Study Protocol for HEARTS Pre-registration (including analysis plan)

1. Title of the Study

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 (RCT)

2. Investigators

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3. Background and Rationale

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 population has reported experiencing significant mental distress[1]. However, access to effective MHPSS in Puntland remains critically limited[2-4]. This is, in part, due to the fact that Somalia is a Muslim nation[5], where the influence of faith on perceptions of mental health and help-seeking behaviours[6,7] leads many people in Puntland to avoid availing of existing evidence-based mental health and psychosocial (MHPSS) support programmes[3]. There is, therefore, an urgent need for culturally relevant, faith-aligned, and evidence-informed MHPSS initiatives in the Puntland region.

Reflecting a collaboration between Trinity College Dublin; World Vision Ireland; World Vision Somalia; the Ministry of Health in Puntland, Somalia; and the pilot community in Puntland, this study aims to evaluate the implementation of a novel Islamic-faith based and community-led MHPSS approach co-developed together with communities in Puntland. The approach is called "Healing and Empowering - Achieving Resilience through Spiritual Nurture", or 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.

4. Objectives

Primary Objective:
To assess preliminary evidence of HEARTS' effectiveness in improving psychological distress, somatic symptoms, functional impairment, and subjective wellbeing.

Secondary Objectives:
(i) To assess preliminary evidence of HEARTS' effectiveness in improving social connectedness, positive and negative emotions, meaning in life, sources of support (including Islam), performance of Islamic duties, and positive Islamic coping; (ii) To identify the extent to which any changes in the secondary outcomes explain any changes observed in the primary outcomes; (iii) to identify HEARTS participants' levels of satisfaction with HEARTS following their participation using quantitative methods, (iv) 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, and (v) 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.

Commented [CZ1]: Should I split these up into secondary and tertiary objectives (tertiary being level of satisfaction, facilitator outcomes, and qualitative data)?

Commented [FV2R1]: up to you - not sure it matters tbh!

Commented [KH3R1]: agreed. I think it's ok as is.

5. Methods

Study Design:

This is an unmasked pilot cluster randomised controlled trial (RCT) comparing HEARTS with a waitlist control group. Randomisation to immediate treatment or waitlist control is based on clusters of 10 individuals stratified by gender (male and female), with clusters representing the five villages within the community of implementation (to the greatest extent possible). HEARTS participants are quantitatively assessed without any assessor-masking at the following four timepoints:

- Baseline (T0)
- Midway through immediate treatment study arm – three weeks into treatment (T1)

- Immediately following immediate treatment study arm – six weeks into treatment (T2)
- Immediately following waitlist control study arm – 12 weeks into treatment (T3)

Data from HEARTS facilitators (the individuals delivering the HEARTS sessions) will also be collected and analysed. The same facilitators facilitate a HEARTS group across both study arms (immediate treatment and waitlist control) and, as such, do not undergo randomisation. HEARTS facilitators are quantitatively assessed at the following four timepoints:

- Pre-facilitator training (T0)
- Immediately following facilitator training (T1)
- Immediately following immediate treatment study arm – six weeks into treatment (T2)
- Immediately following waitlist control study arm – 12 weeks into treatment (T3)

Participants

We have enrolled 100 individuals (60 women, 40 men) from across the five villages in the community of implementation (located in Puntland, Somalia). These individuals have self-selected into participation on the basis of experiencing psychological distress.

We have also enrolled 12 community members to serve as HEARTS facilitators (six men, six women). These individuals underwent a 3-day, 16-hr long in-person training on HEARTS facilitation prior to the pilot beginning.

Inclusion Criteria for Participants:

- Being 18+ years of age
- Being of Islamic faith
- Self-report of psychological distress

Inclusion Criteria for Facilitators:

- Being 18+ years of age
- Being of the Islamic faith
- Knowledge of the Qur'an
- Willingness to train others in the HEARTS approach
- Able to read and write in Somali
- Passionate about supporting people and their wellbeing

Exclusion Criteria for Participants and Facilitators:

- Being identified as at high-risk for suicide per the Patient Health Questionnaire-9 (PHQ-9)[8] and the Columbia-Suicide Severity Rating Scale (C-SSRS)[9]. Being high-risk for suicide was identified through a two-step process. First, all potential participants were administered the PHQ-9. If their total score on the PHQ-9 was 15 or above or they answered in any affirmative way to question #9 (asking directly about thoughts of self-harm or suicide), they are then administered the C-SSRS, which identifies level of suicide risk. Individuals who are classified as high-risk according to the C-SSRS are screened out.

Recruitment

HEARTS participants were recruited via a Community Awareness Raising event that was led by World Vision Somalia Monitoring, Evaluation, and Learning (MEAL) team working on the HEARTS project. This event was held 05-07 August 2026 and involved local community authority (including the mayor of the community), the village committee, religious elders/faith leaders, and community members across the five villages. These sessions reached a total of 200 adults, and were aimed at explaining HEARTS, how it was created, and the pilot implementation and its associated research. This included explaining HEARTS core vision, its faith-integrated approach, the pilot implementation plan and timeline, the study design (i.e., that there are two study arms), and participant and facilitator inclusion/exclusion criteria. Community members were provided with printed off copies of the Participant Information Leaflet translated into Somali.

Community members who expressed interest in participating (n = 90) were documented by the World Vision Somalia MEAL team, who subsequently contacted them to confirm their interest and inform them of the next steps in the process (namely, screening). Because we aimed to recruit 100 total participants, these 90 community members helped identify 10 additional participants. We thus recruited 100 total community members as HEARTS participants (60 women, 50 men). Potential HEARTS facilitators were identified via consultation with the community mayor, as well as through returning to community members who had participated in a series of initial HEARTS co-design workshops held in the community in November 2025. We recruited 12 total facilitators (six men, six women).

Screening and Assessment Procedures

HEARTS Participants: Prior to beginning their participation during the week of 13 September 2026, but following randomisation and assignment of unique participant IDs, all 100 HEARTS participants met with trained enumerators to do the following in order: (i) gather informed consent to participate in the data collection (research) associated with HEARTS; (ii) complete the screening process; and (iii) complete baseline data collection. Note that, for ethical reasons, participating in the data collection was not required for an individual to participate in the HEARTS sessions. However, all 100 participants consented to data collection.

Immediately after gathering consent, trained enumerators conducted the screening process for participants. This involved first administering the PHQ-9. If a participant had a total score of 15 or above or above or answered in any affirmative way to question #9 (asking explicitly about suicidal thoughts and thoughts of self-harm), they were then administered the C-SSRS, which identifies level of suicide risk (low risk, medium risk, or high risk). Any individuals who were classified as high-risk according to the C-SSRS would have been screened out; none of the participants were screened out in our sample. To be classified as high-risk per the C-SSRS, a respondent has to acknowledge: (i) that they have had thoughts of killing themselves; (ii) have intention on acting on those thoughts; (iii) and/or created or initiated a plan to kill themselves.

Immediately following screening, all 100 participants completed baseline (T0) data collection by the trained enumerators using Kobo Toolbox via electronic devices. During data collection, the trained enumerators asked out loud all questions and inputted participant responses into Kobo Toolbox. This was done, in part, to enable people with low literacy to take part in the data collection. The consent gathering and screening for HEARTS participants occurred between 1-2 September 2026. Baseline data collection occurred between 3-4 September 2026.

In addition to T0 data collection, over the course of the 12-week pilot RCT, all 100 participants will be assessed by trained enumerators at the three-week (T1), six-week (T2), and 12-week (T3) timepoints. As of 4 November 2026, T0, T1, and T2 data collection have been completed, with a 98.3% response rate.

HEARTS Facilitators: Prior to beginning their participation in the HEARTS facilitator training on 01 September 2026, all 12 HEARTS facilitators met with trained enumerators to do the following in order: (i) gather informed consent to participate in the data collection (research) associated with HEARTS; (ii) complete the screening process; and (iii) complete baseline data collection Note that, for ethical reasons, participating in the data collection was not required for an individual to be a facilitator for HEARTS. However, all 12 facilitators consented to data collection.

Immediately after gathering consent, trained enumerators conducted the screening process for facilitators. This involved first administering the PHQ-9. As with the HEARTS participants, i a facilitator had a total score of 15 or above or above or answered in any affirmative way to question #9 (asking explicitly about suicidal thoughts and thoughts of self-harm), they were then administered the C-SSRS, which identifies level of suicide risk. Any individuals who were classified as high-risk according to the C-SSRS would have been screened out, but no facilitators were screened out. Immediately following screening, all 12 participants were completed baseline (T0) data collection by the trained enumerators using the Kobo Toolbox via electronic devices. As with participants, the trained enumerators asked out loud all questions and inputted facilitator responses into Kobo Toolbox. Consent gathering and screening for HEARTS facilitators occurred on 31 August 2026. Baseline data collection occurred on 1 September 2026.

Randomisation of HEARTS participants:

Randomisation of HEARTS participants occurred on 06 September 2026, after consent gathering, screening, and baseline data collection had already occurred among the 100 participants. All 100 participants were randomised via stratified randomisation, where they were first stratified by gender (male or female), grouped into same-gender clusters of 10 participants, and then each cluster was randomised to either the immediate treatment or waitlist control study arm, using a "coin-flip" feature to ensure that each study arm had near-equivalent proportion of male and female groups.

Randomisation thus occurred at the cluster (group) level, using Microsoft Excel's randomisation formula. First, participant groups (clusters) of 10 participants of the same sex were created for a total of 10 groups (four male groups, six female groups). To the greatest extent possible, participants in each cluster (across both immediate treatment and waitlist control study arms) were from the same village in the community. Each group was assigned an identification number (Group 1 to Group 10). Groups 1-4 were male groups (n = 4) and Groups 5-10 were female groups (n = 6). Within each gender, groups were then randomly ranked: each group was assigned a separate random number using the "=RAND()" function in Microsoft Excel, and groups were ranked by that number (1-4 for male groups; 1-6 for female groups). To ensure that each study arm (immediate vs waitlist) contained five total groups, a "coin flip" cell was set-up using the formula "=RANDBETWEEN(2,3)". By randomly choosing either '2' or '3', this "coin-flip" cell decided how many male groups (two or three) would be assigned to the immediate treatment study arm), which, in turn, decided how many female groups (two or three) would be assigned to the immediate treatment study arm. Once the "coin-flip" formula was established and had chosen '2', then the two highest ranked male groups from the "=RAND()" assignment (i.e., male groups '1' and '2') were assigned to the immediate treatment, while the three top highest ranked female groups were assigned to the immediate treatment. The remaining groups from both sexes were assigned to the waitlist control treatment.

Facilitator Assignment

Following participant randomisation, each participant group was assigned a facilitator pair of the same gender. Where possible, same-gender facilitators were created based on both facilitators being from the same village. Each facilitator pair was assigned one HEARTS participant group for each study arm (immediate treatment and waitlist control). Due to having an extra male facilitator pair (three facilitator pairs for two male HEARTS groups per study arm), one male facilitator pair was split up for each study arm, with the two single male facilitators from that pair joining one of the other male facilitator pairs as a third co-facilitator.

Primary outcomes of interest among HEARTS participants:

At each of the four timepoints, the following primary outcomes were assessed:

- *Psychological Distress* – Kessler-10 questionnaire[10]
- *Psychological Distress* – four distress items from the Somali Distress and Resilience Scale[11]
- *Psychological Distress* – assessed by two items reflecting local idioms of distress ("*murug*" and "*welwel*) using a Likert scale ranging from 1 (not at all) to 4 (extremely)
- *Functional Impairment* - 12-item version of the WHO's Disability Assessment Schedule (WHODAS 2.0)[12]
- *Subjective wellbeing* – WHO-5 questionnaire[13]
- *Somatic Symptoms* – Somatic Symptom Scale-8[14]

Mechanisms of interest among HEARTS participants

This study will also assess for changes in the following mechanism variables across the four timepoints and will aim to identify how any changes in these variables explain any observed changes in the primary outcomes listed above (i.e., through indirect effects).

Psychosocial variables:

- *Social connectedness* - Oslo Social Support Scale[15] and three items from the Somali Distress and Resilience Scale[11]
- *Positive and negative emotions* - PANAS-10[16]
- *Meaning in life* - Meaning in Life questionnaire[17]
- *Other sources of support* - assessed by the following Likert scale items drawn from Rutledge, 2025[18]:
    - "I feel that God cares about my life and situation"
    - "I feel close to Allah"
    - "I draw support from God"

  AND the following item from the Somali Distress and Resilience Scale (REF):

  "Rank the importance of the following areas that you draw strength from, with 1 being the most important and 7 being the least important. Please only use each ranking once:
    - Belief in the afterlife (*akhirah*).
    - An individual (including historical figures) who I look up to as a role model.
    - My sense of oneness (*walaal-nimo*) with the Somali community.
    - Prayer and/or religious rituals.
    - Having a sense of control over my life.
    - Knowing that God ("Allah") will support me.
    - Feeling hope that tomorrow will be better."

- *Frequency of performing Islamic duties* - assessed by the 'Islamic duty' subscale of the Psychological Measure of Islamic Religiousness (PMIR)[19]
- *Positive Islamic coping* - assessed by the 'Positive Islamic coping' subscale of the PMIR[19]

Outcomes of interest among HEARTS facilitators:

- *Knowledge regarding mental health* – as assessed by a questionnaire created by study team
- *Practices regarding mental health* – as assessed by a questionnaire created by study team
- *Attitudes regarding mental health* – as assessed by a questionnaire created by study team
- *Competencies to facilitate HEARTS* – as assessed by a questionnaire created by study team
- *Frequency of performing Islamic duties* - assessed by the 'Islamic duty' subscale of the Psychological Measure of Islamic Religiousness (PMIR)[19]
- *Positive Islamic coping* - assessed by the 'Positive Islamic coping' subscale of the PMIR[19]

Demographic variables:

Demographic variables of sex and age will be examined and accounted for in analyses. This will include through running descriptive statistical tests of both age and sex, as well as by including them as fixed effects in the linear effects modelling and as control variables in the mediation analyses (see 'Data Analysis' below).

Implementation Outcomes of Interest

The following implementation outcomes will be collected immediately following the pilot:

- *Satisfaction with HEARTS among HEARTS participants*. This is quantitatively assessed using an adapted version of the Client Services Satisfaction Questionnaire[19]
- *Fidelity checklists*. These checklists are completed after each session for each HEARTS group by the corresponding facilitator pair. These checklists document the number of participants who attended the session, whether each of the activities in each session were completed (yes/no), the reason why any uncompleted activity was not completed, the approximate time spent on each activity (in minutes), and any relevant comments from facilitators.
- *Group feedback on each session.* Every HEARTS session has a 25-minute discussion at the end where participants are invited to share feedback specific to that session.

Facilitators anonymously record this feedback in a feedback form, as well as write down their own feedback.

Qualitative Data – Feedback Forms and Interviews/FGDs

Qualitative data will be collected through multiple methods. First, at the end of each HEARTS session, HEARTS participants and facilitators engage in a group discussion to share feedback on that specific session, focusing on (i) what they liked about the session/what went well; (ii) what they did not like about the session/what did not go well; and (iii) how that HEARTS session could be improved. HEARTS facilitators record this feedback anonymously within an annex in the HEARTS delivery manual. These anonymous feedback notes will be analysed using content analysis at the end of the pilot.

Additional qualitative data will be collected immediately following the 12-week pilot via key informant interviews (KIIS) and focus group discussions (FGDs). This data will be collected both from HEARTS participants and HEARTS facilitators by trained enumerators. This qualitative data collection will use a semi-structured interview guide and will focus on the experience of participating/facilitating, what participants/facilitators enjoyed, what they did not enjoy, how HEARTS could be improved for future implementation, what support could help foster sustainable HEARTS implementation in the community, qualitative appraisal of the HEARTS facilitator training (only for facilitator interviews), and overall lessons learned.

Data Source and Study Population

Data Source: De-identified data collected from ~100 HEARTS participants and 12 facilitators enrolled in the HEARTS programme. The 100 participants include 50 participants in the immediate treatment study arm and 50 participants in the waitlist control study arm. Data is collected using Kobo Toolbox by trained enumerators. Enumerators are aware of the study arm each of the participants they assess has been assigned to (immediate treatment or waitlist).

Study Population: All 100 participants and 12 facilitators enrolled in the HEARTS programme, which runs from the week of 13 September 2026 until the week of 30 November 2026 (12 total weeks; six weeks per study arm).

Data Management and Confidentiality

All participants and facilitators give informed consent prior to collecting any of their data. All personal data is pseudonymised, with participant identification numbers being assigned to each participant in order to match them to their data. All personal data is collected by World Vision Somalia staff using Kobo, an encrypted digitised system, through password protected devices. Only authorised users are granted access to the data collected via Kobo, which is password protected. Following data collection, all personal data will be stored on these password protected and encrypted devices, which will be kept at the World Vision Somalia

office. All data is subsequently uploaded into encrypted, password-protected online Kobo servers, hosted in Ireland, with access restricted to authorised users. The data will also be backed up to an encrypted World Vision Ireland-owned folder in a GDPR-compliant online platform (Box). These online folders will only be accessible by individuals on the research team from World Vision Ireland and World Vision Somalia. After uploading, all data is deleted from the devices used to collect the data. All personal participant information and consent forms will be retained in these secure cabinets/computers/servers for 3 years, per Trinity College Dublin (TCD) data retention guidelines, after which it will be destroyed. All audio recordings from interviews will be destroyed following their transcription and pseudonymisation (no longer than 1 month following the interviews). Data will be shared only with members of the research team. All participant identification numbers (matching them to their data) will be destroyed following publication of the findings, after which it is not possible for participants to withdraw their data. Data will not otherwise be linked back to identifiable individuals. TCD has entered into a joint controller agreement with World Vision Ireland for the purposes of this study. World Vision Ireland has entered into a Controller-to-Controller agreement with World Vision Somalia for the purposes of this study.

6. Treatment Conditions

HEARTS immediate treatment: HEARTS is an Islamic faith-based, community led MHPSS approach that combines practices, teachings, and principles from Islam with components from psychological interventions that are known to be effective in supporting mental health and psychosocial wellbeing (such as psychoeducation, emotional regulation, and cognitive reframing). HEARTS is group-based, with each group having 10 participants of the same sex (male or female). Each group is facilitated by two trained facilitators of the same sex. Currently in its pilot version, HEARTS contains six sessions, with weekly sessions of 120 minutes each. Each session contains 10 activities, most of which are repeated in the same order across all six sessions. Please see Table 1 below for an overview of the content repeated in each session:

Table 1. Repeated activities in each HEARTS session

Time	Activity	Purpose
10 minutes	**Preparation and opening prayer**	Greet participants and settle into the space. Begin with an opening prayer (*Al-Sharh*), inviting participants to reflect on the *ayah*.
5 minutes	**Principles of mutual respect**	Review the principles of mutual respect for the HEARTS sessions.
5 minutes	**Review the agenda for the session**	Inform participants of the agenda for the session.
10 minutes	**Review the home practice from the previous session**	Check in on how participants found the practice from last session and celebrate their effort.

5 minutes	**Breathing exercise**	Conduct a quick breathing exercise, helping participants relax and prepare for the main content.
45 minutes	**Main content / skill practice**	Introduce the main topic for the session and practice and/or discuss the topic together
5 minutes	**Practice at home**	Introduce the home practice for the coming week.
20 minutes	**Group Discussion – feedback on the session**	Lead participants in a group discussion to gather their feedback on the session. Take anonymous notes with consent of participants using Annex 3.
15 minutes	**Offering gratitude and closing prayer**	Invite participants to share closing reflections and offer *shukr*. Lead participants in a closing prayer (*Al-Asir*) and provide concluding remarks.

In addition to the repeated activities, each session also has two core, longer activities designed as the active therapeutic components in the session, where practices and beliefs from Islam are combined with mechanisms from psychological interventions. Table 2 below has an overview of each of the six HEARTS sessions.

Table 2. Overview of the six HEARTS sessions

Session #	Session Title	Objectives
Session 1	**The Beginning of the HEARTS Journey**	Introduce the participants to the HEARTS approach
Session 2	**Understanding Adversity and its Common Reactions**	Better understand adversity, normalise its impacts on wellbeing, and share similar experiences
Session 3	**Using *Sabr* and *Qadar* to Respond to Adversity**	Discuss, learn, and practice how to use *sabr* and *qadar* to manage the difficult feelings arising from adversity
Session 4	**Spending time in *Dua* to Shift Unwanted Thoughts**	Discuss, learn, and practice how to use time in *dua* to identify, reflect on, and shift unwanted thoughts to thoughts of Allah's love and a sense of *tawakkul*
Session 5	**Reconnecting with our Faith to Stay Active During Difficult Times**	Discuss, learn, and practice how to stay active during difficult times
Session 6	**Finishing the HEARTS Journey**	Congratulate and reflect on progress made in HEARTS, review the strategies learned, and discuss how to maintain these strategies in the future

HEARTS is a manualised intervention, meaning that facilitators use a HEARTS facilitator manual to guide their facilitation of each session. In addition to the content for each of the six HEARTS sessions, this facilitator manual also has an Introduction section and a collection of Annexes that are intended to complement some of the session activities. These annexes include the fidelity checklist for each HEARTS sessions, a form to record anonymous feedback shared during the group feedback discussions in each session, the instructions for how to practice each sessions' 'practice at home' activity, and a referral list for facilitators should they need to refer any participant to additional, more specialised support.

HEARTS waitlist: The five HEARTS groups (n = 50 participants) randomised to the waitlist control group will wait six weeks to begin their participation in HEARTS, with their HEARTS groups starting during the week of 26 October 2026 following the assessment at week 6 (T2).

7. HEARTS Facilitator Training and Supervision

All 12 HEARTS facilitators (six men, six women) participated in a 3-day training from September 1, 2026-September 3, 2026 (4.5 hours per day). This training was led by the PhD student leading HEARTS (Charles Zemp), the HEARTS team from World Vision Somalia, and three staff members from the noncommunicable disease (NCD) department of the Ministry of Health (MoH) in Puntland, Somalia. The training focused on introducing facilitators to HEARTS, reviewing the facilitator manual, and learning and practicing the content across all six all HEARTS sessions. The training also included learning and practicing of basic helping skills, group facilitation skills, recognising and managing participant distress, as well as discussion of the supervision that HEARTS facilitators receive over the course of the 12-week pilot.

HEARTS facilitators participate in six group supervision sessions (1.5 hrs each) over the course of the 12-week pilot. These sessions occur after the 1st, 3rd, and final (6th) HEARTS session for each study arm (immediate treatment and waitlist control). One supervision group for each gender has been established, and supervision is led by a staff member of the same sex from the NCD department of the Puntland MoH. As of 4 November 2026, four group supervision sessions have occurred for each facilitator gender.

The supervision in HEARTS is informed by the Integrated Model for Supervision (IMS)[20], which focuses on achieving three goals through supervision of MHPSS providers: (i) provide emotional support to facilitators, (ii) build their skills, and (iii) monitor the quality of the work they are doing. Prior to beginning their supervision, the two supervisors underwent a half-day training with an MHPSS expert who was a co-author of the IMS. This individual will also provide the two supervisors with their own supervision four times over the course of the 12-week pilot. Following the pilot, this person will have one final meeting with the supervisors to discuss lessons learned and how the supervision component of HEARTS could be improved.

8. HEARTS Enumerator Training

Prior to beginning enumeration, HEARTS enumerators underwent four days of training (4.5 hours per day). This training focused on explaining HEARTS as an MHPSS approach, the use of Kobo Toolbox, research ethics, consent, and confidentiality, in-depth review and practice focused on the HEARTS data collection tools and protocols, and a brief introduction to psychological first aid (PFA). The enumerator training was led by the MEAL team at World Vision Somalia, except for the introduction to PFA, which was led by the PhD student leading the HEARTS approach.

9. Ethical Approval for Study Procedures

The study procedures were reviewed and approved by both the Research Ethics Committee of the School of Psychology, Trinity College Dublin (Reference No. 6289) and the Non-communicable Diseases Program of the Ministry of Health of the Puntland State Government of Somalia (Reference No. MOH/NCD/ERC/2026/001).

10. Data Analysis Plan

Statistical Analysis:

Software:
All statistical analyses will be performed using SPSS v.31.

Primary objective:

Changes in the six primary outcomes will be examined using linear mixed-effects models under an intent-to-treat approach (all randomised participants analysed in their allocated arm), estimated by maximum likelihood, with missing data handled under a missing-at-random assumption. A sensitivity analysis will be conducted if missingness appears related to group or to outcome values.

Models will include fixed effects of group (immediate vs. waitlist), time (baseline, T1, T2, T3; categorical), group × time, age, and facilitator pair. Because each facilitator pair delivered HEARTS to same-sex clusters only (one immediate and one waitlist cluster), sex is nested within facilitator pair; facilitator pair will therefore be included as a fixed effect, which also adjusts for sex (the stratification factor) and balances delivery across arms. A random intercept for participant will account for repeated measures, and an unstructured residual covariance across timepoints will be considered.

Because there are only 10 clusters, cluster-level variance may be imprecisely estimated. A random intercept for cluster will nonetheless be included, with Kenward-Roger small-sample

corrections, and the intraclass correlation will be reported. If the model fails to converge or the cluster variance is estimated at zero, cluster-robust standard errors with a small-sample correction will be used instead.

The waitlist study arm receives HEARTS after T2 data collection; T1 and T2 therefore provide controlled comparisons between arms, whereas T3 does not, as both arms will have received the intervention by then. The primary test of HEARTS' effectiveness is the group × time interaction at T1 and T2 (baseline-adjusted group differences at each timepoint, estimated from the model). T3 data will thus not be analysed with comparison tests, but instead focus only on inferential statistics and descriptive analyses to examine maintenance of effects in the immediate arm and change following delivery in the waitlist arm. T3 data will therefore be interpreted as non-controlled. Holm-Bonferonni correction will be applied across the six primary outcomes. Effect sizes (Cohen's d, calculated as the model-estimated group difference divided by the pooled baseline standard deviation) will be reported with 95% confidence intervals.

Prior to analysis, data will be checked for accuracy, missing values, and violations of the assumptions of linear mixed-effects modelling. If assumptions are violated, outcomes will be transformed or model re-specifications will be used.

Secondary objective:

Changes in the mechanism will be assessed using the same procedures as for the primary outcomes. To examine the extent to which changes in the mechanisms may account for changes in the primary outcomes, exploratory mediation analyses will be conducted. For each primary outcome, a parallel mediation model (PROCESS macro in SPSS) will test the indirect effect of treatment group on change in the primary outcome (baseline to T2) through change in the mechanisms (baseline to T1), adjusting for age and facilitator pair. Indirect effects will be tested using 5,000 bootstrapped samples with 95% confidence intervals. Because PROCESS does not account for clustering and uses listwise deletion, results will be interpreted with caution, and the analyses will be treated as hypothesis-generating. No correction for multiple testing will be applied, and findings will be interpreted accordingly.

Descriptive analyses will be used to identify quantitative levels of satisfaction with HEARTS among all $n = 100$ HEARTS participants at T3.

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 over the four facilitator data collection timepoints, a series of one-way repeated-measures ANOVAs will be used. Prior to analysis, data will be checked for accuracy, missing values, and violations of the assumptions of linear mixed-effects modelling. If assumptions are violated, outcomes will be transformed or model re-specifications will be used. If the omnibus test for an outcome is statistically significant ($p <$

0.05), post-hoc comparisons between timepoints using Holm or Bonferroni corrections will be used.

Qualitative Analysis

All data generated from KIIs and/or FGDs will be analysed using content analysis using NVivo version 15.

11. Dissemination Plan

Findings will be submitted to a peer reviewed journal, included in a PhD dissertation, presented at relevant conferences and/or via other dissemination methods (i.e., webinars, etc.), as well as reported back to the community of implementation.

12. Funding

This study has emanated from research funded by Taighde Éireann - Research Ireland under grant number EPSPG/2025/3113, and by Irish Aid within the Ireland's Civil Society Partnership programme.

13. Role of the Funding Source

Neither Taighde Éireann - Research Ireland nor Irish Aid had any involvement in the study design, pilot implementation, or data collection. They will have no role in data analysis or data interpretation.

References

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