INFORMATION SHEET

Date: [22/10/2020]

Project: Feasibility and usability of the ADDP Brain Plus App for cognitive training: a remote user study

School of Computer Science Ethics Reference: CS-2019-R32

Funded by: EU Funded ADDP Grant

We would like to invite you to participate in this study, which forms part of the ADDP Brain+ project (https://www.addp.eu). This study is a part of EU H2020 Fast track to Innovative project in collaboration with the University of Oxford, Aarhus University, Alzheimer Europe, European Brain Council and Brain+ company. The overall aim of the project is to identify the perceptions of target user groups about technologies for the detection and prevention of early Alzheimer's disease.

Before you decide whether you want to take part, please take time to read the following information carefully as it is important for you to understand why the research is being done and what your participation will involve. Ask me if there is anything that is not clear or if you would like more information.

Purpose of the research

The purpose of this research is to assess the efficacy and usability of the ADDP App developed by Brain+ (https://www.brain-plus.com). The app is a type of cognitive training to exercise your memory, attention and problem-solving skills. In the future, the app might potentially help to detect and prevent pre-symptomatic Alzheimer's Disease.

Why have I been invited?

You have been invited to take a part in this study because you are a healthy adult who is concerned that your memory might be declining, but consider yourself to be capable and do not have a diagnosis of Alzheimer's Disease or dementia. To take a part in this study you will need to have a PC and a tablet with Android 8.0 or higher.

Volunteering to take part

Participation in this study is voluntary and relies on you providing some data. You should read this information sheet to understand what data will be collected, maintained and used, and if you have any questions or need clarification you should ask the researcher. You should not agree to take part in this research until you have had all your questions answered satisfactorily. You are free to withdraw at any time, without giving a reason.

Taking Part

This project will require you to attend two remote sessions on MS Teams. The first one will consist of the cognitive tests and the baseline measurement and the second one will be the outcome measurement. Each session will last approximately 1 hour.

Session 1: You will be asked to read the Participant Information Sheet (which copy you should have also received when you signed up for this study) and sign the Consent Form using MS Forms. The link and instructions will be provided by the researcher. The researcher will then help you to install the ADDP Brain + app and the Shopping game on your tablet. We will gather some information about your lifestyle using the ADDP app. You will be asked to provide some personal data such date of birth, gender, family history of dementia, years in education, smoking habits, sports activities, dietary habits (if you eat vegetables, sugars or fish), general mood and health, leisure activities and sleeping habits. If these are known to you, we will also ask you about your long term sugar levels, ketone levels, blood pressure and cholesterol level. Next, we will assess your cognitive performance using the Monteraclo Cognitive Assessment test. We will also conduct two short (up to 5 minutes) behavioural tests to measure your working memory span, reaction time and cognitive inhibition – The Stroop Test and The Digit Span Task. Those tests will be conducted online using Pavlovia.org. and links will be provided by the researcher.

Afterwards, you will be asked to perform a working memory task. The task is gamified and will be delivered through the Starry Night Game (also implemented in the ADDP app). During the game, some celestial bodies (star constellations or planets) will appear on the screen. Your task is very simple - to remember their locations. After a few seconds break, the test screen will appear, and you will be required to drag the object to its previous location (Figure 1). In some instances, you will be distracted by a mini-game during the break, which asks you to catch stars using the circle (Figure 2). The game will last about 30 minutes.

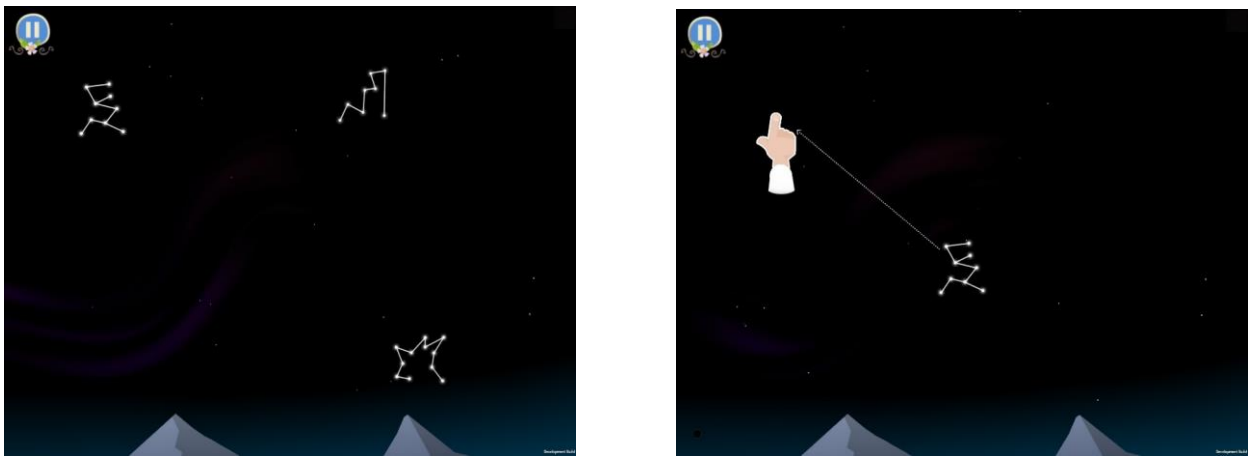

Figure 1 Starry Night Game

Figure 2 Mini Distraction Game

After you finished the Starry Night, you will be asked to play the shopping game on your tablet. The game takes 5-10 minutes to complete and consist of two main tasks. Firstly, you will be shown a shop layout (Figure 3) for 10 seconds. Your task is to remember the locations of presented sections. Next, you will see instructions on the screen to navigate to the specific location (Figure 4). To navigate you can use the arrow button in the left bottom corner of your screen and to look around you can use the touchscreen.

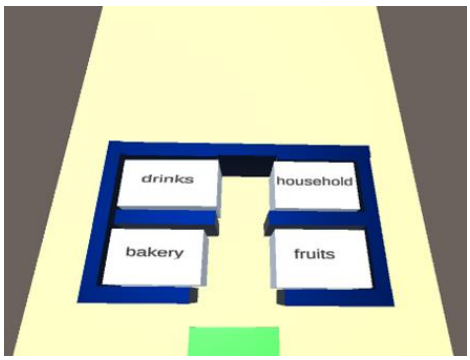

Figure 3 Shop Layout

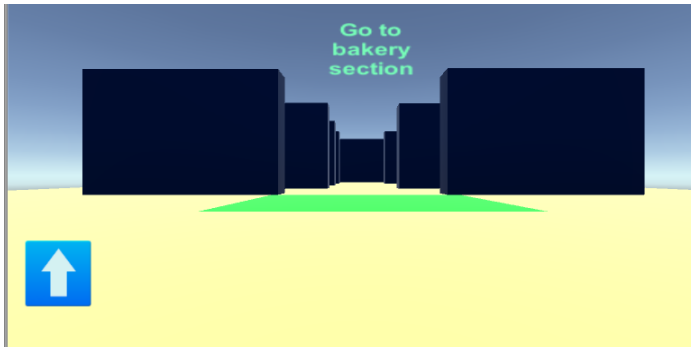

Figure 4 Navigation Task

The second task will require you to remember items on a shopping list (Figure 5) and then find and select them in the shop (Figure 6) using your touchscreen.

Olive Oil
Flour
Biscuits

Figure 5 Shopping List

Figure 6 Shopping Task

After the baseline session, the researcher will schedule the next session with you. You will be asked to play the ADDP Brain+ game for 30 minutes daily for 5 days week. During the second session, we will collect the same data to measure if playing the game improves memory and cognitive function.

Benefits and risks of the research

Your participation will help us to develop and optimise the ADDP app for possible AD and dementia detection and prevention in the future. There are no financial benefits from taking a part in this study, however, you will receive the newest version of the ADDP Brain+ app for three months and £20 Amazon voucher.

Use of your data

All the data will be kept confidential. All data collection, storage and processing will comply with the principles of the Data Protection Act 1998 and the EU Directive 95/46 on Data Protection. Details

and results of this study may be published in scientific publications, such as journals, and/or presented at conferences and seminars, and/or research web site depositories.

Future use of your data

Your data may be archived and reused in future for purposes that are in the public interest, or for historical, scientific or statistical purposes. All research data created by the project will be deposited in the University of Nottingham research data archive. UoN will retain and preserve research data in line with UoN requirement for a minimum of 7 years or longer it is of continual value to users.

Procedure for withdrawal from the research

You may withdraw from the study at any time and do not have to give reasons for why you no longer want to take part. If you wish to withdraw please contact the researcher who gathered the data. If you receive no response from the researcher please contact the School of Computer Science's Ethics Committee.

Clinical implications

This is not a clinical study. All the data collected are purely for the research purpose. The ADDP App is on its current stage of development and it is a cognitive training game rather than a screening tool, therefore we will not be able to detect any symptoms of Alzheimer's Disease or provide any clinical diagnosis regarding your mental health. If you are concerned about your memory decline, you can find more information on the Alzheimer's Society website - https://www.alzheimers.org.uk/, https://www.alzheimers.org.uk/about-dementia/symptoms-and-diagnosis/symptoms/memory-loss-dementia.

Contact details of the ethics committee

If you wish to file a complaint or exercise your rights you can contact the Ethics Committee at the following address: cs-ethicsadmin@cs.nott.ac.uk

If you have a concern about any aspect of this study, you should ask to speak to Dr Aleksandra Landowska (Aleksandra.Landowska@nottingham.ac.uk) who is leading this study, or Dr Max Wilson (Max.Wilson@nottingham.ac.uk) who will do their best to answer your questions.