RESEARCH PROTOCOL

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

Contents

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2) INTRODUCTION

Background: Research conducted in IAPT found that 53% of patients' successfully completing low intensity interventions for depression/anxiety experienced relapse within one year following treatment; eight out of ten relapse events occurred within the first 6-months post-treatment. In depth understanding of the factors that contribute to, or may ameliorate, IAPT relapse is limited.

Aims: Our research aims to improve long-term benefits for IAPT patients following low intensity treatment for depression/anxiety, enhancing patient outcomes and service efficiency.

Method: 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 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.

Benefits/Impact and deliverables:

1-New evidence generated from our research will inform the development of an evidence-based transdiagnostic relapse prevention toolkit, specifically designed to guide IAPT services to sustain longer-term improvements following low intensity interventions.
2-The transdiagnostic relapse prevention toolkit will be co-produced with multiple stakeholders to ensure acceptability to the target setting and clinical group. It will include patient mediated resources and a set of training materials for IAPT services to integrate into their curricula to standardise care and support integration of best practice.
3-At project end, we will have enhanced our understanding of the patient, service, and context factors contributing to or ameliorating relapse, and we will have delivered an intervention, ready for robust clinical and cost evaluation.

Further funding will be sought for this evaluation. If successful in reducing relapse and improving long-term clinical outcomes for patients receiving low intensity interventions in IAPT, our work will confer substantial benefits on productivity and population health, and enable more efficient/better equipped services to support service-users following treatment.

3) BACKGROUND

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 (Lorimer et al., 2021, Wojnarowski et al, 2019). After treatment for depression, the prevalence of a second episode is 50%, rising to 90% after three episodes (Burcusa & Lacono, 2007). The recurrence rate following treatment for anxiety is similarly high, between 39% to 56% (Vervliet, Craske & Hermans, 2013).

The impact of depression and anxiety on social, occupational functioning, physical morbidity and mortality are high (Ferrari et al., 2013, Roy-Byrne et al., 2008); exerting high economic and health burden. Depression and anxiety are estimated to reduce England's national income (GNP) by approximately £80 million annually (Hewlett & Moran, 2014).

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, video) 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 (NHS Digital, 2021). 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) (NHS England, 2021).

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 (Delgadillo et al, 2018, Ali et al., 2017). Of these, 49% relapse within 2 months and 79% within six months (Ali et al., 2017). 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 (Radhakrishnan et al, 2013). 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.

According to contemporary guidelines (Bockting et al, 2015), relapse is defined as the return of symptoms within a short period (i.e., 6 months) after achieving initial remission (i.e. symptoms below the threshold as measured by scoring tools) at the end of treatment.

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.

Our study will be the first to illuminate the perspectives of multiple stakeholders including IAPT patients, IAPT practitioners, service managers, clinical academics, IAPT trainers, policy-makers, and national leads. In addition, the evidence from this research will inform the development of a transdiagnostic relapse prevention toolkit targeting both depression and anxiety symptoms specifically designed to guide NHS IAPT services in sustaining longer-term improvements from low

intensity interventions. This will be the first toolkit that will be co-produced and refined with multiple stakeholders to ensure acceptability to the target setting and clinical group.

Outline of funding:
This research project has been granted funded by the NIHR Research for Patient Benefit (Competition 46). Grant Reference Number: NIHR204037

4) STUDY OBJECTIVES

4.1 Primary Question/Objective:

The overall research aim is to improve long-term benefits for IAPT patients following low intensity treatment for depression/anxiety, enhancing patient outcomes and service efficiency. To meet this aim we have three objectives:

Phase 1: Gain a comprehensive understanding of factors that contribute to, or may ameliorate, relapse following low intensity interventions for depression/anxiety in IAPT by exploring multiple stakeholders' perspectives.

Phase 2: Co-develop with multiple stakeholders a transdiagnostic relapse prevention toolkit to maintain treatment gains over time and prevent relapse of both depression and anxiety.

Phase 3: Finalised the developed toolkit and identify potential blockage to engagement and uptake, and potential solutions/implementation strategies to assist the uptake and facilitation of our transdiagnostic relapse prevention toolkit in IAPT services.

4.2 Secondary Question/Objective:

Not Applicable.

5) STUDY DESIGN & PROTOCOL

5.1 Participants

-Adult patients (aged 18 or over), that have received low intensity treatment for anxiety and/or depression in IAPT services located in Northern England and have achieved IAPT criteria for recovery.

-Practitioners and Key Informants: 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, national leads or any other knowledgeable person on this topic.

5.2 Study Design and Procedures

Study Design

Our research aims to improve long-term benefits for IAPT patients following low intensity treatment for depression/anxiety, enhancing patient outcomes and service efficiency. To meet this aim we will conduct a research programme including 3 phases:

Phase 1 will include qualitative interviews, Phase 2 will involve co-production workshops, and Phase 3 will focus on the review of the developed intervention and on its implementation plan.

Phase 1: Qualitative interviews
Using qualitative methods, we will conduct individual semi-structured interviews with multiple stakeholders (i.e. patients, practitioners and key informants) to develop an in-depth understanding of barriers and facilitators that contribute to, or may ameliorate relapse, following low intensity treatment for depression/anxiety in IAPT.

Phase 2: Co-production workshops
The aim of Phase 2 is to co-develop with multiple stakeholders a transdiagnostic toolkit to prevent relapse following low intensity treatment for depression and anxiety in IAPT. We will conduct two co-design workshops subsequently, first with patients and then with mixed professionals (i.e., IAPT practitioners and mixed professionals including practitioners and key informants). Each co-design workshop will last a maximum of 5 hours. Participants will be informed about the research background of the study, and findings from Phase 1 will be presented and discussed and a group voting exercise will follow. Following discussion of findings, stakeholders will be asked to identify which evidence-base elements (derived from Phase 1) should be prioritised for inclusion in the transdiagnostic relapse prevention toolkit. This will be done via a 2-round electronic voting exercise informed by the RAND Appropriateness Methodologies. In the first round, participants will be rating the items independently. In the second round, participants will discuss their ratings in light of their knowledge of other people's ratings and following discussion, participants will re-rate the items. Following the group voting exercise, stakeholders will be asked to identify how the transdiagnostic relapse prevention toolkit can best be shaped and implemented, to assist the uptake and facilitation of it in IAPT services.

Phase 3: Final review and Implementation plan
Phase 3 aims to review and finalise the transdiagnostic relapse prevention toolkit developed in Phase 2 and decide on the best path to implementation.

Quantitative data will include demographics and clinical measures. Quantitative data will be analysed descriptively.

Study Procedures

Phase 1:
-Providing consent and completion of questionnaires (15 minutes): Participants will complete a consent form online via Qualtrics. Contact details for the research team will be provided on the PIS in case participants want to ask any questions. Alternatively, researchers may undertake verbal consent (via telephone or Zoom/Teams) by following the verbal consent protocol. Participants will complete questionnaires online via Qualtrics or by telephone/Zoom/Teams with a researcher.
-Qualitative interviews with patients and mixed professionals (up to 1 hour): Interviews will be conducted by a researched via telephone or online (via Zoom or Teams), pending on participant preferences.

Phase 2:
-Providing consent and completion of questionnaires (15 minutes): Participants will complete a consent form online via Qualtrics. Contact details for the research team will be provided on the PIS in case participants want to ask any questions. Alternatively, researchers may undertake verbal consent (via telephone or Zoom/Teams) by following the verbal consent protocol. Participants will complete questionnaires online via Qualtrics or by telephone/Zoom/Teams with a researcher.
-Co-development workshops (i.e., group meeting) with patients and mixed professionals (up to 5 hours): Group meetings will be facilitated by 2 people, an experienced researcher and a patient and public involvement representative. Group meetings will be conducted online (via Zoom or Teams). Group meetings will allow time for breaks and lunch.

Phase 3:
-Providing consent and completion of questionnaires (15 minutes): Participants will complete a consent form online via Qualtrics. Contact details for the research team will be provided on the PIS in case participants want to ask any questions. Alternatively, researchers may undertake verbal consent (via telephone or Zoom/Teams) by following the verbal consent protocol. Participants will complete questionnaires online via Qualtrics or by telephone/Zoom/Teams with a researcher.
-Final review meeting and implementation (i.e., group meeting) with patients and mixed professionals (up to 3 hours): This group meeting will be conducted online (via Zoom or Teams) and will allow time for breaks and lunch.

Patient questionnaires to be used across all phases include:

-Demographic questionnaire. This includes background information including age, gender, ethnicity, sexuality, educational qualifications, employment status, religion, disabilities, mental health problem for which you have received treatment (i.e. anxiety, depression or both) and GP surgery details.

-Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a 9-item measure of the severity of depression. Total scores of 5, 10, 15, and 20 represent cut-points for mild, moderate, moderately severe and severe depression, respectively.

-Generalised Anxiety Disorder Scale (GAD-7) (Spitzer, Kroenke, Williams, & Löwe, 2006). The GAD-7 is a 7-item measure of the severity of anxiety. Total scores of 5, 10 and 15 are taken as cut-off points for mild, moderate and severe anxiety respectively.

-Work and Social Adjustment Scale (WSAS) (Mundt, Marks, Shear, & Greist, 2002). The WSAS comprises 5 items assessing the extent to which a person's mental health problem interferes with their (1) functioning at work, (2) home management, (3) social leisure activities, (4) private leisure activities, and (5) family/relationships.

-Optional Experiences Questionnaire (optional to complete): This questionnaire contains 6 open questions, and it is aimed to allow patients to provide information about their experiences following their treatment (e.g., treatment gains, recommendations/suggestions for care following treatment)

Professional participants will be asked to complete a demographic questionnaire only (via Qualtrics). This includes background information including age, gender, ethnicity, sexuality, educational qualifications, religion, disabilities, primary role and experience in mental health settings.

5.3 End of study

The study has reached the end once data collection and data analysis of the three phases of the project have been completed and the relapse prevention toolkit has been finalised

6) STUDY PARTICIPANTS

6.1 Inclusion Criteria:

The inclusion criteria included in this section correspond to all phases, i.e. Phase 1, Phase 2 and Phase 3.

Patients: Aged 18 or over, can speak and read English, 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. 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: IAPT managers/service leads, policymakers, commissioners, IAPT trainers, clinical academics, and national leads.

6.2 Exclusion Criteria:

All phases. Patients lacking consent.

6.3 Recruitment:

Phase 1: Qualitative interviews

-Patients:
Eligible patients will be identified from discharge records from IAPT services located in Northern England and will be invited by their IAPT service to participate in the study within 6 months following low intensity treatment. Eligible patients will receive an invitation pack (i.e. advert, participant information sheet, and a 'consent to contact form') by email or via SMS or post (pending on service methods of communication with patients), or will be contacted via telephone/Zoom/Teams by their IAPT service.

We will also recruit patients by advertisement. Advertisements using our ethically approved flyer may be placed online (e.g. social media adverts or postings on user/care forums) or physically displayed (e.g. in IAPT waiting rooms, community venues or via press-release).

-Practitioners:
Eligible IAPT practitioners will be recruited by direct invitation (emails) distributed within the team, attendance by a researcher at team meetings, by advertisement displayed at sites, on intranets and social media. All advertising methods will used ethically approved study documents.

-Key stakeholders:
IAPT and third sector leads/managers/commissioners, policy-makers, IAPT trainers, clinical academics, and national leads will be identified via existing team contacts with clinical academics, NHS and third sector services, by contacting universities training IAPT practitioners, and by reviewing IAPT policy documents.

Participants will be contacted via direct invitation (email) with snowballing techniques used to recruit additional participants. An advertisement will also be displayed on social media. All advertising methods will used ethically approved study documents.

Phase 2: Co-development workshops

-Patients:
Recruitment details and strategies described for Phase 1 also apply for Phase 2.
If struggling with recruitment, patients from Phase 1 who agreed to be re-contacted about future studies may also be invited to participate.

-Practitioners:
Recruitment details and strategies described for Phase 1 also apply for Phase 2.
If struggling with recruitment, practitioners from Phase 1 who agreed to be re-contacted about future studies may also be invited to participate.

-Key stakeholders:
Recruitment details and strategies described for Phase 1 also apply for Phase 2.
If struggling with recruitment, key stakeholders from Phase 1 who agreed to be re-contacted about future studies may also be invited to participate.

Phase 3: Review and implementation meeting

-Patients:
Patients from Phase 1 and/or Phase 2 who agreed to be re-contacted about future studies will be prioritised to be invited to participate. If there are not enough participants, recruitment for patients will open following the same eligibility criteria and procedures described in Phase 1.

-Practitioners:
Practitioners from Phase 1 and/or Phase 2 who agreed to be re-contacted about future studies will be prioritised to be invited to participate. If there are not enough participants, recruitment for patients will open following the same eligibility criteria and procedures described in Phase 1.

-Key stakeholders:
Key stakeholders from Phase 1 and/or Phase 2 who agreed to be re-contacted about future studies will be prioritised to be invited to participate. If there are not enough participants, recruitment for patients will open following the same eligibility criteria and procedures described in Phase 1.

6.4 Randomisation:

Not applicable.

6.5 Participants who withdraw consent [or lose capacity to consent]:

For all the phases of this research programme, loss of capacity to consent is unlikely to be a significant risk as the data collection will take place on a single occasion and there will be minimal gap between consent and data collection.

7) OUTCOME MEASURES

Please note this is a qualitative research programme and therefore the primary outcome concept does not apply.

Impact and deliverables:

1-New evidence generated from our research will inform the development of an evidence-based transdiagnostic relapse prevention toolkit, specifically designed to guide IAPT services to sustain longer-term improvements following low intensity interventions.
2-The transdiagnostic relapse prevention toolkit will be co-produced with multiple stakeholders to ensure acceptability to the target setting and clinical group. It will include patient mediated resources and a set of training materials for IAPT services to integrate into their curricula to standardise care and support integration of best practice.
3-At project end, we will have enhanced our understanding of the patient, service, and context factors contributing to or ameliorating relapse, and we will have delivered an intervention, ready for robust clinical and cost evaluation. Further funding will be sought for this evaluation. If successful in reducing relapse and improving long-term clinical outcomes for patients receiving low intensity interventions in IAPT, our work will confer substantial benefits on productivity and population health, and enable more efficient/better equipped services to support service-users following treatment.

8) DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

Personal Information
Emails sent by patients and professionals will hold their name and contact details (email/phone number/address) (consent to contact form), while consent forms for qualitative interviews/group meetings will hold participant names only. This will only be used to arrange interviews/group meetings with participants or for dissemination of a summary of the findings at the end of the study (if they consented to this) and will only be available to members of the research team who have the correct governance approvals.

If a participant would prefer, consent will be collected verbally (via telephone or Zoom/Teams). A recording separate to the qualitative interview/group meeting, will be made of this consent where the participant will be asked to state their name clearly and consent statements read aloud individually with the participant confirming yes or no to each statement. This recording will be transferred to an encrypted University server and given an anonymous name (not the participant name).

Personal details will be held on an encrypted University server used to arrange interviews/group meetings with participants or for dissemination of a summary of the findings at the end of the study (if they consent to this). This will only be available to members of the research team who have the correct governance approvals.

Consent will be obtained using electronic consent forms or verbal consent, recorded on an encrypted recorder prior to the interview/group meeting commencing or via Zoom/Teams (pending on participant preference).

Pseudonymised personal data

Patient demographics will be collected but will be pseudonymised. All participants on entry to the study will be allocated a study ID which will appear on the demographic form. Only researchers involved in data collection and analysis will have access to the pseudonymisation key.

Audio recordings of interviews/group meetings may contain personal identifiable information such as patient names, service names, etc. Transcription of audio recordings will be conducted by an approved University of Manchester supplier and completed transcriptions will be stored within a secure area for access by the researchers working on the studies only. When transcribed, transcripts will be checked and any personal information will be removed.

Pseudonyms will be used for the purposes of transcription and verbatim quotations used within publications. Audio recordings will be destroyed after transcription and checking.

Following patient consent, NHS/third sector IAPT sites will be asked to provide routine outcome measures data form their therapy sessions that will be linked to the data of patients. Following linkage, all identifiers will removed.

Anonymised personal data

Following completion of the study all data collected via interviews/group meetings/questionnaires will be anonymised.

Audio and/or video recordings

Audio and video recordings may contain personal identifiable information. Video recordings will not be used and will be destroyed immediately after the interview/group meeting took place. Transcription of audio recordings will be conducted by an approved University of Manchester supplier and completed transcriptions will be stored within a secure area for access by the University of Manchester researchers working on the study only. Transfer of audio recordings to the transcribing company will be done via a secure file transfer system. When transcribed, transcripts will be checked and any personal information will be removed. Pseudonyms will be used for the purposes of transcription and verbatim quotations used within publications.

Arrangements for storage of personal data and research data after the study has ended:
In line with the University of Manchester Information Governance Office Records Retention Schedule guidance, consent forms for non-interventional low risk studies shall be held until the end of the study +2 years. This guideline also applies for participants that do not wish for a summary of findings. With participant consent, we would also like to retain your contact details for 5 years in order to provide you with a summary of the findings for this study and also to inform you about future studies that you may be interested in.

In line with the University of Manchester Information Governance Office Records Retention Schedule Research Data Management Policy, the minimum default period for research data is 5 years after publication.

To provide the gift voucher to participants, full name and email address will be shared with our Finance department who will send the voucher to participants. Participant's full name and email address will be securely retained by Finance for a period of up to 7 years for audit purposes only and then destroyed. It will not be used for them for any other purpose.

9) STATISTICAL CONSIDERATIONS

9.1 Statistical Analysis

Phase 1: Qualitative interviews
Qualitative methods - Constant comparative method using inductive and deductive coding. Interview transcripts will be analysed using framework analysis (Ritchie & Spencer, 1994) with inductive coding informed by the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009). The CFIR is a pragmatic comprehensive multilevel framework used to guide and/or optimise the implementation of complex evidence-based interventions from design to evaluation and it is composed of five domains: intervention characteristics, outer setting, inner setting, characteristics of individuals, and process of implementation. Each of these 5 domains include a number of sub-domains. Deductive coding will be used to enhance granularity within each CFRI domain.

Phase 2: Co-development workshops
RAND Health/University of California, Los Angeles Appropriateness Methodology will be used. Statistical analysis of the scores generated at each round of voting will be conducted in line with standard RAND procedures (Fitch et al., 2001).

Phase 3: Final review and implementation meeting
Participants will review and provide feedback on the proposed intervention and will decide the best path to
implementation. We will document our intervention according to the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014).

All phases:

Quantitative rating data will be analysed descriptively (e.g., demographics, clinical measures).

9.2 Sample Size

Phase 1: Qualitative interviews

The sample size are broadly in line with conventional estimates for qualitative analysis designs. Sample size has been defined following theoretical sufficiency criteria (Charmaz, 2006; Dey, 1999), indicated by the thoroughness of data collection and analysis, which from previous experience is expected to be achieved by 20-25 participants for each of the studies, i.e. a total of 40-50 participants.

-IAPT patients: 20-25
-IAPT practitioners and other key stakeholders: 20-25
-Total: 40-50

Phase 2: Co-development workshops (i.e., group meetings)

Sample size for the co-development workshops, which will include consensus exercises, are informed by numbers recommended by the RAND methodology (Fitch et al., 2001). A sample size of 9 participants allows the panel to be largely enough to account for diversity of representation while being small enough to facilitate everyone's involvement in the discussions.

-IAPT patients: 9
-IAPT practitioners and other key stakeholders: 9
-Total: 18

Phase 3: Final review and implementation meeting

Similarly, to phase 2, Sample size for the final review and implementation meeting has been defined by a number considered to be largely enough to account for diversity of representation while being small enough to facilitate everyone's involvement in the discussions.

-IAPT Patients: 3-5
-IAPT Practitioners and other key stakeholders: 3-5
-Total: 10

Total Sample across phases: 78

10) DATA MONITORING AND QUALITY ASSURANCE

The responsibility for monitoring the study is delegated to the chief investigator. The study will be subject to the audit and monitoring regime of The University of Manchester. The research programme team comprising Dr Cintia Faija, Professor Penny Bee and Professor Karina Lovell alongside with the external collaborators (i.e. Dr Amy Blakemore, Dr Jaime Delgadillo and Professor Dean McMillan) and the PPI co-applicant (Mr Paul Edwards) will convene and meet regularly throughout the study project.

The study will be subject to the audit and monitoring regime of the University of Manchester.

11) SAFETY CONSIDERATIONS AND ADVERSE EVENTS

This project does not include interventional research. However, a procedure to asses and report risk to principal investigators and/or the clinician of the research team is in place (i.e., CO-IMPROVE Risk Protocol).

12) PEER REVIEW

The study was reviewed by a Panel of external reviewers as part of the NIHR RfPB (Research for Patient Benefit) application process.

13) ETHICAL and REGULATORY CONSIDERATIONS

13.1 Approvals

NHS Research Ethics Committee and HRA approval will be obtained before commencing research. The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2020.

13.2 Risks

Phase 1:
We expect this study to cause minor inconvenience to patients and professionals as it will take up to 75 minutes of their time (including consent, completion of questionnaires and interview). We will ensure participants understand this prior to taking part.

The main ethical concern relates to the potential vulnerability of the patient population who may still be experiencing symptoms of anxiety and/or depression at the time of the interview. Our team is very experienced in working with this population. We will ensure all participants receive clear information about the study (including receipt of a participant information sheet) and have the opportunity to ask questions before giving their consent.

Other ethical concern is related to the disclosure of risk by participants, whether this is to themselves or others. There could also be the risk of identification of bad practice, an example of this could be a service user who has had a bad experience, or an NHS staff member who is not following Trust policy and procedure. Reasons for breaking confidentiality will be explained in the participant information sheet.

There is a small risk that patients could become distressed when talking about their experiences of anxiety and/or depression. A distress protocol will be followed by researchers involved in conducting interviews. This protocol pinpoints that researchers will seek further advice from team clinicians if concerns are raised. We also included in our participant information sheet links to additional sources of support that patients can contacted if required.

There is a low possibility that professionals disclose malpractice as part of an interview. Researchers who become aware of malpractice will discuss this with the principal investigators and/or clinician from the research team and follow any directions given.

Phase 2:
Taking part in a co-development workshop (i.e., group meeting) might cause some inconvenience to patients and professionals as it will require up to 5 hours of their time. We will ensure participants understand this prior to taking part. In addition, regular comfort breaks will be scheduled following online meetings advice to prevent fatigue and ensure people are Ok during the meeting. The facilitators will be regularly checking on participants and sensing how they are doing over the meeting and action accordingly.

At the start of the group meeting, ground rules of the group meeting will be set to remind participants about e.g., not speaking over each other and being respectful, limiting the amount of identifiable information discussed (trying not to list place names and names of people), breaking confidentiality if disclosures are made.

The main ethical concern relates to the potential vulnerability of the patient population who might be experiencing symptoms of anxiety and/or depression at the time of the workshop. Our team is very experienced in working with this population. We will ensure all participants receive clear information about the study (including receipt of a participant information sheet) and have the opportunity to ask questions before giving their consent.

We expect that there is a very low risk of this study causing patient distress as it will focus on the development of the intervention (recovery and relapse prevention toolkit) and will therefore not require any data collection about personal mental health problems. If a patient does become distressed, the distress protocol will be followed.

Other ethical concern is related to the disclosure of risk by participants, whether this is to themselves or others. There could also be the risk of identification of bad practice, an example of this could be a service user who has had a bad experience, or an NHS staff member who is not following Trust policy and procedure. Reasons for breaking confidentiality will be explained in the participant information sheet.

Phase 3:
Taking part in a group meeting might cause some inconvenience to patients and professionals as it will require up to 3 hours of their time. We will ensure participants understand this prior to taking part. In addition, regular comfort breaks will be scheduled following online meetings advice to prevent fatigue and ensure people are Ok during the meeting. The facilitators will be regularly checking on participants and sensing how they are doing over the meeting and action accordingly.

At the start of the group meeting, ground rules of the group meeting will be set to remind participants about e.g., not speaking over each other and being respectful, limiting the amount of identifiable information discussed (trying not to list place names and names of people), breaking confidentiality if disclosures are made.

The main ethical concern relates to the potential vulnerability of the patient population who might be experiencing symptoms of anxiety and/or depression at the time of the group meeting. Our team is very experienced in working with this population. We will ensure all participants receive clear information about the study (including receipt of a participant information sheet) and have the opportunity to ask questions before giving their consent.

We expect that there is a very low risk of this study causing patient distress as it will focus on revising the intervention (recovery and relapse prevention toolkit) and identifying an implementation strategy. This study does not require any data collection about personal mental health problems. If a patient does become distressed, the distress protocol will be followed.

Other ethical concern is related to the disclosure of risk by participants, whether this is to themselves or others. There could also be the risk of identification of bad practice, an example of this could be a service user who has had a bad experience, or an NHS staff member who is not following Trust policy and procedure. Reasons for breaking confidentiality will be explained in the participant information sheet.

All Phases:

Patients taking part in any of the three phases of the project, will be asked to complete questionnaires that include clinical information (i.e. ratings of depression symptoms using the PHQ-9 and ratings of anxiety symptoms using the GAD-7). As these measures will be collected following treatment, it is likely that patients will no longer be under the care of an IAPT service. If a low or high level of risk is identified (patients rating 1, 2 or 3 for Question 9 of the PHQ9) when patients complete these measures online, a message will appear advising them to contact one of a number of support organisations or individuals e.g., their GP, The Samaritans or 999.
Patients will also be informed prior to completion of the measures, and after completing them, that their responses will not be monitored and that if they are in distress they should contact one of a number of support organisations or individuals e.g., their GP, IAPT service, NHS 111, The Samaritans, 999 or their local A&E department.
Risk for the researchers

We expect the risk of researcher distress to be low. Researchers will however receive regular supervision from line manager and principal investigators in case of any distress by interviewing/conducting group meetings with patients with mental health problems.

All interviews/group meetings will be conducted remotely, i.e. by telephone or online (via Zoom or Teams), so there is no physical risk for the researcher conducting the interviews/group meetings.

14) STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

15) FUNDING and RESOURCES

The CO-IMPROVE research project is funded by the National Institute for Health Research (NIHR), Research for Patient Benefit (Ref: NIHR 204037).

16) PUBLICATION POLICY

Our research will generate new evidence to understand and inform an intervention to maintain treatment gains and prevent relapse following recovery from low intensity interventions in IAPT services, improve long-term benefits for patients, increase treatment effectiveness over time and enhance service efficiency.

We will work with our PPI co-applicant and PPI advisory panel to develop a bespoke engagement strategy to target service users, IAPT practitioners, service managers, commissioners, national IAPT leads, policy-makers and third sector networks. We will identify and address potential boundaries impeding knowledge flow between these groups.

We will work with our PPI co-applicant and PPI advisory panel to ensure that communications are clear, concise and accessible, and take account of the needs and preferences of relevant audiences. We anticipate using a range of media including tailored and targeted summary briefings, engagement events, online communications (e.g. webinars, blogs) and mainstream/social media. Local, national and international dissemination will occur via patient, professional and research-orientated conferences and blogs. The selection of specific engagement activities and communication channels will be informed by current evidence on dissemination and knowledge mobilisation, to ensure our findings are available to policy makers to underpin new public health strategies and person-centred health policy and care. An appropriate NIHR 'house-style' will be adopted to build recognition and credibility for outputs. A summary of the research findings will be sent to the research participants who have agreed to this in the consent form.

We will develop a written publication strategy, publishing in high-impact academic, professional and patient focused journals, ensuring that we make an enduring contribution to the evidence base.

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