Community-based mentoring to reduce maternal and perinatal mortality in adolescent pregnancies in Sierra Leone (2YoungLives): a pilot cluster-randomised controlled trial

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Summary

Background Sierra Leone has very high maternal and neonatal mortality rates, and a large proportion of these deaths occur in adolescents, a particularly vulnerable group, and is usually driven by poverty, lack of education, and sparse employment opportunities. We evaluated the feasibility and potential effects of a community-based mentoring intervention from pregnancy up to 1 year after birth to inform a subsequent larger trial aiming to reduce mortality among adolescent girls and their newborns (2YoungLives).

Methods We conducted a parallel-arm, pilot, hybrid implementation–effectiveness cluster randomised controlled trial of the introduction of the 2YoungLives intervention as an adjunct to maternity care in rural and urban communities served by 12 peripheral health units in five districts of Sierra Leone. Clusters were randomly allocated 1:1. All pregnant adolescent girls aged younger than 18 years living in those cluster communities and presenting for maternity care were eligible. The primary outcome was a composite of maternal and perinatal deaths (including stillbirths and neonatal deaths), assessed in all randomly allocated participants who remained in follow-up. The trial was prospectively registered (ISRCTN32414369).

Findings Between July 4, 2022, and Nov 30, 2023, 673 girls were included in the trial; six clusters with 372 girls were allocated to 2YoungLives (intervention group; 361 included in primary analysis) and six clusters with 301 girls were allocated to the control group (279 included in primary analysis). Loss to follow-up accounted for less than 10% in both groups. The incidence of the primary composite outcome by intention to treat was significantly lower in the intervention group (23 [6%] of 361 compared with 35 [13%] of 279 in the control group [adjusted risk ratio 0·52, 95% CI 0·34 to 0·81, p=0·0034; risk difference –0·05%, 95% CI –0·10 to –0·01]). The number needed to treat with 2YoungLives to prevent one maternal or perinatal death was 18 (95% CI 10 to 92).

Interpretation 2YoungLives, a community-based mentoring intervention for adolescent girls from pregnancy up to 1 year after birth, was feasible to implement in urban and rural communities in Sierra Leone and significantly reduced a composite of maternal deaths, stillbirths and neonatal deaths.

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Introduction

Sierra Leone has one of the world's highest maternal mortality rates (MMRs) with 443 deaths per 100 000 livebirths recorded in 2020, more than double the global average.[1,2] Sub-Saharan Africa, where Sierra Leone is located, had the highest MMR among all global regions, at 545 deaths per 100 000 livebirths. In Sierra Leone, this burden falls heavily on adolescent girls (aged 10–19, as defined by WHO) who account for approximately 20–40% of all maternal deaths.[3,4] Over a third of women aged 20–24 years gave birth before age 18 years, and 10% gave birth before age 16 years. The lifetime risk of maternal death in Sierra Leone is one in 52, with evidence suggesting this risk might be even greater for adolescents.[1] Infants born to adolescent mothers also face heightened risks of illness and death.[3] More than two-thirds of maternal deaths result from haemorrhage, hypertension, and sepsis, and roughly a third are linked to unsafe abortions (particularly among adolescents).[2] Many of these deaths are preventable with the use of simple, cost-effective interventions available in Sierra Leone, but inequalities in access, availability, and quality of care persist, along with delays in care provision and escalation.[4] Reducing maternal mortality among adolescent girls is crucial to achieving the Sustainable Development Goal 3 target of reducing global maternal mortality to below 70 per 100 000 livebirths by 2030.

Poverty, lack of education, and limited employment opportunities disproportionately affect adolescent girls, and all are risk factors for adolescent pregnancy.[5] Once

Research in context

Evidence before this study

A 2015 Cochrane review found that community-based interventions improved maternal and neonatal health outcomes, particularly in low-income and middle-income countries. However, it did not include mentoring interventions, and it was unclear how many trials included adolescents. Meta-analyses of youth mentoring programmes, including community-based ones, have generally found statistically significant effects on psychological, social, educational, or development outcomes. Most of these studies were conducted in North America and Europe, rarely included pregnant adolescents, and provided insufficient data on health effects . To address this gap, we conducted a global scoping review of one-to-one community-based mentoring interventions aimed at improving the health and wellbeing of pregnant and parenting adolescent girls. We searched Embase, MEDLINE, Cochrane Central Register of Controlled Trials, CINAHL, PsycINFO, Web of Science, International Bibliography of the Social Sciences, Global Health, and grey literature sources (ie, PubMed and Google Scholar). We also manually searched reference lists, websites, reports, and clinical trial registries (ISRCTN, PROSPERO, and ANZCTR). We used the search terms "pregnancy" OR "parenting" AND "adolescent" AND "mentoring" AND "community" with the limiter "human". We only included studies of adolescents younger than 19 years with no language or publication year limitations. The final search date was July 23, 2023. We identified 13 studies conducted between 1991 and 2020, most of which were from North America and focused on Black American and Hispanic adolescents. These studies reported reductions in repeat pregnancies and risk behaviours, higher educational attainment, employment, and social support, as well as improving psychological outcomes and experiences of implementers, mentors, and adolescent mothers. Only one study, combining mentoring with home visitation, showed potential effectiveness in reducing infant mortality, low birthweight, and child maltreatment. A successful mentoring programme in Malawi, focused on young mothers living with HIV, pragmatically addressed barriers like stigma, poverty, health system complexity, and food insecurity but did not report health outcomes. No randomised controlled trials of community-based mentoring interventions for pregnant adolescents aimed at reducing maternal and perinatal mortality in low-income and middle-income countries have been identified. To our knowledge, the 2YoungLives trial in Sierra Leone is the first of its kind.

Added value of this study

Our study addresses a key gap in the current evidence around the effect of community-based mentoring interventions for pregnant and parenting adolescent girls in low-income and middle-income countries. These countries bear the highest burden of maternal and perinatal mortality and morbidity, and it is therefore essential that simple, effective and scalable innovations targeted at reducing these adverse outcomes are evaluated in environments where they are most needed. We have shown that, in line with current evidence, 2YoungLives, a community-based mentoring intervention in urban and rural areas, is feasible and significantly reduces a composite outcome of maternal and perinatal mortality.

Implications of all the available evidence

Our findings support the implementation of 2YoungLives in Sierra Leone. We have shown that in this low-income setting, 2YoungLives reduces a composite of maternal deaths, stillbirths, and neonatal deaths. Broader implementation and scale-up could substantially contribute to the reduction of maternal and neonatal mortality in this country, and potentially similar contexts worldwide.

pregnant, stigma and family abandonment present additional barriers to essential health-care access, preventing many girls from receiving adequate care before, during, and after pregnancy. For example, financial constraints can substantially delay or completely prevent access to necessary medical services, transportation, and essential medications.[6] Social complexities and high rates of child marriage (39%), adolescent pregnancy (28%), and gender-based violence (approximately 50%) also prevent adolescent girls from realising their full potential.[6,7] The majority of Sierra Leone's population is young (62·5% are younger than 25 years[8]) and improving their sexual and reproductive health remains crucial, as recognised by successive government policies. The creation of the National Secretariat for the Reduction of Teenage Pregnancy in 2013, along with the development of the first multi-agency, cross-ministry National Strategy (2013–15), was hindered by the Ebola epidemic, which also led to a sharp rise in adolescent pregnancy rates for reasons including restricted access to health-care services, loss of public trust in and use of health-care systems, and economic slowdown and loss of caregivers (which drove girls and young women to engage in transactional sex to support their households).[9] However, a revised, updated version of the strategy that included child marriage (linked to half of adolescent pregnancies) was relaunched in 2018.[10]

Efforts have primarily focused on preventing adolescent pregnancy and child marriage through basic education, life skills training, and access to quality sexual and reproductive health services. However, structural and social determinants leading to adolescent pregnancies and life-threatening risk persist. It is essential to identify interventions that support pregnant girls, prevent subsequent pregnancies, and promote positive parenting, as these are key to saving the lives of both mothers and their infants. Community awareness, enhancing youth-friendly services, and fostering collaboration among

stakeholders (including government and community actors) are also crucial to reintegrating girls into their families, communities, and educational systems. The 2022 *Lancet* Series on optimising child and adolescent health and development underscores the importance of a comprehensive approach that integrates evidence-based interventions across health, education, and social systems to protect and nurture the health and developmental potential of every child and adolescent.[11]

This type of holistic approach guided the development of 2YoungLives, a community-based mentoring programme for adolescents in Sierra Leone. Created in 2017 by the grass-roots organisation Lifeline Nehemiah Projects (LNP), the programme was developed in partnership with girls and community stakeholders to provide support from pregnancy to 1 year after birth. A post-Ebola household survey found a maternal death rate of one in ten among those aged younger than 18 years in eastern Freetown, and a subsequent qualitative study identified contributing factors such as stigma and abandonment by families, insufficient adult support, and delayed care-seeking.[12] One of the potential interventions identified was a mentoring scheme for the most vulnerable pregnant girls.[12] The mentoring scheme takes the very simple but intuitive idea that relationships are protective and that increased social capital leads to better health and wellbeing, a concept of surviving and thriving outlined by *The Global Strategy for Women's, Children's and Adolescents' Health (2016–2030)*.[13]

From 2017 to 2020, 2YoungLives was piloted in five sites with promising results. More than 250 girls were mentored with no maternal deaths and few perinatal deaths. Girls reported close strong relationships with mentors and a sense of wellbeing; all ran a small business to enable them to eat well in pregnancy and save money for their birth; and many returned to live with their families. Some returned to school and others completed vocational training and gained employment.[14] A theory of change was co-developed and relationship building, engagement and advocacy, educational, social and economic empowerment, and respectful community engagement and involvement were important mechanisms of action to consider.[15] However, a more robust and formal assessment was needed to understand how 2YoungLives could be replicated in other communities and how it could address determinants of adolescent maternal and perinatal mortality. The aim of this study was therefore to assess the feasibility of implementing 2YoungLives in new communities to inform procedures for a subsequent fully powered cluster trial evaluating the effectiveness, implementation, and cost-effectiveness of 2YoungLives in Sierra Leone.

Methods

Study design and participants

The 2YoungLives trial was a parallel-arm, cluster-randomised controlled pilot hybrid (effectiveness–implementation) trial of the introduction of the 2YoungLives intervention as an adjunct to maternity care in rural and urban communities served by 12 peripheral health units (clusters) in five districts of Sierra Leone. The trial structure was based on recommended guidelines for developing and evaluating complex interventions[16] and conducting hybrid type 2 effectiveness–implementation research that aims to place similar focus on assessing the effect of an intervention and understanding how best to implement it.[17] We have previously reported details for the study rationale, trial design, and methods and there were no substantial changes in this study.[15] We have also reported the results of the qualitative research that identified barriers and potential solutions to reduce maternal adolescent mortality, which were the basis for the development of the 2YoungLives intervention.[12]

The selection of clusters was informed by adolescent pregnancy rates and advice from community and regional leads to ensure they had not been previously exposed to 2YoungLives and were geographically separated to reduce contamination bias between clusters (ie, participants from the control clusters seeking care in intervention clusters). The clusters represent government peripheral health units and the named and demarked communities they serve. All pregnant adolescent girls younger than 18 years living in those cluster communities and presenting for maternity care were eligible. Data were collected on routinely collected clinical variables in medical records and official registers (ie, maternal and delivery register, referrals register, and outreach register). In intervention clusters, pregnant adolescents could also self-refer or be referred by a friend or family member who heard about 2YoungLives from community engagement activities. There were no exclusion criteria other than age.

The study protocol specified a waiver of individual written consent for data collected on girls, as the consent process for the clinic level patient data are done as part of standard clinic processes and not as a separate standalone event.[15] Several measures were implemented to protect the rights of participants: data were anonymised or de-identified ensuring that no personal identifiers were linked to the data; access to the data was limited; participants were informed about the study through engagement activities, public notices, or consent forms for linked trial studies, providing the girls with an opportunity to raise any concerns; and approval was obtained from ethics boards, community leaders, and local and regional management teams at health facilities and referral hospitals (gatekeepers). Before study initiation, the trial was registered (ISRCTN32414369) and approved by the ethics committee at King's College London, London, UK (HR/DP-21/22–26320) and the Office of the Sierra Leone Ethics and Scientific Review Committee. Reporting in this publication is consistent with the CONSORT statement for cluster trials.[18] An international advisory group and trial committee oversaw all activities of the different workstreams of a global

health research group (including the 2YoungLives trial). There was a prespecified data analysis plan but no data monitoring committee nor interim analysis, however a risk register was developed to assess the effect and likelihood of specific risks for the programme and partnership.

Community engagement

Meaningful community and stakeholder engagement and involvement has been crucial to embracing challenges as opportunities for trial success. In a very remote cluster, parents hesitated to support the intervention due to previous unmet promises from non-governmental organisations. The LNP implementing team addressed this by bringing key stakeholders from this cluster to Freetown to witness former mentored girls working as plumbers or electricians and supporting their families, which led to the stakeholders subsequently encouraging participation. Three clusters had initially low recruitment, prompting the local research teams and investigators to further investigate. Discussions were held with local community members and stakeholders, health-care providers, and other non-governmental organisations to understand why fewer adolescent girls were attending antenatal care compared with previous years and similar sites. Proposed explanations included successful contraception programmes (not indicated by facility-level data), a preference for a new clinic in the same community that provided more respectful care, over-reporting of age due to stigma and fear of punitive policies for underage pregnancies, or avoiding care at facilities for similar reasons. In the intervention group, the LNP implementing team engaged with community leaders and health-care providers to understand and alleviate these concerns, rebuilding trust and ensuring access to maternity care for the girls. To understand how many eligible girls had not been included for any of these reasons, community-based surveys were conducted. These surveys were part of a separate retrospective study that involved a different data collection process from the trial. Local trained community women in both intervention and control sites identified all girls under 18 who delivered during the trial period and collected anonymous data on real age, identified age, and reported age when accessing care (including reasons for discrepancies), facility, and primary outcome data.

Randomisation and masking

Before trial commencement, a computer-generated central randomisation and data management system (Medscinet) was used for allocating clusters (1:1) to either the intervention group (usual care plus 2YoungLives) or control group (usual care alone). The clusters were masked to the investigators and study teams and only revealed by the statistician 2 weeks before the implementation start date to give sufficient time for organising community engagement activities in the intervention group, leading to recruitment and training of mentors and team coordinators and enrolment of girls into 2YoungLives. A minimisation algorithm was used to ensure balance between groups regarding cluster size and distance to the referral hospital. Once the cluster had commenced the intervention, masking of girls, health-care providers, and local investigators was not possible.

Procedures

The 2YoungLives intervention included a multifaceted community-based mentoring scheme as an adjunct to usual maternity care.[15] The intervention comprised four core components: community engagement and involvement; recruitment, training, and supervision of mentors; mentor–mentee matching; and mentoring and additional activities. LNP devised a three-visit community engagement and involvement strategy to ensure the intervention's acceptance and tailoring to local contexts, engaging those who could provide diverse perspectives.[19] Building trusting relationships through listening, discussing, and connecting with communities was crucial, with additional community engagement and involvement visits made as needed. Women passionate about supporting vulnerable girls were recruited as mentors based on their experience, community knowledge, commitment, kindness, and trustworthiness, in collaboration with community stakeholders. Each cluster had a team of four mentors and one coordinator who was recruited to support mentors and communicate with the central LNP team. All mentors and coordinators received a 4-day manualised training programme covering basic maternal, newborn, and infant health, and topics such as confidentiality, safeguarding, and good communication. Ongoing support and supervision were provided by local coordinators and the central LNP management team. Mentors and coordinators, who were volunteers, received a monthly stipend for expenses. Eligible adolescent girls were enrolled as they came forward to a maximum of 36 (three to four girls per mentor) girls per cluster. This process helped us to assess the feasibility of the intervention in a pragmatic way while avoiding selection bias. Girls could join at any stage of pregnancy and received mentoring for 1 year after birth regardless of their pregnancy outcome. The coordinator matched mentors and girls based on geographical proximity and shared language.

2YoungLives activities included at least weekly face-to-face meetings between mentors and mentees for comfortable and confidential conversations; promoting health services uptake (eg, supporting mentees to register at a government health facility, and inviting midwives to monthly meetings to break down barriers to attendance); reminding mentees to attend or attending with them for antenatal care; accompanying mentees to health facilities during labour or for emergency care (or ensuring another birth partner was available) and advocating for skilled birth attendants; visits from mentors to mentees' families to advocate for family support if appropriate; flexible

support for pregnancy and parenthood depending on the mentee's network; discussing small business options with mentees and accompanying them to purchase initial supplies; encouraging and subsidising return to school or vocational training; practical sessions on making healthy baby food; promoting postpartum contraception; and emphasising the importance of early health-seeking behaviour for their babies. Monthly site meetings with all mentors and mentees provided peer support, cooking, eating, and group discussions. Visitors such as health-care providers, teachers, and community members attended to discuss health topics and educational opportunities.

The intervention and control groups received usual maternity care, following local and national guidelines for Sierra Leone,[20,21] based on the 2016 WHO antenatal model.[22] This model recommends a minimum of eight antenatal contacts to provide quality, respectful, person-centred care. The National Reproductive, Maternal, Newborn, Child, and Adolescent Health Strategy outlines interventions for positive pregnancy and prioritises skilled birth attendance and essential newborn care within emergency obstetric and newborn care.[20]

Outcomes

Baseline characteristics of the study population included maternal age, sickle cell disease, Ebola survivor status, disability, parity, multiple pregnancy, and blood pressure measurements. The primary outcome was a composite of maternal and perinatal mortality including maternal death (all-cause, occurring during pregnancy, labour, or within 42 days of birth), stillbirth (born with no signs of life at or after 28 weeks of pregnancy, but before or during birth), and neonatal death (deaths among livebirths during the first 28 days). We report the effect of 2YoungLives on both the composite and its components for all girls in the study—those who experienced any one of the components were considered to have experienced the composite outcome.

Secondary maternal outcomes included post-abortion care, mode of delivery (vaginal births, assisted vaginal births, caesarean sections, or vaginal breech), term and preterm births, births attended by health-care workers (skilled health professionals, unskilled health professionals, traditional birth attendants, or unattended), place of birth (community, peripheral health unit, or hospital) and complications (malaria, obstetric fistula, hypertension, pre-eclampsia or eclampsia, haemorrhage, fever, anaemia, or hysterectomy). Secondary neonatal outcomes included: Apgar score greater than 7 at 5 min, birthweight, resuscitation, immediate breastfeeding, kangaroo mother care, and admission to neonatal intensive care unit. Additional secondary and process of care outcomes included timing and quality of first antenatal visit (under 12 weeks' gestation, provision of long-lasting insecticidal net, HIV and syphilis testing), total number of antenatal checks (including those with blood pressure measurement), intermittent preventive treatment of malaria in pregnancy, tetanus–diphtheria vaccinations, delivery monitored with partograph, uterotonic prophylactic given immediately after delivery, maternal referrals in pregnancy and childbirth (for obstetric fistula, fever, haemorrhage, hypertensive disorders, and others), neonatal referrals, postnatal checks, 6 weeks postnatal contraception and immunisation uptake, infant immunisation at 6 weeks, and 1 year infant mortality. All major pregnancy complications were included as outcomes and no additional adverse event reporting was conducted.

Statistical analysis

This pilot study was planned primarily to show the feasibility of a larger trial and to help with planning it. In anticipation of the possibility of a positive finding, we did perform a power calculation, based on optimistic assumptions about the treatment effect, and the effect of clustering on the standard error. We assumed at least 42 deliveries per site, with 20% of pregnant adolescents experiencing a primary adverse outcome (maternal death or perinatal death which included stillbirth or neonatal death) during the trial duration and based on preliminary visits to similar communities. These numbers would provide 84% power to detect a 55% relative risk reduction of the primary outcome (from 20% to 9%) assuming a modest intracluster correlation of 0·02 based on previous experiences in the region.[23]

We conducted two main statistical analyses. The intention-to-treat analysis aimed to compare outcomes in intervention and control clusters that included all girls (as originally allocated after randomisation, including withdrawals and losses to follow-up), and the per-protocol analysis to compare outcomes in intervention and control clusters including only those girls who were assigned a mentor and received the intervention originally allocated. The main intention-to-treat analysis included logistic regression adjusting the standard errors for clustering (equal weight to each girl) and then a secondary analysis using random effects generalised least squares regression. Adjustments were done for important baseline characteristics (ie, maternal age and abnormal blood pressure at first visit, where measured). Multiple regression was used to correct for potential bias due to missing data, with an appropriate dummy variable to represent missingness of covariates (if applicable), a valid approach for baseline covariates in randomised trials. The handling of missing covariates has been investigated in some detail[24,25]; in our experience, multiple regression methods (as used here) involve the same assumptions as multiple imputation, make essentially the same corrections for potential bias, and give very similar answers and coverage. It was not possible to mask clusters to the received intervention, but outcome assessments were masked to researchers analysing the data.

Role of the funding source
The funder had no role in the study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between July 4, 2022, and Nov 30, 2023, 673 girls were included across the 12 study clusters in Sierra Leone (figure). Six clusters (372 girls) were randomised to the intervention group and six clusters (301 girls) to the control group. The total number of girls per cluster differed between the intervention group (range 37–87) and the control group (18–72). Community engagement and involvement activities, as well as the recruitment and training of mentors and coordinators in intervention clusters, occurred after allocation and before enrolment of girls (April 4, to June 30, 2022). The intervention was implemented in these clusters at the scheduled time, with no substantive adaptations, and all approached girls consented to be enrolled in 2YoungLives. Outcome data collection continued until May 5, 2024. For the intention-to-treat analysis, we included data from 673 girls (372 intervention, 301 control; of which 361 [intervention] and 279 [control] had primary outcome data) and 675 babies (374 intervention, 301 control; of which 351 and 262 had primary outcome data). Withdrawals and losses to follow-up accounted for less than 10% in both groups. 18 girls did not complete the whole year mentoring, with relocation to another community being the main reason. For the per-protocol analysis of the primary outcome, we included data from 479 girls (200 intervention, 279 control).

Although there were more girls in the intervention group than the control group, the characteristics of girls were similar (table 1). Mean maternal age was 16·4 years. 13 (4%) girls in the intervention group and six (2%) girls in the control group were aged 14 years or younger. Most girls were not Ebola survivors, did not have sickle cell disease, had no previous births, and carried a singleton pregnancy. The intervention group had higher proportions of girls with known learning and physical disabilities (eight [2%] of 360 *vs* one [<1%] of 275). The characteristics of girls by cluster and district and those included in the per-protocol analysis are presented in the appendix (pp 1–3). There were no missing data in the covariates used for adjustment of the treatment effect.

Table 2 reports the intervention effect on the primary composite outcome and individual components of maternal and perinatal mortality (including causes, when reported, in the appendix [p 4]). The incidence of the primary composite outcome was lower in the intervention group (23 [6%] of 361 girls) than the control group (35 [13%] of 279 girls; aRR [adjusted risk ratio] 0·52, 95% CI 0·34 to 0·81; risk difference –0·05%, 95% CI –0·10 to –0·01). The number needed to treat with 2YoungLives to prevent one maternal or perinatal death was 18 (95% CI 10 to 92). The per-protocol analysis produced similar findings, with a greater risk reduction (aRR 0·46, 0·24 to 0·89; risk difference –0·06%, –0·11 to –0·15) and the number needed to treat being 15 (95% CI 9 to 65). The difference in the primary composite outcome was principally related to a lower incidence in the perinatal composite outcome (stillbirth and neonatal death) in the intervention

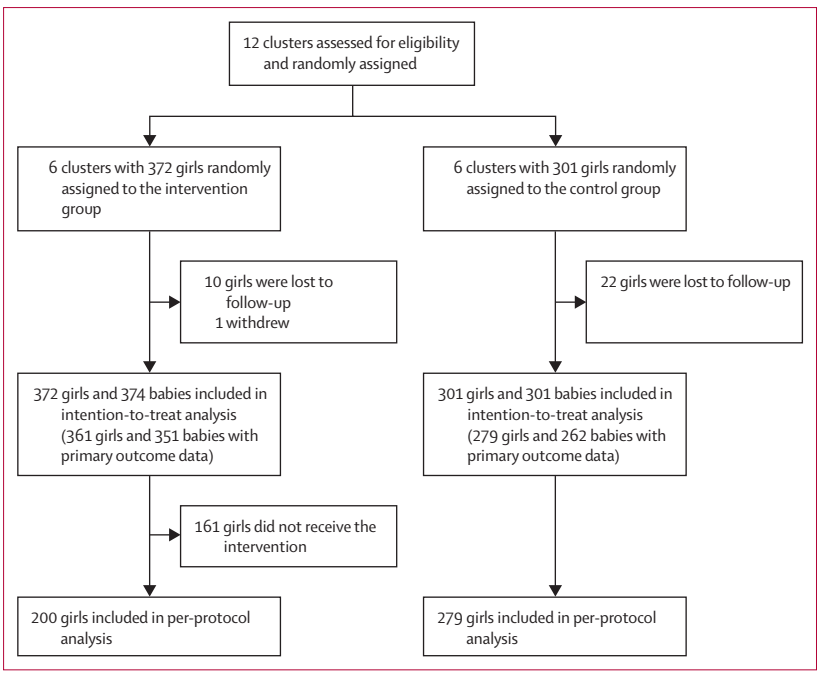

Figure: **Trial profile**

	Intervention group (k=6; n=361)	Control group (k=6; n=279)
Mean maternal age, years; range	16·26 (0·84); 13–17	16·52 (0·76); 12–17
Girls aged 15–17 years	348 (96%)	273 (98%)
Girls aged ≤14 years	13 (4%)	6 (2%)
Sickle cell disease	3/360 (1%)	0/275
Ebola survivor	1/359 (<1%)	0/275
Disability	8/360 (2%)	1/275 (<1%)
Had no previous births	328/360 (91%)	264/276 (96%)
Multiple pregnancy	7/357 (2%)	2/274 (1%)
Blood pressure at first antenatal visit		
Data available	345/361	266/279
Mean systolic blood pressure	106·28 (12·43)	107·15 (10·73)
Mean diastolic blood pressure	65·08 (9·39)	66·65 (8·59)
Abnormal blood pressure	6/345 (2%)	2/266 (1%)

Data are mean (SD) or n (%). n/N indicates that the denominator only includes participants with a relevant measurement for that variable. k=cluster.

Table 1: **Baseline characteristics**

See Online for appendix

	Intervention group (6; n=361)	Control group (k=6; n=279)	Risk ratio* (95% CI)	Risk difference (95% CI)	p value
Intention to treat					
Primary composite outcome	23/361 (6%)	35/279 (13%)	0·52 (0·34–0·81)	..	0·0034
Maternal death†	0/361	1/279 (<1%)	..	..	..
Perinatal death	23/361 (6%)	35/279 (13%)	0·52 (0·34–0·81)	..	0·0034
Stillbirth	12/361 (3%)	17/279 (6%)	0·58 (0·21–1·56)	..	0·29
Antepartum stillbirth	5/361 (1%)	9/279 (3%)	0·41 (0·08–1·93)	..	0·26
Intrapartum stillbirth	7/361 (2%)	8/279 (3%)	0·79 (0·31–2·02)	..	0·63
Neonatal death	11/361 (3%)	18/279 (6%)	0·47 (0·21–1·04)	..	0·064
Early neonatal death	8/361 (2%)	13/279 (5%)	0·49 (0·21–1·13)	..	0·097
Late neonatal death	3/361 (1%)	5/279 (2%)	0·44 (0·10–1·89)	..	0·27
Per protocol					
Primary composite outcome	11/200 (6%)	35/279 (13%)	0·46 (0·24–0·89)	..	0·022
Maternal death†	0/200	1/279 (<1%)	..	..	..
Perinatal death	11/200 (6%)	35/279 (13%)	0·46 (0·24–0·89)	..	0·024
Stillbirth	3/200 (2%)	17/279 (6%)	0·24 (0·09–0·65)	..	0·0044
Antepartum stillbirth	1/200 (1%)	9/279 (3%)	0·13 (0·01–1·08)	..	0·059
Intrapartum stillbirth	2/200 (1%)	8/279 (3%)	0·42 (0·10–1·68)	..	0·22
Neonatal death	8/200 (4%)	18/279 (6%)	0·65 (0·29–1·44)	..	0·30
Early neonatal death	6/200 (3%)	13/279 (5%)	0·67 (0·31–1·46)	..	0·32
Late neonatal death	2/200 (1%)	5/279 (2%)	0·61 (0·09–3·84)	..	0·61
Primary composite outcome					
Intention to treat	23/361 (6%)	35/279 (13%)	..	−0·05 (−0·10 to −0·01)	0·015
Per protocol	11/200 (6%)	35/279 (13%)	..	−0·06 (−0·11 to −0·15)	0·011

Data are n/N (%), unless otherwise stated. n/N (%) indicates that the denominator only includes participants with a relevant measurement for that variable. k=number of clusters. *Analysis adjusted for maternal age and abnormal blood pressure at first visit (where measured). †One girl in the control group had both a maternal and a perinatal death, so the figures for the primary composite are identical to those for the perinatal deaths.

Table 2: **Primary composite outcome and its components**

group (23 [6%]) compared with the control group (35 [13%]; aRR 0·52, 0·34 to 0·81) as there was only one maternal death.

Prespecified analysis of the individual components of the primary composite outcome found lower event rates in the intervention group but did not show a statistically significant difference in the proportion of maternal deaths (none in the intervention group *vs* one [<1%] in the control group), stillbirths (12 [3%] of 361 *vs* 17 [6%] of 279; aRR 0·58, 95% CI 0·21–1·56), or neonatal deaths (11 [3%] of 361 *vs* 18 [6%] of 279; 0·47, 0·21–1·04). However, per-protocol analysis of the individual components of the primary composite did find a significant difference in the proportion of stillbirths (three [2%] of 200 and 17 [6%] of 279; 0·24, 0·09–0·65), particularly driven by antenatal stillbirths. The estimated intracluster correlation for the primary outcome was 0·015.

Maternal secondary outcomes show that, in both the intervention and control groups, the proportion of girls who had post-abortion care (seven [2%] of 358 *vs* four [1%] of 277), spontaneous vaginal births (316 [92%] of 345 *vs* 248 [93%] of 266), and caesarean sections (20 [6%] of 345 *vs* nine [3%] of 266) were similar (table 3). The mean gestational weeks at delivery was similar among intervention and control groups (37·31 [SD 2·11] *vs* 37·53 [1·71]) as were the number of preterm births (97 [29%] of 332 *vs* 83 [32%] of 261). There was a significant increase in births attended by skilled health professionals for girls allocated to the intervention group compared with the control group (254 [73%] of 346 *vs* 109 [41%] of 266; aRR 1·80, 95% CI 1·11–2·92). The proportion of complications was similar in the intervention and control groups for malaria, obstetric fistula, pre-eclampsia or eclampsia, haemorrhage, fever, and anaemia.

Additional neonatal outcomes are presented in table 4. There were no statistically significant differences in the proportion of babies having an Apgar score greater than 7 at 5 min (11 [4%] of 295 and eight [4%] of 224; aRR 0·96, 95% CI 0·35 to 2·64), requiring resuscitation (119 [37%] of 317 *vs* 71 [29%] of 242; 1·23, 0·29 to 5·18), breastfeeding within 1 h of birth (307 [97%] of 316 *vs* 236 [97%] of 243; 1·00, 0·96 to 1·03), having a low birthweight (33 [11%] of 293 *vs* 10 [5%] of 220; 2·61, 0·85 to 8·06), initiating kangaroo mother care (248 [78%] of 318 *vs* 203 [83%] of 247; 0·93, 0·72 to 1·20), or being admitted into the neonatal care unit (six [2%] of 320 *vs* four [2%] of 243). Newborns in the intervention group were significantly more likely to weigh less than those in the control group (risk difference −155·3, −214·57 to −96·04). Additional and process of care outcomes (appendix pp 6–7) showed a higher proportion of girls in the intervention group who attended for antenatal care at less than 12 weeks' gestation (including those being tested for HIV); had referrals for pregnancy complications; had two or three postnatal visits; and started contraception at 6 weeks. See appendix (pp 9–13) for results for the intention-to-treat population that contains all girls in randomised clusters (including those who withdrew or were lost to follow-up).

The community-based surveys found a total of 250 additional girls (104 in intervention clusters and 146 in control clusters) who would have been eligible for the trial but who either over-reported their age at included facilities, received antenatal care in other communities, or did not receive any care at all. Sadly, 72 (29%) of them

had at least one component of the primary outcome. Surveys in intervention and control clusters found four unrecorded maternal deaths (one *vs* three), 36 stillbirths (17 *vs* 19), and 44 neonatal deaths (seven *vs* 37). Although surveys were retrospective, trial results were found to be similar when those girls identified in the survey according to the area where they lived were included in the analysis (appendix p 8). More than two-thirds of the surveyed girls over-reported their age when accessing care, with a trend of younger girls reporting higher ages (ie, girls aged 14 years reporting themselves to be aged 22–23 years, compared with girls aged 17 years reporting themselves to be aged 18–19 years). The main factors that appear to contribute to misreporting of age include the policy landscape around gender-based issues (ie, stigma, fear of law enforcement, and imprisonment of boys), how age is calculated, and how age is recorded by clinic and hospital staff.

Discussion

In this cluster-randomised controlled pilot trial of 2YoungLives, a community-based mentoring intervention versus standard care for pregnant adolescents in Sierra Leone, we showed that 2YoungLives was feasible to implement in urban and rural communities and significantly reduced the combined rate of maternal and perinatal deaths, primarily driven by a significant reduction in perinatal mortality. This reduction in perinatal mortality is particularly noteworthy as it shows the potential of community-based interventions, like 2YoungLives, to address deep-rooted disparities and improve outcomes for pregnant adolescents and their newborns in Sierra Leone, even where access to health care and health-care infrastructure remain inadequate. When outcomes of all girls who received the intervention were assessed (per-protocol analysis), a similar reduction was found in the composite outcome, with a significant reduction in stillbirths. 2YoungLives resulted in significantly more deliveries attended by skilled birth attendants and a reduction in mean birthweight with no significant differences in caesarean sections, Apgar scores, need for resuscitation, preterm birth, low birthweight, or admission to neonatal care units among other secondary outcomes. Care processes such as referrals, postnatal visits, and contraception were increased in the intervention group despite no significant differences compared with the control group. Overall, all primary and many secondary treatment effects were in the direction favouring 2YoungLives, with no indication of harm to the pregnant adolescent or the newborn. The retrospective community-based surveys conducted alongside the trial underscore significant barriers to health-care access and poor outcomes experienced by adolescent girls in Sierra Leone.

We hypothesised that 2YoungLives could save lives and improve the health and wellbeing of pregnant adolescents and their babies while simultaneously enhancing livelihoods through relationship building, access and engagement with maternity services, advocacy with families and health workers, empowerment (health,

	Intervention group (k=6; n=361)	Control group (k=6; n=279)	Effect measure* (95% CI)	p value
Post-abortion care†	7/358 (2%)	4/277 (1%)	..	..
Misoprostol	3/7 (60%)	4/4 (100%)	..	..
Combination mifepristone and misoprostol	1/7 (20%)	0	..	..
Manual vacuum aspiration	0	0	..	..
Dilation and curettage	1/7 (20%)	0	..	..
Mode of delivery				
Spontaneous vaginal birth	316/345 (92%)	248/266 (93%)	..	..
Assisted vaginal birth	1/345 (<1%)	3/266 (1%)	..	..
Caesarean birth	20/345 (6%)	9/266 (3%)	aRR 1·67 (0·88 to 3·18)	0·11
Vaginal breech	8/345 (2%)	6/266 (2%)	..	
Mean gestation at delivery, weeks	332; 37·31 (2·11)	261; 37·53 (1·71)	MD −0·21 (−0·76 to 0·34)	0·41
Term birth, 37–42 weeks	235/332 (71%)	178/261 (68%)	aRR 1·01 (0·86 to 1·18)	0·84
Preterm birth, <37 weeks	97/332 (29%)	83/261 (32%)	aRR 0·94 (0·65 to 1·37)	0·78
Delivered by				
Skilled birth attendants‡	254/346 (73%)	109/266 (41%)	aRR 1·80 (1·11 to 2·92)	0·016
Unskilled birth attendants‡	70/346 (20%)	132/266 (50%)	aRR 0·40 (1·14 to 1·09)	0·074
Traditional birth attendants and others	22/346 (6%)	24/266 (9%)	..	..
Unattended	0/346	1/266 (<1%)	..	..
Place of delivery				
Community	21/346 (6%)	26/267 (10%)	..	..
Peripheral health unit	239/346 (69%)	192/267 (72%)	aRR 0·97 (0·72 to 1·30)	0·85
Hospital	86/346 (25%)	49/267 (18%)	aRR 1·36 (0·52 to 3·52)	0·52
Complications				
Malaria	81/337 (24%)	54/262 (21%)	aRR 1·21 (0·61 to 2·42)	0·57
Obstetric fistula	0/337	1/265 (<1%)	..	..
Hypertension	8/337 (2%)	5/263 (<1%)	..	..
Pre-eclampsia or eclampsia	8/341 (2%)	2/262 (<1%)	..	..
Haemorrhage	2/337 (1%)	2/262 (<1%)	..	..
Fever	79/337 (23%)	54/262 (21%)	aRR 1·21 (0·58 to 2·51)	0·61
Anaemia	38/337 (11%)	20/262 (8%)	aRR 1·71 (0·31 to 9·51)	0·53
Hysterectomy	0/341	0/265	..	..

Data are n (%) or mean (SD). n/N (%) indicates that the denominator only includes participants with a relevant measurement for that variable. aRR=adjusted risk ratios. k=cluster. MD=mean difference. *Risk ratios adjusted for maternal age and abnormal blood pressure at first visit (where measured). †Details of post-abortion care missing for two girls in the intervention group. ‡Skilled birth attendants included doctors, midwives, surgical assisting community health officers, state enrolled community health nurse-midwives; and unskilled birth attendants included community health officers, community health assistants, state enrolled community health nurses and maternal and child health aides.

Table 3: **Maternal secondary outcomes**

	Intervention (k=6; n=351)	Control (k=6; n=262)	Effect measure* (95% CI)	p value
Apgar score >7 at 5 min	11/295 (4%)	8/224 (4%)	aRR 0·96 (0·35 to 2·64)	0·95
Resuscitation	119/317 (37%)	71/242 (29%)	aRR 1·23 (0·29 to 5·18)	0·77
Weighed within 24 h of birth	293/351 (83%)	220/262 (84%)	aRR 0·99 (0·92 to 1·07)	0·87
Mean baby weight (g)	2895·90 (468·37)	3048·34 (386·23)	MD −155·3 (−214·57 to −96·04)	<0·001
Low birthweight (<2500 g)	33/293 (11%)	10/220 (5%)	aRR 2·61 (0·85 to 8·06)	0·093
Breastfed within 1 h of birth	307/316 (97%)	236/243 (97%)	aRR 1·00 (0·96 to 1·03)	0·87
Initiation of kangaroo mother care	248/318 (78%)	203/247 (83%)	aRR 0·93 (0·72 to 1·20)	0·60
Baby admitted to the NICU	6/320 (2%)	4/243 (2%)	..	..
Prematurity	4/6 (67%)	1/4 (25%)	..	..
Low birthweight	1/6 (17%)	0	..	..
Respiratory distress	1/6 (17%)	3/4 (75%)	..	..
Congenital abnormalities	0	0	..	..
Other	0	0	..	..

Data are n (%). n/N (%) indicates that the denominator only includes participants with a relevant measurement for that variable. All counts are of live babies, not mothers. aRR=adjusted risk ratios. k=cluster. MD=mean difference. NICU=neonatal intensive care unit. *Risk ratios adjusted for maternal age and abnormal blood pressure at first visit (where measured).

Table 4: **Neonatal secondary outcomes**

social, and economic) and respectful community engagement.[17] It is likely that mentors' health knowledge and support during the first and subsequent antenatal visits, and advocacy for early access to care, escalation, and referral when pregnancy and childbirth complications arose are important mechanisms in the reduction of maternal and perinatal mortality. Mentors ensured girls accessed care when needed, sometimes paying for routine treatments when not available in the clinic. Girls' empowerment and mentors' emotional and practical support and companionship during antenatal visits and birth could also have influenced the behaviour of doctors, midwives, and other health-care providers, in turn affecting the quality of antenatal and intrapartum care provided (including delivery by a skilled birth attendant), all of which have been found to prevent most stillbirths.[26] Continuous support and companionship in labour and childbirth have been shown to improve pregnancy outcomes and are included in WHO guidelines and standards for improving the quality of maternal and newborn care in health facilities.[27,28] Getting to know the health-care provider in their own adolescent-friendly space, and through facilitated discussions as part of the 2YoungLives monthly meetings, could also have improved girls' confidence and involvement in the health service, increasing their likelihood of taking up antenatal care and seeking care in labour or in an emergency. Improvement in health-care providers' knowledge and attitudes towards adolescent pregnancy could also have potentially increased the availability of adolescent-friendly and respectful care.[29] Similarly, having a trustworthy adult in their lives might have allowed girls to ask advice of mentors and access care promptly, and the small businesses they set up during pregnancy for economic empowerment could have also allowed girls to make independent decisions about when to go to hospital as they could pay for their own transport.[30] In some clusters, community members also supported girls to be transferred to the hospital and, with the support of the LNP team, arranged for replacement blood donations as needed. There are many examples of large-scale mindset changes within communities because of the high priority placed on community engagement and involvement in 2YoungLives.

For example, in one community, historical mistrust between traditional birth attendants and facility staff meant that many women were giving birth at home without a skilled birth attendant. The LNP team brokered and facilitated a meeting bringing all parties and community leaders together, allowing for a new mutual understanding. Exposed to the scale of the problem, the community leaders called a further meeting in the absence of the LNP team, during which the community put in place a series of new by-laws to mitigate this problem. These efforts led to traditional birth attendants and health workers working cooperatively, and an uptake of skilled care in the facility.[19] In addition, in various sites, mentors took on the informal role of advocating for any pregnant girls in the peripheral health units, meaning that quality of care might have been improved for all, for example through reducing delays in assessment and referral. This effort went further in some sites where team coordinators hosted open door adolescent antenatal care in their homes, giving girls the option of accessing care in a familiar women-only space within the safety of a peer group. These endeavours might be potential mechanisms by which community engagement and involvement could be affecting the primary outcome.

The lower number of neonatal deaths in intervention sites might be explained by the higher numbers of postnatal visits and neonatal referrals but also mentors' emotional and practical support, knowledge, and promotion of basic newborn health and positive parenting practices (ie, skin-to-skin contact; early and exclusive breastfeeding; assessment of danger signs like poor feeding, fever, or convulsions, and the need to seek prompt medical care; and immunisations), which are all crucial to prevent neonatal mortality.[31] Although newborns in the intervention group weighed slightly less than those in the control group, this finding likely reflects the lower incidence of perinatal deaths in the intervention group (as stillbirths were not consistently weighed), or more low birthweight and preterm babies surviving.

Based on our literature search, this is the first trial of its kind to be published about safely implementing and evaluating an innovative, simple, and locally developed community-based mentoring intervention for pregnant

and parenting adolescents in low-income and middle-income countries. The potential effects of the intervention are strengthened by its relevance to settings where the burden of maternal and perinatal mortality is highest, making it potentially generalisable to similar contexts in sub-Saharan Africa. Our trial sites encompassed suburban and rural communities, with a network of peripheral health units and tertiary hospitals serving a diverse urban and rural population in line with national referral pathways. As such, our findings are likely to be generalisable to all adolescents in Sierra Leone and similar contexts. The low rate of loss to follow-up and minimal missing data due to successful co-developed data collection strategies (ie, close liaison with community health workers and outreach teams) combined with rigorous oversight by the in-country implementation and research teams, adds to the confidence in the quality and completeness of our data.

Limitations of this study include the limited power as this trial was intended as a pilot but given the possible treatment effect showed potential efficacy in the primary outcome. The group allocation for girls, mentors, and health-care providers was unmasked, however study assignment was masked to the statistician and the researchers who analysed the data. Because of the large number of secondary outcomes that have been analysed, it is possible some of the significant results are false positives and these should be tested further in future studies. The per-protocol analysis could suggest a causal treatment effect, as it focuses on girls who received the intervention; however, this interpretation depends on the assumption that these girls are representative of the broader population. Given the country-specific needs assessment informed the development of 2YoungLives, such approaches would need to be considered to tailor the intervention in different settings with strong community engagement expertise. A mixed methods process implementation evaluation was undertaken in parallel to this trial to measure implementation determinants and outcomes (acceptability, fidelity, reach, and adoption), explore experiences and mechanisms of effect, and contextualise findings and will be reported elsewhere. This evaluation will provide a more comprehensive understanding of the broader effects of 2YoungLives on girls' empowerment such as the small business start-ups and the educational bursaries.

Our study has produced useful data on the feasibility of recruitment and data collection, treatment effects, barriers and facilitators, and key strategies for implementation success (such as the importance of culturally intelligent community engagement and involvement which allows nuanced understandings of each unique community and how it operates). Policy makers might argue that the next pragmatic and ethical step should be to scale up across different districts and save the lives of more pregnant adolescents and babies in Sierra Leone. Scientists, however, might interpret these results with caution and recommend capitalising on learning from this pilot study, refining the pilot trial protocols, and conducting a large confirmatory trial to evaluate the effectiveness, implementation, and cost-effectiveness of 2YoungLives, and to confirm generalisability before scaling up. Future research should also evaluate the longer-term effects of 2YoungLives on girls, their children, mentors, and their communities.

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Data sharing
The dataset will be available to appropriate academic parties on request from the co-Chief Investigators (CFT and LN) in accordance with the data sharing policies of King's College London, with input from the co-investigator group where applicable.

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