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UNIVERSITY OF PLYMOUTH

ICR The Institute of Cancer Research

Real world testing of an AI-enabled app as an early intervention and support tool in the mental health referral care pathway
PARTICIPANT INFORMATION SHEET

Research Ethics Committee (REC) Approval Reference: 22/PR/0467
University of Plymouth Faculty of Health Research Ethics and Integrity Committees: 3173
Integrated Research Application System (IRAS) Reference: 310377
Medicines & Healthcare products Research Authority (MHRA) Approval Reference: CI/2022/0053/GB

We would like to invite you to take part in this research project. You should only take part if you want to. Choosing not to take part will not disadvantage you in any way. Before you decide if you wish to take part, you need to understand why the research is being done and what taking part will involve.

Please take up to one week to read the following information carefully and talk it through with others to decide if you would like to participate or not. Please contact us at the above email if there is anything that is not clear or if you would like more information.

Wysa is an **AI** (**Artificial Intelligence**) **chat bot** that provides mental health support tools when you need it, whatever the time of day. Wysa provides mental health support by providing real-time online conversations for mental health support via a mobile phone. Wysa is working with the NHS to develop a version for use in **IAPT (Improving Access to Psychological Therapies)** services, and to undertake a research project to examine the impact on referrals and waiting lists.

1. Why is this research being conducted?

As a result of an increase in referrals to NHS Mental Health Services, waiting times for assessment and treatment can be over 12 weeks. Wysa is a mental health and wellbeing **app** that has been used by people across the world to support their mental health. It uses an AI chat bot and different activities to help people manage their mental health.

The aim of the study is to evaluate whether providing Wysa to people waiting for their first appointment can help to reduce their symptoms of depression or anxiety. We are evaluating this for approximately 480 people who have **self-referred** or been referred to the IAPT programme. If the project shows that it does help, it will assist us in providing evidence to improve the support offered while waiting for an appointment.

2. Who is conducting the research?

The study is being led by Professor Rohit Shankar and a team from the University of Plymouth in collaboration with the Institute for Cancer Research, Wysa Ltd, and the **Central North West London NHS Foundation Trust (CNWL).** Mental health services run by the CNWL will be conducting all clinical activity. The Institute for Cancer Research is involved purely due to their statistical expertise in research. This study is in no way related to cancer, the detection of cancer or risks related to cancer.

This research project is funded by an award from the National Institute for Health Research (NIHR) (Award Number: AI_AWARD02176) and the Secretary of State for Health.

3. Why have I been invited to participate?

You have either been referred or have self-referred, to the Improving Access to Psychological Therapies (IAPT) programme. We are reaching out to people who are on the IAPT waiting list to take part in our research study. As you are currently waiting for support from IAPT, you are being asked if you would like to be involved in this.

4. Do I have to take part?

No, taking part is entirely voluntary. It is up to you to decide whether or not to take part. You will receive a phone call from a research assistant at CNWL who will ask if you want to provide your **consent** to participate in the study. They will document your **verbal consent** on the form, and then send you a signed copy of the consent form for your records. In case you are providing consent in person, or if you would prefer to give consent via email rather than a telephone call, you will also be given a signed copy of the form for you to keep. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

5. What can I expect?

If you choose to take part, you will be asked to provide consent on the phone with the research assistant . On the same phone call, the research assistant will also ask some **demographic** questions (e.g. age, gender, ethnicity) because there are great differences in how people use and access technology, and this information will help us to understand this better. These questions have been developed by research experts and patient groups. You will then be randomly assigned to either receive access to Wysa or be part of the **Control group** that doesn't have access to Wysa during the research period. Your GP will be informed that you are taking part in this research project. They will receive a copy of this Participant Information Sheet, but they will not have access to your study information, unless you give the research team permission to discuss with them if anything of concern arises as a result of your participation in this study.

If you are in the group that has access to Wysa, you will receive a link to download and access Wysa's mental health support tools immediately. You will register and access Wysa for mental health support at an interval of your choice during the study window. Whenever you would like to seek a mental health conversation, Wysa will be accessible for your use. If you are in the **Control group**, we ask you not to download Wysa during the initial three months following your referral to IAPT. You will be sent a link to access Wysa after you have completed the second set of questionnaires, which will be around three months after you signed up for the study.

Both groups will have access to Wysa for a further 12 months.

Questionnaires

You will follow the normal IAPT **care pathway** whichever group you are in and will be asked to complete routine questionnaires measuring anxiety and depression symptoms. You will complete the same questionnaires again three months later, at the end of the study period. Members of the Wysa group will complete these questionnaires via the app or via online survey, and members of the control group will be asked to complete the questionnaires either on paper, online, or on a phone call.

Your responses will be shared with your IAPT **clinician** as part of your usual care. When your information is used for research purposes, your personal data will be changed so it is no longer attributed to you. This process is called **pseudonymisation** and is a commonly employed method in research.

Interview

During the three month study period, you may also be invited to take part in a phone or video interview. These interviews will last for 40-60 minutes, and you will be asked questions about your experiences using Wysa. The interviews will be held privately between you and a researcher. The sessions shall be recorded, subject to your permission, **pseudonymised**, and **transcribed** by a **third-party supplier** of the University of Plymouth. If you choose not to have your interview recorded, the researcher can transcribe your answers during the interview.

6. Are there any benefits to taking part?

Using Wysa has the potential to reduce your symptoms of depression and anxiety, and to improve your experience of appointments with the IAPT service. If you are assigned to the group that has access to Wysa, you will receive immediate mental health and well-being support from the app, which you can use at a time and place that is convenient for you. It is important to note that use of Wysa will be in addition to treatment you will receive in the IAPT service. We expect that this will improve your quality of life and satisfaction with care. This research will also benefit patients in the future.

7. Are there any potential risks in taking part?

Wysa is being provided as an addition to your appointments with IAPT, so all participants will still be assessed and treated in line with current NHS and IAPT guidance.

You might come across occasions where Wysa doesn't understand what you are saying or might just keep giving the same answer. We understand this could be frustrating, but we will use this information to help improve Wysa in the future

All research projects carry some risk that might not be known about before the research project starts, but we do everything we can to help make sure these don't happen. The main risk of this research project is that it could increase your level of distress - such as if using Wysa is causing frustration and anxiety. You can withdraw from the project at any time if you feel it is making your symptoms worse. There is also a risk of physical impact of increased reliance on mobile phone screen time, which could be mitigated through mobile phone screen access time controls. There is also a risk of storage of potentially identifiable conversations with Wysa, for example if you were to reference your full name or the name of others when interacting with Wysa. There is a procedure which is run on the system to prevent storage of such information, but should this occur and information cannot be deleted, a notification will be made on your clinical record providing you the ability to review this information and ask for its removal from Wysa.

WYSA SOS pathway

During text interactions with you, if Wysa detects language or phrases which have been flagged as indicative of risk of self-harm, suicidality, harm from others or harm to others, Wysa will clarify with you if it has understood your meaning correctly. If you confirm yes, the Wysa will trigger the SOS pathway. You can also trigger this pathway manually at any time by clicking on the SOS button on the top right side of the screen.

When triggered, the SOS pathway provides links to local crisis helpline numbers and processes, reminding you that Wysa is an AI chat bot and is unable to help you during emergencies, but you can call these numbers for immediate support. It will also signpost you to local and national charities and helplines for support. You will be reminded of grounding activities you can do during this time and any crisis care plans you have created.

When you trigger the SOS pathway an alert is sent to the electronic patient record via the API with IAPTUS informing an allocated clinician of the event.

Criminal disclosures

If you disclose criminal activity during telephone triage or during consent to study interactions the Psychology assistant will follow the NHS Trusts confidentiality and disclosure policy, informing you that your right to confidentiality may be breached if the responsible clinician believes you or someone else is at imminent risk of harm. This will then be escalated via the clinical pathway or to the police/social care if required.

If you disclose criminal activity to Wysa during interaction with the app, you will be reminded that the app is a chatbot only and cannot further discuss this. If you indicate harm to yourself or others the above SOS pathway will be triggered.

8. What if something goes wrong?

If you have any questions or concerns about any aspect of the way you have been treated during the course of this research then you should immediately inform the Chief Investigator, Professor Rohit Shankar at rohit.shankar@plymouth.ac.uk or 01752 600600. The normal CWNL NHS Foundation Trust complaints process can be used by contacting them on email: feedback.cnwl@nhs.net or phone: 0300 013 4799.

The University of Plymouth holds insurance policies which apply to this study. If you are harmed due to someone's negligence, then you may have grounds for a legal action.

9. How will we use information about you?

The University of Plymouth is the sponsor for this study and will be the **data controller**. The University of Plymouth, the Institute for Cancer Research, and Wysa will act as **data processors** for this study. This means that all research partners are responsible for looking after your information, using it properly and 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.
  10 years after the study has completed for the purpose of contacting you about possible related follow-up studies.

We will need to use information from your medical records and collected via Wysa for this research project.

This information will include your NHS number, name, and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

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**.**

10. 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 in Wysa. This is optional and not required to participate in the study; permission to optionally provide permission will be asked during your consent to this study.

11. What happens to the data provided?

The information you provide during the study is known as the **research data**. All research data will be securely stored and managed according to University of Plymouth rules and expected practices.

Any research data from which you can be identified (e.g. name, app usage statistics and interview audio recording) is known as **personal data**. This data will be accessed via your digital interactions with Wysa and stored on an UK hosted server and on secure university network drives. Audio recordings will be created from interview sessions via a digital recorder. This data will be directly transferred from the device to a secured drive and transcribed by a 3rd party. Once the transcription is completed, the original files will be destroyed.

Other research data will be stored for ten years after publication or public release of the research and stored on a secure university network drive. Dr Meinert and his research team will have access to the research data. Responsible members of the Institute of Cancer Research and the University of Plymouth may be given access to data for monitoring and/or audit of the research.

All data will be stored on a password-protected network drive within the University of Plymouth's network. Access to these files will be limited to the study research team. Electronic data shall will be coded using a unique participant number and primary critical pseudonymisation (creation of a fictitious name linked to participant numbers) process. Any physical copies of consent forms will be stored securely at CNWL.

We would like your permission to use direct quotes with a fictitious name in any research outputs.

We would like your permission to use anonymised data in future studies and to share data with other researchers. All personal information that could identify you will be removed or changed before the information is shared with other researchers or results are made public.

If you consent to take part in the research, any information you provide may be inspected and used by administrators of the study. Each participant will be anonymised using a unique identifier to maintain confidentiality, and all data will be securely stored and managed according to University of Plymouth rules and expected practices. Raw, un-anonymised audio data will be securely stored

separately from the anonymisation key and deleted when it is no longer needed. The anonymised transcripts will be securely stored according to University of Plymouth protocols and regulations.

12. Will the use of my data meet GDPR rules?

GDPR stands for the **General Data Protection Regulation**. In the UK we follow the GDPR rules and have a law called the **Data Protection Act**. All research using patient data must follow UK laws and rules.

Universities, NHS organisations and companies may use patient data to do research to make health and care better. When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a 'legitimate interest' in using patient data.

Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'. If they could do the research without using patient data, they would not be allowed to get your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS **Research Ethics Committee** checks this before the research starts.

13. Will what I share be confidential?

All information provided during interviews will be labelled with a unique ID (not with your personal details), kept strictly confidential and not attributed to you. Participants will be allocated a study ID number and any information collected will only be seen by the study team. The data derived from interactions with Wysa will be stored and used by Wysa, Ltd for up to 10 years to train and improve its system. This data will be stored using a unique ID and will not include your name.

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

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- at https://www.plymouth.ac.uk/your-university/governance/information-governance/privacy-notices
- by asking one of the research team
- by sending an email to dpo@plymouth.ac.uk , or
- by ringing us on 01752 588959.

15. What will happen to the results of the project?

The results of this evaluation study, if positive, will be used for the purpose of deciding whether the system can be used providing evidence to support the use of Wysa to improve the support offered while waiting for an appointment. We will publish findings from the study in academic journals as well as in more generally accessible platforms, the selection of which will be guided by participants and members of the public.

16. Who has reviewed the project?

The study has been reviewed and given a favourable approval by the Health Research Authority, the Stanmore Research Ethics Committee, and the University of Plymouth.

17. Legal basis

As universities we use **personally identifiable information (PII)** to conduct research to improve health care and services. As publicly funded organisations, we have to ensure that this work is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

18. International transfers

There may be a requirement to transfer information to countries outside the UK (for example, to a research partner). Where this information contains your personal data, the University of Plymouth 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 UK law in respect of its data protection standards, the University of Plymouth will enter into a data sharing agreement with the recipient organisation that incorporates UK approved standard contractual clauses that safeguard how your personal data is processed. Transfer of your data outside the UK is optional and is not required to participate in this study; permission to optionally provide permission will be asked during your consent to this study.

19. 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 University of Plymouth 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.

- The following Research Collaborators / Partners in the study:
    - The Institute for Cancer Research – The Institute for Cancer Research will access research and personal data for the purpose of completing an evaluation of Wysa.
    - Wysa, Ltd. – Wysa, Ltd. will access personal data for the processing of interactions with its digital health conversational agent.
    - Central North West London (NHS Foundation Trust) - CNWL (NHS Foundation Trust) will access personal data for the purpose of providing mental health services.

20. Complaints

If you wish to raise a complaint on how we have handled your data, please contact the University of Plymouth's Data Protection Officer via email at dpo@plymouth.ac.uk and/or post at Data Protection Officer, University of Plymouth, Drake Circus, Plymouth, PL4 8AA.

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

If you have any concerns about the Ethical conduct of this study, please contact via post the Research Administrator, Faculty of Health Ethics Committee, John Bull Building. Tamar Science Park, Research Way, Plymouth, Devon, PL6 8BU or via email at FOHEthics@plymouth.ac.uk

21. What should I do if I want to take part?

If you agree to take part, you will either be read the consent form over the phone by one of our research staff and asked to consent verbally to participate in the study or given the consent form to sign digitally via email. If you provide consent over the phone, the research staff member will document your consent on the form and will email you a copy of the signed form for your records. However, you do not need to have received the consent form before starting to use Wysa. You will be randomly assigned an access link to Wysa either now or in three months' time. You are free to withdraw at any point, even after you have used Wysa or provided any research data.

And lastly, we understand that you may feel uneasy about giving information about yourself to someone you don't know over the phone. As mentioned earlier, please do not feel pressured to answer any questions you don't want to. Below are the contact numbers and emails of our team members, should you want to speak to them.

Contact for further information:

- Professor Rohit Shankar - rohit.shankar@plymouth.ac.uk
- Professor Ceire Costelloe – ceire.costelloe@icr.ac.uk
- Dr Becky Inkster – becky@beckyinkster.com
- Dr Edward Meinert – edward.meinert@plymouth.ac.uk
- CNWL IAPT Service - cnwl.clw-wysa@nhs.net

Thank you for taking the time to read this participant information sheet. Please do not hesitate to contact the study team as above for any further information or if you have any questions.