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Feasibility testing a community music programme to improve maternal mental health among pregnant women in Khayelitsha, South Africa

Submission date
20/07/2026

Recruitment status
Recruiting

Registration date
22/07/2026

Overall study status
Ongoing

Last Edited
17/08/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Poor maternal mental health during pregnancy is common in South Africa and can negatively affect both mothers and their babies. Many women experience stress, anxiety, depression, and social isolation during the perinatal period, while access to mental health services remains limited.

The Community Health Intervention through Musical Engagement (CHIME) programme is a culturally grounded group intervention that uses participatory music and singing to support maternal mental health and wellbeing. Previous work in The Gambia found that the intervention was acceptable and showed promising effects on reducing psychological distress.

This study aims to adapt CHIME for use in Khayelitsha, South Africa, and to assess whether it is feasible and acceptable to conduct a larger effectiveness trial.

Who can participate?

Pregnant women aged 16 years or older who are between 16 and 24 weeks pregnant, live in the selected study communities in Khayelitsha, and speak isiXhosa.

What does the study involve?

Participants will be recruited from Nolungile Clinic as well as community networks such as door-to-door, snowball sampling, and NGOs in Khayelitsha. Participants will be randomly assigned either to receive the CHIME intervention immediately or to receive usual care and later receive a shortened version of the programme.

Women participating in CHIME will attend six group sessions involving participatory singing, music activities, and discussions related to emotional wellbeing, coping, resilience, and social support during pregnancy.

Participants will complete interviews and questionnaires at the start of the study, after the intervention, and 6 months later. Some participants and facilitators will also take part in focus groups or interviews about their experiences of the programme.

What are the possible benefits and risks of participating?
Possible benefits include improved emotional wellbeing, increased social support, reduced isolation, and learning coping strategies during pregnancy.
Possible risks include emotional discomfort when discussing personal experiences. Participants who require additional support will be referred to appropriate mental health services.

Where is the study run from?
The study is coordinated by Stellenbosch University and will take place in Khayelitsha, Cape Town (South Africa)

When is the study starting and how long is it expected to run for?
July 2026 to September 2027

Who is funding the study?
The study is funded through the NIHR Global Health Research Group in Community Health Intervention through Musical Engagement for Maternal Mental Health (CHIME)

Who is the main contact?
Prof. Sarah Skeen, skeen@sun.ac.za

Contact information

Type(s)
Principal investigator

Contact name
Prof Sarah Skeen

ORCID ID
https://orcid.org/0000-0002-7464-2861

Contact details
Office 6023, 6th Floor, Clinical Building, Francie van Zijl Drive
Department of Global Health, Faculty of Medicine and Health Sciences, Stellenbosch University
Cape Town
South Africa
7505
+27 (0)21 938 9758
skeen@sun.ac.za

Type(s)
Public, Scientific

Contact name
Dr Stefani Du Toit

ORCID ID
https://orcid.org/0000-0001-7947-3043

Contact details

Office 6023, 6th Floor, Clinical Building, Francie van Zijl Drive
Department of Global Health, Faculty of Medicine and Health Sciences, Stellenbosch University
Cape Town
South Africa
7505
+27 (0)21 938 9758
dutoits@sun.ac.za

Type(s)
Principal investigator

Contact name
Prof Lauren Stewart

ORCID ID
https://orcid.org/0000-0002-6221-6064

Contact details
School of Psychology, University of Roehampton
London
United Kingdom
SW15 4JD
+44 (0)20 8392 3100
Lauren.Stewart@roehampton.ac.uk

Additional identifiers

Study information

Scientific Title
An individual feasibility randomised controlled trial of the Community Health Intervention through Musical Engagement (CHIME) programme to improve maternal mental health among pregnant women in Khayelitsha, South Africa

Acronym
CHIME-SA

Study objectives
1. To assess the feasibility and acceptability of the CHIME intervention and trial procedures among perinatal women and community facilitators
2. To identify barriers and facilitators to implementation.
3. To inform improved design and delivery of the intervention for a future definitive trial.
4. To identify delivery costs and pilot methods for assessing cost-effectiveness
5. To assess whether the outcome and covariate measures are understandable and acceptable
6. To estimate parameters required for a definitive trial, including sample size, and potential effect sizes
7. To determine whether progression to a full-scale effectiveness trial is warranted based on prespecified criteria.

GREEN (Go): Progression to a definitive trial without major modifications: the CHIME intervention and trial procedures are feasible and acceptable, with high acceptability and feasibility among participating perinatal women and community facilitators; recruitment reaching ≥75% of the target sample within the planned recruitment period; retention at the post-intervention assessment of ≥75%; randomisation procedures acceptable to ≥75% of eligible participants; and evidence of adequate intervention fidelity (≥75% of intervention sessions delivered as intended).

AMBER (Amend): Progression following refinement: moderate acceptability and feasibility among participants and facilitators, with barriers identified that are potentially addressable; recruitment reaching 50–75% of the target sample; post-intervention retention of 50–75%; randomisation procedures acceptable to 50–75% of eligible participants; and/or moderate intervention fidelity (50-75% of intervention sessions delivered as intended), where improvements may be achievable through adaptations to training, supervision, or delivery procedures.

RED (Further development required): Progression to a definitive trial will not be recommended if the overall findings indicate substantial challenges that cannot reasonably be addressed through further development or refinement of the trial and/or intervention. This may include: low acceptability or feasibility among participants and/or facilitators; recruitment substantially below target (<50%); low post-intervention retention (<50%); limited acceptability of randomisation procedures (<50%); and/or inadequate intervention fidelity across sessions (less than 50% of intervention sessions delivered as intended).

Progression decisions will be informed by the overall pattern of findings from the feasibility trial, including quantitative indicators and qualitative insights from participants, community facilitators, and the process evaluation. No single criterion will be used in isolation to determine progression. Instead, criteria will be considered collectively to assess whether the intervention and trial procedures can be optimised for a future definitive effectiveness trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 11/04/2025, Health Research Ethics Committee 1 (Research Development and Support Division, PO Box 19063, Tygerberg, Cape Town, 7505, South Africa; +27 (0)21 938 9075; siti@sun.ac.za), ref: N24/11/148

2. Approved 01/04/2025, University of Roehampton Research Integrity and Ethics Committee (Research Services and Ethics Officer Research Office/Grove House University of Roehampton London, SW15 5SL, United Kingdom, London, SW15 5SL, United Kingdom; +44 (0)20 8392 5785; ethics@roehampton.ac.uk), ref: PSYC 24-505

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Health services research, Prevention

Study type(s)

Health condition(s) or problem(s) studied
Perinatal mental health difficulties including symptoms of depression, anxiety, psychological distress, and reduced wellbeing

Interventions
Current interventions as of 17/08/2026:

This study is a feasibility individual randomised controlled trial evaluating an adapted version of the Community Health Intervention through Musical Engagement (CHIME) programme in Khayelitsha, South Africa. Participants will be recruited from selected clinics and from the surrounding community, using door-to-door recruitment and snowball sampling. Participants will be randomly assigned in a 1:1 ratio to one of two groups: an intervention arm, which will receive the CHIME programme immediately, or a waitlist control arm, which will receive usual care and later be offered a shortened version of the programme. Randomisation will be stratified according to Patient Health Questionnaire Score (PHQ-9 scores). The stratification will be based on the following categories 0-9: minimal to mild, 10-14: moderate, 15+: severe. Randomisation will be overseen by an external statistician using a web-based randomisation programme.

Participants in the intervention arm will receive the CHIME intervention. CHIME uses local musical traditions and participatory singing as a culturally resonant, non-stigmatising entry point for engaging with mental health during pregnancy. Group singing is intended to lift mood and enhance social connection to promote psychological resilience, social support, wellbeing, and coping. The intervention was adapted from an intervention developed in The Gambia in partnership with pregnant women and community members in Khayelitsha, Cape Town, and is designed to complement, not replace, routine antenatal care. Facilitators use a structured facilitator handbook comprising a menu of topic modules, each linked to one of seven co-developed songs in isiXhosa, covering social support, emotional wellbeing, anxiety, self-care, stress and rest, intimate relationships, mother–infant bonding, nutrition and antenatal care engagement, and birth and postnatal planning. Materials include a check-in-to-module selection guide, weekly health messages, and lullaby-creation activities.The programme is delivered through six weekly group sessions lasting one hour, by two trained community health workers who co-facilitate each group.

Participants in the control arm will receive care as usual during the study period and will receive a waitlist truncated version of the intervention after completion of follow-up assessments.

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Previous interventions:

This study is a feasibility individual randomised controlled trial evaluating an adapted version of the Community Health Intervention through Musical Engagement (CHIME) programme in Khayelitsha, South Africa. Participants will be recruited from selected clinics and from the surrounding community, using door-to-door recruitment and snowball sampling. Participants will be randomly assigned in a 1:1 ratio to one of two groups: an intervention arm, which will receive the CHIME programme immediately, or a waitlist control arm, which will receive usual care and later be offered a shortened version of the programme. Randomisation will be overseen by an external statistician using a web-based randomisation programme.

Participants in the intervention arm will receive the CHIME intervention. CHIME uses local musical traditions and participatory singing as a culturally resonant, non-stigmatising entry point for engaging with mental health during pregnancy. Group singing is intended to lift mood and enhance social connection to promote psychological resilience, social support, wellbeing, and coping. The intervention was adapted from an intervention developed in The Gambia in partnership with pregnant women and community members in Khayelitsha, Cape Town, and is designed to complement, not replace, routine antenatal care. Facilitators use a structured facilitator handbook comprising a menu of topic modules, each linked to one of seven co-developed songs in isiXhosa, covering social support, emotional wellbeing, anxiety, self-care, stress and rest, intimate relationships, mother–infant bonding, nutrition and antenatal care engagement, and birth and postnatal planning. Materials include a check-in-to-module selection guide, weekly health messages, and lullaby-creation activities.The programme is delivered through six weekly group sessions lasting one hour, by two trained community health workers who co-facilitate each group.

Participants in the control arm will receive care as usual during the study period and will receive a waitlist truncated version of the intervention after completion of follow-up assessments.

Intervention Type
Behavioural

Primary outcome(s)
1. Whether progression to a full-scale effectiveness trial is warranted based on the CHIME intervention and trial procedures being feasible and acceptable, measured using recruitment rates, attendance rates, retention rates and intervention fidelity at post-intervention

Key secondary outcome(s)
1. Depressive symptoms measured using the Patient Health Questionnaire-9 (PHQ-9) at post-intervention and 6 months post birth

2. Anxiety symptoms measured using Generalised Anxiety Disorder-7 (GAD-7) at post-intervention and 6 months post birth

3. Symptoms of common mental disorders measured using the Self Reporting Questionnaire-20 (SRQ-20) at post-intervention and 6 months post birth

4. Psychological well-being measured using the WHO-5 Wellbeing Index at post-intervention and 6 months post birth

Completion date
30/09/2027

Eligibility

Key inclusion criteria
1. Pregnant women between 16–24 weeks gestation
2. Aged 16 years or older
3. Residing within the selected study areas in Khayelitsha, South Africa
4. Able to communicate in isiXhosa
5. Willing and able to provide informed consent (or assent with caregiver consent for participants under 18 years)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
65 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Current severe mental health crisis posing risk to self or others
2. Current symptoms of psychosis

Date of first enrolment
13/07/2026

Date of final enrolment
30/10/2026

Locations

Countries of recruitment
South Africa

Study participating centre
Institute for Life Course Health and Research
Office 6023, 6th Floor, Clinical Building, Francie van Zijl Drive
Department of Global Health, Faculty of Medicine and Health Sciences, Stellenbosch University

Cape Town
South Africa
7505

Sponsor information

Organisation
Stellenbosch University

ROR
https://ror.org/05bk57929

Organisation
University of Roehampton

ROR
https://ror.org/043071f54

Funder(s)

Funder type

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Data generated through the project will be made available after a 2-year embargo period, upon reasonable request and subject to appropriate governance criteria, including ethical approval, data protection requirements, and intended use. Request should be made to Prof. Sarah Skeen (skeen@sun.ac.za).

IPD sharing plan summary

Available on request