Predictors of psychological treatment outcomes for common mental health problems in IAPT service users

RESEARCH PROTOCOL
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Version 6

Study Title:	Predictors of psychological treatment outcomes for common mental health problems in IAPT service users	
Study Acronym:		
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For guidance on filling out the protocol see:
http://www.biomedcentral.com/bmcpublichealth/authors/instructions/studyprotocol

Contents

1 Abstract

[In progress]

Background: Common mental health problems are common and linked to increased morbidity and mortality. Psychological treatments, such as cognitive-behavioural therapy are effective, however, there are mixed findings and overall, appear only effective for half of the treated adults. Identifying predictors of treatment outcomes could have important clinical implications and allow for tailoring of treatments or development of new interventions.

Methods/Design: In this cohort study, we will assess the impact of a wide range of factors on psychological treatment outcomes for CMHP in the IAPT services. A baseline questionnaire will assess sociodemographic, clinical, treatment-related and psychosocial factors.

Discussion

2 Keywords

Psychological therapies, Cognitive behavioural therapy, common mental health problems, depression, anxiety disorders, older adults, treatment outcome predictors, IAPT services

3 List of abbreviations

CMHP	Common mental health problems
IAPT	Improving Access to Psychological Therapies
CBT	Cognitive behavioural therapy
LEAP	Lived experience advisory panel
PII	Personally identifiable information

4 Background

Common mental health problems (CMHP), such as depression and anxiety disorders, are highly prevalent in adults, with 1 in 5 people being affected (1). CMHP are associated with other health problems and can impact quality of life (2, 3). This is particularly relevant to the population in the present time as we live in an ageing population.

Psychological treatments, such as cognitive-behavioural therapy (CBT) are effective in the treatment for depression and anxiety (4, 5). However, it is not clear whether older people benefit more or less than younger people and overall, only half of people treated recover (6-9).

Knowing who benefits from psychological treatment most (or least) can help mental health practitioners adapt treatment to individual patients or develop new treatments for those who do not benefit from current approaches.

A recent systematic literature review conducted by this team of researchers into treatment outcome predictors identified factors across different domains, related to their person (e.g level of education), their condition (e.g. symptom severity at the start of treatment) of the treatment for their condition (e.g. number of sessions attended) (Manuscript in preparation).

In addition to this, the proposed study aims to investigate self-compassion and resilience, which have both been linked to positive mental health outcomes but not studied as predictors previously (10, 11).

In this proposed study we want to investigate the factors that make psychological treatments work in the IAPT services. Participants aged 18 years or above will be asked to complete an online questionnaire at the beginning of their treatment. The primary outcome we will measure is recovery, measured by change in symptom severity for the condition being treated before and after treatment.

The researchers involved in this programme of work adhere to the 1996 version of the Declaration of Helsinki, as referred to in the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Schedule 1 parts 1.2 and 2.6: The health of our patients will be our first consideration; we shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient.

4.1 Research question

What are the predictors of psychological treatment outcomes for common mental health problems in adults (18+ years) in the Improving Access to Psychological Therapies (IAPT) services?

Secondly, do these factors affect psychological treatment outcomes differently for older (65+ years) and working age adults (18-64 years)?

Patient and Public Involvement (PPI)

4.2 Past PPI

A meeting with members of the Lived Experience Advisory Panel (LEAP) took place in May 2021 where participant materials and recruitment was discussed. The panel consisted of three people, with further feedback received from one member remotely. A main point of the feedback received was the careful handling of questions which may trigger emotional responses in participants, such as the questions around stressful life events and associated coping. Subsequent to this feedback, amendments have been made to the participant information sheet and consent form to advise participants of the sensitive nature of these questions and to include information on where to seek help. Further, the section has been made optional in the main questionnaire so that participants who do not wish to answer these questions, can skip this part of the questionnaire.

Further, the panel have advised that the download of software to complete the optional cognitive function tests would not be acceptable. Therefore, we were in discussion with potential collaborators in Russia who have developed DigitalPsyTools (12), a web-based platform to administer these tests without having to download software. However, concerns were raised about security and confidentiality risks involving Russia. Due to the difficulty in finding a solution to administer these tests effectively remotely, the decision has been taken to remove the cognitive function measures from this study.

Lastly, concerns were raised regarding the language used in the study invitation letter, the consent form and the Participant Information Sheet. These documents were substantially re-written and new versions created.

4.3 Future PPI

A further meeting with the LEAP members is planned to take place prior to the submission of the application for NHS Ethics approvals. A further meeting may be scheduled following REC/HRA feedback on any changes required.

During recruitment and the course of the study, two meetings will be scheduled in order to discuss any issues arising from recruitment and/or running of the study.

At the end of study, two meetings will be scheduled to share a lay summary of findings and to discuss dissemination.

5 Methods/Design

5.1 Type of study

This is a cohort study of 700 participants (350 younger adults (< 65 years), 350 older adults (65+years). Quantitative data will be collected via baseline questionnaires. This will be complemented with treatment related and outcomes measures which are routinely collected by the IAPT services.

Participants

Participants will be recruited through the NHS Sussex Partnership Foundation Trust IAPT services. The research team will also apply to for the study to be adopted to the NIHR portfolio with the aim to include other IAPT services. The participants are adults (18+ years) who have been diagnosed with a common mental health problem and are awaiting the start of their psychological treatment in the IAPT services, following their initial assessment.

5.1.1 Inclusion/exclusion criteria

Inclusion criteria are that participants will:

(1) Be aged 18 years or over;
(2) Are offered treatment in the IAPT service in step 2 or step 3 of depression and/or an anxiety disorder
(3) Read and understand English at the required level in order to respond to the PIS and the questionnaire.*

*The study team have considered how the study could be made more widely accessible but the questionnaires are validated in English only and this project does not have sufficient resource to offer the materials in other languages.

5.2 Aims & Objectives

We aim to identify predictors of psychological treatment outcomes for common mental health problems in IAPT service users. In a recent systematic review carried out by this research team, predictors of treatment outcomes for CMHP in older adults (65+ years) identified were across different domains, relating to the person (e.g. level of education), their condition (e.g. symptom severity at start of treatment) or treatment for their condition (e.g. number of sessions attended). Another systematic review into predictors that primarily included younger adults identified similar factors (13), however, also revealed differences such as effects of gender or having social support. Very few studies have compared predictors of treatment outcomes between younger and older adults.

In this study we want to explore a wide range of factors that may be important predictors for outcomes of psychological treatments, as identified in our systematic review and compare whether these factors affect treatment outcomes for older and younger adults differently.

Recruitment and consent methods

Initial Eligibility Assessment
All adults with sufficient knowledge of written English who have been offered treatment in the IAPT services are eligible to participate in the study. The IAPT service will identify potential participants (those who have completed their initial assessment and are waiting for the start of their treatment) and send a study invitation letter via email or by post.

Participant information sheet (PIS)
Potential participants will be provided with a link to the PIS in the study invitation letter, where the study invitation letter is sent electronically. or will be able to access it via a QR code where the study invitation letter is sent by post.

Consent
The consent form will be sent to potential participants along with the PIS. The potential participants will be given contact details of a member of the research team for any questions relating to the participation in the study before providing consent online, via paper form or on the phone with the a member of the research team. Potential participants not wanting to take part in the study will continue to await the start of their treatment.

5.3 Assessment process

The majority of assessments will be conducted at baseline (T0), which includes measures routinely collected in IAPT services as well as measures taken via completion of a questionnaire. Post-treatment (T1) measures will only include measures routinely collected in IAPT services.

Assessment	Carried out by	What the assessment is for	How is the assessment carried out	At what stage is the assessment carried out	Copy of assessment is in Appendix Y/N
Consent	IAPT service/Research team	Obtaining informed consent	Via online consent form	Baseline (T0)	Y
PHQ-9 GAD-7 OCI SPIN MI PCL-5	IAPT service (routinely collected)	Baseline symptom severity/ Outcome assessment	Via validated questionnaires	T0 and T1	N

PDSS WSAS					
DOB Gender	IAPT service (routinely collected)	Will be used for analysis of study data	Routinely asked questions in IAPT services	Baseline (T0)	N
Ethnicity Date of birth Occupation Education	Research team	Will be used for analysis of study data	Via baseline (T0) questionnaire	Baseline (T0)	Y
Condition/Problem indicator Step 2 / Step 3 Type of treatment Number of sessions Referred on to next step? Treatment end date	IAPT service (routinely collected)	Will be used for analysis of study data	Routinely recorded information in IAPT services	Ongoing	N
How long affected by condition Whether previously affected by problem Other diagnosed mental health problems Whether taking prescribed medicine for this condition? Other physical health problems?	Research team	Potential predictor of treatment outcome – will be used for analysis of study data	Via baseline (T0) questionnaire	Baseline (T0)	Y
Perceived health (PROMIS global physical health	Research team	Potential predictor of treatment	Via baseline (T0) questionnaire	Baseline (T0)	Y

scale) (14)		outcome – will be used for analysis of study data			
Loneliness (UCL Loneliness scale, ULS-4) (15)	Research team	Potential predictor of treatment outcome – will be used for analysis of study data	Via baseline (T0) questionnaire	Baseline (T0)	Y
Locus of control (Revised LoC scale) (16)	Research team	Potential predictor of treatment outcome – will be used for analysis of study data	Via baseline (T0) questionnaire	Baseline (T0)	Y
Personality (Ten-Item Personality Inventory-(TIPI) (17)	Research team	Potential predictor of treatment outcome – will be used for analysis of study data	Via baseline (T0) questionnaire	Baseline (T0)	Y
Self-compassion (Sussex-Oxford Compassion for the Self Scale (SOCS-S) (18)	Research team	Potential predictor of treatment outcome – will be used for analysis of study data	Via baseline (T0) questionnaire	Baseline (T0)	Y
Resilience (CD-RISC, 10-item version) (19)	Research team	Potential predictor of treatment outcome – will be used for analysis of	Via baseline (T0) questionnaire	Baseline (T0)	Y

		study data			
Stressful life events (Elders Life Stress Inventory (ELSI) ** (20)	Research team	Potential predictor of treatment outcome – will be used for analysis of study data	Via baseline (T0) questionnaire	Baseline (T0)	Y
Current impact of events (Impact of Events Scale-6 (IES-6) ** (21)	Research team	Potential predictor of treatment outcome – will be used for analysis of study data	Via baseline (T0) questionnaire	Baseline (T0)	Y
Coping (Brief COPE) ** (22)	Research team	Potential predictor of treatment outcome – will be used for analysis of study data	Via baseline (T0) questionnaire	Baseline (T0)	Y

** Response to these measures has been made optional to allow participants to skip these questions which might cause emotional distress.

5.4 Randomisation process & allocation concealment

Not applicable for this study - No randomisation is proposed in this study. All participants will receive the usual care following completion of the initial questionnaire assessing potential predictors.

5.5 Procedure

A procedure flowchart is attached.

Once the participant has consented to take part in the study, the participant will complete a study questionnaire with baseline measures. There are several options: online, via paper or with the help from a member of the research team on the phone. The questionnaire includes socio-demographic and health-related questions and psychosocial measures.

After completion of the questionnaire, the participant will continue to wait for the start of their treatment. Outcome measures in form of during and/or post-treatment scores on PHQ-9/GAD-7 or other anxiety disorder-specific measures will be accessed from the respective IAPT system(s) of each Trust.

5.6 Therapy protocols

5.6.1 Intervention procedure

Not applicable. The aim of this study is not to evaluate a new intervention, but to collect predictors of treatments already used in IAPT services.

Control / comparison procedure

Describe the control/comparison clearly defining what is meant by placebo, treatment as usual or standard care for example.

Not applicable – see above.

5.7 Primary & Secondary Outcome Measures

Primary outcome measures

The primary outcome measure will be recovery. This will be calculated using the IAPT definition of recovery, assessing the change in symptom severity as measured by the scores on the corresponding scale for each presenting problem. These measures are routinely taken in the IAPT service before the start of therapy and post-therapy.

We will also conduct secondary analyses on changes in symptom severity by presenting problem.

The Patient Health Questionnaire (PHQ-9)(23) is a 9-item self-report measure of depression symptom severity used in all IAPT services. Items are rated on a four-point scale. Scores under 10 are considered sub-clinical, 10-14 mild, 15-19 moderate and 20+ severe.

Generalised Anxiety Disorder Assessment (GAD-7) (24) is a 7-item measure of generalised anxiety used in IAPT. Items are rated on a 4-point scale and the measure has excellent psychometric properties. The cut-off score for this scale is 8 and above.

Obsessive-Compulsive Inventory (OCI) (25) is a 42-item measure of obsessive-compulsive disorder used in IAPT. Items are rated on a 5-point scale. The cut-off score for this scale is 40 and above.

Social Phobia Inventory (SPIN) (26) is a 17-item measure of social phobia used in IAPT. Items are rated on a 5-point scale. The cut-off score for this scale is 19 and above.

Agoraphobia-Mobility Inventory (MI) (27) is a 27-item measure of agoraphobia used in IAPT. Items are rated on a 5-point scale, with each situation being rated twice to reflect the degree that the situation is avoided. The cut-off score is above an item average of 2.3.

PTSD Checklist for DSM-5 (PCL-5) (28) is a 20-item measure for PTSD used in IAPT. Items are rated on a 5-point scale. The cut-off score for this scale is 32 and above.

Panic Disorder Severity Scale (PDSS) (29) is a 7-item measure to grade panic disorder severity used in IAPT. Items are rated on a 5-point scale. The cut-off score for this scale is 8 and above.

Secondary outcome measures

Functioning (WSAS): The Work and Social Adjustment Scale (WSAS) (30) is a 5-item measure of daily occupational and social functioning that is used routinely in IAPT.

6 Data Management & Analysis

6.1 Summary of the Types of Data

- Quantitative data will be generated from the completion of 700 online questionnaires administered via Qualtrics, the information from each will be read into R, a statistics software.
- Quantitative data will be obtained from the respective system of the IAPT service(s) taking part in the study. This information will be accessed once, at the end of the participants' treatment and includes socio-demographic (age, gender), pre and post-treatment symptom severity measures for the condition being treated and information relating to the treatment received, e.g. type of treatment, number of sessions attended (see section 6.2). Pre and post-treatment symptom severity measures will be used to assess recovery and treatment effectiveness. Socio-demographic information and information related to treatment will be assessed in the study as potential predictors of treatment outcomes. The PI will send a monthly report of study participants to the Clinical Research Coordinator (CRC). The CRC will retrieve the IAPT system data for the participants that have completed treatment and send to the PI in a password protected file. The PI will match the IAPT system data with the questionnaire data. Once the datasets have been matched and checked, data will be anonymised and read into R, a statistics software, for analysis.

6.2 Research Variables Form (RVF)

Type of data	Variable name	Outcomes/units	Source/Any Instructions
Consent	Has the subject given consent freely	Yes/no	Consent form
Quantitative	PHQ-9 GAD-7 OCI SPIN MI PCL-5 PDSS WSAS	Total Total Total Total Total Total Total Total	Routinely collected information in IAPT, to be retrieved from IAPT system.
Demographics	DOB Gender	DD/MM/YYYY M/F/other	Routinely collected information in IAPT, to be retrieved from IAPT system.
Demographics	DOB Education Occupation	Number Multiple choice Multiple choice	Baseline qnre
Clinical (quantitative)	How long affected by condition Whether previously affected by problem Other diagnosed mental health problems Whether taking prescribed medicine for this condition? Other physical health problems?	Multiple choice Yes/No/Prefer not to say Yes/No/Prefer not to say and follow up question: which one, answered via multiple choice Yes/No/Prefer not to say Yes/No/Prefer not to say and follow up question: which one, answered via multiple choice	Baseline qnre
Clinical (quantitative)	Condition/Problem indicator		Routinely collected information in IAPT, to be retrieved from

	Step 2 / Step 3 Type of treatment Number of sessions attended Referred on to next step? Treatment end date		IAPT system.
Psychosocial (quantitative)	Perceived health (PROMIS global physical health scale) Loneliness (UCL Loneliness scale, ULS-4) (15) Locus of control (Revised LoC scale) Personality (Ten-Item Personality Inventory-(TIPI) Stressful life events (Elders Life Stress Inventory (ELSI) Current impact of events (Impact of Events Scale-6 (IES-6) Coping (Brief COPE) Self-compassion (Sussex-Oxford	Completion of this item is optional Completion of this item is optional Completion of this item is optional	All collected in baseline qnre

	Compassion for the Self Scale (SOCS-S) Resilience (CD-RISC, 10-item version)		

Sample size & Power calculations

For our primary analysis, the sample size calculations for the logistic regression was based on Peduzzi et al (1996), who recommend number of events per predictive variable (EPV) of 10 or greater. The model will be built gradually. Initially, bivariate logistic regressions will be performed to explore associations between the outcome and predictor variables. Any variables with a p-value of <.25 will be selected for the multivariate model (Bursac et al., 2008). As the exact number of predictors is therefore unknown at this stage, the calculation below was based on different number of predictors (see attached document). Based on this calculation a sample size of 500 participants is required. This is also in line with recommendations by Bujang et al (2018) who recommend a minimum sample size of 500.

The sample size calculation also needs to account for two factors:

- For our analysis we require individuals that have had at least two sessions, Recent data from the IAPT services show that just under half of the referrals complete a course of treatment (31). However, this is also balanced by our expectation that individuals that enrol in the study would be less likely to drop out of treatment.
- Not all referrals may reach 'caseness' at the beginning of their treatment and we would not be able to assess recovery.

Therefore the total suggested sample size is 700, split equally between younger and older adults.

The sample size calculation for our secondary analysis looking at predictors of continuous symptom severity outcomes, sample sizes have been calculated for multiple linear regressions. Using G*Power, different calculations were made looking at target effects sizes based on existing literature (32, 33), see attached document. The sample size required for this analysis can be accommodated with the sample size calculated for the primary analysis.

6.3 *Planned data analysis*

A descriptive summary of all variables will be created for each time point, for each group separately.

Recovery (y/n), as per the IAPT definition, will be calculated for as primary outcome measure for each participant. Age categories (<65 year and 65+ years) will be entered into the logistic regression models with the predictors, as well as their interaction term, in order to ascertain the effect of age category, the predictor in question and their interaction. The model will be built gradually. Initially, bivariate logistic regressions will be performed to explore associations between the outcome and predictor variables. Any variables with a p-value of <.25 will be selected for the multivariate model (Bursac et al., 2008).

As a secondary sub-analysis, we will perform simple and multiple linear regressions, using the continuous outcome variables (standardised change score in symptom severity) for each presenting problem. The model will be built gradually. Initially, simple regressions will be performed to explore associations between the outcome and predictor variables. Any variables with a p-value of <.25 will be selected for the multiple regression model (Bendel & Afifi, 1977).

Missing data will be assessed and analysis performed on patterns of missingness. Multiple imputation will be performed using the MICE package in R.

6.4 *Dummy results tables*

Descriptive table of baseline socio-demographic and clinical measures

Variable	Younger adults (18-64 years)	Older adults (65+ years)
Sociodemographic		
Age (years)		
Female (%)		
Ethnicity		
Occupation status		
Education		
Clinical		
Condition		
Duration		
Psychotropic medication use		
Comorbidities - psychological		
Comorbidities - physical		
PHQ-9		
GAD-7		

OCI
SPIN
MI
PCL-5
PDSS
WSAS

Recovery rate outcomes for the two age-groups

	Younger adults (18-64 years)		Older adults (65+ years)	
Treatment outcome measures	Recovered	Not recovered	Recovered	Not recovered
Recovered	x	x	x	x
Reliable improvement	x	x	x	x
Reliable deterioration	x	x	x	x

Pre- and post-treatment outcomes for the two age-groups

	Younger adults (18-64 years)		Older adults (65+ years)	
Treatment outcome measures	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
PHQ-9	x	x	x	x
GAD-7	x	x	x	x
OCI	x	x	x	x
SPIN	x	x	x	x
MI	x	x	x	x
PCL-5				
PDSS				
WSAS				

Logistic Regression table for predictors of treatment outcomes

	Individual regressions	Multiple regression

	OR	CI	Wald		p	OR	CI	Wald		p
Baseline PHQ-9, GAD-7 etc.										
Age										
Gender										
Ethnicity										
Education										
Occupation										
Condition										
Duration										
Age at onset										
Psychotropic medication use										
Comorbidities psychological										
Comorbidities physical										
Type of therapy										
Number of sessions attended										
Perceived health										
Loneliness										
Locus of control										
Personality										
Self-compassion										
Resilience										
Stressful life events										
Current impact of stressful life events										
Coping										

Linear Regression table for predictors of treatment outcomes

	Individual regressions					Multiple regression				
	B	SE(B)	β	F	p	B	SE(B)	β	F	p
Baseline PHQ-9,										

GAD-7 etc.										
Age										
Gender										
Ethnicity										
Education										
Occupation										
Condition										
Duration										
Age at onset										
Psychotropic medication use										
Comorbidities psychological										
Comorbidities physical										
Type of therapy										
Number of sessions attended										
Perceived health										
Loneliness										
Locus of control										
Personality										
Self-compassion										
Resilience										
Stressful life events										
Current impact of stressful life events										
Coping										

6.5 Data collection, entering, coding and checking process

The data manager for this study will be the Chief Investigator.

Part of the research data collected in this study will be collected via a questionnaire, which can be completed in different ways: online, via paper or with help from a

member of the research team via a video/telephone call. The online questionnaire is housed on Qualtrics and can be accessed via a link or QR code which will be provided to the participants. If completed in paper form, the questionnaire will be returned to the member of the research team who will enter the data into Qualtrics. Hard copies will be stored in a locked cupboard at the participating site or at the University of Sussex. Where the questionnaire is completed via phone, the member of the research team will enter the responses directly into Qualtrics.

The other part of the research data will be retrieved from the respective IAPT service system. The PI will provide a monthly list of study participants to the CRC, who in turn will retrieve the required information from the IAPT system. The data will then be returned to the PI via a password-protected file. Once the datasets are merged, it will be anonymised by removing participant name and converting date of birth into age in years, only retaining a unique anonymised ID for each participant. See flowchart attached.

Quality assurance checks will be carried out throughout the study to check for any problems with completing the questionnaire, to check for missing data, to check the correct transfer of information from Qualtrics into R and the correct merging of data generated by the research team with that obtained from the respective IAPT service systems.

Following completion of data collection, data will be extracted from Qualtrics into R using the 'qualtRics' package in R.

6.6 *Missing data policy*

Analyses will be performed on the patterns of missingness in the data, as well as sensitivity analysis and multiple imputation using the MICE package in R.

6.7 *Potential bias*

No bias identified at this point.

6.8 *Data custodian and data ownership*

Name of data custodian: Alexandra Schmidt, University of Sussex,
Email: as2085@sussex.ac.uk

6.9 *Data quality and Standards*

The research team adhere to the good practice and standards principles which are set out in the Sussex Partnership Policy for Data Protection, Security and Confidentiality

2013 and the Sussex Partnership Foundation Trust Research Policy 2015 and comply with the University of Sussex's Research Data Management Policy. Processing of identifiable data will comply with The General Data Protection Regulation and the Data Protection Act (2018).

All research will be carried out under the above standards and will be reviewed by the NHS Health Research Authority and, where applicable, an NHS Ethics Committee. The R&D departments of participating NHS Trusts will provide confirmation of capacity and capability where the HRA declare this is expected.

All members of the research team and any other individuals from collaborating Trusts involved in collecting, inputting, processing, using and sharing data will have had Information Governance Training.

Data management will be a standard item on the agenda for the research team.

Data consistency and the quality of the data collection will be controlled by adhering to the Research Assistant Data Management Plan (in appendix).

6.10 Data security

Participant details will be stored on a secure University of Sussex Drive (OneDrive). Consent forms and questionnaires will be stored in Qualtrics and linked to the baseline questionnaire via an anonymised link if completed online. Qualtrics can only be accessed through a password protected account. If completed in paper form, hard copies will be stored in locked cupboards at the participating NHS Trust/University of Sussex. Once research data has been extracted from Qualtrics and merged with the IAPT system data, the dataset will be anonymised. The study data file in R which will be used for data analysis will not contain identifiable information and unique study identifiers will be used.

Electronic files will be stored on a secure University of Sussex Drive (OneDrive) Only non-identifiable information will be included on electronic files aside from an Excel spreadsheet which will link participant names and date of birth with their unique study ID. This Excel file will be used to enable the information flow between the CI and CRC for merging the research data collected via questionnaire with the information from the IAPT system(s).

A limited number of research team members (mainly the CI and CRC) will have access to the participant's personal data collected for the purposes of the study once they have received consent from the participant.

Monitors or auditors from regulatory authorities, such as the Health Research Authority, or the sponsor organisation may have access to the participant's personal data during the study for purposes relating to their taking part in the study and consent will be sought for this from the participant.

Data generated from the study will be analysed by members of the research team, primarily the CI. Quantitative data will be analysed using the software 'R' on password protected University of Sussex computers.

The research data generated from the study will be stored for at least 10 years from the end of the study.

6.11 Data sharing

Consent will be sought from each participant to allow anonymised sharing of research data for publications.

The data will be analysed at group level and individual participants will not be identified. Results of the study will be written up for publication in a national journal, planned by mid 2023.

7 Project management

Project Team Member	Role/ Responsibilities	Contact Details
Alexandra Schmidt	Chief Investigator	as2085@sussex.ac.uk
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8 Ethical considerations

Due to potential emotional stress triggered by questions on stressful life events and associated coping, answering these questions has been made optional following advice from the lived experience advisory panel. Further the PIS and consent form advise of the potentially sensitive content of the questionnaire and provide contact details of organisations that may provide help should a participant feel distressed.

The consent form is proposed to be completed online with a link that will take participants to the main questionnaire. Both documents are in Qualtrics and will be anonymously linked via a randomly generated ID to ensure participant confidentiality. Consent forms completed via paper will be stored in separate locked cupboards at the the participating site/University of Sussex.

9 Discussion of practical and operational issues

NHS HRA requires that both investigators and sponsors follow specific procedures when notifying and reporting adverse events in research studies. These procedures are described in this section of the protocol. The procedures are aligned with the requirements set out for non-CTIMP studies on the HRA website.

Definitions for adverse events and reactions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient treated on a study protocol, which does not necessarily have a causalrelationship with a study intervention. An AE can thereforebe any unfavourable and unintended sign, symptom or disease temporally associated with the use of a studyintervention, whether or not related to that study treatment.
Adverse Reaction (AR)	All untoward and unintended responses related to a studyintervention. A causal relationship between a studyintervention and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out as there is evidence or arguments to suggest a causal relationship.
Unexpected Adverse Reaction (UAR)	An adverse reaction, the nature or severity of which is not consistent with the information about the trial intervention.

Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR) or Suspected Unexpected Serious Adverse Reaction (SUSAR)	Respectively any adverse event, adverse reaction or unexpected adverse reaction that: • results in death • is life-threatening* • requires inpatient hospitalisation or prolongation of existing hospitalisation** • results in persistent or significant disability or incapacity • consists of a congenital anomaly or birth defect

Life-threatening (*), in the definition of 'serious', refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

Hospitalisation (**) is defined as an inpatient admission, regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Hospitalisations for a pre-existing condition (including elective procedures that have not worsened) do not constitute an SAE.

Clinical judgement should be exercised in deciding whether an AE/AR is serious in other situations. Important AE/ARs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious

10.1 Investigator Assessment

(a) Seriousness
When an AE/AR occurs, the investigator responsible for the care of the patient must first assess whether the event is serious using the definition given in Table 1.

(b) Causality
The Investigator must then assess the causality of all events in relation to the research procedures using the definitions in Table 2. There are 5 categories: unrelated, unlikely, possible, probable and definitely related. ARs that are not serious do not need to be reported in an expedited manner.

Table 2. Definitions of causality for adverse events

Relationship	Description	Event Type
Unrelated	There is no evidence of any causal relationship	SAE or AE
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial intervention). There is another reasonable explanation for the event (e.g. the patient's clinical condition, other concomitant treatment).	SAE or AE
Possible	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after the trial intervention). However, the influence of other factors may have contributed to the event (e.g. the patient's clinical condition, other concomitant treatments).	SAR or AR
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.	SAR or AR
Definitely	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.	SAR or AR

(c) Expectedness

The expectedness of the SAE will be accessed centrally by the Site Clinical Lead. If a SAE is assessed as being related and unexpected, it will be reported to the Research Ethics Committee which issued the favourable ethical opinion within 15 days from the CI becoming aware of the event. The CI will also report the event to the study sponsor.

(d) Recording and Reporting of Adverse Events/Adverse Reactions for this study

Table 3 Summary of Recording/Reporting:

Type of Event	Action Required
Adverse Event	Report to site RA/CI within 5 working days. RA/CI to log event for discussion.
Serious Adverse Reaction	Reported to site RA/CI. RA/CI to log event for discussion.
Suspected Unexpected Serious Adverse Event (SUSAR)	Report to REC using non-CTIMP SAE report form on the HRA website. Report to study sponsor.

10 Schedule of events: Project timetable

Enrolment – Recruitment/Enrolment to the study will be performed by the respective IAPT service and will continue from project start date to end of the data collection phase.

Eligibility screen – All adults that have been offered treatment in the IAPT services will be eligible for taking part in the study.

Informed consent – Informed consent will be obtained from participants and stored on a password protected account on Qualtrics if completed online (either individually or with help from the a member of the research team during a video/telephone call). If completed in paper form, the consent form will be stored in a locked cupboard at the participating site/University of Sussex.

Completing baseline measures – Baseline measures outlined in section 6.2 will be obtained via the online or paper questionnaire or by accessing routinely collected information from the IAPT system(s). This will be ongoing throughout the data collection phase.

Commence treatment – Once participants have completed the baseline measures, they will continue to await the start of their psychological treatment in the IAPT service. No further additional involvement is required. The outcome measures for the study are routinely collected by the IAPT service(s) and will be accessed with the support from the CRC in the IAPT service(s).

11 Projected outputs and Dissemination

The results of this study will be written up and submitted to a national journal for publication. Further, abstracts may be submitted for poster presentations at conferences with a focus on mental health. Findings may also be disseminated to charity or voluntary organisations, depending on interest.

12 Plans for Translation

The main aim of this study is to identify predictors of psychological treatment outcomes in the IAPT services. Identifying factors that affect psychological treatment outcomes would allow for the development of personalised treatment approaches, matching patients to existing evidence-based treatments or developing new interventions for non-responders to current practices.

13 Gantt Chart

The Gantt Chart for the study is in the appendix.

14 Appendices

Project plan

Gantt Chart

Procedure
Recruitment process and information sharing flow chart
Safeguarding protocol and flowchart

Sample size calculation document

Data management

RA Data Management Plan

Measures

The following measures and tools will be used and are attached. Time points are baseline (T0), post-treatment (T1).

1. **Study invitation letter**. To be sent along within approximately one week following the initial assessment (before T0).
2. **Study e-leaflet**. To be sent along with study invitation letter (before T0).
3. **Patient Information Sheet**. (before T0)
4. **Consent form**. (before T0)
5. **Baseline questionnaire** (T0)

Outcome/process measures

6. **PHQ-9**. This is a 9-item self-report measure of depression symptom severity. This is the primary outcome measure (T0, T1)
7. **GAD-7**. This is a 7-item measure of generalised anxiety. (T0, T1)
8. **OCI.** This is a 42-item measure of obsessive-compulsive disorder (T0, T1)
9. **SPIN.** This is a 17-item measure of social phobia (T0, T1)
10. **MI.** This is a 27-item measure of agoraphobia (T0, T1)
11. **PCL-5** This is a 20-item measure for PTSD (T0, T1)
12. **PDSS** This is a 7-item measure to grade panic disorder severity. (T0, T1)
13. **WSAS**. The Work and Social Adjustment Scale (WSAS) is a 5-item measure of daily occupational and social functioning. (T0, T1)

Psychosocial predictor measures

14. **PROMIS global physical health scale**. This will be used to assess perceived health. (T0)
15. **UCLA Loneliness scale (ULS-4)**. This will be used to ask participants about feelings of loneliness (T0)
16. **Locus of Control Scale.** This will be used to assess participants' locus of control. (T0)
17. **Personality (TIPI)**. This scale will be used to assess participants' personality. (T0)
18. **Self-compassion- Sussex-Oxford Compassion Scales (SOCS)** This scale will be used to assess participants' self-compassion (T0)
19. **Resilience (CD-RISC)** This scale will be used to assess participants' resilience (T0)
20. **Stressful life events (ELSI)**. This measure will be used to ascertain stressful life events the participants may have experienced in the past year. (T0)
21. **Impact of stressful events** (T0)
22. **Coping (Brief COPE).** This measure will be used to assess the participants' coping style in relation to experienced stressful life events. (T0)

15 Amendments

There are no amendments.

16 Competing interests

All authors declare no competing interests.

17 Authors' contributions

Alexandra Schmidt – Principal Investigator
Dr Darya Gaysina – Academic Supervisor
Dr Clara Strauss – Academic Supervisor
Dr Nick Grey – Academic Supervisor

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