Participant Information Sheet/Consent Form for Clinicians – 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 research project called **Using a motivational RehabChat App for Brain Injury Rehabilitation**. You are able to participate because you are working as a clinician at a clinical service providing rehabilitation for clients with brain injury or stroke, in South Australia.

This Participant Information and Consent Form tells you about the research project and the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research. Participation in this research is voluntary. If you don't wish to take part, you don't have to.

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 co-worker. If you decide you want to take part in the research project, you will be asked to sign the consent section.

By signing the Consent Form, 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

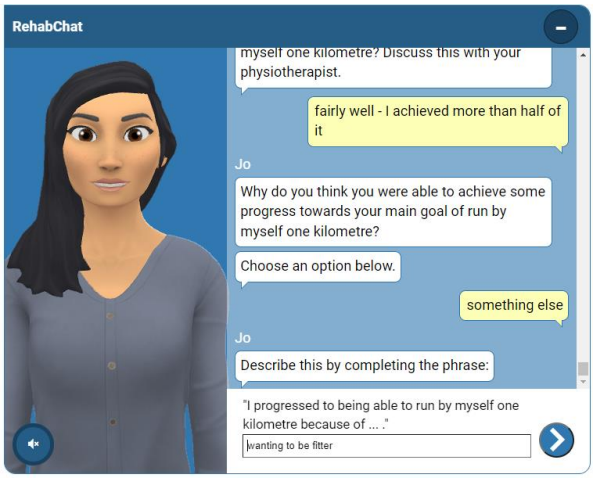
RehabChat is a goal-setting chatbot App that can be used on a hand-held device (tablet/iPad) or a computer (laptop/desktop). It has been designed using software developed by an Adelaide software company – Clevertar Pty Ltd.
- RehabChat can have motivational conversations with a person about their rehabilitation goals and recovery.

- 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=eyJhcHBsaWNhdGlvbiI6IEvMDd9&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 investigate

- how useful the RehabChat App is in rehabilitation care
- and how easy it is to use RehabChat.

The results of this research will be used to 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?

In this study, RehabChat will be used by a client/s of yours for up to 6-weeks alongside their usual rehabilitation care at your clinic (a clinical service providing brain injury or stroke rehabilitation in South Australia). You will provide clinical oversight of your client using RehabChat. All participants will provide feedback about their experience at the end of the trial. All participants in this study have previously been trained to use RehabChat.

- You will then screen your current clients (with whom you have been providing care for at least three appointment sessions) for eligibility to be involved in the pilot trial.
- You will supervise any of your clients that are recruited to the study whilst they use RehabChat for up to six weeks alongside their usual rehabilitation.

At the start and finish of RehabChat being used by your client/s, and at one month after finishing use of RehabChat, you will complete a series of questionnaire questions – this will take approximately 20 minutes each time. At the end of the trial, you will complete a short questionnaire about your experience supervising your client using RehabChat, and participate in a 1:1 interview with a member of the research team to discuss your experience and views about using RehabChat in your clinic.

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.

4. a) Details of the trial using RehabChat for up to 6 weeks alongside usual care

RehabChat will be used on a hand-held device (tablet/iPad) or a computer (laptop/desktop). You will provide clinical oversight of your client whilst they use RehabChat alongside their usual rehabilitation care. The research team will provide support for all participants when needed.

The specific ways in which RehabChat will be used alongside usual care are:

1. Using RehabChat in your clinic appointment time, to
- Define the main rehabilitation goal, and enter these into RehabChat;
- Define sub-goals to be achieved at the end of the 1st, 2nd, 3rd, 4th and 5th weeks (or timed as appropriate for your client's needs), and enter these into RehabChat;
- prescribe home program activities relevant to the main rehabilitation goal
- enter the home program details into RehabChat
2. The client will use RehabChat at home to practise their home program
3. Using RehabChat in the clinic at the end of the 1st – 5th weeks (or timed as appropriate for your client's needs), to
- review the client's progress towards achieving their weekly sub-goals
- if needed, make changes to RehabChat, for example regarding the home program.
4. The client continues to use RehabChat at home to practise their home program in-between each clinic appointment
- finish using RehabChat after the final review at the end of the 6th week.

5 Other relevant information about the research project

If you and your client do not use RehabChat alongside usual care, you will still have the option of learning more about RehabChat in an additional session with a member of the research team, following which you can provide your feedback.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoid jumping to conclusions. We will audio record the 1:1 interviews so that the feedback can be accurately collected and analysed.

Results from the project may be included in publications or presentations. 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.

Following completion of the study, you will not have any follow-up from the research team.

There are no costs associated with participating in this research project.

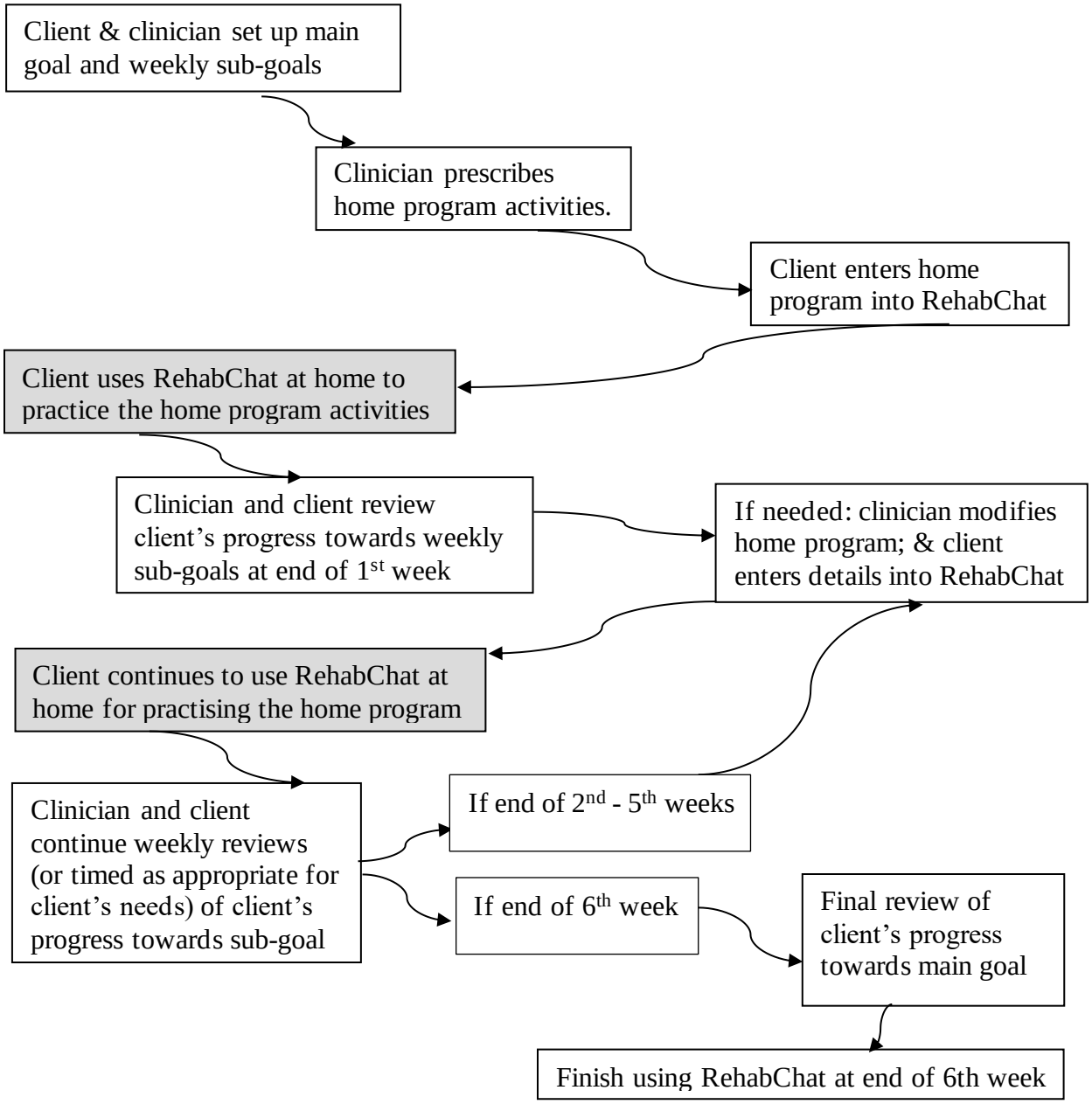
Up to 40 participants will be taking part in this project : up to 20 clinicians, and up to 20 clients.

6 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, or to take part and then withdraw, will not affect your work, or your relationship with staff at these services, or your relationship with the researchers.

Flow-chart: using RehabChat alongside usual care: (grey shading = home-based use)



7 What are the possible benefits of taking part?

There are no direct benefits to you from your participation in this research; however, your participation will contribute to developing 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 stressed. If so, please discuss any concerns with the research team who will aim to resolve any questions or issues promptly. You can tell us if you are stressed or feel uncomfortable about anything during the project. If needed, you may like to contact 'Beyond Blue' telephone 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. These may include 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, and details about your prior experiencing using rehabilitation technology and chatbots.

Audio recordings will be taken of the 1:1 interview conducted at the end of the trial. Any confidential information will be deleted form the audio file prior to it being transcribed into text. This ensures that no individual can be identified from the transcribed text.

Information and data obtained during this project will be stored securely and confidentially on the Flinders University Cloud drive under password control. Any paper records will be filed 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 the completion of the project or from the date of publication of this research.

During this project, your client/s will use RehabChat. 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/ .

It is anticipated that results of this project will be published and/or presented in a variety of forums and may inform 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. 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 (08) 8201 2226.

Research contact persons

Name	Dr Judith Hocking
Position	Lead Researcher, CNHS
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	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)
HREC Executive Officer	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*

Withdrawal of Participation Form for Clinicians – RehabChat – Rehabilitation Use

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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.