

# Primary Care Trial Efficacy of Alternative Modalities (PCTEAM)

<b>Submission date</b> 08/08/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/08/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 20/05/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Problems with anxiety and depression can have a big impact on peoples lives. Effective treatments that can be offered quickly are important to help support people to address these and other common mental health problems. This study aims to test if a recently developed group (the Take Control Course) can be helpful for people with a broad range of common mental health problems. The Take Control Course has been tested before and been found to be helpful in reducing symptoms of anxiety and depression and improving work and social functioning. However, we need to compare those accessing the Take Control Course with similar people accessing the established individual interventions to find out if these are similarly effective. We want to see how these two treatments compare in the short and longer term. The study will involve interviewing people to find out how they found the two treatments and the things that they felt helped them improve. We will also compare the costs of each treatment to find out which is most cost-effective.

### Who can participate?

Adults with a range of common mental health problems, including mild to moderate anxiety and depression.

### What does the study involve?

Participants will be randomly allocated to either the Take Control Course or individual brief interventions. Each of these interventions lasts for about six sessions. Participants will be asked to fill in a number of questionnaires to be completed before the start of treatment, and at 6 months and 12 months after the initial research appointment. These questionnaires can be completed face-to-face or over the phone if this is more convenient for participants. The study team may contact participants to ask if they want to be interviewed about their experience of the study interventions. However, clients can take part in the research and choose not to be contacted about being interviewed.

### What are the possible benefits and risks of participating?

There are no benefits to participating in the research beyond those expected from accessing the regular interventions offered within the service. As with all therapy, some people may find talking about their emotions and experiences in therapy upsetting. However, the risk of this will

be no greater than when receiving any the standard interventions offered within the service or any other form of therapeutic interventions.

Where is the study run from?

The study is run in Salford, Greater Manchester, UK. It will be available to clients accessing services from Salford Six Degrees Social Enterprise. They provide the low-intensity Primary Care Mental Health Service in Salford, UK. Low-intensity services within the UK provide relatively brief psychological interventions, which can be accessed quickly (e.g. within 4 weeks).

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

The study started in July 2014 and will run until July 2016.

Who is funding the study?

Economic and Social Research Council (ESRC) (UK).

Who is the main contact?

Dr Lydia Morris

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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Lydia Morris

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

16228

## Study information

**Scientific Title**

Primary Care Trial Efficacy of Alternative Modalities (PCTEAM): a randomised controlled trial

**Acronym**

PCTEAM

**Study objectives**

1. To examine whether Take Control Course (TCC) is non-inferior to an active control condition (low-intensity interventions) in a randomised controlled trial with long-term follow-up.  
Hypothesis: Participants in both groups will show reductions in symptom scores on measures of anxiety and depression and outcomes in the TCC group and individual low-intensity interventions (LII) will be non-inferior.
2. Further examination of the reliability and convergent and predictive validity of the Reorganisation of Conflict measure.
3. Nested qualitative component: To explore participants experiences of the TCC and individual LII, specifically, to examine what experiences contribute to psychological change.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee North West-Greater Manchester East Ethics Committee, 11/04/2014, ref. 14 /NW/0160

**Study design**

Randomised; Interventional; Design type: Treatment

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Topic: Mental Health, Primary Care; Subtopic: Anxiety, Depression, Not Assigned; Disease: Depression, Anxiety, All Diseases

**Interventions**

Low-intensity interventions: The Low-intensity interventions delivered within the service are based on principles of CBT. The interventions offered include aspects, such as psycho-education

and cognitive and behavioural strategies; for example, behavioural activation, cognitive restructuring, sleep management and problem solving.

Take Control Course (TCC), The TCC is a group treatment. It consists of six weekly sessions (sessions last an average of one hour). The TCC is not focused on client self-disclosure, but rather emphasises experiential learning, videos, facilitator presentations and worksheets.

Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

1. Patient Health Questionnaire Depression Scale (PHQ9); Timepoint(s): Baseline, 6 months and 12 months post baseline
2. Generalised Anxiety Disorder Questionnaire (GAD7); Timepoint(s): Baseline, 6 months and 12 months post baseline

### **Secondary outcome measures**

1. Adult Service Use Schedule (AD-SUS); Timepoint(s): Baseline, 6 months and 12 months post baseline
2. EQ5D; Timepoint(s): Baseline, 6 months and 12 months post baseline
3. PSYCHLOPS; Timepoint(s): Baseline, 6 months and 12 months post baseline
4. Work and Social Adjustment Scale (WSAS); Timepoint(s): Baseline, 6 months and 12 months post baseline

### **Overall study start date**

01/07/2014

### **Completion date**

30/07/2016

## **Eligibility**

### **Key inclusion criteria**

1. Adults aged 16 and above
2. Suitability for low-intensity services. This includes individuals with mild-moderate depression and anxiety that has emerged within the 12 months prior to referral (i.e. the problem is not a chronic and enduring one). However, other mild to moderate problems can be addressed within this service context and clinical decision-making is according to stepped care models, i.e. other factors that are considered are level of suicidality (see exclusion criteria) and the extent to which problems impair functioning
3. Sufficient English language skills to understand material (i.e. verbal and written language abilities required to read and complete simple worksheets and understand verbal presentations)

### **Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Planned Sample Size: 150; UK Sample Size: 150

**Key exclusion criteria**

1. Clients under 16
2. Suitability for higher intensity services that is primarily determined after first assessment with the service; for example, clients with Post Traumatic Stress Disorder or severe Obsessive Compulsive Disorder; clients with persistent self-injury requiring clinical management or who were potentially intent on and/or planning suicide; clients who are currently experiencing psychotic symptoms; have current substance dependence; or have an organic brain impairment, such as dementia
3. Literacy or language difficulties that will preclude them from reading simple worksheets or from conversing with a healthcare professional

**Date of first enrolment**

01/07/2014

**Date of final enrolment**

30/07/2016

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

School of Psychological Sciences

Manchester

United Kingdom

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**Sponsor information****Organisation**

University of Manchester (UK)

**Sponsor details**

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**Sponsor type**

University/education

**ROR**

<https://ror.org/027m9bs27>

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

Economic and Social Research Council (ESRC) (UK)

**Alternative Name(s)**

ESRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No