

Queen's University Belfast (UK)

Sponsor details

Research and Regional Services Department Lanyon North University Road Belfast Northern Ireland United Kingdom BT7 1NN +44 (0)28 9097 5800 rrs@qub.ac.uk

Sponsor type

University/education

Website

http://www.qub.ac.uk/rrs

ROR

https://ror.org/00hswnk62

Funder(s)

Funder type

Government

Funder Name

Research and Development Office for the Health & Personal Social Services (UK) (reference no: EAT/2528/03)

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	01/01/2010		Yes	No

Results article results

01/04/2011

Yes

No