A community-based landmark trial to save the lives of pregnant adolescents and their newborns in sub-Saharan Africa

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Sub-Saharan Africa has the highest maternal mortality rate in the world, estimated in 2020 to be 545 maternal deaths per 100 000 livebirths, more than 136 times higher than that of the lowest region.[1] In Sierra Leone, adolescent girls (aged 10–19 years) account for up to 40% of all maternal deaths, nearly all of which are preventable.[2,3] Efforts to prevent adolescent pregnancies have had limited success, and comprehensive approaches to optimising child and adolescent health are badly needed.[4]

The 2YoungLives trial[5] in Sierra Leone, a study by Cristina Fernandez Turienzo and colleagues in the *Lancet*, grew out of a community-based mentoring programme for pregnant adolescents, created in partnership with the grass-roots organisation Lifeline Nehemiah Projects. Mentors were volunteers who received training and ongoing support from local coordinators. The theory of change underlying the trial was based on the importance of strong social relationships, community engagement, and empowerment (health, social, and economic) of girls, and advocacy with family and health workers.

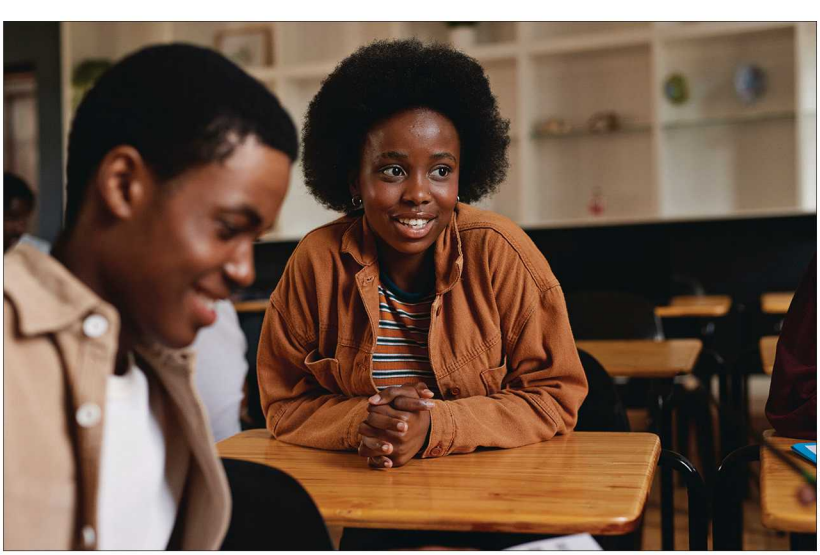
The 2YoungLives trial was a parallel-arm, cluster randomised controlled pilot hybrid trial with the dual foci of evaluating the effects of the intervention and understanding how best to implement it. The primary outcome was a composite of maternal and perinatal mortality. The trial, in which 673 pregnant adolescent girls (mean age 16·4 years) were enrolled, was conducted in communities served by 12 geographically separated health units in Sierra Leone. Losses to follow-up were less than 10% in both groups.

In the intention-to-treat analyses, 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; adjusted risk ratio [aRR] 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 was 15 (95% CI 8 to 70). There were other benefits for the intervention group, such as significantly more deliveries by skilled birth attendants (254 [73%] of 346 *vs* 112 [41%] of 270; aRR 1·78, 95% CI 1·10 to 2·88).

The 2YoungLives study report[5] provides a masterclass in the development, implementation, rigorous evaluation, and report of a programme to address what was before now a persistent and seemingly intractable public health problem. The study followed best practices in the design and implementation of complex interventions.[6] The authors have clearly illustrated the importance of community engagement in identifying and fixing correctable problems, and the equally crucial importance of previous and ongoing qualitative research and surveys to lay the foundation of such programmes, identify and correct problems, and to understand the results.

A subsequent report will describe and evaluate another important component of the trial intervention: helping the girls to become economically self-sufficient. Evidence regarding how many started their own businesses and how many went to school to learn a trade will help to encourage policy makers in Sierra Leone and elsewhere to support a programme such as 2YoungLives. Such evidence should also be a component of an economic analysis of the mentoring programme. In addition, as the authors state, future research should evaluate the longer-term effects of the programme on the girls, their children, the mentors, and their communities.

For more on the **Lifeline Nehemiah Projects** see https://www.lifelinenehemiahprojects.org/



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The authors have raised an important question about the next step: immediate country-wide implementation or a large, definitive confirmatory trial? The *Lancet* study, which began life as a pilot trial, has shown clear benefits in addressing major problems affecting the lives of adolescent girls and their children. Although the trial was not powered to detect differences in maternal mortality, it was powered to detect important effects in the composite primary outcome, while simultaneously resolving issues affecting implementation of the intervention.

In this instance, the term pilot trial is at its core a question of semantics, not science. Policy makers, grant reviewers, and front-line workers could rightly question the ethics of spending more time, effort, and money on a confirmatory trial, when there is clear evidence of benefit, an innovative and thoroughly developed and tested intervention, and high need. Efforts might be better spent on addressing challenges in widespread implementation. One such issue is the accurate determination of age, which was the sole eligibility criterion. A survey of 250 girls (supplemental to the main analysis) who would have been eligible for the trial revealed that, for reasons including stigma, fear of law enforcement, and imprisonment of boys for sex with a minor, more than two-thirds over-reported their age when accessing care (well intentioned laws had unintended negative consequences). Another potential challenge is the sustainability of the intervention, including the mentors' commitment of time and effort, as well as the availability of teams to work with local communities to identify and address problems as they arise. The latter are questions which can be answered by ongoing monitoring. Roll-out to the entire country should be accompanied by data collection for key outcomes, as is done in phase 4 drug trials.

The 2YoungLives trial has made major contributions, both in the lives of extremely vulnerable adolescent mothers and their newborns in Sierra Leone, and to health researchers who wish to design studies to address complex health problems in the parts of the world that need it most.

I declare no competing interests.

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