Participant Information Sheet/Consent Form

Support Person

The Queensland Aphasia Research Centre (QARC) at the Surgical, Treatment and Rehabilitation Service (STARS) in Metro North Hospital and Health Service

Title	The usability, feasibility, acceptability and efficacy of providing a Comprehensive High-dose Aphasia Treatment (CHAT) program via Telerehabilitation (TeleCHAT)
Short Title	TeleCHAT study
Protocol Number	Version 4
Project Sponsor	The University of Queensland
Coordinating Principal Investigator/ Principal Investigator	Dr Annie Hill, The University of Queensland
Associate Investigator(s)	**The University of Queensland:** Dr Jade Dignam Professor David Copland Ms Genevieve Vuong **The Royal Brisbane and Women's Hospital:** Dr Clare Burns **Surgical Treatment and Rehabilitation Service:** Ms Kylie Short Ms Penni Burfein Dr Kana Appadurai
Location	The Queensland Aphasia Research Centre (QARC) at the Surgical, Treatment and Rehabilitation Service (STARS) in Metro North Hospital and Health Service

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Part 1 What does my participation involve?

You are invited to participate in this project because you are a carer/family member/communication partner of person with aphasia post stroke, and you have been invited by the person with aphasia to participate in this study. Your experiences and opinions will assist researchers in:

- identifying the enablers and barriers to changing speech pathology practice,
- identifying the usability, feasibility, acceptability and efficacy of the TeleCHAT program within a multidisciplinary service framework post stroke,

- developing a strategy for implementing TeleCHAT into clinical practice more broadly.

1 Introduction

You are invited to take part in this research project, which is called *The usability, feasibility, acceptability and efficacy of providing a Comprehensive High-dose Aphasia Treatment (CHAT) program via Telerehabilitation (TeleCHAT)*. You have been invited by the person with aphasia because you are their support person (carer/family member/communication partner). Your contact details were provided by the project speech pathology site liaison.

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

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

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to be involved in the research described
• Consent to the use of your personal as described.

You will be given a copy of this Participant Information and Consent Form to keep.

You may also be the person with aphasia's proxy (adult consenting on behalf of person with aphasia). If this is the case, you must complete this Participant Information and Consent Form for your own involvement as a support person, as well as the 'Proxy Participant Information and Consent Form' for the person with aphasia's involvement.

2 What is the purpose of this research?

The purpose of this project is to evaluate the usability, feasibility, acceptability and efficacy of providing a Comprehensive High-dose Aphasia Treatment (CHAT) program via Telerehabilitation (TeleCHAT).

There is strong evidence that aphasia therapy improves communication outcomes and individual benefit more when aphasia therapy is given in a higher dose, at a higher intensity, and over a longer period of time. This evidence is not routinely being translated into practice. There is a critical gap between the treatment that people with aphasia require to live successfully and the services that they receive. Speech Pathologists throughout Australia are seeking new models of care to meet the clinical guidelines for stroke management recommendation that aphasia therapy be delivered intensively. The University of Queensland has developed a Comprehensive, High-dose Aphasia Treatment (CHAT) for rehabilitation in aphasia. Results from studies on Aphasia CHAT (previously Aphasia LIFT) have shown its efficacy. CHAT is part of another research study that aims to make it a standard of care for aphasia therapy. This feasibility study aims to evaluate the usability, feasibility, acceptability and efficacy of providing a Comprehensive High-dose Aphasia Treatment (CHAT) program via telerehabilitation (TeleCHAT). Telerehabilitation is the delivery of rehabilitation services via

technology and the Internet. Specifically, this project aims to: a) determine the usability, feasibility and acceptability of providing TeleCHAT - a Comprehensive High-dose Aphasia Treatment (CHAT) program into the home via telerehabilitation, from the perspectives of the participants with aphasia, their family members, and their treating clinicians; b) determine if TeleCHAT produces good clinical outcomes for participants; c) identify the barriers and enablers to the implementation of TeleCHAT within the Queensland Aphasia Research Centre (QARC). A separate future study will compare the results of this TeleCHAT study to in person CHAT.

This research has been initiated by the researcher Dr Annie Hill

The research has been funded by The University of Queensland and QARC.

This research is being conducted by The University of Queensland in collaboration with Metro North Hospital and Health Service.

3 What does participation in this research involve?

If you would like to be involved in the study, you will give your written consent.

Your main role in the study will be to assist the participant with aphasia in participating in the 8 week TeleCHAT program home via telerehabilitation. In order to provide assistance and participate in the intervention you will be asked to attend a training session conducted by The University of Queensland researchers in your home with the participant with aphasia. Training in the use of the telerehabilitation technology will also be provided.

Participation in the TeleCHAT program will include participant assessment and goal setting, family education sessions and therapy sessions (impairment, functional, computer and group). This will consist of a total of 50 hours of therapy (over the 8 week period) in addition to assessments. Each therapy or family education session will be 1 hour in length. There are 1-2 sessions per day, for 3-4 days a week during the 8 week therapy period. You may not need to be involved in all therapy sessions. In total, you will be involved in the study for approximately 3 months. All sessions will be video recorded. The video recordings will be reviewed by members of the research team to ensure that the treatment is being delivered as per the protocol.

You will be asked to complete a questionnaire before and after the training workshop. This should take no longer than 30 minutes to complete.

For 3 months after the TeleCHAT program, the person with aphasia will need to fill out a weekly diary log about how they are managing their aphasia. You may need to help them with this task.

In addition to the above you will be asked to provide basic information on costs associated with travelling to clinics to attend rehabilitation services. This information will allow researchers to model potential cost savings using telerehabilitation.

Finally, after completion of the TeleCHAT program, a researcher will also contact you to schedule an interview at a time that is convenient to you. This interview will consider your perspective on patient outcomes, the usability, feasibility and acceptability of implementing TeleCHAT.

This table shows the time commitments of the TeleCHAT program for the support person.

What you need to do	**Time taken**
Training session	1-2 hours
Goal setting session	1-2 hours

Therapy sessions Each therapy session goes for 1 hour. There are 1-2 sessions a day, for 3-4 days a week.	6-7 hours per week for 8 weeks (1-2 hours/day for 3-4 days/week)
Questionnaires and Interviews	1.5 hours total
Help person with aphasia with completing a weekly diary log post-TeleCHAT	15 minutes, 1-2 times a week for 3 months

While your assistance would be greatly appreciated, it is important to note that you are under no obligation to participate in this study and that you will have the opportunity to withdraw from the study at any time. If you withdraw, the research team will determine whether the person with aphasia is able to continue the program independently, or if there is an alternative person who can continue to support the person with aphasia to complete the therapy program.
There are no costs associated with participating in this research project, nor will you be paid for your participation.

4 Other relevant information about the research project

Up to 48 participants with aphasia and their family members (n= 16 per year) will take part in this project between 2021-23. 2-3 other participants with aphasia and their family members will participate in the same group (at the same time) as you.

This study is only being conducted from the Queensland Aphasia Research Centre to the person with aphasia's home via telerehabilitation.

A speech pathologist and possibly a speech pathology student or allied health assistant will provide therapy. Students and/or allied health assistants will always be under the supervision of a senior speech pathologist.

We are also asking staff about their views on the aphasia therapy program.

The TeleCHAT program is a temporary substitution for all other aphasia therapy services. Therefore, the person with aphasia will not be able to receive any other speech therapy for their aphasia while they participate in TeleCHAT.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship nor that of the participant with aphasia with professional staff or your relationship with the Queensland Aphasia Research Centre; Surgical Treatment and Rehabilitation Service (STARS); or The University of Queensland.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any direct benefits from this research; however, the results of this project will assist service providers in making decisions about

providing intensive aphasia rehabilitation via telerehabilitation. This knowledge may help to improve current services available for people with aphasia and their families. You may gain a feeling of achievement through being involved in assisting the person with aphasia with their therapy. The TeleCHAT program may also educate you on how to best support the person with aphasia during and after the program finishes.

7 What are the possible risks and disadvantages of taking part?

A potential disadvantage of taking part in this study is the long and intensive period of involvement (approximately 14-15 weeks, with 6-7 hours of involvement per week during therapy (8 weeks)).
Risks of taking part may include stress, fatigue or frustration experienced during completion of the therapy, interviews, questionnaires or assessment. Risks will be mitigated by the provision of frequent short breaks, and offering of support when needed. You may feel that some of the questions we ask during the assessments are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you becomes upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge

Whilst all care will be taken to maintain privacy and confidentiality, you may experience embarrassment if another person with aphasia were to repeat things said during the aphasia group therapy.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you withdraw, the research team will determine whether the person with aphasia is able to continue the program independently, or if there is an alternative person who can continue to support the person with aphasia to complete the therapy program.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

9 What happens when the research project ends?

If you would like to be informed of the overall findings of this research your mailing address will be recorded and you will be sent a summary of the findings of the research on the completion of the study. This will be approximately 1 year following completion of the study.

Part 2 How is the research project being conducted?

10 What will happen to information about me?

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Data collected for the project will be in re-identifiable form in the case that you withdraw from the project or want to access your data. All data will be stored securely at The University of Queensland School of Health and Rehabilitation Sciences. Paper forms will be stored securely in a locked filing cabinet in a room locked when unattended and digital files will be stored on password protected laptops/ computers. Data will be transferred for storage and management to an online database using the secure web based server/application UQ Research Data Manager (RDM). Members of the research team, including the investigators listed above as well as professional research staff, will have access to it for 15 years following completion of the project. Information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. You may be involved in some treatment sessions with the person with aphasia, and these treatment sessions may be audio and video recorded. Your participation in interview(s) will be audio and video recorded. Interview(s) will be transcribed into a written format. De-identified transcripts will be analysed by members of the research team.

Your data may be useful to future research studies in this area. If this is required you will be contacted and separate consent will be obtained.

In any publication, information will be provided in such a way that you cannot be identified. The personal information that the research team collect and use will include demographic information (qualification, level of experience), information from questionnaires and audio and video recordings from treatment sessions and interviews.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission.

In accordance with relevant Australian and/or Queensland privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored in a locked filing cabinet in a room locked when unattended and/or on secure online databases on password-protected laptops or computers. It will be disclosed only with your permission, or as required by law.

11 Complaints and compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

12 Who is organising and funding the research?

This research project is being conducted by The University of Queensland. Dr Annie Hill will lead the research.

It is being funded by The University of Queensland and QARC.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

13 Who has reviewed the research project?

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

14 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the researcher on (07) 3346 6110 or any of the following people:

Research contact person

Name	Dr Annie hill
Position	Principal research fellow and speech pathologist
Telephone	(07) 3365 8876
Email	aj.hill@uq.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Ethics officer – Royal Brisbane and Women's Hospital HREC
Position	Ethics officer– Royal Brisbane and Women's Hospital HREC
Telephone	(07) 3646 5490
Email	RBWH-Ethics@health.qld.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	The Royal Brisbane and Women's Hospital HREC
HREC Executive Officer	Dr Gordon McGurk (Chair); Ann-Maree Gordon (coordinator)
Telephone	(07) 3646 5490 or (07) 3646 6132
Email	RBWH-Ethics@health.qld.gov.au

Local HREC Office contact

Name	Dr Tamara Periera
Position	Human Ethics Coordinator
Telephone	(07) 3443 1656
Email	humanethics@research.uq.edu.au

Consent Form

Support Person

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Location	The Queensland Aphasia Research Centre (QARC) at the Surgical, Treatment and Rehabilitation Service (STARS) in Metro North Hospital and Health Service

Declaration by Participant

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

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

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

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project.

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

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher†

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

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

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

Form for Withdrawal of Participation

Support Person

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Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my relationships with the researchers or The University of Queensland or the Queensland Aphasia Research Centre or the Surgical, Treatment and Rehabilitation Service (STARS).

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

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