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Primary Care Trial Efficacy of Alternative Modalities (PCTEAM)

Submission date
08/08/2014

Recruitment status
No longer recruiting

Registration date
08/08/2014

Overall study status
Completed

Last Edited
20/05/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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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 the12 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
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details

Oxford Road
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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?
HRA research summary			28/06/2023	No	No