Investigating a Communication Enhanced Environment (CEE) model early after stroke: A before-after non-randomised controlled pilot study.

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1 Abbreviations and Definitions of Terms

CEE model: Communication Enhanced Environment model, an adapted model of an Enriched Environment, an environment that provides patients following stroke opportunities to engage in language activities during inpatient rehabilitation.

PWA: Patients following stroke with aphasia.

PWOA: Patients following stroke without aphasia.

Language activities: Language tasks that consist of solitary or interactive language activities.

Solitary language activities: Activities that may promote aphasia recovery such as reading, writing, listening to the radio, and the use of iPad applications.

Interactive language activities: activities which are based in communicative interactions that involve an exchange of information with a communication partner involving talking, gesture and/or facial expression, reading, writing or drawing to communicate.

EE: Enriched Environment, an environment that promotes physical, cognitive and social activity.

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2. Protocol Synopsis

Study Title:	Investigating a Communication Enhanced Environment model on acute and rehabilitation wards early after stroke: A before-after non-randomised controlled pilot study
Study type:	Interventional
Study Intervention:	A Communication Enhanced Environment (CEE) model will be developed from pre-intervention observations of inpatient language activities and investigations of barriers and facilitators to communication together through focus groups with hospital staff and interviews with patients on the acute and rehabilitation wards. Sixteen patients following stroke will be recruited in this prospective before-after non-randomised controlled pilot study set in an acute and a rehabilitation ward of a metropolitan private hospital. The study includes: i) The baseline phase which involves observation of patients following stoke (n=8, 4 patients with aphasia (PWA) and 4 patients without aphasia (PWOA)); the collection of qualitative data through focus groups and semi-structured interviews to determine patient and staff perceived barriers and facilitators to communication; ii) the implementation phase where a CEE model will be developed and embedded in usual care; iii) the post-implementation phase which will involve repeated baseline data collection on a different cohort of patients (n=8, 4 PWA and 4 PWOA) to determine i) how solitary and interactive language activity levels changed following implementation of the CEE model, ii) the differences post CEE implementation in hospital staff's use of communication promoting strategies when interacting with patients, iii) the differences post CEE implementation in staff and patient perceptions of the barriers and facilitators to inpatient language activities. The CEE model will include the provision of: i) CEE model equipment, for example reading materials such as books and magazines, and access and encouragement to reside in a communal dining area; ii) CEE model education, support and training for staff with the aim to develop the ability to facilitate language activities for patients after stroke. The training program will be guided by research evidence, expert opinion and baseline data. Staff will complete a questionnaire pre and post training to determine changes in their knowledge, skills and attitudes regarding communication and aphasia. **Control treatment:** Patients following stroke with and without aphasia will be observed and video recorded over two weekdays and one weekend day pre (n=8) and post (n=8) implementation of a CEE model. Behavioural mapping will record patient interactive and solitary language activity observed within the first minute of 5-minute intervals in 4-hour time periods between 7am and 7pm. *Solitary language activities* are activities that may promote aphasia recovery such as reading, writing, listening to the radio, and the use of iPad applications. *Interactive language activities* are activities which are based in communicative interactions that involve an exchange of information with a communication partner involving talking, gesture and/or facial expression, reading, writing or drawing to communicate.

Objectives of the Study:	This study aims to investigate a CEE model on an acute and rehabilitation ward and if stakeholders perceive a CEE model as valuable by addressing the following research questions: - Does a CEE model increase the amount of time PWA and PWOA spend in participating in solitary and interactive language activities on acute and rehabilitation wards during the early post-stroke period? - What are the differences in patients' experience of communication in a CEE model compared to patients' experience of communication in a standard environment on in-patient acute and rehabilitation wards? - What is the experience of implementing a CEE model for staff working with PWA and PWOA within in-patient acute and rehabilitation wards? - Do staffs' perceptions of their knowledge of, skills with, and attitude towards communication and aphasia change following implementation of a CEE model?
Number of Centres:	1
Study duration:	5 years
Study Hypothesis:	A CEE model will increase patient engagement in solitary and interactive language activities and improve staff and patient experiences of communication compared to a standard ward environment.
Primary outcomes:	The primary outcome is the change in the proportion of solitary and interactive language activities as a percentage of total observed activity after the implementation of the CEE model. Timepoint: Patient observations completed within 21 days post stroke.
Secondary outcomes:	The differences post CEE model implementation in staff and patient perceptions of the barriers and facilitators to inpatient language activities. Timepoint: Within 18 months of embedding the CEE model.
Study design:	Before-after non-randomised pilot study
Key inclusion criteria:	Patients will be eligible for inclusion if they have/are: admitted to the acute or rehabilitation ward for a stroke, less than 21 days post stroke during baseline phase or post-implementation phase, the ability to provide informed consent as determined by the medical team, a Glasgow Coma Scale[1] score greater than 10 at the time of screening , an estimated length of hospital stay greater than 14 days, adequate English proficiency to participate in semi-structured interviews and are above 18 years of age. Patients with aphasia will also have an Aphasia Quotient below 93.7 on the Western Aphasia Battery-Revised.[2] Staff participants: One representative from each acute and rehabilitation staff group including medical, nursing, volunteers, and allied health staff members (n=17), who are over 18 years old.
Key exclusion criteria:	Patients will be excluded if they have/are: uncorrected hearing or vision, not medically stable, a documented diagnosis of dementia, traumatic brain injury or previous aphasia, a documented current untreated depression at the time of acute admission or are a participant in another research trial which may affect this study's outcome measures.
Study Procedures:	**Baseline phase:** Eligible patients during the baseline phase will be observed and video recorded for 4 hours on 3 consecutive days (one weekend and two weekdays) and will complete a semi-structured interview to explore their experiences of communication, and their perceptions of barriers and facilitators to inpatient language activities during their inpatient admission.

	Staff will participate in a one-hour focus group to explore their perceptions of barriers and facilitators to inpatient language activities. A focus group interview schedule will be used across all focus groups. **Implementation phase:** The CEE model will be implemented within the acute and rehabilitation wards. **Post-implementation phase:** Intervention group patient observations and interviews, and staff focus groups will replicate baseline data collection.
Safety parameters	Patients and/or their significant others may experience increased levels of distress during recruitment and/or data collection. This may be the result of adjustment following stroke and/or diagnosis of aphasia and increased awareness of impairment. No other risks known regarding participation in this project. The baseline assessments and interview will be conducted by the Chief Investigator who has experience in supporting patients during this early stage of stroke recovery. If a patient or any significant others becomes upset or distressed, the assessment or interview will be paused with the option to discontinue and counselling strategies will be provided.
Statistical methods /analysis	Patient demographic and stroke characteristics will be presented using descriptive statistics. One-way ANOVA or the Kruskal-Wallis and chi-square tests will examine differences in characteristics between groups. Time spent observed in interactive and solitary language activities will be expressed as a percentage of total observations. A mixed design ANOVA will be used to calculate the within-subjects variable of presence of aphasia and the between-subjects variable of a CEE on language activity levels of patients by comparing baseline to intervention phase observations. A qualitative description research approach will be used for the qualitative component of this research. The mixed methods design will enable the triangulation of the qualitative and quantitative data.
Sample size determination:	The patient sample size was selected for this pilot study to collect data across each observation period for each patient group in the baseline and intervention phases (see document: Observation_protocol_SD_version 3_23-02-16). The sample size for staff participants was selected to capture a sufficient breadth of professional perspectives.

3. Introduction

Aphasia is an acquired communication disorder that affects approximately 30% of first ever ischaemic stroke survivors[3] and persists in up to 61% of survivors one-year post stroke.[4] Aphasia impacts all communication modalities with significant negative consequences for social participation, interpersonal relationships, autonomy, capacity to work and quality of life.[5]

Patients following stroke with aphasia (PWA) have been observed to spend less than 28% of their day communicating and 44% of their day alone during their first weeks of inpatient rehabilitation.[6] Inadequate opportunities for communication places PWA at risk of developing maladaptive behaviours such as learned non-use of language.[7]

Environmental Enrichment (EE) refers to conditions which promote physical, cognitive and social activity and has been shown in animal models of stroke to enhance neuroplasticity[8], promote better learning and memory and contribute to significant improvements in motor function.[9] The human equivalent model[10] in a rehabilitation unit results in patients spending more time engaged in activity and less time sleeping and alone.[11]

4. Objectives

Aphasia is a complex language impairment and PWA may need additional support within an Enriched Environment. This pilot study seeks to develop and test an adapted model of an Enriched Environment, a Communication Enhanced Environment (CEE), as a strategy to provide PWA and patients following stroke without aphasia (PWOA) more opportunities to engage in language activities during inpatient rehabilitation. Within this study language activities include both *solitary activities* that may promote aphasia recovery such as reading, writing, listening to the radio, and the use of iPad applications, and *interactive activities* which are based in communicative interactions that involve an exchange of information with a communication partner involving talking, gesture and/or facial expression, reading, writing or drawing to communicate.

4.1 Hypotheses

A CEE will increase patient solitary and interactive language activities and improve staff and patient experiences of communication compared to a standard ward environment.

5. Study design

This mixed methods pilot study is a prospective before-after non-randomised controlled design in an acute and a rehabilitation ward of a metropolitan private hospital. The study involves three phases:

i) *Baseline:* observe and quantify the current ward environment;

ii) *Implementation* of the CEE model;

iii) *Post-implementation:* assess the impact of the CEE model.

6. Study Population

i) *Patients:* The baseline group (n=8, 4 PWA, 4 PWOA) recruited within the baseline phase, and the intervention group (n=8, 4 PWA, 4 PWOA) recruited during the post-implementation phase.

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ii) *Staff participants:* One representative from each acute and rehabilitation staff group including medical, nursing, volunteers, and allied health staff members (n=17), who are over 18 years old.

6.1 inclusion and exclusion criteria

Patients will be eligible for inclusion if they have/are: admitted to the acute or rehabilitation ward for a stroke, less than 21 days post stroke during baseline phase or intervention phase, the ability to provide informed consent as determined by the medical team, a Glasgow Coma Scale[1] score greater than 10 at the time of screening , an estimated length of hospital stay greater than 14 days, adequate English proficiency to participate in semi-structured interviews and are above 18 years of age. Patients with aphasia will also have an Aphasia Quotient below 93.7 on the Western Aphasia Battery-Revised.[2]

Patients will be excluded if they have/are: uncorrected hearing or vision, not medically stable, a documented diagnosis of dementia, traumatic brain injury or previous aphasia, a documented current untreated depression at the time of acute admission or are a participant in another research trial which may affect any of this study's outcome measures.

Staff and volunteers who are over 18 years old will be eligible to participate in this study.

7. Study Assessments and Procedures

Baseline

All recruited patients will complete the Montreal Cognitive Assessment,[11] and The NIH Stroke Scale.[12] PWA will also complete the Western Aphasia Battery-Revised.[2] Patients' behaviour will be observed and video recorded for four hours per day on a Sunday, Monday and Tuesday between 7am to 7pm. A behaviour mapping tool (Appendix A) developed for this study will record patient engagement in language activities in the first minute of each five-minute interval across each four-hour observation period. Semi-structured interviews will explore patients' perceptions of barriers and facilitators to inpatient language activities. An interview schedule will be used across all interviews (Appendix B.). Supportive communication strategies will be used to facilitate PWA participation in interviews with transcriptions annotated to capture any non-verbal responses.

Staff will participate in a one-hour focus group to explore their perceptions of barriers and facilitators to inpatient language activities. A focus group/interview schedule (Appendix C.) will be used across all focus groups.

Implementation

The CEE model will be implemented within the acute and rehabilitation wards.

Post implementation

Intervention group patient observations and interviews, and staff focus groups will replicate baseline data collection.

8. Study Treatment

The CEE model incorporates the following strategies to encourage engagement in language activities:

i) Staff training to facilitate patients' communication and provide opportunities to engage in language activities;

ii) Patient access to:

a) Communication enhancement resources such as iPads and audiobooks;

b) Communal areas to facilitate engagement amongst patients.

9. Participant Completion and Discontinuation

9.1 Participant Completion

Participants will have completed the study when they have completed the semi-structured interview.

9.2 Participant withdrawal

Participation in this study is voluntary. The participant can withdraw from taking part in the study at any time without giving a reason for withdrawing.

10. Data analysis

10.1 Primary Analysis

The proportion of observed episodes where PWA and PWOA are engaged in language activities at baseline and post implementation will be analysed using a mixed design ANOVA.

10.2 Secondary Analysis

The differences in staff and patient perceptions of the barriers and facilitators to inpatient language activities and communication post CEE implementation will be analysed through a qualitative description approach. Triangulation of the qualitative and quantitative data will be conducted.

11. Data management

The data collected will be confidential. No identifying information will be attached to the data and any information that may reveal participant's identity will be removed. The master list of participant names and codes will be kept in a locked filing cabinet at the hospital site which will only be accessible by the research team. All data will be accessed, used and stored in accordance with Commonwealth Privacy Laws. The de-identified data will be stored on a password-controlled computer and/or in a locked cabinet at Edith Cowan University. Electronic data will be backed up on a password controlled hard drive only accessible by the Chief Investigator.

The data collected from this study will have a significant contribution to the aphasia research area and therefore will be stored for 15 years following the completion of this study. Data may be accessed for future studies by the study investigators or higher degrees by research (HDR). In the case of HDR use of the data, the use of the data will be bound by a two-way confidentiality agreement. The data may be used for teaching purposes only with the additional written permission from participants. The data may be made accessible to consumer groups (for example the Australian Aphasia Association) and information may be made available through the National Stroke Foundation and scientific journals. Confidentiality will be maintained in all circumstances. Non-identifiable data will be accessible by researchers through data sharing archives. This data will be governed by an overarching body to ensure data are only used for approved purposes. Researchers who access this data from the data bank will not have access to the participant keys that attach participants to codes therefore data will only be re-identifiable by the Chief Investigator. Data will be deleted from electronic storage and hard copy data will be shredded by the chief

investigator after 15 years completion of the research study (with Ethics Committee approval, Ethics approval numbers: HPH431 and ECU HREC 12149). Non-identifiable data will be added to data archives for data sharing. Researchers who access data archives will not have access to information attaching participants to coded data.

12. Study Report

This study will be published in a PhD thesis as part of the Chief Investigator's Higher Research Degree. Outcomes from this study will be published in peer review journals and at conferences.

13. Administration Procedures

13.1 Ethical Considerations

This research is likely to have a significant impact on aphasia recovery following stroke and will form the basis for future study designs. This study will develop a teaching and learning package that can be used in the future to facilitate and promote increased levels of communication activity during early stroke recovery. The implementation of a CEE may address missed opportunities for language stimulation, harness increased levels of neuroplasticity and optimise aphasia language recovery after stroke. The benefit of a CEE may extend beyond patients with aphasia and may improve health care experience and communication access for all patients following stroke. Additionally, these benefits may extend beyond patients involved in the study as trained staff may use skills and knowledge obtained in the training program to enhance the communication environment of all patients they care for.

13.2 Ethical Review Committee

All processes and documentation used within this study will be reviewed and approved by the Edith Cowan University Research Ethics Committee and the site Ethics Committee. The Chief Investigator will complete the annual ethics reports and will be responsible for reporting any adverse events to the Ethics Committees.

13.3 Informed Consent

Participants will be excluded if they do not have adequate English proficiency to participate in semi-structured interviews and focus groups. Any participants that require an interpreter will be excluded from inclusion in this study as determined by the medical team.

Patients with aphasia will be provided with aphasia friendly information sheets and consent forms with simple language, bold key words and pictorial support. This will be read and explained by the researcher. Supported conversation strategies will be used to support and facilitate patients with aphasia's involvement and understanding of the research process, informed consent and their rights to withdraw at any time. This will be provided by the Chief Investigator who is a qualified speech pathologist with experience in communicating with patients with aphasia using supported conversation techniques to facilitate and support communication. A detailed information will also be provided to the 'person responsible' for all patients.

13.4 Protocol Amendments

All protocol amendments will be reviewed and accepted by the Edith Cowan University Research Ethics Committee and the site research Ethics Committee.

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Appendix A. Behavioural mapping tool

Time (5 min):_____	**NO LANGUAGE ACTIVITIES OBSERVED *(describe)***			**COMMENTS**
Location (select one)	**People present**	**INTERACTIVE LANGUAGE ACTIVITIES**	**'OTHER' FUNCTIONAL LANGUAGE ACTIVITIES**	
Amenities Bedroom Hall Therapy area Family Mtg Room Activity room **ON WARD** Doctor's room Dining room Communal area *(describe)* **OFF WARD** Outside Off-unit *(describe)* Other *(describe)*	Nurse Personal care assistant Doctor Physio OT SP DT Social worker Family/Friend Other patient Alone Other *(describe)*	In person Telephone Therapy session/ward round Other *(describe)* **Patient** Verbal communication Non-verbal gesture/facial expression *(describe)* Written aids (writing or reading (circle)) Pictorial aids *(describe)* Other communication aid *(describe)* **Communication partner/s** Verbal communication Non-verbal gesture/facial expression*(describe)* Written aids Pictorial aids Other communication aid *(describe)*	Typing/writing Reading *(describe)* Texting (mobile phone) Listening to radio/music Watching TV Internet use *(describe)* Word games with a partner Other *(describe)* **NON-FUNCTIONAL/ NON-PROPOSITIONAL LANGUAGE ACTIVITIES** Singing Word games (alone) Language apps (alone) Copying written letters, words, sentences (alone). **OTHER** Talking to observer Talking to self: appropriate/inappropriate (describe)	
Time (5 min):_____	**NO LANGUAGE ACTIVITIES OBSERVED *(describe)***			**COMMENTS**
Location (select one)	**People present**	**INTERACTIVE LANGUAGE ACTIVITIES**	**'OTHER' FUNCTIONAL LANGUAGE ACTIVITIES**	
Amenities Bedroom Hall Therapy area Family Mtg Room Activity room **ON WARD** Doctor's room Dining room Communal area *(describe)* **OFF WARD** Outside Off-unit *(describe)* Other *(describe)*	Nurse Personal care assistant Doctor Physio OT SP DT Social worker Family/Friend Other patient Alone Other *(describe)*	In person Telephone Therapy session/ward round Other *(describe)* **Patient** Verbal communication Non-verbal gesture/facial expression *(describe)* Written aids (writing or reading (circle)) Pictorial aids *(describe)* Other communication aid *(describe)* **Communication partner/s** Verbal communication Non-verbal gesture/facial expression*(describe)* Written aids Pictorial aids Other communication aid *(describe)*	Typing/writing Reading *(describe)* Texting (mobile phone) Listening to radio/music Watching TV Internet use *(describe)* Word games with a partner Other *(describe)* **NON-FUNCTIONAL/ NON-PROPOSITIONAL LANGUAGE ACTIVITIES** Singing Word games (alone) Language apps (alone) Copying written letters, words, sentences (alone). **OTHER** Talking to observer Talking to self: appropriate/inappropriate (describe)	

Appendix B. Patient interview guide

Investigating Communication Enhanced Environments after stroke

Patient Interview guide, version 1_11-8-15

Tell me about what kind of activities you do while you are here (in hospital).

Describe your experience of communicating with people on the ward.

What makes it easier to communicate with people on the ward?

What makes it hard to communicate with people on the ward?

What can we do to make communicating with people easier?

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Appendix C. Staff focus group guide.

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Staff focus group guide, version 1_27-7-15

STAFF FOCUS GROUP GUIDE BASELINE PHASE

What kind of language activities or language tasks do patients following stroke currently participate in on the ward?

What kind of language activities or language tasks would you like see patients following stroke have access to on the wards?

Describe your experience of communicating with patients following stroke at the moment.

Can you tell me about anything that facilitates your ability to communicate with patients following stroke on the ward?

Can you tell me about any barriers you experience that impact your ability to communicate with patients following stroke on the ward?

What changes would you like to see to enhance communication between staff and patients following stroke on the ward?

What changes would you like to see to enhance communication between visitors and patients following stroke on the ward?

How could we enhance or optimise communication and language tasks and activities for patients following stroke on the ward?

What do you think a communication and language enhanced stroke ward environment might look like?

STAFF FOCUS GROUP GUIDE POST-IMPLEMENTATION PHASE

Describe your experience of communicating with patients following stroke at the moment.

Can you tell me about any barriers you experience that impact your ability to communicate with patients following stroke on the ward?

Describe the differences in the communication environment since implementing the model.

What changes did you see to enhance communication between staff and patients following stroke on the ward?

What changes did you see to enhance communication between visitors and patients following stroke on the ward?

What was it like to use the model?

How do you feel about the model?

Can you tell me about anything that helped you use the model with patients following stroke on the ward?

Can you tell me about any barriers you experienced while implementing the model?

How can we improve the model?

Communication Enhanced Environments after Stroke

Study procedure version 2_23-02-16

BASELINE:

Staff recruitment: The Chief Investigator will recruit staff participants through a verbal explanation of the study and the provision of the information sheets and written consent forms. Staff will be provided 48 hours to discuss the study and ask questions before consenting to participate. Staff interviews and focus groups will commence as staff participants are recruited. Staff will participate in a one-hour focus group or a one-hour semi-structured interview (in person or via telephone) to explore staff perceptions of environmental barriers and facilitators to language activity and communication on in-patient acute and rehabilitation wards.

Patient recruitment: All consecutively admitted patients following stroke during the baseline period will be screened for eligibility to participate in the study. The hospital site investigators will identify potential patient participants that meet the inclusion and exclusion criteria. Patients following stroke with aphasia will be identified by the hospital speech pathology or medical team as having a diagnosis of aphasia (aphasia diagnosis will be confirmed via Western Aphasia Battery-Revised (WAB-R)[1] Aphasia Quotient score <93.7 during data collection). The site investigators will approach potential participants and gain verbal consent from the patient to be approached by a member of the research team and have their 3-point identification released to the research team. This will be documented in the patient's integrated medical progress notes. Once verbal consent has been gained and documented, the site investigators will email the Chief Investigator the patient alert proforma identifying the patient as meeting the inclusion/exclusion criteria. The research team will liaise with the medical team to confirm the potential participant meets the inclusion criteria: (i) admitted to the in-patient unit for recent stroke, (ii) are less than 21 days post stroke and during baseline phase or intervention phase, (iii) have the ability to provide informed consent as determined by the medical team iv) Glasgow Coma Scale[2] greater than 10 at the time of screening, (v) have an estimated length of stay greater than 14 days and (vi) have adequate English proficiency to participate in semi-structured interviews. Patients will be excluded if they (i) have uncorrected hearing or vision (for example hearing impairment without hearing aids, vision impairment without glasses), (ii) are not medically stable, (iii) have a documented diagnosis of major depression or (iv) have a documented history of dementia or significant cognitive decline, traumatic brain injury or previous aphasia at the time of admission for the acute event, (v) or are a participant in a research study that will influence this study's outcomes. Patient participant recruitment will follow the patient participant consent procedure (see document: SD_Communication Enhanced Environments after Stroke consent procedure version 1_3-2-15). A record of identifying participant details attached to patient codes will be kept at the hospital site in a locked filing cabinet. An email summary of the baseline assessment results will be sent to the hospital speech pathology generic email address. The patient will be identified by patient code and ward/room number. The hospital speech pathology team will write a summary of the assessment results in the patient's integrated medical progress notes.

Patient data collection: All recruited patient participants will complete the NIH Stroke Scale[3] (by someone trained in using this tool) and the Montreal Cognitive Assessment (MoCA).[4] Participants with aphasia will also complete an

assessment of aphasia, the WAB-R[1] and provide a personal narrative language sample on their reason for admission to confirm a diagnosis of aphasia. After patient recruitment has been completed, the Chief Investigator and/or trained medical team members will recruit the patient's family, friends and significant others to consent to video recording and observations of their interactions with patient participants.

Observations of patient participants will commence 1-3 days after obtaining written consent. Patients' behaviour will be observed by the Chief Investigator or a Research Assistant, and video recorded for a total of 12 hours to enable behaviour mapping of video data (see document: Observation_protocol_SD_version 3_23-02-16). Patients will be observed and video recorded for 4 hours per day on weekend day and two consecutive weekdays between 7am to 7pm. The observation periods will be grouped into 4-hour observation intervals (e.g. 7am-11am, 11am-3pm and 3pm-7pm). Each day the patient will be observed and video recorded for one observation interval. The participant will be observed and video recorded during a different observation interval each day to gain a general insight into the patients' activities (see Figure 1. below). Patients who do not consent to video recording will be provided with the option of audio recording and manual observation conducted by the researcher to enable the collection of case notes regarding patient behaviour. An observational protocol developed for this study will be used to measure the frequency patient participants engage in language activities. These will be categorised into *solitary language activities* for example reading, writing, listening to the radio, use of iPad applications, and *interactive language activities* defined as i) an interaction involving an exchange of information, ii) with a communication partner including gesture and/or facial expression, reading, writing or drawing for the purpose of communication and use of technology including talking on the telephone. The observational protocol will be based on the behavioural mapping techniques of Janssen et al.[5] Patients' solitary and interactive language activities will be recorded in 5-minute intervals and activity observed within the first minute of the observation interval will be recorded on a checklist of the predetermined behaviours. Semi-structured supported conversation interviews for patient participants will be conducted within 5 days of the last observation. The interviews will explore patients' perceptions of environmental barriers and facilitators to language activities and communication and their experience of communication on the acute and rehabilitation wards.

IMPLEMENTATION:

A model of a CEE will be implemented within the acute and rehabilitation wards. The model will be developed as part of the research project. We hypothesise that our model of CEE will include the provision of:

i) CEE equipment, for example reading materials such as books and magazines, access to a computer with internet and access to a communal dining area,

ii) CEE education, support and training for staff, patients and their family, friends and significant others with the aim to develop the ability to support and facilitate 'language activity' and 'communication activity' for patients after stroke. This will be accessible via multiple modalities including one-on-one training and group training sessions, as well as through the provision of video and written resources. A questionnaire will be administered pre and post training in order to determine staffs' perceptions of changes in their knowledge, skills and attitude towards

communication and aphasia. Additionally, feedback regarding the content and format of the training program will be obtained through questionnaires administered after the completion of the training program. Training and support provided in the implementation phase will be continued until the end of the intervention phase.

POST-IMPLEMENTATION:

Staff participant semi-structured interviews and focus groups will be conducted. Staff will participate in a one-hour semi-structured interview or a one-hour focus group to explore staff perceptions of environmental barriers and facilitators to language activities and communication.

The procedures for participant recruitment and data collection during the post-implementation phase will replicate those used in the baseline phase.

There is no travel commitment for all participants as all data collection and training will be conducted at the hospital.

Observation interval	Observation time	Day 1: Sunday	Day 2: Monday	Day 3: Tuesday
1	7am-8am	PWA1 PWOA1	PWA3 PWOA3	PWA2 PWOA2
	8am-9am			
	9am-10am			
	10am-11am			
2	11am-12pm	PWA2 PWOA2	PWA1 PWOA1	PWOA PWOA3
	12pm-1pm			
	1pm-2pm			
	2pm-3pm			
3	3pm-4pm	PWA3 PWOA3	PWA2 PWOA2	PWA1 PWOA1
	4pm-5pm			
	5pm-6pm			
	6pm-7pm			

Figure 1. CEE Observation schedule

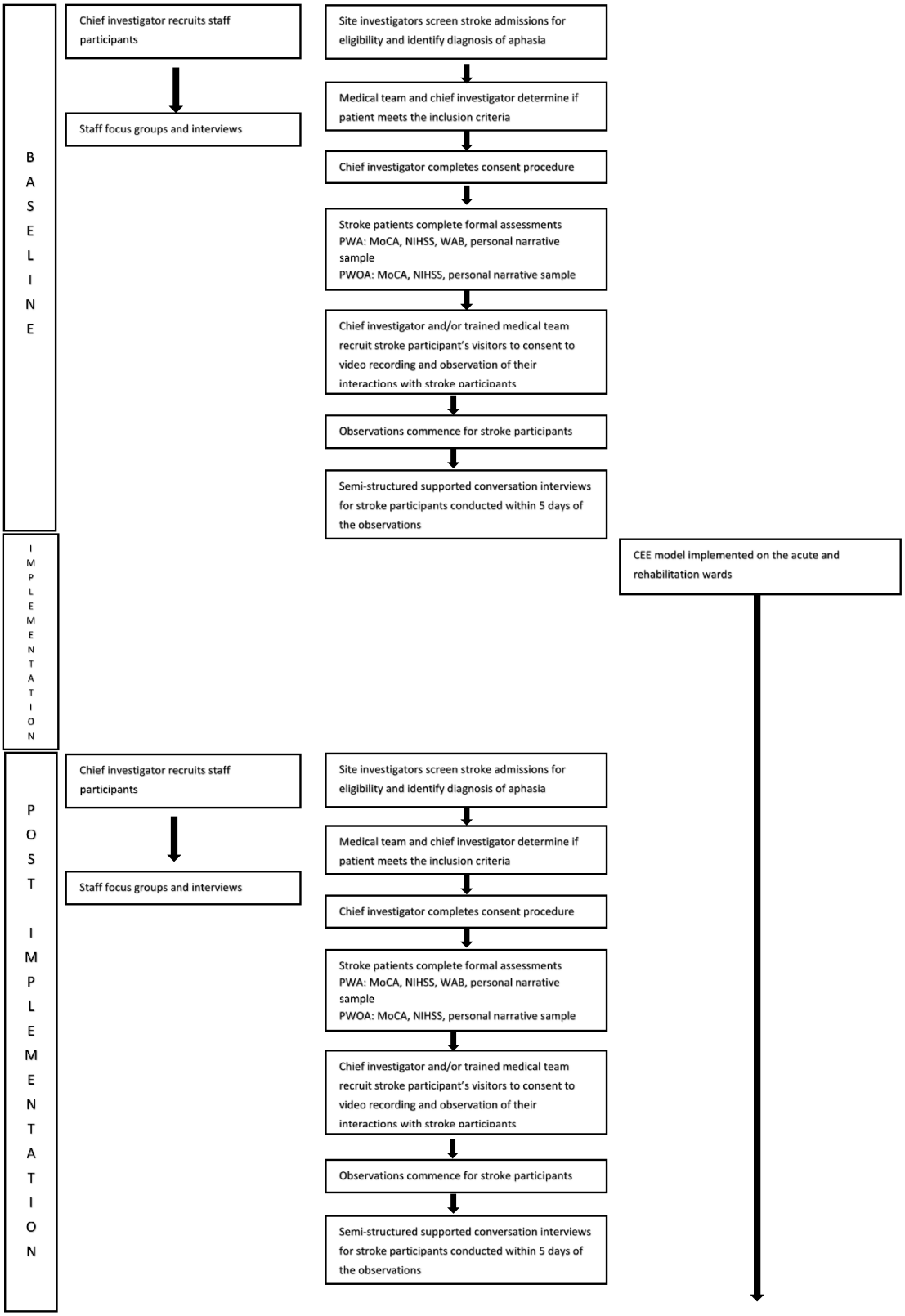

Figure 2. Study flow diagram

References

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2. Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. Lancet. 1974;2(7872): 81–4.

3. NIH stroke scale [Internet]. Bethesda, Md, National Institute of Neurological Disorders and Stroke (U.S.). 2011 [cited 2016 Feb 10]. Available from https://www.ninds.nih.gov/sites/default/files/NIH_Stroke_Scale.pdf

4. Nasreddine ZS, Phillips NA, Bédirian, V, et al. The Montreal Cognitive Assessment, MoCA: A brief screening tool for mild cognitive impairment. J Am Geriatr Soc. 2005;53(4); 695-9.

5. Janssen H, Ada L, Bernhardt J, et al. An enriched environment increases activity in stroke patients undergoing rehabilitation in a mixed rehabilitation unit: A pilot non-randomized controlled trial. Disabil Rehab, 2014; 36(3), 255–262. doi: 10.3109/09638288.2013.788218

Communication Enhanced Environments after Stroke consent procedure

Version 1_3-2-15

Patient participants

The following consenting procedure will be used for all participants who are identified as potential research participants. Recruitment will only be completed by the Chief Investigator.

1. Check the patient meets the inclusion criteria and exclusion criteria.
2. Read the participant information sheet to the patient. Use the pictures on the participant consent form to support their comprehension of verbal information. Use gesture, written and pictorial support to facilitate verbal communication as required.
3. Provide the person responsible with the person responsible information sheet and consent form.
4. Provide time for the patient and the person responsible to discuss the study and ask questions to their satisfaction.
5. Ask the patient if they consent to the study using simple closed questions (e.g. “Do you understand what the study is about?”, “Do you have any questions about the study?”, “Do you want to be in the study?”, “Will you sign the form?”. Use multi-modal communication strategies and repeat information/questions as required. Use the pictures on the participant consent form to support patient comprehension of verbal information.
6. If the patient agrees to participate in the study, ensure they sign the consent form witnessed by someone independent of the study.
7. Provide the patient with a copy of the information sheet and consent form for their own records.
8. Add the participant study number to the consent form
9. Store the signed consent forms in a locked cabinet at the hospital site. This cabinet will only be accessible by the research investigators.

D'Souza S, *et al*. *BMJ Open* 2021; 11:e043897. doi: 10.1136/bmjopen-2020-043897

Investigating Communication Enhanced Environments after stroke

Observation Protocol version 3_ 23-2-16

During the baseline and intervention period, patients' behaviour will be observed and video recorded for a total of 12 hours. Patients who do not consent to video recording will be provided with the option of audio recording and manual observation. This will enable the collection of relevant notes about factors that might influence the interactions that may not be captured in the video or behavioural mapping, for example the context of the interactions or details about the environment.

Patients will be manually observed and video recorded for four hours per day on two weekdays and one weekend day between 7am to 7pm. The observations will be grouped into three x 4-hour observation intervals (e.g. 7am-11am, 11am-3pm, 3pm-7pm). Each day the patient will be observed and video recorded for one of the 4-hour observation intervals. The 4- hour observation period will be split into 5-minute intervals. All language and communication activity observed within the first minute of the 5-minute interval will be recorded on the behavioural mapping sheet with predetermined behaviours (Appendix 1). The free smart phone app 'Impetus' can be used to time 1-minute observations. You can set the timer to vibrate briefly when the 1-minute observation interval begins and ends.

Observation times (see Figure 1.) will be randomly selected by drawing out of an envelope. This will be conducted by the primary investigator prior to commencing patient observations. It may not be possible to observe the patient during the planned observation time, for example as a result of scheduled testing or home visits. If this occurs, patients can be observed during the next available observation interval. Changing or modifying the observation schedule should be avoided where possible.

Observation interval	Observation time	Day 1: Sunday	Day 2: Monday	Day 3: Tuesday
1	7am-8am	*PWA1 **PWOA1	PWA3 PWOA3	PWA2 PWOA2
	8am-9am			
	9am-10am			
	10am-11am			
2	11am-12pm	PWA2 PWOA2	PWA1 PWOA1	PWA3 PWOA3
	12pm-1pm			
	1pm-2pm			
	2pm-3pm			
3	3pm-4pm	PWA3 PWOA3	PWA2 PWOA2	PWA1 PWOA1
	4pm-5pm			
	5pm-6pm			
	6pm-7pm			

Figure 1. Observation schedule
*PWA: patient with aphasia
**PWOA: patient without aphasia

DISCOURSE SAMPLE

You must collect a personal narrative discourse sample for each participant at the beginning of the first observation. Once you have set up the video camera and have started recording, ask the patient "what has brought you into hospital?". Once the patient has finished telling you their personal narrative, tell the patient you will now start the observations.

VIDEO RECORDING SET-UP

Place the video camera facing the patient approximately 1-2 metres away from them. Ensure the camera is placed in an area where it is unlikely to be moved for the duration of the observation time (for example at the end of the patient's bed). Ensure the camera frame is capturing the patient as well as their surroundings (e.g. potential communication partners, visitors, etc). If the patient relocates, reposition the camera to ensure the patient and their surroundings remain in frame. Observe and manually record the patient's behaviour and their environment according to the procedure for behavioural mapping.

Do not record the patient in the bathroom or shower or during any other inappropriate circumstances (this may include sensitive conversations, culturally sensitive situations or if the patient requests). If the patient indicates that they don't want to be recorded or becomes agitated, upset or distressed, use the 'withdrawal from observations visual resource' (if appropriate) and ask the patient:

1. Do they want you to stop video recording?

2. Do they want to be manually observed and audio recorded instead?
   If the patient responds 'no', ask the patient-

3. Can you come back another time to observe them?

If the patient asks you to stop recording you must cease recording immediately. The patient may allow you to continue with manual observations or come back another time to complete the observations. If the patient allows you to complete manual observations and audio recording, follow the audio-recording set-up and protocol below.

AUDIO RECORDING SET-UP AND PROTOCOL

This protocol is to be followed if the patient or their family indicate they do not want to be video recorded however agree to audio recording and manual observations. Place the cap on the video camera and continue recording in order to capture audio. If using a battery-operated audio recorder, place it on a table close to the patient (within 1 metre). Ensure the audio recorder is placed in a location where it will not be touched or moved throughout the

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observation time. Observe and manually record the patient's behaviour and their environment according to the procedure for behavioural mapping. Ensure spare batteries for the audio recorder are available if required.

COMMUNICATION PARTNERS AND VISITORS

Take note of all communication partners and visitors who have provided consent to video recording and/or observations of their patient interactions. If someone enters the room during recording politely interrupt the interaction, introduce yourself and inform the person that the patient is being video recorder recorded as a part of the study the patient has agreed to participate in. Ask the visitor if they would like to go out of the room with the researcher to find out about the study and the video recording. Provide a verbal explanation of the study and provide the 'Visitors/communication partners' information and consent form'. Offer the visitor the option of no video or manual recoding during their interaction with the patient. If the person chooses not to participate in manual or video observations inform the person that any incidental recordings of them will be deleted and will not be included in the study. The researcher will step out of the room for the duration of their visit.

PROCEDURE FOR BEHAVIOURAL MAPPING

- Position self where the patient can be clearly observed
- Remain inconspicuous as possible
- Circle ALL appropriate components on the observation schedule in regards to location, activity, people present and details of language and communication observed within the first minute of each five-minute interval.
- You can circle more than one key per section if required (except for location).
- If you require a toilet break, leave the camera recording while you take a break. If you miss a 1-minute observation, place a line through the observation interval on the behavioural mapping sheet and write 'unobserved-toilet break'.

TIME

- Write the time at the beginning of the 1-minute observation interval

LOCATION

- Circle only one location
- If the patient is moving between two locations, circle the location the patient is moving towards

AMENITIES: Toilet, shower.

BEDROOM: Around the patient's room or bed. If the patient is outside of their doorway this is considered 'hall'.

HALL: Any hallway within the hospital ward.

THERAPY AREA: In an allied health therapy session, including occupational therapy, physiotherapy, speech pathology, nursing.

FAMILY MEETING ROOM: Family meeting room.

DOCTOR'S ROOM: Doctor's office.

DINING ROOM: Dining room during meal times or any other time.

COMMUNAL AREA: Communal dining area.

OUTSIDE: Outside areas including the garden, car park.

OFF UNIT: Off-site locations, home visits, testing off site.

OTHER: Anything that doesn't fit into the above categories-provide description of location.

PEOPLE PRESENT

People present include any person that is near the patient and is able to have an interaction with the patient. If you do not know how to classify the person make a note to check with staff at a later time and complete the observation schedule.

Exceptions: People who are near the patient but are unable to interact with the patient, e.g. cognitive or behavioural issues, barriers between person and the patient preventing them from interacting- e.g. curtain drawn, people in the way. If an interaction is occurring despite objects in the way, the communication partner is considered as a 'person present'.

PEOPLE PRESENT: Nurse, nurse assistant, doctor, physio (physiotherapist), OT (occupational therapist), SP (speech pathologist), DT (dietician), SW (social worker), family/friend, other patient, alone (no-one present that is conducive to interactions), other (describe).

ACTIVITIES

UNOBSERVED: If you are unable to observe the patient. Place a line through the observation

interval and write unobserved.

NO LANGUAGE ACTIVITY: If the patient is observed not engaged in any communication activity.

- Circle 'no activity' on the checklist
- Write what the patient is doing, e.g. 'sleeping'

INTERACTIVE LANGUAGE ACTIVITIES: Defined as an interaction involving an immediate communicative exchange with a communication partner. Interactive language activities may include talking, gesture and/or facial expression, reading, writing or drawing for the purpose of communication, use of communication aids or AAC devices and use of technology including talking on the telephone. Non-verbal gesture or facial expression includes eye contact to

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initiate interactions, hand gestures (e.g. waving, thumbs up), body movements for the purpose of conveying a communicative message (e.g. shrugging) and/or facial expressions for the purpose of communication. Communication aids or AAC devices includes any use of alternative and augmentative devices for the purpose of communication, e.g. high-tech or low-tech AAC devices such as letter boards, pictures/photos, whiteboard, writing or drawing, smart phones, iPad. Please describe communication aids observed.

OTHER FUNCTIONAL COMMUNICATION ACTIVITIES: All other communication activities that do not involve a direct immediate communicative exchange with a communication partner. Functional communication activity may include reading, typing/writing, emailing, internet use, watching TV, listening to talking on the radio. Note the patient must be looking directly at the TV to be considered 'watching TV'. If the TV is on in the background, do not include this as 'watching TV'.

NON-FUNCTIONAL/NON-PROPOSITIONAL LANGUAGE ACTIVITIES: Singing, word games (carried out alone), language apps (used alone), copying written letters, words or sentences (carried out alone).

OTHER: Communication or language activities that do not fit the criteria of interactive language activity, 'other' functional communication activities, non-functional/non-propositional language activities or may be a confounding variable (for example, talking to self and talking to the observer). If a patient is talking to themself, note if this is appropriate (for example, saying 'excuse me' after burping) or inappropriate (for example, an extensive monologue) and describe the context. If the patient's verbal output is inaudible, write this is in the space underneath 'talking to self'.

Note: If the patient is using a computer, phone, smart device, or iPad where the activity they are engaged in (e.g. texting, emailing, playing a game, etc) cannot be accurately determined, note this in the comments section. After the 1-minute observation interval has been completed ask the patient if they mind sharing if what activity they were completing on their device and record this in the relevant section. If the patient does not wish to share this information with you, record this in the 'other' section.

COMMENTS

Describe the context of the interactions or details about the environment in the comments section. This will provide information regarding factors that may influence the interactions, for example 'background noise'. Additionally, write down any information that may be missed in the video data, for example, people out of the camera frame, interactions that may be overheard in the room that might impact on the current interactions.

Draw a line under the final comment after the one-minute observation had been completed. Write any additional observations within the final 4 minutes below this line (see example).

If you have any queries or questions regarding this observation protocol or the observation protocol please contact chief investigator Sarah D'Souza.

Patient participant information and consent form
Communication activity in hospital

This research project is being undertaken as **part of** the **requirements** of a **PhD at Edith Cowan University**.

Researchers' contact details

Edith Cowan University		
Chief Investigator/ PhD student	**Sarah D'Souza**	Ph: 0439 982 451
Principal Supervisor	Professor Beth Armstrong	Ph: 08 6304 2769
Co-Supervisor	Associate Professor Natalie Ciccone	Ph: 08 6304 2047
Co-Supervisor	Associate Professor Erin Godecke	Ph: 08 6304 5901
Co-Supervisor	Associate Professor Deborah Hersh	Ph: 08 6304 2563
Hunter Stroke Service, University of Newcastle and Hunter Medical Research Institute		
Adjunct Supervisor	Dr Heidi Janssen	Ph: 02 40420417

You are **invited** to participate in a research project. Sarah D'Souza, a speech pathologist and PhD student is leading the study as Chief Investigator. This study has received ethical **approval** from **ECU** Human Research **Ethics Committee** and the Hollywood Private Hospital Research Ethics Committee.

This project is investigating the **hospital environment** to see how this **influences** patient **communication activity**. Communication activity involves communication, such as **talking** with other patients, **socialising**, **reading** the paper, using the **telephone**, talking to staff, or engaging in group activities including **therapy**.

You have been **selected** to participate as you have had a **stroke** and are receiving **treatment at Hollywood Private Hospital**. We are **interested** in seeing **how** the hospital **surroundings affect what you do** throughout the day.

What would you have to do?

You will be **asked** to provide **consent** to **agree to participate** in the study.

You will be **asked to consent** to:

- Complete **three tests** to see how your stroke has affected **you** including your **language, concentration** and **memory**. These tests will be conducted at the **beginning of the project**. The tests will take approximately **1 hour** to complete with an option to complete the tests

over **two separate 30 minute sessions** and with as many **breaks** as you may need.

- A **researcher** spending approximately **1 hour discussing with you** your **opinion** regarding **how** your rehabilitation **surroundings affect your stay in hospital** and **your communication activity** levels.

- A researcher **video recording, observing** and **writing down** what is happening in your **environment** including **your activities**. You will be observed and recorded for a total of **12 hours** over **3 days**.

  You may **not want** to be **video recorded**. If you **request**, you will **not** be **video recorded**. You can ask not to be video recorded at **any time**. In this case the researcher will **only observe, audio record** and **write down** what is **happening in your** environment **including** your activities.

- A researcher **looking at your hospital medical file** to collect **information** regarding:
  - Your **details** (such as your age, your living arrangements, your occupation and your level of functioning before your stroke)
  - Any **conditions** or **diseases** you may have
  - Information about your **stroke** (for example when it happened**,** the **area** of the **brain** affected, how it has **affected your functioning** and **abilities**)
  - Details about **how long** you have **been in hospital** since your stroke

If you decide to participate in this study, you **will not miss out** on any **treatment**. Participation will **not cost** you **anything** and **after** completing the **tests** and the **interview** you will be asked to continue participating in your **normal activities**.

We will **not record** if you are **behind closed curtains** or completing sensitive tasks such as when you are in the **toilet** or **shower**.

We may use the **recordings** of **you** to make a **training package** (including a video). You can have **your face blurred out** if you want. If you **do not want** to be in the training package we will **not include you** in the training package or video.

Your hospital **discharge** will **not be affected** because you are in this study. **You** will be **discharged** from hospital when the hospital **medical team decides** that you are **ready**.

There are **no known risks** of participating in this study. If you feel uncomfortable at any time, you are free to **tell the researcher** and **observations** within your room will **stop immediately**. You may become **upset** during the **tests** or the **interview**. If this happens you can **ask** to take a **break or stop** the interview.

There will be **no immediate benefit** to you from participating in this research; however your participation will allow the collection of

information that may **help improve** stroke **hospital wards** which may **benefit** future stroke survivors.

Participating in this study is completely **voluntary**. You **do not have to** participate if you don't want to. If you decide to participate you may **withdraw** at **any time** without giving a reason and withdrawing **will not disadvantage** you in any way and will **not affect** your hospital **treatment**. If you **decide** that you do **not want to participate** in the study, you **can ask** to **remove** all of your **information** from the study.

All the **information** you give will be **confidential**. You will **not be identified** by name. You will be **assigned** a unique **code** and any information that may reveal your **identity** will be **removed**.

All personal health information will be accessed, used and stored in accordance with Commonwealth Privacy Laws. **Information** from all the people in the study is **combined** and **summarised.**

We will **store** all your electronic **information** on a **password locked computer** and **password locked hard drive only accessible by the Chief Investigator**. Your hard copy information will be **kept** in a **locked cabinet** at Edith Cowan University. You information will **only** be **accessible to researchers** named on **this study**.

The **results** of this study may be **published** in research **journals** or presented at **conferences**. Your **name** will **not** be **used**.

Data may be **used** in higher degree by **research studies** in the **future**. **Confidentiality** will be **maintained** and no identifying information will be used.

Data will be **accessible by researchers** through data sharing archives. This data will be governed by an overarching body to ensure data is **only used for approved research** purposes. Researchers who access this data from the data bank will not have access to participant information and therefore **will not know your identity**.

Read this information and be sure you **understand** its content **before** you **agree** to participate in this study.

If **you** would **like** to **participate** in this study, please **sign the form** below and **return** it to a **staff** member or a member of the **research team**.

Questions or further information?
You **may wish** to **discuss** this information with your **doctor, a relative or friend before agreeing** to take part in this study.

If you are interested in participating, please tell the researchers. If you have any questions or require any further information about the research project, please contact: Sarah D'Souza [Ph: 0439 982 451].

Thank you for considering the invitation to take part in this research project.

Yours sincerely,

Sarah D'Souza

If you have any **concerns or complaints** about the research project and wish to **talk to an independent person**, you may contact:

Kim Gifkins

Senior Research Ethics Advisor

Edith Cowan University

270 Joondalup Drive

JOONDALUP WA 6027

Phone: **(08) 6304 2170**

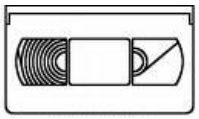
Email: research.ethics@ecu.edu.au

This project has been approved by the ECU Human Research Ethics Committee and the Hollywood Private Hospital Research Ethics Committee.

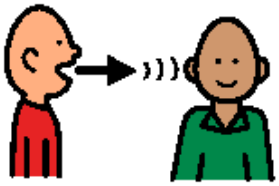
You have been **asked to participate** in a **research** study.

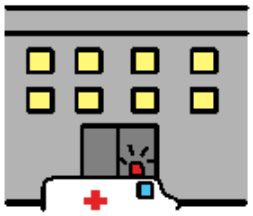


A researcher will **record you** with a **tape recorder** or a video **camera, watch** and **write down** what is happening in your **environment** including **your activities.**

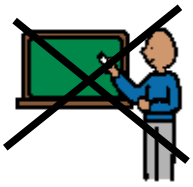




A **researcher** will **discuss** with you **your opinion** regarding **how** your hospital **surroundings affect your stay in hospital** and **your communication activity levels.**

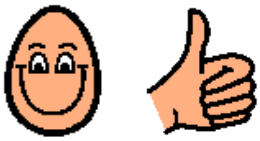


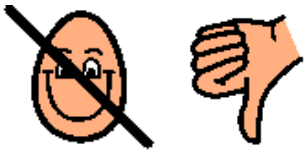


Your **name** and **personal details** will be kept **private.**

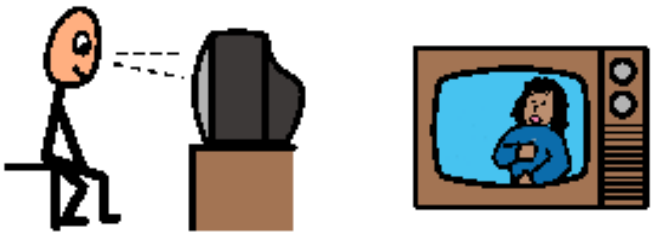


You can **say no at any time.**

"Ok" 

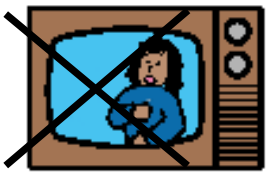
"No thank you" 

We may use the **recordings** of **you** to make a **training package** (including a video).



You can have **your face blurred out** if you want.

If you **do not want** to be in the training package we will **not include you** in the training package or video.

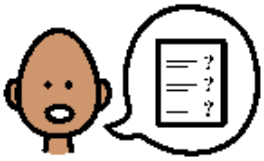


I **agree to take part** in the above research project and give my **consent freely**.

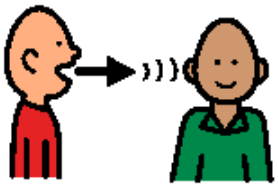
I have been **given a copy** of the **Information Statement** and I understand that the **project** will be **carried out** as **explained**.

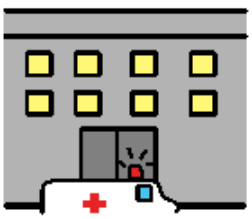
I understand and agree to:

- Complete **three tests** to assess how the stroke has affected **me**, my **language, concentration** and **memory,** at the **beginning of the project**.

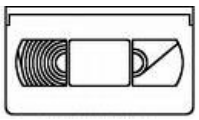


- A **researcher** spending approximately **1 hour discussing** with me my opinion regarding how my hospital **environment affects** my stay in hospital and **what I do.**



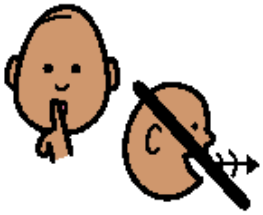


- A researcher **video recording, observing** and **writing down** what is happening in my **environment** including **my activities**.

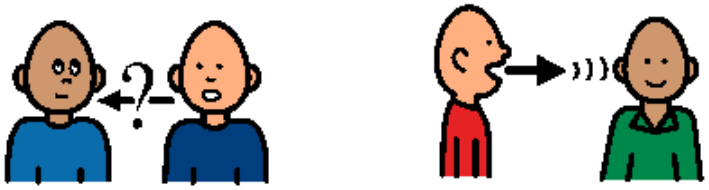




- A researcher **looking at my hospital medical file** to collect **information** for the study.


I **understand** that **my identity, personal information** and **data** will remain **confidential**.




I have had the **opportunity** to **ask questions** about the study and am **satisfied** with the **responses** that have been provided.



Would you like to be involved? **Yes** **No**

I **agree** to the **recordings** of **me** to make a **training package (including a video).** **Yes** **No**

I would like **my face blurred** out. **Yes** **No**

Your Signature

Signature: _____

Print name: _____

Date: _____

Witness

Signature: _____

Print name: _____

Date: _____

Person responsible information sheet

Patient communication activity in hospital after stroke

This research project is being undertaken as part of the requirements of a PhD at Edith Cowan University.

Researchers' contact details

Edith Cowan University		
Chief Investigator/ PhD student	Sarah D'Souza	Ph: 0439 982 451
Principal Supervisor	Professor Beth Armstrong	Ph: 08 6304 2769
Co-Supervisor	Associate Professor Natalie Ciccone	Ph: 08 6304 2047
Co-Supervisor	Associate Professor Erin Godecke	Ph: 08 6304 5901
Co-Supervisor	Associate Professor Deborah Hersh	Ph: 08 6304 2563
Hunter Stroke Service, University of Newcastle and Hunter Medical Research Institute		
Adjunct Supervisor	Dr Heidi Janssen	Ph: 02 40420417

The participant is invited to take part in a research project. Sarah D'Souza, a Speech Pathologist and PhD student, is leading the study as Chief Investigator. This study has received ethical approval from ECU Human Research Ethics Committee and Hollywood Private Hospital Research Ethics Committee.

This project is investigating the hospital environment to see how this influences patient activity.

The participant has been selected to take part in this study as they have had a stroke and are receiving treatment at Hollywood Private Hospital. We are interested in

seeing how the hospital surroundings affect their communication activity throughout the day. Communication activity involves communication, such as talking with other patients, socialising, reading the paper, using the telephone, talking to staff, or engaging group activities including therapy.

This information sheet will explain the research project and will detail what is involved in the study. You will be given a copy of this information to keep for your reference.

Please read through all of the information carefully. You can ask the researcher questions about the study at any time.

Purpose of the research

Little is known about the impact of the hospital rehabilitation environment on patient communication activity levels during stroke recovery. This study will investigate how the hospital stroke ward environment influences patient communication activity levels. The information gathered from this study will assist in improving the Hollywood Private Hospital stroke ward environment to help the recovery of stroke survivors in the future.

What does the patient have to do?

- Complete three tests and a recording of them talking to see how their stroke has affected their functioning including their language, concentration and memory. These tests will be conducted at the beginning of the project. The tests will take approximately 1 hour to complete with an option to complete the tests over two separate 30 minute sessions and with as many breaks as the participant needs.

- Spend approximately 1 hour discussing with the researcher their opinion regarding how their rehabilitation surroundings affect their stay in hospital and activity levels.

- Allow the researcher to video record, observe and write down what is happening in the participant’s environment including their activities for a total of 12 hours over a 3 day period. Video recording is a useful way of capturing the details of everyday activities on

the ward. Often, people forget that the camera is there. Obviously, personal or private activity such as toileting would not be filmed. The participant may not want to be video recorded. If they request, they will not be video recorded. In this case the researcher will only observe, audio record and write down what is happening in their environment including their activities.

- A researcher will look at the participant's hospital medical file to collect information regarding:
    - The participant's details (such as their age, living arrangements, occupation and level of functioning before stroke)
    - Any relevant conditions or diseases the participant may have
    - Information about the participant's stroke (for example when it happened, the area of the brain affected, how it has affected their functioning and abilities)
    - Details about how long the participant has been in hospital since their stroke

The participant will not miss out on any treatment. Participation will not cost anything. After completing the tests and the interview the participant will be asked to continue their normal activities.

The participant's hospital discharge will not be affected because they are in this study. The participant will be discharged from hospital when the hospital medical team decides that they are ready.

There are no known risks of participating in this study. If the participant feels uncomfortable at any time, you or the participant are free to tell the researcher and observations within their room will stop immediately. The participant may become upset during the tests or the interview. If this happens you or the participant can ask to take a break or stop the interview.

There will be no immediate benefit to you or the participant from taking part in this research; however **their participation will allow the collection of information that may help improve stroke hospital wards which may benefit future stroke survivors.**

Participating in this study is completely voluntary. The participant can withdraw from taking part in the study at any time without giving a reason for withdrawing.

The participant can request access to their research data at any time. They can request any of the information collected to be amended or removed if it is incorrect or they disagree with it. Please contact Sarah D'Souza (phone: 0439 982 451) if you would like to discuss accessing the participant's information.

The video, audio and written data will be identified by code. The information you provide will remain completely confidential. There will be no identifying information attached to the data and any information that may reveal the participant's identity will be removed. A list of participant names and codes will be kept in a locked filing cabinet at Hollywood Private Hospital and will only be accessible by the research team. All personal health information will be accessed, used and stored in accordance with Commonwealth Privacy Laws. The data will be stored on a password controlled computer or in a locked cabinet at Edith Cowan University. Electronic data will be backed-up on a password controlled hard drive only accessible by the Chief Investigator. Data will be stored for a maximum of 15 years after completion of the study. Video and audio recordings will then be permanently deleted and hard copy data will be shredded.

Non-identifiable data will be accessible by researchers through data sharing archives. This data will be governed by an overarching body to ensure data is only used for approved research purposes. Researchers who access this data from the data bank will not have access to participant information therefore data will not be re-identifiable.

The results of this study may be published in research journals or presented at conferences. The results will not include any information that may identify participants. Data may be used in higher degree by research studies in the future. In this circumstance, confidentiality will be maintained and no identifying information will be used.

Data collected from this study (including videos) may be used to develop training packages to improve future stroke survivors' communication activity levels in the future. We can blur out

the participant's face if they want. If they do not want to be in the training package we will not include them in the training package.

At the end of the research project a summary of the results will be provided to you and the participant.

If you have any questions or require any further information about the research project, please contact: Sarah D'Souza [Ph: 0439 982 451].

Yours sincerely,

Sarah D'Souza

If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact:

Kim Gifkins

Senior Research Ethics Advisor

Edith Cowan University

270 Joondalup Drive

JOONDALUP WA 6027

Phone: (08) 6304 2170

Email: research.ethics@ecu.edu.au

This project has been approved by the ECU Human Research Ethics Committee and the Hollywood Private Hospital Research Ethics Committee.

Visitors and communication partners information and consent form

Investigating Enhanced Environments after stroke

This research project is being undertaken as part of the requirements of a PhD at Edith Cowan University.

Researchers' contact details

Edith Cowan University		
Chief Investigator/ PhD student	Sarah D'Souza	Ph: 0439 982 451
Principal Supervisor	Professor Beth Armstrong	Ph: 08 6304 2769
Co-Supervisor	Associate Professor Natalie Ciccone	Ph: 08 6304 2047
Co-Supervisor	Associate Professor Erin Godecke	Ph: 08 6304 5901
Co-Supervisor	Associate Professor Deborah Hersh	Ph: 08 6304 2563
Hunter Stroke Service, University of Newcastle and Hunter Medical Research Institute		
Adjunct Supervisor	Dr Heidi Janssen	Ph: 02 40420417

Description of the research project

This study is exploring patient's experiences following stroke in regards to the environment of an in-patient stroke rehabilitation unit. We want to explore patients' communication activity, which includes activities such as talking with other patients and visitors, socialising, reading the paper, using the telephone, talking to staff, or engaging group activities including therapy.

The participant has agreed to take part in this study. They have agreed to be video recorded for a total of 12 hours over a three day period.

Your interactions with the patient will be video recorded and manually recorded by the chief investigator to explore patient communication activity levels. You can choose to be observed by the researcher only if you do not want to be video recorded. You do not need to do anything other than complete your usual tasks and activities. We will not record if you are having sensitive conversations with the participant, if they are behind closed curtains or completing sensitive tasks such as toileting or showering.

We may use the recordings of you to make a training package (including a video). You can have your face blurred if you want. If you do not want to be in the training package we will not include you in the training package.

There will be no cost to you associated with the investigation. Participation is completely voluntary. You do not have to participate if you don't want to. If you decide to participate you may withdraw at any time without giving a reason and withdrawing will not disadvantage you or the participant in any way.

You may also benefit from the knowledge that you are helping future stroke survivors. It is possible that you may not benefit from participating in this study. There are no known risks associated with participating in this study.

Confidentiality of information

The video, audio and written data will be identified by code. There will be no identifying information attached to the data and any information that may reveal your identity will be removed. A list of participant names and codes will be kept in a locked filing cabinet at Hollywood Private Hospital and will only be accessible by the research team. All data will be accessed, used and stored in accordance with Commonwealth Privacy Laws. The data will be stored on a password controlled computer or in a locked cabinet at Edith Cowan University. Electronic data will be backed-up on password controlled hard drive only accessible by the Chief Investigator. Data will be stored for a maximum of 15 years after completion of the study. Video and audio recordings will then be permanently deleted and hard copy data will be shredded.

Non-identifiable data will be accessible by researchers through data sharing archives. This data will be governed by an overarching body to ensure data is only used for approved research purposes. Researchers who access this data from the data bank will not have access to participant information therefore data will not be re-identifiable.

The results of this study may be published in research journals or presented at conferences. The results will not include any information that may identify participants. Data may be used in higher degree by research studies in the future. In this circumstance, confidentiality will be maintained and no identifying information will be used.

Please read this Information Statement and be sure you understand its content before you consent to take part.

If you would like to take part, please complete the consent form and return it to Sarah D'Souza or a member of the research team.

Questions or further information?

If you have any questions or require any further information about the research project, please contact: Sarah D'Souza [Ph: 0439 982 451]

Thank you for considering the invitation to take part in this research project.

Yours sincerely,

Sarah D'Souza

If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact: Kim Gifkins

Research Ethics Officer

Edith Cowan University

270 Joondalup Drive

JOONDALUP WA 6027

Phone: (08) 6304 2170

Email: research.ethics@ecu.edu.au

This project has been approved by the ECU Human Research Ethics Committee and the Hollywood Private Hospital Research Ethics Committee.

I _____ (print name), give my consent freely and agree to participate in observations of my interactions with the participant.

Yes **No** (please circle)

I agree to the researcher video recording my interactions with the participant

Yes **No** (please circle)

I agree to be included in a training package (including a video).

Yes **No** (please circle)

If I am included in the video training package I would like my face blurred out.

Yes **No** (please circle)

I understand the project will be conducted as stated in the information letter, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give a reason for withdrawing.

I understand personal information will remain confidential to the researchers.

I have been given the opportunity to raise any questions or concerns I have and am satisfied with the responses I was given.

Participant

Print name: _____

Signature: _____

Phone number: _____

Email address: _____

Date: _____

Witness

Print name: _____

Signature: _____

Date: _____

Staff information and consent form

Investigating Enriched Environments after stroke

This research project is being undertaken as part of the requirements of a PhD at Edith Cowan University.

Researchers' contact details

Edith Cowan University		
Chief Investigator/ PhD student	Sarah D'Souza	Ph: 0439 982 451
Principal Supervisor	Professor Beth Armstrong	Ph: 08 6304 2769
Co-Supervisor	Associate Professor Natalie Ciccone	Ph: 08 6304 2047
Co-Supervisor	Associate Professor Erin Godecke	Ph: 08 6304 5901
Co-Supervisor	Associate Professor Deborah Hersh	Ph: 08 6304 2563
Hunter Stroke Service, University of Newcastle and Hunter Medical Research Institute		
Adjunct Supervisor	Dr Heidi Janssen	Ph: 02 40420417

Description of the research project

This study is exploring staff and patient's experiences in regards to the environment of the Edwards and Woods wards at Hollywood Private Hospital. We want to explore patient communication activity, which includes activities such as talking with other patients, socialising, reading the paper, using the telephone, talking to staff, or engaging group activities including therapy. We would like to explore staffs' perceptions of barriers and facilitators to communication activity on the wards and address these in order to enhance the ward environment.

Staff have been selected to participate in order to gain a range of perspectives in regards to the day to day operations, procedures, policies and interactions that influence the environment of the Edwards and Woods wards. A training program for staff will be designed to address barriers and facilitators identified on the wards.

There are two components of this research study that involve staff. You may wish to consent to participate in one or both parts of this study.

Part 1: Patients will be video recorded for a total of 12 hours over a three day period. Your interactions with the patient will be video recorded and manually recorded by a member of the research team to explore patient communication activity levels. You can choose to be observed by the researcher only if you do not want to be video recorded. You do not need to do anything other than complete your usual daily tasks and activities. We will not record if you are behind closed curtains or completing sensitive tasks such as toileting or showering the patient.

We may want use the recordings of you to make a training package (including a video). We will show you the video we want to use and explain exactly how this will be used before we do anything. You can have your face blurred out if you want. If you don't want to be included in the training package we will not include any videos of you in the training package.

Part 2: You will be asked to take part in the following:

- A focus group with the researcher and your co-workers for approximately 1 hour to explore your perceptions of environmental barriers and facilitators to activity.
- Attend a training program for approximately 1.5 hours. This will focus on training staff to promote patient communication on the ward. This session will be located at Hollywood Private Hospital and will be offered over several dates to facilitate your ability to attend. If you are unable to attend the training program we may provide training and video resources to facilitate your participation in training.
- Complete an anonymous short questionnaire before and after attending the training program to gain feedback on training and explore your perception of changes in your knowledge, skills and attitudes towards communication and aphasia.
- A final focus group with the researcher for approximately 1 hour to again explore your perceptions of environmental barriers and facilitators to activity.
  The focus groups will be tape recorded however at any stage you may ask for the tape to stopped, edited or have your comments erased.

There will be no cost to you associated with the investigation. Participation is completely voluntary. You do not have to participate if you don't want to. If you decide to participate you may withdraw at any time without giving a reason and withdrawing will not disadvantage you in any way.

You may benefit from gaining knowledge and skills regarding communication from attending the training program. Additionally, you may also benefit from the knowledge that you are helping future stroke

survivors. It is possible that you may not benefit from participating in this study. There are no known risks associated with participating in this study.

Confidentiality of information

The information you provide during the interviews will be audio recorded by the Chief Investigator. Your perspectives and opinions will be analysed and grouped into common 'themes' and 'stories'. This will be used to inform the development and review of the training program.

The video, audio and written data will be identified by code. The information you provide will remain completely confidential. There will be no identifying information attached to the data and any information that may reveal your identity will be removed. A list of participant names and codes will be kept in a locked filing cabinet at Hollywood Private Hospital and will only be accessible by the research team. All data will be accessed, used and stored in accordance with Commonwealth Privacy Laws. The data will be stored on a password controlled computer or in a locked cabinet at Edith Cowan University. Electronic data will be backed-up on a password controlled hard drive only accessible by the Chief Investigator. Data will be stored for a maximum of 15 years after completion of the study. Video and audio recordings will then be permanently deleted and hard copy data will be shredded.

Non-identifiable data will be accessible by researchers through data sharing archives. This data will be governed by an overarching body to ensure data is only used for approved research purposes. Researchers who access this data from the data bank will not have access to participant information therefore data will not be re-identifiable.

The results of this study may be published in research journals or presented at conferences. The results will not include any information that may identify participants. Data may be used in higher degree by research studies in the future. In this circumstance, confidentiality will be maintained and no identifying information will be used.

A summary of the results will be provided through Hollywood Private Hospital 18 months after the completion of the study.

Please read this Information Statement and be sure you understand its content before you consent to take part.

If you would like to take part, please complete the consent form and return it to Sarah D'Souza, Claire Tucak or a member of the research team.

Questions or further information?

You may wish to consult with your manager before agreeing to take part in this study.

If you have any questions or require any further information about the research project, please contact: Sarah D'Souza [Ph: 0439 982 451]

Thank you for considering the invitation to take part in this research project.

Yours sincerely,

Sarah D'Souza

If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact: Kim Gifkins

Research Ethics Officer

Edith Cowan University

270 Joondalup Drive

JOONDALUP WA 6027

Phone: (08) 6304 2170

Email: research.ethics@ecu.edu.au

This project has been approved by the ECU Human Research Ethics Committee and the Hollywood Private Hospital Research Ethics Committee.

I _____ (print name), give my consent freely and agree to participate in (please circle):

Part 1:

Yes	No	**Observations** of your interactions with patients following stroke.
Yes	No	**Video recording** of your interactions with patients following stroke.

Part 2:

Yes	No	Complete two focus groups with the researcher, complete two short questionnaires and attend a training program.

I understand the project will be conducted as stated in the information letter, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give a reason for withdrawing.

I understand personal information will remain confidential to the researchers.

I have been given the opportunity to raise any questions or concerns I have and am satisfied with the responses I was given.

Participant

Print name: _____

Signature: _____

Phone number: _____

Email address: _____

Date: _____

Witness

Print name: _____

Signature: _____

Date: _____

Volunteer information and consent form

Investigating Enriched Environments after stroke

This research project is being undertaken as part of the requirements of a PhD at Edith Cowan University.

Researchers' contact details

Edith Cowan University		
Chief Investigator/ PhD student	Sarah D'Souza	Ph: 0439 982 451
Principal Supervisor	Professor Beth Armstrong	Ph: 08 6304 2769
Co-Supervisor	Associate Professor Natalie Ciccone	Ph: 08 6304 2047
Co-Supervisor	Associate Professor Erin Godecke	Ph: 08 6304 5901
Co-Supervisor	Associate Professor Deborah Hersh	Ph: 08 6304 2563
Hunter Stroke Service, University of Newcastle and Hunter Medical Research Institute		
Adjunct Supervisor	Dr Heidi Janssen	Ph: 02 40420417

Description of the research project

This study is a Communication Enhanced Environment (CEE) at Hollywood Private Hospital. A CEE involves several initiatives that aim to provide more opportunities for communication for stroke survivors on the ward. One of these initiatives involves the participation of volunteers.

As a volunteer participant, you will be asked to take part in the following:

- Attend a training program for approximately 1.5 hours. This will focus on training volunteers in communicating with patients following stroke with communication difficulties. This session will be located at Hollywood Private Hospital and will be offered over several dates to facilitate your ability to attend. If you are unable to attend the training program we may provide training and video resources to facilitate your participation in training.
- Complete an anonymous short questionnaire before and after attending the training program to obtain your feedback on the training session.

- A focus group with the researcher and other volunteers for approximately 1 hour to explore your perceptions of communicating with patients following stroke. The focus group will be tape recorded however at any stage you may ask for the tape to stopped, edited or have your comments erased.
- Host a communal dining and lounge area once a week to offer tea and coffee and provide social companionship for patients following stroke.
- Your interactions with the patient may be video recorded and manually recorded by a member of the research team to explore patient communication activity levels. You can choose to be observed by the researcher only if you do not want to be video recorded. We will not record if you are having sensitive conversations with the patient/s.

There will be no cost to you associated with participating in this study. Participation is completely voluntary. You do not have to participate if you don't want to. If you decide to participate you may withdraw at any time without giving a reason and withdrawing will not disadvantage you in any way.

You may benefit from gaining knowledge and skills regarding communication from attending the training program. Additionally, you may also benefit from the knowledge that you are helping future stroke survivors. It is possible that you may not benefit from participating in this study. There are no known risks associated with participating in this study.

Confidentiality of information

The information you provide during the interviews will be audio recorded by the Chief Investigator. Your perspectives and opinions will be analysed and grouped into common 'themes' and 'stories'.

The video, audio and written data will be identified by code. The information you provide will remain completely confidential. There will be no identifying information attached to the data and any information that may reveal your identity will be removed. A list of participant names and codes will be kept in a locked filing cabinet at Hollywood Private Hospital and will only be accessible by the research team. All data will be accessed, used and stored in accordance with Commonwealth Privacy Laws. The data will be stored on a password controlled computer or in a locked cabinet at Edith Cowan University. Electronic data will be backed-up on a password controlled hard drive only accessible by the Chief Investigator. Data will be stored for a maximum of 15 years after completion of the study. Video and audio recordings will then be permanently deleted and hard copy data will be shredded.

Non-identifiable data will be accessible by researchers through data sharing archives. This data will be governed by an overarching body to ensure data is only used for approved research purposes.

Researchers who access this data from the data bank will not have access to participant information therefore data will not be re-identifiable.

The results of this study may be published in research journals or presented at conferences. The results will not include any information that may identify participants. Data may be used in higher degree by research studies in the future. In this circumstance, confidentiality will be maintained and no identifying information will be used.

A summary of the results will be provided through Hollywood Private Hospital 18 months after the completion of the study.

Please read this Information Statement and be sure you understand its content before you consent to take part.

If you would like to take part, please complete the consent form and return it to Sarah D'Souza, Claire Tucak or a member of the research team.

Questions or further information?

If you have any questions or require any further information about the research project, please contact: Sarah D'Souza [Ph: 0439 982 451]

Thank you for considering the invitation to take part in this research project.

Yours sincerely,

Sarah D'Souza

If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact: Kim Gifkins

Research Ethics Officer

Edith Cowan University

270 Joondalup Drive

JOONDALUP WA 6027

Phone: (08) 6304 2170

Email: research.ethics@ecu.edu.au

This project has been approved by the ECU Human Research Ethics Committee and the Hollywood Private Hospital Research Ethics Committee.

I _____ (print name), give my consent freely and agree to participate in (please circle) this study as described in this information and consent form.

I understand the project will be conducted as stated in the information letter, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give a reason for withdrawing.

I understand personal information will remain confidential to the researchers.

I have been given the opportunity to raise any questions or concerns I have and am satisfied with the responses I was given.

Participant

Print name: _____

Signature: _____

Phone number: _____

Email address: _____

Date: _____

Witness

Print name: _____

Signature: _____

Date: _____