ISRCTN21721966 https://doi.org/10.1186/ISRCTN21721966

TherapyMatch-D: A randomized controlled trial of psychological treatment selection for depression

Submission date
31/07/2023

Recruitment status
No longer recruiting

Registration date
22/08/2023

Overall study status
Ongoing

Last Edited
08/08/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Reviews of clinical trials have concluded that different types of psychological interventions for depression are equally efficacious. Therefore, the largest public provider of psychological services in England, Talking Therapies, routinely offers Cognitive Behavioural Therapy (CBT) and Counselling for Depression (PCE-CfD) as front-line treatments. Despite efforts to improve recovery rates, 1 out of 2 patients accessing any evidence-based psychotherapy usually do not recover from depression. Recent studies have suggested that identifying subgroups of patients that respond differently to diverse treatment modalities or intensity can improve clinical outcomes. One retrospective study used a large routine care dataset of patients who accessed either CBT or PCE-CfD. Researchers found that in about 30% of patients if matched to their optimal treatment using artificial intelligence, patients were twice as likely to recover from depression. The aim of this study is to pilot the effectiveness of using a treatment selection model based on that prior study. The researchers will explore if it is feasible and effective for more patients to recover from depression by being provided with a treatment recommendation compared to allocation as usual.

Who can participate?
Patients aged 18+ years with depression deemed suitable for high-intensity therapies in participating Talking Therapies sites

What does the study involve?
Talking Therapies sites will be randomly allocated to the TherapyMatch-D group (experimental) or allocation as usual group (control). During the initial assessment, clinicians in both groups will input suitable patients' data into a computer programme. In the TherapyMatch-D group, patients who according to prior research would benefit more from either CBT or PCE-CfD will be provided a treatment recommendation and then use shared decision-making with the clinician to reach a final decision. Patients in the control sites will not be given a recommendation and will follow routine care procedures to select treatment, which normally consists of shared decision-making. The researchers will then compare the outcomes of both groups to explore if the treatment selection model is feasible and effective. Furthermore, interviews will be conducted

with some patients and clinicians to explore their views and experiences of using artificial intelligence to inform treatment selection.

What are the possible benefits and risks of participating?
Participants will help researchers to learn if using the TherapyMatch-D artificial intelligence method is feasible and effective in making better treatment selection recommendations for patients accessing talking therapies for depression. The researchers do not expect that taking part in the study will lead to any disadvantages or risks to therapists or to patients.

Where is the study run from?
Grounded Research Team at Rotherham Doncaster and South Humber NHS Trust (RDaSH) (UK)

When is the study starting and how long is it expected to run for?
April 2022 to August 2026

Who is funding the study?
MindLife UK

Who is the main contact?
1. Prof Jaime Delgadillo, jaime.delgadillo@nhs.net
2. Dr Paulina Gonzalez Salas Duhne, p.gonzalez1@nhs.net

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Dr Paulina Gonzalez Salas Duhne

ORCID ID
http://orcid.org/0000-0003-4010-1503

Contact details
Doncaster and South Humber NHS Foundation Trust
2 St Catherine’s Close
Tickhill Road Hospital site
Balby
Doncaster
United Kingdom
DN4 8QN
+44 (0)3000 212 456
p.gonzalez1@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

281430

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56659, IRAS 281430

Study information

Scientific Title
A pilot cluster randomized controlled trial of psychological treatment selection for depression

Acronym
TherapyMatch-D

Study objectives
As a pilot study, no hypothesis testing is undertaken. The aim is to explore the feasibility and effects of an artificial intelligence treatment selection model for depression to improve clinical outcomes in adults accessing two psychological therapies for depression in primary mental health services compared to allocation as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/07/2023, HRA London - Riverside Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8150, +44 (0)207 104 8243, +44 (0)207 104 8255; riverside.rec@hra.nhs.uk), ref: 23/LO/0487

Study design
Randomized; Interventional; Design type: Screening, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Depression

Interventions
Talking Therapy sites will be randomised to the TherapyMatch-D group (experimental) or allocation as usual (control). During the initial assessment, clinicians in both groups will input pseudo-anonymized data from consenting patients into a computerized artificial intelligence programme.

In the TherapyMatch-D group, patients who according to prior research would benefit more from either Cognitive Behavioural Therapy (CBT) or Person Centred Experiential Therapy (also known as Counselling for Depression; PCE-CfD) will be provided with a treatment recommendation and then use shared decision making to reach a final decision.

In the allocation as usual group, patients will not be given a recommendation and will select treatment in the usual way (shared decision-making).

Following treatment selection, patients across both groups will undergo treatment as usual (CBT or CFD-PCE).

Furthermore, as part of a substudy, interviews will be conducted with patients and clinicians to explore their views and experiences of using artificial intelligence to inform treatment selection.

Intervention Type
Behavioural

Primary outcome measure
Reliable and Clinically Significant Improvement (RCSI) in depression, measured by the Patient Health Questionnaire-9 questionnaire (PHQ-9) at the end of the treatment period (last session of therapy, either CBT or PCE-CfD)

Secondary outcome measures
1. Adherence to treatment selection recommendation measured using a question embedded in the TherapyMatch-D computer programme ("does the treatment selected match the recommended treatment by the TherapyMatch-D app?") during initial assessment with client
2. Outcome expectancy (OE) measured using a question embedded in the TherapyMatch-D computer programme (“At this point in time, how confident are you that this kind of treatment will work for you on a scale of 0 (not at all) to 10 (definitely)?”) during initial assessment with client
3. Anxiety measured using the Generalized Anxiety Disorder (GAD-7) at initial assessment, and at each therapy session throughout treatment
4. Functional impairment measured using the Work and Social Adjustment Scale (WSAS) questionnaire at initial assessment, and at each therapy session throughout treatment
5. Clinical, demographic and service utilisation data (such as age, employment status, self-reported disability, index of multiple deprivation, ethnicity, chronicity, antidepressant medication, diagnoses, number of therapy sessions, reason for discharge) measured using the TherapyMatch-D computer programme questionnaire and routine data collected by Talking Therapy sites. Data will be collected at initial assessment, and throughout routine treatment provided
6. Personality profile measured using the Standardized Assessment of Personality–Abbreviated

Scale (SAPAS) at initial assessment
7. Adverse events measured using compare rates of reliable deterioration in patients across both arms of the trial at the end of the trial

Overall study start date
01/04/2022

Completion date
01/08/2026

Eligibility

Key inclusion criteria
Therapists/Counsellors:
1. Be employed by a participating IAPT service on a permanent contract, or be employed as temporary staff with a contract that is at least as long as the expected timescale for the project (1 year)
2. Hold a UK-recognized qualification and be approved by IAPT to carry out routine assessments in an IAPT service
3. Attended a group/individual training on how to utilize the computer programme TherapyMatch-D

Patients
1. Adults (18 years of age or older).
2. With depression (defined as scoring at least 10 on the PHQ-9), including those with co-morbid anxiety and those taking antidepressant medication (we will monitor and examine potential confounding effects of comorbidity and medication).
3. Seeking mental health care in IAPT services at Step 3 (normally via self-referral, GP referral or stepped up from Step 2 low-intensity IAPT treatment).
4. Deemed eligible for high-intensity treatment in IAPT by assessing therapists (often patients who do not improve at the earlier steps of care), regardless of any prior mental health treatment from IAPT or elsewhere (we will monitor and examine potential confounding effects of prior treatment and baseline severity).
5. Able to take part in the initial assessment in English without the need for interpreters or substantial communication adaptations.

Note. The researchers will gather information from all consenting participants (216 per arm). However, only those will a differential treatment response as identified by the algorithm in the TherapyMatch-D computer programme, which we estimate would be approximately 30% of the 216 participants (64 participants per arm), will be included in the primary outcome analysis.

In the sub-study, purposive sampling will be used to recruit 4 patients from each arm of the trial (2 per intervention) and 4 clinicians from each arm of the trial. This will result in a planned sample size of 16 participants.

Participant type(s)
Patient, Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 432; UK Sample Size: 432

Key exclusion criteria
Therapists/Counsellors:
1. Employment contract with IAPT service is shorter than the expected timescale for the study (1 year)
2. Currently in training (since they are not yet fully qualified to carry out routine assessments) without holding a UK-recognized qualification
3. Failure to attend a group/individual training on how to utilize the digital tool TherapyMatch-D

Patients:
1. Individuals below 18 years old
2. Lack of ability to provide informed consent to participate (as determined by the assessing therapist as part of a routine assessment)
3. Patients who do not provide informed consent to participate
4. Patients who are assessed as ineligible for treatment in IAPT (e.g., those who are signposted to other services, or lacking capacity to consent to an assessment). Specific criteria for IAPT exclusion are detailed elsewhere. Common examples include having other severe mental health disorders, highly acute suicide risk, and comorbid substance use disorder that interferes with the person's ability to engage in therapy
5. Unable to take part in the initial assessment due to language or communication barriers, or requiring substantial adaptations or interpreters

Date of first enrolment
25/09/2023

Date of final enrolment
01/08/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
IAPT Services
NHS Greater Manchester Mental Health NHS Foundation Trust
Chorlton House
70 Manchester Road
Manchester

United Kingdom
M21 9UN

Study participating centre
Lancashire and South Cumbria Talking Therapies
LSCFT/Mindsmatter
Lancashire & South Cumbria NHS Foundation Trust
Daisyfield Centre
Appleby St
Blackburn
United Kingdom
BB1 3BL

Study participating centre
Leeds Mental Wellbeing Service
Leeds Community Healthcare NHS Trust
Burmantofts Health Centre
Cromwell Mount
Leeds
United Kingdom
LS9 7TA

Study participating centre
Barnsley IAPT
South West Yorkshire Partnership NHS Foundation Trust
Rose Tree Avenue
Cudworth
Barnsley
United Kingdom
S72 8UA

Study participating centre
Doncaster IAPT
Talking Shop
63 Hall Gate
Doncaster
United Kingdom
DN1 3PB

Sponsor information

Organisation
Rotherham Doncaster and South Humber NHS Foundation Trust

Sponsor details
2 St Catherine's Close
Tickhill Road Hospital
Balby
Doncaster
England
United Kingdom
DN4 8QN
+44 (0)7818560176
j.mckie@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.sheffield.ac.uk/

Funder(s)

Funder type
Industry

Funder Name
Mindlife UK

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/09/2026

Individual participant data (IPD) sharing plan
In order to comply with the requirements of the research ethics committee, sensitive data must be requested in writing to the data custodian (Chief Investigator). Anonymized data may be made available upon reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version 2	11/08/2023	05/10/2023	No	No
Protocol file	version 2.3	18/07/2024	08/08/2024	No	No