

# The benefits of using digital technology (the Wysa app and AI chatbot) to support assessments, waits for therapy and treatment within NHS Talking Therapies services for patients, clinicians, services and the wider healthcare system

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| <b>Submission date</b><br>20/09/2023   | <b>Recruitment status</b><br>No longer recruiting             | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>19/10/2023 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>25/04/2025       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Demand for mental health services is currently outstripping capacity and has increased significantly since the COVID-19 pandemic, with the Centre for Mental Health estimating that up to 10 million people, including 1.5 million children, are likely to need new or additional mental health support as a direct result of the crisis.

The NHS Long Term Plan aims to promote digitally enabled care, improve access to mental health support for 1.9 million people, and support NHS Trusts in meeting their referral key performance indicators. Wysa's solution is well-placed to support these goals by providing an engaging and easy-to-access digital intervention approach that can be implemented from the point of self-referral.

The study aims are to establish real-world evidence of the effectiveness of Wysa as a referral and triage tool, to establish the impact of Wysa as a self-help mental health support tool for patients waiting for treatment, and to establish the effectiveness of therapist-enabled Wysa interventions on mental health outcomes. The study also aims to evaluate the user experience of the range of Wysa therapeutics, and finally to establish if the adoption of Wysa therapeutics results in any service-related efficiencies, for example, clinical or administrative time savings.

### Who can participate?

The target population of the study will include individuals over the age of 18 years who are referred, or self-refer, to NHS Talking Therapy Services for mental health support, and who at any stage of their IAPT journey, download and use any of the Wysa functionality.

The cCBT programmes will be accessed by a subset of the patients who are accepted for step 2

treatment. Step 2 treatment is usually offered to patients experiencing mild or moderate depression and/ or anxiety symptoms as recommended by NICE guidelines for stepped care in NHS Talking Therapy services.

What does the study involve?

The study does not require participants to do anything other than engage in their usual care as provided by their NHS Talking Therapies service. If they are using Wysa their data will be analysed as part of this study and will not affect their care in any way.

What are the possible benefits and risks of participating?

Benefits: Access to the Wysa Everyday Mental Health App (and for those who are prescribed step 2 treatment, access to AI-enabled conversational treatment programmes to aid their recovery). Risks: Excessive screen time with very prolonged use of the App.

Where is the study run from?

All treatment occurs with the Talking Therapies NHS service. Analytics will be conducted remotely by the Wysa research team.

When is the study starting and how long is it expected to run for?

November 2022 to July 2025

Who is funding the study?

Wysa Limited (UK)

Who is the main contact?

Dr Lila Varsani, lila@touchkin.com

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Lila Varsani

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

320441

**Protocol serial number**

V1.0, IRAS 320441

## Study information

**Scientific Title**

The benefits of adopting WYSA therapeutics for patients, clinicians, services and the wider healthcare system

**Study objectives**

1. The WYSA digital referral assistant will improve self-referral completion rates in comparison with baseline rates.
2. The WYSA digital referral assistant will save clinician assessment time.
3. WYSA CBT programmes will improve symptoms of depression and/or anxiety disorders.
4. Use of the WYSA app will reduce symptomatology whilst waiting for treatment, and improvement rates will be greater for those who engage more frequently with the app.

**Ethics approval required**

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**Ethics approval(s)**

approved 24/02/2023, London - Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)77647564805; londoncentral.rec@hra.nhs.uk), ref: 23/LO/0072

**Study design**

Real-world quantitative evaluation

**Primary study design**

Interventional

**Study type(s)**

Prevention, Treatment

**Health condition(s) or problem(s) studied**

Symptoms of low mood and/or anxiety

**Interventions**

The study is a real-world quantitative evaluation to investigate the impact of WYSA therapeutics on clinical outcomes, as well as service benefits such as increased referrals and clinical/admin time savings, and the experience of using the products in people with mild to moderate common mental health disorders. The evaluation will include an analysis of app usage data and clinical outcome data in order to establish engagement levels with WYSA therapeutics, as well as WYSA's efficacy at improving mental health outcomes.

All participants who are referred, or refer themselves to NHS Talking Therapies service for mental health support and are accepted and meet the inclusion criteria, will be included in the study.

The study will last for 10 months: 3 months of evaluation, refinement and technical integration, 6 months of data collection, and 1 month of post-evaluation analysis and preparation for dissemination. Outcome measures will include client satisfaction questionnaires, PHQ9 and GAD7 scores and time savings.

### **Intervention Type**

Mixed

### **Primary outcome(s)**

1. Access to services will be measured by comparing referral numbers before and after the introduction of the Wysa Digital Referral Assistant. Time saved for clinicians will be measured using the time taken to reach a treatment outcome decision for patients who have completed the Wysa Digital Assistant compared with those who have not.
2. Clinical improvement measured using the Patient Health Questionnaire-9 (PHQ-9) and General Anxiety Disorder-7 (GAD-7) scores at referral, start of treatment and at discharge.

### **Key secondary outcome(s)**

1. Patient engagement and satisfaction with the app, measured through aggregated usage metrics collected by Wysa and app score ratings every 4 weeks
2. Functional impairment is measured using the Work and Social Adjustment Scale at the start and end of treatment

### **Completion date**

31/12/2025

## **Eligibility**

### **Key inclusion criteria**

1. Willing and able to provide informed consent
2. Aged 16 years or older
3. User is confident in their ability to speak and understand English at a proficient level
4. Own an electronic device capable of supporting Wysa
5. A valid email address, NHS number; phone number
6. Referred or self-referred to proceed through the standard IAPT care pathway

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

16 years

### **Sex**

All

## **Key exclusion criteria**

1. Patients ineligible for the standard IAPT care pathway
2. Patients with previous and current known severe and enduring mental illnesses
3. Patients with current psychosis or a history of psychotic symptoms in the last 6 months
4. Patients with active suicidal ideation/ intent
5. Patients with significant cognitive disorders
6. Patients with a current diagnosis of a personality disorder
7. Patients with referrals for specialist presentations of pre-existing, diagnosed conditions requiring a specialised assessment beyond the standard clinical pathway
8. Not capable of providing self-consent

## **Date of first enrolment**

01/11/2023

## **Date of final enrolment**

30/06/2025

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

**Dorset Healthcare University NHS Foundation Trust**

Sentinel House

4-6 Nuffield Road

Nuffield Industrial Estate

Poole

United Kingdom

BH17 0RB

## **Sponsor information**

### **Organisation**

Wysa Ltd

## **Funder(s)**

### **Funder type**

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

This study will not be using identifiable personal data, all data will be pseudonymised. The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository, therefore no data sharing, due to the absence of data sharing agreements with any other stakeholders, services or individuals. Only the results of analyses will be shared with service providers.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

| Output type                                   | Details     | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | version 2   |              | 11/10/2023 | No             | Yes             |
| <a href="#">Participant information sheet</a> | version 3.0 | 12/12/2023   | 18/12/2023 | No             | Yes             |
| <a href="#">Protocol file</a>                 | version 1.1 | 27/11/2023   | 18/12/2023 | No             | No              |