ISRCTN35418604 https://doi.org/10.1186/ISRCTN35418604

Evaluating culturally adapted behavioural activation therapy for patients with depression in Pakistan

Submission date
23/06/2021

Recruitment status
No longer recruiting

Registration date
18/07/2021

Overall study status
Completed

Last Edited
09/12/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to evaluate a mental health therapy called Behavioural Activation for patients suffering from depression in Pakistan. The researcher intends to compare the effectiveness of manualized Behavioural Activation Therapy developed for depressed Muslim clients (BA-M) with that of a Treatment As Usual (TAU) group.

Who can participate?
Patients above 18 years of age with depression as the main issue to treat

What does the study involve?
Participants will be randomly allocated to receive therapy in one of two groups: either the therapy that is normally provided on those targeted sites (based on Cognitive Behavioural Therapy) or the new treatment that we are testing called Behavioural Activation (BA-M). In each group the therapist will explain fully the treatment that participants will receive. Before and after the sessions, the therapist will help participants to complete some short questionnaires about health. With consent therapy sessions will be recorded to check that the therapist is delivering the therapy correctly. Participants in the BA-M group can also agree to be interviewed when the therapy sessions end about what they thought of the therapy.

What are the possible benefits and risks of participating?
There is a risk of patients becoming distressed during treatment either from BA or standard therapy. However, both types of treatment are being delivered by trained professionals and participants could benefit from having therapy.

Where is the study run from?
1. Leeds Institute of Health Sciences, University of Leeds (UK)
2. Centre for Clinical Psychology, University of the Punjab, Lahore (Pakistan)

When is the study starting and how long is it expected to run for?
July 2019 to June 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr Saima Dawood, saimadawoodkhan.ccpsy@pu.edu.pk
2. Dr Ghazala Mir, g.mir@leeds.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Saima Dawood

Contact details
Centre for Clinical Psychology
University of the Punjab, New Campus
Lahore
United Kingdom
545900
+92 (0)333 4225020
saimadawoodkhan.ccpsy@pu.edu.pk

Type(s)
Scientific

Contact name
Dr Saima Dawood

Contact details
Centre for Clinical Psychology
University of the Punjab, New Campus
Lahore
Pakistan
545900
+92 (0)333 4225020
saimadawoodkhan.ccpsy@pu.edu.pk

Additional identifiers

Protocol serial number
MREC 19-034 (Leeds, UK); 4-78/NBC-459/20/726 (Pakistan)

Study information

Scientific Title
A randomised control trial to evaluate culturally adapted behavioural activation therapy for patients with depression in Pakistan

Acronym
CAT-D PAKISTAN

Study objectives
Culturally adapted behavioural activation (BA) therapy will reduce symptoms of depression more than treatment as usual in Pakistan.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 10/01/2020, University of Leeds Ethics Committee (Faculty of Medicine and Health Research Ethics Committee, Worsley Building, Clarendon Way, Leeds LS2 9NL, UK; +44 (0)113 343 4897; governance-ethics@leeds.ac.uk), ref: MREC 19-034 UOL
2. Approved 26/11/2020, National Bio Ethics Committee (Pakistan Health Research Council, Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad, Pakistan; +92 (0)51 9224325, 9216793; nbcpakistan.org@gmail.com), ref: 4-87/NBC-459/20/726

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

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

Interventions
Patients were recruited from the targeted sites through the referral of a respective psychiatrist or consultant. After consent, participants were interviewed and screened for depression. Pre and post assessments were carried out by blind assessors. After completion of the assessment, participants were randomly assigned in blocks of two to either the BA group or Treatment As Usual (TAU). The pre-assessment was done first so that each could be screened for depression. The BA group received treatment according to the manual. The TAU group received treatment as usual (provided in those targeted sites).

Four hospitals and clinics (research target sites) in Lahore were selected to provide control and intervention sites but due to COVID-19, one target data site was converted into a Corona Centre by the Government (which was a government hospital). Clients were asked to visit one of the recruitment sites once or twice a week (hospital or Centre Clinic) to receive therapy sessions of 60 minutes duration each (minimum of 6) from a therapist trained in BA-M. The number of sessions was extended if therapists felt there was a need and participants were willing to continue. There were no charges for the therapy. Intervention group therapists had already been trained before the commencement of the trial in relevant areas drawing on materials and experience from a relevant prior study (Mir et al 2015).

Baseline measures were taken before randomisation and at follow up assessments at 4 months. All clients were asked to fill in measures before each session about depression and activity

levels. Other measures relating to quality of life and religious coping were gathered at baseline and 4 months after recruitment. Sessions were recorded where clients consented to this and a random selection of recordings will be assessed for adherence to the manual by two members of the research team.

A qualitative study was also undertaken. Clients and therapists from the BA-M group were interviewed to explore their feedback about the therapy. One therapist from each site was selected along with a purposive sample of three participants. Across the sites the researchers ensured gender and demographic variables were taken into account in the client sample as well as representation of clients who completed and withdrew from therapy. Exploration of how and why the intervention operates in practice within this low resource setting was examined. The researchers explored the views of diverse stakeholders on the intervention and examine implementation, mechanisms of action, acceptability, fidelity, sustainability and potential for scaling up, including obstacles and enabling factors.

Intervention Type
Behavioural

Primary outcome(s)
Depression measured using the Personal History Questionnaire (PHQ-9) at baseline, each therapy session and 3 months follow up

Key secondary outcome(s)
1. Activity level of the clients in the course of treatment measured through Behavioral Activation for Depression Scale (BADS) at baseline, each therapy session and 3 months follow up
2. Degree of depression measured with the Depression scale of the Symptom Checklist (Revised) at pre and post and 4 months follow-up after recruitment
3. Overall quality of life and general health measured by Quality of Life Scale at baseline and 4 months after recruitment

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Above 18 years of age
2. 10 or higher score on PHQ-9 to screen for depression
3. Absence of any other comorbidity related to psychosis
4. Able to understand the study measures
5. Capable of giving consent as a participant for clinical research

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
92

Key exclusion criteria
Psychiatric patients who have been diagnosed with other comorbid psychological disorder such as bipolar disorder and schizophrenia coming in the above mentioned psychiatric setups and clinic

Date of first enrolment
18/01/2020

Date of final enrolment
02/03/2021

Locations

Countries of recruitment
Pakistan

Study participating centre
University of the Punjab
Centre for Clinical Psychology
Phase III
Lahore
Pakistan
545900

Study participating centre
King Edward Medical University
Department of Psychiatry
Lahore
Pakistan
545900

Study participating centre
Punjab Institute of Mental Health (PIMH)
Shadman

Lahore
Pakistan
545900

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. This will be the University of Leeds Data Repository. The policy of the University of Leeds is to make datasets available for sharing via the University of Leeds Research Data Leeds Repository as soon as reasonably possible once datasets are finalised. Anyone wishing to re-analyse the qualitative data will be asked to contact the principal investigator so that they are fully aware of the context and purpose of the qualitative data collection before any further analysis is done.
The only restriction or delays to data sharing beyond the time required to finalise datasets and to produce any relevant accompanying documentation and metadata is the need to ensure the researchers are able to retain control of data that will be published. The reuse of the data will be subject to strict conditions. An example of a data-sharing agreement in use at the University of Leeds can be found here:
http://timescapes.leeds.ac.uk/assets/files/archive/archive-user-terms-and-conditions.pdf
Anonymized quantitative and qualitative data will be shared on completion of the study for an indefinite period. Consent was obtained for use of data for new research from participants.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/08/2023	28/05/2024	Yes	No
Participant information sheet	version v1.0	14/07/2021	23/07/2021	No	Yes
Participant information sheet	version v1.0	14/07/2021	23/07/2021	No	Yes