Participant Information Sheet/Consent Form for Clients – RehabChat – Rehabilitation Use

Health/Social Science Research - *Adult providing own consent*

Title	Mixed methods feasibility pilot trial of a Motivational Embodied Conversational Agent for Brain Injury Rehabilitation
Short Title	Using a Motivational RehabChat App for Brain Injury Rehabilitation
Protocol Number	14079
Principal Investigator	A/Prof Belinda Lange
Associate Investigator(s)	Dr Judith Hocking, Dr Richard Leibbrandt, Dr Candice Oster, Prof David Powers
Locations	Clinical services in South Australia which provide rehabilitation for clients with brain injury or stroke

Part 1 What does my participation involve?

1 Introduction

- You are invited to take part in this project called **Using a motivational RehabChat App for Brain Injury Rehabilitation**. You are able to participate because you are currently receiving rehabilitation following your brain injury or stroke at a clinical service in South Australia, and your clinician has said you are eligible to participate in this project. Also, you are also aged 18 years or older.
- This Participant Information and Consent Form tells you about the research project, and what it means to take part in it. Knowing what is involved will help you decide if you want to take part.
- Please read this information carefully. You can ask questions about anything that you don't understand or want to know more about. Before you decide about taking part or not, you might want to talk about it with someone you trust. If you don't want to take part, you don't have to.
- If you decide you want to take part in the project, you will be asked to sign the consent form. By signing it you are telling us that you:
- Understand what you have read
- Consent to take part in the research project described
- Consent to the use of your personal and health information as described.

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

2 About RehabChat

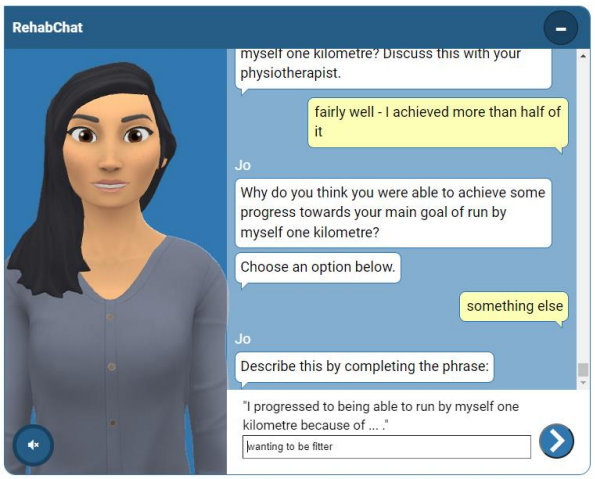
- RehabChat is a goal-setting App that can have a motivational conversation with you about your rehabilitation. RehabChat can be used on a hand-held device (tablet/iPad) or a computer (laptop/desktop).
- It has been designed using software from an Adelaide company called Clevertar Pty Ltd.
- RehabChat has been developed by the researchers in consultation with clients and clinicians of the South Australian Brain Injury Rehabilitation Service (SABIRS).

- Motivation is important for brain injury rehabilitation.
- Using RehabChat could help improve recovery after brain injury or stroke.

Using a hand-held device

https://images.unsplash.com/photo-1554415707-c1426270e0da?ixlib=rb-1.2.1&ixid=eyJhcHBfaWQiOjEyMDd9&auto=format&fit=crop&w=500&q=60 (viewed 12-11-20)

How the RehabChat App looks



Customised dialogues. Software is Conversagent from Clevertar https://www.clevertar.com/

3 What is the purpose of this research?

- The aims of this project are to find out how useful RehabChat is for clients with brain injury or stroke to use during their rehabilitation, and how easy it is to use RehabChat.

- The results of this research will be used improve the design of RehabChat to better suit the clinic settings. This research has been initiated by, and will be conducted by, members of the research team at Flinders University and supported by funding from the Lifetime Support Authority (LSA).

4 What does participation in this research involve?

If you are interested in taking part in this research, you will be asked to read and sign a consent form before any part of the study is completed.

- All participants in this study have previously been trained to use RehabChat.

- Your **clinician will supervise you** using RehabChat.

- You will **use RehabChat for up to 6 weeks** while you have your usual rehabilitation therapy. The research team are available to help you with any queries or issues you may have.

- You will **have some assessments during this project**. Short assessments taking 5-10 minutes will be done twice a week while you're using RehabChat for up to 6 weeks, and also during both the week before and also after you use RehabChat. For these assessments, you will answer some questions either in a phone discussion with a member of the research team, or by completing a questionnaire. The questions will ask about your motivation and levels of energy, and also about anxiety and depression.

Longer assessments will be done once just before starting to use RehabChat, once just after you've finished using RehabChat, and finally once more at a month after finishing RehabChat. These longer assessments will take approximately 20 minutes, and will include you completing questionnaire questions about your motivation during rehabilitation, anxiety and depression, and what you think about using RehabChat.

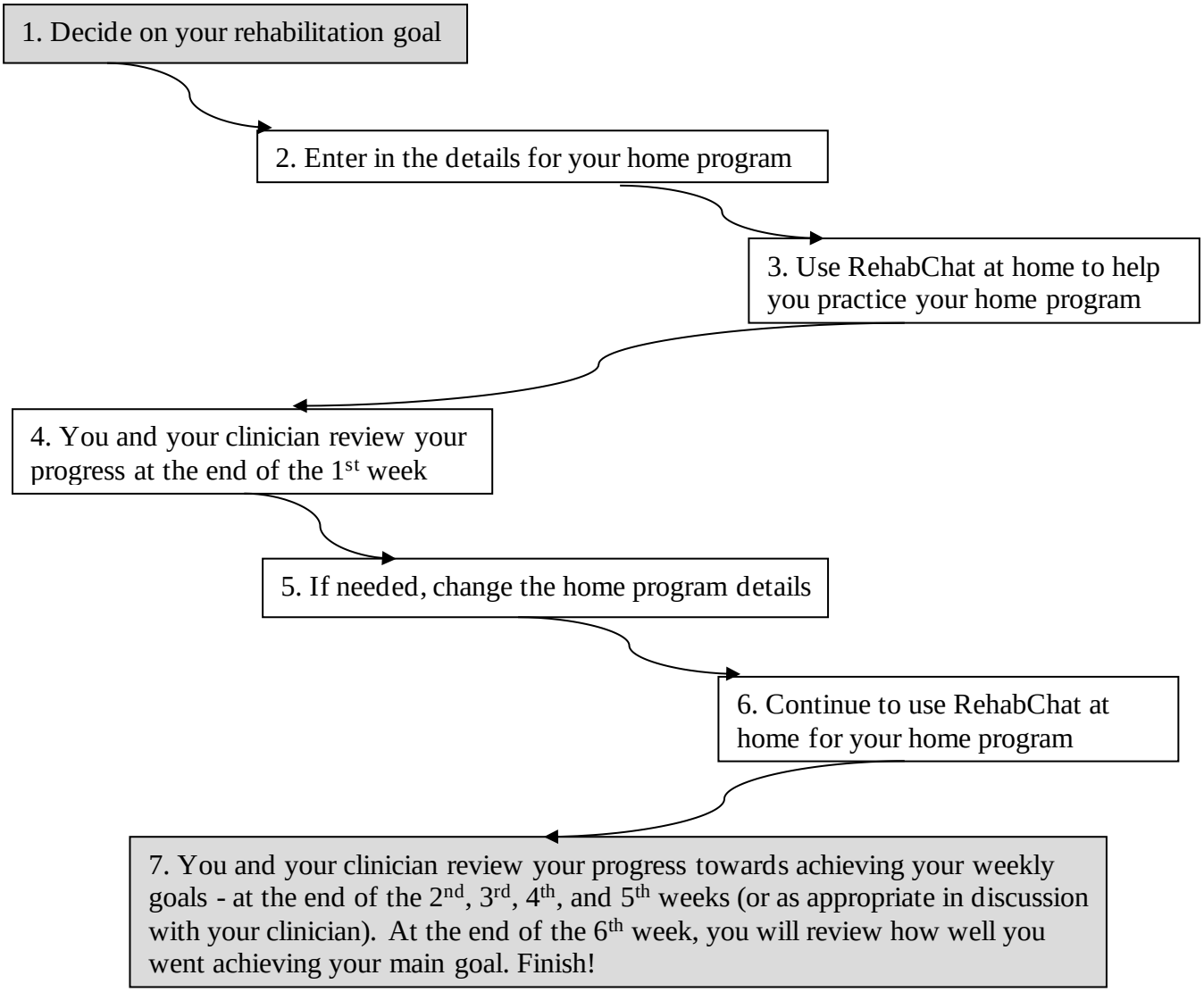
- You will also **have an interview** with a member of the research team to discuss your experiences of using RehabChat, and what you thought about it. This interview will last about 45 minutes, and will be held just after you've finished using RehabChat.

- You will **use RehabChat to do the following** (see the Flowchart below):

- Set a rehabilitation goal that you want to work towards
- Decide on some steps you can achieve in the 6 weeks, to help you work towards your goal

- Record the details of two activities that you will practice at home – your clinician will prescribe these
- Practice your home program activities at home
- Review your progress towards achieving your rehabilitation goal

Flow-chart: using RehabChat for up to 6 weeks alongside your usual rehabilitation care



5 Other relevant information about the research project

If you and your clinician don't use RehabChat alongside your usual rehabilitation care, you can still have the option of learning more about RehabChat in an additional session with a member of the research team, and then providing feedback about this.

This research project has been designed to make sure the researchers interpret the results fairly, and don't jump to conclusions.

- Up to 40 participants will be taking part in this project: up to 20 clients, and up to 20 clinicians.
- We will take an audio recording of the interview so that your feedback can be accurately collected and analysed.
- Results from this project may be included in publications or presented at conferences or in journal articles. No identifying information of the participants will be shared outside of the project, nor in any report or other write-up or presentation of the project.

- Your participation will not affect any rights you have to compensation under common law.
- There are no costs associated with participating in this research project.
- After this project is finished, you will not have any follow-up from the researchers.

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

It is your choice if you want to take part in this project or not. 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 being in the project at any time.

- 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.
- Whether you take part or not, or if you take part and then later withdraw, will not affect your clinical care.
- Also, it won't affect your relationship with staff, or your relationship with the researchers.

7 What are the possible benefits of taking part?

There are no direct benefits to you if you take part in this research; however, your participation will help develop a motivational RehabChat App which could be used by people with an acquired brain injury. As well, all participants will be paid a $50 Coles-Myer gift card to acknowledge their efforts.

RehabChat is in its early stages of development and is not yet proven to be clinically effective.

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

- When using RehabChat, you may become tired or stressed. If this does happen, please talk to your clinician, or discuss it with the research team.
- The research team will aim to resolve any questions or issues promptly.
- You can tell us if you are worried or feel uncomfortable about anything during the project.
- If needed, you may like to contact 'Beyond Blue' counselling on 1300 224 636. The research team will not provide any counselling.

Confidentiality

The research team will keep data and information confidential and secure.

9 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
- you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team
- the researchers will not collect additional information from you
- information already collected will be retained to ensure that the results of the research project can be analysed properly and to comply with law.

You should be aware that data collected up to the time you withdraw be included in the research results.

10 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons such as research member/s becoming ill. As well, the researchers may recommend that you cease your involvement in this project if this is in your best interests.

11 What happens when the research project ends?

At the end of this study, we can provide you with a summary report of the research so that you can be aware of the outcomes. Individual results will not be available. If you are interested in receiving a summary of the study findings, please discuss with the researcher. The research team will otherwise not make any contact with you after the project ends.

Part 2 How is the research project being conducted?

12 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. Your 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.

- The personal information collected in this project is individually identifiable, and will include: your name, contact details, age, gender, occupation/vocation, and details about your prior experiencing using technology and chatbots. During this project, your medical / health records will not be reviewed at all. When using RehabChat, you will only use your first name or nickname, and not enter any confidential information.

- Audio recordings will be taken of the interview. Any confidential information will be deleted form the audio recording prior to it being transcribed into text. This ensures that no individual can be identified from the transcribed text.

- Information and data gathered during this project will be stored securely and confidentially on the Flinders University Cloud drive under password control or in a locked filing cabinet at the College of Nursing and Health Sciences (CNHS), Flinders University. Only the research team will have access to the data. All records and data from this project will be deleted or destroyed after five years from when the project is completed, or from when this research is published.

- The software company – Clevertar - stores the data entered into RehabChat. Clevertar's privacy policy explains how information entered into RehabChat will be managed; this policy can be found at https://clevertar.com/privacy-policy/ .

- Results of this project may be published and/or presented in a variety of forums and may help plan future research. Confidentiality will be assured by not including any identifying information about you in published reports or presentations about this research project, or in future research which uses information and results from this project. Any information obtained for the purpose of this research project and for the future research described that can identify you will be treated as confidential and securely stored.

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

13 Complaints and compensation

If you suffer any distress or psychological stress 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. You are welcome to discuss your needs by contacting your treating health professional, or Beyond Blue (ph. 1300 224 636).

14 Who is organising and funding the research?

The research team is organising this research. This project is supported by funding from the Lifetime Support Authority. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). You or your family will not benefit financially from participating in this research project even if, for example, knowledge gained from the project proves to be of commercial value to Flinders University, or leads to discoveries that are of commercial value to Flinders University, the researchers or their institutions.

15 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). 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. The Central Adelaide Local Health Network Human Research Ethics Committee has reviewed and approved this project.

16 Further information and who to contact

The person you may need to contact will depend on the nature of your query – see below for details. 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:

Research contact person

Name	Dr Judith Hocking
Position	Lead Researcher, CNHS, Flinders University
Telephone	0466 187 793
Email	Judith.hocking@flinders.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

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC Executive Officer, contactable through the HREC Support Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.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

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC Executive Officer, contactable through the HREC Support Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

Local HREC Office contact

Name	Ms Bernadette Swart
Position	Manager CALHN Research Office
Telephone	(08) 7117 2209
Email	Health.CALHNResearchGovernance@sa.gov.au

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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 understand that audio recordings will be taken of 1:1 interview and that the recording will be de-identified and transcribed to text.

I have had an opportunity to ask questions and I am satisfied with the answers I have received. I have had the opportunity to discuss my participation in this study with a family member, friend or support person.

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

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

☐ I am happy to be contacted about any future research related to this RehabChat project.

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 - *Adult providing own consent*

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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 routine care, or my relationships with the researchers or clinical 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.