

Participant Information Sheet

A Pilot Feasibility Study to Evaluate the Efficacy of Virtual Reality -based Self-attachment Intervention in a Non-clinical Population

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Co-investigator: Dr Dasha Nicholls (Imperial College London)

Co-investigator: Neophytos Polydorou (PhD student AI4Health)

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Co-investigator: Dr Barney Gilbert (Imperial College London)

Advisor: Dr Kamran Saedi (retired Psychiatrist)

You are being invited to take part in a research study of the Algorithmic Human Development group at Imperial College London. Before you decide whether you would like to take part, it is important to understand why the research is being done and what it involves. This information sheet tells you the purpose of the research study and aims to give you more detailed information about how the research study will be carried out. Do not hesitate to ask us if anything is not clear or if you would like more information. Take time to decide if you wish to take part. Thank you for reading this.

1) What is the purpose of the study?

We have developed the Self-attachment technique (SAT) for trying to increase positive emotions and moods and to reduce negative emotions and moods. In our pilot 8-week SAT project in 2020, the participants using their childhood photos felt an increase in their self-and-other compassion, cheerfulness, and problem-solving ability after the daily practice of the exercises.

For this study we have developed a mobile app with a virtual reality (VR) environment for practicing SAT in which you will interact with your childhood avatar that is created from your favourite childhood photo. The core of SAT intervention for volunteers like yourselves is based on eight weekly online Zoom group sessions and the daily practice of the SAT protocols involves interacting with your favourite and non-favourite childhood photos and the avatar created from your favourite photo. This consists of the following steps: (i) to create a compassionate connection to your childhood self, represented either by a favourite and a non-favourite childhood photo or by the customised avatar which can animate to the basic

emotions (happy, sad, angry, fearful, surprised, disgusted and neutral), (ii) to develop an imaginative, loving bond with your childhood self, using your favourite songs that express love and compassion, (iii) to maximise your positive emotions by imaginatively singing, dancing and laughing with your childhood self and finally (iv) to project your negative emotions to your non-favourite photo/unhappy avatar and then try to comfort your childhood self by verbal reassuring, giving yourself facial/head/neck massage, and uttering appropriate affirmations, thus trying to reduce your negative emotions and moods. You are asked to spend at least 15 minutes twice a day, i.e., at least 30 minutes a day, to imaginatively interact in this positive way with your childhood self.

The aim of our current pilot study is to evaluate the performance of SAT protocols where participants practice SAT protocols using childhood photos or virtual avatars via a Google cardboard, which you would purchase for a few pounds/dollars sending us your receipt for a refund, and our VR mobile app. Before the protocols, in the middle, on its completion and in a three-month follow up, you will fill out seven short questionnaires via Qualtrics to evaluate your well-being, self-compassion, cheerfulness and problem-solving ability.

This study is being undertaken as part of a PhD study.

2) Why have I been invited?

You have been invited either because you took part in the SAT workshops in May or because you have responded to our invite in social media such as Facebook and Instagram. All healthy adults in the age group 20-65 who speak fluent English, have no history of psychiatric illness, are not on psychiatric medication, have no organic brain disease such as dementia, MS or Parkinson disease and no drug or alcohol addictions, are not under any other type of psychological therapy during the 8-week course of SAT protocols and who can commit the required daily time for practicing SAT twice a day for a total of 30 minutes a day can volunteer to take part in this study.

3) Do I have to take part?

It is up to you whether you decide to join the research study. If you agree to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are free to withdraw at any time, without giving a reason.

4) What will happen to me if I take part?

If you decide to take part, you will be asked to fill in a demographic questionnaire and two self-rating health questionnaires to measure your depression and anxiety. All questionnaires will be organized using the Qualtrics platform. If you have clinical levels of depression and/or anxiety, we will advise you to go to your GP or seek help from a mental health charity like Mind. If you meet all the inclusion and exclusion criteria, then you would be eligible to be selected for our study on a first come first serve basis. Thirty individuals would then be selected for the study.

You are required to provide your favourite childhood photo as well as a disliked childhood photo. Also, you are required to purchase a Google cardboard and have either an Android or iPhone mobile device. You need a basic Google cardboard (see picture) that is compatible with the screen size of your mobile set, is closed on all sides (similar to the picture) and has a button that allows you to touch the screen (see top right corner of the picture). This costs only a few pounds or US dollars, and you can claim your expenses for this purchase by sending your receipt to Neophytos Polydorou.



5) What do I have to do?

If you are selected for the study, you are required to take part in eight weekly online Zoom group sessions at 6pm UK time on Saturdays or Sundays. Each session will last up to two hours and consist of a presentation by Abbas Edalat of the new SAT protocols to be undertaken for the following week and a discussion of the experiences of participants in the previous week. You will be required to individually practice the Self-attachment protocols described in each weekly online group session in the following week for 15 minutes twice a day. You will also be asked to fill out a simple diary to describe the experience you have during the daily practice of the protocol in each session. A short weekly evaluation of the protocol practised will be filled out by you at the end of each week

6) What are the possible disadvantages and risks of taking part?

The main issue is that taking part in the study will demand 30 minutes of your time every day for eight weeks, which is a significant commitment. This means you need to dedicate yourself to a new learning task that initially you may find challenging. In fact, you may initially find practicing the protocol difficult since it may take you up to two to three weeks for you to learn to create the imaginative affectional bond with your childhood self.

7) What are the potential benefits of taking part?

In the eight weeks, you will learn the Self-attachment protocol which will help you to maximise your positive affects and minimize your negative affects at the time of stress in life. This may enhance your well-being and empower you in your personal life and work. We cannot promise the study will help you but the information we get might help improve the protocol and develop virtual reality for enhancing positive affects in healthy individuals.

8) What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during this study then you should immediately inform the Investigator Prof Edalat (email: a.edalat@imperial.ac.uk). If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team rgitcoordinator@imperial.ac.uk.

9) What will happen to the results of the research study?

The results of the research study will be published as a paper in a relevant academic journal/conference. You will not be identified in this paper, and we will share the paper with you for your information

10) Who is organising and funding the research?

Imperial College London is the study sponsor. This research is organised by the Algorithmic Human Development research group at Imperial College London. It is supported by the voluntary work of the non-profit Empowered Human Foundation (www.empowered-human.org).

11) Who has reviewed the study?

This study was given approval by the Science, Engineering and Technology Research Ethics Committee (SETREC) and approval by the Head of Computing Department

Contact for Further Information

Prof. Abbas Edalat at: a.edalat@imperial.ac.uk or

Neophytos Polydorou at: neophytos.polydorou19@imperial.ac.uk.

Thank you for reading this.

You may retain this information sheet for reference and you can print a copy of you online consent via Qualtrics

Transparency Notice

How will your information be used about you?

Research Study Title: A Pilot Feasibility Study to Evaluate the Efficacy of VR-based Self-attachment Intervention in a Non-clinical Population

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Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

We will need to use information from you for this research project.

This information will include your initials, name, gender, age, education, contact detail, country of residence, marital status, past surgery, past psychiatric illness, past or current psychotherapy. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results.

We will write our reports in a way that no-one can work out that you took part in the study.

Legal Basis

As a university we use personal information to conduct research that will either be in the public interest, or the legitimate interests of the College.

As a publicly-funded organisation we have to ensure that when we use personally-identifiable information from people who have agreed to take part in research, it is either in the public interest, or that our legitimate purposes are both properly notified to you and are not overridden by your rights.

We will conduct scientific research in compliance with the law and the recommendations and guidance published by the UK Information Commissioners Office (ICO). This will follow similar rules to health and care research but may not meet the definition of the College's public interest task. In such cases we will be holding and using your data for what are deemed our "legitimate interests".

International Transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

Sharing your information with others

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information by asking one of the research team.

Complaint

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via

telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.