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Evaluating a culturally adapted treatment for depression in Bradford

Submission date	Recruitment status
08/06/2021	No longer recruiting
Registration date	**Overall study status**
12/07/2021	Completed
Last Edited	**Condition category**
06/09/2024	Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Some people in Muslim communities experience higher rates and longer periods of mental ill health than other groups. Therapies that draw on faith as a resource can help prevent long-term depression and improve people's quality of life. However, little is known about how to develop faith-based approaches for people with depression in the UK. Community-based services that may work have little or no impact on mainstream NHS healthcare and reach only a small minority of people.
National healthcare policies state that professionals should take account of cultural identity and provide appropriate healthcare for minority ethnic and religious groups. Professionals may get little practical support to do this however and there is very little research evidence about how to meet the specific needs of this population. This study aims to measure the impact of a culturally adapted therapy that has been developed to meet the needs of Muslim patients with depression. The approach is based on a mental health therapy called Behavioural Activation and the researchers have used evidence from existing research and practice to produce a guidance manual for therapy. They will gather feedback on how effective Muslim participants and those involved in delivering the therapy find the culturally adapted treatment compared to Muslim participants who receive the standard support for depression.

Who can participate?
Adult clients from Bradford who have depression and identify themselves as Muslim. Clients can be from any ethnic background

What does the study involve?
People with depression who take part in the study will be allocated to receive either the culturally adapted or the standard treatment or support for depression. Before each therapy or support session, they will be asked to complete two short questionnaires about their health and some personal details about themselves. They will also be asked to complete the same questionnaires 3 months after they get involved in the study.

What are the possible benefits and risks of participating?
Behavioural activation is an evidence-based treatment that is widely used in primary care and can help people with depression. The culturally adapted version of behavioural adaptation does

not change the basic elements of the treatment and it is unlikely that there will be any risk of harm from the study. The researchers cannot guarantee any specific treatment benefits from the adapted therapy but they should be able to find out whether this approach works better in Muslim communities than the standard treatment or support that is usually provided.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
November 2019 to September 2023

Who is funding the study?
Bradford Clinical Commissioning Group (UK)

Who is the main contact?
Prof. Ghazala Mir
g.mir@leeds.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Prof Ghazala Mir

Contact details
Worsley Building
Clarendon Way
Leeds
United Kingdom
LS2 9NL
+44 (0)113 3434832
g.mir@leeds.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
295105

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 295105

Study information

Scientific Title
Evaluation of a culturally adapted treatment for Muslim clients with depression in Bradford: comparison with treatment as usual in IAPT and community mental health organisations

Acronym
ECAT-D

Study objectives
Does culturally adapted Behavioural Activation (BA) reduce depression in adult Muslims in Bradford when delivered by a) trained IAPT staff and b) trained non-specialist staff in voluntary sector organisations?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2021, Yorkshire & The Humber - Sheffield Research Ethics Committee (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ, UK; +44 (0)207 104 8364, +44 (0)207 104 8222, 0207 104 8131; sheffield.rec@hra.nhs.uk), REC ref: 21/YH/0068

Study design
Pragmatic block randomized trial with qualitative process evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of depression in Muslim adults

Interventions
Culturally-adapted BA (BA-M) is an innovative adaptation of an effective therapy for depression, developed and piloted by researchers at the University of Leeds and York with NIHR funding. Standard BA, on which the culturally adapted approach is built, is an established and effective manualised psychological therapy.

The adapted treatment enhances standard BA through additional resources in the form of: a Values Assessment tool, a self-help booklet for clients that draws on religious teachings to reinforce therapeutic goals, a list of local resources with whom those delivering therapy are encouraged to collaborate where helpful; evidence-based guidance on how to engage with clients to treat depression and to understand the social context in which such clients live. Involvement of family members and liaison with external sources of support is also recommended where helpful for treatment.

Eighteen staff from four community mental health organisations in the voluntary sector (henceforth VSOs) have attended a one-off 5-day training course, delivered by an academic at the University of Bradford and an NHS therapist involved in published studies on training non-

specialists in BA. The VSO staff have been assessed as competent to deliver BA and clinical support to deliver the therapy from IAPT supervisors in Bradford District Care Trust has been organised, including regular supervision and peer group meetings.

BA-M training has also been delivered to 30 staff from NHS Primary Care Mental Health (IAPT) Services and VSOs, drawing on materials and experience from relevant prior studies. Managers and supervisors also attended the training to support implementation. Lessons from the pilot trial about engagement with Muslim clients and delivery of the therapy were presented and supplemented through feedback on the use of the approach in practice and trainees' ideas on how the approach should be adapted to the service and context in Bradford. Existing successful strategies for retaining Muslim clients in therapy were also discussed.

During the course of the proposed trial, the research team will work with VSOs to facilitate a workshop for mental health and community organisations serving diverse faith groups in Bradford (e.g. Hindu, Sikh and Jewish communities) to explore the wider relevance of the culturally adapted approach to people with depression in these communities. The study will aim to include people with lived experience and those with religious expertise. The potential for the self-help booklet to be adapted for different faith groups and, if relevant, mechanisms for producing faith-specific versions of the booklet will be discussed.

RECRUITMENT: Over a 12 month period, assessment staff within organisations involved in the research will identify eligible Muslim clients and provide them with information about the study. Clients will be allocated to staff that provide mental health support, following the organisation's normal routines as closely as possible and taking account of staff capacity. Formal consent will be taken at the first therapy/support session by the staff to whom clients have been allocated. Staff trained to deliver BA-M will use the adapted therapy with client participants and staff not trained to deliver BA-M will deliver treatment as usual.

Recruitment will support inclusion of those with limited English ability in the trial; routine practice within all organisations involved in the study is for bilingual members of staff to support service users who do not have English language reading skills through either translated materials (e.g. PHQ-9 is available in a number of different languages) or verbal explanation of questions for languages in which staff have fluency. Languages spoken by staff vary across organisations but include Urdu, Punjabi, Bengali and Hindko, which are common languages in the Bradford Muslim community. For other languages interpreters will be employed to support communication where possible. Ethics committee approved versions of information sheets and consent forms will be translated into Urdu, Arabic and French, which have been identified by the CCG as the three most common written languages used by Muslims in Bradford. Staff involved in the study may still need to provide verbal explanations and support to fill in forms for service users who do not speak these languages or English or do not have literacy skills in any language.

Anonymised data will be collected from eligible IAPT and VSO clients over a 12 month period with 3-month follow-up. Clients agreeing to take part in the trial will be allocated to receive either standard treatment/support or at least 6 weekly sessions of BA-M delivered by trained IAPT or VSO staff members. Four booster sessions will also be offered following completion of therapy in line with routine IAPT practice in Bradford.

A Values Assessment will be conducted early in the BA-M therapy process to identify those clients for whom faith is an important value. Where clients in the treatment arm do not wish to draw on faith as a resource for health, they will receive standard BA; those who do will be supported to do so by those delivering therapy and offered a self-help resource. All staff delivering the adapted therapy will have access to the BA-M manual, which could still be relevant

in all cases to understanding the client's cultural context eg in terms of relationships with family or community members. Clients will not be approached by researchers unless they have given prior consent to care staff to be contacted for a qualitative interview.

TREATMENT AS USUAL (TAU) will be delivered by staff not trained in BA-M. In IAPT settings TAU will comprise low-intensity Cognitive Behavioural Therapy. In VSO settings TAU will comprise one or more of the following: one to one counselling, life coaching, exercise, peer to peer groups, walking & cycling groups, cooking sessions, arts and craft sessions, confidence building workshops, community travel, welfare and housing support, education and training sessions, befriending and wellbeing services.

THERAPY SITES: Within IAPT, clients will be screened for eligibility by staff in IAPT and secondary mental healthcare teams and referred to the City IAPT team for the intervention.

TAU in IAPT will be offered across therapy sites in Bradford, Airedale, Wharfedale and Craven as well as by therapists not trained in BA-M within the City IAPT team.

VSOs involved in the trial are Sharing Voices Bradford, Naye Subah and Womenzone. These organisations will recruit from their service users. Staff involved in assessment will provide an accessible information sheet about the trial to eligible clients. Allocation to staff within the organisations will follow normal processes and formal consent will be taken at the first therapy /TAU session by staff to whom potential client-participants are allocated. TAU within these organisations will be offered by staff who have not been trained to deliver the culturally adapted BA therapy to clients that are allocated to them via the organisation's normal processes.

REFERRALS for the adapted therapy are currently sought, from GPs, community organisations and other relevant agencies identified by IAPT and VSO staff as well as through self-referral. All participants will be subject to usual care including referral and assessment of risk. IAPT and VSO staff as well as referral agencies will follow normal practice for client safety if these arise during the trial, including existing organisational protocols for distress and dealing with suicidal clients. The impact of COVID-19 on mental health within this population will also be explored with clients at assessment stage

Discharge: Follows completion of therapy/TAU or continued non-attendance after at least three attempts to re-engage, taking account of the many environmental stressors that influence clients from socially excluded populations. IAPT and VSO staff will determine additional solutions to dropout and processes for maintaining contact with participants, based on existing successful strategies. These will be documented in the therapy manual and inform the process evaluation as well as data collection procedures.

In VSO settings discharge differs for each organisation. Naye Subah and Sharing Voices discharge after three consecutive non-attendances and no response to follow-up by telephone call or letter. Womenzone discharge if there is no response after contacting non-attending clients via phone and offering to extend or rearrange sessions and providing incentives where possible.

QUANTITATIVE EVALUATION: Statistical analysis will be conducted by Professor Robert West who will also oversee data collection processes. Baseline measures will be taken before therapy /TAU begins using PHQ-9 and BAD-SF and, for client participants in the treatment arm, Brief RCOPE, a religious coping questionnaire will also be used. The Patient Health Questionnaire (PHQ) is a validated and self-administered brief measure of depression severity. The Behavioral Activation for Depression Scale (BADS) Short Form is a brief and validated version of a measure

of client engagement in rewarding activity over the course of BA treatment. The Brief RCOPE is a validated 14-item measure of religious coping with major life stressors. All measures have been validated and used extensively in studies of depression across a range of diverse populations and are included in the BA-M treatment manual. In order to avoid contamination of treatment as usual activities, the religious coping questionnaire will not be used in the control arm as this could potentially introduce the idea of religious coping to client participants with whom this might not otherwise have been discussed. PHQ-9 and BAD-SF measures will be collected before each therapy/TAU session. Follow up assessments will be collected at 3 months post recruitment.

For all participants demographic details will be gathered at baseline to support comparison between samples, including religion, gender, ethnicity and age. For clients, data on depression severity, anti-depressant medication will be collected at baseline and 3 months follow up. The researchers will also identify rates of referral and treatment during the 12 months implementation period and at 3 months post-completion to explore whether these rates increase and are sustained. Regular reports will be summarized and results discussed with a project steering group during the implementation period to inform local activity.

Analysis of PHQ-9 data will follow national IAPT methods for calculating recovery rates, reliable improvement and reliable recovery. As the delivery of the adapted therapy by VSO staff is particularly innovative (though based on previous evidence that this is feasible an initial analysis of data from the first 25 PHQ-9 forms collected at VSO sites will be conducted to assess the safety of therapy delivery in VSO settings. Anonymized quantitative results will be discussed by the Project Steering Committee for this data and for the broader subsequent analysis. The broader analysis will produce comparisons between clients receiving BA-M in the City IAPT team or VSO settings and:
1. The general population of clients receiving TAU in Bradford IAPT as a whole (using routinely collected data)
2. Muslim clients receiving TAU
3. Subgroup analysis of Muslim clients who receive BA without drawing on faith identity as a resource for health

The groups will be compared using Welch's t-test applied to the coefficient of CABA in the multi-level regression model. Further exploration will be undertaken by use of multi-level regression with measurements clustered within patients and patients within therapists also adjusting for relevant confounders such as age and sex and agreed before analysis with the clinical team. There will be a concern regarding data missing at 3 months follow up. Since PHQ-9 is measured at every session, the last observation will be carried forward for the main analysis. The multilevel regression will better control for missingness. In addition, sensitivity analyses will be undertaken to determine the extent of any plausible bias.

Demographic data for each group of clients will also be used to analyse variation in outcomes by subgroups (gender, age, comorbidity, ethnic group) through regression analysis. The researchers will also consider the impact of activity levels, choice of treatment (i.e. standard/adapted BA), therapist background and experience and therapy site on client outcomes in both groups. Client religious coping will be measured within the intervention group at baseline. completion of therapy and 3 months follow up. This measure will not be used within the TAU group in order to prevent contamination of results.

QUALITATIVE EVALUATION: Therapists will offer clients in the treatment arm the opportunity to discuss participation in qualitative interviews or to ask further questions. Telephone numbers and other contact details will be obtained of those agreeing to be contacted. The PI will approach these individuals after a minimum of 48 hours and obtain formal additional consent for

qualitative interviews. Information sheets and consent forms will be available in Urdu, Arabic and French as the three most relevant languages and locally used interpreters will be employed where necessary to enable participation. Details of individuals who have agreed to be interviewed and electronic consent forms will be sent as encrypted documents via email, in line with University of Leeds Information Management Guidance. Verbal informed consent will be recorded on audio equipment and only obtained if it is technically difficult to obtain written consent because of limited literacy; a note will be made on the consent form to record this.

Monthly/regular participant observation of team meetings at which routine discussions about the use of the therapy in practice will contribute to qualitative data. Qualitative interviews with a range of stakeholders at IAPT and VSO sites (up to 16 staff delivering culturally adapted therapy, 4-6 managers and supervisors, 15-20 diverse service users who receive treatment and 10-15 who drop out) will explore the experience of the intervention in terms of: barriers and facilitators to implementation or access, impact, reach, acceptability, contextual and other influences on delivery and/or perceived impact, mechanisms of impact and unanticipated effects. Quantitative process measures will assess staff fidelity to the new treatment through assessment of therapy recordings against an existing adherence checklist, developed during the pilot trial (up to 30 sessions recorded by therapists, to include a sample from each organisation delivering therapy). The number of referred clients with depression in a 12 month period who attend at least one therapy session, number of clients identifying religion as an important value during Values Assessment and number of new or enhanced service links and referral pathways developed to support the use of the therapy will also be recorded as part of the process evaluation and details will be explored during qualitative interviews.

Knowledge will be validated and coproduced with local stakeholders, drawing on quantitative and qualitative data, to ensure credibility and relevance to local context as well as refinement of a logic model for how the intervention works in practice.

POWER CALCULATION: The anticipated sample size for client-participants is 250 for the intervention arm and 285 for the control arm. The range of PHQ9 is 0 to 27 with a standard deviation of 6.5. A threshold of 10 is used to indicate depression. Thus, it is anticipated that almost all patients will have a baseline value of at least 10, and given that the intervention and the usual treatments are known to be effective, many patients will report PHQ9 scores below 10 at 3 months. The researchers anticipate that the standard deviation of the change in PHQ9 will be 5 units. This provides power of 90% to detect a difference in the mean change in PHQ9 of 1.4 units with 90% and of 1.2 units of 80%. Hence the trial is adequately powered for the primary outcome. There will also be an opportunity to explore secondary outcomes and secondary analyses, particularly as the multilevel regression work is able to take full advantage of the additional PHQ9 measurements.

COMMUNITY AND CLIENT GROUP INVOLVEMENT: A Service User Advisory Group (SUAG) that has been established by Sharing Voices will work in parallel with, and be represented on, the Project Advisory Group, influencing decision-making about the overall trial and supporting validation of findings. Dissemination materials will be co-produced with the SUAG.

Removed 03/04/2023:
It is noted that allocation to treatment and control groups is not randomised, so that there could be an imbalance between the groups. This will be accounted for by taking the change in PHQ-9 score from baseline to 3 months, rather than a single value of PHQ-9. In addition, a random intercept for the therapist will be included in the regression analysis which adjusts for differences in therapist performance – as allocation is not randomized, this is necessary either by a random effect as proposed or as fixed effects which would be less efficient.

Intervention Type
Behavioural

Primary outcome(s)
Depression severity and response to treatment measured using a self-completion questionnaire (PHQ-9) at baseline, each therapy session and 3-month follow up

Key secondary outcome(s))
1. Activity levels measured using the 9-item validated Behavioural Activation for Depression Scale (BADSF) at baseline, each therapy session and 3-month follow up
2. Religious coping measured using Brief RCOPE at baseline, completion of therapy and 3-month follow up

Completion date
30/09/2023

Eligibility

Key inclusion criteria
Muslim clients aged over 16 years with a depression score >10 on PHQ-9, including clients prescribed medication

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
193

Key exclusion criteria
Individuals with depression and another primary disorder for which other empirically supported treatments exist (e.g. post-traumatic stress disorder (PTSD), schizophrenia or psychosis) and any problem requiring immediate hospitalisation

Date of first enrolment
16/09/2021

Date of final enrolment

28/02/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bradford District Care Trust
Bradford District Foundation
Care Trust
Address Level 3, Horton Park Centre
Horton Park Avenue
Bradford
United Kingdom
BD7 3EG

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Bradford Clinical Commissioning Group

Results and Publications

Individual participant data (IPD) sharing plan
All anonymised data will be archived and curated at the University of Leeds Research Data Repository, with each dataset assigned a DOI, in line with Medical Research Council Guidelines to

support sharing of research data with long-term value. The process for requesting access can be obtained from researchdataenquiries@leeds.ac.uk who can also advise on timing for availability. Consent from participants will be obtained, there are further details at https://archive.researchdata.leeds.ac.uk/information.html.

IPD sharing plan summary

Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		17/05/2024	17/05/2024	No	No
Funder report results			05/09/2024	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			12/07/2021	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes