

**THE EFFECT OF SEXUAL AND REPRODUCTIVE HEALTH EDUCATION AND
COMMUNITY DIALOGUE ON ADOLESCENT PREGNANCY RATES: A CLUSTER
RANDOMIZED TRIAL IN A RURAL ZAMBIAN CONTEXT.**

Robin Mzati Sinsamala



Centre for International Health

Department of Global Public Health and Primary Care

University of Bergen, Norway

2021

**THE EFFECT OF SEXUAL AND REPRODUCTIVE HEALTH EDUCATION AND
COMMUNITY DIALOGUE ON ADOLESCENT PREGNANCY RATES: A CLUSTER
RANDOMIZED TRIAL IN A RURAL ZAMBIAN CONTEXT.**

Robin Mzati Sinsamala

This thesis is submitted in partial fulfilment of the requirements for the degree of
Master of Philosophy in Global Health at the University of Bergen.

Centre for International Health

Department of Global Public Health and Primary Care

University of Bergen, Norway

2021

Table of Contents

Acronyms and Abbreviations	2
Background	3
Global overview	3
Consequences	3
Risk factors.....	5
Economic support	8
Sexual and reproductive health education.....	12
Study context	16
Objective	19
Methods.....	19
Study design.....	19
Setting and Participants.....	19
Randomization	20
Interventions.....	20
Outcomes.....	21
Power analysis	22
Data collection and management.....	22
Statistical analysis	23
Ethical approval.....	24
References	25
Academic Paper	31
Annexes.....	62
1. Ethical approval from Zambia	
2. Ethical approval from Norway	
3. RISE baseline questionnaire	
4. RISE seventh follow-up face to face questionnaire	
5. RISE seventh follow-up ACASI	

Acronyms and Abbreviations

AIDS – Acquired Immunodeficiency Syndrome

CSE – Comprehensive Sexuality Education

CCT- Conditional Cash Transfer

CT- Cash Transfer

HIV – Human Immunodeficiency Virus

ITT – Intention to Treat

LMICs – Low- and Middle-Income Countries

MoGE – Ministry of General Education

MoH -Ministry of Health

PTA -Parent Teacher Association

RISE - Research Initiative to Support the Empowerment of Girls

SDGs – Sustainable Developmental Goals

SSA – Sub Saharan Africa

SRH – Sexual and Reproductive Health

STIs – Sexually Transmitted Infections

UCT- Unconditional Cash Transfer

YC - Youth Clubs

ZDHS – Zambia Demographic and Health Survey

Background

Global overview

It is estimated that more than 21 million adolescent girls aged 15-19 years become pregnant every year. As a consequence, more than 16 million births and approximately 3.9 million abortions occur per year among adolescent girls, with 90 percent occurring in LMICs (1–3). Among these, estimates from LMICs indicate that 2.5 million girls under the age of 16 years give birth every year (2), and most of girls are already sexually active by the time they reach 19 years (4). Challenges like forced marriages, early and unplanned pregnancies and unsafe abortions among adolescent girls, are common public health concerns, especially in LMICs (5–7).

In recent years the United Nations, through the sustainable development goals (SDGs), has recognised the need to prevent adolescent pregnancy since it contributes to high maternal mortality rate, and therefore included reduction of child birth among adolescents on its agenda for 2030 (4). Governments, non-governmental organisations and other stakeholders have invested resources to combat adolescent pregnancy, however progress is still lagging in sub-Saharan Africa (SSA) compared to other regions of the world (2). For instance, the SSA has the highest adolescent birth rate at 104 births per 1,000 women per year, compared to Latin America and Caribbean at 63 births per 1,000 (2,8).

Consequences

Early pregnancies among adolescents is a pressing public health hurdle and poses detrimental health and social consequences for the young mother and infant (4,9).

Complications from early pregnancies are estimated to be the fourth leading cause of death among girls aged 15-19 years in LMICs (10), with Africa having the highest maternal mortality rate among adolescent girls (570 per 100,000 live births) (11). There is also an increased risk of other adverse maternal and neonatal outcomes like unsafe abortions, preterm delivery, low birth weight and severe neonatal conditions compared to mothers 20 years or older (1,9,10,12,13). In addition, teenagers who become pregnant due to unsafe sex are also at an increased risk of contracting sexually transmitted infections (STIs) like HIV/AIDS, genital herpes, gonorrhoea, chlamydia and syphilis (11,14).

Socially, pregnant girls can face discrimination from parents and peers, and abandonment by their partners who tend to be absent throughout the pregnancy period. Social discrimination could sometimes be as the result of the societal perspective that views teenage pregnancy as a consequence of promiscuity by the girl, and therefore the blame and responsibility is borne by the girl (1,15). Additionally, most girls who fall pregnant in LMICs, tend to lose friends or are avoided by their friends because they may believe that associating with a pregnant friend could influence them to get pregnant as well. Further parents advise their children against socializing with a pregnant friend or teenage mother due to the negative labels teenage pregnancy has in the community (16). The constant struggle to cope with the challenges of being a single mother may lead to psychological distress and affect their mental health. Lack of support and empathy from family, peers and partner can result into feelings of abandonment, loneliness and despair, which are also exacerbated by the prospective responsibility of taking care of the child on their own (15). Due to pregnancy many girls are forced by their family, culture and religion to enter marriage whilst young as a way of dealing with the shame that comes with becoming pregnant early (10,17).

Early pregnancy interferes with school attendance leading to high school dropout among teenage girls who might not get the chance to enrol again, consequently affecting income generating opportunities and economic independence, in the long run, leading to intergenerational transmission of poverty (15,18). School offers the possibility for employment, as those who go further with their education have an increased likelihood for financial independence (1). Furthermore, most children born to adolescent mothers are disadvantaged at birth and through childhood, which has implications on their chances of completing education and becoming productive members of the society. This is due to factors during pregnancy and in upbringing (nutrition, child-mother interaction and environment) that affect the cognitive abilities of a child and are essential for school performance (13).

Risk factors

Worldwide, several studies have reported a strong association between sociodemographic factors like education, poverty (or socioeconomic status) and access (or the lack thereof) to sexual and reproductive health (SRH) services and pregnancy among adolescent girls (1,3,22–25,7,9,10,16,19,19–21). The education status (being in or out of school) is one of the significant predictors of pregnancy among teenagers, as adolescents who are in school experience fewer pregnancies since they are too busy with school work and know that it is unacceptable for them to become pregnant, whereas it is much more acceptable for out-of-school girls to get pregnant and married (7). Moreover, the lack of education decreases the likelihood of achieving some economic independence and economic dependence on others is associated with higher risk for pregnancy (24). Parents' education level is also a contributing factor as the likelihood of early pregnancy is higher among teenagers with

parents having low education than among those who have high educated parents. This can be due to the fact that parents with high education tend to be (socio-economically) better off and can afford to pay for the school necessities and the parents act as role models in education attainment for their children, amongst other reasons (26).

Poverty is one of the all-encompassing factors for adolescent pregnancy (27) as it is both a predictor and a consequence of early pregnancies (10,11,20,25). Girls from poor households have an increased risk of school dropout and early marriage compared to those from well-to-do families (27). Poverty puts adolescents in difficult dilemmas as they try to cope with the challenges of being a teenager. Typically, in Africa, adolescent girls are pressured to engage in sexual activities in exchange for money or material needs. This creates imbalance of power in the relationship as most girls are unable to exercise control over their sexual decisions (1). Often, the sexual relationships are with older partners who can manipulate them by taking advantage of their situation (28). Sometimes the pressure to engage in these sexual relationships comes from what they have observed or assume other peers are doing in similar situations (15). Moreover, parents may vaguely suggest to their girls to find a boyfriend who can provide for their economic needs (16). The dealings that comes with these practices may lead to unsafe sex, eventually culminating into early pregnancies (29). In addition, most girls from underprivileged families have poor living conditions and lack services that are essential in preventing adolescent pregnancy. As a result the poverty cycle continues (3).

In SSA, cultural practises entombed in the cultural values influence negative connotations associated with sexuality, contraceptive use and abortion for girls (30). For instance, adolescent girls are not at liberty to discuss freely topics regarding sexuality as it is deemed

culturally inappropriate and depraved in this setting. Sexuality discussions or messages from parents or guardians and other older people in the community are regarded as taboo and are held in secret (20). Most cultural norms creates a distance between parents and children when it comes to discussions around sexuality messages because of the discomfort by parents in talking about sexual issues, or the fear that sharing sexuality information will encourage sexual activities among their children (31). Nevertheless, girls are expected to take control over their own sexuality without proper and clear guidance (32).

Embedded in most cultures are social norms that dignify practises which expose adolescent girls to greater risks of pregnancy. For example, girls are not expected to use contraceptives and asking for contraceptives entails that they are revealing their engagement in sexual practises or are promiscuous. On the other hand, boys receive applause for such practises and are deemed “real men” amongst their peers. Additionally, boys are not as affected as girls when pregnancy occurs (16,33) (34). Gender norms are inequitable towards women in general and may have direct negative implications on SRH outcomes of adolescent girls (35). In this instance, boys tend to have power over girls and that can aggravate sexual exploitation by boys. For instance, it is expected that boys should pursue girls, whereby girls are expected to be submissive when pursued (32,34,36). These inequalities expose girls to an increased risk of pregnancy and other associated risks (32).

In LMICs, some negative SRH outcomes can also be attributed to the lack of SRH services as most of these services are either unavailable or inadequate (20). The lack of SRH services is a big contributing factor to non-use and misconceptions on contraception leading to early pregnancy (1,7). Existing SRH services can, be difficult to access due to barriers perpetrated by religious beliefs, cultural influence and government policies (37). The conservative

standpoint of most religious beliefs teaches girls that sex is sacred and should be practised only in marriage and emphasize abstinence as the only way to hold themselves pure for marriage. This does not prevent girls from having sex but they do it in secret, which makes it difficult for them to access and use contraceptives (1,16). Government policies create a better environment for access to SRH services, but inappropriate implementation, poor enforcement and inadequate resources can result into undesirable outcomes. For instance adolescent may face negative attitudes from health workers who may refuse to give them contraceptives (23). SRH information and services might be dismissed if the community perceive them as incompatible with their cultural values and threatens the status quo (38). The repercussion is that more adolescent girls experience the negative outcomes such as early pregnancies, early marriages and transmission of STIs.

Economic support

Economic support interventions known as cash transfers (CT) have been on the rise as a key strategy to address some of the social determinants of health such as poverty. These interventions have been implemented to target a certain group of individuals or households to influence behaviour change (39–41). There are variations in the way CT programs are implemented in different settings. Some programs can be implemented on a condition that beneficiaries fulfil specific prerequisites for cash to be transferred, this is known as conditional cash transfers (CCT). The conditions under CCT may vary depending on the nature of the intervention. For instance some may require that participants fulfil certain conditions such as attending school (42), while other programs may reward positive sexual behaviour outcomes like negative tests of STI's to receive the money (43). Another way of implementing CT interventions is where there are no stringent requirements for participants

to receive the transfer, and these are known as unconditional cash transfer (UCT). There might however be some inclusion criteria such as gender, poverty level and orphaned or vulnerable children, to be eligible as a recipient (39,41,44). In Africa UCT interventions are often the preferred option because they are relatively cost effective in terms of the administrative costs since they do not require monitoring the compliance of the beneficiaries to the program (45).

The evidence available so far from SSA has shown mixed impact of cash transfer programs on preventing pregnancy, early marriage, delaying sexual debut, reducing transmission of STIs and contraception use (39,40). For instance, a cash transfer program in Malawi where participants were randomly assigned to two intervention arms (CCT on school attendance and UCT) and a control, with the prevalence of HIV and HSV-2 infections as the primary outcome among girls aged 13 to 22 year, found that the intervention reduced the odds of HIV infection by 71% in the CCT group (AOR 0.29, 95%CI 0.09-0.98) and 53% in the UCT group (AOR 0.47, 95%CI 0.14-1.5). The program also reduced the odds of HSV-2 infection by 63% in the CCT group (AOR 0.37, 95%CI 0.13-1.03) and by 92% in the UCT group (AOR 0.08, 95%CI 0.01-0.58) after 18 months. This difference was measured by testing the participants and was supported by self-reported sexual behaviour change. Furthermore, the program reduced pregnancy rates in the UCT group (AOR 0.16, 95%CI 0.04-0.68) compared to the control group (44). An evaluation of program found that the CCT group reported a decrease in early marriages and sexual activity after one year. Moreover, most girls stayed in school and that substantially delayed and the likelihood of adolescent pregnancy. However the differences gradually disappeared in the long-term evaluation of the two intervention arms (46). One of the reason for that could be the widespread practice of transactional sex in the study area, as the authors reported that the practice was not uncommon for the sexually

active group at baseline. Thus suggesting that girls that were receiving CT intervention could have gone back to engaging into relationships in exchange for gifts or money after the intervention was discontinued (44).

In a randomized controlled trial done in South Africa, where the CT was conditioned on 80% school attendance, to measure effect on HIV incidence among girls aged 13-20 years of age. The study found that the intervention offered no protection on HIV incidence between the two groups (HR 1.17, 95%CI 0.81-1.72). Furthermore, the intervention did not decrease the incidence of pregnancy, age at sexual debut, transactional sex and school attendance.

However, those in the intervention group were less likely to report having had sex in the past 3 months than those in the control. Irrespective of the study groups, those who attended school more than 80% of the time had a reduced risk of contracting HIV and that supports the association between school attendance and certain SRH outcome.

Conditioning CT on school attendance could have affected the outcomes of this study as school attendance was already high in the area because of the free primary and secondary education. In addition, the presence of a social protection system (cash support) to poor households in South Africa could have levelled out the difference between the groups, since most households, even those in the control group, can already afford some school necessities for their children (45).

Another trial in Tanzania was designed to reduce HIV transmission using CCT among males and females aged 18 to 30 years old. Transfer of cash was on a condition that they tested negative for curable STIs every 4th month of the 12 months study period. The participants were randomized into two arms namely high value CCT (20 dollars per testing) and low value CCT (10 dollars per testing). The program reduced the transmission of STIs with 27%

(ARR 0.73, 95% CI: 0.47-0.99) in the high value arm compared to the control and a 31% (ARR 0.69, 95% CI: 0.45-0.92) reduction was also found in the high value arm compared to the low value arm at the end of the 12 months period. In contrast to most behaviour change where the effect usually disappears when the program ends, the evaluation done one year after the program found that the effects on the high value CCT were sustained (40,43). A Kenyan national UCT program for orphans and vulnerable children evaluated the impact of the intervention on pregnancy and early marriage among females aged 12 to 24 years after 4 years. The study found a reduction of pregnancy by 34% among those that had never given birth before, but no effect was found on early marriage. As indicated in the study, the program kept most girls in school and that could have delayed sexual activity. The authors suggested to interpret the study as quasi experimental since certain elderly-headed households in the treatment group were prioritized in areas where there were more eligible households compared to the allotted budget, but the same was not done in the control group, as such makes it difficult to infer causality (47).

Building on the findings of these studies it indicate that cash support interventions have beneficial potential in empowering girls by enabling good decision making with regards to their sexuality and preventing pregnancies, transactional sex, and the need for multiple sexual partners (39). In addition, such interventions can increase school enrolment and attendance among girls, since in most households, inability to pay school fees and buy uniforms challenges school attendance. Cash support may relieve some of the expenditure and consequently improve the household economy during the period of the program (40,48).

Sexual and reproductive health education

Globally, information on SRH has been disseminated to young people through education programmes as a means of preventing SRH problems such as adolescent pregnancy, transmission of HIV/AIDS and sexually transmitted infections (STIs), and early marriages. These interventions have been delivered through peers, schools, mass media and community youth centres targeting adolescents (10,19,54–59,37,38,44,49–53).

Comprehensive SRH education programmes have been shown to be more beneficial to adolescents than less comprehensive programmes like abstinence only programmes (60). In North America for example, a review of evidence showed that programmes focusing on only sexual abstinence are less effective in reducing biological and behaviour outcomes such as pregnancy and contraceptive use than those centred on comprehensive SRH among adolescents (61)(62). In some parts of the world, SRH education has been integrated in society and is part of the school curriculum. This has enabled governments to create an environment through policies where it is acceptable to discuss sexuality issues openly (63).

In SSA however, SRH education programmes have shown inconsistent effects on pregnancy, HIV and STIs (50) due to a number of factors. Firstly, implementation and delivery of educational programmes might have contributed to the programs being effective or not. This implies that the process of putting into use an intervention that is evidence or theory based is crucial for achieving the intended objectives. This also involves the intensity and duration, which can determine the extent to which the intervention can influence behaviour change (45). However problems arise if the intervention is poorly delivered or it is intrinsically faulty (64). Secondly, the context, which include social (socio-cultural values, language, socio-economic status, epidemiological and geographical) and political or

organisational (available local resources, staff, financing, health information), within which the program is implemented, can act as barrier on the effectiveness of interventions (45,65,66). Of note is that the interaction between context and implementation plays a major role on the success of a program (65). Thirdly, interventions that are not evidence or/and theory based can affect the impact of a program, since they cannot properly validate and measure the causal relation. Therefore inconsistencies may arise in justifying the effectiveness or the lack thereof (64).

The context or setting has been a challenge in most of the trials done in SSA. For instance, a trial in Zimbabwe, conducted from 2003 to 2007, investigated the effectiveness of a community intervention on HIV and reproductive health. The intervention had three components: youth programme both for school goers and dropouts, a community-based program for parents and community stakeholders and training of healthcare providers to improve accessibility to the rural clinics for young people. The study reported a 15% and 24% (AOR 1.15, 95%CI: 0.81-1.64 and AOR 1.24, 95% CI: 0.93-1.65) increase in the likelihood of contracting HIV and HSV-2, respectively, among males and females aged 18 to 22 years. Overall, there was however a 36% decrease in pregnancies among all women aged 18 to 22 years in the intervention group (AOR 0.64, 95%CI:0.49-0.83). All the intervention components are regarded as very promising, and it is likely that the findings could be attributed to the socio-economic landscape at the time the trial was conducted. As a result of the political instability in the country, there was increased poverty levels, higher mobility among the participants away from the study areas and high attrition rates of the clinic staffs (49).

Another example where the context most likely influenced the results was a trial conducted in South Africa from 2004 to 2010 on a school-based HIV/ STI intervention promoting and improving knowledge and skills on abstinence and condom use. This was based on social cognitive theory where 12-hour modules were introduced in the school schedule as part of the school subjects. The trial had self-reported “unprotected vaginal intercourse” as a primary outcome. Overall, the intervention reduced the odds of the primary outcome with 58% (OR 0.42, 95%CI:0.22-0.84). The trial reported a reduction in the odds of unprotected intercourse of 49% (OR 0.51, 95%CI:0.30-0.85) in the short term (3 months, 6 months, and 12 months), but the effect of the intervention in the long term (after 42 months and 54 months) disappeared (OR 0.95, 95%CI:0.58-1.54) compared to the control (50). The authors suggested that the model was based on a Western theoretical model which did not consider the cultural structures of the South African context and that might have resulted into less impact on behaviour. But the long-term effects of a school-based programme like this might have been affected by the fact that adolescents who were aged 12 to 18 years at the beginning of the trial, are more likely to get married and be sexually active as they become older. The existing HIV programmes, due to the HIV epidemic in South Africa, might have washed out the impact of the trial over time since most of the participants (also in the control) acquired knowledge about HIV from other programmes (50).

In some trials the interaction between the context and implementation (delivery) could have affected the outcomes of the trials. For example, a school-based trial on an HIV prevention programme was done in three sites, Dar es Salaam, Tanzania, and Cape Town and Mankweng, South Africa from 2004 to 2010. The intervention consisted of 11-17 hours teacher led classroom sessions on SRH. The intervention showed an impact on delayed sexual debut (OR 0.65, 95% CI: 0.48 to 0.87) only in Dar es Salaam. There were no important

differences between the study arms on delayed sexual debut and condom use in Cape Town and Mankweng. The authors commented that the intervention content and delivery in the three sites varied slightly in terms of teaching. In Tanzania, the intervention was delivered by science teachers who are more respected than other teachers in that context, and that could explain the difference in the outcome compared to South Africa. In addition there were several other similar programs running in South Africa that could have influenced the outcomes in the control arm and thus led to contamination of the results (67).

Contextual and implementation barriers could have impacted the findings of the trial in Mwanza region, Tanzania, which was done to measure the biological and behaviour impact of a SRH intervention in 20 rural communities. The intervention had several components but the four major ones included reproductive health education in primary schools, provision of youth friendly SRH services, community based condom promotion and distribution, and community wide activities like drama, poetry and dance (68). The primary outcomes were the prevalence of HIV and HSV-2. A follow up survey, done to investigate the long term impact of the intervention (5-7 years later), found that there was no important difference in the intervention effect on the primary outcomes compared to the control (69). In the short-term evaluation, the study reported an effect on knowledge but no effect on pregnancy outcomes. The authors suggested the problem was that they did not include interventions targeting social norms and a restrictive social environment could have limited the participants' opportunities to implement the things they had learned regarding condoms and safe sex (70). The authors also explain that this could be due to the length of time since the exposure to the in-school intervention (wash out effects over time) and that adolescents' sexual behaviour was more influenced by the community norms than the intervention since they had grown up and were out of primary school (69).

The unsatisfactory findings in SSA may make one question the effectiveness of SRH education interventions. As discussed earlier, most of these outcomes could have been influenced by insufficient implementation or particular contextual factors (64). In addition, it is unrealistic to expect a lasting effect since most adolescent girls reach an age where it seems desirable to get pregnant and get married, but one can expect long term impact on the use of contraceptive like condoms. It is very crucial to integrate these interventions with local policies and engage parents, siblings, out-of-school friends and boyfriends as they are more likely to support the behaviour transition of the participants (70). Therefore, inclusion of parents, friends and other community stakeholders in the comprehensive SRH programmes has the potential to improve the SRH of adolescents and arm young people with the necessary knowledge about their sexuality, reduce misinformation and enable good decision making around issues to do with their SRH (60).

Study context

Zambia, like most countries in the SSA region, has currently a young population with persons below 18 years representing 52.5 percent of the total population (28). According to the recent 2018 Zambia Demographic and Health Survey (ZDHS), overall, 35 percent of adolescent girls have given birth by the time they are 18 years (10,71). The survey also revealed that the prevalence of adolescent pregnancy in rural areas is nearly double that in urban areas (37% and 19%, respectively) (20,71). The country still has a high maternal mortality ratio (398/100, 000 live births) and abortion contributes to about 30% of maternal deaths with 80% abortion-related deaths occurring among teenagers (72). Most girls that get pregnant in rural areas come from underprivileged households and have dropped out of school. Inability by the parents to provide for the school necessities like school fees and

uniforms due to poverty result into high school dropout rates (73). Further, parents may pressure their daughters into getting married for economic gains like bride price, or in some cases girls may willingly engage in sexual relations in exchange for money and gifts (10). As a result, most girls fail to realize their full potential and degrade their human capital as they assume responsibilities of being a young mother without enough support and resources to provide for the child and themselves (73).

To address the SRH needs of young people Zambia introduced school based comprehensive sexuality education (CSE) program in 2014 which included topics like gender relations, sexual behaviour, contraceptive methods, values, attitudes and self-realization. However, several challenges have prevented the program from achieving substantial effects. These challenges include lack of adherence to the program, as some teachers choose what to teach depending on what they consider suitable as per the norms of the community on sexuality issues. This result into withholding some information such as contraception use to prevent pregnancy, which could be useful to sexually active learners (38).The lack of guidance on how to integrate the SRH education into the curriculum and lacking of teaching resources poses a challenge and that leads to many teachers basing the lessons on abstinence as the only way to avoid pregnancy (38). This impacts the effectiveness of sexuality education negatively since what is taught in practice differs substantially from what the paper framework indicates (10). As a result, there is insufficient knowledge on pregnancy risks which probably contributes to the stagnation of adolescent pregnancy rates persists among adolescents (16).

Even though Zambia has seen a slight decrease in adolescent fertility nationwide, the rates are still unacceptably high (71). One aspect contributing to this is low or non-use of

contraceptives, as they are portrayed as bad in the community (16,38). In addition, socio-cultural and religious norms consider it taboo for parents or guardians to talk about sexuality related issues with their children and instead the focus is on abstinence as the best approach to avoid pregnancy, and as a result they do not get the necessary guidance needed at this stage of life (20). Community norms contributes largely to adolescent pregnancy because they promote early sexual debut and influence certain sexual behaviour among adolescents as girls are groomed to be mothers and focus on child bearing roles (74). Girls are taught about sexuality and marriage when they reach puberty at initiation ceremonies, and that creates nuanced expectations about sex. To live up to those expectations some girls may try it out without proper direction on how to avoid the negative consequences that follow such as teenage pregnancy (20).

Based on findings from the literature and formative research, the Research Initiative to Support the Empowerment of girls (RISE) trial was launched in Zambia in 2016. To target several factors contributing to early pregnancy the trial introduced multicomponent interventions lasting for two years (2016 to 2018). This included providing economic support to girls and their families in one arm and combining the economic support with a community component in another arm. The community component encompassed youth clubs, to promote SRH knowledge, and community dialogue and meetings to develop supportive community norms. The trials primary outcomes were incidence of births within 8 months of the end of the intervention period, incidence of births before girls' 18th birthday and proportion of girls who sit for the grade 9 exams (10). There are many secondary outcomes in this trial and this study measures the effect of the interventions on one of them.

Objective

The main objective of this sub-study was to measure the effectiveness of a combined economic and community intervention and of an economic support only on the incidence of pregnancy among adolescents in Zambia by the end of the intervention period in 2018.

Methods

Study design

This study used data from the RISE cluster randomized controlled trial which was conducted in Zambia from 2016 to 2020. The trial had two intervention arms and one control arm. The three arms included: 1) economic support only, 2) combined economic support with community intervention, 3) control arm. The units of randomisation were schools which were at least 8 km apart and located in 12 districts of Southern and Central provinces of Zambia. All the selected schools consisted of primary (grade 1-7) and junior secondary grades (grade 8-9). The trial randomized a total of 157 clusters (63 to the combined intervention (CI) arm, 63 to the economic (E) arm and 31 to the control arm). A detailed description of the methods can be found in the trial protocol paper (10) (Trial registration: ISRCTN12727868).

Setting and Participants

Included were all adolescent girls in grade 7 in the selected schools who received consent from parents and who assented (<18 years) or consented (\geq 18 years) to take part before randomization. More than 80% of the girls in grade 7 had to assent/consent for a school to be included in the study. The Southern and Central provinces districts were chosen because

they have medium school dropout rates, and early marriage and pregnancy are common. In total 4922 participants were recruited in to trial (10).

Randomization

After recruitment and baseline interviews, schools were randomized. In total there were six randomization ceremonies, each for two districts. Officials, chiefs, head teachers and PTA chairpersons were invited to the randomization ceremony. Schools were stratified by district and randomized to the three arms of study. For each ceremony, an independent researcher from the Centre for Interventions Science in Maternal and Child Health (CISMAC), generated 1000 allocations from a computer. The allocations were numbered and tickets corresponding to the allocations were drawn from a box. In this trial the study participants were not masked because it is difficult to blind interventions of this kind (10).

Interventions

The participants received the interventions for 27 months from September 2016 for 27 months until November 2018. One intervention arm contained economic support to parents or guardians and girls. This was in a form of financial support; girls received monthly cash support of 30 Zambian Kwacha (ZMW) and payment of school fees for those in grade 8 to 9 (maximum ZMW 1500 per year) while parents or guardians received yearly cash support of ZMW 350. The economic support package targeted the major players in determining pregnancy among adolescents. As economic support would improve school enrolment, alleviate the household from poverty making it less compelling for parents to marry off their daughters, and reduce the risk of transactional sex among girls. Cash was transferred to parents and girls by a committee of a teacher and two parents from PTA. During follow up interviews girls were asked whether they had received the money and in the right amount.

There was no age limit for CT if girls were in school, but the transfer stopped after the 18th birthday for those who dropped out of school. The discontinuation of transfers also applied for those that did not take part in the follow-up contacts.

The other arm combined the economic support with a community intervention to parents or guardians and girls. The community intervention had two components namely, (1) every second month discussions and dialogue with parents and the community in encouraging supportive norms that can help delay early pregnancy and marriage and promote girl's education, (2) setting up youth clubs to offer comprehensive SRH education to in- and out-of-school adolescents of both genders. Adolescent girls participating in the trial and boys in grade 7 in 2016 from the randomly allocated schools were invited to the youth club every 2 weeks during school terms. The topics for discussions included early marriage, risks of early pregnancy, gender roles, education, myths around contraceptives and SRH. The lessons were delivered by a teacher together with a community health assistants (CHAs) or a community health workers (CHWs). The selected teachers and CHAs or CHWs were given a 5 days training on the SRH curriculum and facilitation methods plus a refresher training midway through the intervention period. For each combined intervention school, two youth peer educators (unmarried women under 20 years) were selected from the local community to mobilize girls and boys for the youth club meetings. The control arm, like the other two arms, received writing materials like exercise books, pencils and pens besides the standard school and health services as an incentive to participate (10).

Outcomes

The main outcome in this analysis was the incidence of pregnancies conceived at the end of the intervention period. The outcome was measured by combining the responses to the

questions “Do you have your own child?”, “Have you ever given birth?” and “Have you ever been pregnant?”. The time of conception was estimated from information on date of birth or end of pregnancy and duration since last menstrual period before the pregnancy. Data collected up to the 7th follow up round in the second half of 2019 was used. Pregnancies that were conceived before the randomization were excluded.

Power analysis

We assumed 10 % loss to follow up (n=492), giving an average cluster size of 28 girls (4922/157) for the 157 clusters. We assumed that the cluster number would be intact, i.e., 63 in the economic (E), 63 in the combined intervention (CI) and 31 in the control arm. We assumed an ICC of 0.00737 for pregnancy before age 16 based on the ICC for “ever pregnant” in the cluster randomized trial in Malawi by Baird et al [personal communication](10). We assumed an average cumulative incidence of pregnancies by the end of the intervention of 26% in the control arm. In the economic arm we assumed a cumulative incidence of 20%, corresponding to a 23% relative reduction compared to the control, and we estimated that this would give us 88% power to detect a difference. In the combined arm we assumed a cumulative incidence of 16%, corresponding to a 38.5% relative reduction compared to the control arm, and we estimated that we would have 99% power to detect this difference. For the comparison between the combined and economic intervention, we estimated that we would have 80% power to detect a difference if the cumulative incidences were 16% and 20%, respectively.

Data collection and management

Data was collected by trained research assistants using face-to-face interviews at baseline and every 6 months. For those that had moved to other places, telephone interview were

done. From the fourth round, Audio Computer Assisted Survey Instruments (ACASI) were adopted as an additional data collection tool. The data collection tools were translated to the major local languages in the study districts and then back translated to ensure content was maintained. Data collection tools were piloted to ensure that they were appropriate for the trial. Information from the interviews was recorded electronically using tablets. Each participant was given a unique number for linking of information. Access to personal numbers was only given to the Data Manager, the Principal Investigator and the Co-Principal investigator and data was stored on password-protected computers and tablets. All personal identifiers will be deleted at the completion of the trial.

Statistical analysis

Stata 16 (StataCorp, College Station, TX, USA) software was used to analyse the data. Baseline characteristics were summarized using proportions for binary variables and means and standard deviations (SD) for continuous variables. The variable pregnancy was summarized as a cumulative incidence by 15th November 2018. Outcomes were compared between the combined intervention arm, the economic arm and control arm. The primary analysis was analysed according to the initial group allocation (intention to treat (ITT)), to report an estimate of the effect of the interventions. The ITT analysis accounted for the design effect of clustering and the stratified randomization. Survival analysis was used to compare the incidence in the different arms. For all incidence rates, the denominator was person years at risk, and participants who withdrew or were lost to follow-up were right censored at the time when we last received information about them. We analysed data collected up to the 7th follow-up. Initially we intended to use Cox Proportional Hazard model in the analysis, but the Proportional Hazards assumptions were not satisfied.

Therefore, the Parametric Model (Weibull) was employed based on the supposition that the intrinsic data structure of pregnancies was expected to follow its distribution and we present outputs from both models. We adjusted for age at entry and time since randomization was used as the timescale.

Ethical approval

Ethical approval was given by the University of Zambia Biomedical Research Ethics Committee (ref no 021- 06-15) and the Regional Ethics Committee of Western Norway (REK/ref no 2015/895). Permission to conduct the study was obtained from Ministry of General Education (MoGE), Ministry of Health (MoH) and district education offices in the study districts (10). Parental consent was sought after an information meeting between researchers and parents or guardians. Assent/consent from the girls were sought after they were directly informed. The interviews were conducted in privacy with strict confidentiality.

References

1. Yakubu I, Salisu WJ. Determinants of adolescent pregnancy in sub-Saharan Africa: A systematic review. *Reprod Health*. 2018;15(1).
2. WHO. Recommendations on adolescent sexual and reproductive health and rights. 2017. 1–88 p.
3. Wado YD, Sully EA, Mumah JN. Pregnancy and early motherhood among adolescents in five East African countries: A multi-level analysis of risk and protective factors. *BMC Pregnancy Childbirth*. 2019;19(1):1–11.
4. World Health Organization. Reducing early and unintended pregnancies among adolescents. *Fam Plann*. 2016;1–4.
5. Gausman J, Langer A, Austin SB, Subramanian S V. Contextual Variation in Early Adolescent Childbearing: A Multilevel Study From 33,822 Communities in 44 Low- and Middle-Income Countries. *J Adolesc Heal [Internet]*. 2019;64(6):737–45.
6. Kamal SMM, Hassan CH, Alam GM, Ying Y. Child marriage in Bangladesh: Trends and determinants. *J Biosoc Sci*. 2015;47(1):120–39.
7. Munakampe MN, Zulu JM, Michelo C. Contraception and abortion knowledge, attitudes and practices among adolescents from low and middle-income countries: A systematic review. *BMC Health Serv Res*. 2018;18(1):1–13.
8. UNFPA. United Nations Population Fund UNFPA Strategic Plan 2018–2021. 2018;1–38.
9. Ganchimeg T, Ota E, Morisaki N, Laopaiboon M, Lumbiganon P, Zhang J, et al. Pregnancy and childbirth outcomes among adolescent mothers: a World Health Organization multicountry study. *BJOG*. 2014;121 Suppl:40–8.
10. Sandøy IF, Mudenda M, Zulu J, Munsaka E, Blystad A, Makasa MC, et al. Effectiveness of a girls' empowerment programme on early childbearing, marriage and school dropout among adolescent girls in rural Zambia: Study protocol for a cluster randomized trial. *Trials [Internet]*. 2016;17(1):1–15.
11. Liang M, Simelane S, Fortuny Fillo G, Chalasani S, Weny K, Salazar Canelos P, et al. The State of Adolescent Sexual and Reproductive Health. *Journal of Adolescent Health*. 2019.
12. Karataşlı V, Kanmaz AG, İnan AH, Budak A, Beyan E. Maternal and neonatal outcomes of adolescent pregnancy. *J Gynecol Obstet Hum Reprod*. 2019;48(5):347–50.
13. Fall CHD, Sachdev HS, Osmond C, Restrepo-Mendez MC, Victora C, Martorell R, et al. Association between maternal age at childbirth and child and adult outcomes in the offspring: A prospective study in five low-income and middle-income countries (COHORTS collaboration). *Lancet Glob Heal [Internet]*. 2015;3(7):e366–77.
14. Marino JL, Lewis LN, Bateson D, Hickey M, Skinner SR. Teenage mothers. *Aust Fam Physician*. 2016;45(10):712–7.
15. Kumar M, Huang K-Y, Othieno C, Wamalwa D, Madeghe B, Osok J, et al. Adolescent

- Pregnancy and Challenges in Kenyan Context: Perspectives from Multiple Community Stakeholders. *Glob Soc Welf* [Internet]. 2018 Mar 25;5(1):11–27.
16. Svanemyr J. Adolescent pregnancy and social norms in Zambia. *Cult Heal Sex* [Internet]. 2019;0(0):1–15.
 17. Çift T, Korkmazer E, Temur M, Bulut B, Korkmaz B, Ozdenoğlu O, et al. Adolescent pregnancies: Complications, birth outcomes and the possible solutions. *Ginekol Pol*. 2017;88(7):393–7.
 18. Salam RA, Faqqah A, Sajjad N, Lassi ZS, Das JK, Kaufman M, et al. Improving Adolescent Sexual and Reproductive Health: A Systematic Review of Potential Interventions. *J Adolesc Heal*. 2016;59(2):S11–28.
 19. Dongarwar D, Salihu HM. Influence of Sexual and Reproductive Health Literacy on Single and Recurrent Adolescent Pregnancy in Latin America. *J Pediatr Adolesc Gynecol* [Internet]. 2019;32(5):506–13.
 20. Menon JA, Kusanthan T, Mwaba SOC, Juanola L, Kok MC. “Ring” your future, without changing diaper - Can preventing teenage pregnancy address child marriage in Zambia? *PLoS One*. 2018;13(10):1–17.
 21. Chirwa GC, Mazalale J, Likupe G, Nkhoma D, Chiwaula L, Chintsanya J. An evolution of socioeconomic related inequality in teenage pregnancy and childbearing in Malawi. *PLoS One*. 2019;14(11):1–16.
 22. Knopf AS, McNealy KR, Al-Khattab H, Carter-Harris L, Oruche UM, Naanyu V, et al. Sexual learning among East African adolescents in the context of generalized HIV epidemics: A systematic qualitative meta-synthesis. *PLoS One*. 2017;12(3):1–20.
 23. Svanemyr J, Amin A, Robles OJ, Greene ME. Creating an enabling environment for adolescent sexual and reproductive health: A framework and promising approaches. *J Adolesc Heal* [Internet]. 2015;56(1):S7–14.
 24. Pradhan R, Wynter K, Fisher J. Factors associated with pregnancy among adolescents in low-income and lower middle-income countries: A systematic review. *J Epidemiol Community Health*. 2015;69(9):918–24.
 25. Nguyen PH, Scott S, Neupane S, Tran LM, Menon P. Social, biological, and programmatic factors linking adolescent pregnancy and early childhood undernutrition: a path analysis of India’s 2016 National Family and Health Survey. *Lancet Child Adolesc Heal* [Internet]. 2019;3(7):463–73.
 26. Kassa GM, Arowojolu AO, Odukogbe AA, Yalew AW. Prevalence and determinants of adolescent pregnancy in Africa: A systematic review and Meta-analysis 11 *Medical and Health Sciences* 1117 *Public Health and Health Services*. *Reprod Health*. 2018;15(1):1–17.
 27. Joint United Nations Programme on HIV/AIDS (UNAIDS), African Union (AU). Empower young women and adolescents girls: Fast-tracking the end of the AIDS epidemic in Africa. 2015;32.
 28. Ezekwe AC. *African Research Review. Int Multi-disciplinary*. 2018;12(50):135–42.

29. Asare BYA, Baafi D, Dwumfour-Asare B, Adam AR. Factors associated with adolescent pregnancy in the Sunyani Municipality of Ghana. *Int J Africa Nurs Sci*. 2019;10(July 2018):87–91.
30. Håkansson M, Oguttu M, Gemzell-Danielsson K, Makenzius M. Human rights versus societal norms: A mixed methods study among healthcare providers on social stigma related to adolescent abortion and contraceptive use in Kisumu, Kenya. *BMJ Glob Heal*. 2018;3(2):1–13.
31. Isaksen KJ, Musonda P, Sandøy IF. Parent-child communication about sexual issues in Zambia: a cross sectional study of adolescent girls and their parents. *BMC Public Health*. 2020;20(1):1–12.
32. Ninsiima AB, Leye E, Michielsen K, Kemigisha E, Nyakato VN, Coene G. “Girls have more challenges; they need to be locked up”: A qualitative study of gender norms and the sexuality of young adolescents in Uganda. *Int J Environ Res Public Health*. 2018;15(2).
33. Kenny L, Koshin H, Sulaiman M, Cislighi B. Adolescent-led marriage in Somaliland and Putland: A surprising interaction of agency and social norms. *J Adolesc [Internet]*. 2019;72(January):101–11.
34. Moreau C, Li M, De Meyer S, Vu Manh L, Guiella G, Acharya R, et al. Measuring gender norms about relationships in early adolescence: Results from the global early adolescent study. *SSM - Popul Heal*. 2019;7(October 2018).
35. Okigbo CC, Speizer IS, Domino ME, Curtis SL, Halpern CT, Fotso JC. Gender norms and modern contraceptive use in urban Nigeria: A multilevel longitudinal study. *BMC Womens Health*. 2018;18(1):1–17.
36. Stoebenau K, Kyegombe N, Bingenheimer JB, Ddumba-Nyanzi I, Mulindwa J. Developing Experimental Vignettes to Identify Gender Norms Associated With Transactional Sex for Adolescent Girls and Young Women in Central Uganda. *J Adolesc Heal [Internet]*. 2019;64(4):S60–6.
37. Rokicki S, Fink G. Assessing the reach and effectiveness of mHealth: Evidence from a reproductive health program for adolescent girls in Ghana. *BMC Public Health*. 2017;17(1):1–14.
38. Zulu JM, Blystad A, Haaland MES, Michelo C, Haukanes H, Moland KM. Why teach sexuality education in school? Teacher discretion in implementing comprehensive sexuality education in rural Zambia. *Int J Equity Health*. 2019;18(1):1–10.
39. Bastagli F, Hagen-Zanker J, Harman L, Barca V, Sturge G, Schmidt T. The Impact of Cash Transfers: A review of the evidence from low- and middle-income countries. *J Soc Policy*. 2019;48(3):569–94.
40. Owusu-Addo E, Renzaho AMN, Smith BJ. The impact of cash transfers on social determinants of health and health inequalities in sub-Saharan Africa: A systematic review. *Health Policy Plan*. 2018;33(5):675–96.
41. Cooper JE, Benmarhnia T, Koski A, King NB. Cash transfer programs have differential effects on health: A review of the literature from low and middle-income countries.

- Soc Sci Med [Internet]. 2020;247(October 2019):112806.
42. Experiments N. Editorial Identification of Treatment Effects. 2008;1131(2007):1127–31.
 43. De Walque D, Dow WH, Nathan R, Abdul R, Abilahi F, Gong E, et al. Incentivising safe sex: A randomised trial of conditional cash transfers for HIV and sexually transmitted infection prevention in rural Tanzania. *BMJ Open*. 2012;2(1).
 44. Baird SJ, Garfein RS, McIntosh CT, Özler B. Effect of a cash transfer programme for schooling on prevalence of HIV and herpes simplex type 2 in Malawi: A cluster randomised trial. *Lancet [Internet]*. 2012;379(9823):1320–9.
 45. Pega F, Walter S, Liu SY, Pabayo R, Lhachimi SK, Saith R. Unconditional cash transfers for reducing poverty and vulnerabilities: Effect on use of health services and health outcomes in low- and middle-income countries. *Cochrane Database Syst Rev*. 2014;2014(6).
 46. Baird S, McIntosh C, Özler B. Cash or condition? Evidence from a cash transfer experiment. *Q J Econ*. 2011;126(4):1709–53.
 47. Handa S, Peterman A, Huang C, Halpern C, Pettifor A, Thirumurthy H. Impact of the Kenya Cash Transfer for Orphans and Vulnerable Children on early pregnancy and marriage of adolescent girls. *Soc Sci Med [Internet]*. 2015;141:36–45.
 48. Owusu-Addo E. Perceived impact of Ghana’s conditional cash transfer on child health. *Health Promot Int*. 2016;31(1):33–43.
 49. Cowan FM, Pascoe SJ, Langhaug LF, Mavhu W, Chidiya S, Jaffar S, et al. The Regai Dzive Shiri project: results of a randomized trial of an HIV prevention intervention for youth. *AIDS [Internet]*. 2010 Oct;24(16):2541–52.
 50. Jemmott JB, Jemmott LS, O’Leary A, Ngwane Z, Lewis DA, Bellamy SL, et al. HIV/STI risk-reduction intervention efficacy with South African adolescents over 54 months. *Heal Psychol [Internet]*. 2015;34(6):610–21.
 51. Mwilike B, Shimoda K, Oka M, Leshabari S, Shimpuku Y, Horiuchi S. A feasibility study of an educational program on obstetric danger signs among pregnant adolescents in Tanzania: A mixed-methods study. *Int J Africa Nurs Sci [Internet]*. 2018;8(February):33–43.
 52. Borawski EA, Tufts KA, Trapl ES, Hayman LL, Yoder LD, Lovegreen LD. Effectiveness of Health Education Teachers and School Nurses Teaching Sexually Transmitted Infections/Human Immunodeficiency Virus Prevention Knowledge and Skills in High School. *J Sch Health [Internet]*. 2015 Mar;85(3):189–96.
 53. Menna T, Ali A, Worku A. Effects of peer education intervention on HIV/AIDS related sexual behaviors of secondary school students in Addis Ababa, Ethiopia: A quasi-experimental study. *Reprod Health [Internet]*. 2015;12(1):1–8.
 54. Mmbaga EJ, Kajula L, Aarø LE, Kilonzo M, Wubs AG, Eggers SM, et al. Effect of the PREPARE intervention on sexual initiation and condom use among adolescents aged 12-14: A cluster randomised controlled trial in Dar es Salaam, Tanzania. *BMC Public*

- Health. 2017;17(1):1–10.
55. Morales A, Espada JP, Orgilés M. A 1-year follow-up evaluation of a sexual-health education program for Spanish adolescents compared with a well-established program. *Eur J Public Health*. 2016;26(1):35–41.
 56. Alzate MM, Dongarwar D, Matas JL, Salihu HM. The Effect of Sexual Literacy on Adolescent Pregnancy in Colombia. *J Pediatr Adolesc Gynecol*. 2019;
 57. Fonner VA, Armstrong KS, Kennedy CE, O’Reilly KR, Sweat MD. School based sex education and HIV prevention in lowand middle-income countries: A systematic review and meta-analysis. *PLoS One*. 2014;9(3).
 58. Duflo E, Dupas P, Kremer M. Education, HIV, and Early Fertility: Experimental Evidence from Kenya. *Am Econ Rev [Internet]*. 2015 Sep;105(9):2757–97.
 59. Knopf AS, McNealy KR, Al-Khattab H, Carter-Harris L, Oruche UM, Naanyu V, et al. Sexual learning among East African adolescents in the context of generalized HIV epidemics: A systematic qualitative meta-synthesis. *PLoS One [Internet]*. 2017;12(3):1–20.
 60. Vanwesenbeeck I, Westeneng J, de Boer T, Reinders J, van Zorge R. Lessons learned from a decade implementing Comprehensive Sexuality Education in resource poor settings: The World Starts With Me. *Sex Educ [Internet]*. 2016;16(5):471–86.
 61. Underhill K, Operario D, Montgomery P. Abstinence-only programs for HIV infection prevention in high-income countries. *Cochrane Database Syst Rev*. 2007;(4).
 62. Oringanje C, Mm M, Eko H, Esu E, Meremikwu A, Je E. Interventions for preventing unintended pregnancies among adolescents (Review) summary of findings for the main comparison. 2016;(2).
 63. United Nations Educational S and CO. Comprehensive s e x u a l i t y e d u c a t i o n . 2015.
 64. Rychetnik L, Frommer M, Hawe P, Shiell A. interventions. 2006;119–27.
 65. Pfadenhauer LM, Gerhardus A, Mozygemba K, Lysdahl KB, Booth A, Hofmann B, et al. Making sense of complexity in context and implementation: The Context and Implementation of Complex Interventions (CICI) framework. *Implement Sci*. 2017;12(1):1–18.
 66. Pettifor A, MacPhail C, Hughes JP, Selin A, Wang J, Gómez-Olivé FX, et al. The effect of a conditional cash transfer on HIV incidence in young women in rural South Africa (HPTN 068): a phase 3, randomised controlled trial. *Lancet Glob Heal*. 2016;4(12):e978–88.
 67. Mathews C, Aarø LE, Grimsrud A, Flisher AJ, Kaaya S, Onya H, et al. Effects of the SATZ teacher-led school HIV prevention programmes on adolescent sexual behaviour: Cluster randomised controlled trials in three sub-Saharan African sites. *Int Health [Internet]*. 2012;4(2):111–22.
 68. Larke N, Sc B, Sc M, Phil D, Cleophas-mazige B, Sc M, et al. Impact of the MEMA kwa

- Vijana Adolescent Sexual and Reproductive Health Interventions on Use of Health Services by Young People in Rural Mwanza, Tanzania : Results of a Cluster Randomized Trial. *J Adolesc Heal* [Internet]. 2010;47(5):512–22.
69. Doyle AM, Ross DA, Maganja K, Baisley K, Masesa C, Plummer ML, et al. Long-Term Biological and Behavioural Impact of an Adolescent Sexual Health Intervention in Tanzania : Follow-up Survey of the Community-Based MEMA kwa Vijana Trial. 2010;7(6).
 70. Plummer ML, Wight D, Obasi AIN, Wamoyi J, Mshana G, Todd J, et al. A process evaluation of a school-based adolescent sexual health intervention in rural Tanzania: The MEMA kwa Vijana programme. *Health Educ Res*. 2007;22(4):500–12.
 71. Central Statistical Office (CSO) [Zambia], Ministry of Health (MOH) [Zambia] and II. Demographic and Health Survey: 2018 Key Indicators. *Demogr Heal Surv* [Internet]. 2018;61.
 72. Zulu JM, Goicolea I, Kinsman J, Sandøy IF, Blystad A, Mulubwa C, et al. Community based interventions for strengthening adolescent sexual reproductive health and rights: How can they be integrated and sustained? A realist evaluation protocol from Zambia. *Reprod Health*. 2018;15(1):1–8.
 73. Banda E, Svanemyr J, Sandøy IF, Goicolea I, Zulu JM. Acceptability of an economic support component to reduce early pregnancy and school dropout in Zambia: a qualitative case study. *Glob Health Action* [Internet]. 2019;12(1).
 74. Petroni S, Steinhaus M, Fenn NS, Stoebenau K, Gregowski A. New Findings on Child Marriage in Sub-Saharan Africa. *Ann Glob Heal* [Internet]. 2017;83(5–6):781–90.
 75. Handa S, Halpern CT, Pettifor A, Thirumurthy H. The Government of Kenya’s cash transfer program reduces the risk of sexual debut among young people age 15-25. *PLoS One*. 2014;9(1).
 76. Kemigisha E, Bruce K, Ivanova O, Leye E, Coene G, Ruzaaza GN, et al. Evaluation of a school based comprehensive sexuality education program among very young adolescents in rural Uganda. *BMC Public Health*. 2019;19(1):1–11.
 77. Svanemyr J, Zulu J, Sandøy IF. Lessons from an intervention trial providing sexual and reproductive health education in Zambia: the perspectives of teachers, health workers and parents. 2021. not published.
 78. Chavula MP, Svanemyr J, Zulu J, Sandøy IF. Experiences of teachers and community health workers implementing sexuality and life skills education in youth clubs in Zambia. 2021. Not published.
 79. Fadnes LT, Taube A, Tylleskär T. The Internet Journal of Epidemiology How to identify information bias due to self-reporting in epidemiological research. *Internet J Epidemiol* [Internet]. 2009;(2).
 80. Hernan MA, Hernandez-Diaz. Beyond the intention to treat in comparative effectiveness reaserch. *NIH Public Access*. 2012;9(1):48–55.

Academic Paper

THE EFFECT OF SEXUAL AND REPRODUCTIVE HEALTH EDUCATION AND COMMUNITY DIALOGUE ON ADOLESCENT PREGNANCY RATES: A CLUSTER RANDOMIZED TRIAL IN A RURAL ZAMBIAN CONTEXT.

Robin Mzati Sinsamala¹ Hanne Keyser Hegdahl^{1,2}, Ingvild Fossgard Sandøy^{1,2}

1 Department of Global Public Health and Primary Care, Centre for International Health,
University of Bergen, Bergen, Norway

2 Centre for Intervention Science in Maternal and Child Health (CISMAC)

Correspondence: rksinsamala@gmail.com

Robin Mzati Sinsamala

University of Bergen

Department of Global Public Health and Primary Care

Centre for International Health

Post Box 7804

NO-5020 BERGEN

NORWAY

Abstract

Background: To date Zambia and other sub-Saharan Africa (SSA) countries are still burdened by high rates of adolescent pregnancy. Sexual and reproductive health (SRH) education has shown impact on knowledge and attitude, but inconsistent effects on behaviour and biological SRH outcomes. Similarly, cash transfer (CT) interventions have shown mixed impacts on adolescent pregnancy. Teenage pregnancy is a strongly association with poverty, school dropout and little SRH knowledge. This study, therefore, measures the effectiveness of economic support and of a combined economic and community intervention on the incidence of pregnancy among adolescents in Zambia.

Methods: This cluster randomized controlled trial included schools in rural Zambian communities as clusters. In total 157 clusters and 4922 girls from grade 7 in the selected schools were recruited. Study arms comprised: 1) economic support, 2) combined economic support and community intervention, 3) control. We used data collected up to the 7th follow up to measure the incidence of pregnancy by the end of the intervention period in 2018. The outcome was compared between the three study arms using intention to treat analysis. Hazards Ratios (HR) were calculated using Parametric Weibull regression models with time since randomization as a time scale.

Results: The participants mean age was 14.1 (SD 1.34). The difference in pregnancy incidence between the combined intervention and control was 17% (HR 0.83 (95% CI 0.68-1.00) and between economic support and control was 16% (HR 0.84 (95% CI 0.69-1.02), and the confidence interval for both estimates included the null value. There was no difference between the combined intervention versus economic support only on pregnancy incidence (HR 0.99 (95% CI 0.83-1.17).

Conclusion: This study indicates that the small differences found in pregnancy incidence between the intervention and control arms was largely due to the economic support intervention. SRH education and community dialogue had no added impact on incidence of pregnancy by the end of the intervention.

Trial registration: ISRCTN registry: ISRCTN12727868, (4 March 2016).

Key words: Adolescents, Cash Transfer, Community dialogue, Economic support, Education, Pregnancy, Randomized controlled trial, Sexual and Reproductive Health

Background

Adolescent pregnancy is a major public health concern in most low- and middle-income countries (LMICs) (1). Estimates show that more than 21 million adolescent girls aged 15-19 years become pregnant every year. As a consequence, more than 16 million births and approximately 3.9 million abortions occur per year among adolescent girls, with 90 percent occurring in LMICs (1–3), and 2.5 million girls under the age of 16 years give birth every year (2). Sub-Saharan Africa (SSA), has the highest adolescent (15-19 years) birth rate at 104 births per 1,000 women per year worldwide (2,8). The United Nations, through the sustainable development goals (SDGs), has recognised the need to prevent adolescent pregnancy since it contributes to high maternal mortality rates, and therefore included reduction of child birth among adolescents on its agenda for 2030 (4).

Complications from early pregnancies are estimated to be the fourth leading cause of death among girls aged 15-19 years (10). Early pregnancy also increases the risk of other adverse maternal and neonatal outcomes like unsafe abortions, preterm delivery, low birth weight and severe neonatal conditions (1,9,10,12,13). Discrimination from parents and peers, and abandonment by their partners due to pregnancy may lead to psychological distress and affect girls mental health (15). Early pregnancy interferes with school attendance leading to high school dropout among teenage girls who might not get the chance to enrol again, consequently affecting prospective income generating opportunities and economic independence, in the long run, leading to intergenerational transmission of poverty (15,18). There is a strong association between sociodemographic factors like education, poverty (or socioeconomic status) and access (or the lack thereof) to sexual and reproductive health

(SRH) services and pregnancy among adolescent girls (1,3,22–25,7,9,10,16,19,19–21). The education status (being in or out of school) is one of the important predictors of pregnancy among teenagers, as adolescents who are in school experience fewer pregnancies, since they are busy with school work and know that it is unacceptable for them to become pregnant, whereas it is much more acceptable for out-of-school girls to get pregnant and married (7). Additionally, adolescent girls with educated parents have a low likelihood of early pregnancy, since they tend to be (socio-economically) better off and can afford to pay for school necessities and the parents act as role models in education attainment, amongst other reasons (26).

Poverty is one of the all-encompassing factors for adolescent pregnancy (27) as it is both a predictor and a consequence of early pregnancies (10,11,20,25). Girls from poor households have an increased risk of school dropout and early marriage compared to those from well-to-do families (27). In SSA, adolescents from poor households face difficult dilemmas as they try to cope with the challenges of being a teenager which often result into engagement in sexual relationships in exchange for money or material needs (1). In some cases parents may parents vaguely suggest to their daughters to find a boyfriend who can provide for their economic needs (16). Practises entombed in certain cultural values influence negative connotations associated with sexuality, contraceptive use and abortion for girls (30).

Sexuality discussions or messages from parents or guardians and other older people in the community are regarded as taboo and are held in secret in most of the African contexts (20). Conversations around sexuality issues are avoided by most parents because they fear that sharing such information will encourage sexual activities among their children (31).

Nevertheless, girls are expected to take control over their own sexuality without proper and clear guidance (32).

In LMICs, negative SRH outcomes can also be attributed to the lack of SRH services as most of these services are either unavailable or inadequate (20). The lack of SRH services is a big contributing factor to the non-use of and misconceptions about contraceptives, potentially leading to early pregnancy (1,7). Existing SRH services can in addition be difficult to access due to barriers perpetrated by religious beliefs, cultural influence and government policies (37).

Economic support interventions known as cash transfers (CT) have been on the rise as a key strategy to address some of the social determinants of health such as poverty. These interventions have been implemented as conditional CT (CCT) or unconditional (UCT) to a certain group of individuals or households to influence behaviour change (39–41). The evidence available so far from SSA has shown mixed impact of cash transfer programs on preventing pregnancy, early marriage, delaying sexual debut, reducing transmission of STIs, and contraception use (39,40). For instance, CT to girls reduced the odds of pregnancy by 84% in the UCT group after 18 months in a trial in Malawi, but the difference disappeared after 2 years (44, 46). In contrast a CT program (CCT) in South Africa did not find any difference on pregnancy, sexual debut or transactional sex among girls (45). A Kenyan national UCT program reduced pregnancy rates by 34% among those that had never given birth before, but no effect was found on early marriage (47).

Building on the findings of these studies it seems like cash support interventions can have beneficial potential in empowering girls in some settings. And keeping girls in school by paying their school fees can help prevent pregnancy, transactional sex, and the need for multiple sexual partners (39). In addition, the interventions can increase school enrolment and attendance among girls. Cash support may relieve some of the expenditure and

consequently improve the household economy during the period of the program (40,48). However, some CT interventions did not find an effect maybe due to the short duration of the intervention or the conditionality of the CT (UCT or CCT). CCT programs would make participants behave according to the prerequisites, for the incentives, but may revert to their old behaviours once the intervention ends. While UCT may result into small impact on behaviour change since participants get the incentives regardless their behaviour.

Globally, information on SRH has been disseminated to young people through education programmes as a means of preventing of SRH problems such as adolescent pregnancy, transmission of HIV/AIDS and sexually transmitted infections (STIs), and early marriages (10,19,54–59,37,38,44,49–53). In SSA, SRH education programmes have shown inconsistent effects on pregnancy, HIV and STIs and other SRH outcomes (50). This could be as a result of problems arising during implementation and delivery of educational programmes, duration and intensity of the intervention, contextual barriers (social, organisational and political setting) which affect the effectiveness of interventions, or because the educational programmes have not been evidence-based (64). Trials done in Zimbabwe (49), South Africa (56, 67) and Tanzania (67, 68) substantiate that the interplay of the aforementioned factors play a crucial role for the effectiveness of SRH education programs.

Study context

According to the recent 2018 Zambia Demographic and Health Survey (ZDHS), overall, 35 percent of adolescent girls have given birth by the time they are 18 years (10, 71). Girls in rural areas experience more pregnancies than those in urban areas. Most girls that get pregnant come from poor households where they cannot afford to provide for school necessities like school fees and uniforms and that result into low secondary school

enrolment rates. School girls who become pregnant often drop out of school and many of them never return although Zambia has had a reenrolment policy since the 1990s (73). Due to widespread myths and cultural taboo surrounding sexuality issues in the community, Zambia introduced a school based comprehensive sexuality education (CSE) program in 2014 to address the SRH needs of young people. However, some challenges have prevented the program from achieving substantial effects. For example, lack of adherence to the program, and lack of guidance on how to integrate the SRH education into the school curriculum (38). As a result, insufficient knowledge on pregnancy risks probably contributes to the stagnation of adolescent pregnancy rates (16).

Community norms also contributes to adolescent pregnancy because they promote early sexual debut. Most girls are expected behave like grownups when they reach puberty and that may subtly send a message that they are ready for sex. Furthermore, initiation ceremonies influence certain sexual behaviour among adolescents, as girls are groomed to be mothers and there is a focus on child bearing roles (74). These norms create nuanced expectations about sexuality and marriage. To live up to these expectations some girls may try it out without proper direction on how to avoid the negative consequences that follow such as teenage pregnancy (20). Further, contraceptives are portrayed as bad in most Zambian communities due to myths around contraceptives use and the perception that those using them are promiscuous. As a result, there is low or non-use which contributes to adolescent fertility (16,38).

Based on findings from the literature and formative research, the Research Initiative to Support the Empowerment of girls (RISE) trial was launched in Zambia in 2016. To target several factors contributing to early pregnancy the trial introduced multicomponent

interventions. This included providing economic support to girls and their families in one arm and combining the economic support with a community component which encompassed youth clubs, to promote SRH knowledge, and community meetings to develop supportive community norms in another intervention arm. The trials primary outcomes were incidence of births within 8 months of the end of the intervention period, incidence of births before girls' 18th birthday and proportion of girls who sit for the grade 9 exams (10). There are many secondary outcomes in the trial and this sub-study measures one of them. We measure the effectiveness of a combined economic and community intervention and of economic support only on the incidence of pregnancy among adolescents in Zambia by the end of the intervention period in 2018.

Methods

Study design

This study used data from the RISE cluster randomized controlled trial which had two intervention arms and one control arm. The clusters were rural schools and surrounding communities. The three arms included: 1) economic support only, 2) combined economic support and community intervention, 3) control arm. The units of randomisation were schools and their surrounding communities in 12 districts of Southern and Central provinces of Zambia. The selected schools were at least 8 km apart and all consisted of primary (grade 1-7) and junior secondary grades (grade 8-9). A detailed description of the methods can be found in the trial protocol paper (10).

Setting and Participants

Included were all adolescent girls in grade 7 in the selected schools who received consent from parents and who assented (<18 years) or consented (≥ 18 years) to take part before randomization. More than 80% of the girls in grade 7 had to assent/consent for a school to be included in the study.

Randomization

After recruitment and baseline interviews, schools were randomized. In total there were six randomization ceremonies, each for two districts. Officials, chiefs, head teachers and PTA chairpersons were invited to the randomization ceremony. Schools were stratified by district and randomized to the three arms of study. For each ceremony, an independent researcher generated 1000 allocations from a computer. The allocations were numbered and tickets corresponding to the allocations were drawn from a box. In this trial the study participants were not masked due to the nature of the intervention (10).

Interventions

One intervention arm contained economic support to girls and parents or guardians. This was in a form of financial support; girls received monthly cash support of 30 Zambian Kwacha (ZMW) and payment of school fees for those in grade 8 to 9 (maximum ZMW 1500 per year) while parents or guardians received yearly cash support of ZMW 350. The other intervention arm combined the economic support with a community intervention. The community intervention included meetings for parents and community members with discussions on girl's education and prevention of early marriage and pregnancy, and establishment of youth clubs (YC) for in- and out-of-school youth, where comprehensive SRH education was given to both participants and their classmates (10). The control arm,

like the other two arms, received writing materials like exercise books, pencils and pens, besides the standard school and health services, as an incentive to participate. The interventions begun in September 2016 and lasted until November 2018.

Outcomes

The main outcome in this analysis was the incidence of pregnancies conceived up to the end of the intervention period. The outcome was measured by combining the responses to the questions “Do you have your own child?”, “Have you ever given birth?” and “Have you ever been pregnant?”. The time of conception was estimated from information on date of birth or end of pregnancy and duration since last menstrual period before the pregnancy. Data collected up to the 7th follow up round in the second half of 2019 was used. Pregnancies that were conceived before randomization were excluded.

Power analysis

We assumed 10 % loss to follow up, giving an average cluster size of 28 girls. We assumed that the cluster number will be intact, i.e., 63 in both intervention arms and 31 in control. We assumed an ICC of 0.00737 for pregnancy before age 16 based on the ICC for “ever pregnant” in the cluster randomized trial in Malawi by Baird et al [personal communication](10). We assumed an average cumulative incidence of pregnancies by the end of the intervention of 26% in the control arm. In the economic arm we assumed a cumulative incidence of 20%, corresponding to a 23% relative reduction compared to the control, and we estimated that this would give us 88% power to detect a difference. In the combined arm we assumed a cumulative incidence of 16%, corresponding to a 38.5% relative reduction compared to the control arm, and we estimated that we would have 99%

power to detect this difference. For the comparison between the combined and economic intervention, we estimated that we would have 80% power to detect a difference if the cumulative incidences were 16% and 20%, respectively.

Data collection

Data was collected by trained research assistants using face-to-face interviews at baseline and then every 6 months for follow up. Those that moved from the study area were interviewed via telephone. From the fourth round, Audio Computer Assisted Survey Instruments (ACASI) were adopted as an additional data collection tool. The data collection tools were translated to the major local languages in the study districts and then back translated to ensure content was maintained.

Statistical analysis

Stata 16 (StataCorp, College Station, TX, USA) software was used to analyse data. Baseline characteristics were summarized using proportions for binary variables and means and standard deviations (SD) for continuous variables. The variable pregnancy was summarized as a cumulative incidence by 15th November 2018. Outcomes were compared between the combined intervention arm, the economic arm and control arm. The primary analysis was by intention to treat (ITT), to report an estimate of the effect of the interventions. The ITT analysis accounted for the design effect of clustering and of the stratified randomization. Survival analysis was used to compare the incidence in the different arms. For all incidence rates, the denominator was person years at risk, and participants who withdrew or were lost to follow-up were right censored at the time when we last received information about them. We analysed data collected up to the 7th follow-up. Initially we intended to use Cox

Proportional Hazard model in the analysis, but the Proportional Hazards assumptions were not satisfied. Therefore, the Parametric Model (Weibull) was employed based on the supposition that the intrinsic data structure of pregnancies was expected to follow its distribution and we presents outputs from both models. We adjusted for age at entry and time since randomization was used as the timescale.

Ethical approval

Ethical approval was given by the University of Zambia Biomedical Research Ethics Committee (ref no 021- 06-15) and the Regional Ethics Committee of Western Norway(REK/ref no 2015/895). Permission to conduct the study was obtained from Ministry of General Education (MoGE), Ministry of Health (MoH) and district education offices in the study districts (10). Parental consent was sought after an information meeting between researchers and parents or guardians. Assent/consent from the girls were sought after they were directly informed. The interviews were conducted in privacy with strict confidentiality.

Results

In total, 157 schools were included in the study from which 4922 girls were recruited. In total 4549 (92.4%) were interviewed in the 7th follow-up and 373 (7.5%) were lost to follow up among the three study arms. The main reasons for the loss to follow up were unavailability of the participants for data collection, e.g., due to transfers to other schools (Figure 1). In total 4909 participants were included in the ITT analysis since we did not have any information after randomization on 13 girls and they were therefore not included in the analysis.

Table 1 shows baseline characteristics for the three study arms. There were no large differences between the three arms at baseline. But more girls (11%) reported to have had a boyfriend in the control arm compared to the other two arms. Age ranged from 10 to 20 with an overall mean age of 14.1 years (SD 1.34).

The cumulative incidence of pregnancy by the end of the intervention period was 26% in both intervention arms and 29% in the control arm (Table 2). The hazard ratio (HR) was 0.83 (95% CI 0.68, 1.00) between the combined intervention arm and control arm, HR 0.84 (95% CI 0.69, 1.02) between economic support only and the control arm and HR 0.99 (95% CI 0.83, 1.17) between the combined intervention arm and economic support only arm (Table 2, Figure 2). Although the confidence intervals included the null value, the data are compatible with 17% and 16% reduction in pregnancy incidence in the combined arm and the economic arm compared to the control group, respectively. The comparison of the two intervention arms, indicated that there was no difference between the combined intervention versus economic support on incidence of pregnancy.

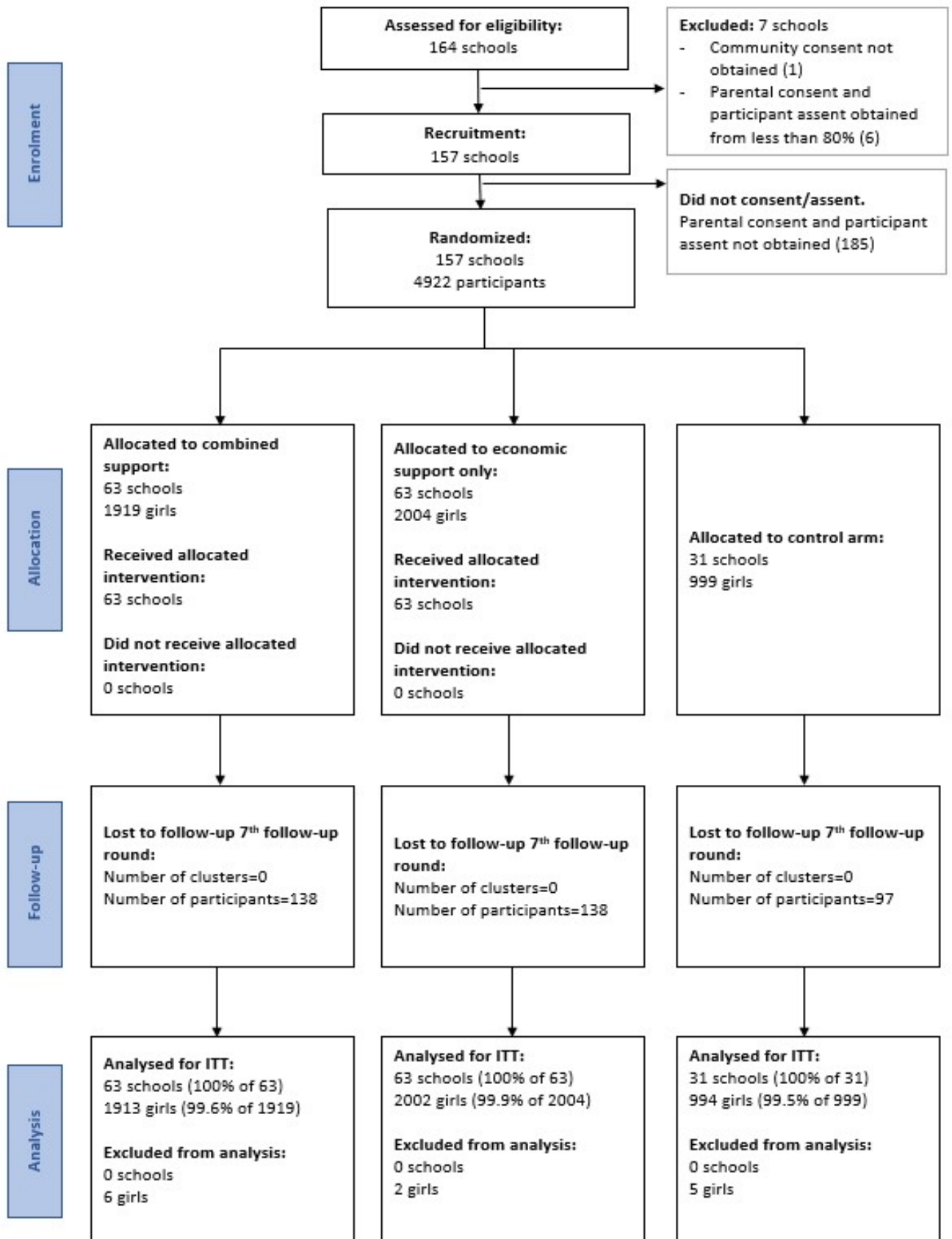


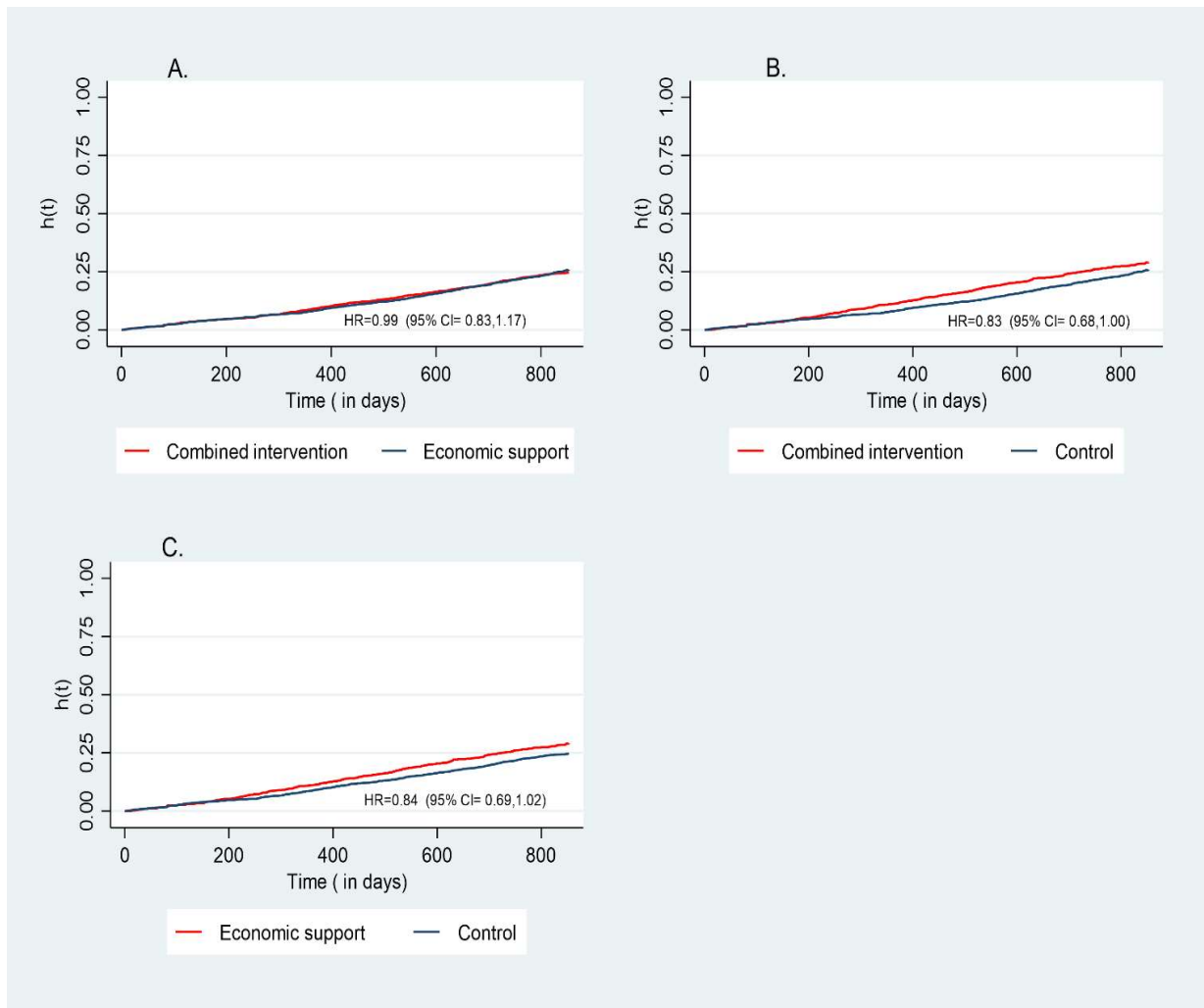
Figure 1. Flow diagram of the cluster randomized trial.

Table 1. Baseline characteristics of the study population

Baseline variables	Total	Combined intervention	Economic support	Control
Cluster, n	157	63	63	31
Participants, n	4922	1919	2004	999
Age, years (mean SD)	14.1 (1.34)	14.0 (1.32)	14.1 (1.38)	14.1 (1.29)
Ever been pregnant, n (%)				
Yes	26 (0.5%)	9 (0.5%)	12 (0.6%)	5 (0.5%)
No	4895 (99%)	1909 (99%)	1992 (99%)	994 (99%)
Missing	1 (0%)	1 (0%)	0 (0%)	0 (0%)
Married, n, (%)				
Yes	6 (0.1%)	1 (0.1%)	4 (0.2%)	1 (0.1%)
No	4915 (100%)	1917 (100%)	2000 (100%)	998 (100%)
Missing	1 (0%)	1 (0.1%)	0 (0%)	0 (0%)
Ever had a boyfriend^a, n (%)				
Yes	439 (9%)	148 (8%)	186 (9%)	105 (11%)
No	4475 (91%)	1768 (92%)	1814 (91%)	893 (90%)
Missing	8 (0.2%)	3 (0.2%)	4 (0.2%)	1 (0.1%)
Girls using contraceptives are at risk of infertility^b, n (%)				
Yes	2134 (43.4%)	820 (43%)	888 (44%)	426 (43%)
No	1642 (33%)	632 (33%)	654 (33%)	356 (36%)
Don't know	1146 (23%)	467 (24%)	462 (23%)	217 (22%)
Can get pregnant three days after menstruation^b, n (%)				
Yes	3162(64%)	1203 (63%)	1311 (65%)	648 (66%)
No	579 (12%)	221 (11.5%)	237 (12%)	121 (12%)
Don't know	1165 (24%)	494 (26%)	456 (23%)	215 (22%)
Missing	16 (0.3%)	1 (0%)	0 (0%)	15 (1.5%)
Highest level of school parent/guardian^c, n (%)				
Never attended	323 (7%)	138 (7%)	119 (6%)	66 (7%)
Primary	2500 (51%)	951 (50%)	995 (50%)	554 (55%)
Secondary	1770 (36%)	702 (37%)	748 (37%)	320 (32%)
Higher than secondary	319 (6.5%)	126 (6.6%)	139 (7%)	54 (5%)
Missing	10 (0.2%)	2 (0.1%)	3 (0.2%)	5 (0.5%)

Percentages may not add up to 100% because of rounding. SD= Standard deviation. ^a Proxy for ever had sex:

Ever had a boyfriend; ^b Proxy for SRH knowledge:1) Do young girls who use contraceptive pills or injections are at risk of becoming infertile, 2) Can a girl get pregnant if she has unprotected sex with a boy 3 days after the end of her menstrual period; ^c Proxy for socioeconomic status: Guardian/parent highest level of education.



A) the combined intervention arm vs economic support arm, B) the combined intervention vs control arm, C) the economic support arm vs the control arm.

Figure 2. Kaplan-Meier failure curves (the incidence of pregnancy) by comparison between the three study arms.

Table 2. Effectiveness of the interventions on pregnancy incidence

	Combined intervention arm (CI) N=1913	Economic support arm (E) N=2002	Control arm (C) N=994	CI vs C HR (95%CI)	E vs C HR (95%CI)	CI vs E HR (95%CI)
Incidence of pregnancy	492 (26%)	517 (26%)	290 (29%)			
Parametric model (Weibull)				0.83 (0.68, 1.00)	0.84 (0.69, 1.02)	0.99 (0.83, 1.17)
Cox PH regression				0.83 (0.68, 1.00)	0.84 (0.68, 1.02)	0.99 (0.84, 1.17)

Discussion

The results indicate a reduction in pregnancy incidence in the intervention arms with a 16% in the economic support intervention and 17% in the combined intervention, compared to the control arm. There was no differences on pregnancy incidence in the combined intervention arm compared to the economic intervention. Our results indicate that SRH education and community dialogue intervention had no added effect beyond the economic support on pregnancy incidence by the end of the intervention period.

Our findings on economic support suggest that the intervention could be useful as a preventive strategy against teenage pregnancy. This may be particularly relevant in SSA even though the available evidence indicate varied effects of such interventions. This is supported by other trials done in SSA that have found results for cash support interventions that are larger than our findings. For example, the Malawi CT trial resulted into a reduction of over 70 % in pregnancy rates after one year of implementation (42). And a Kenyan orphan and vulnerable children (OVC) CT program that found a difference almost double compared to our study on economic support (47). These studies advance the suggestion that cash support programs have the capacity to influence change on early pregnancy.

It is important to note that cash support interventions could offer a plausible addition to pregnancy prevention programs as evidence suggest that economic support reduces the burden of poverty to the household and provide overall economic security (10,47). Cash support has potential to prevent girls from poor households to get married early in order to escape poverty and secure a better economic status for themselves and their family (10,47,75). This indicates that the economic stability offered by cash support to the

households and payment of school fees for girls, can prevent pregnancy. We believe therefore that understanding the pathway through which cash support programs work, for example, knowing necessary threshold of the cash given to induce the outcome, could ensure proper implementation of an appropriate program that can achieve maximum impact. So far the available evidence show that cash support interventions can produce short term impacts but its durability in long term is still unclear (40).

The results from our study did not show any extra protection against adolescent pregnancy by adding SRH education and community dialogue component. This does not imply that SRH education has no potential to achieve better SRH outcomes among adolescents in SSA, as evidence from Europe, United States, Mexico and Nigeria indicates impact on sexual behaviour and biological outcomes like pregnancy (63). Among trials done worldwide, including SSA, clearer effects of SRH education were found on knowledge and attitude than on behaviour, and more studies found effects on behaviour than biological outcomes (50,54,68). Moreover, unpublished finding from RISE show a difference of the community intervention on sexual behaviour than on pregnancy.

Appropriate delivery of sexuality messages is essential for the intervention to have substantial impact, but social cultural norms and values may alienate such messages. This could be the case in our study as qualitative evidence from RISE underline that some facilitators or teachers were confronted by their own cultural beliefs and were uncomfortable when teaching certain topics on SRH (77 not published). For example, it is a widespread perception in our study context that teaching about contraception promotes promiscuity among teenagers, which is a cause of concern for both teachers and parents. As a result, less emphasis may be put on such controversial topics when teaching. Additionally,

it may be difficult for teachers to communicate what seem as rather neutral and technical messages in English but are perceived to have a sensitive and explicit connotations when translated to local languages and could offend learners (77,78 not published). This may be a difficult barrier to overcome and therefore challenges the effectiveness of SRH programs. Further research could delve more into these challenges and establish strategies to overcome them.

The study also included an intervention component on parent and guardians since they play a pivotal role for the SRH of their children. The contribution of parents cannot be underestimated since they are the authority figures in the household and the community. Findings from a cross sectional study using data from this trial indicated that girls' impressions of their parents' willingness and comfort to discuss sexuality topics were associated with parent-child-communication. In addition, the views of the parents on topics such contraceptives encouraged the girls to discuss sexuality matters with their parents (31). Therefore, parents' perceptions on sexuality issues could promote or discourage the assimilation of such messages aiming to influence behaviour change (26,31). Qualitative interviews in the trial sites revealed that some parents emphasized more on the importance of education completion and abstinence from sex without expressing and ignoring the need for comprehensive SRH education (77,78). It might therefore be that the implementation of the intervention was challenged by a certain level of reluctance and scepticism from parents. The conservative stance on sexuality matters from some parents affects proper communication with their children.

Further, qualitative evidence from this trial indicate that some parents were unhappy with the inclusion of contraceptive messages in the program, but some of the teachers and

facilitators managed to deliver lessons about the use of contraceptives regardless (78). This is in line with another qualitative study done in a similar setting in Zambia that showed that parents were against teaching of certain components of SRH education as they regarded such topics as reserved and only to be taught by the village elders (38). In that regard it could be likely that some teachers would want to avoid confrontation with parents and focus on abstinence only messages even though some of their pupils are sexually active (77). Since it takes time to transform behaviours that are strongly rooted in the socio-cultural structures of the community and that have been practised for a long time, it might therefore be unrealistic to expect immediate impact on community norms within the two years of the intervention. Additionally, it could be that the SRH education component did not make a difference because participants from the other arms were exposed to some sexuality education through the already existing comprehensive sexuality education curriculum in schools.

Strengths and Limitations

The strength of this cluster randomized trial is that the intervention packages of this trial were carefully designed and implemented predicated on the contextual assessment, discussions with different key stakeholders and literature review, which indicated that a multicomponent program was likely to have a greater impact on adolescent SRH outcomes. In addition, there was good follow-up of the participants. The findings can possibly be extrapolated to the rural population among adolescent girls in Zambia as there was no stringent exclusion criteria, and those who dropped out of school or married during the intervention were still included in the analysis which made the results more applicable to the real world.

As with all cluster randomized trials, ours has also some limitations. Firstly, the outcome was measured through self-reporting and it is reasonable to suspect information bias, that includes recall bias and social desirability bias (79). The source of recall bias in our study could be from erroneous responses to retrospective questions. To minimize recall bias participants were contacted regularly (every 6 months) to respond to questions on pregnancy and other outcomes of the trial. The motivation to give socially acceptable responses by participants when responding to questionnaires could be a source of social desirability bias in this study. As it is not an uncommon phenomenon with self-reported data that participants tend to reply based on what is the acceptable viewpoint in the community than what is actual on the ground, which can affect the validity of data. To preserve their reputation, participants could have given responses that presented their best status to the interviewer by giving false information, leaving out some information and modifying the responses (79). To reduce social desirability bias, the Audio Computer Assisted Survey Instruments (ACASI) was adopted as an interview tool to ensure the best possible privacy when answering the questionnaires.

Secondly, we did not have a quantitative measure for the fidelity of the SRH education since we did not know whether the content for YC meetings was delivered as intended without leaving out topics like contraceptive use which could have affected how well the intervention worked. The qualitative interviews indicate that most teachers delivered the intervention as intended. Finally, there could be a potential risk of contamination since the schools were only 8 km apart and it could be possible that participants from different study arms interacted. And if those in the economic support and control groups got exposed to the community intervention, effect estimates for this intervention could be affected. We employed intention to treat analysis to provide a balanced comparison among the arms, but

the treatment effects could have been underestimated if some participants were not exposed to the community intervention or did not receive the economic intervention because they moved away. Therefore, an alternative approach would have been to estimate the effect in an “as treated” analysis after adjusting for confounders (80).

Conclusion

Evidence presented in this study shows that differences found on pregnancy incidence was largely due to the economic support only intervention. The SRH education and community dialogue did not offer extra protection against teenage pregnancy. This demonstrate that economic support programs can be a viable alternative in dealing with teenage pregnancy since they address a dominant determinant of health (poverty).

References

1. Yakubu I, Salisu WJ. Determinants of adolescent pregnancy in sub-Saharan Africa: A systematic review. *Reprod Health*. 2018;15(1).
2. WHO. Recommendations on adolescent sexual and reproductive health and rights. 2017. 1–88 p.
3. Wado YD, Sully EA, Mumah JN. Pregnancy and early motherhood among adolescents in five East African countries: A multi-level analysis of risk and protective factors. *BMC Pregnancy Childbirth*. 2019;19(1):1–11.
4. World Health Organization. Reducing early and unintended pregnancies among adolescents. *Fam Plann*. 2016;1–4.
5. Gausman J, Langer A, Austin SB, Subramanian S V. Contextual Variation in Early Adolescent Childbearing: A Multilevel Study From 33,822 Communities in 44 Low- and Middle-Income Countries. *J Adolesc Heal [Internet]*. 2019;64(6):737–45.
6. Kamal SMM, Hassan CH, Alam GM, Ying Y. Child marriage in Bangladesh: Trends and determinants. *J Biosoc Sci*. 2015;47(1):120–39.
7. Munakampe MN, Zulu JM, Michelo C. Contraception and abortion knowledge, attitudes and practices among adolescents from low and middle-income countries: A systematic review. *BMC Health Serv Res*. 2018;18(1):1–13.
8. UNFPA. United Nations Population Fund UNFPA Strategic Plan 2018–2021. 2018;1–38.
9. Ganchimeg T, Ota E, Morisaki N, Laopaiboon M, Lumbiganon P, Zhang J, et al. Pregnancy and childbirth outcomes among adolescent mothers: a World Health Organization multicountry study. *BJOG*. 2014;121 Suppl:40–8.
10. Sandøy IF, Mudenda M, Zulu J, Munsaka E, Blystad A, Makasa MC, et al. Effectiveness of a girls' empowerment programme on early childbearing, marriage and school dropout among adolescent girls in rural Zambia: Study protocol for a cluster randomized trial. *Trials [Internet]*. 2016;17(1):1–15.
11. Liang M, Simelane S, Fortuny Fillo G, Chalasani S, Weny K, Salazar Canelos P, et al. The State of Adolescent Sexual and Reproductive Health. *Journal of Adolescent Health*. 2019.
12. Karataşlı V, Kanmaz AG, İnan AH, Budak A, Beyan E. Maternal and neonatal outcomes of adolescent pregnancy. *J Gynecol Obstet Hum Reprod*. 2019;48(5):347–50.
13. Fall CHD, Sachdev HS, Osmond C, Restrepo-Mendez MC, Victora C, Martorell R, et al. Association between maternal age at childbirth and child and adult outcomes in the offspring: A prospective study in five low-income and middle-income countries (COHORTS collaboration). *Lancet Glob Heal [Internet]*. 2015;3(7):e366–77.
14. Marino JL, Lewis LN, Bateson D, Hickey M, Skinner SR. Teenage mothers. *Aust Fam Physician*. 2016;45(10):712–7.

15. Kumar M, Huang K-Y, Othieno C, Wamalwa D, Madeghe B, Osok J, et al. Adolescent Pregnancy and Challenges in Kenyan Context: Perspectives from Multiple Community Stakeholders. *Glob Soc Welf* [Internet]. 2018 Mar 25;5(1):11–27.
16. Svanemyr J. Adolescent pregnancy and social norms in Zambia. *Cult Heal Sex* [Internet]. 2019;0(0):1–15.
17. Çift T, Korkmazer E, Temur M, Bulut B, Korkmaz B, Ozdenoğlu O, et al. Adolescent pregnancies: Complications, birth outcomes and the possible solutions. *Ginekol Pol*. 2017;88(7):393–7.
18. Salam RA, Faqqah A, Sajjad N, Lassi ZS, Das JK, Kaufman M, et al. Improving Adolescent Sexual and Reproductive Health: A Systematic Review of Potential Interventions. *J Adolesc Heal*. 2016;59(2):S11–28.
19. Dongarwar D, Salihu HM. Influence of Sexual and Reproductive Health Literacy on Single and Recurrent Adolescent Pregnancy in Latin America. *J Pediatr Adolesc Gynecol* [Internet]. 2019;32(5):506–13.
20. Menon JA, Kusanthan T, Mwaba SOC, Juanola L, Kok MC. “Ring” your future, without changing diaper - Can preventing teenage pregnancy address child marriage in Zambia? *PLoS One*. 2018;13(10):1–17.
21. Chirwa GC, Mazalale J, Likupe G, Nkhoma D, Chiwaula L, Chintsanya J. An evolution of socioeconomic related inequality in teenage pregnancy and childbearing in Malawi. *PLoS One*. 2019;14(11):1–16.
22. Knopf AS, McNealy KR, Al-Khattab H, Carter-Harris L, Oruche UM, Naanyu V, et al. Sexual learning among East African adolescents in the context of generalized HIV epidemics: A systematic qualitative meta-synthesis. *PLoS One*. 2017;12(3):1–20.
23. Svanemyr J, Amin A, Robles OJ, Greene ME. Creating an enabling environment for adolescent sexual and reproductive health: A framework and promising approaches. *J Adolesc Heal* [Internet]. 2015;56(1):S7–14.
24. Pradhan R, Wynter K, Fisher J. Factors associated with pregnancy among adolescents in low-income and lower middle-income countries: A systematic review. *J Epidemiol Community Health*. 2015;69(9):918–24.
25. Nguyen PH, Scott S, Neupane S, Tran LM, Menon P. Social, biological, and programmatic factors linking adolescent pregnancy and early childhood undernutrition: a path analysis of India’s 2016 National Family and Health Survey. *Lancet Child Adolesc Heal* [Internet]. 2019;3(7):463–73.
26. Kassa GM, Arowojolu AO, Odukogbe AA, Yalew AW. Prevalence and determinants of adolescent pregnancy in Africa: A systematic review and Meta-analysis 11 *Medical and Health Sciences* 1117 *Public Health and Health Services*. *Reprod Health*. 2018;15(1):1–17.
27. Joint United Nations Programme on HIV/AIDS (UNAIDS), African Union (AU). Empower young women and adolescents girls: Fast-tracking the end of the AIDS epidemic in Africa. 2015;32.

28. Ezekwe AC. African Research Review. Int Multi-disciplinary. 2018;12(50):135–42.
29. Asare BYA, Baafi D, Dwumfour-Asare B, Adam AR. Factors associated with adolescent pregnancy in the Sunyani Municipality of Ghana. Int J Africa Nurs Sci. 2019;10(July 2018):87–91.
30. Håkansson M, Oguttu M, Gemzell-Danielsson K, Makenzius M. Human rights versus societal norms: A mixed methods study among healthcare providers on social stigma related to adolescent abortion and contraceptive use in Kisumu, Kenya. BMJ Glob Heal. 2018;3(2):1–13.
31. Isaksen KJ, Musonda P, Sandøy IF. Parent-child communication about sexual issues in Zambia: a cross sectional study of adolescent girls and their parents. BMC Public Health. 2020;20(1):1–12.
32. Ninsiima AB, Leye E, Michielsen K, Kemigisha E, Nyakato VN, Coene G. “Girls have more challenges; they need to be locked up”: A qualitative study of gender norms and the sexuality of young adolescents in Uganda. Int J Environ Res Public Health. 2018;15(2).
33. Kenny L, Koshin H, Sulaiman M, Cislaghi B. Adolescent-led marriage in Somaliland and Putland: A surprising interaction of agency and social norms. J Adolesc [Internet]. 2019;72(January):101–11.
34. Moreau C, Li M, De Meyer S, Vu Manh L, Guiella G, Acharya R, et al. Measuring gender norms about relationships in early adolescence: Results from the global early adolescent study. SSM - Popul Heal. 2019;7(October 2018).
35. Okigbo CC, Speizer IS, Domino ME, Curtis SL, Halpern CT, Fotso JC. Gender norms and modern contraceptive use in urban Nigeria: A multilevel longitudinal study. BMC Womens Health. 2018;18(1):1–17.
36. Stoebenau K, Kyegombe N, Bingenheimer JB, Ddumba-Nyanzi I, Mulindwa J. Developing Experimental Vignettes to Identify Gender Norms Associated With Transactional Sex for Adolescent Girls and Young Women in Central Uganda. J Adolesc Heal [Internet]. 2019;64(4):S60–6.
37. Rokicki S, Fink G. Assessing the reach and effectiveness of mHealth: Evidence from a reproductive health program for adolescent girls in Ghana. BMC Public Health. 2017;17(1):1–14.
38. Zulu JM, Blystad A, Haaland MES, Michelo C, Haukanes H, Moland KM. Why teach sexuality education in school? Teacher discretion in implementing comprehensive sexuality education in rural Zambia. Int J Equity Health. 2019;18(1):1–10.
39. Bastagli F, Hagen-Zanker J, Harman L, Barca V, Sturge G, Schmidt T. The Impact of Cash Transfers: A review of the evidence from low- and middle-income countries. J Soc Policy. 2019;48(3):569–94.
40. Owusu-Addo E, Renzaho AMN, Smith BJ. The impact of cash transfers on social determinants of health and health inequalities in sub-Saharan Africa: A systematic review. Health Policy Plan. 2018;33(5):675–96.

41. Cooper JE, Benmarhnia T, Koski A, King NB. Cash transfer programs have differential effects on health: A review of the literature from low and middle-income countries. *Soc Sci Med* [Internet]. 2020;247(October 2019):112806.
42. Experiments N. Editorial Identification of Treatment Effects. 2008;1131(2007):1127–31.
43. De Walque D, Dow WH, Nathan R, Abdul R, Abilahi F, Gong E, et al. Incentivising safe sex: A randomised trial of conditional cash transfers for HIV and sexually transmitted infection prevention in rural Tanzania. *BMJ Open*. 2012;2(1).
44. Baird SJ, Garfein RS, McIntosh CT, Özler B. Effect of a cash transfer programme for schooling on prevalence of HIV and herpes simplex type 2 in Malawi: A cluster randomised trial. *Lancet* [Internet]. 2012;379(9823):1320–9.
45. Pega F, Walter S, Liu SY, Pabayo R, Lhachimi SK, Saith R. Unconditional cash transfers for reducing poverty and vulnerabilities: Effect on use of health services and health outcomes in low- and middle-income countries. *Cochrane Database Syst Rev*. 2014;2014(6).
46. Baird S, McIntosh C, Özler B. Cash or condition? Evidence from a cash transfer experiment. *Q J Econ*. 2011;126(4):1709–53.
47. Handa S, Peterman A, Huang C, Halpern C, Pettifor A, Thirumurthy H. Impact of the Kenya Cash Transfer for Orphans and Vulnerable Children on early pregnancy and marriage of adolescent girls. *Soc Sci Med* [Internet]. 2015;141:36–45.
48. Owusu-Addo E. Perceived impact of Ghana’s conditional cash transfer on child health. *Health Promot Int*. 2016;31(1):33–43.
49. Cowan FM, Pascoe SJ, Langhaug LF, Mavhu W, Chidiya S, Jaffar S, et al. The Regai Dzive Shiri project: results of a randomized trial of an HIV prevention intervention for youth. *AIDS* [Internet]. 2010 Oct;24(16):2541–52.
50. Jemmott JB, Jemmott LS, O’Leary A, Ngwane Z, Lewis DA, Bellamy SL, et al. HIV/STI risk-reduction intervention efficacy with South African adolescents over 54 months. *Heal Psychol* [Internet]. 2015;34(6):610–21.
51. Mwilike B, Shimoda K, Oka M, Leshabari S, Shimpuku Y, Horiuchi S. A feasibility study of an educational program on obstetric danger signs among pregnant adolescents in Tanzania: A mixed-methods study. *Int J Africa Nurs Sci* [Internet]. 2018;8(February):33–43.
52. Borawski EA, Tufts KA, Trapl ES, Hayman LL, Yoder LD, Lovegreen LD. Effectiveness of Health Education Teachers and School Nurses Teaching Sexually Transmitted Infections/Human Immunodeficiency Virus Prevention Knowledge and Skills in High School. *J Sch Health* [Internet]. 2015 Mar;85(3):189–96.
53. Menna T, Ali A, Worku A. Effects of peer education intervention on HIV/AIDS related sexual behaviors of secondary school students in Addis Ababa, Ethiopia: A quasi-experimental study. *Reprod Health* [Internet]. 2015;12(1):1–8.
54. Mmbaga EJ, Kajula L, Aarø LE, Kilonzo M, Wubs AG, Eggers SM, et al. Effect of the

- PREPARE intervention on sexual initiation and condom use among adolescents aged 12-14: A cluster randomised controlled trial in Dar es Salaam, Tanzania. *BMC Public Health*. 2017;17(1):1–10.
55. Morales A, Espada JP, Orgilés M. A 1-year follow-up evaluation of a sexual-health education program for Spanish adolescents compared with a well-established program. *Eur J Public Health*. 2016;26(1):35–41.
 56. Alzate MM, Dongarwar D, Matas JL, Salihu HM. The Effect of Sexual Literacy on Adolescent Pregnancy in Colombia. *J Pediatr Adolesc Gynecol*. 2019;
 57. Fonner VA, Armstrong KS, Kennedy CE, O'Reilly KR, Sweat MD. School based sex education and HIV prevention in low and middle-income countries: A systematic review and meta-analysis. *PLoS One*. 2014;9(3).
 58. Duflo E, Dupas P, Kremer M. Education, HIV, and Early Fertility: Experimental Evidence from Kenya. *Am Econ Rev [Internet]*. 2015 Sep;105(9):2757–97.
 59. Knopf AS, McNealy KR, Al-Khattab H, Carter-Harris L, Oruche UM, Naanyu V, et al. Sexual learning among East African adolescents in the context of generalized HIV epidemics: A systematic qualitative meta-synthesis. *PLoS One [Internet]*. 2017;12(3):1–20.
 60. Vanwesenbeeck I, Westeneng J, de Boer T, Reinders J, van Zorge R. Lessons learned from a decade implementing Comprehensive Sexuality Education in resource poor settings: The World Starts With Me. *Sex Educ [Internet]*. 2016;16(5):471–86.
 61. Underhill K, Operario D, Montgomery P. Abstinence-only programs for HIV infection prevention in high-income countries. *Cochrane Database Syst Rev*. 2007;(4).
 62. Oringanje C, Mm M, Eko H, Esu E, Meremikwu A, Je E. Interventions for preventing unintended pregnancies among adolescents (Review) summary of findings for the main comparison. 2016;(2).
 63. United Nations Educational S and CO. Comprehensive s e x u a l i t y e d u c a t i o n . 2015.
 64. Rychetnik L, Frommer M, Hawe P, Shiell A. interventions. 2006;119–27.
 65. Pfadenhauer LM, Gerhardus A, Mozygemba K, Lysdahl KB, Booth A, Hofmann B, et al. Making sense of complexity in context and implementation: The Context and Implementation of Complex Interventions (CICI) framework. *Implement Sci*. 2017;12(1):1–18.
 66. Pettifor A, MacPhail C, Hughes JP, Selin A, Wang J, Gómez-Olivé FX, et al. The effect of a conditional cash transfer on HIV incidence in young women in rural South Africa (HPTN 068): a phase 3, randomised controlled trial. *Lancet Glob Heal*. 2016;4(12):e978–88.
 67. Mathews C, Aarø LE, Grimsrud A, Flisher AJ, Kaaya S, Onya H, et al. Effects of the SATZ teacher-led school HIV prevention programmes on adolescent sexual behaviour: Cluster randomised controlled trials in three sub-Saharan African sites. *Int Health [Internet]*. 2012;4(2):111–22. Available from:

<http://dx.doi.org/10.1016/j.inhe.2012.02.001>

68. Larke N, Sc B, Sc M, Phil D, Cleophas-mazige B, Sc M, et al. Impact of the MEMA kwa Vijana Adolescent Sexual and Reproductive Health Interventions on Use of Health Services by Young People in Rural Mwanza, Tanzania : Results of a Cluster Randomized Trial. *J Adolesc Heal* [Internet]. 2010;47(5):512–22.
69. Doyle AM, Ross DA, Maganja K, Baisley K, Masesa C, Plummer ML, et al. Long-Term Biological and Behavioural Impact of an Adolescent Sexual Health Intervention in Tanzania : Follow-up Survey of the Community-Based MEMA kwa Vijana Trial. 2010;7(6).
70. Plummer ML, Wight D, Obasi AIN, Wamoyi J, Mshana G, Todd J, et al. A process evaluation of a school-based adolescent sexual health intervention in rural Tanzania: The MEMA kwa Vijana programme. *Health Educ Res*. 2007;22(4):500–12.
71. Central Statistical Office (CSO) [Zambia], Ministry of Health (MOH) [Zambia] and II. Demographic and Health Survey: 2018 Key Indicators. *Demogr Heal Surv* [Internet]. 2018;61.
72. Zulu JM, Goicolea I, Kinsman J, Sandøy IF, Blystad A, Mulubwa C, et al. Community based interventions for strengthening adolescent sexual reproductive health and rights: How can they be integrated and sustained? A realist evaluation protocol from Zambia. *Reprod Health*. 2018;15(1):1–8.
73. Banda E, Svanemyr J, Sandøy IF, Goicolea I, Zulu JM. Acceptability of an economic support component to reduce early pregnancy and school dropout in Zambia: a qualitative case study. *Glob Health Action* [Internet]. 2019;12(1).
74. Petroni S, Steinhaus M, Fenn NS, Stoebenau K, Gregowski A. New Findings on Child Marriage in Sub-Saharan Africa. *Ann Glob Heal* [Internet]. 2017;83(5–6):781–90.
75. Handa S, Halpern CT, Pettifor A, Thirumurthy H. The Government of Kenya’s cash transfer program reduces the risk of sexual debut among young people age 15-25. *PLoS One*. 2014;9(1).
76. Kemigisha E, Bruce K, Ivanova O, Leye E, Coene G, Ruzaaza GN, et al. Evaluation of a school based comprehensive sexuality education program among very young adolescents in rural Uganda. *BMC Public Health*. 2019;19(1):1–11.
77. Svanemyr J, Zulu J, Sandøy IF. Lessons from an intervention trial providing sexual and reproductive health education in Zambia: the perspectives of teachers, health workers and parents. 2021. not published.
78. Chavula MP, Svanemyr J, Zulu J, Sandøy IF. Experiences of teachers and community health workers implementing sexuality and life skills education in youth clubs in Zambia. 2021. Not published.
79. Fadnes LT, Taube A, Tylleskär T. The Internet Journal of Epidemiology How to identify information bias due to self-reporting in epidemiological research. *Internet J Epidemiol* [Internet]. 2009;(2).
80. Hernan MA, Hernandez-Diaz. Beyond the intention to treat in comparative

effectiveness reaserch.NIH Public Access. 2012;9(1):48–55.

Annexes

ANNEX 1



THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: 260-1-256067
Telegrams: UNZA, LUSAKA
Telex: UNZALU ZA 44370
Fax: + 260-1-250753
E-mail: unzarec@unza.zm

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

Assurance No. FWA00000338
IRB00001131 of IORG0000774

7th September, 2015.

Our Ref: 021-06-15.

Dr. Patrick Musonda,
University of Zambia,
Department of Public Health,
P.O Box 50110,
Lusaka.

Dear Dr. Musonda,

RE: RESUBMITTED RESEARCH PROPOSAL: "RANDOMIZED CLUSTER TRIAL ON THE EFFECTIVENESS OF A GIRL EMPOWERMENT PROGRAMME ON EARLY CHILDBEARING, MARRIAGE AND SCHOOL DROPOUT AMONG ADOLESCENT GIRLS IN RURAL ZAMBIA" (REF. NO. 021-06-15)

The above-mentioned research proposal was presented to the Biomedical Research Ethics Committee on 18th August, 2015. The proposal is approved.

CONDITIONS:

- This approval is based strictly on your submitted proposal. Should there be need for you to modify or change the study design or methodology, you will need to seek clearance from the Research Ethics Committee.
- If you have need for further clarification please consult this office. Please note that it is mandatory that you submit a detailed progress report of your study to this Committee every six months and a final copy of your report at the end of the study.
- Any serious adverse events must be reported at once to this Committee.
- Please note that when your approval expires you may need to request for renewal. The request should be accompanied by a Progress Report (Progress Report Forms can be obtained from the Secretariat).
- **Ensure that a final copy of the results is submitted to this Committee.**

Yours sincerely,

M.C Maimbolwa PhD
CHAIRPERSON

Date of approval: 7th September, 2015.

Date of expiry: 6th September, 2016.

ANNEX 2

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Øyvind Straume	55978496	09.09.2015	2015/895/REK vest
			Deres dato:	Deres referanse:
			12.05.2015	

Vår referanse må oppgis ved alle henvendelser

Ingvild Fossgard Sandøy

Senter for internasjonal helse/Institutt for global helse og samfunnsmedisin
Univ i Bergen

2015/895 Klyngerandomisert studie på effekten av å styrke jenters posisjon på tidlig svangerskap, ekteskap og skolefravall blant tenåringsjenter i rurale Zambia

Forskningsansvarlig: University of Zambia, University of Bergen

Prosjektleder: Ingvild Fossgard Sandøy

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK vest) i møtet 20.08.2015. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikkloven § 4.

Prosjektomtale

The aim of this cluster randomized trial, in which schools will be randomly allocated to one of two intervention arms or a control arm, is to measure (1) the effectiveness of providing a unique package of economic support to girls and their families that targets both the poverty dimension and the school drop-out dimension of adolescent pregnancy and marriage in a Zambian context, and (2) whether economic support combined with a community approach targeting social norms and sexual and reproductive health knowledge can have an even stronger impact on the same outcomes.

Vurdering

With reference to your application and your response to the remarks from REK vest, the committee reviewed the application again in their meeting on the 20th of August 2015. In addition, the committee has obtained an expert review.

The expert review concludes that it is not advisable just to drop the control arm with no intervention, but to reassess the intervention provided in the other groups. In Your response, you stress that in order to determine whether the economic support makes a difference, it is important to have a control group which is offered the same standard of services as girls in Zambia are being offered at present and are likely to be offered during the coming date.

The committee concludes that the project can be carried out according to the application. However, the committee assumes that the expert conclusions are taken into consideration as best they can.

Research project end date: 31.12.2019.

Vedtak

REK vest approve the project according to the application.

Sluttmelding og søknad om prosjektendring

Prosjektleder skal sende sluttmelding til REK vest på eget skjema senest 30.06.2020, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK vest dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang

Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Ansgar Berg
Prof. Dr.med
Komitéleder

Arne Salbu
sekretariatsleder

Kopi til:gomafm@unza.zm; postmottak@uib.no

ANNEX 3

RISE BASELINE SURVEY QUESTIONNAIRE 2016

Instructions for interviewer/supervisors:

- i. This interview will be conducted immediately after the Case record form has been filled in
- ii. Inform the participant that this is not a test and that there are no right or wrong answers. Ask the participant to be honest in her answers, and not to give answers that she thinks we want. We need to know what young people really think to develop the best programmes to empower girls.
- iii. Do not read response options to the respondent unless the question tells you to do so.

- Study ID number
- Date and time of data collection *(should be entered automatically)*

Any information you give me during this interview will be kept confidential, and your name will not be recorded together with this information. So please be honest when you respond.

SECTION A: DEMOGRAPHIC DATA

1. How many persons living in your household* are below 18 years?

**A household is a group of people who live together and have meals together and they have one person they identify as head. Persons who are temporarily away, such as at boarding school, should also be counted.*

2. How many persons living in your household are 18 years or above?

3. Are any of your biological parents living with you?

- Yes
- No

4. Is your biological mother alive? *(skip if living with biological mother)*

- Yes
- No

5. Is your biological father alive? *(skip if living with biological father)*

- Yes
- No

6. What is the main material of the floor in your house?

- Natural floor (earth, sand, dung)
- Rudimentary floor (wood planks, bamboo)

- Finished floor (parquet or polished wood, vinyl, ceramic tiles, concrete cement, carpet)

7. What is the main material of the roof of your house?

- Natural roofing (no roof, thatch, palm leaf)
- Rudimentary roofing (rustic mat, palm/bamboo, wood planks, cardboard)
- Finished roofing (metal/iron sheets, wood, calamine/cement fibre/asbestos, ceramic tiles, cement roofing shingles, mud tiles)

8. Do you have any of the following in your home?

a) Mobile phone

- Yes
- No

b) Radio

- Yes
- No

c) Television

- Yes
- No

d) Refrigerator

- Yes
- No

e) Electricity

- Yes
- No

f) Bicycle

- Yes
- No

g) Plough

- Yes
- No

h) Animal-drawn cart

- Yes

No

i) Cattle

Yes

No

If no to 8i, skip q9

9. How many cattle does your household have? ____

10. Does any member of your household own# any agricultural land?

Yes

No

#Includes customary land

11. These days, would you say that this household usually has enough food to eat, sometimes has enough food to eat, seldom has enough food to eat, or never has enough food to eat?

Usually/always

Sometimes

Seldom

Never

12. How many meals, excluding snacks, do you normally have in a day? __

13. In the last one week, did you or any member of your household have to go to bed hungry because you didn't have enough food to eat?

Yes

No

14. Last week, did you use

Lotion

Yes

No

Soap

Yes

No

Make-up

Yes

No

If no to 14 a-c, skip q 15

15. If you used any of the items above, who paid for this?

- Your father
- Your mother
- Someone else in the family
- Your boyfriend
- Yourself
- Other, specify _____

16. Who do you ask if you need money?

- Your father
- Your mother
- Someone else in the family
- Your boyfriend
- No one
- Other, specify _____

17. If there is a need to provide a clarification, please add it here:

SECTION B: EDUCATION BACKGROUND/DATA

18. How old were you when you first enrolled in grade 1? ___ years

19. Have you repeated any grade?

Yes

No

20. What kind of transport did you use to come to school today? *If did not attend school today, ask about the last time she attended school.*

- Walk
- Cycle
- Bus
- Motorcycle
- Car
- Other. Specify _____

21. How long did it take you to get to school from your home today (in minutes)? *If did not attend school today, ask about the last time she attended school.*

.....

22. Are you a boarder?

Yes

No (*If No, skip the next two questions*)

23. What type of a boarder are you?

Weekly

Monthly

Termly

24. Is there an adult supervising the boarding facility?

Yes

No

25. How far do you expect that you will go in your education?

Complete grade 7

Complete grade 9

Complete grade 12

Go to college or university

Don't know

26. If you had enough money to pay school fees and could choose freely, how far would you wish to go in your education?

Complete grade 7

Complete grade 9

Complete grade 12

Go to college or university

Don't know

We would like to know whether you agree or disagree with the following statements about education. Do you agree very much, agree, neither agree nor disagree, disagree, or disagree very much with the statements I will read?

27. My mother thinks that it is important for me to continue to junior secondary school and complete grade 9.

1 *Strongly agree/agree very much*

2 *Agree*

- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much
- Does not have a mother

28. My father thinks that it is important for me to continue to junior secondary school and complete grade 9..

- 1 Strongly agree/agree very much
- 2 Agree
- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much
- Does not have a father

29. If I complete grade 9, I will significantly increase my future income.

- 1 Strongly agree/agree very much
- 2 Agree
- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much

30. If I complete grade 9, I will benefit even if it doesn't increase my future income.

- 1 Strongly agree/agree very much
- 2 Agree
- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much

SECTION C: KNOWLEDGE, BELIEFS AND NORMS TO PREGNANCY, MARRIAGE, CONTRACEPTIVES AND STIs

Below are some statements on pregnancy, family planning and sexually transmitted infections. Are these statements correct or not correct in your opinion?

Knowledge

31. Young girls who use contraceptive pills or injections are at risk of becoming infertile.

- Yes/Correct
- No/Not correct

I don't know

32. A girl can get pregnant if she has unprotected sex with a boy three days after the end of her menstrual period.

Yes/Correct

No/Not correct

I don't know

33. When a girl uses contraceptive pills or the injection for family planning, this protects her against sexually transmitted infections (STI).

Yes/Correct

No/Not correct

I don't know

Beliefs and norms

We would like to know whether you agree or disagree with the following statements about education. Do you agree very much, agree, neither agree nor disagree, disagree, or disagree very much with the statements I will read?

34. In my school, most learners my age have had sexual intercourse.

1 Strongly agree/agree very much

2 Agree

3 Neither agree nor disagree

4 Disagree

5 Strongly disagree/disagree very much

35. In my school, most learners do not use a condom if they have sexual intercourse.

1 Strongly agree/agree very much

2 Agree

3 Neither agree nor disagree

4 Disagree

5 Strongly disagree/disagree very much

36. Girls below 18 years of age who have a child are treated with more respect than girls below 18 years who do not have a child.

1 Strongly agree/agree very much

- 2 Agree
- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much

37. Girls below 18 years of age who have a child are a significant economic burden to their family.

- 1 Strongly agree/agree very much
- 2 Agree
- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much

38. Overall it is better for girls to have a child before their 18th birthday than to wait until later.

- 1 Strongly agree/agree very much
- 2 Agree
- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much

39. My mother would strongly disapprove if I became pregnant now.

- 1 Strongly agree/agree very much
- 2 Agree
- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much
- Does not have a mother

40. My father would strongly disapprove if I became pregnant now.

- 1 Strongly agree/agree very much
- 2 Agree
- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much
- Does not have a father

41. My neighbours would strongly disapprove if I became pregnant now.

- 1 *Strongly agree/agree very much*
- 2 *Agree*
- 3 *Neither agree nor disagree*
- 4 *Disagree*
- 5 *Strongly disagree/disagree very much*

42. If I become a mother before my 18th birthday, adults will treat me with more respect.

- 1 *Strongly agree/agree very much*
- 2 *Agree*
- 3 *Neither agree nor disagree*
- 4 *Disagree*
- 5 *Strongly disagree/disagree very much*

43. If I become a mother before my 18th birthday, I will become a significant economic burden to my family.

- 1 *Strongly agree/agree very much*
- 2 *Agree*
- 3 *Neither agree nor disagree*
- 4 *Disagree*
- 5 *Strongly disagree/disagree very much*

44. Overall it will be better for me if I have a child before I am 18 than to wait until later.

- 1 *Strongly agree/agree very much*
- 2 *Agree*
- 3 *Neither agree nor disagree*
- 4 *Disagree*
- 5 *Strongly disagree/disagree very much*

45. Girls below 18 years of age who are married are treated with more respect than girls below 18 years who are not married.

- 1 *Strongly agree/agree very much*
- 2 *Agree*
- 3 *Neither agree nor disagree*
- 4 *Disagree*
- 5 *Strongly disagree/disagree very much*

46. My neighbour approve when girls below 18 years of age get married.

- 1 Strongly agree/agree very much
- 2 Agree
- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much

SECTION D: MARITAL STATUS

I now have some questions about your marital status

47. Are you married?

- Yes
- No

Skip q48-50 if said yes to q47.. Skip q51 if no to y 47.

48. My mother would like me to get married within the next 3 years

- 1 Strongly agree/agree very much
- 2 Agree
- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much
- Does not have a mother

49. My father would like me to get married within the next 3 years

- 1 Strongly agree/agree very much
- 2 Agree
- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much
- Does not have a father

50. My neighbours would approve if I get married within the next 3 years

- 1 Strongly agree/agree very much
- 2 Agree
- 3 Neither agree nor disagree
- 4 Disagree
- 5 Strongly disagree/disagree very much

51. *If yes to q47,* how old were you when you first started living with your husband?
Years

52. *If no to q47:* At what age do you want to get married?__

If said yes to q47, skip q 53 and 54.

53. Have you ever had a boyfriend?

Yes

No

If no, skip q54

54. Do you currently have a boyfriend?

Yes

No

Now we will ask you some questions about your behaviour. Please answer honestly. Remember that no one at your school or home will know your answers.

55. Have you ever given birth?

Yes

No

If no to q55, skip q 56 and 57.

56. If yes, on which date and in which year did you give birth? _____

Does not remember exact date

56.b If does remember exact date, enter month and year _____

57. How many children have you given birth to in total in your life (include both those who are alive and those who have died)?

.....

If yes to q55, skip q58

58. Have you ever been pregnant?

Yes

No

59. Are you currently pregnant?

Yes

No

I don't know

60. If yes, how old were you when you first became pregnant? years

61. Have you ever used a contraceptive method, e.g. condom?

Yes

No

If no to q61, skip q 62

62. The last time you used a contraceptive method, where did you get it?

- Government hospital
- Government health centre/post
- Mobile clinic
- Community-based distributor
- Private hospital/clinic
- Pharmacy
- Mission hospital/clinic
- Shop.
- Friends/relatives

Please tell us your views about the following statements even if you have never tried to obtain a condom or other contraceptive.

63. If you needed a contraceptive, e.g. a condom, how easy or difficult would it be for you to obtain one: very easy, easy, neither easy nor difficult, difficult, or very difficult?

1 Very easy

2 Easy

3 Neither easy nor difficult

4 Difficult

5 Very difficult

64. I would be able to go to a clinic to fetch condoms

1 Strongly agree/agree very much

2 Agree

- 3 *Neither agree nor disagree*
- 4 *Disagree*
- 5 *Strongly disagree/disagree very much*

65. I would be able to go to a pharmacy or a shop to buy condoms

- 1 *Strongly agree/agree very much*
- 2 *Agree*
- 3 *Neither agree nor disagree*
- 4 *Disagree*
- 5 *Strongly disagree/disagree very much*

Capture GPS coordinates

Thank you very much for answering my questions. Let me mention again that all the information you have given me will be kept confidential, and your name will not be recorded together with this information. Thank you very much for participating in this interview and this study.

ANNEX 4

ENGLISH ROUND 7 Face to face interview

Time of starting interview

I am one of the research assistants from the RISE project.

I'm sure you remember that we have been keeping in touch with you to find out how you are doing and ask you some questions about your life. The reason why we ask these questions is because we want to understand more about the lives of girls in Zambia. Like last time, I would like to ask you a few questions which will take about 20 minutes. Is this a convenient time to talk?

- Yes
- No

When I ask you these questions I would like you to feel free with me – like I'm your friend or sister. I am not here to judge you or report what you say. In my mind, everyone is free to make their own choices and there is no right or wrong way to do things – people are different and make different choices.

Everything you tell me is confidential. It will not be shared with any of your friends, family, teachers or anyone in the community. When we finish with this interview, your answers will be put together with the other answers from all the other 4900 girls taking part in the RISE project in Zambia. Your name will not be seen anywhere. Think of it like a vote – we only see how many people voted, not anyone's names. Let me ask you, since this project started, has there ever been a time when the information you shared with RISE has been shared with others?

During the interview I will be asking you different types of questions. Many of the girls in the RISE project have had difficulties understanding some of the questions and that is no problem. So please do not hesitate to ask me to clarify any question, or even say it in any other language if you feel that would be better. 😊

We are asking all girls to be open because the only way that we can REALLY know what girls in Zambia need is if we get honest answers to the questions we ask.

START OF FOLLOW-UP INTERVIEW

To start the interview, we are asking all the RISE girls about their schooling and work. There is no right or wrong way to do things, some girls will stay in school and others will leave school to do other things – both are OK.

Q1 Are you currently going to school?

- Yes
- No
- Chooses not to respond

3rd September 2019

Q2 A. Which school are you enrolled at?

Q2 B. Which grade are you enrolled in? (range 6-10)

Q3 How many days did you go to school last week?

Allowed range 0-5

Q4 When did you last attend school?

Month __

Year __

Allowed range 2016-2019

Q5 Which grade were you enrolled in just before you stopped going to school?

if dropped out since the last interview round, ask Q6

Q6 Why have you stopped going to school?

Read the response options. Tick the main reason

- a) It was not possible for you to continue school.
- b) It was possible for you to continue, but you preferred not to go to school.

Q7 Why was it not possible for you to continue school?

DO NOT read out the options - tick those that fit with the girl's answers

More than one response is possible

- a) ~~You~~ Could not afford it
- b) It is too far to travel to the nearest school
- c) You did not get enough marks on your last exam
- d) Your guardians would not allow you to continue
- e) You have family obligations such as taking care of family members or you are pregnant
- f) Other, specify

Q8 Why did you prefer not to go to school?

DO NOT read out the options - tick those that fit with the girl's answers

More than one response is possible

- a) You rather wanted to stay at home to take care of your family
- b) You rather wanted to work and earn money.
- c) Other, specify

Q9 Do you have an income generating activity (for example work for someone or run a small business?)

- Yes
- No
- Chooses not to respond

Q10 How much income do you have from that income generating activity in a normal month? –

Amount__ZMW

3rd September 2019

Thanks for answering those questions!

I am now going to ask you some questions where I will read out statements about things adolescent girls typically do. I would like you to listen to them and then tell me HOW MANY apply to you. Do not tell me which ones apply, just tell me how many. In order to make sure you understand what to do, I first give you an example of statements:

- a) You go to church every day*
- b) You read books every day*
- c) You like to cook*
- d) You help your siblings with their homework*

After reading the statements, I want you to tell me how MANY of these are correct for you? None, one, two, (three) or all. Please note that we will never know which ones apply to you. For example we will never know whether you read books every day. We will only know how common the four things we mention are for young girls in general. So how MANY of these are correct for you?

Pause for the girl to respond

Here is another example of statements:

- a) You have had headache at least once*
- b) You have a sister*
- c) You get the menstrual period regularly every month*
- d) You want to become a teacher*

I want you to tell me how MANY of these are correct for you? None, one, two, (three) or all. Again, we will never know whether you get the menstrual period regularly based on the answer you have given me. We will only know how common the four things we mention are for young girls in general. So how MANY of these four things are correct for you?

Pause for the girl to respond

Is this clear? I CAN EXPLAIN IT AGAIN IF YOU LIKE

Q11 I will now mention three things that adolescent girls typically do. Please listen to them and then tell me HOW MANY you have experienced. Do not tell me which ones, just tell me how many. Here are the three things:

- a) You have had a cough or a running nose in the past five years
- b) You have been admitted to a hospital/clinic for a fracture in the past one year
- c) You have been treated for malaria in the past five years

Now, how MANY of these are correct for you? **None, one, two or all? **

- none
- one
- two
- all

Q12 Now I am going to read you another list. Please listen to all of the things and then tell me HOW MANY you have done. Again, not which ones, just how many.

- a) You have had diarrhoea at least once in your life
- b) You often feel sick during your monthly menstrual period
- c) You are allergic to food products containing maize
- d) You have been pregnant at least once

Now, how MANY of these are correct for you? **None, one, two, three or all? **

- None
- one
- two
- three
- All

I will now ask you some questions regarding contraception.

Q13. When a girl uses contraceptive pills or the injection for family planning, does this protect her against sexually transmitted infections (STI)?

- Yes
- No
- Don't know
- Chooses not to respond

Q14. Can family planning pills and injections make young girls lose the ability to conceive?

- Yes
- No
- Don't know
- Chooses not to respond

Q15. Can family planning pills and injections cause miscarriages or deformed children?

- Yes
- No
- Don't know
- Chooses not to respond

Q16. Can contraceptive pills accumulate in a woman's body and make her sick?

- Yes
- No
- Don't know

3rd September 2019

- Chooses not to respond

Q17. Can the use of contraceptives pills or injections increase a woman's sexual desire and make her to be sleeping around more?

- Yes
- No
- Don't know
- Chooses not to respond

Q18. Does the condom offer protection against sexually transmitted infections?

- Yes
- No
- Don't know
- Chooses not to respond

Q19. Is the condom a reliable birth control method?

- Yes
- No
- Don't know
- Chooses not to respond

Q20. Can a condom disappear inside the woman's body if it slips off the man?

- Yes
- No
- Don't know
- Chooses not to respond

Q21. Is it true that the only time a person should use a condom is when they have sex with someone for the first time?

- Yes
- No
- Don't know
- Chooses not to respond

Q22. Do condoms break easily if they are not expired?

- Yes
- No
- Don't know
- Chooses not to respond

Q23. Can HIV pass through a condom?

- Yes
- No
- Don't know
- Chooses not to respond

In the next part of the interview, we are asking all the RISE girls about their lives, and their health. Some of the questions may seem sensitive and you may feel shy to answer – but remember I am also a woman and have been a girl myself 😊. I know how it is to be a girl and the things that happen. So you can feel free with me.

Remember that what you tell me will not be shared with anyone. If any of the questions are not clear, you can ask me to clarify at any time.

I first have some questions about health care utilization

Q24 Have you been admitted to a clinic or hospital in the last 6 months?

- Yes
- No
- Chooses not to respond

Q25 Were you admitted due to pregnancy related issues?

- Yes
- No
- Chooses not to respond

Q26 Have you visited any outpatient clinic or pharmacy/drug shop or traditional birth attendant or healer in the last 6 months?

- Yes
- No
- Chooses not to respond

Q27 Was your visit to these places or people due to pregnancy or birth related issues?

- Yes
- No
- Chooses not to respond

The next section asks some more questions about boyfriends, pregnancy and childbirth.

When girls grow up many changes happen in their lives. For example many girls get boyfriends, fall in love and some get pregnant. I myself know many girls who have gone through these things. Everyone is allowed to make their own choices. Whichever situation you are in, you are not the only one and I will not judge you or report anything you say – you can trust me and feel free to answer the truth.

Q28 Have you ever had a boyfriend?

- Yes
- No

3rd September 2019

- Chooses not to respond

Q29 Do you have your own child?

- Yes
- No
- Chooses not to respond

Q30 Have you ever given birth?

- Yes
- No
- Chooses not to respond

Q31 How many times have you given birth?

Q32 When did you give birth the first time?
(If given birth more than once):

Q33 When did you give birth the second time?

Q34 (If given birth more than twice): When did you last give birth?

Q35 Where did you deliver the last time you gave birth?

(Don't read the options)

- Outside a health facility
- In a clinic
- In a hospital
- Chooses not to respond
- Other, specify

Q36 How did you deliver the last time you gave birth?

- Normal delivery
- Caesarean section, that is, did they cut your belly open to take the baby out?
- Chooses not to respond

Q37 Was the baby alive and breathing when it was born?

- Yes
- No
- Chooses not to respond

Q38 Did you receive treatment for high blood pressure while you were pregnant?

- Yes
- No
- Chooses not to respond

Q39 Were you diagnosed with high blood pressure before you got pregnant?

3rd September 2019

- Yes
- No
- Chooses not to respond

Q40 Was the baby born more than one month before the due date?

- Yes
- No
- Don't Know
- Chooses not to respond

Q41 Can you estimate how many months the pregnancy was when you gave birth, based on your last menstrual period?

Q42 If the girl states a number lower than 5, ask her to clarify because a delivery before this is normally regarded as miscarriage or abortion

Check with the girl that the responses to the two previous questions are correct. If the pregnancy was 9 months, is it correct that the baby was born more than one month before the due date. Add a comment to explain the discrepancy

Q43 Did you give birth to one baby or twins?

- One (singleton)
- Twins
- Chooses not to respond

Q44 Do you have an under-five card for the child?

- Yes
- No
- Chooses not to respond

Q45 A. How much did the (first) baby weigh when he/she was born?

Record the weight in grams

If don't know enter 89

Please enter the weight in grams. If the girl does not know, enter 89

Q45 B. How much did the second baby weigh when he/she was born? *Record the weight in grams*

If don't know enter 89

Please enter the weight in grams. If the girl does not know, enter 89

Q46 A. Did the (first) baby weigh less than 2500 g when he/she was born?

- Yes
- No
- Don't Know
- Chooses not to respond

Q46 B. Did the second baby weigh less than 2500 g when he/she was born?

- Yes

3rd September 2019

- No
- Don't Know
- Chooses not to respond

Q47 Did you have any other complications with the birth for which you received treatment?

- Yes
- No
- Chooses not to respond

Q48 Please mention the other birth complications you were treated for

The next questions are a little bit more about your monthly cycle and pregnancy.

Q49 Have you ever skipped a period?

- Yes
- No
- Don't know
- Chooses not to respond

Q50 When you skipped your period was it because you were pregnant?

- Yes
- No
- Don't know
- Chooses not to respond

Q51 Have you ever been pregnant?

- Yes
- No
- Don't know
- Chooses not to respond

If no to Q50, ask Q51B

Q51B Did you ever report that you had been pregnant or given birth in an earlier interview?

- Yes
- No
- Don't know
- Chooses not to respond

If yes to Q51B, ask Q51C and 51D

Q51C When did you report that you had been pregnant or given birth?

Q51D Why are you not providing the same answer today?

3rd September 2019

Q52 Are you currently pregnant?

- Yes
- No
- Don't know
- Chooses not to respond

Q53 How many times have you been pregnant?

Q54 When did your last pregnancy end?

If the girl is currently pregnant, this question refers to the previous pregnancy

Month

Has to be less than or equal to 12

Year

Allowed range 2015-2019

You have entered month in 2019. Please check that this is correct.

Q55 Can you estimate how many months you had been pregnant when the last pregnancy ended, either with a birth, an abortion or miscarriage?-----months

Q56 Have you ever had a miscarriage/spontaneous abortion?

- Yes
- No
- Don't know
- Chooses not to respond

*The next part of the interview is going to ask some questions about **boyfriends and** contraceptives.*

Q57 Have you ever slept with a boyfriend or any other man/boy?

- Yes
- No
- Chooses not to respond

Q58 Are you married or living with a boyfriend?

- Yes
- No
- Chooses not to respond

Q59 (if yes to 58) When did you get married or start living with your boyfriend?

Month_

Has to be less than or equal to 12

Year_

Allowed range 2015-2019

You have entered month in 2019. Please check that this is correct.

If no to Q58, ask Q60

Q60. Do you currently have boyfriend?

- Yes
- No
- Chooses not to respond

I will now ask you some questions about contraceptives which I would like you to respond to even if you have never used contraceptives. I want you to let me know what you think, for example based on what you have heard from others, it does not have to be based on your own personal experiences.

Q61. *If you needed a contraceptive, would you know where to obtain it?*

- Yes
- No
- Don't know
- Chooses not to respond

Q62. *If you needed a contraceptive, would you be afraid of getting it because people in your community would disapprove?*

- Yes
- No
- Don't know
- Chooses not to respond

Q63. *If you needed a contraceptive, would you be afraid of going to the clinic because the health workers might not treat you with respect?*

- Yes
- No
- Don't know
- Chooses not to respond

Q64. *If you needed a contraceptive, would the distance to the clinic be too long for you to go?*

- Yes
- No
- Don't know
- Chooses not to respond

Q65. *If you needed contraceptives and the clinic was nearby, would you be able to obtain it?*

- Yes
- No
- Don't know
- Chooses not to respond

3rd September 2019

Q66. If you wanted to use a condom during sexual intercourse, would you be able to ask your partner to use one?

- Yes
- No
- Don't know
- Chooses not to respond

If yes to 30, 31, 51 or 57, ask 67 -69

I now have some questions about your experiences with contraceptives.

Q67. Have you ever used a contraceptive method to prevent pregnancy?

- Yes
- No
- Chooses not to respond

Q68. The last time you had sexual intercourse, did you or your partner use a male or female condom?

- Yes
- No
- Chooses not to respond

Q69. The last time you had sexual intercourse, had you recently taken family planning pills, injections or implant that could protect you against pregnancy?

- Yes
- No
- Chooses not to respond

If no to q68-69, ask q70.

Q70. What were your reasons for not using condom, pills, or injections or implant the last time you had sexual intercourse? READ THE OPTIONS AND CHECK ALL THAT APPLY

- You wanted to get pregnant
- You were using natural family planning methods, e.g. safe periods or withdrawal
- You could not get pregnant at that time
- You were afraid of side effects from family planning method
- You had problems getting family planning
- Your husband/boyfriend/partner didn't want to use anything
- You didn't want to use anything
- You forgot to use a family planning method
- Other, specify

We are now moving to the next part of the interview. Here you will answer the questions yourself. Before we do that, would you like to ask me any questions?

**NOTE TO RA: NOW GO TO ACASI. **

3rd September 2019

Ask the girl whether she has any comments after doing the ACASI. Then explain that you just have a few more questions for her before the interview ends.

Before we finish the interview, please let me know whether there are any questions you would like to go back to.

Q81. Is your biological mother alive?

- Yes
- No
- Chooses not to respond

Q82. Is your biological father alive?

- Yes
- No
- Chooses not to respond

Q83. Are any of your biological parents living with you?

- Yes
- No
- Chooses not to respond

This is the end of the interview, thank you for taking time to answer my questions. We are very grateful. Your participation is extremely important for this project because it gives us an opportunity to understand how the RISE girls are faring. To learn what is best for adolescent girls we cannot only get information from those who are in school, but we also need to learn from those who have dropped out of school or gotten married. Thus please keep us informed if you move anywhere or your contact number changes by calling us on the number you find on this business card. For example, if you get married, please call us and let us know how we can get in touch with you and your husband. We will offer you a compensation for your time each time we manage to interview you in 2019 and 2020 when this study will finish.

Do you have any questions that you may want to ask me before we finish the interview? Or do you have any comments about your experiences with the RISE project?

As an appreciation of your collaboration, we would like to give you K60 as compensation for your time.


























Thank you very much again! We will contact you again in 4-6 months from now for another session of interview.





























3rd September 2019

Capture Location

ANNEX 5

ACASI Seventh follow up

Field	Question	Answer
intid <i>(required)</i>	Please enter your FRA ID: <i>Response constrained to: .>=901 and .<=928</i>	
id <i>(required)</i>	Please insert Participant ID:	
namecheck <i>(required)</i>	Please ask the participant to confirm that the following information is correct: Participant Name: [girl_name] School: [school] Owner Name: [owner_name] Is this correct? <i>Please confirm the information is correct before selecting "YES". If you need to change the participant ID number after selecting "YES", please close the form without saving and start again.</i> <i>Question relevant when: 1</i> <i>Response constrained to: .=1</i>	1 Yes  2 No 
Introduction	Welcome to the ACASI part of the interview. Here you will be able to read as well as listen to the questions in private. The questions and the answers options have been recorded so that you can listen to the questions and choose the answer that is right for you. If you want to hear the questions in another language, it is easy for the research assistant to change the language for you, so just ask her to help. Before you start, please make sure the volume is high enough so you can hear clearly – you can adjust the volume by pressing you press on the "volume" sign in the top right corner so that you can listen to the question and options before proceeding. Please respond as truthfully as you can to the following questions.	
Skip <i>(required)</i>	For every question we ask you to choose the response that is correct for you. If there are certain questions you do not want to respond to, you can choosetick the "Skip" option. Please tick choose the "Skip" option below as a test. <i>Response constrained to: .=2</i>	1 Yes  0 No  2 Skip 
label1	In this questionnaire we will start with 6 practice questions. You may discover that some of the questions you may have been asked before. This is because we want to give you an opportunity to respond to the questions in privacy also. Take your time and listen to the whole question and all the possible answers before selecting the answer that is right for you. If you need to repeat the questions, this is not a problem. Remember, there are many girls who need help during the interview process, so don't be afraid to ask if you have questions.	
test1 <i>(required)</i>	This is a practice question: Did you eat beans yesterday?	1 Yes  0 No  2 Skip 
test2 <i>(required)</i>	This is a second practice question. Do you have a brother?	1 Yes  0 No  2 Skip 
test3 <i>(required)</i>	This is a third practice question. How many chickens do you have? <i>Response constrained to: .>=0 or .=99</i>	
test4 <i>(required)</i>	This This is the fourth practice question. Are you a girl? <i>Response constrained to: .=1</i>	1 Yes  2 No 
test5 <i>(required)</i>	This is a fifth practice question. Which year did you enroll in grade 7?	1 2015  2 2016  3 2017  4 2018  0 Skip 
test6 <i>(required)</i>	This is a sixth practice question. Which colour do you like better of the ones mentioned below?	1 Blue  2 Red  3 Green  4 Yellow 
label	Well done! Now we have finished the practice questions and will start the questionnaire. Remember that your answers will not be shared with anyone – not even the person interviewing you can see them, so feel free to be as honest as possible. If at any point you want to go back to a previous question, you can swipe from left to right.	
label2	Information about health care utilization	
AC7FU1 <i>(required)</i>	Q1. Have you been admitted to a clinic or hospital in the last 6 months?	1 Yes  0 No  2 Skip 

Field	Question	Answer
AC7FU2 (required)	Q2. Were you admitted due to pregnancy or birth related issues? <i>Question relevant when: selected(\${AC7FU1} , '1')</i>	1 Yes 
		0 No 
		2 Skip 
AC7FU3 (required)	Q3. Have you ever given birth?	1 Yes 
		0 No 
		2 Skip 
AC7FU4 (required)	Q4. Have you ever been pregnant? <i>Question relevant when: selected(\${AC7FU3} , '0') or selected(\${AC7FU3} , '2')</i>	1 Yes 
		0 No 
		2 Skip 
AC7FU5 (required)	Q5. Are you currently pregnant? <i>Question relevant when: selected(\${AC7FU3} , '1') or selected(\${AC7FU4} , '1') or selected(\${AC7FU3} , '2') or selected(\${AC7FU4} , '2')</i>	1 Yes 
		0 No 
		2 Skip 
AC7FU6 (required)	Q6. How many months do you think the pregnancy is now? <i>Question relevant when: selected(\${AC7FU5} , '1')</i> <i>Response constrained to: .>=1 and .<=9 or .=99</i>	
AC7FU7a (required)	Q7a. Have you ever had a live birth?	1 Yes 
		0 No 
		2 Skip 
AC7FU7b (required)	Q7b. Have you ever had a miscarriage/spontaneous abortion?	1 Yes 
		0 No 
		2 Skip 
AC7FU7c (required)	Q7c. Have you ever had a stillbirth?	1 Yes 
		0 No 
		2 Skip 
AC7FU8 (required)	Q8. How many times have you been pregnant? <i>Question relevant when: selected(\${AC7FU4} , '1') or selected(\${AC7FU3} , '1')</i> <i>Response constrained to: .>=1 and .<=10 or .=99</i>	
AC7FU9 (required)	Q9. When did your last pregnancy end? <i>Question relevant when: selected(\${AC7FU4} , '1') or selected(\${AC7FU3} , '1')</i>	1 2014 
		2 2015 
		3 2016 
		4 2017 
		5 2018 
		6 2019 
		0 Skip 
AC7FUEND	Thanks a lot for responding to these questions! Please let the one who is interviewing you know that you have completed answering all the questions.	
AC7FUendform	The form must be closed properly. Please ask for assistance	