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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

Submission date	Recruitment status	[X] Prospectively registered
20/09/2023	No longer recruiting	[X] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
19/10/2023	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
25/04/2025	Mental and Behavioural Disorders	[ ] 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

Contact details
1 London Street
Reading
United Kingdom
RG1 4PN
+44 (0)7764756405
lila@touchkin.com

Additional identifiers

Integrated Research Application System (IRAS)
320441

Protocol serial number
V1.0

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
Ethics approval required

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

Primary study design
Interventional

Study design
Real-world quantitative evaluation

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?
Participant information sheet	version 2		11/10/2023	No	Yes
Participant information sheet	version 3.0	12/12/2023	18/12/2023	No	Yes
Protocol file	version 1.1	27/11/2023	18/12/2023	No	No