(Note: This Information Sheet and Informed Consent Forms will be provided online on the research study website. The text will be reproduced verbatim and the design will follow the layout used in this document as closely as possible).

PARTICIPANT INFORMATION SHEET

Research study title: Pilot evaluation of a personalised, prevention mHealth partner, SYD, and its impact on Quality of Life on NHS staff

Short study title: SYD (See Yourself Differently) for NHS

Ethical Approval Reference: 21/HRA/0308
IRAS number: 294071

We would like to invite NHS staff such as yourself, to take part in our research study. Joining the study is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it means for you. Please read this information carefully and take as much time as you need to consider if you would like to participate.

- The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part.
- The next part gives you more detailed information about how the study is conducted.

PART 1

Study aim
This research study explores the benefits of a conversational health application focused on promoting good health, called SYD, which stands for 'See Yourself Differently'. SYD is a mobile health (mHealth) platform with a mobile app component that uses Artificial Intelligence (AI) to provide evidence-based lifestyle and wellbeing recommendations, personalised to each user, aimed to empower the user to take control of their own wellbeing through small but meaningful steps. The recommendations are based on high quality evidence analysed by a team of expert scientists with the AI engine used to select a particular relevant recommendation, based on the likely benefits and choices of previous users.

The aim of this study is to establish how SYD can measure and potentially improve key aspects of general Quality of Life, such as physical health, psychological health

(stress, anxiety and depression), social relationships and environment, specifically for NHS staff.

Why is this important?
The majority of ill health suffered by people across the world can be prevented by changes in lifestyle, for example diet, sleep and physical activity. This study looks at the benefits SYD could provide to healthcare workers as evidence shows that individuals who work in healthcare roles have an increased risk of developing physical and mental conditions that are detrimental to their health and quality of life. For example, healthcare workers are more likely to develop stress, anxiety and depression compared to the general population. This is particularly relevant at present when many healthcare workers have encountered increased psychological distress during the COVID-19 pandemic.

Summary of the study
Participants taking part in this research study will be assigned to one of 2 groups at random. Participants in Group A will be invited to download and interact with SYD at the time of joining the study. Participants in Group B will be invited to download and interact with SYD 3 months after joining the study. All participants are asked to complete study assessments to assess changes in their quality of life over 6 months. Assessments will be completed monthly throughout the first 3 months. The final assessment will be completed at the end of Month 6.

Why am I invited?
You are invited because you are a member of NHS staff and aged 18 years or older.

Eligible participants
You will need to meet all of the following criteria to be eligible to take part in this study:

- Be an active NHS staff member
- Be at least 18 years old
- Own a smartphone device which you can use for this study.
- Have an NHS email address which you can use for this study
- Have sufficient English language ability to familiarise yourself with the study and to engage with the SYD application and the study assessments
- Have mild to moderate levels of anxiety or depressive symptoms, as assessed via a standardised assessment called Hospital Anxiety and Depression Scale (HADS).

You will not be eligible to take part in the study if you:

- Are currently receiving any psychological intervention, for example counselling therapy
- Are currently receiving clinical treatment as part of another clinical trial

- Considered clinically extremely vulnerable from COVID-19 by the government guidance.

You will be asked to confirm this before you join the trial. These eligibility criteria have been chosen to select a group of NHS staff who are most likely to benefit from and able to engage with the SYD recommendations. We realise that your situation may change during the course of the study, for example some participants may start psychological treatment or finish their NHS employment. If this is the case, you can remain in the study if you wish to. Please note that SYD is intended for general information and educational purposes only, not as medical advice or a substitute for medical advice provided by a doctor or other qualified health practitioner. This is explained in the 'What are the risks and benefits of taking part?' section of this information sheet and you will be reminded of this if you report a change during the course of the study. If your NHS employment ends during the course of the study, you can provide us with an alternative email address to continue in the study.

PART 2

Who is running this study?
The study is sponsored by Southern Health NHS Foundation Trust. The Chief Investigator is Prof Shanaya Rathod. The SYD app has been developed, and is run by, iamYiam, a digital technology company based in the UK.

How does SYD work?
SYD is a platform with a mobile app component that uses Artificial Intelligence (AI) to provide evidence-based recommendations, personalised to each user, to improve wellbeing. Users receive a personalised health assessment and can track their quality of life in 9 different key areas: physical health, emotional health, financial health, purpose, social life, brain power, self-esteem, environment, and career. SYD encourages users to choose specific health goals and helps them obtain these through researched and evidenced, personalised lifestyle recommendations by engaging with you via its conversational agent.

Why now?
SYD is already used by thousands of users in the UK and internationally. It is mostly provided by corporate employers (for example banks) to their staff as part of their employee wellbeing programmes. Evidence from our existing users SYD can improves wellbeing and increase quality of life for most users.

These results led the research investigators at Southern Health NHS Foundation Trust to collaborate with the iamYiam researchers to conduct this study. They aim to determine if mobile health technology can improve quality of life of NHS staff reporting anxiety and stress. This is particularly important during the COVID-19

pandemic in which NHS staff face an unprecedented health crisis and psychological distress.

More information about iamYiam and SYD can be found on https://syd.iamyiam.com.

Below are some examples of images from the SYD app:

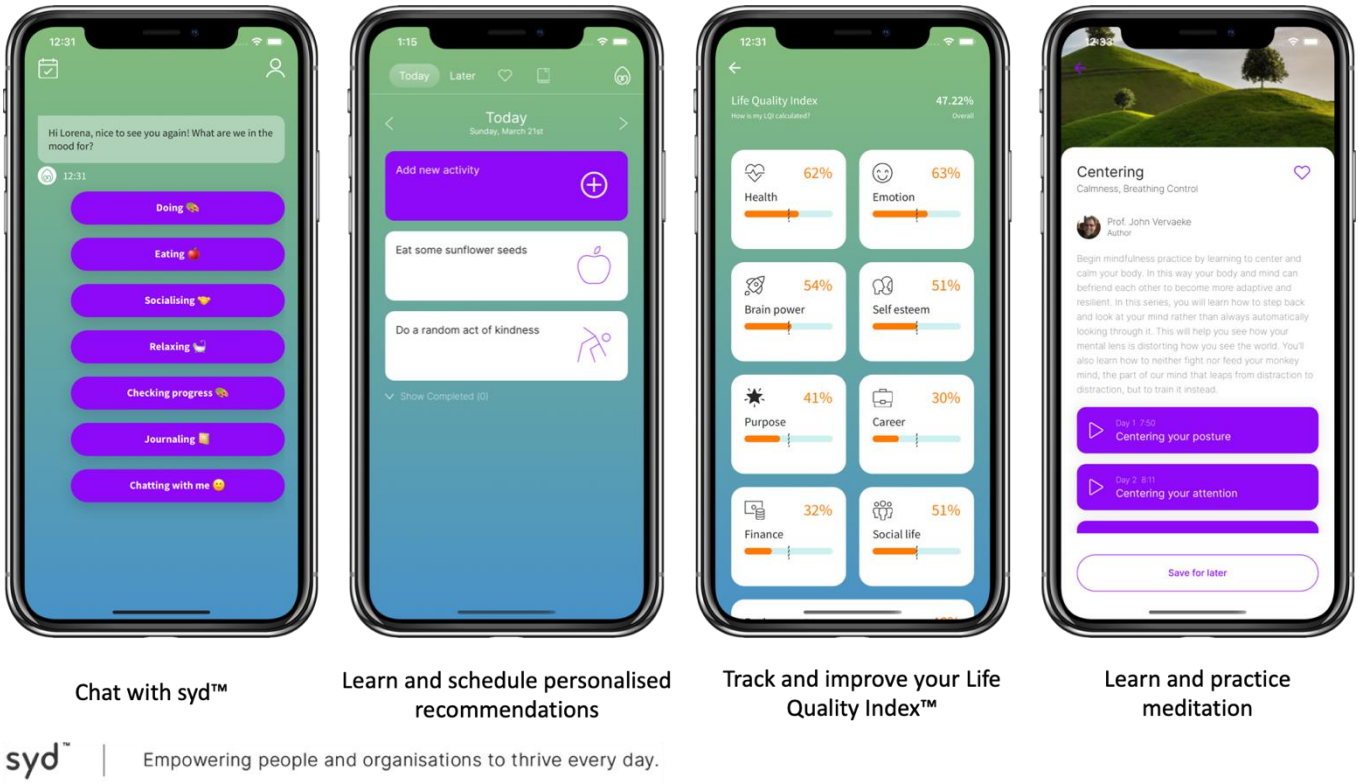

Figure 1 – The SYD mobile app.

What would taking part involve?
As part of the study you will be asked to:

1. Engage with the SYD application on your smartphone
2. Complete study assessments involving questions regarding your quality of life and wellbeing using a study website

This survey website is smartphone friendly so you can complete the assessments on your mobile phone if preferred. Assessments completed via the study website will be evaluated independently by the research team at Southern Health NHS Foundation Trust.

Joining the study

Screening Phase:

If you decide to take part in this research, we will first ask you to provide informed consent to complete a brief screening assessment on the study website to indicate if you meet the eligibility criteria.

We will ask you to confirm that:

(1) You have read and understood information contained in this information sheet.
(2) You are an active NHS staff member and have NHS email address which you can use for this study.
(3) You are at least 18 years old.
(4) You own a smartphone device which you can use for this study.
(5) You are currently not receiving any psychological intervention (for example counselling)
(6) You are currently not receiving any clinical treatment as part of any other clinical trial
(7) You are not considered clinically extremely vulnerable from COVID-19.

You will be asked to complete a brief standard assessment called 'Hospital Anxiety and Depression Scale' (HADS) to assess if you suffer from mild levels of anxiety or depressive symptoms.

Answers to the above questions and the HADS assessment will determine whether you are eligible to join the study. We will ask you to provide your name and email address so we can keep record of the assessment. We will also ask you if you would like to be contacted about future ethically approved research in the field of digital health technology or mental health. If you are not eligible to join the study, you will not be contacted regarding this study any further. If your screening assessment scores indicate that you might suffer from more severe anxiety and depression, you will be advised to contact your GP to discuss further support. All eligible participants will be invited to complete an informed consent prior to joining the study.

After you have joined the study

Assessment before interacting with SYD

After you have provided informed consent to take part in the study, you will be asked to complete a brief questionnaire about yourself and standard Quality of Life assessments to provide your wellbeing scores at the start of the study.

Group allocation

To understand how SYD impacts on staff wellbeing, we would like to compare two groups of participants over the same period of time – a group interacting with SYD for a period of 3 months (Group A) and a group with no access to SYD for a period of 3 months (Group B). After the initial period of 3 months, both groups will have

access to SYD for further 3 months for the rest of the study duration. All participants will have free-of-charge access to SYD after the end of the study.

Participants will be assigned at random to one of these groups. This means that you are equally as likely to be assigned to either group. You will not know which group you will be in when you provide consent to join the study. An email clarifying the group allocation will be sent to you immediately after you have completed the Quality of Life assessments at the start of the study.

Activities and assessments for the two Groups

Participants assigned to Group A will be provided with a sign-up code to download the SYD app immediately after providing consent and will be encouraged to interact with SYD particularly over the first 3 months of the total period of 6 months.

Participants assigned to Group B will complete brief quality of life assessments for the first 3 months in the study. They will be invited to interact with SYD for the remaining 3 months of the study. It is vital that participants in Group B complete study assessments during the first 3 months as this will allow us to evaluate if SYD is effective in helping NHS staff or not, and if it makes more or less difference to users as the year moves on and hopefully COVID-19 pandemic pressures decrease.

Flowchart of SYD interaction

	Month in study						**Post study**
Access to SYD	**1**	**2**	**3**	**4**	**5**	**6**	
Group A	x	x	x	x	x	x	Ongoing access to SYD
Group B				x	x	x	Ongoing access to SYD

Study assessments

Participants in both Groups will be asked to complete the following self-assessments on the study website:

		Month in study					
Study assessments	**Baseline**	**1**	**2**	**3**	**4**	**5**	**6**
Questions about your quality of life	x	x	x	x			x
Questions about your mental health	x	x	x	x			x

Participants in both groups will be provided with detailed instructions on installing and using the SYD app at the time when they are invited to interact with the app.

In order to provide enough information to evaluate the effect of SYD, we would ask you to interact with the SYD app at least once daily and undertake 3 to 4 recommendations each week. We fully appreciate that this might not be possible due

to various reasons, including work pressures such as shift work. You can still be part of the study even if you are cannot interact with SYD regularly throughout the whole study duration. It is entirely up to you to decide which recommendations you would like to act on.

We will also ask you to provide feedback on SYD through the dedicated area in the app. Both your feedback and how often you interact with SYD will be used to evaluate if SYD can help NHS staff.

After the Study
Participants in both groups will have free access to SYD after the end of the study for their personal use. No information will be collected for the purpose of this study after 6 months.

What are the risks and benefits of taking part?
We do not anticipate there being any risk associated with participating in this study. All information provided on the SYD app is intended for general information and educational purposes only, not as medical advice or a substitute for medical advice provided by a doctor or other qualified health practitioner. You should not delay seeking medical advice, disregard medical advice or discontinue medical treatment as a result of information provided by SYD. If you have any questions about any medical matter, please consult your doctor prior to joining the study. This is explained in the SYD User Terms, which you will be asked to read carefully and accept before accessing SYD. You can read the User Terms here: https://syd.iamyiam.com/en/terms/

As part of this study you will receive a personalised health assessment and evidence-based recommendations for actions you can take to improve your quality of life and wellbeing. All study participants will be able to continue accessing SYD free-of-charge after the end of the study.

SYD is already used by thousands of users in the UK and internationally. Evidence from our existing users shows that SYD can help improve wellbeing and increase quality of life, however we do not know if there will be improvements in quality of life for healthcare workers and for you personally as there are no previous studies investigating the use of SYD, or another preventative mobile health technology, amongst healthcare staff.

The data from this research will provide an evidence base on the use of mobile health technologies as a prevention tool. The findings of this study will be used to assess and modify SYD to better suit the needs of healthcare professionals and other users. If the study shows that SYD can help improve the wellbeing of healthcare workers, we will work with NHS organisations to explore if it can be offered to other healthcare staff.

Do I have to take part?
No, it is entirely up to you to decide whether to take part or not. You are also free to withdraw from the study at any time, without giving a reason and without consequence. You can withdraw from the study assessments by contacting the study research team by either sending an email to research@southernhealth.nhs.uk or via the "opt-out" link included in email communications about the study. If you withdraw from the study, we will keep the information that you have provided up until that point. You can also contact iamYiam to cancel your SYD account and withdraw your consent for iamYiam to process your personal data. You may ask iamYiam to delete your personal data records, however some of your data will remain on an anonymised basis within the aggregated datasets and AI algorithms.

Will my taking part in the study be kept confidential?
All information which is collected about you, during the course of the research will be kept strictly confidential.

Southern Health NHS Foundation Trust is the Sponsor for this study. We will be using information from you in order to undertake 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. We are collecting and storing this personal identifiable information in accordance with data protection law which protects your rights. 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.' All data use is strictly within the terms of the Data Protection Act (DPA, 2018). Further information about your rights with respect to your personal data is available at: https://www.southernhealth.nhs.uk/patients-and-carers/privacy-notice/

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the health information about you that you have provided up until that point. To safeguard your rights, we will use the least amount of personally identifiable information as possible. At the end of the study the anonymous data will be kept for up to 5 years and then will be destroyed.

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. For example, if many people left a study because the intervention wasn't helpful and we didn't collect that data, we wouldn't be able to show that the intervention was causing the problem.

You can find out more about how we use your information by emailing the study team: research@southernhealth.nhs.uk

iamYiam will act as the Data Controller for data submitted via the SYD platform. This means that iamYiam is responsible for looking after your information submitted via SYD and using it properly. Personal identifiable data related to gender, year of birth, email address, first and last name, personal IP address and personal health information will be gathered through the SYD application. This data will be held in secured and encrypted servers from Amazon's AWS Cloud Computing Service located in London UK. No data acquired from SYD related to the participants in this study will ever leave the EEA. The data held in the data repositories is encrypted so that operational staff cannot use operational tools to read the data. Any changes to data are audited and logged so that any anomalies can be detected. iamYiam is compliant with the GDPR and ISO 27001 requirements and holds appropriate insurance to provide indemnity in the event of a data breach.

Data sharing

The information collected about you as part of this study will be shared between the Southern Health NHS Foundation Trust and the iamYiam researchers. We will only share the data collected in the study to analyse and then produce findings. Before sharing the study data with iamYiam researchers, participants will be assigned a unique participant study number (RCTxxx). This will allow researchers to share data specific to a study participant without exposing personally identifiable information. As the same participant study number (RCTxxx) is used within the SYD app, iamYiam researchers would be able to link the study data to the personally identifiable data collected within the SYD app. Data gathered for the purpose of this study and the app will not be shared beyond the two organisations, unless there is a need to independently verify results at the request of regulators.

What will happen to the results of the research study?

The data collected during the study will be analysed and reported. The results will be disseminated through publications to peer review journals, and conference presentations. Be assured that you will not be identified in any report or publication. A summary of results will be made available to participants at the conclusion of the study.

What if there is a problem?

Southern Health NHS Foundation Trust as Sponsor has appropriate indemnity and insurance in place, in the unlikely event that anyone suffers any harm due to negligence, as a direct consequence of 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 Complaints and Patient Experience Team (contact details below).

If you remain unhappy or have a complaint about any aspect of this study, please contact:

Complaints and Patient Experience Team
FREEPOST RSJL-JXSX-ATUE
5 Sterne Road
Tatchbury Mount, Calmore
Southampton
Hampshire
SO40 2RZ
023 8231 1200
shft.patientexperience@nhs.net

For any questions regarding this study, please contact:
research@southernhealth.nhs.uk

INFORMED CONSENT FORM – ELIGIBILITY CHECK

Research study title: Pilot evaluation of a personalised, prevention mHealth partner, SYD, and its impact on Quality of Life on NHS staff

Short study title: SYD (See Yourself Differently) for NHS

Ethical Approval Reference: 21/HRA/0308
IRAS number: 294071
Chief Investigator, Prof Shanaya Rathod

So that we can be sure you meet the eligibility criteria the study, please read the following statements, and select each statement if you understand and agree with them. Please feel free to contact a member of the research team if you have any questions.

I confirm that:

1. I have read and understood the information sheet dated 26/10/2021 (version 1.8) for the above study.	
2. I am active NHS staff member and have NHS email address which I can use for this study.	
3. I am at least 18 years old	
4. I own a smartphone device which I can use for this study.	
5. I have sufficient English language ability to engage with the SYD application and the study assessments.	
6. I am currently not receiving any psychological intervention (for example counselling).	
7. I am currently not receiving any clinical treatment as part of any other clinical trial.	
8. I am not considered clinically extremely vulnerable from COVID-19.	

I agree to:

9. Complete a standard assessment of anxiety and depression (Hospital Anxiety and Depression Scale)	
10. Provide my name and email address to record the result of the assessment.	
11. Be contacted about future ethically approved research in the field of digital health technology or mental health (OPTIONAL)	

INFORMED CONSENT FORM – MAIN STUDY

Research study title: Pilot evaluation of a personalised, prevention mHealth partner, SYD, and its impact on Quality of Life on NHS staff

Short study title: SYD (See Yourself Differently) for NHS

Ethical Approval Reference: 21/HRA/0308
IRAS number: 294071
Chief Investigator, Prof Shanaya Rathod

So that we can be sure you understand the study and would like to take part, please read the following statements, and select each statement if you understand and agree with them. Please feel free to contact a member of the research team if you have any questions.

I confirm that:

1. I have read the information sheet dated 26/10/2021(version 1.8) for the above study.	
2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason without my rights being affected.	
4. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.	
5. I understand that the information collected about me will be shared between the Southern Health NHS Foundation Trust and the iamYiam researchers.'	
6. I agree to take part in the above study.	