Randomised Evaluation of Shared Prescribing for Elderly people in the Community over Time

Submission date

Recruitment status

No longer recruiting

Registration date 02/05/2001

Overall study status

Completed

Last Edited

02/05/2001

Condition category

19/12/2017 Other

[X] Prospectively registered

[X] Protocol

Statistical analysis plan

[X] Results

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers G0001150

Study information

Scientific Title

Randomised Evaluation of Shared Prescribing for Elderly people in the Community over Time

Acronym

RESPECT

Study objectives

Principal research questions to be addressed:

- 1. Is shared pharmaceutical care for elderly people in the community effective in:
- 1.1 improving the quality of prescribing?
- 1.2 improving patient's knowledge about their disease and medication?
- 1.3 improving compliance?
- 1.4 reducing adverse events?
- 1.5 and thus improving quality of life?
- 2. Is shared pharmaceutical care for elderly people in the community cost-effective?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Primary care

Interventions

General practices, pharmacies and patients will be grouped according to the Primary Care Trust to which they belong. These five groups will begin the intervention (pharmaceutical care) in five successive phases, the order of which will be randomly determined. All five will act as controls until the intervention begins, e.g. community pharmacists will provide their usual dispensing services during this 'control period'.

The experimental intervention is pharmaceutical care (PC), in which pharmacists co-operate with doctors, patients and carers in designing, implementing and monitoring a pharmaceutical care plan (PCP). GPs and community pharmacists in the same PCT are asked to attend the same training block. This consists of one workshop for community pharmacists on PC for the elderly and one joint workshop for pharmacists and GPs on how to work together. These workshops encourage a problem-based approach to the application of pharmaceutical care.

Once trained, community pharmacists meet recruited patients and follow a specific step by step procedure advocated for the development of a PCP. In addition pharmacists educate patients and, if appropriate, carers about the indication for each medication and its use, and withdraw unwanted medicines with patients' consent. If patients need compliance aids such as dosette boxes or reminder charts, the pharmacists provide these services. They continue to update and implement the PCP, and monitor outcome at least monthly in association with patients and their GPs.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Medication Appropriateness Index (Validated for the UK).

Secondary outcome measures

Patients' knowledge, compliance and concordance, practice-reported (and therefore more serious) adverse events, and self-assessed health outcome.

Economic: Cost of treatment to NHS, patients and society as a whole.

Overall study start date

01/02/2002

Completion date

28/02/2006

Eligibility

Key inclusion criteria

Patients aged more than 75 years with repeat prescriptions for five or more drugs (excluding drugs taken only when required), who are living at home, well oriented in time and place, and able to give their consent to take part. Their GPs' consent is also necessary.

Participant type(s)

Patient

Age group

Not Specified

Sex

Target number of participants

760

Key exclusion criteria

Patients in residential or nursing homes. Patients who took part in our feasibility study of vulnerable elderly people or who normally use a pharmacy which has refused to participate in the trial. Patients with dementia who score 6 or below on the Abbreviated Mental Test.

Date of first enrolment

01/02/2002

Date of final enrolment

28/02/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre School of Pharmacy

London United Kingdom WC1N 1AX

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

http://www.mrc.ac.uk

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

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?
<u>Protocol article</u>	protocol	07/06/2004		Yes	No
Results article	cost effectiveness results	01/01/2010		Yes	No
Results article	effectiveness results:	01/01/2010		Yes	No