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Title Page

A pilot study to assess the practicality, acceptability and feasibility of a randomised controlled trial to evaluate the impact of a pharmacist complex intervention to stroke patients in their own homes.

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Abstract

Objective

To test the practicality, acceptability and feasibility of recruitment, data collection, blood pressure monitoring and pharmaceutical care processes, in order to inform the design of a definitive randomised controlled trial of a pharmacist complex intervention to stroke patients in their own homes.

Methods

Patients with new stroke from acute, rehabilitation wards and a neurovascular clinic (NVC) were randomised to usual care or to an intervention group who received a home visit at 1, 3 and 6 months from a clinical pharmacist. Pharmaceutical Care comprised medication review, medicines and lifestyle advice, pharmaceutical care issue (PCI) resolution and supply of individualised patient information. A pharmaceutical care plan was sent to the General Practitioner and Community Pharmacy. Blood pressure and lipids were measured for both groups at baseline and at 6 months. Questionnaires covering satisfaction, quality of life and medicine adherence were administered at 6 months.

Results

Of 430 potentially eligible patients, 30 inpatients and 10 NVC outpatients were recruited. Only 33/364 (9.1%) NVC outpatients had new stroke. Thirty five patients completed the study (intervention = 18, usual care = 17).

Questionnaire completion rates were 91.4% and 84.4% respectively. Blood pressure and lipid measurement processes were unreliable. From 104 identified PCIs, 19/23 (83%) recommendations made to General Practitioners were accepted.

Conclusions

Modifications to recruitment is required to include patients with TIA. Questionnaire response rates met criteria but completion rates did not which merits further analysis.

Lipid measurements are not necessary as an outcome measure. A reliable BP monitoring process is required.

Key Messages:

What is known

- Recurrent stroke accounts for approximately 25% of all strokes
- Systematic reviews of complex interventions in stroke conclude that few have been adequately developed or evaluated
- There is scope for pharmaceutical care to optimise stroke secondary prevention

This study adds:

- Consider inclusion of patients with TIA to improve recruitment rate. Face to face invitation to participate is more successful than postal invitation
- If BP is to be used as an outcome, a reliable process for measurement is required
- Although questionnaire return rate was acceptable, reasons for lower completion rates require investigation
- Iterative feasibility testing is necessary to inform an randomised control trial

INTRODUCTION

National and European stroke guidelines state that patients requiring admission to hospital should be admitted to a stroke unit staffed by a coordinated multidisciplinary stroke team.[1, 2] In the acute setting this usually includes a specialist clinical pharmacist whilst on discharge from hospital, pharmaceutical care is generally managed by non-specialist community pharmacists. A proportion of stroke patients on discharge do not have contact with the community pharmacist because they are unable

to visit the pharmacy in person.[3, 4] Qualitative studies in stroke patients' homes have identified the barriers and difficulties which patients experience taking their medicines.[3, 4] Stable medicine routines, appropriate medicine and illness beliefs, communication at the secondary/ primary care interface, individualised information and practical help from healthcare staff with medicine organisation are the key factors in optimising medicine taking behaviour.[3, 4]

Medication and lifestyle modification may reduce recurrent vascular events in patients with stroke by 80% over five years.[5] One third of stroke patients discontinue secondary prevention medication within one year[6] and recurrent stroke accounts for approximately 25% of all strokes.[7]

There is evidence that pharmacists can manage control of blood pressure (BP) in diabetics with cardiovascular disease to reach targets.[8] In stroke patients, a systematic review of interventions to improve BP through adherence to antihypertensive medicines included one pharmacist led study.[9] The intervention consisted of 6 x 1 hour face to face counselling sessions in 160 patients for 6 months in a hospital outpatient clinic. The design and reporting of this study limits its interpretation.[10] Pharmacist telephone interventions in stroke patients have been shown to help reach secondary stroke prevention goals.[11] The Cochrane review of interventions in secondary prevention of stroke[12] concludes that there is no clear evidence of change in modifiable risk factors with educational or behavioural interventions alone without also organisational changes. Systematic reviews have concluded that few complex interventions in stroke have been 'adequately developed or evaluated' due to multiple primary outcomes, insufficient statistical powering and poor intervention development.[12,13] Our complex intervention is based on previous pharmaceutical needs assessment.[3] We propose to undertake a randomised

controlled trial (RCT) to evaluate a complex intervention [14] of structured pharmaceutical care (Appendix 1) delivered by a pharmacist to stroke patients in their own homes with the hypothesis that the intervention will increase the proportion of patients reaching target blood pressure (BP). In line with Cochrane,[12] elements of education and behavioural intervention for patients and their carers/stroke service providers and organisational interventions including associated communication and follow up with the multidisciplinary team (MDT) would be included. This pilot study assesses the feasibility of the processes required for an RCT to define an appropriate primary outcome measure and potential sample size for a future RCT.

OBJECTIVES

This pilot study aimed to test the practicality, acceptability and feasibility of recruitment, data collection, BP monitoring and pharmaceutical care processes in order to inform the design of a definitive RCT of a pharmacist complex intervention to stroke patients in their own homes.

Pilot Study Outcomes

The outcome was determination of feasibility of the following processes:

- Recruitment - consent rate, drop out rate, eligibility criteria, randomisation process
- Data collection – availability and accessibility of clinical and prescribing data from primary and secondary care patient records, questionnaire return and completion rates
- BP measurement - setting/method/operator, drug treatment effect, variability

- Pharmaceutical care – process of identification and method of resolving care issues

Pilot study criteria (proposed – agreed by expert group consensus)

Recruitment – two thirds of inpatients eligibility, 50% consent and 10% attrition

Data Collection – Clinical and prescribing data accessible at time of retrieval from hospital and GP computer systems. 90% questionnaire return and completion rates.

BP – consistency (90%) in measurements taken by clinical pharmacy researcher and nurse in different settings.

Pharmaceutical care – identified care issues are recorded, categorised according to an internationally recognised method [15], acted upon and followed up.

Ethics

The local Research Ethics Committee approved the study in June 2009 (09/S1103/21) and local National Health Service Research and Development Management approval was granted.

METHOD

Participants and setting

Approximately 1400 stroke patients per annum are diagnosed in the regional health organisation which has 3 acute stroke wards, 3 stroke rehabilitation centres and an outpatient neurovascular clinic (NVC).

Inclusion criteria

Patients with a confirmed diagnosis of stroke who were either discharged home from an inpatient hospital unit or attended the NVC.

Exclusion criteria

(1) Dysphasia (assessed by Speech and Language therapy) or confusion (assessed by the Mini Mental State Examination (MMSE) score < 24) severe enough to prevent patients from understanding the rationale for the study or giving informed consent

(2) Discharge to long term nursing care

(3) Terminal illness

(4) Inability to nominate a community pharmacy

Recruitment

Patients due for discharge from acute and rehabilitation stroke units were identified by the ward team who obtained permission from potentially eligible inpatients to be approached by the clinical pharmacist researcher who visited the patient to discuss the study, provide a patient information sheet and obtain consent. Stroke patients attending the outpatient NVC were identified through the electronic patient management system and posted an invitation letter, patient information sheet and consent form for postal return.

Patients were included from all care settings as previous work by the research team has shown that all stroke patients have pharmaceutical care needs.[3]

Randomisation

Randomisation would be required in a definitive study to compare outcomes between groups. Randomisation to intervention or usual care group was undertaken using sequentially numbered opaque envelopes prepared by an independent person to ensure allocation concealment. Previous work suggests patients living alone have more problems with their medicines.[3] Therefore stratification was applied prior to randomisation to ensure equal numbers of living alone in each group. The researcher and wider healthcare team were not blinded to the treatment arm of the study.

Data Collection and Intervention

The intervention tool was designed from previous work[3,16,17] and includes a pharmaceutical care plan and individualised patient information sheet (Appendix 1). To populate the intervention tool, the clinical pharmacist researcher collected data from clinical records and from patient interview whilst in hospital (inpatients) or at the one month visit (NVC outpatients). The following data were collected:

- Blood pressure and cholesterol measurements
- Current medication
- Lifestyle records (smoking, diet, alcohol, physical exercise)
- Social and practical support (e.g. difficulty in organising repeat prescriptions, physically taking medicines)
- MMSE

An assessment was made of current medication against stroke evidence based guidelines for secondary prevention taking into account co-morbidities and the need for additional therapy. Suitability of doses and medication type was assessed for the individual taking into account medicine interactions, renal and liver function, co-morbidities and potential side effects. Medicines were also assessed for suitability of formulation and medicine device in relation to stroke patient physical abilities.

Pharmaceutical care issues (i.e. problems or potential problems) were identified by the clinical pharmacist researcher, recorded on the tool and followed up with the most appropriate member of the multidisciplinary team.

A copy of the individualised patient information sheet was provided to patients after the interview and the intervention tool was sent to the patient's General Practitioner (GP) and nominated Community Pharmacy.

At 1, 3 and 6 months after discharge or outpatient NVC visit, the clinical pharmacist researcher visited each patient in their own home to identify additional issues which

may have arisen since last visit and resolve outstanding issues which had not been satisfactorily concluded.

These time points were selected as it is known that non-adherence occurs more often with new than existing medicines,[18] a USA study has shown that 25% of 2888 patients discontinued one or more stroke medicines 3 months post discharge[19] and adherence declines substantially after the first 6 months of treatment.[20] Prior to each home visit, the clinical pharmacist researcher visited the patient's GP practice to update the intervention tool with relevant data, for example medicine changes and blood pressure (BP) results. Following each home visit, a letter was sent to the GP and community pharmacist recording issues and recommended actions where appropriate with an invitation to discuss with the clinical pharmacist researcher if required.

All patients were posted a questionnaire for self completion after the 6 month home visit for return in a stamped addressed envelope to another member of the research team blinded to treatment allocation. Quality of life using the Euroqol-5D, a questionnaire previously used in stroke patients, adherence (MARS – Medication Adherence Rating Scale), medicine beliefs (BMQ - Beliefs about Medicines Questionnaire) and depression (HAD - Hospital Anxiety and Depression) were measures included in the questionnaire.[21-24] A patient satisfaction section used a modified version of a validated satisfaction questionnaire and included additional questions for the intervention group specifically regarding the 1 and 3 month home visits.[25-27] The MMSE was repeated at the 6 month home visit to confirm patient ability to complete the questionnaire was unchanged. If changed, the patient would be transferred to the usual care group. Pharmaceutical care issues were identified during the clinical medication review process and recorded throughout the study in the

intervention group and at the 6 month home visit in both groups. Issues requiring resolution were included in a letter to the GP for both groups.

BP and cholesterol measurements were accessed at the time of the 6 month home visit and the proportion of patients meeting targets compared.

The clinical pharmacist researcher measured BP in the intervention group at each home visit and in the usual care group at the 6 month home visit. All patients were required to attend a short clinic appointment at the Wellcome Trust Clinical Research Facility (WTCRF) at six months for assessment of outcomes (BP, self reported adherence and patient knowledge questionnaire) by independent nurses blinded to randomisation to minimise potential bias. Patients unable to attend the WTCRF clinic were visited by nurses in their own home.

Usual care

Patients were discharged from all settings following standard procedures. This group received one home visit at 6 months to collect comparison data to the intervention group. Ability to provide a clinical pharmacy service to inpatients may have affected the level of pharmaceutical advice the usual care group received prior to discharge.

RESULTS

Recruitment Process

Of 66 inpatients and 364 NVC outpatients identified as being potentially eligible for inclusion, 331 outpatients were excluded on the basis of having a Transient Ischaemic Attack (TIA) or diagnosis other than stroke and four inpatients did not agree to be approached by the researcher. Of the 95 invited to participate, 10 inpatients were excluded, 45 declined, resulting in 30 inpatients and 10 NVC outpatients being

randomised. Eighteen patients in the intervention group and 17 in the usual care group completed the study as 5 were lost to follow up (Figure 1).

Recruitment occurred between July and November and participants were followed up over the following six months. The two groups were similar demographically (Table 1).

Table 1 Baseline characteristics*

Characteristic	Intervention group (n=18)	Control group (n=17)	P value
Mean Age (SD)	74.2 (8.8)	71.9 (7.3)	0.401
Sex, female (%)	9 (50.0)	5 (29.4)	0.305
Living alone (%)	4 (22.2)	5 (29.4)	0.711
Type of stroke (%)			
lacunar anterior	5 (27.8)	6 (35.3)	0.725
partial anterior	9 (50.0)	7 (41.2)	0.854
partial occipital	0	3 (17.6)	0.104
total anterior	3 (16.7)	1 (5.9)	0.603
intracerebral haemorrhage	1 (5.6)	0	1.000
History of stroke care setting at recruitment(%)			
acute stroke unit only	6 (33.3)	7 (41.1)	0.897
acute stroke and rehabilitation unit	7 (38.9)	6 (35.3)	0.826
neurovascular outpatient clinic	5 (27.8)	4 (23.5)	0.706
Mean Systolic BP mmHg (SD)	140.7 (21.8)	128.5 (19.6)	0.087
Mean Diastolic BP mmHg (SD)	78.4 (12.7)	72.5 (8.4)	0.057
BP \leq 140/85 mmHg (diabetes 130/80 mmHg)	6 (33.3)	9 (52.9)	0.407
Mean Total cholesterol mmol/L (SD)	4.4 (1.2)	4.4 (1.1)	
Baseline cholesterol \leq 5 mmol/L (%)	11 (61.1)	13 (76.5)	0.471
Community pharmacy medicines provision			
patient collects	7 (38.9)	9 (52.9)	0.621
carer collects	4 (22.2)	2 (11.8)	0.658
pharmacy delivers	7 (38.9)	6 (35.3)	0.826

* numbers of patients unless otherwise stated

Data collection process

The hospital and GP practice patient record systems were accessible for all participants.

At recruitment, total cholesterol and low density lipoprotein (LDL) measurements were unavailable in 5 and 27 patients respectively, resulting in clinical and prescribing data being available for only 8 (23%) patients.

During the six month study period, complete sets of clinical and prescribing data were available for 16 of 35 (46%) patients. For 1 patient in the usual care group, not a single BP measurement was recorded. Monitoring of cholesterol and LDL was not undertaken for 7 and 19 patients respectively.

90% of questionnaires were returned. Completion rates for the questionnaires are shown in Table 2.

Table 2 Questionnaire completion rates, n(%)

Questionnaire	Intervention (n=18)	Usual care (n=17)
BMQ	16 (88.9)	15 (88.2)
Perception of benefit	16 (88.9)	15 (88.2)
MARS	16 (88.9)	11 (64.7)
Euroqol 5D	16 (88.9)	14 (82.4)
Euroqol thermometer	17 (94.4)	14 (82.4)
HAD	17 (94.4)	11 (64.7)
Satisfaction	14 (77.8)	13 (76.5)

Blood Pressure Process

In the intervention group, intra individual patient BP measurements varied irregularly at 1, 3 and 6 months. There was also variation between the researcher measurements in the home setting and the nurse measurements in the home setting or the clinic. At the 6 month follow up, the mean (SD) number of BP measurements per patient taken

in primary care was 2.2 (1.0) for the intervention group and 1.9 (1.7) for the usual care group. One patient had no BP measurements recorded. Five participants opted to have the WTCRF visit in their own home.

Pharmaceutical Care

The total number of care issues identified in the intervention group was 104 (mean 5.8 (2.1) per patient range 3- 10) which fell into the following categories[17]: additional medicine (n=10), unnecessary medicine (n=1), wrong medicine (n=1), dose too low (n=5), adverse drug reaction (n=11), interaction (n=8), inappropriate compliance (n=18) and monitoring and patient advice (n=50). Monitoring included recommendations for checking records for laboratory tests, International Normal Ratio (INR) and BP measurements. Written and verbal information was provided about medicines and lifestyle behaviours. Pharmaceutical Care Issues identified from observation of medicine taking behaviour in patients own homes included a patient taking two brands of the same antihypertensive, doses remaining in medication compliance aids, stockpiling medicine, use of expired medicines and dispensing errors.

In the intervention group, 23 recommendations were made to GPs, of which 19 (83%) were accepted (Table 3).

Table 3 Pharmaceutical care recommendations to GP (n=23)

Additional drug required

Calcium/Vitamin D recommended in two patients with osteoporosis
 Proton pump inhibitor recommended for aspirin associated dyspepsia
 Additional antihypertensive recommended for five patients^a

Unnecessary drug

Recommended to stop dipyridamole as warfarin started

Wrong drug

Recommended changing dipyridamole to licensed modified release formulation

Dosage too low

Recommended increasing dose of levothyroxine based on thyroid function tests
 Recommended titrating dose of antihypertensive in two patients

Adverse drug reaction

Recommended discontinuing dipyridamole in patient experiencing headache
Recommended increasing to indicated dose of proton pump inhibitor for GI prophylaxis
Recommended stopping tamsulosin in patient with postural hypotension
Recommended monitoring potassium in patient with hyperkalaemia recently started spironolactone**
Recommended check of creatine kinase in suspected statin induced myopathy

Interaction

Recommended change of statin in patient prescribed simvastatin and carbamazepine

Inappropriate compliance

Recommended warfarin added to multicompartement compliance aid following risk assessment

Other

Recommended malnourished patient referred to dietician^b

Recommended patient with high HbA1c referred to diabetes clinic

Recommended follow up of blood pressure following isolated high result

^a recommendation not accepted in two patients

^b recommendation not accepted

DISCUSSION

Strengths and weaknesses

No data were available from non respondents which could limit generalisability.

One single researcher may not reflect practice which could influence the generalisability but a strength was that the researcher was a clinical pharmacist and the intention is that the intervention would be delivered by a qualified prescribing pharmacist.

Recruitment

The proportion of patients attending the NVC with a diagnosis of new stroke was small (9.1%) and only a third of those eligible consented to participate compared to two thirds in the inpatient group. There is potential to increase eligibility by including those with confirmed diagnosis of TIA in addition to stroke as issues are similar.

Higher recruitment of inpatients may have been influenced by personal contact with the researcher allowing the opportunity for questions and clarification. A similar method should be used for NVC outpatient recruitment in a definitive RCT as

opposed to the postal method used in this study. This may also elucidate why patients refused to participate as most (22/45) failed to give a reason or reply.

Consideration should be given to screening patients at the first visit to identify those with greater pharmaceutical care needs to determine whether a second face to face visit is necessary. Recruitment may be unaffected but the intervention may be more efficient.

Consideration should be given to further stratifying patients according to complexity of pharmaceutical care needs. This would require to be taken into account when calculating the sample size for a future study.

Data Collection

Data collection from hospital and GP practices was straightforward but electronic transfer methods should be explored to reduce the need for GP practice visits.

Lack of GP measurement of total and LDL cholesterol was the main reason for the low percentage of available data. The rate was too low for meaningful analysis. Given this and the evidence that stroke secondary prevention should include cholesterol lowering agents irrespective of blood total cholesterol,[1] cholesterol measurement would be excluded from a definitive RCT as it would not be a meaningful outcome measure.

Questionnaires were distributed by post and given the attrition rate was only 10%, this method is acceptable. Overall completion rate did not meet the set criterion and was less in the usual care group, possibly due to less researcher contact and was lowest for the MARS and HAD sections. It would be desirable to review the content and explore a shorter version of the questionnaire.

Blood Pressure

The frequency of routinely collected BP measurements from GP records was insufficient for use as an outcome measure in a future study. The intra individual variation observed in single BP measurements taken by the clinical pharmacist researcher and research nurses suggests that a more reliable method of BP measurement is required if BP is to be used as a future measure of effect of an intervention. Although Ambulatory blood pressure monitoring (ABPM) is recommended by the National Institute for Health and Care Excellence for the accurate diagnosis of hypertension, it may be burdensome for patients. Other studies [12,29] have taken multiple readings, have brought patients to clinics or used home BP monitors, which are also burdensome. There is a need to further test for patient acceptability to estimate size of effect for future power calculations. A future study could not rely on routinely recorded BP measurements by primary care clinicians. BP measurements require to be taken by investigators as part of a definitive RCT.

Pharmaceutical care

Communication of care issues with GPs was by letter and although there was high acceptance of recommendations, it would be desirable to align with local emerging e-communication and paperlite methods.

The nature of the identified pharmaceutical care issues (Table 3) supports the benefit from a pharmacist delivered intervention. Although home visits allowed identification of issues that otherwise would not be identified, telephone contact should be considered as an option for follow up consultations. An RCT published in abstract form only, showed that pharmacists providing telephone follow up to 30 stroke patients versus usual care improved adherence to secondary prevention medicines (anti-thrombotics specifically) and achieved BP, lipid level and glucose control goals, an effect sustained up to one year.[11]

A prescribing pharmacist delivering the intervention in the main study has the potential to reduce the reliance on the GP to make changes and is in line with the current Scottish Government vision as set out in the Prescription for Excellence document.[28] This is supported by a recent RCT which found a prescribing pharmacist increased the proportion of patients with TIA or minor stroke reaching target BP and LDL levels compared to nurses reporting results to primary care physicians.[29]

A pharmacist led intervention targeting stroke patients' medicine needs in their own homes would concur with the LoTS care trial recommendations of providing a specialised bespoke service.[30]

Usual care

There were no differences in feasibility of data collection or questionnaire completion rates in the usual care group as compared to the intervention group. The contamination risk from interventions made by community pharmacists and other MDT members is unknown but the risk is similar for both intervention and usual care groups.

CONCLUSION

This study highlighted that before designing a definitive RCT, the following need to be considered: modification of the recruitment and invitation process and inclusion of patients with TIA to increase eligibility and participation; removal of cholesterol measurements as a meaningful outcome measure; a reliable BP monitoring process and further qualitative analysis to improve questionnaire completion rates.

This pilot study tested the feasibility of a number of processes. Findings suggest there is a need for further feasibility testing of the process of BP monitoring and its acceptability to patients as this is the proposed outcome for the definitive RCT.

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Conflict of Interests

None to declare

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