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Evaluating the effectiveness of an Islamic-faith based mental health support programme to reduce psychological distress and improve wellbeing among individuals in Somalia

Submission date
04/11/2026

Recruitment status
No longer recruiting

Registration date
04/11/2026

Overall study status
Ongoing

Last Edited
04/11/2026

Condition category
Mental and Behavioural Disorders

[ ] 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
Over the past four decades, Somalia has been experiencing a prolonged humanitarian crisis characterised by ongoing violence, recurring drought, poverty, and overall instability. These conditions have had profound mental health consequences for Somalis, including in Puntland - a state in Northwest Somalia - where an estimated one-third of the populations has reported experiencing significant mental distress. However, access to effective MHPSS in Puntland remains critically limited. This is, in part, due to the fact that Somalia is a Muslim nation, where the influence of faith on perceptions of mental health and help-seeking behaviours leads many individuals in Puntland to avoid availing of existing evidence-based mental health and psychosocial (MHPSS) support programmes. There is, therefore, an urgent need for culturally relevant, faith-aligned, and evidence-informed MHPSS initiatives in the Puntland region.
This study aims to evaluate the implementation of a novel MHPSS approach co-developed together with communities in Puntland. The approach is called Healing and Empowering - Achieving Resilience through Spiritual Nurture (HEARTS). Drawing from insights shared by community members in Puntland, HEARTS is a manualised MHPSS approach that combines practices, teachings, and principles from Islam with components from existing psychological interventions that are known to be effective in improving mental wellbeing. This study aims to achieve the following:
1. To assess preliminary evidence of HEARTS' effectiveness in improving the following primary outcomes: psychological distress, somatic symptoms, functional impairment, and subjective wellbeing
2. To assess preliminary evidence of HEARTS' effectiveness in improving the following secondary outcomes: social connectedness, positive and negative emotions, meaning in life, sources of support (including Islam), performance of Islamic duties, and positive Islamic coping
3. To identify the extent to which any changes in the secondary outcomes explain any changes observed in the primary outcomes
4. To identify HEARTS participants' levels of satisfaction with HEARTS following their participation using quantitative methods

5. To identify the impact of the HEARTS facilitator training in improving facilitators' knowledge, attitudes, and practices related to mental health, as well as their competencies to facilitate HEARTS
6. To identify reception to HEARTS among HEARTS participants and HEARTS facilitators, as well as recommendations for how HEARTS could be improved for future implementation in their community and other Muslim contexts using qualitative methods

Who can participate?
Members of the community in Puntland where HEARTS is being piloted, aged 18 years and over, who self-report psychological distress can be screened for participation in HEARTS

What does the study involve?
Participants are put into groups (clusters) based on gender, and each cluster is randomly allocated to either receive HEARTS immediately (weeks 1-6) or to wait to receive HEARTS (weeks 7-12). Facilitators have been paired up and assigned to facilitate one HEARTS group per study arm (immediate or waitlist). Participants and facilitators complete data collection at multiple timepoints throughout the 12 weeks to identify if HEARTS is effective in improving wellbeing and how it could be improved.

What are the possible benefits and risks of participating?
The possible benefits of participating are experiencing improvements in any of the outcomes listed above, while also being provided with a space to come together with other community members of the same gender to discuss similar experiences and support each other. Participants are also provided a small allowance in the amount of $10 USD per session for attending HEARTS sessions. Facilitators are provided with a stipend in the amount of $100 USD per month for 3 months. The possible risks of participating include experiencing distress during the HEARTS sessions, potential breach of confidentiality by fellow participants and/or session facilitators, as well as experiencing stigma from other group members and/or the community at large.

Where is the study run from?
This study is run from both Somalia and Ireland. Somalia is the site of initial the co-design workshops for HEARTS, participant recruitment and HEARTS implementation, while Ireland is the site of overall study design and oversight.

When is the study starting and how long is it expected to run for?
August 2026 to December 2026

Who is funding the study?
This study is funded by Taighde Éireann - Research Ireland under grant number EPSPG/2025 /3113, and by Irish Aid within Ireland's Civil Society Partnership programme.

Who is the main contact?
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Study information

Scientific Title
Healing and Empowering - Achieving Resilience through Spiritual Nurture (HEARTS): evaluating the impact of an Islamic faith-based, community-led, mental health and psychosocial support approach to reduce psychological distress and improve wellbeing among individuals in Somalia: a pilot cluster randomised controlled trial

Acronym
HEARTS

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 16/06/2026, Research Ethics Committee of the School of Psychology, Trinity College Dublin (Áras an Phiarsaigh, Trinity College Dublin, Dublin 2, Dublin, D02 PN40, Ireland; +353 (0)1 896 1886; psych.ethics@tcd.ie), ref: 6289

2. Approved 11/04/2026, Non-communicable Diseases Program of the Ministry of Health of the Puntland State Government of Somalia (CF45+C8G, Wadada Wasaaraddaha (Ministries Road), Garowe, N/A, Somalia; N/A; info@moh.pl.so), ref: MOH/NCD/ERC/2026/001

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Parallel

Purpose
Health services research, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Psychological distress, subjective wellbeing, functional impairment, somatic symptoms, social connectedness, positive and negative emotions, meaning in life, positive Islamic coping

Interventions
HEARTS is a community-led, Islamic faith-based mental health and psychosocial support (MHPSS) intervention aimed at improving psychological distress and wellbeing. HEARTS combines practices, teachings, and principles of Islam with components from evidence-based psychological interventions that are known to be effective in reducing distress and improving wellbeing. HEARTS is a manualised intervention, meaning that facilitators use a HEARTS facilitator manual to guide their facilitation of each session.

Facilitators of HEARTS are community members who have been trained to facilitate the HEARTS intervention using the HEARTS facilitator manual. HEARTS sessions occur for 2 hours once a week for 6 consecutive weeks. This cluster RCT has a total duration of 12 weeks.Participants are allocated to study arm via stratified (by gender) cluster randomisation. The immediate treatment study arm participates in HEARTS for the first 6 weeks. The waitlist control study arm participants in HEARTS for the second 6 weeks.

Intervention Type
Behavioural

Primary outcome(s)
1. Psychological distress (HEARTS participants) measured using the Kessler-10 Questionnaire at baseline, 3 weeks, 6 weeks, 12 weeks

2. Psychological distress (HEARTS participants) measured using the Somali Distress and Resilience Scale at baseline, 3 weeks, 6 weeks, 12 weeks

3. Psychological distress (HEARTS participants) measured using changes in welwel and murug (local idioms of distress) at baseline, 3 weeks, 6 weeks, 12 weeks

4. Subjective well-being (HEARTS participants) measured using the WHO-5 Questionnaire at baseline, 3 weeks, 6 weeks, 12 weeks

5. Functional impairment (HEARTS participants) measured using the WHO-DAS 2.0 questionnaire at baseline, 3 weeks, 6 weeks, 12 weeks

6. Somatic symptoms (HEARTS participants) measured using the Somatic Symptoms Scale-8 at baseline, 3 weeks, 6 weeks, 12 weeks

Key secondary outcome(s)

1. Social connectedness (HEARTS participants) measured using the Oslo Social Support Scale-3 at baseline, 3 weeks, 6 weeks, 12 weeks

2. Social connectedness (HEARTS participants) measured using the Somali Distress and Resilience Scale at baseline, 3 weeks, 6 weeks, 12 weeks

3. Positive and negative emotions (HEARTS participants) measured using the Positive and Negative Affect Schedule (PANAS-10) questionnaire at baseline, 3 weeks, 6 weeks, 12 weeks

4. Meaning in life (HEARTS participants) measured using the Meaning in Life questionnaire at baseline, 3 weeks, 6 weeks, 12 weeks

5. Sources of support (HEARTS participants) measured using one item from the Somali Distress and Resilience Scale; the following two items: "I feel close to Allah" and "I draw support from God" at baseline, 3 weeks, 6 weeks, 12 weeks

6. Frequency of performing Islamic duties (HEARTS participants and facilitators) measured using the Islamic duty subscale from the Psychological Measure of Islamic Religiousness at baseline, 3 weeks, 6 weeks, 12 weeks

7. Positive Islamic coping (HEARTS participants and facilitators) measured using the Positive Islamic Coping subscale from the Psychological Measure of Islamic Religiousness at baseline, 3 weeks, 6 weeks, 12 weeks

8. Knowledge, attitudes, and practices regarding mental health (HEARTS facilitators) measured using a questionnaire developed by the study team at baseline, pre-facilitator training, post-facilitator training, 6 weeks, 12 weeks

9. Competencies to facilitate HEARTS (HEARTS facilitators) measured using a questionnaire developed by the study team at baseline, pre-facilitator training, post-facilitator training, 6 weeks, 12 weeks

10. Qualitative reception to HEARTS (HEARTS participants and facilitators) measured using a semi-structured interview schedule developed by the study team at 12 weeks

11. Ideas for how HEARTS could be improved (HEARTS participants and facilitators) measured using a semi-structured interview schedule developed by the study team at 12 weeks

12. Ideas for how HEARTS could be sustained in the community (HEARTS participants and facilitators) measured using a semi-structured interview schedule developed by the study team at 12 weeks

13. Feedback on each HEARTS session (HEARTS participants and facilitators) measured using a feedback form used during each HEARTS session to capture anonymous feedback at weekly over the 12-week duration of the HEARTS RCT

Completion date

31/12/2026

Eligibility

Key inclusion criteria
HEARTS participants:
1. 18+ years of age
2. Islamic faith
3. Self-report of psychological distress

HEARTS facilitators:
1. 18+ years of age
2. Islamic faith
3. Knowledge of the Qur'an
4. Able to read and write in Somali
5. Willingness to train others in the HEARTS approach
6. Passionate about supporting people and their wellbeing

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Identified as at high risk for suicide

Date of first enrolment
05/08/2026

Date of final enrolment
07/08/2026

Locations

Countries of recruitment
Somalia

Sponsor information

Organisation
Trinity College Dublin

ROR
https://ror.org/02tyrky19

Organisation
World Vision Ireland

Funder(s)

Funder type

Funder Name
Research Ireland

Alternative Name(s)
Taighde Éireann, Taighde Éireann - Research Ireland, Researchirel, Science Foundation Ireland, Irish Research Council

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Funder Name
Irish Aid

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
The anonymous datasets generated during and/or analysed during the current study will be stored in a publicly available repository (Zenodo)

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			04/11/2026	No	No
Other files			04/11/2026	No	No
Participant information sheet			04/11/2026	No	Yes
Participant information sheet			04/11/2026	No	Yes
Participant information sheet			04/11/2026	No	Yes
Participant information sheet			04/11/2026	No	Yes
Protocol file			04/11/2026	No	No