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

Submission date
12/03/2024

Recruitment status
No longer recruiting

Registration date
17/04/2024

Overall study status
Ongoing

Last Edited
03/02/2026

Condition category
Mental and Behavioural Disorders

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

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
327432

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Protocol Number: HSK/SF/UH/05701

Central Portfolio Management System (CPMS)
55794

Study information

Scientific Title
The Inspirited 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

Study type(s)
Treatment

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 Inspirited 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 Inspirited 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(s)
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

Key secondary outcome(s))
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

Completion date
20/03/2026

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
24 years

Sex
Female

Total final enrolment
0

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
United Kingdom

England

Study participating centre
Birmingham
-
Birmingham
England
-

Study participating centre
London
-
London
England
-

Sponsor information

Organisation
University of Hertfordshire

ROR
https://ror.org/0267vjk41

Funder(s)

Funder type
Government

Funder Name
Public Health Research Programme

Alternative Name(s)
NIHR Public Health Research Programme, The Public Health Research (PHR), PHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Protocol article		22/08/2025	27/08/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes