Study ID code:

Sheffield Hallam University

Pre-Clinical Development of Cog-LAB: Transition from TRL3 to TRL4

Participant Information Sheet

Hello, this study is being conducted to compare a new tablet app (Cog-LAB) with existing standardised tasks. This is a voluntary study and you are not obliged to take part. You may withdraw at any point during the research. This sheet outlines why the research is being conducted and what you, as a participant, would be required to do. If you have any queries please feel free to ask questions after reading this information or at any time during the study.

What is this study about?

After a head injury or stroke individuals can experience problems with certain tasks that involve remembering to do things, planning and completing two activities at once. It is important that these changes are accurately measured by clinicians so that strategies can be put in place for rehabilitation. Existing tests can be expensive and time-consuming while not accurately reflecting the problems people may be having in their day to day lives. This means that many people with brain injury or stroke do not get properly evaluated post-injury. The Cog-LAB task addresses this problem by measuring a number of different cognitive functions at the same time using a computerised task, in a quicker and easier way than existing measures and using a task that better fits with the *real world* things that people need to do (i.e. cooking a meal).

Do I have to take part?

This study is voluntary and you decide whether you want to take part in the research. If you do decide to participate then you will be asked to sign a written consent form to show that you are fully informed and willing to take part (this will be sent online so a tick mark could be provided in place of an electronic signature). Please be aware that if you do participate you are able to stop taking part in the research at any time without question. You are also able to withdraw any of your results up to two weeks after the final testing session. It will not be possible to withdraw results after two weeks as your data will have been anonymised.

What will I have to do if I say yes?

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If you would like to take part, you will be asked to do the following:

- Sign a consent form
- Complete a number of brief tasks that measure planning and your ability to inhibit responses and generate strategies (these will be completed online or over the telephone).
- Complete a task that assesses your ability to remember to do things in the future (this will be completed online or over the telephone).
- Complete the Cog-LAB tablet-based task. It may be the case that you will need to complete this task at a later date because we are programming changes to the task right now (this will be completed online by accessing a link that we send to you).

In total these tasks will take approximately three hours to complete, although test time might be briefer depending on your approach and can be done over several sessions if required. The researcher will liaise with you through email or over the telephone. We will provide you with general feedback about your scores if you request this.

Where will all of this take place?

Given the current situation with Covid-19, we are moving the testing to take place online or over the telephone. The researcher will give you lots of guidance on how on how to do this.

How long will the study take?

In total these tasks should take no longer than three hours to complete and can be done over several sessions if required, we may need to come back to at a later date to complete Cog-LAB online.

What will happen to my results?

Your test scores will be calculated by the researchers. All of your results will be made anonymous, this means that your information will be given a code and this code will be used on all data associated with you. All data collected from you will be stored in a locked filing cabinet within a restricted access building or stored on a password protected and encrypted PC. Your anonymised data will be stored on a database so that other researchers can refer to it.

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Is this study safe?

Yes. This research has been reviewed and approved by the Faculty Research Ethics Committee (FREC) at Sheffield Hallam University and by the Grow Med Tech Funding committee.

What are the advantages of taking part?

Findings of this research will form a standardised document that will allow the task to be used with people who have experienced a head injury or stroke. In this way clinicians can compare the performance of someone after brain injury or stroke to someone of the same age who has not had brain injury or stroke, to see whether they are performing normally on Cog-LAB.

What are the disadvantages of taking part?

There are no foreseeable risks to this research and it is not expected that any of the tasks should cause you any discomfort or distress. If you are unhappy completing the tasks you are entitled to discontinue your participation in the study. Test sessions may be quite long; to make this experience as comfortable as possible for you, you will be able to take breaks during test sessions whenever you need them, for whatever reason.

Can I know my results?

You can request a feedback document that will tell you how well you did on the tasks. We will not be able to tell you how you have done in relation to other people, as we are not allowed to discuss other people's results.

When can I ask questions?

You are free to ask any questions at any point during the research. If you have any questions now please feel free to ask. If you think of any questions after you leave here today please feel free to contact me.

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PLEASE REMEMBER THAT ALL RESULTS WILL REMAIN CONFIDENTIAL AND WILL BE MADE ANONYMOUS. YOU ARE FREE TO WITHDRAW FROM THIS STUDY AT ANY TIME DURING THE RESEARCH.

Thank you for taking the time to read this.

The University undertakes research as part of its function for the community under its legal status. Data protection allows us to use personal data for research with appropriate safeguards in place under the legal basis of **public tasks that are in the public interest.** A full statement of your rights can be found at https://www.shu.ac.uk/about-this-website/privacy-policy/privacy-notices/privacy-notice-for-research. However, all University research is reviewed to ensure that participants are treated appropriately and their rights respected. This study was approved by UREC with Converis number ER21950290. Further information at https://www.shu.ac.uk/research/ethics-integrity-and-practice

You should contact the Data Protection Officer if:	**You should contact the Head of Research Ethics (Professor Ann Macaskill) if:**
• you have a query about how your data is used by the University • you would like to report a data security breach (e.g. if you think your personal data has been lost or disclosed inappropriately) • you would like to complain about how the University has used your personal data	• you have concerns with how the research was undertaken or how you were treated
DPO@shu.ac.uk	a.macaskill@shu.ac.uk
Postal address: Sheffield Hallam University, Howard Street, Sheffield S1 1WBT Telephone: 0114 225 5555	

If you have any questions about the research that you do not wish to discuss with the researcher please contact: Peter Fearnley, Research and Innovation, Senior Administrator.

Telephone: 0114 2254219 **Email**: p.p. fearnley@shu.ac.uk

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Study investigators

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