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Pharmacist-led home based clinical medication review in stroke

Submission date	Recruitment status	[_] Prospectively registered
12/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/03/2017	Circulatory System	

Plain English summary of protocol

Background and study aims
Pharmacists carrying out reviews of patients medicines have shown that they can identify and resolve medication-related problems. Pharmacists also help patients find ways of taking their medicines appropriately and improve management of their conditions. Studies have shown pharmacists improve stroke patients satisfaction, retain quality of life and help reduce admissions to hospital. Our previous work investigated the beliefs and concerns of stroke patients and identified barriers to medicine taking. We have designed a care plan incorporating these findings. A pilot study was planned to explore the feasibility of undertaking a much larger trial to test if a pharmacist applying this care plan to stroke patients in their own home can make a difference to their health and reduce the risk of further stroke.

Who can participate?
Men and women, aged 53-92 years, who were being discharged from hospital in NHS Lothian following a stroke were recruited over a 4-month period from one of the three acute stroke units or three rehabilitation units or the neurovascular outpatient clinic.

What does the study involve?
Patients were randomly allocated to one of two groups: a study group or a usual care group. The study group received three visits in their own homes from a clinical pharmacist researcher at 1, 3 and 6 months after discharge from hospital. The pharmacist obtained information about the patients medicines, conditions being treated and relevant test results from the patients General Practitioner (GP) and completed a care plan for each patient. The care plan facilitated and allowed assessment of the gathered patient information against current national clinical standards and guidelines for prevention of another stroke.

Examples of what was assessed:
1. Whether the patient was on all the medicines currently recommended for prevention of another stroke
2. Whether the doses were appropriate for the patients kidney function and clinical results
3. Whether medicines were interacting
4. Whether other diseases required treatment and possible need for additional medicines

The pharmacist also gave help with practical issues around medicine taking such as physical taking of medicines and formation of medicine taking routines. Also, advice on lifestyle issues such as smoking, diet, alcohol intake and exercise was given if necessary. Following each visit, a letter was sent to the patients GP and Community Pharmacist recording medicine-related problems and recommended actions to resolve problems where appropriate with an invitation to discuss with the clinical pharmacist researcher if required.
The usual care group were discharged from hospital following standard procedures which did not involve a detailed care plan and follow up at home by the clinical pharmacist researcher. All patients in both of the groups received a questionnaire at 6 months which included sections to measure patient satisfaction, quality of life and beliefs about medicines. A memory test was also completed at time of recruitment and at 6 months.

What are the possible benefits and risks of participating?
The benefit to the study group was that they received follow up after discharge from hospital in their own homes by a clinical pharmacist researcher with experience in stroke who ensured that patients were on the correct medicines at the correct doses for prevention of another stroke and were taking them appropriately. Blood pressure, lipid (fat) levels and blood sugar test results were monitored to assess whether medicines were being taken and target measurements achieved. Any issues identified by the pharmacist were resolved and communicated to the patients GP and community pharmacist. There were no more risks than usual care and in fact there was opportunity for improved care.

Where is the study run from?
The study was run from NHS Lothian Pharmacy Service (UK) in collaboration with stroke physicians.

When is the study starting and how long is it expected to run for?
The study started in July 2009 and was completed in 2010.

Who is funding the study?
The study was funded by the Chief Scientist Office as part of the NHS Lothian Health Services Research Programme (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
7874

Study information

Scientific Title
A randomised exploratory trial of a pharmacist-led home based clinical medication review in people after stroke

Study objectives
Feasibility study of home based pharmacist-led clinical medication review using an evidence based pharmaceutical care plan at 1 month and 3 months after discharge from hospital. Follow up at 6 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lothian Local Research Ethics Committee 03, 11/06/2009, ref: 09/S1103/21

Study design
Single-centre randomised interventional process of care trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Topic: Stroke Research Network; Subtopic: Primary Care; Disease: Community study

Interventions
Pharmacist home-based clinical medication review in people after stroke versus usual care. The pharmacist visits the intervention group at home and uses the pharmaceutical care plan as a structured approach to identify pharmaceutical problems, resolves the problems and communicates with relevant healthcare professionals. Visits are undertaken at 1 month and 3 months after discharge from hospital. All patients are followed up at 6 months with blood pressure measurements being undertaken by independent researchers.

Study entry: single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Recruitment rate - eligibility and participation. Measured 6 months after recruitment (due for completion May 2010)

Key secondary outcome(s))
At 6 months:
1. EUROQoL
2. Beliefs about Medicines Questionnaire
3. Self-reported adherence
4. Medication adherence

Completion date
30/05/2010

Eligibility

Key inclusion criteria
1. Patients with stroke due for discharge home from acute, rehabilitation or out-patient neurovascular clinic settings
2. Male and female, aged 53-92 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Discharge to long-term care
2. Terminal serious illness
3. Severe confusion such that the patient does not have capacity to understand or give informed consent
4. Unable to nominate a community pharmacy
5. Severe dysphasia

Date of first enrolment
21/07/2009

Date of final enrolment
30/05/2010

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Western General Hospital
Edinburgh
United Kingdom
EH4 2XU

Sponsor information

Organisation
NHS Lothian (UK)

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2017		Yes	No