

# The feasibility of delivering a study using the Inspired Minds faith-based culturally adapted mental health and wellbeing intervention for young Muslim women

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<b>Registration date</b> 17/04/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/08/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The mental health and well-being of young people is a growing issue. Young women are three times more likely to be affected by mental health problems than young men, which can affect the rest of their lives. Mental health issues also affect minority ethnic populations differently, with evidence of increased long-term depression among Muslims compared with others. British Muslims are also less likely to access mental health services, partly because many services do not understand and address their cultural needs. This study will evaluate a programme developed by Inspired Minds (IM), a Muslim charity that aims to help promote and improve the mental health and well-being of young Muslim women aged 18-24 years old. The IM programme consists of group therapy sessions that have been specially developed to reflect the Muslim faith and culture. The study will investigate whether it is possible to compare the IM programme with a typical mental health programme (like that of the National Health Service) and how well these plans and ways of collecting information work. This ‘feasibility’ study will be conducted in East London and Birmingham communities, in the UK. The project will help understand how the IM programme works, what helps young Muslim women get involved, and their experiences participating. It will then inform a larger study to show if the IM programme improves young women’s mental health and well-being.

### Who can participate?

Young Muslim women aged between 18-24 years old who have self-diagnosed or been referred from another source with low mood or mild depression

### What does the study involve?

Young Muslim women seeking help for mental health problems from IM will be asked if they would like to take part. Sixty women will be allocated randomly (like flipping a coin) to one of two groups. One will be the culturally tailored IM programme. The other will be a standard mental health programme. The participants will be asked questions about their mental health and well-being. A group or individual discussion will also be conducted to understand their

experience of the programmes better and gather the views of the therapists delivering the sessions.

What are the possible benefits and risks of participating?

Participants will benefit from having the opportunity to try a novel intervention and to be involved in research. It is unknown if the intervention is better than usual care (although it is believed to be). There may be some burden, as with most research, because of having to complete questionnaires.

Where is the study run from?

Two locations in East London and Birmingham in community centres/mosques.

When is the study starting and how long is it expected to run for?

March 2024 to February 2026

Who is funding the study?

The National Institute for Health and Care Research (NIHR) Public Health Research (PHR) Programme

Who is the main contact?

Megan Smith (Trial Manager), m.smith25@herts.ac.uk

### **Study website**

<https://im-adaptedstudy.co.uk/>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

327432

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Protocol Number: HSK/SF/UH/05701, CPMS 55794, IRAS 327432

## Study information

### Scientific Title

The Inspired Minds Adapted Intervention: Feasibility study of a faith-based culturally adapted intervention to promote mental health and wellbeing in young Muslim women

### Acronym

IM-Adapted

### Study objectives

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

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 27/06/2024, University of Hertfordshire Health, Science, Engineering and Technology ECDA (University of Hertfordshire, Hatfield, AL10 9AB, United Kingdom; -; hsetecda@herts.ac.uk), ref: HSK/SF/UH/05701

### Study design

Two-arm cluster randomized controlled feasibility trial

### Primary study design

Interventional

### Secondary study design

Cluster randomised trial

## **Study setting(s)**

Community

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

## **Health condition(s) or problem(s) studied**

Low mood or mild depression

## **Interventions**

This study is a two-arm, cluster-randomised, controlled feasibility trial delivered in groups in two locations 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's experiences. Randomisation will be conducted online, stratified by location (London and Birmingham) and ensuring equal numbers in each group.

Eligible participants will be allocated randomly (in groups of approximately 10) to receive one of the following:

1. The 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 delivered by an Inspired Minds specialist trained therapist.
2. Usual psychoeducation group support - includes low-intensity CBT, but excludes specific Islamic messages and tailoring delivered by mental health professionals trained in usual psychoeducational

The Inspired Minds (IM)-Adapted programme, IM-Adapted, 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 intervention IM-Adapted recognises the broader cultural identities of young Muslim women and addresses issues of stigma, social structures, and religious explanations for depression, using the best practice approaches. This involves creating positive messages from Islamic teachings relating 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. The 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 and CBT models used in cultural adaptations. The intervention also uses a place-based community approach by delivering in a mosque or community centre. Participants who receive the intervention will receive the IM-Adapted programme in six weekly sessions (approximately 90 minutes per session) in groups of 8-10. Information will be collected from participants at the start (baseline), at 6 and 24 weeks. This will include questionnaires on depression, anxiety, well-being, quality of life, religious coping, service use and session attendance. Some participants and staff will be asked about their experience in the study.

## **Intervention Type**

Behavioural

### **Primary outcome measure**

The feasibility outcomes to determine progression will be:

1. Referral rate measured using the number of people referred for screening via any route by the end of recruitment
2. Number of exclusions measured by the number of participants who do not consent to take part in the study for any reason including those who do not meet the inclusion criteria during screening
3. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by the end of recruitment
2. Retention rates at follow-up recorded as the number of participants who consent to participate and remain in the study until the end of follow-up at 24 weeks post randomisation
3. Participant engagement and adherence measured using the attendance rate at the intervention sessions as a proportion of the total number of sessions at 6 weeks
4. Feasibility, acceptability, barriers and facilitators to interventions and training of therapists measured using focus groups after the 6-week intervention
5. Data quality and follow-up completion rates, including health economic data measured using missing data at 6 weeks and 24 weeks post randomisation
6. Training and delivery model (adherence, engagement, confidence) measured using intervention logs and rated against the adherence checklist at weekly intervention sessions up to 6 weeks
7. Adverse event rate recorded as the frequency, type and severity of event by treatment arm at the end of follow-up at 24 weeks post randomisation
8. The existence of early evidence that the intervention is not inferior to usual care is measured using analysis of primary outcome data collected at baseline and 24 weeks.
9. Feasibility of required sample size and other requirements for future trial measured using sample size calculation computed using follow-up data at 24 weeks.

Further outcome measures are:

1. Distress measured using the Patient Health Questionnaire-9 (PHQ9) at baseline, 6 weeks and 24 weeks
2. Well-being measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, 6 weeks and 24 weeks
3. Anxiety measured using the Generalised Anxiety Disorder Assessment (GAD-7) at baseline, 6 weeks and 24 weeks
4. Overall health-related quality of life measured using the EQ-5D-5L scale at 6 weeks and 24 weeks
5. Non-health-related resource use for participants of the intervention measured using the Client Service Receipt Inventory (CSRI) at 6 weeks and 24 weeks
6. Religious coping measured using the Brief Religious Coping measure (R-COPE) at baseline, 6 weeks and 24 weeks

### **Secondary outcome measures**

1. Health-related quality of life measured using the EuroQol EQ-5D-5L scale at baseline, after 6 weeks and 24 weeks
2. Non-health-related resource use for participants measured using the Client Service Receipt Inventory baseline, after 6 weeks and 24 weeks
3. Religious coping measured using R-Cope baseline, after 6 weeks and 24 weeks

**Overall study start date**

01/03/2024

**Completion date**

28/02/2026

## Eligibility

**Key inclusion criteria**

1. Muslim women aged 18-24 years old 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 (74) (low mood/mild symptoms) and willing to participate in the study.
2. Eligible young women with comorbidities that are not contradictions to the study (e.g., chronic pain)
3. Eligible young women on current treatment with antidepressants, other drugs, or psychological therapy will be included provided these individuals are not excluded because of disease severity.

**Participant type(s)**

Service user

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

24 Years

**Sex**

Female

**Target number of participants**

60

**Key exclusion criteria**

1. Those who score under 5 or above 14 on the PHQ-9 scale at screening.
2. Those considered unsuitable for whatever reason based on the professional opinion of the mental health professionals during risk assessment (see below). This will include those on current treatment, or with co-morbid conditions that present contraindications to engaging in the study.
3. Those who are identified by the mental health professionals delivering the programme at any point during the conduct of the study as being severely depressed, having psychosis, schizophrenia, or requiring hospitalisation.
4. Participants must be able to read and understand English, although it is not anticipated that this will lead to any exclusions given the age group.

**Date of first enrolment**

19/09/2024

**Date of final enrolment**

30/09/2025

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Birmingham**

United Kingdom

0

**Study participating centre**

**London**

United Kingdom

0

## **Sponsor information**

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**Sponsor type**

University/education

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**ROR**

<https://ror.org/0267vjk41>

# Funder(s)

## Funder type

Government

## Funder Name

Public Health Research Programme

## Alternative Name(s)

NIHR Public Health Research Programme, PHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

The main study findings will be published in a peer-reviewed, open-access journal within one year of the end of the trial.

## Intention to publish date

28/02/2027

## Individual participant data (IPD) sharing plan

The data is being collected for the specific purpose of undertaking a feasibility study. It will not be adequately powered for statistical hypothesis testing and we therefore do not anticipate sharing data, even in an anonymised format, with outside parties. However, requests for data access can be made and will be considered by contacting the Trial Manager (Megan Smith; m.smith25@herts.ac.uk).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		22/08/2025	27/08/2025	Yes	No