PARTICIPANT INFORMATION SHEET

Study Title: The benefits of adopting WYSA therapeutics for patients, clinicians, services and the wider health care system.

Chief Investigator: Dr Lila Varsani
Co Investigator: Dr Nicole Main

What is Wysa?

Wysa is an AI (**Artificial Intelligence)** chatbot that provides mental health support tools and conversational care when you need it, whatever the time of day. Wysa also offers a conversational electronic referral assistant, available 24/7, so that self referrals can be made quickly and easily, as well as computerised Cognitive Behavioural Therapy (cCBT) programmes.

Why is this research being conducted?

A key issue with current mental health service provision is lack of timely access to therapy or professional support. NHS talking therapies services are overwhelmed with high volumes of referrals and limited numbers of available trained therapists which means that there are often significant waits involved at different stages of the pathway.

We believe that the Wysa digital offer can add to what is currently being offered by mental health services such as NHS talking therapies in several ways:

- At referral - by providing you with the option to self-refer using a conversational agent at a time that is convenient.
- Whilst waiting for treatment - Wysa has 150 + self help tools to improve your mental health and wellbeing, as well as helping to prevent escalation of symptoms whilst waiting. The Wysa app also offers access to a 24/7 chatbot and daily check-ins and/or reminders (e.g. for medication).
- As a treatment intervention - The Wysa cCBT programmes can be prescribed to those with mild to moderate depression and anxiety disorders as an alternative choice to telephone, video or face to face therapy.
- Following discharge - continued access to the app for 12 months post registration, to enable you to maintain the gains they have made during their therapy.

We are conducting this feasibility study (primary investigation) to help us to understand and gather evidence as to whether the Wysa products are helpful in improving patients' mental health and wellbeing. The study has been designed with clinical staff from East London

Foundation Trust and Dorset NHS talking therapies services. Your participation in the study will assist the Wysa team to evaluate the effectiveness of the Wysa products.

The main measure of effectiveness of the products will be through clinical outcome measures for low mood and anxiety (PHQ9 & GAD7) which the chatbot will ask you to complete each week.

The study aims are as follows:

1. To establish real-world evidence of the effectiveness of Wysa as a referral and triage tool.
2. To establish the impact of Wysa as a self help support tool for patients waiting for treatment.
3. To establish the effectiveness of Wysa cCBT interventions on mental health outcomes.
4. To evaluate user experience of the range of Wysa therapeutics.
5. To establish if the adoption of Wysa therapeutics results in any service related efficiencies, for example clinical or administrative time savings

The study will include a minimum of 100 people who have self-referred or been referred to the NHS talking therapies programme. This innovative solution is not currently being offered in the NHS whilst evidence is being gathered. If the project shows positive outcomes, it will assist us in providing evidence that adopting Wysa products within the NHS would be beneficial for the patients and the service.

Who is conducting the research?

The study is being led by the clinical team at Wysa, a team from Dorset University Foundation NHS Trust and a team from East London Foundation Trust.

What can I expect?

You will receive your usual care with the NHS talking therapies team with the additional option to use the Wysa chatbot to complete your self referral information, and to download the Wysa app to access the conversational care and self-help tools whilst you are waiting for treatment. (Please see the onboarding sheet for participants for further instructions). You may also be offered a Wysa cCBT programme - if you choose to take this option, you will be given a full set of instructions by your therapist and you will also have a minimum of 2 review sessions with your therapist. If you are using Wysa your anonymised data will be analysed as part of this study, however please be assured that this will not affect your care with the NHS talking therapies team.

How will we use information about you?

We will need to use information from you for this research project. This information will include your scores on the questionnaires (PHQ9 & GAD7) as well as demographic data such as your name, date of birth and postcode. The research team will use this information to do the research or to check your records to make sure that the research is being done properly.

The Wysa research team will use patient identifiers such as your date of birth to be able to match your Wysa data with the data that the NHS talking therapies service holds for you. Once the two data sets are matched your data will be stored using only a code number. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data, in an anonymised format, so that 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.

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.

What happens to the data provided?

All research data will be stored and managed according to the law.
The pseudonymised data will be analysed by the Wysa team and the results will be shared with the NHS talking therapies teams for their distribution. We will then anonymise the data. We may also publish the results in academic journals.

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 www.hra.nhs.uk/patientdataandresearch
- FAQ Section on the Wysa website https://www.wysa.com/faq
- by asking one of the research team at your NHS talking therapies service
- by sending an email to lila@touchkin.com or emma@touchkin.com

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.

NHS organisations and companies may use patient data to do research to make health and care better. In legal terms this means that they have a 'legitimate interest' in using patient data to prove effectiveness of new treatments.

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.

What will happen to the results of the project?

The results of this study will be used to add to the existing evidence base for the effectiveness of Wysa therapeutics. We will publish findings from the study in academic journals as well as in more generally accessible platforms.

Who has reviewed the project?

The study has been reviewed and given a TBC by the Health Research Authority and local trust research ethics committees.

Legal basis

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.

Complaints

If you wish to raise a complaint on how we have handled your data, please contact Dr Lila Varsani (See email address below)

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 Dr Nicole Main (see email address below)

Key Contacts

- Dr Lila Varsani- lila@touchkin.com
- Dr Nicole Main - nicky@touchkin.com
- Emma Taylor- Emma@touchkin.com

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.

SUMMARY PARTICIPANT INFORMATION SHEET

In this research study we will use information from you that is collected by the Wysa chatbot or by your NHS talking therapies service. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the anonymised data in case we need to check it.

We will make sure no-one can work out who you are from the reports we write.

The participant information sheet tells you more about this.