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Improving long-term benefits for depression and anxiety

Submission date 25/05/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered
		[X] Protocol
Registration date 30/05/2023	**Overall study status** Completed	[ ] Statistical analysis plan
		[X] Results
Last Edited 06/01/2026	**Condition category** Mental and Behavioural Disorders	[ ] Individual participant data

Plain English summary of protocol

Background and Study aims:

Depression and anxiety are associated with high rates of relapse and recurrence after receiving clinically and cost-effective evidence-based psychological treatment, i.e. cognitive behavioural therapy. After treatment for depression, the prevalence of a second episode is 50%, rising to 90% after three episodes. The recurrence rate following treatment for anxiety is similarly high, between 39% to 56%.

The impacts of depression and anxiety on social, occupational functioning, physical morbidity and mortality are high; exerting high economic and health burden. Depression and anxiety are estimated to reduce England's national income (GNP) by approximately £80 million annually.

The NHS has a world-leading psychological therapy programme called 'Improving Access to Psychological Therapy (IAPT)' to help people with depression and anxiety. IAPT services follow National Institute for Health and Care Excellence guidelines recommending the delivery of care based on a stepped-care model, meaning people will be provided the least intrusive and most effective intervention first. Low intensity interventions at the first treatment step, are based on cognitive behavioural therapy (CBT) and involve guided-self-help delivered in a variety of formats (e.g., face-to-face, group, telephone) over a maximum of 8 weeks.

IAPT reported 1.17 million people entered treatment last year and 51.1% achieved IAPT recovery criteria by the end of low and/or high intensity treatment interventions, meeting the national target. Despite having a considerable impact on short-term recovery, long-term effectiveness is more limited.

Research conducted in IAPT found that more than half of people receiving brief talking therapies deteriorated following treatment, with the vast majority doing so within 2 to 6 months.

Our aim is to help patients with depression and anxiety that have received brief talking therapies to stay well over time ensuring changes made during therapy transition to lifelong skills, and burden on services is reduced.

Who can participate?
-Patients: Aged 18 or over, received low intensity treatment in IAPT services located in Northern England and started with case-level depression and/or anxiety, and meet IAPT criteria for recovery in the last session attended.
-Practitioners: Trainees or qualified psychological wellbeing practitioners delivering low intensity interventions in IAPT services located in Northern England.
-Key informants: IAPT managers/service leads, policy-makers, commissioners, IAPT trainers, clinical academics, and national leads.

What does the study involve?
The proposed research will be conducted in three phases. Phase 1 will include qualitative interviews, Phase 2 will involve co-production workshops, and Phase 3 will involve a group meeting focused on reviewing the developed intervention and its implementation plan.

Phase 1: Participants are expected to allocate 15 minutes to provide consent and complete questionnaires and will be involved in a one-time interview for a maximum of 1 hour.
Phase 2: Participants are expected to allocate 15 minutes to provide consent and complete questionnaires. Different groups of stakeholders (i.e. patients and a mixed group of professionals) will take part in a single co-development workshop for a maximum of 5 hours.
Phase 3: Participants are expected to allocate 15 minutes to provide consent and complete questionnaires and will take part in a group meeting for a maximum of 3 hours.

What are the possible benefits and risks of participating?
Although we cannot promise the study will help people personally, the information provided would help us understand what to do differently to help NHS patients in the future to stay well over time and ensure changes made during psychological treatment transition to lifelong skills.

Occasionally, people can feel upset if they think about something distressing that has happened to them. If this happens, people would be advised to make use of the support services listed and/or contact the Principal Investigator for this project.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
December 2022 to December 2024

Who is funding the study?
The funder is the National Institute for Health Research (NIHR), Research for Patient Benefit (Ref: NIHR 204037). This study is organised and sponsored by the University of Manchester. The host trust for this project is Greater Manchester Mental Health NHS Foundation Trust (UK)

Who is the main contact?
Dr Cintia Faija, Cintia.faija@manchester.ac.uk

Contact information

Type(s)
Principal investigator

Contact name

Dr Cintia Faija

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
323641

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR204037, IRAS 323641, CPMS 55925

Study information

Scientific Title
Co-developing Improving Access to Psychological Therapies (IAPT) services to improve long-term benefits for patients with depression and anxiety

Acronym
CO-IMPROVE

Study objectives
Depression and anxiety are associated with high rates of relapse and recurrence after receiving clinically and cost-effective evidence-based psychological treatment, i,e. cognitive behavioural therapy. After treatment for depression, the prevalence of a second episode is 50%, rising to 90% after three episodes. The recurrence rate following treatment for anxiety is similarly high, between 39% to 56%. The impacts of depression and anxiety on social, occupational functioning, physical morbidity and mortality are high; exerting high economic and health burden. Depression and anxiety are estimated to reduce England's national income (GNP) by approximately £80 million annually [19]. The NHS has a world-leading psychological therapy programme called

'Improving Access to Psychological Therapy (IAPT)' to help people with depression and anxiety. IAPT services follow National Institute for Health and Care Excellence guidelines recommending the delivery of care based on a stepped-care model, meaning people will be provided the least intrusive and most effective intervention first. Low intensity interventions at the first treatment step, are based on cognitive behavioural therapy (CBT) and involve guided-self-help delivered in a variety of formats (e.g., face-to-face, group, telephone) over a maximum of 8 weeks. IAPT reported 1.17 million people entered treatment last year and 51.1% achieved IAPT recovery criteria by the end of low and/or high intensity treatment interventions, meeting the national target. In IAPT, a person is deemed to move to recovery if their symptoms were considered a clinical case at the start of their treatment (i.e., symptoms exceed a defined threshold as measured by the scoring tools) and not a clinical case at the end of their treatment (symptoms below the threshold). Despite having a considerable impact on short-term recovery, long-term effectiveness in IAPT is more limited. Specifically, 53% of patients completing low intensity interventions for depression/anxiety relapse within one year, with a further 13% experiencing recurrence in the following year. Of these, 49% relapse within 2 months and 79% within six months. This increases need for further treatment and negatively impacts on patients, services and health economies. The economic success of IAPT rests upon its ability to improve population health and offset treatment costs against substantially greater revenue from reduced healthcare use and work productivity losses. Analysis suggests that the IAPT programme is cost-effective, but that treatment costs are three times higher than initially expected. Current data suggests that attention is urgently needed to prevent relapse for over 300,000 patients annually, with potential for concomitant gains in direct and indirect service expenditure. Relapse has a detrimental impact on healthcare costs and is a significant risk to service efficiency, patient access and experiences. However, little is known about how to maintain treatment benefits and reduce risk of relapse in routine provision in IAPT without escalating costs; our research aims to fill this gap in knowledge.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/05/2023, NHS North West - Greater Manchester (GM) West Research Ethics Committee (Barlow House, 3rd Floor, HRA NRES Centre, Manchester, M1 3DZ, UK; +44 207 104 8379; gmwest.rec@hra.nhs.uk), ref: 23/NW/0109

Study design
Observational

Primary study design
Observational

Study type(s)
Other, Prevention

Health condition(s) or problem(s) studied
Adult patients with anxiety and/or depression meeting NHS Improving Access to Psychological Therapies (IAPT) recovery criteria at discharge of Step 2 care (guided-self-help)

Interventions
This is a mixed-methods study comprising three phases:

Phase 1 seeks to develop an in-depth understanding of barriers and facilitators influencing relapse following low intensity interventions for depression/anxiety in IAPT. Semi-structured interviews will be conducted with patients and mixed stakeholders (e.g., IAPT practitioners, service leads) (n=20-25 for each study, determined by data saturation; 40-50 in total). Framework analysis will be used to inductively and deductively code interview transcripts.

Phase 2 aims to use the evidence from Phase 1 to co-produce, with multiple stakeholders, an acceptable, evidence-based transdiagnostic relapse prevention toolkit for IAPT. An experienced-based co-design framework, comprised of co-design workshops, one conducted with patients and one with mixed stakeholders (N=9 for each, in line with RAND Methodology recommendations) will be conducted.

Following workshops, smaller sustained group work will take place to co-develop how the toolkit would look like.

Phase 3 aims to review and finalise, with multiple stakeholders (n=12-15), the developed toolkit. The best pathway for implementation will be identified to assist the uptake and facilitation of our transdiagnostic relapse prevention toolkit in IAPT services.

Intervention Type
Other

Primary outcome(s)
Phase 1 aims to explore patients and stakeholders perspectives on barriers and facilitators influencing
Recovery maintenance/relapse following low intensity interventions for depression/anxiety in IAPT using semi-structured interviews. Framework analysis will be used to inductively and deductively code interview transcripts.

Phase 2 aims to co-produce, with patients and stakeholders an acceptable, evidence-based transdiagnostic relapse prevention toolkit for IAPT. An experienced based co-design framework, comprised of co-design workshops, one conducted with patients and one with mixed stakeholders will be conducted. The RAND/UCLA Appropriateness Methodology will be used.

Phase 3 aims to review and finalise the developed toolkit with patients and stakeholders using a consensus approach. In addition, the best pathway for implementation will be identified to assist the uptake and facilitation of our transdiagnostic relapse prevention toolkit in IAPT services.

All patient participants will be asked to complete the following questionnaires to describe the clinical sample and to identify maintenance of recovery or relapse at the point of their participation in the research:
1. Patient Health Questionnaire (PHQ-9)
2. Generalised Anxiety Disorder Scale (GAD-7)
3. Work and Social Adjustment Scale (WSAS)
4. Post-Treatment Experiences Questionnaire (optional)

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/12/2024

Eligibility

Key inclusion criteria

Patients:
1. Aged 18 years or over
2. Received low intensity treatment in IAPT services located in Northern England and started with case-level depression and/or anxiety
3. Meet IAPT criteria for recovery in the last session attended. Following IAPT criteria, a person is considered to be at 'caseness' when their symptom score exceeds the accepted clinical threshold for the relevant measure of symptoms (PHQ-9 and GAD-7). A person moves to recovery if their symptoms were considered a clinical case at the start of their treatment and not a clinical case at the end of their treatment. IAPT services located in Northern England.

Practitioners:
Trainees or qualified psychological wellbeing practitioners delivering low intensity interventions in IAPT services located in Northern England.

Key informants may include IAPT managers/service leads, policy-makers, commissioners, IAPT trainers, clinical academics, and national leads.

Participant type(s)

Health professional, Patient, Service user, Other

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

110 years

Sex

All

Total final enrolment

0

Key exclusion criteria

Individuals lacking the capacity to consent

Date of first enrolment

12/06/2023

Date of final enrolment

31/12/2024

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Bolton Psychological Therapies Service
Arndale Chambers
33 Victoria Square
Bolton
England
BL1 1RJ

Study participating centre
Trafford Psychological Therapies
Altrincham Health and Wellbeing Centre
33 Market Street
Altrincham
Trafford
England
WA14 1PF

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
North Cumbria Talking Therapies
Newcastle
England
NE3 3XT

Study participating centre
Kirklees Talking Therapies
Folly Hall Mills
St Thomas Road
Huddersfield
England
HD1 3LT

Study participating centre

Calderdale Talking Therapies
The Dales
Calderdale Royal Hospital
Huddersfield Road
Halifax
England
HX3 0PW

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
England
OL6 7SR

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR
Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

The data sets generated and analysed during the current study will not be publicly available due to privacy and ethical restrictions (i.e. potential for breach of anonymity) but is available upon reasonable request from the principal investigator of the project, Dr Cintia Faija, Email: cintia.faija@manchester.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/12/2024	06/01/2026	Yes	No
HRA research summary			20/09/2023	No	No
Protocol file	version 2	23/02/2023	30/05/2023	No	No