Site: University of Oxford
Chief Investigator: Professor Andrea Cipriani

PARTICIPANT INFORMATION SHEET

PAIDEIA - Personalised Artificial Intelligence versus Designed by Experts Individualised Approach: using digital health to improve and protect mental wellbeing during and after COVID-19 pandemic – PART I

Invitation

You are being invited to take part in a research study. Before you decide if you want to take part in the study or not, it is important to understand why the research is being done and what it will involve. Please read the following information and take your time to consider if this is the right study for you.

What is the purpose of the study?

Due to the COVID-19 pandemic, there have been many challenges associated with managing both mental and physical health for many people. As a result of this, the PAIEDIA study to test a support tool has been developed. The PAIDEIA support tool is aimed to help you understand the impact of social distancing on your mental and physical health as well as the general quality of life and assist with helping you to improve your wellbeing.

We know that the COVID-19 pandemic and social distancing measures impact people differently. Therefore, we have developed a physical exercise and mindfulness intervention that could help with reducing some of the negative aspects on you general wellbeing. Both physical exercises and mindfulness has shown that it could help with improving their mental and physical health. Therefore, we would like to identify if the tools we have developed would help people.

What are the aims of this study?

This is a pilot study delivered online as we recognise participants are no longer able to travel or meet researchers in person. Therefore, one of our aims would be to evaluate the use of online interventions tools by people and if digital methods of care could become standard practice. We recognise this may not always be the preferred method of communicating and

possibly obtaining support. But we equally recognise the need for support that can be provided remotely during this difficult time.

Another aim of the PAIDEIA study would be to use the results from this study to further improve the tools we developed for future populations of patients and potentially, conduct a wider study with a view to use this in the event of any future global or regional pandemics/epidemics where, people living in isolation for a period of time has had a mental health and/or impact on their general wellbeing.

As this is also a pilot study, we aim to recruit 2000 participants online. If you choose to take part, the study will be for 10 weeks, during which time you would need to log into the mindLAMP app to answer some questions and complete some tasks.

What is Artificial Intelligence?

AI is a term use to describe a range of technologies coming together to help deliver tasks which otherwise would be completed by humans. AI goes about completing tasks by taking information from people and decision based on what it has learnt, what advice to provide to give the best possible outcome. AI is becoming a big part of people's lives and it is no different in healthcare. Computers or machines have the ability to 'learn' and complete tasks better. Alexa or Siri are good examples of AI tools.

In the case of PAIDEIA, we have used AI to develop a way to provide advice on how best to improve your mental health and wellbeing.

Why have I been invited?

You have been invited to take part because you are;

- Male or female aged 18-65 years old
- A healthcare professional and/or;
- A student (undergraduate or postgraduate)

Do I have to take part?

Participation in this study is entirely voluntary and it is up to you to decide whether or not to take part. You also have the right to withdraw from the study if you changes your mind at a later date, without giving a reason.

What will happen to me if I decide to take part?

- It is up to you to decide whether or not to take part in the PAIDEIA study.
- If you do decide to take part, you will be asked to complete and sign an electronic consent form. This form will be stored electronically in a confidential manner.
- After successfully completing and submitting the electronic consent form, you will receive an email with details of your unique participant identification code and a full explanation of how to download and access the mindLAMP platform.
- Throughout the study, you will be required to complete the following study procedures summarised in the table below.

- Step count will be recorded throughout the study using location tracking on your mobile device. However, we will not be collecting or storing data about your whereabouts during the study.
- Every 2 weeks, you will be asked to complete a feedback questionnaire. This will be used to personalise the interventions and will continue to be tailored for you throughout the study.

Study procedures	**Platform**	**Data collection timepoints**					
		Screening	**Baseline**	**Week 1-2**	**Week 3-4**	**Week 5-6**	**Week 7-8**
Eligibility assessment	Study Website	**x**					
Informed consent	Study Website	**x**					
Demographics	mindLAMP		**x**				
Mood & wellbeing questionnaires	mindLAMP		**x**		**x**		**x**
Fitness & physical activity questionnaires	mindLAMP		**x**				**x**
Physical exercise survey	mindLAMP		**x**	**x**	**x**	**x**	**x**
Step Count (passive data)	mindLAMP		**x**	**x**	**x**	**x**	**x**
Physical Activity feedback questionnaire	mindLAMP			**x**	**x**	**x**	**x**
Mindfulness feedback questionnaire	mindLAMP			**x**	**x**	**x**	**x**

What should I consider?

Before deciding whether you would like to take part, please consider the following requirements:

- Being willing and able to provide informed consent
- If you are able to read and write in English and have a minimum 7 years of formal education
- Having access to a mobile device (Android 7.0/iOS 14 or later required)
- Being willing and able to complete the study required as specified in the participant information sheet

Please be aware of the following, which may prevent you from participating in this study:

- Currently receiving any treatment (including psychological) for any mental health conditions including but not limited to major depressive disorder, generalised anxiety disorder, schizophrenia, substance abuse, schizoaffective or bipolar disorder or ever experiencing previous psychotic episodes
- Currently receiving medical treatment for a diagnosed medical condition including (but not limited to) asthma, diabetes, hypertension, joint problems
- Having a condition that may deem physical exercise to be unsafe e.g., symptomatic cardiovascular disease
- Visiting the GP for symptoms of depression in the past 6 months
- Deliberately self-harming in the past year or ever attempting suicide
- Experience of a bereavement or another significant traumatic event in the past year
- Having any surgery or invasive procedures within the previous year
- A severe loss of vision, hearing or communicative ability or any other condition which may inhibit the completion of the study procedures as detailed in the participant information sheet)
- Being enrolled in an interventional clinical trial within the last 30 days

Are there any possible disadvantages or risks from taking part?

We do not expect there to be any known potential disadvantages in taking part in this study. You also have the right to not take part or withdraw from the study at any point. The questions we may ask you may of course trigger worry or sadness, but this will be unlikely to be more than how you may be feeling given the current experience.

What are the possible benefits of taking part?

There may be a direct benefit to your health and mental wellbeing by taking part in the PAIDEIA study, especially if the pandemic has impacted you in a very negative way.

Will my taking part in the study be kept confidential?

Your unique identification code will be used to make sure you cannot be identified outside the study. All information, which is collected, about you during the course of the research will be treated as strictly confidential.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 1 year after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 25 years after the end of the study. Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting the PAIDEIA team at paideia.brainhealthctu@psych.ox.ac.uk.

What will happen to the results of this study?

At the end of the study the information collected will be analysed for publication in a recognised medical journal. However, other methods of communication such as social media platforms will be used. Your study doctor will be informed of any publications as well. We will be able to supply a copy of these publications to you on request. The identity of the patients who took part in the study will remain confidential.

What if we find something unexpected?

You will be closely monitored both during and after therapy will be treated as appropriate. You will not be harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the Oxford Brain Health Clinical Trial Unit by email at enquiries.brainhealthctu@psych.ox.ac.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or email ctrg@admin.ox.ac.uk.

How have patients and the public been involved in this study?

In designing this study we have taken into account patient opinions on the frequency of participant visits and the tests that we will carry out. Potential participants were involved in reviewing the Participant Information Sheet.

Who is organising and funding the study?

The PAIDEIA study has been funded by and is sponsored by the University of Oxford.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the Proportionate Review Sub-Committee.

Further information and contact details:

If you have any question, please contact the PAIDEIA team at paideia.brainhealthctu@psych.ox.ac.uk.

Thank you for considering taking part.