**Participant Information Sheet**

**Title of study: Using participatory digital platforms to enhance resilience and mental health of Scottish (NHS Highland) health and care staff during COVID-19**

**Introduction**

You are being invited to participate in a research project. Before you decide, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully. If anything is not clear, feel free to ask any questions to the researchers. You can find their contact details at the bottom of this document.

**What is the purpose of the study?**

We know from previous pandemics (e.g. SARS, MERS) that the psychological toll on health and care workers is immense – with unprecedented health resource, mortality and economic costs. The purpose of this study is to test a digital platform that will facilitate the psychological self-care of NHS Highland staff like yourself and mitigate the potential negative mental health impacts of working through the COVID-19 pandemic. Through the platform you will be able to actively participate in the development of personalised mental health strategies that both treat psychological distress and enhance resilience during the COVID-19 pandemic.

Currently there is little evidence on the experience of this pandemic for health and care workers. This is why we are investigating whether digital psychological interventions have a positive influence on health and care staff’s psychological well-being and resilience during the COVID-19 pandemic.

**Why have I been invited?**

You have been invited to take part because you work as health or care staff within the NHS Highland.

**Do I have to take part?**

No, it is up to you whether you would like to take part and there will be no consequences for choosing not to take part. If you decide to participate, you will be required to sign a consent form. You can withdraw your consent at any time without having to give a reason.

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

If you agree to take part to this study, you will be asked to complete baseline measures, in the form of an online survey. This survey will take less than 10 minutes to complete, and it will include a questionnaire about your psychological wellbeing, mental resilience as well as your levels of depression and anxiety symptoms. These questions are not an assessment of your skills, but will ask you to rate your own experience, feelings, and emotions on your current state.

After the completion of the survey you will be allocated at random by a computer programme to either the intervention group, the treatment as usual (TAU) or the control group. The reason for this is that we aim to find out which treatment is more effective by making a fair comparison between the intervention group, the treatment as usual (TAU) and the control group. This form of study is also known as a randomised controlled trial (RCT). You will have an equal chance to be assigned to either the intervention, the TAU or the control group.

The RCT will last for 4 weeks during which the control group will not receive treatment.

* INTERVENTION AND TAU GROUPS – If you are allocated to either of these groups you will receive apps to download which you will be using for the 4 weeks.
* CONTROL GROUP – If you are allocated to the control group you will be placed on a waiting list and will only download the intervention app after the trial has finished in 4 weeks.
* All groups will be prompted 3 further times to fill out a quick questionnaire of your psychological wellbeing at the beginning of the RCT, after 2 weeks and again after 4 weeks. This should take around 10 minutes of your time.

Detail about the RCT process:

On 17 August 2020, the participants from the intervention and TAU groups will receive a link with a password to download a different version of on online app (corresponding to the intervention group, or the treatment as usual group). The TAU group will receive a digital app validated to improve mental health, while the intervention group will receive a modified version of this app. The control group will receive an email informing them that they will not receive treatment over the next 4 weeks and that they will be placed on the “waiting list” to receive the intervention after the completion of the RCT. You will be asked to download the app and follow the instructions for 4 weeks (until 14 September 2020). If you are randomly allocated to the control group or the treatment as usual group, at the end of the study (14 September 2020) you will receive a link with a password and have access to the intervention programme. All groups will have the option of continuing to receive the intervention or the TAU (the digital app) free of charge after the study has ended for a duration of 3 further months.

**What will I have to do?**

The study will last four weeks and will require brief daily online activities carried out on a digital “app” on your mobile phone. After filling out the first online questionnaire you will be asked to complete daily tasks on the app, which should take a maximum of 15 minutes. After two weeks you will be asked to fill in the initial questionnaires again, and then again in the last week of the project.

**What are the possible disadvantages and risks of taking part?**

The main disadvantage of the study is the time commitment it can require. You will be asked to use the platform every day for between 5-15 minutes for a total of four weeks. You might find it difficult to do so. If, for any reason you feel overwhelmed or suicidal during the study, you can press on an 'SOS' button on the app or survey site which will lead to crisis support resources. This will include crisis numbers of NHS 24 (111), Samaritans and Breathing Space but also the number for the NHS Highland Wellbeing services. When you click on the SOS button a member of the research team will pass your details to the NHS wellbeing team for contact within 48 hours.

**What are the possible advantages of taking part?**

We hope that this intervention provides you with support proven to enhance your psychological wellbeing. We also hope that you will enjoy taking part in the activities embedded in the intervention. However, we are also aware that there may not be advantages in taking part to the study. The outcomes from this study will be used to inform further studies and developments in this area.

**Will my taking part in this study be kept confidential?**

All the information that is collected about you during the course of the research will be kept strictly confidential and will not be made available to anyone who is not directly connected with the study. The personal information required for the registration to the application will only be used to process data during this study for a total of ten weeks (4 weeks for the study, 4 weeks for the roll-out of the intervention to control and TAU groups and 2 weeks for data-analysis). The data will be retained only for study purposes, as part of the intervention updates will be sent via phone and email to participants. These features are part of the participatory design that makes the intervention tailored to their users. UHI will be controlling the data, and as per legal requirements we have stringent data sharing agreements in place. InTechnology plc, the platform used for this study is NHS trusted, certified IS 597957, compliant with ISO/IEC 27001:2013, ISO 27001 and Cyber Essentials and will maintain these standards throughout the processing period. After the duration of the study the personal information will be removed from our records. Data generated will be kept within a secure area of UHI Sharepoint system accessible only to the UHI project researchers. These documents will be subject to the UHI research data retention policy.

**What will happen to the results of the research?**

The study will be registered on a public web-based database where the study design and results can be viewed. The results will also be published in a peer reviewed journal and presented at conferences, but you will not be identified. We will produce a summary of the research findings for the participants of the study and can send this to you if you wish.

**What will happen if I don’t want to carry on with this study?**

You are free to withdraw from the study at any time without giving a reason and will not be penalised in any way. You will not be asked to complete any further activities or questionnaires but the ones that you have completed will be used.

**Who is organising and funding the research?**

The study is funded by the Chief Scientific Office, part of the Scottish Government Health Directorates and organised by Dr Johannes De Kock, University of the Highlands and Islands, who is the Chief Investigator of the research project, and is responsible for overseeing the project. The Chief Scientific Office will have no direct involvement in the conduct of the study.

**What if there is a problem?**

If you have any concerns or wish to discuss the project with someone then you can speak to the research assistant\* who will do their best to answer your question or resolve any difficulties that you have. If you are not satisfied with the response then you can contact the investigators (see details below) who will do their best to address the issues.

**Research team details:**

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**Data protection**

The legal reason for using the data you provide is that it is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. That being the delivery of a course of study or research undertaken at, or by, the university or its students.

**Special category data**

Special category data is personal data which the GDPR says is more sensitive, and so needs more protection. The data collected will include health data which is classed as special category data. The legal reason for using special category (sensitive) data is that it will be processed for scientific or historical research purposes in the public interest.

Data controller : Dr. Johannes H. De Kock for UHI

The data will not be sent outside of the EU. The processing will not involve automated decision making

Your data will be retained for 10 years. This retention period is in respect of the research data as collected. Anonymized data may be kept for longer and the retention period does not apply to any materials published as a result of this project.

The following are your rights in respect of this processing:

• The right to access your personal data

• The right to rectification if the personal data we hold about you is incorrect

• The right to restrict processing of your personal data

• The right to request erasure (deletion) of your personal data

• The right to data portability

For any data protection enquiries please contact UHI’s Data Protection Officer at dataprotectionofficer@uhi.ac.uk

You also have the right to lodge a complaint with the Information Commissioner’s Office about our handling of your data.

**This study has been reviewed by South West – Frenchay Research Ethics Committee**