University of Hertfordshire UH

# THE INSPIRITED MINDS ADAPTED INTERVENTION: FEASIBILITY STUDY OF A FAITH-BASED CULTURALLY ADAPTED INTERVENTION TO PROMOTE MENTAL HEALTH AND WELL-BEING IN YOUNG MUSLIM WOMEN

## IM-ADAPTED

## Study Protocol

**Short title: IM-Adapted**

**Version number: 1.2**

**Funder: NIHR Public Health Research (PHR) Programme**

**Funder Reference: NIHR156425**

**Sponsor: University of Hertfordshire**

**Clinical trial registration number: ISRCTN17842222**

**Research Ethics Committee: University of Hertfordshire Health, Science, Engineering and Technology ECDA**

**Protocol Number: 0365 2025 JAN HSET**

University of Hertfordshire UH

# Table of Contents

University of Hertfordshire UH

## General Information

This document provides details regarding the setting up of, conduct, analysis and dissemination of the NIHR Public Health Research (PHR) Programme funded study (REF: NIHR156425; The Inspirited Minds Adapted Intervention: Feasibility study of a faith-based culturally adapted intervention to promote mental health and well-being in young Muslim women).

The University of Hertfordshire will sponsor this study. University of Kent, Inspirited Minds (IM), University of Leeds, Birmingham City University, University of East Anglia (UEA) and the British Islamic Medical Association (BIMA) will be collaborators in the study. As such, a collaboration agreement will be signed by the parties, specifying responsibilities and financial arrangements.

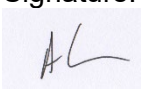
| | |
|---|---|
| Chief Investigator | Prof. Daksha Trivedi |
| Deputy Lead | Prof. Andy Jones |
| Clinical Trial Manager | Megan Smith |
| Sponsor | University of Hertfordshire |
| Study committees | Trial Management Group (TMG)<br>Trial Steering Committee (TSC)<br>Public Involvement Working Group<br>Young Women's Advisory Group (YWAG)<br>Stakeholder Forum |

University of Hertfordshire UH

# Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator(s) agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Good Clinical Practice (GCP) guidelines, the Sponsor's (and any other relevant) Standard Operating Procedures (SOPs), and other regulatory requirements as amended.

We also confirm that we will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given; and that any discrepancies and serious breaches of GCP from the study as planned in this protocol will be explained.

| | | |
|---|---|---|
| Name: Prof. Daksha Trivedi | Role: Chief Investigator | Signature:  Date: 09/07/24 |
| Name: David Wellsted | Role: CTSN/CTU Representative | Signature:  Date: 09/07/24 |
| Name: Allan Clark | Role: Statistician | Signature:  Date: 09/07/24 |
| Name: David Turner | Role: Health Economist | Signature:  Date: 09/07/2024 |

University of Hertfordshire UH

## Glossary of Abbreviations and Key Terminology

Abbreviations and definitions:

| | |
|---|---|
| AE | Adverse Event |
| AR | Adverse Reaction |
| ASR | Annual Safety Report |
| CA | Competent Authority |
| CI | Chief Investigator |
| CRF | Case Report Form |
| ICF | Informed Consent Form |
| ISRCTN | International Standard Randomised Controlled Trial Number |
| PI | Principal Investigator |
| QA | Quality Assurance |
| QC | Quality Control |
| Participant | An individual who takes part in a study |
| RCT | Randomised Controlled Trial |
| REC | Research Ethics Committee |
| SAE | Serious Adverse Event |
| SDV | Source Document Verification |
| SOP | Standard Operating Procedure |
| SSA | Site Specific Assessment |
| TMG | Trial Management Group |
| TSC | Trial Steering Committee |
| MHSW | Mental Health Support Worker |
| IM | Inspirited Minds |
| IM-Adapted | Inspirited Minds (IM)-Adapted |
| YWAG | Young Women's Advisory Group |
| TA | Thematic Analysis |
| PID | Participant Identifier |
| QALY | Quality Adjusted Life Year |
| GCP | Good Clinical Practice |
| QMMP | Quality Management and Monitoring Plan |
| CTSN | Clinical Trials Support Network |
| UHCTSN | University of Hertfordshire Clinical Trial Support Network |

| | |
|---|---|
| Herts YPAG | University of Hertfordshire Young People's Research Advisory Group |
| CTU | Clinical Trials Unit |
| DPIA | Data Protection Impact Assessment |
| eCRF | Electronic Case Report Form |

University of Hertfordshire UH

## Study Summary

| | |
|---|---|
| Full title | The Inspirited Minds Adapted Intervention: Feasibility study of a faith-based culturally adapted intervention to promote mental health and well-being in young Muslim women |
| Short title/Acronym | IM-Adapted |
| Protocol Version Number and Date | 0365 2025 JAN HSET<br><br>09/01/2025 |
| Start Date | 1st March 2024 |
| End Date | 28th February 2026 |
| Study Duration | 24 Months |
| Study Design | A cluster randomised feasibility trial |
| Sponsor | The University of Hertfordshire |
| Chief Investigator(s) | Prof. Daksha Trivedi |
| Funder | NIHR Public Health Research (PHR) Programme |
| REC | University of Hertfordshire Health, Science, Engineering and Technology ECDA |
| Study Objective(s) | Aim: To establish the feasibility of evaluating a faith-based culturally adapted intervention to promote and improve mental health and well-being of young Muslim women in community settings.<br><br>Objectives:<br>• Deliver and evaluate the IM-Adapted group intervention compared with usual psychoeducation<br>• Identify the most effective methods to recruit and randomise participants<br>• Examine the feasibility of delivering the interventions in community settings<br>• Explore implementation and fidelity to the intervention protocol<br>• Determine the acceptability of the interventions, study procedures and barriers to engagement<br>• Estimate adherence rates to the intervention by participants<br>• Explore the feasibility of collecting outcome and resource data |

| | |
|---|---|
| | • Estimate referrals, recruitment and retention rates<br>• Evaluate the safety of the trial<br>• Estimate sample size for a future definitive trial |
| Planned Sample Size | 60 (30 in each arm) |
| Participants | Muslim women aged 18-24<br><br>Inclusion criteria:<br><br>• Muslim women aged 18-24 years self-diagnosed or referred from another source with low mood or mild depression and scoring between 5 and 14 on the Patient Health Questionnaire 9 (PHQ-9) scale (low mood/mild symptoms) and willing to participate in the study.<br>• Participants must be able to read and understand English, although we do not anticipate this will limit inclusion given the age group. |
| Intervention | The Inspirited Minds (IM)-Adapted programme: a faith-based culturally adapted peer support group intervention aimed at promoting and improving mental health and well-being and tailored to the specific needs of Muslim communities. It was co-developed with Muslim service users and therapists. IM works with several Muslim organisations to provide mental health support to young women seeking help.<br><br>The IM-Adapted programme will be delivered in six weekly sessions (90 minutes per session) to groups of 10 by specialist intervention therapists and a co-facilitator (Mental health support worker (MHSW)) identified by IM. |
| Comparison | A low intensity CBT psychoeducation group with no religious or cultural adaptation. Control participants will receive six weekly sessions (90 minutes per session) in groups of 10 delivered by intervention therapists and facilitated by MHSW. |
| Follow up duration | T1 - 6 Week follow-up (during or after the last session)<br>T2 - 24 Week follow-up (24 weeks after first session) |
| Primary Outcomes | • Referral, recruitment, retention<br>• Data quality/completeness<br>• Acceptability to participants<br>• Distress, well-being and anxiety. |
| Secondary Outcomes | • Overall, health related quality of life<br>• Resource use for participants in the intervention<br>• Loneliness<br>• Religious coping |

# 1. Introduction

There is growing concern about the mental health and well-being of children and young people with a striking six-fold increase in the prevalence of long-term mental health conditions in England from 1995-2014 in those aged under 24 (1). Young people are particularly susceptible to the onset of mental illness with over 50% of mental health problems emerging before the age of 14 and 75% before the age of 25 (2). It is of concern that young women aged 16-24 have three times higher prevalence than men (26% vs 9%) with problems more common in young people from minority ethnic backgrounds (3,4). Females aged 24 years or under have also seen the largest increase in the suicide rate over the last three decades (5). Perceived discrimination in young British Muslim students in the UK is associated with increasing anxiety and depression with social stigma remaining strong (6,7). This likely reflects a complex interplay of factors such as social disadvantage, acculturative stress, and discrimination (8,9).

Growing evidence suggests that mental health issues heavily impact Muslims; the largest, fastest growing minority religious group in the UK (10–13). Particularly, high prevalence of anxiety and depression (over 35%) has been reported in young women aged 18-30 largely from Bangladeshi and Pakistani Muslim communities in Britain. Around 45% have reported struggling with mental health (14,15). Young Pakistani and Bangladeshi mothers have also reported high levels of depression (37%) during the pandemic (16).

It is concerning that Muslims are under-referred to therapy services for mental health problems and show poor recovery rates compared to the general population, resulting in inequalities in mental health care and sub-optimal treatment for mental health problems (17,18). There is an unmet need for treatment that is greatest in underserved and ethnic minority communities (Understanding Muslim Mental Health - Research). This can be in explained, in part, due to lack of tailored support to meet the needs of diverse groups with evidence that standard CBT-based interventions are not as effective in promoting mental health and wellbeing in ethnic minority communities (19). The Covid-19 pandemic highlighted the impact of health inequalities with increased mortality in ethnic minority communities which was attributed, in part, to lack of tailored support that did not consider social, cultural, and religious attitudes, beliefs and norms. Tailored support provided at a local level, such as health champions, demonstrated increased reach and engagement with formal services during the pandemic (20). Religiously and culturally tailored interventions that encourage young Muslims to discuss mental health, and improve help-seeking behaviours, mental health, and well-being, need to be developed and tested.

Evidence suggests that incorporating religious and cultural adaptations in tailored interventions for Muslim populations may improve mental health and well-being through ‘positive religious coping’, drawing on internalised spiritual beliefs to promote hope and resilience (17,21–23). Mental health services using such interventions in clinical practice can show promise as religious beliefs can have a positive impact on psychological distress (22,23). Positive engagement with Muslim identity can also counter discriminatory practices, particularly for women who are disproportionately subjected to Islamophobic abuse, stereotypes, and violence (14,24,25). Women from these communities are also subject to a ‘Muslim penalty’ with respect to education outcomes, economic activity, and unemployment (14,26) which can contribute to mental ill health. Religious identity is core for many Muslim patients and needs to be considered for person-centred care in this group (14,21,27). Concerningly, mental health service providers often lack an adequate understanding of cultural sensitivities and cultural competence, leading to inappropriate or ineffective interventions (28). In addition, cultural concepts relating to the causes of mental illness and

social stigma among British Muslims combine with service mistrust to adversely impact service use (29).

Our research will address key public health challenges including how best to engage with communities who do not access mental health services, delivering community/faith-based interventions in non-NHS settings to support young women, training practitioners in this novel approach and use appropriate evaluation frameworks to capture process and outcomes (30,31). It will inform a pathway to testing the effectiveness and cost-effectiveness of the IM-Adapted intervention for young Muslim women, increasing representation of marginalised groups in research.

# 2. Aims and Objectives

## 2.1. Study Objectives

The overall aim of this study is to establish the feasibility of evaluating a faith-based culturally adapted intervention to promote and improve mental health and well-being of young Muslim women in community settings.

The objectives of the study are as follows:

- Deliver and evaluate the IM-Adapted group intervention compared with usual psychoeducation at two sites.
- Identify effective methods to recruit participants to the intervention or the control groups.
- Examine the feasibility of delivering the interventions to participants in community settings by mental health professionals.
- Explore implementation and fidelity to the intervention protocol by mental health professionals.
- Determine the acceptability of the interventions, study procedures and barriers to engagement.
- Estimate adherence rates to the intervention by participants.
- Explore the feasibility of collecting outcome and resource use data.
- Estimate referrals, recruitment, and retention rates at follow-up.
- Evaluate the safety of the trial interventions.
- Estimate number of sites and sample size for a future definitive trial.

## 2.2. Study Outcomes

The primary feasibility outcomes to determine progression to a future definitive trial are as follows:

- Number of participants referred, excluded, and recruited and reasons for not participating
- Retention rates at follow-up
- Participant engagement and adherence (sessions attended)
- Feasibility, acceptability, barriers and facilitators to interventions
- Data quality & follow up completion rates, including health economic data
- Training and delivery model (adherence, engagement, confidence)

- Adverse event rate
- The existence of early evidence that the intervention is not clearly inferior to usual care
- Feasibility of required sample size and other requirements for a future trial

We will measure a range of secondary outcomes with a view to making a decision about which to include in a future definitive trial. The secondary outcome measures (as potential primary outcomes for a definitive trial) are:

- Distress, well-being, anxiety, overall health-related quality of life, loneliness, resource use and religious coping.

## 2.3. Progression Criteria

Progression to a definitive trial will be based on a future application to the NIHR PHR Programme. Based on consideration of our feasibility findings, the Trial Steering Committee will be asked to make a recommendation regarding the appropriateness of a future trial. The following criteria has been developed to determine whether funding for a definitive trial will be sought including items relating to recruitment, retention, adherence, and completion. This progression criteria follows a set of stop-go criteria (based on traffic light colours for the measures where appropriate). Where traffic lights are used, green = progression (subject to a successful new funding application), amber = modifications and improvements required before progressing and red = no progression to a future large trial. For the non-traffic light measures listed below, decisions will be made based on the information available.

### 2.3.1. Stop-go criteria:

- Completion of key outcome measures (% of mental health and well-being measures completed)
    - Green: >= 80%
    - Amber: 51-79%
    - Red <=50%.
- Participant engagement and attendance (% of planned sessions attended):
    - Green: >=67%
    - Amber: 51-66%
    - Red: <=50%
- Successful collection of resource use data (% of participants providing resource use data):
    - Green: >=80%
    - Amber: 70-79%
    - Red: <70%
- Adequate acceptability of interventions to young Muslim women.
- Professionals and support workers are willing to deliver sessions and encourage participant engagement.
- Sufficient referrals (with sufficiency based on the sample size required for a definitive trial, we will calculate from this feasibility study) received from various organisations for young people to participate in the trial.
- Recruitment is such that >=10% of eligible screened participants are recruited.
- Appropriate outcomes measures are identified including one potential primary outcome (>75% of minimum important difference).

- Based on the estimated sample size, a necessary number of additional sites are identified for a definitive trial. No indication that the intervention is significantly less effective than usual care.
- No indication that the intervention has significantly increased the risk of adverse events compared to the control condition.

# 3. Methods

## 3.1. Study Design

A two-arm cluster randomised controlled feasibility trial delivered in groups in two locations (London and Birmingham) in community centres/mosques. Clusters will each comprise 8-10 young women, each attending the same group session.

A nested process evaluation will use focus groups/interviews, intervention logs and intervention observations to capture participant and intervention delivery staff experiences. The evaluation will confirm study processes, interventions, and outcomes, capture delivery fidelity and explore acceptability, barriers to implementation and engagement, document participant recruitment and flow and areas for refinement.

Our embedded mixed methods process evaluation will examine the contextual factors that will affect all aspects of the delivery of the intervention and outcomes and ascertain via a feasibility assessment the outcomes and recruitment strategy required for the design of a full-scale trial (31).The process evaluation will support the study objectives to 1) identify effective recruitment pathways for professionals and participants 2) examine acceptability of the intervention, training, study procedures and barriers to engagement 3) assess fidelity to in the intervention protocol 4) explore adherence to the intervention and training.

## 3.2. Study Setting

Two locations (London and Birmingham) in community centres or mosques.

## 3.3. Study Participants

The target population are young women aged 18-24 self-identifying as Muslims and who are seeking help for feeling low or to improve their mental health from any setting. Young women who potentially meet the criteria for the study will be assessed for suitability by the Inspirited Minds (IM) team when they initially register with IM to make use of their services or complete the study specific self-referral form hosted on the IM website. We will accommodate individuals with learning disabilities or a particular access need where possible.

***Inclusion Criteria***

- Muslim women aged 18-24 years self-diagnosed or referred from another source with low mood or mild depression and scoring between 5 and 14 on the Patient Health Questionnaire 9 (PHQ-9) scale (32) (low mood/mild symptoms) and willing to participate in the study.
- Participants must be able to read and understand English, although we do not anticipate this will limit inclusion given the age group.

***Exclusion Criteria***

- Those considered unsuitable based on the professional opinion of the mental health professionals during the risk assessment. This will include those on current treatment, and/or with co-morbid conditions that present contraindications to engaging in the study (e.g., severe chronic pain).
- Those on current treatment with antidepressants or other drug, or psychological therapy where disease severity (e.g., PHQ-9 below 5 or above 14) or the recommendation of a healthcare professional precludes them from taking part in the study.

### 3.4. Sample Size

As this is a feasibility study, the sample size is not based on a power calculation to estimate the ability to detect a difference in outcomes between study arms. Rather, for a feasibility study, sample size is based on estimating the completion rates of the questionnaires, sessions, or adherence. The NIHR guide to Feasibility and Pilot studies states that the optimal size for pilot studies used to inform sample size calculations is between 70 and 120 participants (33). Assuming a group size of 10 per cluster and an intra-class correlation coefficient of 0.05, our proposed sample size of 60 (30 in each arm) for our *feasibility* study will enable us to estimate critical parameters for such a pilot study, as part of a future large study. Allowing for an estimated loss to follow up of 20% (Co-applicant GM's study unpublished (34,35), we anticipate this will give us approximately 24 participants in each arm at 6 months. This will allow us to estimate the completion rate to within a pre-specified level of precision of +-/10% assuming it was 90%, or +/-13% if it was 80%. We are confident that these are appropriate estimates and represent values that would allow progression to a full trial, and our sample size is also in line with those for feasibility studies audited in the UK (36). The sample size will result in one site having two intervention groups and one control group and the other having two control groups and one intervention group.

## 4. Study Procedures

The Gantt chart shows the timeline of this study, and the study flowchart can be seen below (Figure 1), along with the study schedule (Table 1). The Gantt chart is available to view on the electronic Trial Master File (eTMF). The Case Report Form (CRF) has been designed to reflect and support the flow of the study, and to record details of actions taken and dates.

The research team will use File Notes to record any issues. If appropriate, issues will be reported to the Trial Steering Committee (TSC).

Figure 1. Study Flowchart

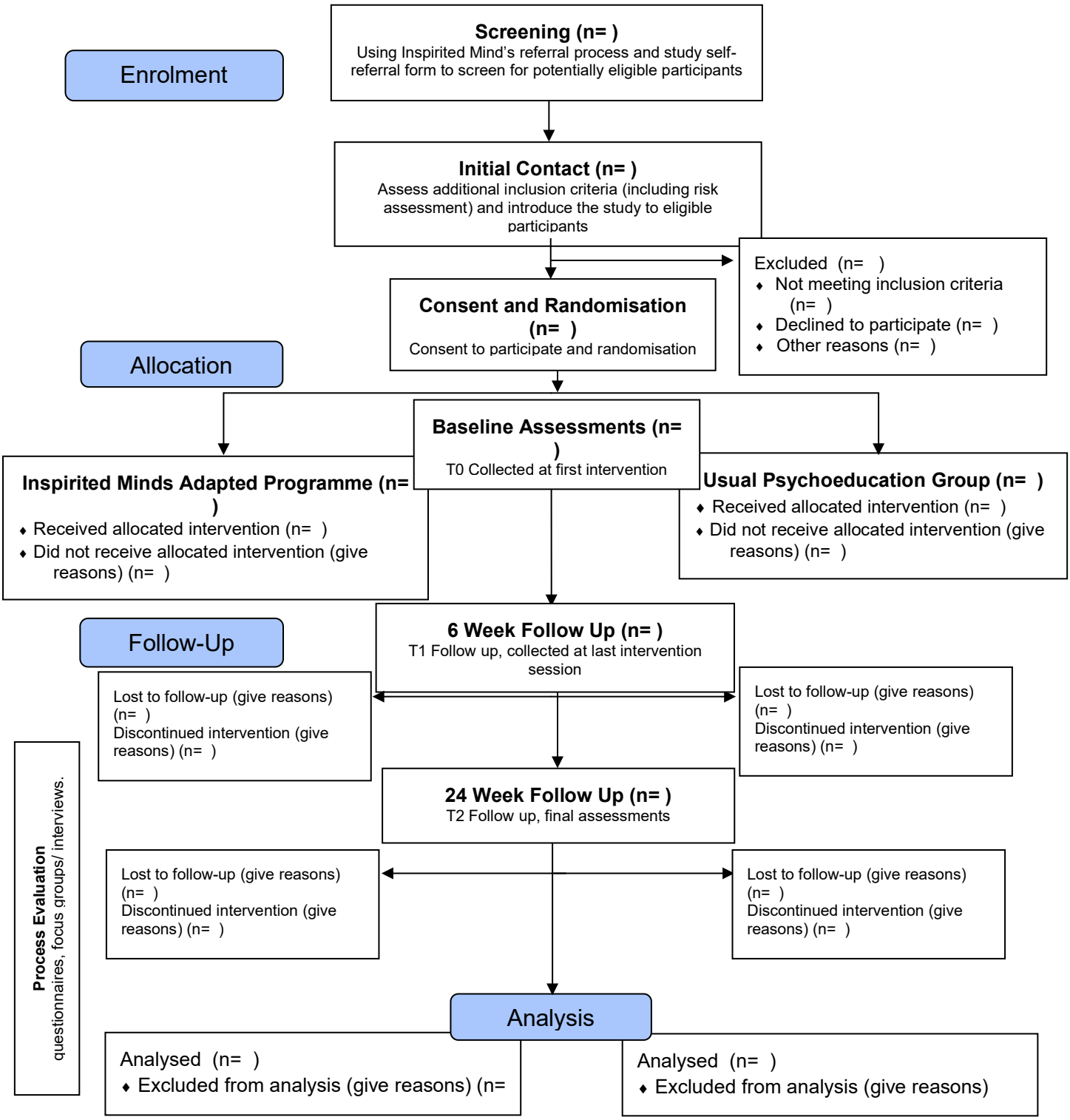


Table 1. Study Schedule

| | STUDY PERIOD | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Screening** | **Randomisation** | **Post-randomisation** | | | | | | | | |
| **TIMEPOINT** | Pre-T0 | Pre-T0 | T0 Baseline | T0-T1 Intervention | | | | | | T1 +6wks | T2 +24wks | |
| **ENROLMENT:** | | | | | | | | | | | | |
| Consent to screen | x | | | | | | | | | | | |
| Eligibility screen | x | | | | | | | | | | | |
| Referral to research team | x | | | | | | | | | | | |
| Informed consent | x | | | | | | | | | | | |
| Randomisation | | x | | | | | | | | | | |
| **INTERVENTION** | | | | **x** | **x** | **x** | **x** | **x** | **x** | | | |
| **ASSESSMENTS:** | | | | | | | | | | | | |
| PHQ-9 | x | | x | | | | | | | x | x | |
| GAD-7 | | | x | | | | | | | x | x | |
| WEMWBS | | | x | | | | | | | x | x | |
| R-COPE | | | x | | | | | | | x | x | |
| Measure of Loneliness | | | x | | | | | | | x | x | |
| EQ-5D-5L | | | x | | | | | | | x | x | |
| CSRI | | | x | | | | | | | | x | |
| Focus Groups | | | | | | | | | | | | x |
| ADVERSE EVENT MONITORING | | | x | x | x | x | x | x | x | x | x | |

Note: T0 = Baseline, T1 = First Follow-Up, T2 = Second Follow-Up. PHQ-9 = Patient Health Questionnaire. GAD-7 = Generalized Anxiety Disorder. WEMWBS = The Warwick-Edinburgh Mental Wellbeing Scale. R-COPE = Brief Religious Coping Measure. CSRI = Client Service Receipt Inventory.

## 4.1. Study Setup

Study set up will involve obtaining approval from the Research Ethics Committee (REC) at the University of Hertfordshire, registration on the International Standard Randomised Controlled Trial Number (ISRCTN) registry and Clinical Research Network (CRN) portfolio and database set-up. Study personnel will be recruited. Good Clinical Practice (GCP) training will be undertaken by those the Chief Investigator (CI) deem requires it for their role in the study. The Trial Steering Committee (TSC), Trial Management Group (TMG), Public Involvement Working Group and Stakeholder Forum will be established, and meeting dates will be agreed. A study website will also be developed and launched.

## 4.2. Recruitment

### 4.2.1. Participant Identification and Screening

Inspirited Minds (IM) will review incoming referrals to their services, via their usual online form, to identify those who might be eligible to join the study (i.e. are the right age, gender and have

reported low mood/depression with no obvious reason why they cannot participate). This referral process is well-established and as well as collecting information on age and gender has an embedded PHQ-9 measure to rate levels of low mood/depression. This survey is typically completed online but can be completed via telephone for those who require additional support. Inspirited Minds hold a database of individuals who are currently using the services of the charity which will also be used to identify potentially eligible participants for the research study. In line with usual IM practice for groups, an online form for those interested in taking part in the study will also be developed. To establish eligibility, this form will also include an embedded PHQ-9 measure to rate levels of low mood/depression.

The NIHR Clinical Research Network East of England (changing to Regional Research Delivery Network East of England from 1st October 2024) will also support recruitment in their capacity as Lead Network. They will work with their counterparts in other regions to help identify organisations and communities that can support recruitment of participants. Young women will also be informed about the study through the Mosques and community groups identified as recruitment sites for the study. Those supporting with recruitment may receive a monetary reward as a recompense for their time. Some young women may find out about the study from their peers, the study website, via social media, or from promotional materials (e.g. poster) displayed locally. These individuals will also be directed to complete the online study self-referral form via IM for initial screening.

The information provided on the study specific self-referral form, or the usual IM self-referral form will be used to assess for potential suitability by a member of the IM team (e.g. support workers or the clinical manager). A member of the IM team will log the number of referrals and the numbers meeting the initial inclusion criteria.

Those who meet the criteria for age, gender and depression (PHQ-9 score between 5 and 14) will be contacted to introduce the study and set up a 30-minute standard risk assessment screening session via telephone or video call. This risk assessment, which is undertaken by IM with new clients irrespective of this study, will be conducted by a trained member of IM staff (based on the NHS Talking Therapies) and information collected will be used to finalise eligibility for participation in the study. Those who meet the eligibility criteria based on the outcome of the risk assessment along with all other information collected will receive the full study information pack. Those who are deemed to be high risk because of either contradictory comorbidities or current treatment or other risks, will not be able to take part in the study but will be offered suitable alternative care. Those who are ineligible based on risk or other eligibility criteria or do not wish to participate in the study will be offered the usual support provided by IM as appropriate. These individuals will be offered the option to give reasons for why they do not wish to participate in the study, but this question will be optional to avoid apparent coercion.

Those who meet all eligibility criteria for the study and would like to take part will be sent the link to the online (via REDCap) informed consent form.

### 4.2.2. Informed Consent

Eligible young women will be asked to complete the online informed consent form. This form can be accessed by a link which will take them to the online form via the REDCap database held by the University of Hertfordshire. Participants will receive a copy of the signed informed consent form via email.

Consenting eligible women will then be recruited to the study and randomised either to the IM-Adapted intervention or the comparison group.

## 4.3. Randomisation

### 4.3.1. Randomisation Procedures

Eligible participants who have provided informed consent to take part in the study, will be randomised in groups of approximately 10, as soon as each group of approximately 10 has accrued. Groups will be allocated to receive six weekly sessions of either the IM-Adapted intervention or the usual psychoeducation support group.

Randomisation, stratified by location (London and Birmingham) and ensuring equal numbers in each group, will be conducted online via the data platform provided by the University of Hertfordshire's Clinical Trials Support Network (CTSN), ensuring allocation concealment. Allocation blinding is not possible, supporting staff will be blinded during data collection when possible but all statistical analyses will be blinded.

The groups will be allocated to the intervention by a process embedded in the web-based data Management system (REDCap).

## 4.4. Baseline

Participants who have been randomised will be sent an email asking them to complete the linked online survey seven days prior to the start of their first therapy sessions. An option of telephone data collection will be offered to those participants who would prefer it. Where required, a reminder will be sent two days prior to the first session.

They will be asked to complete the following baseline measures:

- Patient Health Questionnaire-9 (PHQ-9) (32)
- Generalized Anxiety Disorder (GAD-7) (37)
- The Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) (38)
- Brief Religious Coping Measure (R-COPE) (39) adapted for a previous trial (40) to include additional questions from Kahn and Watson (41)
- EQ-5D-5L (42)
- Client Service Receipt Inventory (43) (CSRI): This measures health and non-health-related resource use for participants of the intervention. This will also be used for the health economics evaluation.
- Direct Measure of Loneliness (44)

## 4.5. Intervention

The Inspirited Minds Adapted (IM-Adapted) programme, is a faith-based culturally adapted peer support group intervention aimed at promoting and improving mental health and well-being and tailored to the specific needs of Muslim communities. It was co-developed with Muslim service users and therapists. The IM-Adapted programme will be delivered in six weekly sessions (approximately 90 minutes per session) to groups of approximately 10 by

specialist intervention therapists and a co-facilitator (MHSW) identified by IM, delivered in a community centre or Mosque.

The intervention recognises the broader cultural identities of young Muslim women and addresses issues of stigma, social structures, religious explanations for depression, utilising best practice approaches. This involves creating positive messages from Islamic teachings that relate to positive religious coping. Behavioural components, each linked to behaviour change theories, include activity scheduling to address negative thoughts and improved mood, impact on behaviour, use of positive logs, journalling, goal setting and modelling positive behaviours. This results in reduced stigma and allows individuals to be more comfortable to seek support; and the use of peer support to tackle loneliness and offer initial steps to improve low mood, address barriers, and improve access to support. It focuses on addressing negative beliefs, and positive and negative coping through religious messages, thereby increasing positive beliefs about mental health (39,41).

Themes addressed by IM-Adapted are:

a) **Culture and related issues** including a lack of communication around mental health, a taboo subject, and beliefs of not being a good Muslim if you are struggling with your mental health
b) **Capacity and coping strategies** including limited adapted treatments to suit more Islamic ways of working and using faith as a way of coping or leading to use of drugs to cope due to needing to mask symptoms
c) **Cognition and beliefs** including rigid beliefs about mental health, and assumptions that if people pray more than they will feel better
d) **Isolation and stigma** due to limited access to specialized treatments and not openly communicating with others and hence feeling like they are the only ones.

The IM-Adapted intervention is CBT based and adapted with Islamic faith messages using cognitive and behavioural underpinnings including insights from GM's (co-applicant) therapeutic approach with Muslim populations(17,23) and CBT models used in cultural adaptations (45–47). The intervention also uses a place-based community approach (48) by delivering in a mosque or community centre.

We will therefore identify assets of importance such as informal social/community networks, community groups, services, volunteers, local organisations supporting the work of IM. Our flexible approach is underpinned by models of place-based interventions that address health disparities, particularly around communication with relevant community, stakeholders, community empowerment and engagement (49). This will further inform the infrastructure and logistics of delivering such as intervention for the future larger trial.

## 4.6. Control Group

The comparison group is a low intensity CBT psychoeducation group with no religious or cultural adaptation (see Table 2) delivered by qualified mental health professionals from IM. As with the intervention arm, control participants will receive six weekly sessions (90 minutes per session) in groups of approximately 10 women. The sessions will include components of CBT in a group format for low mood, including behavioural activation, activity scheduling, thought challenging and understanding their pattern using a 5 areas diagram. Delivery staff in both arms will complete GCP training from the NIHR.

Table 2. Comparison of key characteristics of intervention and control arm group sessions

| **IM Adapted** | **Control Group** |
|---|---|
| Run by Muslim women with specialised training | Run by Psychological Wellbeing Practitioners with NHS standard training |
| Starting the treatment with the Dua (Islamic prayer) | Normal introductions to the session |
| CBT Components including the 5 areas model (50) | CBT components including the 5 areas model (50) |
| Supportive space to have open conversations, using questions around culture and religiosity to prompt discussion and hearing from others | Supportive space to have conversations without religious and cultural prompting |
| Islamic content and stories related to depression from the Quran and stories of the time of the prophet, having discussions around this | Not included |
| Homework setting | Homework setting |
| Journaling every week- allowing time to reflect on cultural and religious learning from the sessions with prompted questions | Not included as part of treatment protocol |
| Ending with cultural and religious reflections and key learning | Ending with general reflections and key learning |
| Ending with a Dua (Islamic prayer) for hope | Not included |
| Being provided with IM booklets around mental health, which is faith based | Booklet and content from the slides |

## 4.7. Follow up Procedures

Follow-up questionnaires will be completed at 6 weeks and 24 weeks after baseline. As with the baseline measures, an email will be sent asking participants to complete the linked online survey. An option of telephone or online (e.g. Zoom) data collection will be offered to those participants where needed. Where required, reminders will be sent e.g. 5 days after initial follow-up contact.

The following measures will be collected at 6 weeks:

- Patient Health Questionnaire–9 (PHQ-9) (32)
- Generalized Anxiety Disorder (GAD-7) (37)
- The Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) (38)
- EQ-5D-5L (42)
- Brief Religious Coping Measure (R-COPE) (39) adapted for a previous trial (40) to include additional questions from Khan and Watson (41)
- Direct Measure of Loneliness (44)

The following will be collected at 24 weeks after first session:

- Patient Health Questionnaire–9 (PHQ-9) (32)
- Generalized Anxiety Disorder (GAD-7) (37)
- The Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) (38)

- EQ-5D-5L (42)
- Client Service Receipt Inventory (CSRI) (43): This measures health and non-health-related resource use for participants of the intervention. This will also be used for the health economics evaluation.
- Brief Religious Coping Measure (R-COPE) (39) adapted for a previous trial (40) to include additional questions from Khan and Watson (41)
- Direct Measure of Loneliness (44)

### 4.8. End of Study

The end of study will be when all participants have completed all scheduled assessments and all questionnaires/data items have been completed and interviews taken place.

A declaration of end of study form will be completed and sent to the relevant Ethics Committee with Delegated Authority (ECDA) at the University of Hertfordshire as soon as practicable, and no later than 90 days, after the study has ended.

### 4.9. Payment

Participants will be given £10 vouchers each time they complete study outcome measures at follow-up (i.e. up to £20 in total). Participants will also be given a £10 voucher for taking part in an interview/focus group as part of the process evaluation.

## 5. Safety

We believe the risk of harm is low as, other than the inclusion of cultural adaptions, the intervention we are testing contains elements that are commonly used in therapeutic practice, whilst the control condition equates to the care given in NHS settings. Inspirited Minds has a well-developed safeguarding procedure which will apply to all participants in this study. In addition, we will capture any concerns from participants on the interventions they receive during the process evaluation.

To monitor safety during the study, any adverse event (AE) (see below definition) occurring during the participation of the study will be reported in accordance with the study protocol and IM policies. We will monitor for any potential harm and unanticipated outcomes during the intervention and the six month follow up period. These will be reported as per the CONSORT harms checklist (51).

An Adverse Event (AE) is defined as any untoward medical occurrence in a participant which does not necessarily have a causal relationship with the study intervention for example:

- An exacerbation of a pre-existing illness
- An increase in the frequency or intensity of a pre-existing episodic event or condition
- A condition (regardless of whether present prior to the start of the study) that is detected after the start of the study (this does not include pre-existing conditions)
- Continuous persistent disease or symptom present at baseline that worsens following administration of the intervention

When an AE occurs, the member of the study team who first becomes aware of the AE must record it on the database and assess whether the event is considered serious (see below definition).

A Serious Adverse Event (SAE) is defined as an untoward occurrence that:

(a) Results in death
(b) Is life-threatening
(c) Requires hospitalisation or prolongation of existing hospitalisation
(d) Results in persistent of significant disability or incapacity
(e) Consists of a congenital anomaly or birth defect
(f) Is otherwise considered significant by the investigator

All SAEs should be communicated to the IM lead therapist and Trial Manager (or delegated person in their absence) within one working day using the provided SAE form. The IM lead therapist and Trial Manager will review the SAE form and disseminate to the CI and the TMG within 72 hours of being informed, where appropriate. The TSC and REC will be informed by the Trial Manager of all SAEs periodically unless the CI escalates the SAE or deems necessary.

If an SAE is considered to be related to the study intervention, and the intervention is discontinued or interrupted for that participant as a result, this will be recorded in the appropriate sections of the database, including withdrawal form if they leave the study.
Should any concerns arise, we will pause the study and immediately inform the NIHR.

# 6. Data Collection, Management and Analysis

## 6.1. Data Collection

Data collection for the majority of outcomes will be by direct online entry of data on the central database, stored on servers based at UH by members of the IM-Adapted study team. Questionnaires will all be self-completed by the participants through the links sent to them via the database. In the case that a participant is unable to complete the outcome measures themselves, this can be done with the support from a member of the research team (e.g., by having the questions read to them). Staff will receive training on data collection and use of the online database. Screening and identification logs will be kept on an electronically secure server held by IM and only anonymous data for the purpose of the research outcome measures (e.g. referral and recruitment numbers) will be shared.

Collection of data for the purpose of process evaluation will occur as follows. A member of the process evaluation team will attend training sessions and will also review training and intervention materials as required. Approximately 10-15% of intervention sessions in both groups, with a minimum of two at each site, will be attended by a researcher and audio recorded to examine implementation and fidelity to the training. Our preparatory work suggests that recording would be more acceptable than written notes, but we will discuss with the Young Women's Advisory Group (YWAG) and take a flexible approach that aligns with the preferences of the participant groups. Drawing on the intervention manual, protocol and observations made during training sessions, we will develop an intervention observation guide that supports documentation of key points of the sessions based on what is observable. For example, this may include the presence or absence of expected components such as Islamic

prayer and conversations about culture and religiosity. As well as observations around the level of engagement from the young women and the roles of the therapist and support worker in the activities undertaken in the room.

In order to understand the nature and fidelity of intervention delivery, a short intervention log will be completed by the therapists for each session to record number of young people attending, any late arrivals or early departures, reasons for any absences, and if planned activities went ahead. There will be a free-text box for any issues that the therapists wish the research team to be aware of, for example, reasons for deviation from the planned activities. These data will be collected either directly onto a database or first collated in a word or excel document, whichever aligns with usual practice.

In order to gather detailed insights into the experiences of all groups involved in delivering and receiving the IM-Adapted programme as well as participation in the research study, a range of focus groups and 1:1 interviews will be undertaken. Focus groups with the therapists and support workers involved in intervention delivery will be conducted to explore experiences of intervention training, delivery, and study processes. All therapists and support workers will be invited, and it is anticipated that one or two focus groups will be carried out per site. A focus group will also be run with IM staff, to gather their experiences of running the intervention and any modifications that may be required or anticipated before progressing to a definitive trial. Further we anticipate running one focus group and/or interviews depending on logistics, with referral partners to gather their experiences of referring their clients or service users to the intervention.

A set of interviews or focus groups will be undertaken with young women to explore their views on the acceptability of the intervention and study design and procedures. For comparison, participants to the control group will also be invited to talk about their experience. A semi-structured schedule will be produced to guide discussion, with input from the YWAG.

Interviews or focus groups will be held with around 24 women in total (12 in each arm and equal numbers in London and Birmingham) and will be conducted by members of the process evaluation team. Where possible purposive sampling will be used to ensure diversity of experiences and perspectives are included, for example age, socioeconomic status, participants that attended all or some of the sessions and time of recruitment to the study (early/late) will be varied. Given the potentially sensitive nature of the subject matter (the mental health of the young women coming from a cultural and religious context where such matters may not be routinely discussed) we anticipate mainly 1:1 interviews rather than focus groups, but either format will be facilitated by someone of Islamic faith. We recognise that because the intervention is delivered in a group context, understanding the group dynamic of the IM-Adapted sessions could provide important insights into the active mechanisms of the programme, therefore at least one focus group dependent on consent. Regarding the intervention, we will explore participants' views about the varying components, with particular focus on the faith-based adaptations and coping strategies, perceived benefits or drawbacks to mental health, facilitators and barriers to engagement and the format of the intervention e.g., number of weeks, length of sessions. Regarding the study design and procedures, we will explore views on recruitment methods, randomisation, questionnaire completion, and motivation for joining and staying in the study. We will explore the role of religious coping to identify the mechanisms underpinning faith-based coping strategies provided as part of a wider package of support.

To estimate the scale of any potential contamination, we will also ask participants what, if anything, they know about the sessions being received by those in the other arm of the study to them (control). For convenience we anticipate interviews and focus groups will all be undertaken online but will be in accordance with participant preference.

## 6.2. Data Management

Participants will be automatically assigned a unique study Participant Identifier (PID). Data will be entered under this identification number onto the central database stored REDCap held on the server at the University of Hertfordshire. Randomisation of participants will also be implemented within this database.

The database will be username and password protected and only accessible to members of the IM-Adapted study team, and external regulators if requested. This access to the study database is controlled and administered by CTSN Data Management. The delegation log will identify all those personnel with responsibilities for data collection and handling, including those who have access to the study database. The servers are protected by UH firewalls and anti-virus products and are patched and maintained (including back-ups) according to best practice.

The REDCap database software provides a number of features to help maintain data quality, including; maintaining an audit trail, allowing custom validations on all data, allowing users to raise data query requests, and search facilities to identify validation failure or missing data.

After completion of the study, the database will be retained on the servers of UH for ongoing analysis of secondary outcomes. The study database and associated design documentation will be routinely archived for a period of 10 years unless otherwise advised by the TMG.

## 6.3. Data Analysis

Data analysis will be largely descriptive, reflecting this fact that this is a feasibility study where the aim is not to test the efficacy of the intervention. Based on our previous work (52), the referral, recruitment and retention will be evaluated using standard reporting following the CONSORT criteria, reporting the proportions (and confidence intervals) of young people reaching each stage of the study, by referral source and study arm. Adherence will be assessed through the proportions of sessions attended, and the extent to which young women continue to apply strategies learnt to improve mental health (survey data at 24 weeks). Feasibility of collecting outcome and resource use data will be evaluated by estimating the proportions of missing data in each of the outcomes assessed. The descriptive statistics of the outcome measures will be given by group, but no formal hypothesis testing will be undertaken. To monitor safety, the number of adverse events (for example, a mental health episode triggered by the content of a session) will be reported by study arm along with the number of participants experiencing one or more events. Recruitment to the study will be monitored through the recruitment logs and reported using the standard CONSORT Criteria.

The sample size for a future trial will be estimated using agreed minimally important difference in the outcomes (from the published literature) and the estimated SD and completion rates from our study. Sensitivity analyses in the estimated number will be undertaken by inflating the SD by 20%. It will not be possible to have an estimated intra-cluster correlation coefficient

so a value of 0.05 will be used, but sensitivity will be allowed for by varying this value from 0.01 to 0.2.

### 6.3.1. Process Evaluation

Qualitative focus group and interview data will be audio recorded and transcribed. If conducted online, Zoom transcription will be enabled and quality checked and corrected in conjunction with the audio recording. The data will be analysed (53) using NVivo to identify common themes that could be used to inform the design of a full-scale trial. This Thematic Analysis (TA) will use a deductive approach based on the themes outlined in the 'Process evaluation' section of this application. The content identified under the different themes will be used to understand the important contextual factors that have influenced the intervention and to provide key insights to improve evaluation design. Data from the intervention logs and intervention observations will be compared against the intervention manual, and findings will be tabulated and summarised narratively to inform our understanding of fidelity to the training and how the intervention was delivered and received. Triangulation of the analysis of the focus groups and interviews, intervention observations and intervention logs will be used to describe delivery of both arms and examine implementation and theoretical fidelity and explore factors affecting engagement across study processes. This will inform the feasibility assessment of the study and refine the design and intervention for a future trial.

### 6.3.2. Economic evaluation

The methods required to evaluate cost-effectiveness of a future trial will be tested in this feasibility study. We will measure resources required to provide the IM-Adapted intervention and the comparator of psychoeducation group support in the two groups. Resources will include staff time, equipment and consumables, accommodation, and staff training. In addition to these resources, an effective intervention may affect the use of health and social care services, as well as costs borne by the young women and their families. These will be recorded by means of a resource use questionnaire (modified client service receipt inventory (CSRI)) at baseline and 24 weeks (43), which, at both baseline and follow up, will ask about the previous 24-week period. This will also record important non-health related resource implications including employment, education, or training status and time off work or usual activities. The precise questions asked in the modified CSRI will be finalised in consultation with members of the research team and the public advisory group to ensure that the most relevant categories of relevant service use are covered. Part of this feasibility study will include an assessment of this instrument, including completeness and ease of use. Any resources identified by the CSRI will be costed using appropriate local and national cost data.

The main outcome measure for the economic evaluation in a future main study would be the Quality Adjusted Life Year (QALY). In the feasibility study we will estimate QALYs using the EQ-5D-5L, collected at baseline, 6 and 24 weeks (42), and scored using a published scoring algorithm (54). In a future full economic analysis, the EQ-5D-5L would be used to generate QALYs using 'area under the curve'. The EQ-5D-5L will be compared descriptively with other outcome measures used in the feasibility study. It is not intended to estimate cost-effectiveness from the feasibility study as the study will not be powered to demonstrate this. Rather, the aim is to trial the proposed health economics measures, ascertain heir completeness and acceptability to respondents, and identify likely main drivers of costs.

## 7. Ethical Considerations

This study will be conducted in accordance with the Data Protection Act (2018) and the guidelines of the Declaration of Helsinki (1964 – Updated Brazil, 2013) (55). Before the start of the study, approval will be sought from the University of Hertfordshire Ethics Committee. The study will be undertaken according to the principles of ICH GCP and all relevant ethics and governance processes.

It is the CI responsibility to produce an annual progress report to be submitted to the REC and to notify them of the end of the study.

Within one year after the end of the study, the CI will submit a final report with the results, including any publications to the REC.

The process for consent is outlined in the methods above. All participants will provide active informed consent to participate before being enrolled in the study.

Risk Management is a key issue for the study and young women who may present significant risk of harm to themselves or others. Inspirited Minds have a safeguarding protocol in place to ensure timely, and appropriate clinical support for the young women involved and this will be utilised for all women taking part in the study. SK from IM will oversee this process to ensure that young people are given appropriate support within an appropriate clinical setting. IM uses the NHS Talking Therapies services risk assessment protocol, develops a safety plan and reviews risk assessment at regular interviews.

The charity has two safeguarding officers who can be contacted for concerns of safeguarding, refer to social services and keep relevant health service practitioner informed based on the nature of any safeguarding concern. All therapists will follow normal practice for client safety if these arise during the study, including existing organisational protocols for distress and dealing with crises. Where there is concern about the young person in the study, a 24-hour contact number for clinical support within the local services will be provided, enabling timely support if the mental health status of the young person deteriorates.

For risks associated with participation in the study (e.g., distress during intervention delivery or conducting interviews or focus groups) IM have a policy in place that if someone gets too distressed, they take a step outside, and one of the mental health practitioners involved in delivering the group will come and check in with them. If required, interviews will be paused and the facilitator will check in with the participant how they are and what action, if any, needs taking. Focus groups will be co-facilitated so, if required, there will a research team member available for 1:1 discussion outside the forum with any participants in distress. The charity also provides the option for anyone to stay behind who is finding things difficult and a risk questionnaire is completed at every session to review risk and the crisis numbers are shared at the end of the session. The trained mental health professionals and the Mental Health Support Workers (MHSW) are the primary point of contact for the young people in the study. Following the relevant study and mental health training provided, these staff will be provided with monthly supervision by IM staff. The TMG and TSC will monitor and review AEs as they occur, and standard study reporting protocols will be followed.

## 8. Quality Assurance and Control

## 8.1. Risk Assessment

The Quality Assurance (QA) and Quality Control (QC) considerations for the study should be based on the formal Risk Assessment performed, that acknowledges the risks associated with the conduct of the study and proposals of how to mitigate them through appropriate QA and QC processes. Risks are defined in terms of their impact on the rights and safety of participants; project concept including study design, reliability of results and institutional risk; project management; and other considerations.

QA is defined as all the planned and systematic actions established to ensure the study is performed, and data generated, documented and/or recorded and reported in compliance with the principles of GCP and applicable regulatory requirements. QC is defined as the operational techniques and activities performed within the QA system to verify that the requirements for quality of the study related activities are fulfilled.

## 8.2. Monitoring

The University of Hertfordshire Clinical Trial Support Network (UHCTSN) staff will review the database (REDCap) data for errors and missing key data points.

The frequency, type and intensity of routine and triggered on-site monitoring will be detailed in the IM-Adapted Quality Management and Monitoring Plan (QMMP). The QMMP will also detail the procedures for review and sign-off of monitoring reports.

## 8.3. Study Oversight

Study oversight is intended to preserve the integrity of the study by independently verifying a variety of processes and prompting corrective action where necessary. The processes reviewed relate to participant enrolment, consent, eligibility, and allocation to study groups; adherence to study interventions and policies to protect participants, including reporting of harms; completeness, accuracy and timeliness of data collection; and will verify adherence to applicable policies detailed in the Compliance section of the protocol.

In multi-centre studies this oversight is considered and described both overall and for each recruiting centre by exploring the study dataset or performing site visits as described in the IM-Adapted QMMP.

### 8.3.1. Trial Steering Committee

The Trial Steering committee (TSC) will meet up to three times a year and will provide overall supervision for the study on behalf of the Sponsor and Funder. It will ensure that the study is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the guidelines for GCP. Details of membership of the TSC and its Terms of Reference will be held on the Trial Master File (TMF). The TSC will include representatives from the public involvement group dedicated to the IM-Adapted study.

We take the view that for the IM-Adapted feasibility randomised study the risk of serious harm to study participants is low, as reported by IM for their routine case load, and therefore believe that harm can be monitored by the TSC. For this reason, a separate Data Monitoring and

Ethics Committee will not be appointed. Data monitoring and monitoring of participant safety will be allocated as a standing agenda item for the TSC. Where data monitoring indicates that serious harm might be occurring in more than two cases over the course of the study, a statistician and methodologist who are independent from the study team will be asked to review the data and make recommendations relating to likely future risk to the study participants, and the need for further independent scrutiny of the data.

### 8.3.2. Trial Management Group

A core team will form the Trial Management Group (TMG) to ensure all practical aspects of the study are progressing well and to identify potential issues as early as possible. They will meet on a monthly basis (or more frequently, if required). Wider study team members will attend meetings where relevant to the phase of the study.

### 8.3.3. Stakeholder Group

A stakeholder group with representation from mental health trusts, mental health services, public health teams, NHS England, mental health charities and voluntary organisations for example will be convened. This group will also include the recruitment site leads from the Mosques and community centres involved in the study. Members of the Young Women's Advisory Group (YWAG) will also be invited to this group. The stakeholder group will meet every 6 months from the start of the study, providing a way for the study team to communicate with the wider community, to follow policy development, to receive input into the design and delivery of the study, communication methods, enhancing engagement and to support the dissemination programme.

### 8.3.4. Clinical Trials Unit (CTU)

The CTSN at the University of Hertfordshire will be acting as the Clinical Trials Unit (CTU) and will provide support on the development, management, and monitoring of the study as well as randomisation and database support.

## 9. Public and Patient Involvement

Participative approaches are embedded throughout the project, including in the development of the proposal. This includes a workshop in November 2022, attended by six women with lived experience of accessing or supporting family members to access mental health services, and the lead therapist from IM. A key point from the discussion was the need for young people's involvement to be inclusive and flexible. The challenges IM faced in finding young Muslim women with lived experience of mental health services to attend the workshop also led to interesting discussions about stigma and cultural sensitivities, which we sought to address in the public involvement plans outlined below.

Through members of the TMG and IM networks 15 young Muslim women aged 16-30, with lived experience of using mental health services and expressed an interest in being members of a project young people's advisory group were identified. The first stage of public involvement for the project (see below) involved an online workshop in November 2023, attended by 10 young women where we collaboratively built on the plans in the proposal to

develop public involvement in the study in ways that work for those we wish to involve. Where required, we may also consult the University of Hertfordshire Young People's Research Advisory Group (Herts YPAG) at key stages (e.g., development of recruitment materials, data collection tools and lay summaries).

### 9.1. Young Women's Advisory Group (YWAG)

Up to 12 UK-based young Muslim women, aged 18-30 and with lived experience of using mental health services and/or affected by mental health issues, will be recruited in Spring 2024. Starting in March 2024, the advisory group will meet every 2-3 months, depending on the stage of the project and the need for public involvement input. The meetings will mainly take place online, with the option for in-person or hybrid meetings/social events so people can get to know each other (budget allowing).

Training and support will be provided as needed, Members of the Young Women's Advisory Group (YWAG) will also have opportunities for involvement outside of meetings (e.g. reviewing documents, attending events), as well as having two YWAG places on the TSC.

A process evaluation will include qualitative data collection from young people, the research team and other stakeholders at key points during the study. Members of the YWAG will be supported to have an active role, informed by guidelines and a toolkit for training young peer researchers co-authored by the IM-Adapted public involvement lead. Members of the YWAG and other public advisory groups where required (e.g., the Herts YPAG) will receive gift vouchers for their involvement.

### 9.2. Public Involvement Oversight and Management

The public involvement working group lead by the IM-Adapted public involvement lead and the public co-applicant will meet monthly to collectively ensure that plans for involvement are embedded throughout the project, are meaningful and effective and reflect cultural sensitivities and lived experience. This group, which includes the CI and Trial Manager will manage and oversee all public involvement activity and report to the TMG regularly.

Ultimately, public involvement will be the responsibility of all, as we believe that it must be embedded in all stages and elements of the project, and for the whole project team to do this in meaningful and effective ways. We will also draw on support from the UH public involvement team and the NIHR Applied Research Collaboration East of England's public involvement workstream where required.

The approaches to involvement were developed with young people in the workshops discussed above. Details will be further developed in collaboration with young advisors once recruited. Plans will be inclusive and flexible throughout, with 'pockets of participation' depending on young people's interests, availability, and personal circumstances.

## 10. Protocol Compliance

The CI will ensure that the study is conducted in compliance with the principles of the Declaration of Helsinki (1964 – Updated Brazil, 2013 (55) and in accordance with all applicable

regulatory requirements including but not limited to the Research Governance Framework, Trust and Research Office policies and procedures and any subsequent amendments. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

A “serious breach” is a breach which is likely to effect to a significant degree –

(a) the safety or physical or mental integrity of the participants of the study; or
(b) the scientific value of the study

The sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

# 11. Data Protection and Participant Confidentiality

## 11.1. Confidentiality

All investigators and research staff will comply with the requirements of the General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018 as well as the University of Hertfordshire University Policies and Regulation document “Data Management Policy” and the University of Hertfordshire Clinical Trial Support Network Standard Operating Procedures.

Confidentiality and anonymity will be ensured throughout the study. Participants may discuss sensitive matters during recorded sessions, interviews or focus groups. This will be managed through close attention to confidentiality, and participants will be made aware of their right to withdraw from the study at any point. The reporting of results and any future publications relating to this study (including quotations) will be fully anonymised, and excerpts will only be used with the explicit consent of participants.

The study staff will ensure that the participants’ anonymity is maintained. The participants will be identified only by a participant ID number on all study documents and any electronic database. Additionally, participant identifiers are required for automated communication (including email addresses and phone numbers) will also be stored in the database, but logically separated from study data by interface and permission constraints. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act 2018, which requires data to be anonymised as soon as it is practical to do so.

A Data Protection Impact Assessment (DPIA) will be conducted and approved by the UH Data Protection Officer prior to ethical approval by the University of Hertfordshire’s REC.

## 11.2. Case Report Form (CRF)

An electronic Case Report Form (eCRF) will be produced in the form of a REDCap database. Access to the database will be managed by UHCTSN and will be restricted and controlled to authorised personnel and will be password protected. The audit trail will be monitored regularly for any unauthorised access. It is the responsibility of the CI/Site Lead(s) to ensure that relevant personnel are delegated to carry out data collection and data entry. The delegation log will identify all those personnel with responsibilities for data collection and handling,

including those who have access to the study database. The eCRF will also detail AEs, including any SAEs and withdrawal forms where appropriate.

### 11.3. Record Retention and Archiving

After completion of the study and reporting of the results, the study database and associated documentation, will be routinely archived for a period of 10 years unless otherwise advised by the funder and/or sponsor.

### 11.4. Compliance

The CI will ensure that the study is conducted in compliance with the principles of the Declaration of Helsinki (1996 - updated Brazil, 2013 (55), and in accordance with all applicable regulatory requirements including but not limited to the Research Governance Framework, Trust and Research Office policies and procedures and any subsequent amendments.

Although steps will be taken to avoid it, accidental protocol deviations may happen at any time. They will be adequately documented on the Protocol Deviation forms (see appendix 2) and reported to the CI and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

#### 11.4.1. Notification of Serious Breaches to GCP and/or the protocol

A “serious breach” is a breach which is likely to effect to a significant degree –
(a) the safety or physical or mental integrity of the participants of the study; or
(b) the scientific value of the study

The sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

## 12. Publication and Dissemination

The TSC have responsibility for ensuring effective dissemination of the study results. The guidance below will be followed when preparing material for dissemination:

### 12.1. The role of the NIHR

- DHSC and NIHR require that NIHR-funded researchers publish their main study findings in a peer-reviewed, open access journal.
- When submitting an article for publication, the NIHR’s contribution must be acknowledged in full.
- Research articles, papers and reports should not use the NIHR logotype, but must use a statement acknowledging funding/support together with the NIHR disclaimer.
- Therefore, the following text should be included in articles and reports:
  This study/project is funded by the NIHR under its Public Health Research (PHR) programme (project reference NIHR156425). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

- The NIHR programme manager should be informed of all accepted journal articles resulting from the study.
- A copy of the final manuscript of any research papers supported in whole or in part by the NIHR should be deposited with Europe PMC upon acceptance for publication, to be made freely available as soon as possible and in any event within six months of the journal publisher's official date of final publication to meet the NIHR open access commitment.
- The NIHR and the Department of Health reserve the right to use data or other material from projects that it funds for policy development and publicity activities. The NIHR and the Department of Health may publicise the outcome of NIHR-funded research studies through its website, in publications and in press releases where appropriate.

## 12.2. Expected output and impact

A dissemination plan will be written and submitted for approval to the TSC.

The immediate output will be that the results of this feasibility study will be used to inform the progression to a full trial. The TSC will make a recommendation about the feasibility of a full-scale trial depending on whether the feasibility progression criteria have been met, and/or whether there is evidence to suggest that the design of the study could be improved.

Dissemination activity will take a range of formats. A project website will be developed, and social media will be used to inform, engage and share findings. The study methodology and findings will be disseminated widely through high impact international peer-reviewed journals, the PHR/NIHR, and at appropriate conferences, workshops and events. Results will be shared with all involved in the IM-Adapted study including the study team members, collaborators, oversight committee, charities, stakeholders, public involvement group and participants as well as relevant organisations including NHS trusts, mental health service user groups and key organisations supporting the Muslim community.

Public and stakeholder involvement will be central to the dissemination via relevant networks (via the TSC and YWAG, mental health services, voluntary sectors including Muslim mental health organisations. Public involvement will be embedded in the study, and with input we will develop a project website and social media presence to inform and engage young women and their families, clinicians, NHS providers and commissioners, and the wider population about the progress, findings and impact of our research. Our YWAG will help develop meaningful and appropriate ways of telling young Muslim women about our research for example in supporting the production of plain English summaries and other outputs, co-authoring journal articles and co-presenting at conferences. Team members have established relevant links with local, regional, and national networks (e.g., Birmingham and London borough councils, South Asian Health Foundation, MIND Birmingham) and these links will be utilised to disseminate the findings and informing relevant policy.

Engagement with society, health, and public health to ensure utilisation of the outcomes is key. The feasibility study is the first stage of a pathway to testing effectiveness to inform guidance in routine care. The outputs from this feasibility study will also be important in helping to refocus current practice and future research, particularly around pathways to effective community engagement. This research will provide essential evidence on the feasibility and methods of conducting community-based trials in Muslim populations who do not access the usual pathways for mental health support and will highlight the need to test the effectiveness and cost-effectiveness of faith based culturally adapted interventions in robust trials.

University of Hertfordshire UH

## 13. References


1. Pitchforth J, Fahy K, Ford T, Wolpert M, Viner RM, Hargreaves DS. Mental health and well-being trends among children and young people in the UK, 1995-2014: Analysis of repeated cross-sectional national health surveys. Vol. 49, Psychological Medicine. Cambridge University Press; 2019. p. 1275–85.
2. Kessler RC, Berglund P, Demler O, Ma R, Jin MA, Merikangas KR, et al. Lifetime Prevalence and Age-of-Onset Distributions of DSM-IV Disorders in the National Comorbidity Survey Replication. 2005.
3. NHS Digital. Mental Health of Children and Young People in England 2021 - wave 2 follow up to the 2017 survey - NHS Digital [Internet]. 2021 [cited 2024 Apr 22]. Available from: https://digital.nhs.uk/data-and-information/publications/statistical/mental-health-of-children-and-young-people-in-england/2021-follow-up-to-the-2017-survey
4. McManus S, Bebbington PE, Jenkins R, Brugha T. NHS Digital. 2016. Mental health and wellbeing in England: the adult psychiatric morbidity survey 2014.
5. Office for National Statistics (ONS). Office for National Statistics (ONS). 2022 [cited 2024 Apr 22]. Suicide releases. Available from: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/suicidesintheunitedkingdom/2021registrations
6. Uddin MF, Williams A, Alcock K. Visibility as Muslim, Perceived Discrimination, and Psychological Distress among Muslim students in the UK. J Muslim Ment Health. 2022;16(1):74–102.
7. Ciftci A, Jones N, Corrigan PW. Mental Health Stigma in the Muslim Community [Internet]. Vol. 7, Journal of Muslim Mental Health ISSN1556-4908. 2013. Available from: http://hdl.handle.net/2027/spo.10381607.0007.102
8. Williams ED, Tillin T, Richards M, Tuson C, Chaturvedi N, Hughes AD, et al. Depressive symptoms are doubled in older British South Asian and Black Caribbean people compared with Europeans: Associations with excess co-morbidity and socioeconomic disadvantage. Psychol Med. 2015 Jul 1;45(9):1861–71.
9. Nadimpalli SB, Kanaya AM, McDade TW, Kandula NR. Self-reported discrimination and mental health among asian indians: Cultural beliefs and coping style as moderators. Asian Am J Psychol. 2016 Sep 1;7(3):185–94.
10. Elshayyal K. Scottish Muslims in numbers: Understanding Scotland's Muslims through the 2011 Census [Internet]. Edinburgh; 2016 Nov [cited 2024 Apr 22]. Available from: https://research.ed.ac.uk/en/publications/scottish-muslims-in-numbers-understanding-scotlands-muslims-throu
11. Cardiff University [Internet]. Understanding Muslim Mental Health - Research.
12. Muslims Council Britain Census 2021. 'First Look' [Internet]. 2021 [cited 2024 Apr 23]. Available from: https://mcb.org.uk/wp-content/uploads/2022/12/MCB-Census-2021-%E2%80%93-First-Look.pdf.
13. Muslim Council of Britain 2015. British Muslims in Numbers A Demographic, Socio-economic and Health profile of Muslims in Britain drawing on the 2011 Census. 2015.

14. Better Community Business Network. ‘Hidden Survivors, Uncovering the Mental Health Struggles of Young British Muslims’ a landmark report [Internet]. 2021 [cited 2024 Apr 23]. Available from: http://bcbn.org.uk/Hidden_Survivors_Full_Report.pdf
15. Fazil Q, Cochrane r. Social and cultural origins of depression in Pakistani women [Internet]. 2003. Available from: https://www.researchgate.net/publication/270898292
16. McIvor C, Vafai Y, Kelly B, O’Toole SE, Heys M, Badrick E, et al. The Impact of the Pandemic on Mental Health in Ethnically Diverse Mothers: Findings from the Born in Bradford, Tower Hamlets and Newham COVID-19 Research Programmes. Int J Environ Res Public Health. 2022 Nov 1;19(21).
17. Mir G, Ghani R, Meer S, Hussain G. Delivering a culturally adapted therapy for Muslim clients with depression. Cogn Behav Therap. 2019;
18. Arundell LL, Barnett P, Buckman JEJ, Saunders R, Pilling S. The effectiveness of adapted psychological interventions for people from ethnic minority groups: A systematic review and conceptual typology. Vol. 88, Clinical Psychology Review. Elsevier Inc.; 2021.
19. Anik E, West RM, Cardno AG, Mir G. Culturally adapted psychotherapies for depressed adults: A systematic review and meta-analysis. Vol. 278, Journal of Affective Disorders. Elsevier B.V.; 2021.
20. Kamal A, Hodson A, Pearce JM. A rapid systematic review of factors influencing covid-19 vaccination uptake in minority ethnic groups in the uk. Vol. 9, Vaccines. MDPI; 2021.
21. Mir G, Meer S, Cottrell D, McMillan D, House A, Kanter JW. Adapted behavioural activation for the treatment of depression in Muslims. J Affect Disord. 2015 Jul 15;180:190–9.
22. Misran RN, Khaiyom JHA, Razali ZA. The Role of Religiosity to Address the Mental Health Crisis of Students: A Study on Three Parameters (Anxiety, Depression, and Stress). Pertanika Journal of Social Sciences and Humanities. 2021 Dec 1;29(4):2833–51.
23. Meer S, Mir G. Muslims and depression: the role of religious beliefs in therapy. Journal of Integrative Psychology and Therapeutics. 2014;2(1):2.
24. European Network Against Racism (ENAR). Forgotten Women: the impact of Islamophobia on muslim women european network against racism [Internet]. 2016. Available from: www.enar-eu.org
25. Runnymede Trust, Elahi F, Khan O. Islamophobia : still a challenge for us all. 2017.
26. Heath A, Martin J. Can religious affiliation explain ‘ethnic’ inequalities in the labour market? Ethn Racial Stud. 2013 Jun;36(6):1005–27.
27. Jabeen T, Snowden A. Can mental healthcare for Muslim patients be person-centred without consideration of religious identity? A concurrent analysis. Vol. 64, Nurse Education in Practice. Elsevier Ltd; 2022.
28. Jozaghi E, Asadullah M, Dahya A. The role of Muslim faith-based programs in transforming the lives of people suffering with mental health and addiction problems. J Subst Use. 2016 Nov 6;21(6):587–93.
29. Pilkington A, Msetfi RM, Watson R. Factors affecting intention to access psychological services amongst British Muslims of South Asian origin. Ment Health Relig Cult. 2012 Jan;15(1):1–22.
30. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance. The BMJ. 2021 Sep 30;374.
31. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ (Online). 2015 Mar 19;350.

32. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. J Gen Intern Med. 2001;16(9):606–13.
33. Teare MD, Dimairo M, Shephard N, Hayman A, Whitehead A, Walters SJ. Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: A simulation study. Trials. 2014 Jul 3;15(1).
34. Khan S, West RM, Mir G. Randomized Control Trial of a Culturally Adapted Behavioral Activation Therapy for Muslim Patients with Depression in Pakistan. World J Psychiatry. 2023;
35. Mir G. 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.
36. Billingham SA, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. BMC Med Res Methodol. 2013;13(1).
37. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A Brief Measure for Assessing Generalized Anxiety Disorder The GAD-7. Arch Intern Med. 2006;
38. Stewart-Brown S, Platt S, Tennant A, Maheswaran H, Parkinson J, Weich S, et al. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): a valid and reliable tool for measuring mental well-being in diverse populations and projects. J Epidemiol Community Health (1978). 2011 Sep 1;65(Suppl 2):A38–9.
39. Pargament K, Feuille M, Burdzy D. The Brief RCOPE: Current psychometric status of a short measure of religious coping. Religions (Basel). 2011 Feb 22;2(1):51–76.
40. Mir G. Evaluating a culturally adapted treatment for depression in Bradford [Internet]. 2024. Available from: https://doi.org/10.1186/ISRCTN54894017
41. Khan ZH, Watson PJ. Research: 'Construction of the pakistani religious coping practices scale: Correlations with religious coping, religious orientation, and reactions to stress among muslim university students'. Int J Phytoremediation. 2006;21(1):101–12.
42. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Quality of Life Research. 2011 Dec;20(10):1727–36.
43. Beecham J, Knapp M. Costing psychiatric interventions. In: G T, editor. Measuring Mental Health Needs [Internet]. 2nd ed. Gaskell; 2001 [cited 2024 Apr 29]. p. 200–24. Available from: pssru.ac.uk
44. Office for National Statistics Census 2021. Recommended national indicators of loneliness. 2021.
45. Chowdhary N, Jotheeswaran AT, Nadkarni A, Hollon SD, King M, Jordans MJD, et al. The methods and outcomes of cultural adaptations of psychological treatments for depressive disorders: A systematic review. Vol. 44, Psychological Medicine. Cambridge University Press; 2014. p. 1131–46.
46. Walpole SC, McMillan D, House A, Cottrell D, Mir G. Interventions for treating depression in Muslim Patients: A systematic review. Vol. 145, Journal of Affective Disorders. 2013. p. 11–20.
47. Chaudhry N, Waheed W, Husain N, Bhatti S, Creed F. Development and pilot testing of a social intervention for depressed women of Pakistani family origin in the UK. Journal of Mental Health. 2009 Dec;18(6):504–9.
48. Hsueh YC, Batchelor R, Liebmann M, Dhanani A, Vaughan L, Fett AK, et al. A Systematic Review of Studies Describing the Effectiveness, Acceptability, and Potential Harms of Place-Based Interventions to Address Loneliness and Mental Health Problems. Int J Environ Res Public Health. 2022 Apr 1;19(8).

49. Dankwa-Mullan I, Pérez-Stable EJ. Addressing Health Disparities Is a Place-Based Issue. Am J Public Health. 2016 Apr;106(4):637–9.
50. Williams C, Garland A. A cognitive-behavioural therapy assessment model for use in everyday clinical practice. Advances in Psychiatric Treatment. 2002;8(3):172–9.
51. Ioannidis JPA, Evans SJW, Gøtzsche PC, O'Neill RT, Altman DG, Schulz K, et al. Better Reporting of Harms in Randomized Trials: An Extension of the CONSORT Statement. Ann Intern Med. 2004 Nov 16;141(10):781.
52. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: An overview of reviews and development of a theoretical framework. BMC Health Serv Res. 2017 Jan 26;17(1).
53. Braun V, Victoria C. Thematic analysis: A practical guide. London: Sage Publications Ltd; 2021.
54. Van Hout B, Janssen MF, Feng YS, Kohlmann T, Busschbach J, Golicki D, et al. Interim scoring for the EQ-5D-5L: Mapping the EQ-5D-5L to EQ-5D-3L value sets. Value in Health. 2012 Jul;15(5):708–15.
55. World Medical Association. World Medical Association Declaration of Helsinki. JAMA. 2013 Nov 27;310(20):2191.