



Information Sheet for Participants

We would like to invite you to participate in a embedded trial investigating whether positive effects are observed based on use of a wellbeing app called Foundations. This is a randomised trial for a portion of participants from the NHS CHECK study. Please take time to read the following information before deciding to take part, and contact the research team on nhscheck@kcl.ac.uk if you have any questions.

What is the purpose of this study?

The research aim is to evaluate whether the use of Foundations mobile application impacts stress, wellbeing, anxiety, depression, functioning, resilience and sleep in a real-world, healthcare worker cohort.

Why have I been chosen?

You have been invited to take part because you are a staff member at, or working with, one of the eighteen participating NHS CHECK sites, who took part in the baseline questionnaire and consented to be contacted by the research team about other studies/important information relating to NHS CHECK.

What will happen if I take part?

If you agree to take part in this eight week study, you will be randomly allocated to either receive full access to a wellbeing app (Foundations) or to a control wait-list group where you will not have access to the wellbeing app during the study but will have access upon study completion. Regardless of which group you are allocated to, you will be asked to answer questions on stress, resilience, wellbeing and sleep or assigned to the control group.

Foundations contains a set of science-based wellbeing activities designed to manage stress and improve mental wellness. The app collects logs about the consumed content and timestamps of the app usage. You will be encouraged to use the app and the app may receive push notifications (from the app) 3 times a week (if you opt in).

Please note that if you consent to participate, you may continue with any current interventions and apps you are currently using, but you are encouraged not to start any new ones.

The Foundations app contains a privacy policy which you will be asked to accept when you first access the app, some elements of which are overridden by participation in this study. This will allow the researchers to determine if there is a wellbeing benefit arising from app usage.

We ask you in the consent to the following data which is collected by the Foundations app being shared with the research team:



- the email address you use to sign up to the Foundations app. This will allow the research team to combine the data from the Foundations app with survey data collected by the research team in relation to stress, resilience, wellbeing and sleep;
- information related to how you perceive your levels of stress, such as the Perceived Stress Scale assessment;
- information about how you feel and your mood (for example, happy, stressed etc.)
- details of how you use the Foundations app (for example, how often you use it, the time spent on each activity, and which functions you use);

Do I have to take part?

Participation is completely voluntary. You should only take part if you would like to. Choosing not to take part will not disadvantage you in any way.

What are the possible benefits of taking part?

All participants who take part will receive access to the Foundations app free of charge. The app contains evidence-based exercises that may help you to manage stress and build your resiliency.

You will also be helpful us understand whether the app is a good way to help you and your colleagues as we respond to the acute stress of COVID-19 pandemic and beyond.

You will also receive financial remuneration for taking part, up to a total of £25.

- Completing baseline survey (£5 voucher)
- Completing week 4 survey (£10 voucher)
- Completing week 8 survey (£10 voucher)
- If you complete all surveys (baseline, week 4 and week 8), you will receive a £25 voucher.

What are the possible risks of taking part?

We appreciate that you are willing to share your experiences and feelings with the research team and we do not foresee any risks occurring from your participation. If you would like emotional support, or completing the survey causes distress, we encourage you to reach out to someone you trust. You may also wish to seek support from your GP or the occupational health department within your Trust. We cannot however respond to information provided by you about your physical and mental health during this research, but what we can do is provide suggestions of outside support which can be found below:

The NHS website at www.nhs.uk contains resources for supporting your mental health and also has a dedicated helpline for NHS staff affected by COVID-19. To contact the NHS helpline, phone 0300 131 7000, or text FRONTLINE to 85258.



Mind's website at www.mind.org.uk has useful resources to help you cope if you are feeling anxious, worried or isolated.

See Samaritans at www.samaritans.org if you are worried about your mental health. You can also call the Samaritans day or night if you need someone to talk to without judgement on 116 123.

The World Health Organisation at www.who.int has a document detailing mental health and psychosocial considerations during this pandemic.

We take your safety and wellbeing very seriously, and should you have any questions or concerns, please contact the research team on nhscheck@kcl.ac.uk.

How will we use information about you?

To evaluate the impact of the app usage, researchers involved in this study will use the app logs (specifically, the data that is set out above in the section titled "What will happen if I take part?") and your answer to survey questions on stress, resilience, wellbeing and sleep. Note that your date of birth and email address will also be collected for the logistical reasons of conducting this study. We will keep all information about you safe and secure by ensuring research data is stored separately from your personal information. All research staff will undergo data protection training and any data held electronically will only be accessible by specified members of the research team. Importantly, the access to this information will be limited to the personnel involved in the study organisation. Research scientists performing the data analyses do not need to know who you are and will be unable to see your name or contact details – your data will be assigned a code number instead. Once we have finished the study, we will keep the app logs and questionnaire answers in order for the researchers involved in the study to conduct the analyses. The researchers involved in the study will write the reports and scientific papers without exposing identities of the participants.

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 anonymous 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.

You can delete the app using the Foundations "delete my account" function in the settings menu. If you select this then all of your personal data will be deleted within 30 days. If you uninstall the app from your device then your data is deleted after 12 months of inactivity. This is in case you decide you would like to use the app again. Data is stored in an encrypted database and all the required technical and organisation controls are in place to protect personal data. There are strict access controls on who can access what data (a need-to-access basis).

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



You can find out more about how we use your information. Questions, comments and requests about your personal data can be sent to the King's College London Data Protection Officer Mr Albert Chan info-compliance@kcl.ac.uk. If you wish to lodge a complaint regarding information rights, please contact the Information Commissioner's Office via www.ico.org.uk.

We will retain your data for 10 years to allow for data analysis and dissemination of our results to the wider scientific community. We may share anonymised data with our trusted research partners, via an official request for authorisation. This data will not be able to be traced back to any individual. Any data sharing and transfer arrangements are compliant with GDPR and King's College London policies. If you would like more information about how your data will be processed in accordance with GDPR please visit the links below:

www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research
<https://www.kcl.ac.uk/terms/privacy.aspx>

How is the project being funded?

This embedded trial is funded by Koa Health.

Whom should I contact for further information?

If you have any questions or require more information about this study, please contact the research team via nhscheck@kcl.ac.uk.

What if I have further questions, or if something goes wrong?

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can email Professor Simon Wessely at King's College London at the following email address: nhscheck@kcl.ac.uk.