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2 Young Lives: mentoring teenagers for safer pregnancy and birth in Sierra Leone

Submission date
10/03/2022

Recruitment status
No longer recruiting

Registration date
14/03/2022

Overall study status
Completed

Last Edited
24/06/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Sierra Leone has one of the highest death rates in young girls and their infants, and they usually die because of complications during pregnancy and childbirth. Young girls are particularly vulnerable and many times belong to disadvantaged communities, usually driven by poverty and lack of education and employment opportunities. Many factors such as stigma, abandonment and neglect lead to a low update of life-saving antenatal care or birth at facilities or with trained staff. In 2017, a community-based mentoring scheme for adolescent girls was developed locally and piloted in a few areas. The preliminary data looks promising. The aims of this study are to assess the feasibility and implementation of the 2 Young Lives mentoring scheme for young girls and to inform trial procedures for a subsequent full trial.

Who can participate?
Pregnant adolescent girls under 18 years old, family members or friends, mentors, staff, and community stakeholders from participating areas

What does the study involve?
Twelve participating areas in Sierra Leone are randomly allocated to the intervention group or the control group. The control group receive standard maternity care, and the intervention group are offered a mentoring scheme in addition to standard maternity care. The mentoring scheme is a locally-designed intervention that provides mentoring from pregnancy through to 1 year after birth for women aged under 18 years. Overall, this encourages mentees to take up antenatal care and hospital birth, re-establish family connections where this is safe and appropriate, promotes health-seeking behaviour, provides practical advice about childbirth, parenting and contraception, and supports mentees to return to education or start vocational training.

What are the possible benefits and risks of participating?
The study will help to find out the best way of running the mentoring scheme so it can be tested out on a larger scale to improve the lives of young women and their babies. Participating in interviews, focus groups discussions or the photovoice project will help the researchers to better understand adolescent girls' everyday lives and their experiences of pregnancy, motherhood and the mentoring scheme. Some girls may find talking about their experiences

helpful, or they may find it upsetting, and if they are upset and want someone to talk to, the team will help them to find someone.

Where is the study run from?
This study is running in communities in Sierra Leone and is being sponsored by King’s College London (UK)

When is the study starting and how long is it expected to run for?
September 2021 to June 2024

Who is funding the study?
National Institute for Health Research (NIHR) Global Health Research Group (CRIBS) (UK)

Who is the main contact?
1. Dr Cristina Fernandez Turienzo, cristina.fernandez_turienzo@kcl.ac.uk
2. Mrs Lucy November, lucy.november@kcl.ac.uk
3. Mrs Mangenda Kamara, mangenda@welbodipartnership.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HR/DP-21/22-26320

Study information

Scientific Title
Feasibility and implementation of '2 Young Lives', a mentoring scheme from pregnancy through to 1-year post-birth for adolescent girls n Sierra Leone

Acronym
2 Young Lives

Study objectives
Implementation of a community-based mentoring scheme for adolescent girls is feasible, acceptable and can inform trial procedures for a subsequent fully powered cluster randomised controlled trial (RCT).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 04/02/2022, King's College London Ethics Committee (Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London, SE1 9NH, UK; +44 (0)20 7848 4020/4077;

rec@kcl.ac.uk), ref: HR/DP-21/22-26320
2. Approved 22/02/2022, Sierra Leone Ethics and Scientific Review Committee (Government of Sierra Leone. Office for the Sierra Leone Ethics and Scientific Review Committee, Directorate of Training and Research, 5th floor, Youyi Building Brookfields, Freetown, Ministry of Health and Sanitation, Sierra Leone; +232 (0)78 36 64 93; efoday@mohs.gov.sl), ref: not applicable

Study design
Cluster interventional unblinded randomized controlled pilot trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Reduction of mortality among pregnant adolescent girls and their infants

Interventions
The allocation ratio of the intervention will be 1:1. Randomisation will be managed via a secure web-based randomisation facility hosted by Medscinet which will with the randomisation programme and hold the allocation code.

Intervention: mentoring scheme + standard maternity care in Sierra Leone (see below details of standard maternity care)
1. Recruitment and training of mentors
2. Weekly 1:1 between mentor + mentee
3. Accompaniment for antenatal and birth care, or emergency care if required
4. Reminders to attend appointments
5. Health education and promotion
6. Flexible support with postnatal care and baby care
7. Support to consider small business options and accompaniment to purchase the first supply of goods
8. Advocacy for girls and with families (if safe + appropriate)
9. Encourage staying in/returning to school/starting vocational training
10. Workshop with teachers in schools (radical inclusion policy)
11. Monthly meetings with all mentors and mentees, cook and eat, peer support, and visitors (e.g. health discussion with midwife, community leaders)
12. Graduation celebration at the end of the mentoring scheme
The mentoring intervention is provided from pregnancy through to 1 year after birth.

Control: standard maternity care in Sierra Leone
Usual maternity care in Sierra Leone (e.g. eight antenatal checks, screening for HIV, Hep B, Intermittent preventive treatment (IPT) against malaria, free insecticide-treated bednet (ITN) at the first antenatal visit, deworming meds, tetanus toxoid immunisations, birth with a skilled birth attendant in a health facility, post-birth observation for 24 hours, baby immunisations, postnatal check, free contraception etc).

Semi-structured interviews, focus groups discussions and a photovoice project will be conducted at 6 and 9-12 months after intervention implementation.

Intervention Type
Mixed

Primary outcome measure
Current feasibility outcome measures as of 17/11/2022:
1. The number of participants identified, recruited and retained, measured using routinely collected data at pregnancy, at birth, at 6 weeks, and 1 year after birth
2. The number of participants ineligible or withdrawing from the study, and data collection and completion of outcome measures, measured using routinely collected data at pregnancy, birth, 6 and 1 year after birth
3. Selection of most appropriate primary outcome measure and sample size calculation, measured at pregnancy, birth, and 6 weeks after birth

Previous feasibility outcome measures:
The feasibility of a future definitive trial assessed using:
1. The number of participants identified, recruited and retained, as measured using routinely collected data at pregnancy, at birth, at 6 weeks, and 1 year after birth
2. The acceptability and experience of the trial process including ineligibility or withdrawal from the study, randomisation, rolling programme, and data completion of outcome measures, measured using routinely collected data, interviews, focus groups and report forms monthly, at 6, 9-12 months after birth
3. The performance of the selected primary outcome in relation to the level of acceptability and relevance, measured using focus groups, interviews and report forms monthly, at 6, 9-12 months
4. Data completeness at follow up, variance of the likely primary outcome and variability of intervention across individuals and sites, measured using routinely collected data, report forms, interviews and focus groups at 6 weeks, monthly, 6, 9-12 months

Primary clinical outcome measures:
The primary clinical outcome is a composite of:
1. Maternal death (all-cause, occurring during pregnancy, labour, or within 42 days of birth), measured using routinely collected data following birth and 6 weeks after birth
2. Stillbirth (born with no signs of life at or after 28 weeks of pregnancy, but before or during birth), measured using routinely collected data following birth
3. Neonatal death (deaths among live births during the first 28 days), measured using routinely collected data following birth and 6 weeks after birth

Secondary outcome measures
Secondary outcome measures:
1. Maternal outcomes measures including i.e. IPT for malaria, number of tetanus toxoid immunisations, caesarean sections, birth at facility, postpartum haemorrage, place of birth, presence of birth attendant, measured using routinely collected data following birth; and

contraception uptake measured using routinely collected data and interviews at 6 weeks, 9-12 months after birth; recurrent pregnancy measured using interviews at 9-12 months after birth.
2. Perinatal outcomes measures including birthweight, Apgar score at 5 minutes, newborn resuscitation, breastfeeding, Kangaroo mother care, admission to neonatal unit, measured using routinely collected data following birth; postnatal immunisation uptake measured using routinely collected data at 6 weeks after birth; and 1-year infant death measured using routinely collected data at 1 year after birth
3. Process and implementation outcomes measures including:
3.1. Antenatal checks, antenatal checks with blood pressure measurement, referrals, postnatal check, measured using routinely collected data following birth and 6 weeks after birth
3.2. Acceptability/satisfaction with the intervention among girls, mentors, healthcare providers and local stakeholders, measured using routinely collected data, interviews and focus groups at 6, 9-12 months
3.3. Reach/number of participating girls when compared to the site population included, measured using routinely collected data at 9-12 months
3.4. Adoption/engagement and uptake of the mentoring scheme, measured using routinely collected data, interviews, and focus groups monthly, 6, 9-12 months
3.5. Fidelity/intervention implemented as intended i.e. number of mentors and team coordinators recruited, number of trainings and workshops, weekly 1:1 meetings, monthly social gatherings, women being accompanied by mentees to register for antenatal care, during labour and to purchase first supply of goods; number of visits from mentor to mentee's family, measured using routinely collected data, report forms, interviews, and focus groups monthly, 6, 9-12 months
4. Adolescent girls' experiences by exploring their views and perspectives on the mentoring, maternity care, thriving, economic, social progress/wellbeing, and potential mechanisms of change, measured using interviews, photovoice at 9-12 months
5. The feasibility of measuring resource use and costs benefits associated with the mentoring scheme measured using cost-consequence analysis at pregnancy, at birth, at 6 weeks, and 1 year after birth

Overall study start date
01/09/2021

Completion date
30/06/2024

Eligibility

Key inclusion criteria
Pregnant adolescent girls under 18 years old

Participant type(s)
Patient

Age group
Other

Upper age limit
18 Years

Sex

Female

Target number of participants
12 clusters

Total final enrolment
673

Key exclusion criteria
Pregnant women older than 18 years old

Date of first enrolment
04/07/2022

Date of final enrolment
30/11/2023

Locations

Countries of recruitment
Sierra Leone

Study participating centre
Moriba Town Lower Banta CHP
Moriba Town
Bonthe District
Sierra Leone
-

Study participating centre
Senehun Kamajei CHC
Senehun Town
Moyamba District
Sierra Leone
-

Study participating centre
Taiama Kori CHC
Taiama Town
Moyamba District
Sierra Leone
-

Study participating centre
Moyamba Junction CHC
Sierra Leone
-

Study participating centre
Mattru Town CHC
Bonthe District
Sierra Leone
-

Study participating centre
Madina Bum CHCs
Madina
Bonthe District
Sierra Leone
-

Study participating centre
Lengekoro CHP
Koinadugu District
Sierra Leone
-

Study participating centre
Heremakono MCHP
Koinadugu District
Sierra Leone
-

Study participating centre
Yataya CHP
Koinadugu District
Sierra Leone
-

Study participating centre
Newton CHC
Western Area

Sierra Leone
-

Study participating centre
PAYCY's Clinic
Western Area
Sierra Leone
-

Study participating centre
Calaba Town CHC
Western Area
Sierra Leone
-

Sponsor information

Organisation
King's College London

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Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) Global Health Research Group (GHRG)

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

Publication and dissemination plan
Planned publications in high-impact peer-reviewed journals and presentations at conferences and seminars.

Intention to publish date
15/02/2025

Individual participant data (IPD) sharing plan
Fully anonymised participant-level quantitative data may be available upon reasonable request and approval. Participants in the qualitative interviews and focus groups discussions are not consenting for their data to be shared publicly or be released to anyone other than the research team and regulatory bodies auditing research practice. Given the very sensitive nature of some topics and the small setting, assurances regarding participant privacy and confidentiality are crucial to meaningful data collection. For inquiries regarding or requests for the data, please contact Mrs Lucy November (lucy.november@kcl.ac.uk) or Dr Cristina Fernandez Turienzo (cristina.fernandez_turienzo@kcl.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/03/2024	26/03/2024	Yes	No
Results article	primary analysis	18/06/2025	24/06/2025	Yes	No