Participant Information Sheet/Consent Form

Participants with Aphasia

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 4.0
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

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this project.

This project is called the **TeleCHAT Study.**

You have been invited because **you have aphasia**.

Your contact details were given from your **speech pathologist or doctor**.

This form tells you about the research project.

It explains **what is involved** with taking part.

You can **decide** if you want to participate.

You can ask **questions**. 

You can talk with a **family member or friend** about this research.

Participation in this project is **voluntary**.

You **do not** have to take part in this project.

If you say **no**, you may continue any speech therapy you received before.

If you want to take part in the project, you will be asked to **sign the consent form**.

By signing you are telling us that you:

- **Understand** what you have read and been told.
- **Consent to take part** in the research project.
- Consent to the use of your **personal and health information** as described.

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

2 What is the purpose of this research?

What is Aphasia?

Aphasia is a language disorder caused by damage to the brain. One cause of aphasia is stroke. Someone with aphasia may have trouble with:

Talking

Listening

Reading

Writing

Research tells us that **more aphasia therapy is better** than less aphasia therapy.

What are the aims of this project?

We want to **assess** the **process** of delivering a comprehensive, high-dose aphasia therapy (CHAT) using **telehealth**. We are calling this program **TeleCHAT.**

Telerehabilitation is when therapy services are delivered to you **in your home** using **technology** such as **videoconferencing** (e.g. FaceTime etc).

We will:

- **Assess the success** of delivering the therapy via telehealth
- Describe **what affects therapy delivery** and patient **participation**
- Identify **what helps** and **what obstructs** the delivery of therapy.

This project will help researchers to deliver **new models of aphasia rehabilitation**.

Dr Annie Hill is leading this research. 

This research has been **funded** by **The University of Queensland.**

This research is being conducted by:

- The University of Queensland
- The Queensland Aphasia Research Centre in the Metro North Hospital and Health Service
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3 What does participation in this research involve?

What do I need to do?

Give **permission** to be involved.

Sign a **consent form**.

Start with some **language tests** (5-6 hours across 2 sessions).

Do training on how to use the telerehabilitation technology.

Come up with goals for therapy with the help of a speech language therapist (1-2 hours).

Participate in **TeleCHAT**, a comprehensive, high-dose **aphasia therapy program.**

Therapy goes for **one (1)** to **two (2) hours per day** for **three (3)** to **four (4) days each week** over **eight (8) weeks**.

Answer **questions** about your **views** on the **therapy program and telehealth delivery** (total of 3 hours)

Do the **language tests** again after therapy (5-6 hours across 2 sessions).

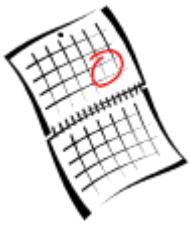
Keep a **diary log** for three months after therapy (15 minutes, 1-2 times a week for 3 months)

Do the **language tests** again 3 months after therapy (5-6 hours over 2 sessions).

This table shows how much time you need to spend in the program.

What you need to do	**Time taken**
Language tests before therapy	5-6 hours over 2 sessions
Training session	1-2 hours
Goal setting session	1-2 hours
Therapy sessions – each therapy session goes for 1 hour. There are 6-7 therapy sessions in a week.	1-2 hours/day for 3-4 days/week over 8 weeks.
Questionnaires and Interviews	3 hours total
Language tests after therapy	5-6 hours over 2 sessions
Diary log for 3 months after therapy	15 minutes, 1-2 times a week for 3 months
Language tests 3 months after therapy	5-6 hours over 2 sessions

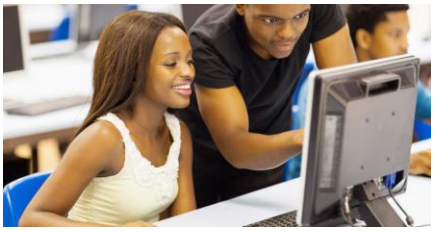
What will happen?



You will be involved in the study for **three (3) months** in total.

Researchers will contact you once you start rehabilitation.

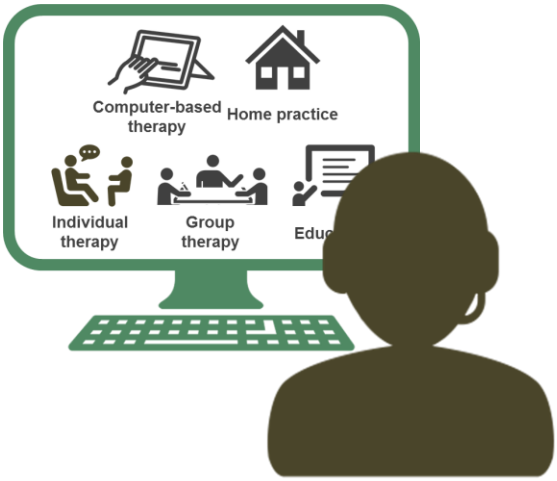
You will complete some **language tests** (5-6 hours across 2 sessions).



A researcher will **train** you on how to use the **telerehabilitation technology** (1-2 hours).

You will come up with **goals** for therapy with the help of a speech language therapist (1-2 hours).

You will attend aphasia therapy **six (6) to seven (7) hours a week** for **eight (8) weeks**.



This **therapy** will include:

- Impairment therapy (1-2 hours per week)
- Functional therapy (1-2 hours per week)
- Computer therapy (1-2 hours per week)
- Group therapy (1-2 hours per week)

Therapy will be delivered from the **Queensland Aphasia Research Centre** at the Surgical, Treatment and Rehabilitation Service (STARS) **to you in your home.**

During therapy, you will complete some **questionnaires** about the **training** and **therapy program** (total of 3 hours).

After therapy finishes, you will do the **language tests again**. You will answer questions about your aphasia again (5-6 hours across 2 sessions).

These tests will be repeated again **one (3) months** later (5-6 hours across 2 sessions).

If you wish, you may invite a **support person (family member or carer)** to participate in this study with you.

Your support person may **help** you **use the technology** and participate with you in **speech therapy sessions**.

They will answer some questions about your aphasia, your therapy and how aphasia affects your life and theirs.

It is **not essential** for a support person to participate with you in this study. The research team will decide if you can participate by yourself or if you may need someone to support you to participate.

Your therapy sessions and interviews will be **audio and video recorded**.

Some information will be **recorded from your medical chart**. Information will be kept **private**. No identifying details will be given to anyone outside the research team.

How will this affect me?

You may be **tape and video recorded**.

There is **no danger** doing this study.

You **may not benefit** from this study.

This research will **not cost** you any **money**.

You will **not be paid** for this research.

This project has been designed to make sure the researchers interpret the results in a fair and appropriate way. We want to avoid jumping to conclusions.

4 Other relevant information about the research project

This study is only being conducted **from the Queensland Aphasia Research Centre** to you **in your home via telehealth**.

Therapy will be **provided** by **a speech pathologist** and possibly a **speech pathology student** or **allied health assistant**. Students and/or allied health assistants will always be **supervised** by a senior speech pathologist.

Other people with aphasia are also doing this study. 2-3 other people with Aphasia will participate in your group. In total, 48 people with aphasia will participate in this study over 3 years.

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

If you take part in this study, you **cannot receive** any **other speech therapy** for your aphasia for the **period of this study** (2-3 months). TeleCHAT will **replace** your usual speech therapy for 2-**3 months.**

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

Your participation is **voluntary**.

You do **not have to participate**.

You can **stop** at any time. 

Saying **no will not affect** your usual **speech therapy**.

Saying no **will not affect** your relationship with:

- The University of Queensland
- Metro North Hospital and Health Service

6 What are the alternatives to participation?

You **can say no** to this research.

You may continue speech therapy you received before if you say no.

7 What are the possible benefits of taking part?

You **may benefit** from this study by receiving therapy to **help your aphasia**, and **help you manage your aphasia** after the study.

This study may help to find **new ways** to **deliver aphasia therapy**.

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

A **disadvantage** of taking part in this study is that you will be involved for a **long time** (3 months).

A **risk** is that you may get **tired, stressed or frustrated** from completing therapy, answering questions and doing language tests.

Tell a researcher if you feel:

- Tired
- Stressed
- Frustrated

You can **stop** and take a **break**. You can have a **rest**.

9 What if I withdraw from this research project?

You **do not have to participate** in this study.

You can **stop** at any time. 

You can **tell a researcher** if you **want to stop**.

You can **tell a researcher** if you **do not want your information** to be **used** if you withdraw from this study

10 What happens when the research project ends?

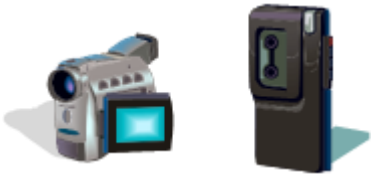
You can **ask for the results** of this study.

We will **mail the results** to you when we finish (about 1 year).

Part 2 How is the research project being conducted?

11 What will happen to information about me?

<u>I understand what will happen to information I give</u>:

I may be **tape / video recorded**. 

The researchers will look at my **medical chart**.

The researchers will **ask my family** about my **aphasia**.

I will need to give some **personal details**.

For example:

- My contact details.
- Information about how I feel about my aphasia.

<u>What will happen to information about me</u>:

Your information will be **kept private**.

Your information will be kept in a way that we **can identify** you **if we need to**.

All paper information will be **kept safely** in a locked filing cabinet.  

Computer files will be kept on a **password-protected computer**.

The information will be **kept** at **The University of Queensland**.

Only **people who are involved with this study** will look at your **information**. These people will be either researchers or speech pathologists involved in your therapy.

Your information will be **kept for fifteen (15) years** after the study.

Your information may be used for **future studies**. We will contact you for **consent** before using this information.

All information you give will be **confidential**.

Your **identity** will not be **revealed**.

Who can check this information?

Your relevant health records and **information** about you can be **checked** by **The University of Queensland and the Royal Brisbane and Women's Hospital Human Research Ethics Committee**.

This is to check the study procedures and data collected.

By signing the consent form, I allow people to look at this information.

What will happen with the results?

The results of this study will be **published in journals**.

The results of this study will be **presented at conferences**.

My **identity** will be kept **confidential**.

We will give you a **copy of the results** if you would like.

12 Complaints and compensation

If you suffer any **harm** in this study **tell the research team**.

You will be given **support** and **treatment**.

13 Who is organising and funding the research?

This research project is being conducted by:

- The University of Queensland
- Metro North Hospital and Health Service

The researchers will **not be paid extra money** for you to do this study.

14 Who has reviewed the research project?

All human research in Australia is reviewed by a **Human Research Ethics Committee** (HREC).

This study has be reviewed by:

- The Royal Brisbane and Women's Hospital
- 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 written to **protect people** participating in research.

15 Further information and who to contact

If you have **questions** about the **research** you can contact:

Name	Research Officer / Project Staff
Telephone 	07 3346 6110
Email 	qarc@uq.edu.au

OR

Name	Dr Annie Hill
Position	Senior Research Fellow and Speech Pathologist, The University of Queensland
Telephone 	07 3365 8876
Email 	aj.hill@uq.edu.au

If you would like to speak to someone about the **research at QARC** contact:

Complaints contact person

Name	Ethics Officer
Position	Ethics Officer, The Royal Brisbane and Women's Hospital HREC
Telephone 	07 3646 5490
Email 	RBWH-Ethics@health.qld.gov.au

If you want to speak to someone about;

- The way the research is being done.
- Your rights.
- Making a complaint.

You can contact the people below.

These people are not involved in the project.

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

Reviewing HREC approving this research and HREC Executive Officer details

Local HREC Office contact

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

Consent Form

Participant with Aphasia

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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 **understand** the **Participant Information Sheet**.

I **understand** what **this research** is about.

I have **asked questions** and I am happy with the answers.

I **agree to participate** in this project.

I **understand** I can **withdraw** at any time.

If I **stop** this project it will **not affect my care** at the Queensland Aphasia Research Centre (QARC).

If I **stop** this project it will **not affect my relationships** with the Queensland Aphasia Research Centre, The University of Queensland or Metro North Hospital and Health Service.

I understand that I will be given a **signed copy of this form** 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

Participant with Aphasia

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Declaration by Participant

I wish to **withdraw from participation** in the above research project.

I understand that this will **not affect my routine care**.

I understand that this will not affect my relationships with the researchers or the Queensland Aphasia Research Centre, The University of Queensland or Metro North Hospital and Health Service

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.