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The use of a patient centred educational exchange (PCEE) to improve patient's self-management of medicines after a stroke; a randomised controlled trial study protocol.

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Title

The use of a patient centred educational exchange (PCEE) to improve patient's self-management of medicines after a stroke; a randomised controlled trial study protocol.

Lay title: A conversation with patients about medications after a stroke

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Abstract

Introduction:

National and international guidelines make recommendations for secondary prevention of stroke including the use of medications. A strategy which engages patients in a conversation to personalise evidence based educational material (patient centred educational exchange (PCEE)) may empower patients to better manage their medications.

Methods and analysis:

This protocol outlines a non-blinded randomised controlled trial (RCT). Consenting patients admitted with a diagnosis of stroke or transient ischemic attack (TIA) will be randomized 1:1 to receive either a patient centred educational exchange (PCEE) comprised of two sessions, one at the bedside before discharge and one by telephone at least ten days after discharge from hospital in addition to usual care (intervention) or usual care alone (control). The primary aim of this study is to determine whether a PCEE improves adherence to antithrombotic, antihypertensive and lipid lowering medications prescribed for secondary prevention of stroke over the three months after discharge, measured using prescription refill data. Secondary aims include: investigation of the impact of the PCEE on adherence over 12 months using prescription refill data, self-reported medication taking behaviour, self-reported clinical outcomes (blood pressure, cholesterol, adverse medication events, and readmission), quality of life, the cost utility of the intervention and changes in beliefs towards medicines and illness.

Ethics and Dissemination:

Communication of the trial results will provide evidence to aid clinicians in conversations with patients about medication taking behaviour related to stroke prevention. The targeted audiences will be health practitioners and consumers interested in medication taking behaviour in chronic diseases and in particular those interested in secondary prevention of stroke.

The Australian New Zealand Clinical Trials Registry number is ACTRN12615000888561. The trial has ethics approval from Metro South Human Research Ethics Committee

(HREC/15/QPAH/531) and The University of Queensland Institutional Human Research Ethics (2015001612).

Strengths and Limitations

- The design of a randomised controlled trial imparts rigor to provide evidence of the impact of a behavioural intervention
- The use of questionnaires, validated as research tools, to elicit patient perceptions, engage the patient in a conversation provides a structure for the healthcare worker.
- The strength of the intervention is that it is underpinned by a combination of theories of behaviour change.
- This study links the use of both prescription refill data as an objective adherence measurement and patient self-reported adherence.
- As is common with many behavioural intervention studies, this study is not blinded once the participant has been allocated to either the intervention or control group, which may introduce bias to the study.

Introduction

Stroke is one of the leading causes of death worldwide[1 2]. About a third of those who suffer from a stroke die within 28 days and a further third are left permanently disabled placing a burden on themselves, their family and the community [3 4]. After an initial stroke the cumulative incidence of a subsequent stroke is about 30%, with the highest occurrence in the first 12 months (12%). [5-7] In an individual experiencing a transient ischaemic attack (TIA) or a minor stroke (<3 on the National Institutes of Health Stroke Scale[8]) the 30 day incidence of stroke is 11-15%.[9] After either a stroke or TIA, International [10-12] and Australian guidelines[13] recommend secondary prevention strategies. Recommendations include the use of antithrombotic therapy, medications for blood pressure lowering and cholesterol lowering medications. The high rate of recurrence in the first weeks and months of a minor stroke or TIA emphasises the importance of early initiation and subsequent persistence to secondary prevention medicines to reduce the risk of subsequent stroke.[9] Stroke survivors may not benefit due to poor adherence to the medications [14-16] or the benefit may be offset by the occurrence of adverse drug events (ADEs).[17]

Medication focused educational interventions to improve secondary prevention of stroke have shown impact on patients' knowledge but other outcome measures have had varied results. [18-20] Debate centres on whether a change in knowledge will result in a change of medicine taking behaviour or whether alternative approaches such as addressing necessities and concerns about medication, [21] agreeing goals, or providing key messages about medication taking will be more effective in changing behaviour. Previously validated questionnaires have been used to identify patients' perceptions of their illness,[22] beliefs about medications[23] and medication taking behaviour[24] and have been used to provide a structure to encourage patient input into a personalised intervention[25]. Another approach to empower patients in medication related self-management has incorporated "academic detailing"[26 27] also described as "educational visiting".[28 29] This method uses a social marketing framework, which is underpinned by social cognitive theory,[30] transtheoretical model of change,[31] and diffusion of innovations theory[32]. This approach encourages information exchange while delivering key messages in order to influence behaviour.

Combining these two strategies, identifying patients perceptions' and beliefs' then using them to personalise educational messages and to engage patients in a conversation, may empower patients to better manage their medications. This approach will be referred to as a patient centred educational exchange (PCEE). The PCEE has been tested for feasibility, and was found to be acceptable to the participants, manageable for the health care professional and the beliefs and perceptions elicited by the questionnaires were able to be used to personalise the conversation.[33] The impact of the PCEE on patient self-management of stroke prevention medications has yet to be determined.

Aim: The primary aim of this study is to determine whether a patient centred educational exchange (PCEE) improves adherence to antithrombotic, antihypertensive and lipid lowering medications prescribed for secondary prevention of stroke over the three months after discharge, measured using prescription refill data.

Secondary aims include: investigation of the impact of the PCEE on adherence over 12 months using prescription refill data, self-reported medication taking behaviour, self-reported clinical outcomes (blood pressure, cholesterol, adverse medication events, and readmission), quality of life, the cost utility of the intervention and changes in beliefs towards medicines and illness.

To address these aims we will conduct a randomised controlled trial, with an intervention comprised of two PCEE sessions; one before discharge from hospital and one by telephone at least ten days after discharge.

Methods and Analysis

This protocol was developed in accordance with the Standard Protocol Items: recommendations for intervention trials (SPIRIT) statement (see online supplementary file 1. SPIRIT checklist).

Study Design and Setting

This study is a non-blinded randomised controlled trial (RCT). Participants will be randomized 1:1 to either the intervention group (intervention and usual care) or the control group (usual care). The setting will be the "Medical Stroke Unit" (MSU) or the Medical Admission and Planning Unit (MAPU), of an Australian tertiary referral hospital.

Study Population

Inclusion criteria: Participants recruited to this study must be aged 18 years or older, have been admitted to the MSU or the MAPU with a principal diagnosis of stroke or TIA, and are planned to be discharged to their home.

The participant should be expected to manage their own medication after discharge home, have a documented Mental Status Questionnaire (MSQ)[34] score of 10/10 at the time of recruitment and be able to provide consent.

Exclusion criteria: Those patients planned for discharge to a residential care facility (eg a nursing or residential care home) where a staff member is responsible for the patients' medication administration, those patients who have been planned for a rehabilitation period of greater than one month as they will be having weekly education sessions, those with an MSQ<10, unable to complete the questionnaire (even) with assistance (this may be due to language difficulties or cognitive impairment) and those who do not provide consent.

Patient and Public involvement

A feasibility study [33] was conducted to inform the design of the PCEE used in this randomised controlled trial. Ten of the 18 participants completed an evaluation of the proposed intervention which resulted in changes to the graphics used, the use of mobile telephones with messaging for follow up calls and bridging sentences between questionnaires and use of the infographic? With respect to the burden of the intervention, seven of the ten indicated that the session was not too long or too short and 9/10 agreed that the materials helped them. Patients were invited to ask a questions and prompted to discuss previous experiences as part of the feasibility study, this has been included in the current protocol.

Patients and public were not involved in development of the research question or outcome measures, they are not involved in the recruitment or ongoing conduct of the current study. Participants are given details to request results of the study.

Recruitment

All admissions to MSU and MAPU will be screened using "bed lists" for five days of every week. Those admissions with a diagnosis of stroke or TIA will be further screened for a documented MSQ of 10/10 and plan for further rehabilitation or discharge to home. The researcher will then approach the potential participants on the ward to determine whether they are willing to participate in the study.

Allocation/Randomisation: The allocation of participants to control or intervention will be concealed until the participant has been consented to reduce allocation bias. After the participant has consented to the study the research pharmacist will contact the clinical trials pharmacist, who is not involved in the study and who will identify the allocation, one to one, to either the intervention or control group. The allocation will be previously determined using a computer generated four block randomisation code using Sealed Envelope Ltd™ [35]. The allocation will be concealed by placing the allocation in sealed opaque envelopes stored in the clinical trials office of the pharmacy department.

Once the participant is allocated the researcher will no longer be blinded to participant's allocation. The reason the researcher will no longer be blinded is that the researcher will conduct the intervention and follow-up calls.

Sample size- The primary outcome is adherence measured by the proportion of days covered (PDC) (defined as the days of medication supplies when the medications were collected divided by the days in the time interval) over the three months after discharge, using prescription refill data for three classes of medications (antithrombotic, antihypertensive and lipid lowering medications).

The sample size calculation used the criterion for significance (alpha) set at 0.05 and the power (beta) at 80%. It is proposed that the intervention will result in a 7% improvement in adherence compared to standard care. This difference of 7% was selected as reasonable; because an effect of this magnitude has been shown with secondary prevention medications used for cardiovascular diseases [36 37] and has been linked to a clinical difference [38]. An effect size of 0.54 (0.07/0.13) was selected using results from a study conducted with participants discharged on similar medications after a diagnosis of acute coronary syndrome[37]. A sample size of 55 in each arm is required for effect size of 0.54. We allowed for a slighter larger pooled standard deviation of 0.15 (effect size 0.7/.15= 0.47) requiring a sample size of n= 73. Adherence data is likely to be skewed [39] and so will not fulfil the requirements for a parametric test. Lehmann [40] suggests the addition of 15% more participants (n=84) when planning to use non-parametric tests such as the Mann Whitney. Assuming attrition rates of approximately 10% we would need to enroll at least 92 participants for each group; we propose to include 100 participants in each arm. It is

predicted that approximately two participants will be recruited per week, estimating a two year recruitment period.

Procedure

Both the intervention and control group will receive usual care. In addition to usual care participants in the intervention group will receive two sessions of a "PCEE", one before discharge and one by telephone at least ten days after discharge. These sessions will be conducted by a clinical pharmacist who attends weekly multidisciplinary MSU meetings, has a postgraduate qualification in clinical pharmacy (MSc Clin Pharm) and training in academic detailing. In this study the intervention pharmacist will also be collecting the study data.

Usual Care

Usual care includes admission to a stroke specific ward, multidisciplinary care by the stroke team, education using Stroke Foundation-Australia materials by the stroke nurse[41], clinical pharmacy services provided by the ward pharmacist and discharge advice provided by the medical staff. Usual care provided by the ward pharmacist includes medication history taking and reconciliation, medication review during the admission, discharge reconciliation, provision of a medication list [42] and medication counselling at discharge.

Control Group

The control group will receive usual care as described above.

Intervention - Patient centered educational exchange (PCEE)

The intervention consists of two sessions, one which will take place at the patients' bedside before the usual pharmacist discharge counselling and the second which will be conducted over the telephone at least ten days after discharge. These sessions are additional to, and designed to integrate with, usual care. The PCEE is structured with an introduction, conversation and conclusion.

The session begins with an "introduction" phase establishing credibility "*I am a pharmacist with an interest in patients taking medication to reduce the risk of stroke*". Next the clinical pharmacist will give the opportunity to the patient to ask a question. "*What one thing*

would you most like to discuss about medications you have been prescribed since your stroke/TIA?" There is an opportunity to answer this question before moving on.

The session will then move into the "conversation"- using previously validated questionnaires to identify patients' perceptions, beliefs and concerns about their stroke in general (using the brief-Illness Perception Questionnaire (brief- IPQ)[22]) and medications in particular (using the Beliefs about Medicine questionnaire specific (BMQ-specific)[23]). There is also an opportunity for the patient to self-report their previous medication taking behavior for the medications of interest (using the Medication Adherence Questionnaire (MAQ)[24]). The identified barriers and enablers will be used to personalise the conversation. A double sided single page document will be personalised and given to the participant (the detailing tool). The detailing tool contains an infographic to help illustrate the discussion about the stroke prevention medications the patient has been prescribed on one side, and four a-priori key messages on the other side (see online supplementary file 2. infographic example).

The four key messages are: **"Know** about your medications prescribed to reduce risk of stroke", "**Organise** ongoing supply of your medications", "Continue to **take** these medications as agreed with your doctors" and "**Report** any new symptoms or concerns to your doctor".

In the final phase, "conclusion", items identified to be discussed when the clinical pharmacist telephones the patient will be listed.

To provide an opportunity for "follow-up" and reinforcement of key messages, the intervention is designed to include two sessions. The clinical pharmacist arranges to telephone the participant at least ten days after discharge to ask them the same questions and to talk about their medications.

It is hypothesised that patients in the intervention group will be influenced to organise ongoing supply of their medications and take their medications as prescribed. In addition, it is hoped that if they identify that they are experiencing unwanted effects from a medication(s) they will not keep taking medication(s) long term rather discuss their concerns with their doctor.

Outcomes

The primary outcome is adherence measured by the proportion of days covered (PDC) over the three months after discharge, using prescription refill data (obtained from the pharmaceutical benefits scheme (PBS)) for the combination of up to three classes of medications (antithrombotic, antihypertensive and lipid lowering medications) prescribed.

Secondary outcomes include:

- Adherence measured by the proportion of days covered (PDC) over the twelve months after discharge, using prescription refill data for up to three classes of medications (antithrombotic, antihypertensive and lipid lowering medications).
- Self-reported medication adherence (measured using the Medication Adherence Questionnaire (MAQ)), organising of ongoing medication supply, and medication taking behaviour and communication to prescriber in response to perceived medication related adverse events.
- Self-reported changes between baseline and 3 and 12 months in perception to their illness (stroke) using Brief-IPQ and changes between baseline and 3 and 12 months in beliefs about medications for stroke prevention using BMQ-specific.
- Clinical outcomes:
    - medication related adverse events (identified by self-report or hospital readmission),
    - self-report of blood pressure (BP) results,
    - self-report of Cholesterol level,
    - re-admission to hospital with stroke and/or myocardial infarction (MI) (identified by self-report or hospital records).
- Changes from baseline to 3 and 12 months in self-reported quality of life using EQ-5D-5L.[43 44].
- Cost utility analysis using a ratio of incremental cost (cost of the PCEE intervention compared to usual care) to incremental benefit (change in quality-adjusted life years).[45]

The complex relationship between the intervention described here and the measures of the impact we expect to make has been described by authors of previous studies [46 47]. Table 1

has been adapted from Shay and colleagues to categorise the study outcome measures by outcome type and who measures it.

Table 1. The proposed measures categorised by outcome type and who measures it.

	Behavioural outcomes	Affective-cognitive outcomes. (This includes knowledge, understanding, satisfaction)	Health outcomes	Economic outcomes
Patient self-reported	Self report of adherence using MAQ	Particpant ability to identify each medication of interest along, reason for use when answering the MAQ	Blood Pressure, Cholesterol levels	
	Self-report of organising medication supply	Participant knowing their : blood pressure, cholesterol level	Blood Pressure,Cholesterol levels	
	Self report of action if they experienced an ADE	Participant beliefs and perceptions using the BMQ-specific and brief-IPQ	Self reported quality of life EQ-5D-5L	Self reported quality of life EQ-5D-5L
			Self reported ADE	
Observer collected	Visit to doctor – Medicare data		Readmission/admission for ADE	Readmission/admission for ADE (S)
	Prescription refills-Pharmaceutical benefits scheme data		Events-Stroke, MI	Events-Stroke, MI
				Time to conduct intervention

Brief-IPQ= brief-Illness Perception Questionnaire [22], BMQ specific= Beliefs about Medicine questionnaire specific[23], MAQ= Medication Adherence Questionnaire [24]) EQ-5D-5L= Quality of Life Measure[43] MI= Myocardial Infarction, ADE=Adverse Drug Event

Behavioural measures

Behavioural measures look at things the participant has done. In this study visiting the doctor and having their medication dispensed is observer collected [48 49]. Pharmaceutical claims data can provide an objective, non-invasive measure of adherence and has been used in many drug trials and in a number of studies similar to this one. A range of methods for use of claims data to measure medication possession ratios and proportion of days covered have been described to assess an individuals' medication adherence [39 48-51].

The Proportion of Days Covered is defined as the days of medication supplies when the medications were collected divided by the days in the time interval. This can be averaged over the total (for example a 90 day interval), or to be more reflective of medication exposure, a shorter interval (for example in Australia most medications for chronic diseases are supplied at approximately one month intervals) can be measured and added together.

The proportion of days covered calculated using multiple short intervals [50 51] can more accurately account for gaps in supply or extra medication supplies. The example shown in Figure 1 adapted from Bijlsma[50] and Bryson[51] shows how the adherence over three lots of 30 day intervals can be calculated using the gaps in supply for three patients obtaining 30 day supplies. The calculation used is; Proportion of 90 days covered= (90 –total of days not covered in each 30 day interval)/90x100.

Figure 1. Examples of Proportion of days covered calculated using multiple 30 day intervals.

Patient 1 obtained medications on the day of discharge, 30 days later and then had a gap of five days before the third supply. Patient 1 PDC= [(30 +0) + (30 +0) + (30-5)]/90x100=94%

Patient 2 obtained the first supply five days before discharge these were not used until the day of discharge so although the second supply was obtained 10 days after the first supply there was only a 5 day gap in supply for the patient. Five days of tablets remaining from the second supply were used in the third interval. The third supply was obtained after a 10 day gap. Patient 2 PDC= [(30 +5-5) + (30 -5) + (30+5-10)]/90x100=89%

Patient 3 obtained medications on the day of discharge, 20 days later and then had a gap of 40 days before the third supply. Patient 3 PDC= [(30 +0) + (30 +10-10) + (30-30)]/90x100=67%

In this study the days covered in each dispensing interval will be calculated for up to three different medications (antithrombotic, antihypertensive, lipid lowering medication) dependant on the medication plan at discharge. These will then be expressed as a mean (across the up to three medications) percentage and analysed as a continuous variable.

Self-reported behavioural measures in this study include self-report of medication adherence using the MAQ [24], organising an ongoing medication supply and action taken if they experience adverse effects from their medication. The MAQ is a well validated scale, previously used in many clinical conditions.[52]

Affective cognitive outcomes

Affective cognitive outcomes include measures of what the participant knows and how they feel, these are usually self-reported.

In this study the affective cognitive group includes metrics such as knowledge and understanding regarding name, type and dose of medications, participants knowing their BP reading or cholesterol level, participants' perceptions of their illness and beliefs about their medications. Participant perceptions of their stroke will be evaluated using the adapted-Brief IPQ at baseline, 3 and 12 months. Beliefs about antithrombotic, antihypertensive and lipid lowering medications will be evaluated using the BMQ-specific at baseline, 3 months and 12 months. Changes in these may be able to be used to explain changes in other measures for example adherence.[47]

Health Outcomes

In this study we will evaluate patient self-reported clinical (Blood Pressure (BP) and Cholesterol) measures and readmissions, subsequent stroke or myocardial infarction, adverse drug reactions and the quality of life measure.

Medication related adverse events will be identified by patient self-report using probe questions adapted from a previously validated trigger tool[53] at 3 months and 12 months for each medication class of interest. Medication related adverse events will also be collected from any readmission notes at 3 months and 12 months post discharge.

Quality of life will be measured using EQ-5D-5L [43] before discharge (baseline), 3 months and 12 months. This tool (EQ-5D-5L) has previously been used in stroke research. [54]

Economic Outcomes

Economic outcomes will be determined from the health service perspective using an incremental cost effectiveness ratio (ICER). The ICER indicates the difference between the intervention and control cost (time and resources costed) per the difference in quality-adjusted life years (QALYs) determined using the quality of life measure EQ-5D-5L. Time taken to deliver the PCEE sessions (intervention group only) will be recorded on the interview schedule at both the bedside (before discharge) and telephone follow-up (7-10

days post discharge) sessions and costed using standard pharmacist salary rates. Any impact of the intervention on health-resource use (e.g. medication use, hospital readmissions) will be considered when estimating costs. Patient interview using EQ-5D-5L will be conducted before discharge (baseline), at 3 months and 12 months. Uncertainty in the estimated ICER will be evaluated using non-parametric bootstrapping techniques.

Data Collection

A schedule of assessments including the timing for data collection is shown in Table 2. Data will be collected by the investigator prior to the patient's discharge, at least 10 days after discharge (intervention group only), at 3 months and at 12 months.

Demographic data collected prior to the patients discharge includes patient age, sex, stroke type, whether they have had a previous stroke, whether they live alone, cholesterol levels and BP on discharge. The demographic data is required to describe the population in the study and to ensure the intervention and usual care groups are comparable.

Participant self-reported data will be obtained by the researcher conducting telephone follow-up using the phone numbers they provide during consent. If the participant does not answer the first call and has provided a mobile telephone number, the researcher will send a text message using the study mobile phone asking for a "good time to talk." The protocol allows for a total of three attempts to contact the participant for follow-up calls.

Table 2. Schedule of enrolment, interventions, and assessments for Patient Centered Educational exchange (PCEE) to improve patients' self-management of medications after a stroke.

TIMEPOINT		*-t1*	*-t2 Before discharge*	*t0 Date of discharge*	*t1 approximately 10 days post discharge*	*t2 approximately 3 months post discharge*	*t3 approximately 12 months post discharge*
			Post-allocation				
Procedure	*Detail*	*Baseline*	*Intervention*		*Intervention*	*Evaluation*	*Evaluation*
ENROLMENT: *Eligibility screen*	*MSQ[1,2]=10 Not for extended rehabilitation*	*X*					
Informed consent		*X*					
Randomisation		*X*					
INTERVENTION:							
First Session (PCEE)	*Bedside Interview Time taken[3]*		*X* *X*				
Second Session (PCEE)	*10 day follow-up interview Time taken[3]*				*X* *X*		
ASSESSMENTS:							
Brief-IPQ, BMQ-specific, MAQ EQ-5D-5L BP,Cholesterol		*X* *X* *X* *X* *X[2]*			*X* *X* *X*	*X* *X* *X* *X* *X[4]*	*X* *X* *X* *X* *X[4]*
PBS/MBS data Admissions, Stroke, MI Self-report of ADRs and Action if ADRs						*X* *X* *X* *X*	*X* *X* *X* *X*

1.-Mental State Quotient [34], 2-these are standard care clinical tests performed as part of routine patient care 3-time taken for PCEE, 4 –self reported by participants. Brief IPQ=Brief Illness Perception Questionnaire [22], BMQ specific=Beliefs about medicines Questionnaire[23], MAQ=Medication Adherence Questionnaire [24], EQ-5D-5L[43], PBS/MBS data=Dispensing data obtained from the Australians Pharmaceutical Benefits Scheme, MI= Myocardial Infarction, ADR=Adverse Drug Reactions

Data Management

Data will be entered electronically from the case record forms using a study number with no identifying information into Microsoft Excel® and SPSS Statistics 25® both stored on a password protected computer. In all reports from this research, information will be provided in such a way that the participant cannot be identified. Data entry and analyses will be performed using Microsoft Excel® and SPSS Statistics 25®.

Data Analysis

An intention to treat analysis will be conducted. Results will be reported as numbers and percentages for categorical variables and means (SD) or medians (IQR) for continuous variables. Demographic data and baseline characteristics in the intervention and control groups will be compared using descriptive statistics. Outcomes and changes in outcomes (from baseline) will be compared at 3 months and 12 months.

Adherence measured using the PDC from the prescription refill data will be compared using the Mann-Whitney two-sided test. Changes from baseline in quality of life, perceptions of illness and beliefs about medicines will be analysed using the Mann Whitney test. Adherence by self-report, medication related adverse events and re-admissions will be analysed using Chi Squared.

Adverse Event Reporting and Quality Assurance: This study involves completing a questionnaire and discussing stroke medications through one face to face interview and three follow up telephone calls for the intervention group. The control group will complete one face to face interview and two follow-up telephone calls. It is possible that during either the face to face interview or one of the telephone interviews, the participant identifies a medication related issue. Although this is unlikely to be as a result of the study the researcher may still have concerns over the patients' safety. If the researcher has concerns requiring immediate

intervention the patients' doctor will be contacted. In the case of the face to face interview in the hospital that will be a medical member of the treating team. In the case of the telephone interview that will be the patients' General Practitioner.

This is a randomised controlled trial where data on adverse drug reactions and events including stroke and readmission will be collected. It is possible that differences can be determined between the two groups before the recruitment period is complete. A data safety monitoring committee (consisting of an independent medical doctor- clinical pharmacologist and pharmacist- Drug Use Evaluation Pharmacist) has been established to analyse the adverse events every 6 months with responsibility to terminate recruitment into the study early if necessary.

This randomised controlled trial will provide evidence about the effect of a patient centred educational exchange on patient adherence, self-reported medication taking behaviour, clinical outcomes, quality of life, changes in knowledge, and beliefs towards medicines and illness. It is expected that communication of results will inform an evidence based approach to communication with patients about medication taking behaviour related to stroke prevention. Communication of results of this study will seek to impact on the practice of health practitioners and consumers interested in patient medicine taking behaviour and those interested in secondary prevention of stroke.

Ethics and Dissemination

This trial has been registered on the Australian New Zealand Clinical Trials Registry, the number is ACTRN12615000888561. The trial has ethics approval from Metro South Human Research Ethics Committee (HREC/15/QPAH/531) and The University of Queensland Institutional Human Research Ethics Approval Number 2015001612.

Participants will be provided with information about the study and asked if they consent to the study; "Participant information and consent form" (see online supplementary file 3. Patient

Information and Consent Form). To obtain consent for medication refill data from the Pharmaceutical Benefits Scheme and occasions of service by visits to Doctor data from Medicare, the patients will be given an extra consent form as required by the Department of Human Services. This is also contained in the "Participant information and consent form". The patient can choose not to supply the extra consent for access to Pharmaceutical Benefits Scheme/Medicare data. The participant is free to withdraw from the study at any time.

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Contributors: JC, NC, DR and JW were all equally involved in the development of this protocol. DR provided advice on academic detailing. JW provided advice on Quality of Life measurement and economic analysis. JC and NC wrote the initial drafts of this paper. All authors have been involved in the reviewing and editing and approval of the final protocol manuscript.

Competing interests: None declared

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Data sharing: The data from this study is not available for data sharing.

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Figures

Figure 1. Examples of Proportion of days covered calculated using multiple 30 day intervals.

Supplementary Files

1. SPIRIT checklist

2. Infographic example

3. Participant Information and Consent Form

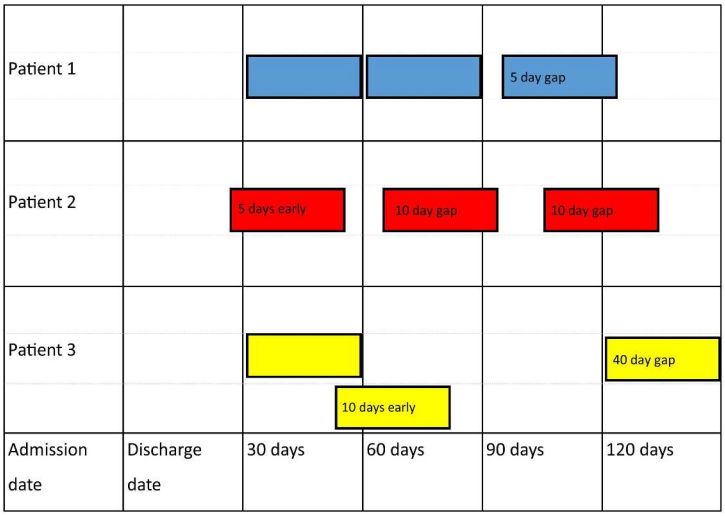


Figure 1. Examples of proportion of days covered calculated using multiple 30 day intervals.

297x209mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	1 (20 items in ANZCTR)
Protocol version	3	Date and version identifier	Y
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-6
	6b	Explanation for choice of comparators	5-6
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7-8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7-8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8-9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11-17
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	17 (Figure2)

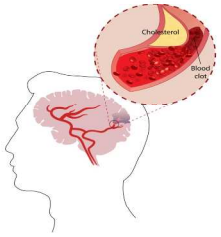
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8-9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-17
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	18-19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	19
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	19
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	19
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	N/A
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	18
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	20
	31b	Authorship eligibility guidelines and any intended use of professional writers	Submitted
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

Medication after a Stroke or TIA



Take your antiplatelet medication called _____ to lower the risk of blood clots forming in the brain.

Take your cholesterol lowering medication called _____ to lower the risk of stroke even if your cholesterol is normal.

Take your blood pressure medication called _____ to lower the risk of stroke.

The University Of Queensland AUSTRALIA

Metro South Health

Medication after a Stroke or TIA

Know about your medications prescribed to reduce the risk of stroke

Organise your ongoing supply of your medications

Continue to **take** these medications as agreed with your doctors

Report any new symptoms or concerns to your doctor

The University Of Queensland AUSTRALIA

Metro South Health

419x297mm (300 x 300 DPI)

Princess Alexandra Hospital

Participant Information Sheet/Consent Form

Title	The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke
Short Title	A conversation with patients about medications after a stroke
Coordinating Principal Investigator/ Principal Investigator	Mrs Judith Coombes
Associate Investigators	Associate Professor Neil Cottrell Dr Graham Hall Dr Nabeel Sheikh Dr Leena Aggarwal Ms Marie Williams Ms Debra Rowett
Location	Princess Alexandra Hospital

Part 1 What does my participation involve?

Introduction

You are invited to take part in this research project, "A conversation with patients about medications after a stroke." This is because you have been diagnosed with a stroke or Transient Ischemic Attack (TIA). The research project is aiming to test a program designed to educate people about the medications prescribed after they have had a stroke or TIA.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Princess Alexandra Hospital.

If you decide you want to take part in the research project, you will be asked to sign the consent section. There are two forms.
By signing the first form, "The study consent form" you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to the research that is described

• Consent to the use of your personal and health information as described.
You will be given a copy of this Participant Information and Consent Form to keep.
The second form is "The participant consent form for release of Medicare and PBS data. Here you will be asked to fill out a consent form authorising the study access to your complete Medicare and Pharmaceutical Benefits Scheme (PBS) data as outlined below. Medicare collects information on your medical visits and procedures, and the associated costs, while PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services who holds this information confidentially.

Definitions of Data used in this study:

Medicare (MBS)

- Date of service *(Date that the service was rendered by the provider, to the patient)*
- MBS Item number *(Items Numbers as per the Medicare Benefits Schedule)*
- MBS Item description *(describes the service as per the Medicare Benefits Schedule)*
- Item category *(where the service sits in the hierarchical structure according to the Medicare Benefits Schedule)*

Pharmaceutical Benefits Scheme (PBS)

- Date of supply *(Date the prescription was supplied by the pharmacy)*
- Date of Prescribing *(Date that the prescription was prescribed by a Medical Practitioner to a patient)*
- PBS Item Number *(Items Numbers reflected in the Pharmaceutical Benefits Scheme)*
- PBS Item Description *(the item description as noted in the Pharmaceutical Benefits Scheme Book)*
- Patient category e.g. general, concession, safety net, doctor's bag *(Patient's eligibility status at the time of supply)*
- Patient contribution *(the contribution paid by the patient)*
- Form category *(Original or repeat prescription)*
- ATC Code *(the code allocated by the World Health Organisation Collaborating Centre for Drug statistics Methodology)*
- ATC Name *(the group the drug falls under in the Anatomical Therapeutic Chemical (ATC) classification system*

What is the purpose of this research?

The purpose of this project is to test a program designed to educate people about the medications people are prescribed after they have a stroke or TIA. The program is designed to improve understanding and organisation of ongoing use of the participants' medications. A total of approximately 200 people will participate in this project.

The results of this research will be used by the study pharmacist, Judith Coombes, to obtain a Doctor of Philosophy (PhD) degree.

What does participation in this research involve?

Participation will only take place after you have given signed consent.

Participation in this project will involve completing a questionnaire on three or four occasions.

The first will be before you are discharged from hospital, the second will take place over the telephone about 3 months after your discharge from hospital and the third over the telephone at

12 months after discharge from hospital. The questionnaire will take about ten minutes to complete. You will be asked about your views of your illness (stroke), your view and opinion of your medicines used for stroke about the way you take your stroke medicines and about your quality of life. There are no right or wrong answers to any of the questions in the interview; it is your view and opinion that is important.

About half of the participants in this study will be chosen by chance (random), to have a longer interview with the researcher to have a conversation about their stroke medications prior to their discharge from hospital. This will take about a further ten minutes. These participants will also be contacted by telephone 7-10 days after discharge from hospital. The telephone call will last for about 10 minutes. The telephone call will involve completing the questionnaire and an opportunity to follow-up on any questions they may have about their medicines.

You will also be asked for consent for the release of your Medicare/PBS claims information.

What are the possible benefits of taking part?
No payment will be provided for participation in this study. We cannot guarantee or promise that you will receive any benefits from this research; however possible benefits may include better understanding of the medications you are using to reduce the risk of a further stroke. It may also help you to organise ongoing use of your medications.

What are the possible risks and disadvantages of taking part?
This study involves completing a questionnaire and for about half the participants discussing your stroke medications through one face to face interview and one telephone call. There is no foreseeable added risk to you above the risks of everyday living.

What if I wish to withdraw from this research project?
If you decide to take part and later change your mind, you are free to withdraw from this research project at any stage. You can ask to withdraw during the interview or you can inform Mrs Judith Coombes your desire to withdraw by telephone on 3346 1944 or 0428814397, email Judith@pharmacy.uq.edu.au or by mail addressed to Judith Coombes, Pharmacy Department, Princess Alexandra Hospital, Ipswich Rd, Woolloongabba QLD 4102.
If you do withdraw your consent during the research project, the investigator will not collect additional information from you or about you, although information already collected will be retained to ensure that the results of the research project can be measured properly. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want the researcher to do this, you must tell the researcher.

What happens when the research project ends?
You may request the study results when it is completed by providing an address that the report can be sent to or at a later date by contacting Judith Coombes (contact details above).

Part 2 How is the research project being conducted?

What will happen to information about me?

By signing the consent form you consent to the study pharmacist collecting and using personal information about you for the research project. Information about you may be obtained from your health records held at this hospital for the purpose of this research. By signing the consent

form you agree to the research team accessing health records if they are relevant to your participation in this research project.

Any information obtained in connection with this research project that can identify you will remain confidential. In all reports from this research, information will be provided in such a way that you cannot be identified.

The information collected on paper will be stored in a locked filing cabinet in a locked office, with access only to the principal investigator stated above. Both written and electronic information containing confidential data will be stored for a period of seven years after publication of the final report or for 10 years, whichever is earlier, and then destroyed.

Who is organising and funding the research?

This research project is being conducted by *Mrs Judith Coombes, Associate Professor Neil Cottrell and Dr Graham Hall ,Dr Nabeel Sheikh, Dr Leena Aggarwal, Ms Marie Williams, Ms Debra Rowett and Associate Professor Jenny Whitty*
Mrs Coombes, Associate Professor Cottrell, Ms Rowett and *Associate Professor Whitty* are affiliated with the School of Pharmacy at The University of Queensland and Dr Hall, Dr Sheikh, Dr Aggarwal, Ms Williams and Mrs Coombes are affiliated with the Princess Alexandra Hospital.

Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of *The Princess Alexandra Hospital*. This study adheres to the Guidelines of the ethical review process of the University of Queensland.
This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

11 Who to contact

If you have any queries or any problems concerning this research project, please contact

Name	Judith Coombes
Position	*Advanced Pharmacist Education*
Telephone	*0428814397, 33461944 or contact the switchboard 3176 2111 pager number 8009*
Email	*Judith@pharmacy.uq.edu.au*

If you would like to speak to an officer not involved in the study or if you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Princess Alexandra Hospital

Position	Coordinator, Metro South Hospital and Health Service Human Research Ethics Committee
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Metro South Health

Queensland Government

The University Of Queensland

Princess Alexandra Hospital

Metro South Health Queensland Government The University Of Queensland

Study Consent Form

Title	The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke
Short Title	A conversation with patients about medications after a stroke
Coordinating Principal Investigator/ Principal Investigator	Mrs Judith Coombes
Associate Investigators	Associate Professor Neil Cottrell Dr Graham Hall Dr Nabeel Sheikh Dr Leena Aggarwal Ms Marie Williams Ms Debra Rowett
Location	Princess Alexandra Hospital

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Senior Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Senior Researcher (please print) _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation -

Title	The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke
Short Title	A conversation with patients about medications after a stroke
Coordinating Principal Investigator/ Principal Investigator	Mrs Judith Coombes
Associate Investigators	Associate Professor Neil Cottrell Dr Graham Hall Dr Nabeel Sheikh Dr Leena Aggarwal Ms Marie Williams Ms Debra Rowett Associate Professor Jenny Whitty
Location	Princess Alexandra Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Princess Alexandra Hospital

Name of Participant (please print) _____

Signature _____ Date _____

Participant ID:

PARTICIPANT CONSENT FORM FOR RELEASE OF MBS/PBS DATA

Consent to release of Medicare and/or Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of "The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke" Study

Important Information

Complete this form to request the release of personal Medicare claims information and/or PBS claims information to "The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke "study.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

By signing this form, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

PARTICIPANT DETAILS

1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth: DD/MM/YYYY

2. Medicare card number: _____

3. Permanent address: _____

Postal address (if different to above): _____

AUTHORISATION

4. I authorise the Department of Human Services to provide my:

☐ Medicare claims history OR

☐ PBS claims history OR

☒ Medicare & PBS claims history

for the period 01/07/2014 to: 31/10/2018 to "The use of a patient centred educational program to improve patient's self-management of medicines after a stroke" Study.

*Note: The Department of Human Services can only extract 4.5 years of data (prior to the date of extraction), The consent period above may result in multiple extractions.

DECLARATION

I declare that the information on this form is true and correct.

5. Signed: _____ (participant's signature) Dated: DD/MM/YYYY **OR**

6. Signed by _____ (full name) _____ (signature) on behalf of participant

Dated: DD/MM/YYYY

☐ Power of attorney** ☐ Guardianship order**

** Please attach supporting evidence

APP 5 – PRIVACY NOTICE

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services. The collection of your personal information by the department is necessary for administering requests for statistical and other data.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or by requesting a copy from the department.

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type
20/04/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash
22/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill

Scrambled ordering Provider number*	Scrambled rendering Provider number*	Date of referral	Rendering Provider postcode	Ordering Provider postcode	Hospital indicator	Item category
	999999A		2300		N	1
999999A	999999A	20/04/09	2300	2302	N	2

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	Scrambled Prescriber number*	Pharmacy postcode
06/03/09	01/03/09	03133X	Oxazepam Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	9999999	2560
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		9999999	2530

Form Category	ATC Code	ATC Name
Original	N05 B A 04	Oxazepam
Repeat	N05 B A 01	Diazepam

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.

** Under co-payments can now be provided for data after 1 June 2012

BMJ Open

The use of a patient centred educational exchange (PCEE) to improve patient's self-management of medicines after a stroke; a randomised controlled trial study protocol.

Journal:	*BMJ Open*
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Primary Subject Heading:	Patient-centred medicine
Secondary Subject Heading:	Communication, Cardiovascular medicine, Health services research, Pharmacology and therapeutics, Research methods
Keywords:	Adherence, Stroke < NEUROLOGY, secondary prevention, medication, academic detailing, STROKE MEDICINE

Protocol Paper V2-0

Title

The use of a patient centred educational exchange (PCEE) to improve patient's self-management of medicines after a stroke; a randomised controlled trial study protocol.

Lay title: A conversation with patients about medications after a stroke

ACTRN12615000888561

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Abstract

Introduction:

National and international guidelines make recommendations for secondary prevention of stroke including the use of medications. A strategy which engages patients in a conversation to personalise evidence based educational material (patient centred educational exchange (PCEE)) may empower patients to better manage their medications.

Methods and analysis:

This protocol outlines a non-blinded randomised controlled trial (RCT). Consenting patients admitted with a diagnosis of stroke or transient ischemic attack (TIA) will be randomized 1:1 to receive either a patient centred educational exchange (PCEE) comprised of two sessions, one at the bedside before discharge and one by telephone at least ten days after discharge from hospital in addition to usual care (intervention) or usual care alone (control). The primary aim of this study is to determine whether a PCEE improves adherence to antithrombotic, antihypertensive and lipid lowering medications prescribed for secondary prevention of stroke over the three months after discharge, measured using prescription refill data. Secondary aims include: investigation of the impact of the PCEE on adherence over 12 months using prescription refill data, self-reported medication taking behaviour, self-reported clinical outcomes (blood pressure, cholesterol, adverse medication events, and readmission), quality of life, the cost utility of the intervention and changes in beliefs towards medicines and illness.

Ethics and Dissemination:

Communication of the trial results will provide evidence to aid clinicians in conversations with patients about medication taking behaviour related to stroke prevention. The targeted audiences will be health practitioners and consumers interested in medication taking behaviour in chronic diseases and in particular those interested in secondary prevention of stroke.

The Australian New Zealand Clinical Trials Registry number is ACTRN12615000888561. The trial has ethics approval from Metro South Human Research Ethics Committee

(HREC/15/QPAH/531) and The University of Queensland Institutional Human Research Ethics (2015001612).

Strengths and Limitations

- The design of a randomising participants to the PCEE will provide the opportunity to take into account other changes which may occur across the time of the study.
- The use of questionnaires, validated as research tools, to elicit patient perceptions will be integrated with the approach used in "academic detailing".
- The strength of the intervention is that it is underpinned by a combination of theories of behaviour change.
- This study links the use of both prescription refill data as an objective adherence measurement and patient self-reported adherence.
- As is common with many behavioural intervention studies, this study is not blinded once the participant has been allocated to either the intervention or control group, which may introduce bias to the study.

Introduction

Stroke is one of the leading causes of death worldwide[1 2]. About a third of those who suffer from a stroke die within 28 days and a further third are left permanently disabled placing a burden on themselves, their family and the community [3 4]. After an initial stroke the cumulative incidence of a subsequent stroke is about 30%, with the highest occurrence in the first 12 months (12%). [5-7] In an individual experiencing a transient ischaemic attack (TIA) or a minor stroke (<3 on the National Institutes of Health Stroke Scale[8]) the 30 day incidence of stroke is 11-15%.[9] After either a stroke or TIA, International [10-12] and Australian guidelines[13] recommend secondary prevention strategies. Recommendations include the use of antithrombotic therapy, medications for blood pressure lowering and cholesterol lowering medications. The high rate of recurrence in the first weeks and months of a minor stroke or TIA emphasises the importance of early initiation and subsequent persistence to secondary prevention medicines to reduce the risk of subsequent stroke.[9] Stroke survivors may not benefit due to poor adherence to the medications [14-16] or the benefit may be offset by the occurrence of adverse drug events (ADEs).[17] Reports of patient adherence to secondary prevention medications vary widely ranging from 40%[14] to 86%[15] and are influenced by the timing and method of measurement. There are many reasons reported for reduction in adherence including: lower income, multiple co-morbidities, minor stroke or TIA,[18] forgetfulness, trivialising stroke and low necessity beliefs in taking medications.[19]

Educational interventions focused on improving patient use of medications for secondary prevention of stroke have shown impact on patients' knowledge but other outcome measures have had varied results.[20-22] Debate centres on whether a change in knowledge will result in a change of medicine taking behaviour or whether alternative approaches such as addressing necessities and concerns about medication, [23] agreeing goals, or providing key messages about medication taking will be more effective in changing behaviour. Previously validated questionnaires have been used to identify patients' perceptions of their illness,[24] beliefs about medications[25] and medication taking behaviour[26] and these have been used to provide a structure to encourage patient input into a personalised intervention.[27] Another approach to empower patients in medication related self-management has incorporated "academic detailing"[28 29] also described as "educational visiting".[30 31] Academic detailing

uses a social marketing framework, to encourage information exchange while delivering key messages in order to influence behaviour. The approach includes the following key features: identifying baseline knowledge and motivations for medication use, defining clear educational and behavioural objectives, establishing credibility, referring to authoritative sources of information, and presenting both sides of controversial issues, stimulating participation in educational interactions, using concise graphic educational materials, highlighting and repeating the essential messages and providing positive reinforcement of improved practices in follow-up communication.[28]

Combining these two strategies, identifying patients perceptions' and beliefs' then using these to personalise educational messages and to engage patients in a conversation, may empower patients to better manage their medications. This approach will be referred to as a patient centred educational exchange (PCEE). The PCEE has been tested for feasibility, and was found to be acceptable to the participants, manageable for the health care professional and the beliefs and perceptions elicited by the questionnaires were able to be used to personalise the conversation.[32] A limitation of this feasibility study was that because the researcher delivered the intervention, the training requirements, use of resources and opinions of staff were not evaluated. The impact of the PCEE on patient self-management of stroke prevention medications has yet to be determined.

Aim: The primary aim of this study is to determine whether a patient centred educational exchange (PCEE) improves adherence to antithrombotic, antihypertensive and lipid lowering medications prescribed for secondary prevention of stroke over the three months after discharge, measured using prescription refill data.

Secondary aims include: investigation of the impact of the PCEE on adherence over 12 months using prescription refill data, self-reported medication taking behaviour, self-reported clinical outcomes (blood pressure, cholesterol, adverse medication events, and readmission), quality of life, the cost utility of the intervention and changes in beliefs towards medicines and illness.

To address these aims we will conduct a randomised controlled trial, with an intervention comprised of two PCEE sessions; one before discharge from hospital and one by telephone at least ten days after discharge.

Methods and Analysis

This protocol was developed in accordance with the Standard Protocol Items: recommendations for intervention trials (SPIRIT) statement (see online supplementary file 1. SPIRIT checklist).

Study Design

This study is a non-blinded randomised controlled trial (RCT). Participants will be randomised 1:1 to either the intervention group (intervention and usual care) or the control group (usual care).

Setting

The setting will be the "Medical Stroke Unit" (MSU) or the Medical Admission and Planning Unit (MAPU), of an Australian tertiary referral hospital.

Study Population

Inclusion criteria: Participants recruited to this study must be aged 18 years or older, have been admitted to the MSU or the MAPU with a principal diagnosis of stroke or TIA, and are planned to be discharged to their home.

The participant should be expecting to manage their own medication after discharge home, have a documented Mental Status Questionnaire (MSQ)[33] score of 10/10 at the time of recruitment and be able to provide consent. The consent form requires the researcher to sign a declaration saying that they have given a verbal explanation of the research project, its procedures and risks, and believe that the participant has understood that explanation. This means the participant is unlikely to have severe problems with verbal communication.

Exclusion criteria: Those patients planned for discharge to a residential care facility (for example a nursing or residential care home) where a staff member is responsible for the patients' medication administration, those patients who have been planned for a rehabilitation period of greater than one month as they will be having weekly education sessions, those with an MSQ<10, unable to complete the questionnaire (even) with assistance (this may be due to language difficulties or cognitive impairment) and those who do not provide consent. Those who are excluded will receive standard care, which includes education, without incurring any disadvantage.

Patient and Public involvement

A feasibility study [32] was conducted to inform the design of the PCEE used in this randomised controlled trial. Ten of the 18 participants completed an evaluation of the proposed intervention which resulted in changes to the final protocol. This included improved graphics to be used in this study, the use of mobile telephones with messaging to facilitate follow up calls, and bridging sentences between questionnaires and the use of the infographic. With respect to the burden of the intervention, seven of the ten indicated that the session was not too long or too short and 9/10 agreed that the materials helped them. The participants were invited to ask a questions and prompted to discuss previous experiences as part of the feasibility study, this has been included in the current protocol.

Patients and public were not involved in development of the research question or outcome measures, they will not be involved in the recruitment or ongoing conduct of the current study. The participants will be given contact details to request the results of the study.

Recruitment

All admissions to MSU and MAPU will be screened using "bed lists" for five days of every week. Those admissions with a diagnosis of stroke or TIA will be further screened for a documented MSQ of 10/10 and plan for further rehabilitation or discharge to home. The researcher will then approach the potential participants on the ward to determine whether they are willing to participate in the study.

Allocation/Randomisation: The allocation of participants to control or intervention will be concealed until the participant has been consented to reduce allocation bias. After the participant has consented to the study the research pharmacist will contact the clinical trials pharmacist, who is not involved in the study and who will identify the allocation, one to one, to either the intervention or control group. The allocation will be previously determined using a computer generated four block randomisation code using Sealed Envelope Ltd™ [34]. The allocation will be concealed by placing the allocation in sealed opaque envelopes stored in the clinical trials office of the pharmacy department.

Once the participant is allocated the researcher will no longer be blinded to participant's allocation. The reason the researcher will no longer be blinded is that the researcher will conduct the intervention and follow-up calls.

Sample size- The primary outcome is adherence measured by the proportion of days covered (PDC) (defined as the days of medication supplies when the medications were collected divided by the days in the time interval) over the three months after discharge, using prescription refill data for three classes of medications (antithrombotic, antihypertensive and lipid lowering medications).

The sample size calculation used the criterion for significance (alpha) set at 0.05 and the power (beta) at 80%. It is proposed that the intervention will result in a 7% improvement in adherence compared to standard care. This difference of 7% was selected as reasonable; because an effect of this magnitude has been shown with secondary prevention medications used for cardiovascular diseases [35 36] and has been linked to a clinical difference [37]. An effect size of 0.54 (0.07/0.13) was selected using results from a study conducted with participants discharged on similar medications after a diagnosis of acute coronary syndrome[36]. A sample size of 55 in each arm is required for effect size of 0.54. We allowed for a slighter larger pooled standard deviation of 0.15 (effect size 0.7/.15= 0.47) requiring a

sample size of n= 73. Adherence data is likely to be skewed [38] and so will not fulfil the requirements for a parametric test. Lehmann [39] suggests the addition of 15% more participants (n=84) when planning to use non-parametric tests such as the Mann Whitney. Assuming attrition rates of approximately 10% we would need to enrol at least 92 participants for each group; we propose to include 100 participants in each arm. It is predicted that approximately two participants will be recruited per week, estimating a two year recruitment period. The first participant was recruited on the 18th December 2015 and the study will be ongoing until April 2019.

Procedure

Both the intervention and control group will receive usual care. In addition to usual care participants in the intervention group will receive two sessions of a "PCEE", one before discharge and one by telephone at least ten days after discharge. These sessions will be conducted by a clinical pharmacist who attends weekly multidisciplinary MSU meetings, has a postgraduate qualification in clinical pharmacy (MSc ClinPharm) and training in academic detailing. In this study the intervention pharmacist will also be collecting the study data.

Usual Care

Usual care includes admission to a stroke specific ward, multidisciplinary care by the stroke team, education using Stroke Foundation-Australia materials by the stroke nurse[40], clinical pharmacy services provided by the ward pharmacist and discharge advice provided by the medical staff. Usual care provided by the ward pharmacist includes medication history taking and reconciliation, medication review during the admission, discharge reconciliation, provision of a medication list [41] and medication counselling at discharge.

Control Group

The control group will receive usual care as described above.

Intervention - Patient centred educational exchange (PCEE)

The intervention consists of two sessions, one which will take place at the patients' bedside before the usual pharmacist discharge counselling and the second which will be conducted over the telephone at least ten days after discharge. These sessions are additional to, and

designed to integrate with, usual care. The PCEE is structured with an introduction, conversation and conclusion.

The session begins with an "introduction" phase establishing credibility "*I am a pharmacist with an interest in patients taking medication to reduce the risk of stroke*". Next the clinical pharmacist will give the opportunity to the patient to ask a question. "*What one thing would you most like to discuss about medications you have been prescribed since your stroke/TIA?*" There is an opportunity to answer this question before moving on.

The session will then move into the "conversation"- using previously validated questionnaires to identify patients' perceptions, beliefs and concerns about their stroke in general (using the brief-Illness Perception Questionnaire (brief- IPQ)[24]) and medications in particular (using the Beliefs about Medicine questionnaire specific (BMQ-specific)[25]). There is also an opportunity for the patient to self-report their previous medication taking behaviour for the medications of interest (using the Medication Adherence Questionnaire (MAQ)[26]). The identified barriers and enablers will be used to personalise the conversation. A double sided single page document will be personalised and given to the participant (the detailing tool). The detailing tool contains an infographic to help illustrate the discussion about the stroke prevention medications the patient has been prescribed on one side, and four a-priori key messages on the other side (see online supplementary file 2. infographic example).

The four key messages are: **"Know** about your medications prescribed to reduce risk of stroke", "**Organise** ongoing supply of your medications", "Continue to **take** these medications as agreed with your doctors" and "**Report** any new symptoms or concerns to your doctor".

In the final phase, "conclusion", items identified to be discussed when the clinical pharmacist telephones the patient will be listed.

To provide an opportunity for "follow-up" and reinforcement of key messages, the intervention is designed to include two sessions. The clinical pharmacist arranges to telephone the participant at least ten days after discharge to ask them the same questions and to talk about their medications.

It is hypothesised that patients in the intervention group will be influenced to organise ongoing supply of their medications and take their medications as prescribed. In addition, it is hoped that if they identify that they are experiencing unwanted effects from a medication(s) they will not keep taking medication(s) long term, rather discuss their concerns with their doctor.

Outcomes

The primary outcome is adherence measured by the proportion of days covered (PDC) over the three months after discharge, using prescription refill data (obtained from the pharmaceutical benefits scheme (PBS)) for the combination of up to three classes of medications (antithrombotic, antihypertensive and lipid lowering medications) prescribed.

Secondary outcomes include:

- Adherence measured by the proportion of days covered (PDC) over the twelve months after discharge, using prescription refill data for up to three classes of medications (antithrombotic, antihypertensive and lipid lowering medications).
- Self-reported medication adherence (measured using the Medication Adherence Questionnaire (MAQ)), organising of ongoing medication supply, and medication taking behaviour and communication to prescriber in response to perceived medication related adverse events.
- Self-reported changes between baseline and 3 and 12 months in perception to their illness (stroke) using Brief-IPQ and changes between baseline and 3 and 12 months in beliefs about medications for stroke prevention using BMQ-specific.
- Clinical outcomes:
    - medication related adverse events (identified by self-report or hospital readmission),
    - self-report of blood pressure (BP) results,
    - self-report of Cholesterol level,
    - re-admission to hospital with stroke and/or myocardial infarction (MI) (identified by self-report or hospital records).
- Changes from baseline to 3 and 12 months in self-reported quality of life using EQ-5D-5L.[42 43].

- Cost utility analysis using a ratio of incremental cost (cost of the PCEE intervention compared to usual care) to incremental benefit (change in quality-adjusted life years).[44]

The complex relationship between the intervention described here and the measures of the impact we expect to make has been described by authors of previous studies [45 46]. Table 1 has been adapted from Shay and colleagues to categorise the study outcome measures by outcome type and who measures it.

Table 1. The proposed measures categorised by outcome type and who measures it.

	Behavioural outcomes	Affective-cognitive outcomes. (This includes knowledge, understanding, satisfaction)	Health outcomes	Economic outcomes
Patient self-reported	Self report of adherence using MAQ	Particpant ability to identify each medication of interest along, reason for use when answering the MAQ	Blood Pressure, Cholesterol levels	
	Self-report of organising medication supply	Participant knowing their : blood pressure, cholesterol level	Blood Pressure,Cholesterol levels	
	Self report of action if they experienced an ADE	Participant beliefs and perceptions using the BMQ-specific and brief-IPQ	Self reported quality of life EQ-5D-5L	Self reported quality of life EQ-5D-5L
			Self reported ADE	
Observer collected	Visit to doctor – Medicare data		Readmission/admission for ADE	Readmission/admission for ADE (S)
	Prescription refills- Pharmaceutical benefits scheme data		Events-Stroke, MI	Events-Stroke, MI
				Time to conduct intervention

Brief-IPQ= brief-Illness Perception Questionnaire [24], BMQ specific= Beliefs about Medicine questionnaire specific[25], MAQ= Medication Adherence Questionnaire [26]) EQ-5D-5L= Quality of Life Measure[42] MI= Myocardial Infarction, ADE=Adverse Drug Event

Behavioural measures

Behavioural measures look at things the participant has done. In this study visiting the doctor and having their medication dispensed is observer collected [47 48]. Pharmaceutical claims data can provide an objective, non-invasive measure of adherence and has been used in many drug trials and in a number of studies similar to this one. A range of methods for use of claims data to measure medication possession ratios and proportion of days covered have been described to assess an individuals' medication adherence [38 47-50].

The Proportion of Days Covered is defined as the days of medication supplies when the medications were collected divided by the days in the time interval. This can be averaged over the total (for example a 90 day interval), or to be more reflective of medication exposure, a shorter interval can be measured and added together (for example in Australia most medications for chronic diseases are supplied at approximately one month intervals). The proportion of days covered calculated using multiple short intervals [49 50] can more accurately account for gaps in supply or extra medication supplies. The example shown in Figure 1 adapted from Bijlsma[49] and Bryson[50] shows how the adherence over three lots of 30 day intervals can be calculated using the gaps in supply for three patients obtaining 30 day supplies. The calculation used is; Proportion of 90 days covered= (90 –total of days not covered in each 30 day interval)/90x100.

Figure 1. Examples of Proportion of days covered calculated using multiple 30 day intervals.

Patient 1 obtained medications on the day of discharge, 30 days later and then had a gap of five days before the third supply. Patient 1 PDC= [(30 +0) + (30 +0) + (30-5)]/90x100=94%

Patient 2 obtained the first supply five days before discharge these were not used until the day of discharge so although the second supply was obtained 10 days after the first supply there was only a 5 day gap in supply for the patient. Five days of tablets remaining from the second supply were used in the third interval. The third supply was obtained after a 10 day gap. Patient 2 PDC= [(30 +5-5) + (30 -5) + (30+5-10)]/90x100=89%

Patient 3 obtained medications on the day of discharge, 20 days later and then had a gap of 40 days before the third supply. Patient 3 PDC= [(30 +0) + (30 +10-10) + (30-30)]/90x100=67%

In this study the days covered in each dispensing interval will be calculated for up to three different medications (antithrombotic, antihypertensive, lipid lowering medication) dependant on the medication plan at discharge. These will then be expressed as a mean (across the up to three medications) percentage and analysed as a continuous variable.

Self-reported behavioural measures in this study include self-report of medication adherence using the MAQ [26], organising an ongoing medication supply and action taken if

they experience adverse effects from their medication. The MAQ is a well validated scale, previously used in many clinical conditions.[51]

Affective cognitive outcomes

Affective cognitive outcomes include measures of what the participant knows and how they feel, these are usually self-reported.

In this study the affective cognitive group includes metrics such as knowledge and understanding regarding name, type and dose of medications, participants knowing their BP reading or cholesterol level, participants' perceptions of their illness and beliefs about their medications. Participant perceptions of their stroke will be evaluated using the adapted-Brief IPQ at baseline, 3 and 12 months. Beliefs about antithrombotic, antihypertensive and lipid lowering medications will be evaluated using the BMQ-specific at baseline, 3 months and 12 months. Changes in these may be able to be used to explain changes in other measures for example adherence.[46]

Health Outcomes

In this study we will evaluate patient self-reported clinical measures (Blood Pressure (BP) and Cholesterol) , readmissions, subsequent stroke or myocardial infarction, adverse drug reactions and quality of life.

Medication related adverse events will be identified by patient self-report using probe questions adapted from a previously validated trigger tool[52] at 3 months and 12 months for each medication class of interest. Medication related adverse events will also be collected from any readmission notes at 3 months and 12 months post discharge.

Quality of life will be measured using EQ-5D-5L [42] before discharge (baseline), 3 months and 12 months. This tool (EQ-5D-5L) has previously been used in stroke research. [53]

Economic Outcomes

Economic outcomes will be determined from the health service perspective using an incremental cost effectiveness ratio (ICER). The ICER indicates the difference between the

intervention and control cost (time and resources costed) per the difference in quality-adjusted life years (QALYs) determined using the quality of life measure EQ-5D-5L. Time taken to deliver the PCEE sessions (intervention group only) will be recorded on the interview schedule at both the bedside (before discharge) and telephone follow-up (7-10 days post discharge) sessions and costed using standard pharmacist salary rates. Any impact of the intervention on health-resource use (e.g. medication use, hospital readmissions) will be considered when estimating costs. Patient interview using EQ-5D-5L will be conducted before discharge (baseline), at 3 months and 12 months. Uncertainty in the estimated ICER will be evaluated using non-parametric bootstrapping techniques.

Data Collection

A schedule of assessments including the timing for data collection is shown in Table 2. Data will be collected by the investigator prior to the patient's discharge, at least 10 days after discharge (intervention group only), at 3 months and at 12 months.

Demographic data collected prior to the patients discharge includes patient age, sex, stroke type, whether they have had a previous stroke, whether they live alone, cholesterol levels and BP on discharge. The demographic data is required to describe the population in the study and to ensure the intervention and usual care groups are comparable.

Participant self-reported data will be obtained by the researcher conducting telephone follow-up using the telephone numbers they provide during consent. If the participant does not answer the first call and has provided a mobile telephone number, the researcher will send a text message using the study mobile phone asking for a "good time to talk." The protocol allows for a total of three attempts to contact the participant for follow-up calls.

Table 2. Schedule of enrolment, interventions, and assessments for Patient Cantered Educational exchange (PCEE) to improve patients' self-management of medications after a stroke.

TIMEPOINT		*-t1*	*-t2 Before discharge*	*t0 Date of discharge*	*t1 approximately 10 days post discharge*	*t2 approximately 3 months post discharge*	*t3 approximately 12 months post discharge*
			Post-allocation				
Procedure	*Detail*	*Baseline*	*Intervention*		*Intervention*	*Evaluation*	*Evaluation*
ENROLMENT: *Eligibility screen*	*MSQ[1,2]=10 Not for extended rehabilitation*	*X*					
Informed consent		*X*					
Randomisation		*X*					
INTERVENTION:							
First Session (PCEE)	*Bedside Interview Time taken[3]*		*X* *X*				
Second Session (PCEE)	*10 day follow-up interview Time taken[3]*				*X* *X*		
ASSESSMENTS:							
Brief-IPQ, BMQ-specific, MAQ EQ-5D-5L BP,Cholesterol		*X* *X* *X* *X* *X[2]*			*X* *X* *X*	*X* *X* *X* *X* *X[4]*	*X* *X* *X* *X* *X[4]*
PBS/MBS data Admissions, Stroke, MI Self-report of ADRs and Action if ADRs						*X* *X* *X* *X*	*X* *X* *X* *X*

1.-Mental State Quotient [33], 2-these are standard care clinical tests performed as part of routine patient care 3-time taken for PCEE, 4 –self reported by participants. Brief IPQ=Brief Illness Perception Questionnaire [24], BMQ specific=Beliefs about medicines Questionnaire[25], MAQ=Medication Adherence Questionnaire [26], EQ-5D-5L[42], PBS/MBS data=Dispensing data obtained from the Australians Pharmaceutical Benefits Scheme, MI= Myocardial Infarction, ADR=Adverse Drug Reactions

Data Management

Data will be entered electronically from the case record forms using a study number with no identifying information into Microsoft Excel® and SPSS Statistics 25® both stored on a password protected computer. In all reports from this research, information will be provided in such a way that the participant cannot be identified. Data entry and analyses will be performed using Microsoft Excel® and SPSS Statistics 25®.

Data Analysis

An intention to treat analysis will be conducted. Results will be reported as numbers and percentages for categorical variables and means (SD) or medians (IQR) for continuous variables. Demographic data and baseline characteristics in the intervention and control groups will be compared using descriptive statistics. Outcomes and changes in outcomes (from baseline) will be compared at 3 months and 12 months.

Adherence measured using the PDC from the prescription refill data will be compared using the Mann-Whitney two-sided test. Changes from baseline in quality of life, perceptions of illness and beliefs about medicines will be analysed using the Mann Whitney test. Adherence by self-report, medication related adverse events and re-admissions will be analysed using the chi-square test.

Adverse Event Reporting and Quality Assurance: This study involves completing a questionnaire and discussing stroke medications through one face to face interview and three follow up telephone calls for the intervention group. The control group will complete one face to face interview and two follow-up telephone calls. It is possible that during either the face to face interview or one of the telephone interviews, the participant identifies a medication related issue. Although this is unlikely to be as a result of the study the researcher may still have concerns over the patients' safety. If the researcher has concerns requiring immediate

intervention the patients' doctor will be contacted. In the case of the face to face interview in the hospital that will be a medical member of the treating team. In the case of the telephone interview that will be the patients' General Practitioner.

This is a randomised controlled trial where data on adverse drug reactions and events including stroke and readmission will be collected. It is possible that differences can be determined between the two groups before the recruitment period is complete. A data safety monitoring committee (consisting of an independent medical doctor- clinical pharmacologist and pharmacist- Drug Use Evaluation Pharmacist) has been established to analyse the adverse events every 6 months with responsibility to terminate recruitment into the study early if necessary.

This randomised controlled trial will provide evidence about the effect of a patient centred educational exchange on patient adherence, self-reported medication taking behaviour, clinical outcomes, quality of life, changes in knowledge, and beliefs towards medicines and illness. It is expected that communication of results will inform an evidence based approach to communication with patients about medication taking behaviour related to stroke prevention. Communication of results of this study will seek to impact on the practice of health practitioners and consumers interested in patient medicine taking behaviour and those interested in secondary prevention of stroke.

Ethics and Dissemination

This trial has been registered on the Australian New Zealand Clinical Trials Registry, the number is ACTRN12615000888561. The trial has ethics approval from Metro South Human Research Ethics Committee (HREC/15/QPAH/531) and The University of Queensland Institutional Human Research Ethics Approval Number 2015001612.

Participants will be provided with information about the study and asked if they consent to the study; "Participant information and consent form" (see online supplementary file 3. Patient

Information and Consent Form). To obtain consent for medication refill data from the Pharmaceutical Benefits Scheme and occasions of service by visits to doctor data from Medicare, the patients will be given an extra consent form as required by the Department of Human Services. This is also contained in the "Participant information and consent form". The patient can choose not to supply the extra consent for access to Pharmaceutical Benefits Scheme/Medicare data. The participant is free to withdraw from the study at any time.

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Contributors: JC, NC, DR and JW were all equally involved in the development of this protocol. DR provided advice on academic detailing. JW provided advice on Quality of Life measurement and economic analysis. JC and NC wrote the initial drafts of this paper. All authors have been involved in the reviewing and editing, and approval of the final protocol manuscript.

Competing interests: None declared

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Data sharing: The data from this study is not available for data sharing.

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Figures

Figure 1. Examples of Proportion of days covered calculated using multiple 30 day intervals.

Supplementary Files

1. SPIRIT checklist

2. Infographic example

3. Participant Information and Consent Form

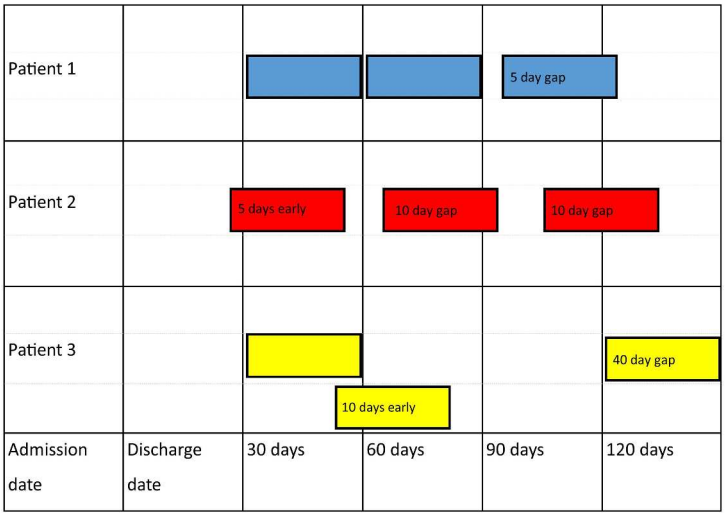


Figure 1. Examples of proportion of days covered calculated using multiple 30 day intervals.

297x209mm (300 x 300 DPI)

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	1 (20 items in ANZCTR)
Protocol version	3	Date and version identifier	Y
Funding	4	Sources and types of financial, material, and other support	20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-7
	6b	Explanation for choice of comparators	5-7
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7-8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7-8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	10
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11-17
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	17 (Table 2)

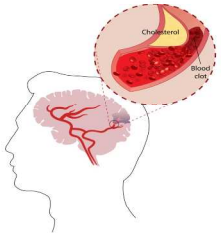
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9-10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	9
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-17
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	18-19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	19
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	19
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	19
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	N/A
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	18
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19
	31b	Authorship eligibility guidelines and any intended use of professional writers	Submitted
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Medication after a Stroke or TIA



Take your antiplatelet medication called _____ to lower the risk of blood clots forming in the brain.

Take your cholesterol lowering medication called _____ to lower the risk of stroke even if your cholesterol is normal.

Take your blood pressure medication called _____ to lower the risk of stroke.

The University Of Queensland AUSTRALIA

Metro South Health

Medication after a Stroke or TIA

Know about your medications prescribed to reduce the risk of stroke

Organise your ongoing supply of your medications

Continue to **take** these medications as agreed with your doctors

Report any new symptoms or concerns to your doctor

The University Of Queensland AUSTRALIA

Metro South Health

419x297mm (300 x 300 DPI)

Princess Alexandra Hospital

Participant Information Sheet/Consent Form

Title	The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke
Short Title	A conversation with patients about medications after a stroke
Coordinating Principal Investigator/ Principal Investigator	Mrs Judith Coombes
Associate Investigators	Associate Professor Neil Cottrell Dr Graham Hall Dr Nabeel Sheikh Dr Leena Aggarwal Ms Marie Williams Ms Debra Rowett
Location	Princess Alexandra Hospital

Part 1 What does my participation involve?

Introduction

You are invited to take part in this research project, "A conversation with patients about medications after a stroke." This is because you have been diagnosed with a stroke or Transient Ischemic Attack (TIA). The research project is aiming to test a program designed to educate people about the medications prescribed after they have had a stroke or TIA.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Princess Alexandra Hospital.

If you decide you want to take part in the research project, you will be asked to sign the consent section. There are two forms.
By signing the first form, "The study consent form" you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to the research that is described

• Consent to the use of your personal and health information as described.
You will be given a copy of this Participant Information and Consent Form to keep.
The second form is "The participant consent form for release of Medicare and PBS data. Here you will be asked to fill out a consent form authorising the study access to your complete Medicare and Pharmaceutical Benefits Scheme (PBS) data as outlined below. Medicare collects information on your medical visits and procedures, and the associated costs, while PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services who holds this information confidentially.

Definitions of Data used in this study:

Medicare (MBS)

- Date of service *(Date that the service was rendered by the provider, to the patient)*
- MBS Item number *(Items Numbers as per the Medicare Benefits Schedule)*
- MBS Item description *(describes the service as per the Medicare Benefits Schedule)*
- Item category *(where the service sits in the hierarchical structure according to the Medicare Benefits Schedule)*

Pharmaceutical Benefits Scheme (PBS)

- Date of supply *(Date the prescription was supplied by the pharmacy)*
- Date of Prescribing *(Date that the prescription was prescribed by a Medical Practitioner to a patient)*
- PBS Item Number *(Items Numbers reflected in the Pharmaceutical Benefits Scheme)*
- PBS Item Description *(the item description as noted in the Pharmaceutical Benefits Scheme Book)*
- Patient category e.g. general, concession, safety net, doctor's bag *(Patient's eligibility status at the time of supply)*
- Patient contribution *(the contribution paid by the patient)*
- Form category *(Original or repeat prescription)*
- ATC Code *(the code allocated by the World Health Organisation Collaborating Centre for Drug statistics Methodology)*
- ATC Name *(the group the drug falls under in the Anatomical Therapeutic Chemical (ATC) classification system*

What is the purpose of this research?

The purpose of this project is to test a program designed to educate people about the medications people are prescribed after they have a stroke or TIA. The program is designed to improve understanding and organisation of ongoing use of the participants' medications. A total of approximately 200 people will participate in this project.

The results of this research will be used by the study pharmacist, Judith Coombes, to obtain a Doctor of Philosophy (PhD) degree.

What does participation in this research involve?

Participation will only take place after you have given signed consent.

Participation in this project will involve completing a questionnaire on three or four occasions.

The first will be before you are discharged from hospital, the second will take place over the telephone about 3 months after your discharge from hospital and the third over the telephone at

12 months after discharge from hospital. The questionnaire will take about ten minutes to complete. You will be asked about your views of your illness (stroke), your view and opinion of your medicines used for stroke about the way you take your stroke medicines and about your quality of life. There are no right or wrong answers to any of the questions in the interview; it is your view and opinion that is important.

About half of the participants in this study will be chosen by chance (random), to have a longer interview with the researcher to have a conversation about their stroke medications prior to their discharge from hospital. This will take about a further ten minutes. These participants will also be contacted by telephone 7-10 days after discharge from hospital. The telephone call will last for about 10 minutes. The telephone call will involve completing the questionnaire and an opportunity to follow-up on any questions they may have about their medicines.

You will also be asked for consent for the release of your Medicare/PBS claims information.

What are the possible benefits of taking part?
No payment will be provided for participation in this study. We cannot guarantee or promise that you will receive any benefits from this research; however possible benefits may include better understanding of the medications you are using to reduce the risk of a further stroke. It may also help you to organise ongoing use of your medications.

What are the possible risks and disadvantages of taking part?
This study involves completing a questionnaire and for about half the participants discussing your stroke medications through one face to face interview and one telephone call. There is no foreseeable added risk to you above the risks of everyday living.

What if I wish to withdraw from this research project?
If you decide to take part and later change your mind, you are free to withdraw from this research project at any stage. You can ask to withdraw during the interview or you can inform Mrs Judith Coombes your desire to withdraw by telephone on 3346 1944 or 0428814397, email Judith@pharmacy.uq.edu.au or by mail addressed to Judith Coombes, Pharmacy Department, Princess Alexandra Hospital, Ipswich Rd, Woolloongabba QLD 4102.
If you do withdraw your consent during the research project, the investigator will not collect additional information from you or about you, although information already collected will be retained to ensure that the results of the research project can be measured properly. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want the researcher to do this, you must tell the researcher.

What happens when the research project ends?
You may request the study results when it is completed by providing an address that the report can be sent to or at a later date by contacting Judith Coombes (contact details above).

Part 2 How is the research project being conducted?

What will happen to information about me?

By signing the consent form you consent to the study pharmacist collecting and using personal information about you for the research project. Information about you may be obtained from your health records held at this hospital for the purpose of this research. By signing the consent

form you agree to the research team accessing health records if they are relevant to your participation in this research project.

Any information obtained in connection with this research project that can identify you will remain confidential. In all reports from this research, information will be provided in such a way that you cannot be identified.

The information collected on paper will be stored in a locked filing cabinet in a locked office, with access only to the principal investigator stated above. Both written and electronic information containing confidential data will be stored for a period of seven years after publication of the final report or for 10 years, whichever is earlier, and then destroyed.

Who is organising and funding the research?

This research project is being conducted by *Mrs Judith Coombes, Associate Professor Neil Cottrell and Dr Graham Hall ,Dr Nabeel Sheikh, Dr Leena Aggarwal, Ms Marie Williams, Ms Debra Rowett and Associate Professor Jenny Whitty*
Mrs Coombes, Associate Professor Cottrell, Ms Rowett and *Associate Professor Whitty* are affiliated with the School of Pharmacy at The University of Queensland and Dr Hall, Dr Sheikh, Dr Aggarwal, Ms Williams and Mrs Coombes are affiliated with the Princess Alexandra Hospital.

Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of *The Princess Alexandra Hospital*. This study adheres to the Guidelines of the ethical review process of the University of Queensland.
This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

11 Who to contact

If you have any queries or any problems concerning this research project, please contact

Name	Judith Coombes
Position	*Advanced Pharmacist Education*
Telephone	*0428814397, 33461944 or contact the switchboard 3176 2111 pager number 8009*
Email	*Judith@pharmacy.uq.edu.au*

If you would like to speak to an officer not involved in the study or if you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Princess Alexandra Hospital

Position	Coordinator, Metro South Hospital and Health Service Human Research Ethics Committee
Telephone	*3343 8049*
Email	*ethicsresearch.pah@health.qld.gov.au* or
Position	Human Ethics Unit Coordinator, University of Queensland
Telephone	*3365 3924*

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Metro South Health Queensland Government The University Of Queensland Australia

Princess Alexandra Hospital

Metro South Health Queensland Government The University Of Queensland Australia

Study Consent Form

Title	The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke
Short Title	A conversation with patients about medications after a stroke
Coordinating Principal Investigator/ Principal Investigator	Mrs Judith Coombes
Associate Investigators	Associate Professor Neil Cottrell Dr Graham Hall Dr Nabeel Sheikh Dr Leena Aggarwal Ms Marie Williams Ms Debra Rowett
Location	Princess Alexandra Hospital

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Senior Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Senior Researcher (please print) _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation -

Title	The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke
Short Title	A conversation with patients about medications after a stroke
Coordinating Principal Investigator/ Principal Investigator	Mrs Judith Coombes
Associate Investigators	Associate Professor Neil Cottrell Dr Graham Hall Dr Nabeel Sheikh Dr Leena Aggarwal Ms Marie Williams Ms Debra Rowett Associate Professor Jenny Whitty
Location	Princess Alexandra Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Princess Alexandra Hospital

Name of Participant (please print) _____

Signature _____ Date _____

Participant ID:

PARTICIPANT CONSENT FORM FOR RELEASE OF MBS/PBS DATA

Consent to release of Medicare and/or Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of "The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke" Study

Important Information

Complete this form to request the release of personal Medicare claims information and/or PBS claims information to "The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke "study.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

By signing this form, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

PARTICIPANT DETAILS

1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth: DD/MM/YYYY

2. Medicare card number: _____

3. Permanent address: _____

Postal address (if different to above): _____

AUTHORISATION

4. I authorise the Department of Human Services to provide my:

☐ Medicare claims history OR

☐ PBS claims history OR

☒ Medicare & PBS claims history

for the period 01/07/2014 to: 31/10/2018 to "The use of a patient centred educational program to improve patient's self-management of medicines after a stroke" Study.

*Note: The Department of Human Services can only extract 4.5 years of data (prior to the date of extraction), The consent period above may result in multiple extractions.

DECLARATION

I declare that the information on this form is true and correct.

5. Signed: _____ (participant's signature) Dated: DD/MM/YYYY **OR**

6. Signed by _____ (full name) _____ (signature) on behalf of participant

Dated: DD/MM/YYYY

☐ Power of attorney** ☐ Guardianship order**

** Please attach supporting evidence

APP 5 – PRIVACY NOTICE

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services. The collection of your personal information by the department is necessary for administering requests for statistical and other data.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or by requesting a copy from the department.

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type
20/04/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash
22/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill

Scrambled ordering Provider number*	Scrambled rendering Provider number*	Date of referral	Rendering Provider postcode	Ordering Provider postcode	Hospital indicator	Item category
	999999A		2300		N	1
999999A	999999A	20/04/09	2300	2302	N	2

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	Scrambled Prescriber number*	Pharmacy postcode
06/03/09	01/03/09	03133X	Oxazepam Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	9999999	2560
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		9999999	2530

Form Category	ATC Code	ATC Name
Original	N05 B A 04	Oxazepam
Repeat	N05 B A 01	Diazepam

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.

** Under co-payments can now be provided for data after 1 June 2012