**Protocol: Evaluating a Culturally Adapted Treatment for Depression in Bradford**

### Setting and aim – Bradford Clinical Commissioning Group is currently offering a culturally adapted version of Behavioural Activation therapy for depression (BA-M), for which there is existing evidence of feasibility (Mir et al 2015) and support from service users and providers (Mir et al 2019). Behavioural Activation, on which the adapted therapy is based, can be effectively delivered by non-specialist mental health staff following training (Richards et al 2016; Ekers et al 2011) and the CCG is keen to increase such capacity within VSOs. BA-M is being delivered by primary care mental health (IAPT) staff within Bradford District Care Trust and by trained staff in community mental health organisations (VSOs). This research aims to evaluate the impact of the adapted therapy on mental health service users. It will also add to current knowledge on faith-sensitive interventions, for which evidence within minority faith groups is currently limited (Koenig et al 2001).

### Duration in months: 24

Principal research question:

Does culturally adapted-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?

**Primary outcome:**

Change in mean depression scores on the PHQ9 scale at 3 months post recruitment compared to baseline scores

**Secondary research questions:**

1. What impact does the intervention have on depression scores and activity levels on completion of therapy and in the longer term compared with treatment as usual?
2. How is the treatment delivered in practice and what factors influence its delivery?
3. What impact does the intervention have on access to therapy, retention rates and reliable recovery rates?
4. How relevant is the approach to a range of faith groups in Bradford and what adaptations might be needed for specific communities?

**Secondary Outcomes**

* Change in mean depression scores on the PHQ9 scale on completion of therapy and at 3 month follow-up compared to baseline scores: amongst the total number of clients receiving the intervention over 12 months compared to the total number of clients receiving treatment as usual in the same time period
* Number of clients moving from a score >10 (signifying a diagnosis of depression) to <11 (signifying remission) on the PHQ9 scale at 3 months follow up compared to baseline
* Number of sessions needed to achieve reduction in depression scores from baseline
* Change in capacity to deliver the adapted therapy: number of staff trained and competent to deliver the therapy
* Change in religious coping for those choosing the culturally adapted version of BA therapy.

### Trial design and sample size

***DESIGN****:* A pragmatic non-randomised trial with mixed method process evaluation of an intervention to reduce depression in clients. All procedures involving contact with research participants will be conducted either online, by telephone or face-to-face, in accordance with relevant COVID-19 guidance on social distancing.

***INTERVENTION AND TRAINING:*** 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 (Mir et al 2015). 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 (Richards et al 2016; Ekers et al 2011). 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 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 (eg Hindu, Sikh and Jewish communities) to explore the wider relevance of the culturally adapted approach to people with depression in these communities. We 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 (eg 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. REC 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[[1]](#footnote-2), 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 by 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

***Inclusion***: Muslim clients over 16 with a depression score >10 on PHQ9, including clients prescribed medication.

***Exclusion***: Individuals with depression and another primary disorder for which other empirically supported treatments exist (eg PTSD, schizophrenia or psychosis) and any problem requiring immediate hospitalisation.

***Discharge***: Follows completion of therapy/TAU or continued non-attendance after at least 3 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.

The TAU protocol for non-attending clients in IAPT is attached as Appendix 1. 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 (Kroenke et al 2001). 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 (Manos et al 2011). The Brief RCOPE is a validated 14-item measure of religious coping with major life stressors (Pargament et al 2011). 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 (see Appendix 1). 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. PHQ9 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. We 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 PHQ9 data will follow national IAPT methods for calculating recovery rates, reliable improvement and reliable recovery. As delivery of the adapted therapy by VSO staff is particularly innovative (though based on previous evidence that this is feasible (Richards et al 2016; Ekers et al 2011) an initial analysis of data from the first 25 PHQ9 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

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 PHQ9 score from baseline to 3 months, rather than a single value of PHQ9. In addition, a random intercept for 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. 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 PHQ9 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 to 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. We will also consider the impact of activity levels, choice of treatment (ie 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 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 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 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. We 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 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.

***DATA MANAGEMENT:*** A Data Management Plan is attached at Appendix 2

## 6. Project Partners

**Bradford Clinical Commissioning Group (Sasha Bhatt, Mental Health Commissioner; Lynne Carter, Head of Equality)** – overall coordination and management of the project and partners, including independent Chairing of monthly Project Steering Committee meetings; organise and cover costs for venues and refreshments for project and research activity meetings; organise and cover costs for transcription (and interpretation/translation if necessary) for 50 qualitative interviews and information sheets; provide clerical support and organise dissemination activities. Cover client involvement costs. Ensure indemnity arrangements are in place for each VSO.

**University of Leeds** (**Dr Ghazala Mir, Associate Professor of Equity and Inclusion; Professor Robert West, Professor of Statistics) –** obtain ethical approval for the trial; co-facilitate workshop involving a range of faith organisations to explore whether/how to adapt existing resources and develop recommendations; deliver training on culturally adapted BA; conduct qualitative interviews and therapy adherence check. Analyse data and write up findings. Support dissemination activities including writing up a publication for a peer-reviewed journal.

**Bradford District Care Trust/IAPT Service (Naomi Holdsworth, Clinical Manager IAPT)**  - take consent, collect and coordinate data on trial measures. Staff to deliver the therapy/TAU and record intervention sessions. Provision of supervision for all those delivering therapy (including those in VSOs). Provision of training for VSOs in assessment of depression and use of PHQ9. Ensure indemnity arrangements for these activities

**Sharing Voices** **(Ishtiaq Ahmed, Strategic Business Manager)** – organisation and co-facilitation of workshop with diverse faith groups; ensure VSO screening clients for eligibility and delivery of therapy/TAU to depressed clients. Ensure VSO staff are trained to screen for depression and that they take informed consent, deliver therapy/TAU and collect trial measures. Sharing Voices will establish, train and support facilitation of a ***Service User Advisory Group*** made up of adult Muslims with experience of depression, including some who have used IAPT services.

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**GANTT CHART**

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| **ACTIVITY/MONTHS** | 1-2 | 3-4 | 5-6 | 7-8 | 9-10 | 11-12 | 13-14 | 15-16 | 17-18 | 19-20 | 21-22 | 23-24 |
| Ethics and set up |  |  |  |  |  |  |  |  |  |  |  |  |
| Quant Data Collection |  |  |  |  |  |  |  |  |  |  |  |  |
| Quantitative analysis |  |  |  |  |  |  |  |  |  |  |  |  |
| Qualitative data collection |  |  |  |  |  |  |  |  |  |  |  |  |
| Qualitative analysis |  |  |  |  |  |  |  |  |  |  |  |  |
| Writing up |  |  |  |  |  |  |  |  |  |  |  |  |
| Dissemination |  |  |  |  |  |  |  |  |  |  |  |  |

APPENDIX 1: Protocol for non-attending clients in IAPT, Bradford District Care Trust

**IAPT Discharge Policy**

**Assessment and TFA’s** [failure to attend]

If client is booked in for an assessment and fails to attend (X2 attempts to be made to contact client within the appointment time via the telephone within the first 10 minutes) If there is no contact within the appointment time, the client will be discharged.

**1st Therapy DNA**

If client is booked in for a First Therapy and fails to attend (X2 attempts to be made to contact client within the appointment time via the telephone within the first 10 minutes) the appointment the client will be discharged.

Risk - If there is current risk present then a discharge letter needs to be sent to the GP; even if self-referral and consent has not been given.

First Therapy appointment to be made following a discharge by clinician

**1st Therapy Cancellations**

If a client calls to cancel a 1st therapy, it will be rebooked by admin unless client has 3 or more CNA’s [client cancellation] or DNA’s [failure to attend]. If client has 3 or more CNA’s or DNA’s, Admin to discharge, or passed to manager if concerns over risk.

**Ongoing Therapy**

*Clients are allowed 3 DNA or CNA’s within one block of treatment. There can be clinical judgement made particularly when risk is concerned. However, this needs to be discussed with managers. If a client DNA’s 2 consecutive appointments in a row this equates to an automatic discharge.*

*If admin have taken a cancellation and this is a 3rd DNA/CNA this will be sent to the clinician with managers copied in.*

*First Therapy appointment should always be released immediately as soon as you know a client is to be discharged, to allow admin 7 days notice to fill an appointment.*

If client is booked in for an ongoing Therapy and fails to attend (X2 attempts to be made to contact client within the appointment time via the telephone within the first 10 minutes). If client has less than 3 DNA’s/ CNA’s and has not DNA’s 2 consecutive appointments in a row, a 7 day letter to be sent. If no contact after 7 client to be discharged.

If client has had 3 DNA’s/ CNA’s or has 2 consecutive appointments in a row – then this is an automatic discharge and the client is to be discharged.

**Discharge Letters**

It is important that discharge letters are completed to inform the GP and/or client the outcome of their treatment.

 If self-referral please send discharge letter to client and to the clients GP if client has consented.

If GP referral send discharge letter to GP and client.

Risk - If there is current risk present then a discharge letter needs to be sent to the GP; even if self-referral and consent has not been given.

APPENDIX 2: DATA MANAGEMENT PLAN

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| **1. Description of the data** |
| **1.1 Type of study** A randomised controlled trial of a therapy intervention for depression**1.2 Types of data**Quantitative data will be collected using measures to assess depression severity, wellbeing and use of religious coping. Data will also be collected on demographic details (including religion, gender, age, ethnicity), therapist competence and use of anti-depressant medication. Rates of referral for therapy and treatment over a 12 months period and at 3 months post-completion of fieldwork will also be collected.Qualitative data will be collected during interviews with a range of stakeholders at Primary Care mental health services (IAPT) and Voluntary Sector Organisation (VSO) sites. Contact details for participants involved in qualitative interviews and consent forms will also be collected. Participant observation of team meetings about use of the therapy in practice and therapy recordings from each organisation delivering therapy will also contribute to qualitative data. All procedures involving contact with research participants will be conducted either online, by telephone or face-to-face, in accordance with relevant COVID-19 guidance on social distancing. **1.3 Format and scale of the data*****Quantitative data***: Widely accepted file formats such as SPSS or Microsoft Excel will be used to record, collate and store data from participating sites. We aim to collect quantitative data on around 535 individuals receiving therapy and 30 staff delivering therapy. ***Qualitative data***Data will be collected in formats suggested by the UK Data Service as accepted standards in widespread use (<https://www.ukdataservice.ac.uk/manage-data/format/recommended-formats>). Digital formats will be used for interviews and documents and handwritten or typed notes for meeting observations. We aim to collect interview recordings and transcripts for 19-22 IAPT or VSO staff members and 25-30 therapy clients as well as around 30 therapy session recordings. Audio files will be stored in MP3 or WAV format and transcribed into Microsoft Office Word or Rich Text Format (rtf.).  |
| **2. Data collection / generation** |
| **2.1 Methodologies for data collection / generation** Measures used to assess depression severity, wellbeing, therapist competence and use of religious coping have been validated, published in peer-reviewed journals and are widely accepted as reliable. Data on demographic details, use of anti-depressant medication, referral for therapy and treatment is routinely gathered in IAPT to inform service development and treatments offered.Interviews and meeting observations will be conducted by an experienced academic researcher with significant knowledge of practical and ethical issues. All research activities will be organised and conducted by the study partner organisations and by staff with relevant experience and training. **2.2 Data quality and standards** A standard approach in line with current routine practice in IAPT will be used to gather and process quantitative data across all organisations to ensure a high quality dataset is produced. A Data Manager within Bradford District Care Trust will oversee data entry on an ongoing basis and will check and clean the data before the finalised raw dataset is completed. A senior member of the research team at University of Leeds will support development of the database in which entries are collated to ensure it meets the requirements for data analysis.To ensure high quality data from the qualitative research, interview guides will be developed by the PI, drawing on experience from previous related qualitative studies. Transcriptions of interviews in English will be checked for accuracy against audio-recordings at an early stage of data collection. On-going analysis of interviews will support flexible use of the interview guides to explore emerging issues. Observation notes taken at meetings will be written up as soon as possible afterwards to support detailed documentation of therapist experiences and concerns. Interpretations of all project data will be double checked by research team members and partners and evidenced through direct evidence from raw data in the form of tables or direct quotations or observation notes.  |
| **3. Data management, documentation and curation** |
| **3.1 Managing, storing and curating data.** Developing datasets will be stored securely by Bradford District Care Trust, which has secure systems and longstanding experience of managing research data. Data will be handled to standards at the University of Leeds and held on institutional computer systems or hard drive(s) and backed up on a daily basis. Data will be anonymised by the Data Manager following completion of data entry.  Audio recordings of qualitative interviews on encrypted devices will be transferred as soon as possible and within 72 hours to the University of Leeds secure drive and will be securely deleted as soon as full transcription to electronic files has occurred. Anonymised data will be transferred to the University of Leeds Storage Area Network (SAN) for longer term storage. The SAN servers are protected against attacks by the University's Institutional firewall, and are located in physically secure data centres with appropriate fire suppression equipment. The SAN is incrementally backed-up nightly (stored for 28 days), and fully backed-up monthly (stored in long-term off-campus secure storage for 12 months). All completed datasets will also be backed-up this way. Daily backups by the IT infrastructure team will satisfy all relevant best-practice policies**3.2 Metadata standards and data documentation**All datasets will be fully documented with study-level (e.g. background, context and methods) and data-level (e.g. for quantitative data full variable and coding scheme details, and for qualitative data transcripts relevant labelling such as interviewee ID, role, age range, gender, location) metadata (<https://www.ukdataservice.ac.uk/manage-data/document>), based on Data Documentation Initiative standards for metadata (<http://www.ddialliance.org>). Generic user IDs will preserve confidentiality.**3.3 Data preservation strategy and standards**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 |
| **4. Data security and confidentiality of potentially disclosive information** |
| **4.1 Formal information/data security standards**The University of Leeds's policies on data safeguarding will be used to guide data security and sharing practices at the University and partner institutions (<https://library.leeds.ac.uk/info/14062/research_data_management/63/safeguarding_data> ).**4.2 Main risks to data security**Risks include unapproved access to personal or sensitive information and introducing viruses or errors to files / datasets. The PI and Data Manager will be responsible for partner compliance with this data management plan. To ensure the risk of participant identification is very low, personally identifying data will be transferred between partner organisations only when essential to conducting the research activities, such as contact details for individuals who have consented to be interviewed for the study. Electronic transfer of consent forms and details of individuals who have agreed to be interviewed will be sent as encrypted documents via email, in line with [University of Leeds Information Management Guidance.](https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/05/Information-Management-Guide.pdf)  Consent forms will be securely stored in partner organisations then scanned and paper forms destroyed once data collection is complete. During transcription of qualitative data all potentially personally identifying information will be removed to anonymise the data. Transcribers will be asked to sign confidentiality agreements. Audio recordings will be made on encrypted devices and will be securely destroyed as soon as the relevant data has been transcribed and checked. Consent forms will be stored at relevant partner sites in secure (locked) cabinets.  |
| **5. Responsibilities** |
| The BDCT Data Manager will ensure compliance with the data management plan in collaboration with the PI and Bradford CCG. The BDCT Data Manager will oversee data collection by IAPT and VSO partners and will be responsible for local data management, data security and quality assurance of data  |
| **7. Relevant institutional, departmental or study policies on data sharing and data security** |
| **Policy** | **URL or Reference** |
| Data Management Policy & Procedures | <https://library.leeds.ac.uk/info/14062/research_data_management/68/research_data_management_policy>   |
| Data Security Policy | <https://leeds.service-now.com/it?id=kb_article&sys_id=6038bfbc0fae728089d7f55be1050e9d>   |
| Data Sharing Policy | <https://library.leeds.ac.uk/info/14062/research_data_management/68/research_data_management_policy>   |
| **8. Author of this Data Management Plan (Name)** and, if different to that of the Principal Investigator, their **telephone & email contact details** |
| Ghazala Mir g.mir@leeds.ac.uk |

1. Available from <https://medicinehealth.leeds.ac.uk/dir-record/research-projects/980/addressing-depression-in-muslim-communities> [↑](#footnote-ref-2)