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Comparing Four Service Delivery Models for Adolescent Girls and Young Women through the "Girl Power" study: Protocol for a Multisite Quasi-experimental Cohort Study

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Title:

Comparing Four Service Delivery Models for Adolescent Girls and Young Women through the "Girl Power" study: Protocol for a Multisite Quasi-experimental Cohort Study

Short Title:

The "Girl Power" protocol

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Abstract

Introduction: In sub-Saharan Africa, adolescent girls and young women (AGYW) face a range of sexual and reproductive health challenges. Clinical, behavioral, and structural interventions have each reduced these risks and improved health outcomes. However, combinations of these interventions have not been compared to each other or to no intervention at all. The "Girl Power" study is designed to systematically make these comparisons.

Methods and Analysis: Four comparable health facilities in Malawi and South Africa (N=8) were selected and assigned to one of the following models of care:

1) Standard of care: AGYW can receive family planning, HIV testing and counseling (HTC), and STI syndromic management in non-integrated separate locations with adults. No youth-friendly clinic modifications or trainings are offered.
2) Youth-Friendly Health Services (YFHS): AGYW are meant to receive integrated family planning, HTC, and STI services in dedicated youth spaces with youth-friendly modifications and providers trained in YFHS.
3) YFHS + behavioral intervention (BI): In addition to YFHS, AGYW can attend twelve monthly theory-driven, facilitator-led, interactive sessions on health, finance, and relationships.
4) YFHS + BI + conditional cash transfer (CCT): In addition to YFHS and BI, AGYW receive up to twelve CCTs conditional on monthly BI session attendance.

At each clinic, 250 AGYW 15-24 years old (N=2000 total) will be consented, enrolled, and followed for one year. Each participant will complete a behavioral survey at enrollment, 6-months, and 12-months. All clinical, behavioral, and CCT services will be captured. Outcomes of interest include uptake of each package element and reduction in HIV risk behaviors. A qualitative sub-study will be conducted.

Ethics and Dissemination: This study has received ethical approval from the University of North Carolina, the University of Cape Town, and Malawi's National Health Science Research Committee. Study plans, processes, and findings will be disseminated to local stakeholders, in peer-reviewed journals, and at conferences.

Strengths and Limitations of the this study

- The Girl Power study is working to address a range of sexual and reproductive health challenges among adolescent girls and young women in two prototypical, yet distinct, sub-Saharan African contexts.
- The Girl Power study is comparing four different models of care to determine which are associated with the greatest uptake of services.
- Each model is being implemented in one clinic in each country; replication would be needed to demonstrate generalizability.
- Implementing multi-level programs for AGYW in SSA has become a major focus of governments and donors over the last several years, but in most cases programmes have not been rigorously evaluated for impact. Girl Power is expected to address this important gap in understanding and provide greater insights into how to support vulnerable AGYW in SSA.

Introduction

In sub-Saharan Africa (SSA), adolescent girls and young women (AGYW) 15-24 years old are vulnerable to a wide range of sexual and reproductive health challenges, including acquisition of HIV and sexually transmitted infections (STI), unintended and unwanted pregnancies, and intimate partner violence (IPV). These overlapping epidemics have many common underlying health system, behavioral, and structural drivers. Although each set of drivers has been addressed in isolation, there are few examples of multi-level interventions for this highly vulnerable population.

AGYW experience these challenges in a service delivery environment characterized by judgmental provider attitudes, a lack of privacy, inconvenient hours, and non-integrated services As a result, service utilization by AGYW for sexual and reproductive health remains low. Youth-friendly health services (YFHS) that include provider training and clinic modifications have increased uptake of such services.[1-4] Eight out of nine randomized or quasi-experimental studies in SSA assessing YHFS models with both components increased service uptake by AGYW.[3,5,6] However, to our knowledge, such a platform has never been tested in combination with behavioral and structural interventions.

Offering behavioral interventions (BIs) within a YFHS platform could further enhance service uptake and address other behavioral risks and psychosocial outcomes. The social context of intimate relationships in SSA is marked by severe gender inequality. Gender norms favor male control over sexual intercourse, leaving young women with less power in sexual decision-making.[7-10] Additionally, many young women have older male partners, often with a transactional dimension, who are more likely to be HIV-infected.[11-15] BIs based on the Theory of Gender and Power,[16,17] and Social Cognitive Theory[18] have been shown to address these power imbalances and reduce multiple partnerships, HSV-2 incidence, and IPV.[19-21] All of these evidence-based interventions address gender norms and involve participatory activities for groups of young women. Synthesizing the most effective elements of these "empowerment" interventions and offering them within a YFHS service delivery platform could help reduce behavioral sources of risk, improve psychosocial outcomes, and generate demand for health services. Assessing evidence-based clinical and behavioral interventions is a critical next step.

Cash transfers are also a promising tool for preventing HIV among AGYW.[22-24] In Malawi, when cash payments were given to girls and their guardians, they were more likely to remain in school, less likely to report age-disparate relationships, and have lower HIV and HSV-2 prevalence.[22] In South Africa, adolescents living in homes receiving a national child grant reported half the incidence of transactional sex and much less age-disparate sex than those in homes not receiving it.[23] A cash transfer program has never been operationalized in a clinical environment and never in combination with a behavioral intervention. Understanding whether a cash transfer provides benefits in combination with a YFHS service delivery platform and empowerment-based BI is not known.

It is becoming widely acknowledged that combination HIV prevention packages that include effective, acceptable, and scalable clinical, socio-behavioral and structural interventions may have the greatest impact.[25-28] However, it is not known how best to combine different intervention levels for maximal effectiveness for multiple outcomes. The Girl Power study is designed to compare three different combinations of evidence-based interventions to one another and to a standard of care and to assess their impact on a range of care-seeking and sexual risk behaviors in two sub-Saharan African countries.

Methods and Analysis

Study Setting

The Girl Power study is an ongoing study (February 2016-November 2017) being conducted in Malawi and South Africa. These countries represent two prototypical, yet distinct sub-Saharan African contexts. In Malawi, first births often occur early, at a median age of 19, and within the context of marriage. [29] In South Africa, sexual activity tends to be outside of the context of marriage, with a somewhat later age of first birth.[30,31] Malawi is characterized by extreme poverty with the majority of the population living on less than $1 per day, whereas South Africa has extreme wealth polarization. In spite of these socio-economic differences, both countries have high HIV prevalence levels—6% of women 20-24 are HIV-infected in Malawi and 17% in South Africa, rates considerably higher than their male

counterparts.[29] Sexual violence is also a serious problem in both countries, with high rates of non-consensual sex reported by young women.[32-34] Additionally, both have public sector health facilities characterized by human resource shortages, stock-outs of pharmaceuticals and supplies, long queues, and providers who exhibit negative attitudes towards AGYW. It was within this context that the Girl Power study was conceptualized.

Four comparable public sector health facilities were selected in each country. In Malawi, the four sites are public-sector health centers in Lilongwe. All sites are on a main road, have antenatal volumes >200 clients per month, and have antenatal HIV prevalence ≥5%. These sites have higher HIV prevalence than the surrounding rural areas where antenatal HIV prevalence is <5%. In South Africa, the four sites are in the Klipfontein and Mitchell's Plain areas in the Western Cape. These are high-density, low socioeconomic peri-urban townships comprised predominantly of informal dwellings. In both countries, each clinic serves distinct communities.

Prior to the study, all sites in both countries offered HIV testing and counseling (HTC), contraception, and STI services in separate locations with separate queues. Condoms were also available at all sites—in the pharmacy at the Malawian sites and throughout the clinic at the South African sites. At all sites in both countries AGYW could receive general health services with the general population. However, there were no distinct YFHS spaces, times, or providers, no BIs, and no opportunities for CCTs.

Study Design and Interventions

Girl Power is a quasi-experimental prospective cohort study comparing four different models of service delivery and their impacts on care-seeking and sexual risk behaviors among AGYW (Figure 1).

In each country, each clinic was randomly assigned to one of the following models of care:

- Model 1: Standard of care (SOC): The SOC offers HTC, contraception, STI syndromic management and condoms to AGYW. However, health care providers have not been trained in YFHS and clinics have not made YFHS modifications, regarding hours, clinic navigation, integration, cost, or space.
- Model 2: YFHS: HTC, contraception, and STI services are offered by health providers who have been trained in YFHS. YFHS modifications have been made to the clinics, including clinic navigation (both countries), a youth-only clinic with service integration (Malawi), free services (Malawi), and longer hours (Malawi).
- Model 3: YFHS + BI: In addition to the YFHS package, participants can attend twelve monthly facilitator-led, small-group interactive sessions. They are based on other evidence-based interventions from the region,[17,19,21] and are motivated by the theory of gender and power and Social Cognitive Theory. These sessions address sexual health topics (e.g. HIV, reproductive health), social issues (e.g. partner communication, peer pressure, and intimate partner violence), financial literacy (e.g. budgeting, saving, and investing), and general topics (e.g. self-esteem, goal-setting, and decision-making). Each session includes an activity to do at home after the session in order to encourage behavior change. Each country adapted curricula in a culturally-responsive manner; although sessions were not identical across countries, they explore similar themes. We expect approximately 12-15 distinct groups at each clinic with approximately 10-20 girls each.
- Model 4: YFHS + BI + conditional cash transfer (CCT): In addition to the YFHS package and empowerment sessions, AGYW received a monthly CCT (approximately $5.50 in Malawi and $7.50 in South Africa) conditional on attending the monthly empowerment session. Each young woman could receive up to 12 CCTs. In Malawi, the CCT is being provided in physical cash and in South Africa the CCT is provided electronically.

Study and clinical personnel, training activities, and clinical modifications by country and model are described in greater detail in Table 1.

Table 1. Girl Power Personnel, Training and Clinical Modifications by Clinic and Country

	Malawi				South Africa			
	Model 1	Model 2	Model 3	Model 4	Model 1	Model 2	Model 3	Model 4
Clinical model	SOC	YFHS	YFHS+BI	YFHS+BI+CCT	SOC	YFHS	YFHS+BI	YFHS+BI+CCT
Personnel								
Research	Research officer: These are young (20-29 years) female full-time staff who are responsible for all consenting, screening, enrollment, and behavioral surveys (1/clinic)				Research assistant: These are female full-time staff responsible for all consenting, screening, enrolment, and behavioral surveys (1/clinic)			
Outreach and navigation	Peer educators: These are young (18-24 years) full-time lay staff who are responsible for recruitment and retention activities. At clinics 2, 3, and 4 they also welcome participants, determine their sexual and reproductive health needs, provide patient education, and help with clinic navigation. (2/clinic)				Outreach workers: These are temporary staff responsible for community outreach and recruitment at study initiation (2/clinic) Peer navigator: These are young full-time staff who welcome participants, discuss sexual and reproductive health needs, fetch patient files, and help with clinic navigation (1/clinic)			
Family planning and STI services	-	Nurses: 4-5 government nurses from these sites were assigned to rotate through the Girl Power clinic.			-	1-3 government nurses provide SRH services to GP participants		
HIV counseling and testing		Counselor: 1 young (≤29 years) female HIV counselor was assigned to the Girl Power clinic.				1-3 government HTC counselors are available to attend to Girl Power participants		
Workshop facilitation	-	-	Facilitators: Young (<29) females lead empowerment sessions (1/facility).		-	-	Facilitators: lead empowerment sessions (1/facility)	
Training								
Protocol training		Study overview and design, clinical data collection, Good Clinical Practice (3 days) (all staff)			Study overview and design, data collection, sexual and reproductive health refresher, values clarification (1-2 days)			
YFHS training		Medical and psychosocial support for adolescents (2 day) (all staff)			-	Medical and psychosocial support for adolescents (1 day)		
Clinical training		Nurses trained on long-acting reversible contraception (5 days) and STI syndromic management (5 days)			All nurses expected to be familiar with these provision of all contraceptive methods and STI syndromic management. Provided on-the-job training.			
Clinical Modifications								
Space	-	Dedicated space for AGYW service delivery in a separate area from general clinic to ensure privacy from adults			-	Dedicated waiting and/or welcome area for AGYW		
Hours	Typically morning hours	AGYW can come in the morning or afternoon			AGYW can come in the morning or afternoon			
Cost	Some services require payment	All services are free			All services are free	All services are free		

Study Population

At each of the eight sites, 250 AGYW will be recruited and followed for one year. Eligibility criteria include being female, 15-24 years old, residing in the clinic's catchment area, and willing to be enrolled for a one-year period. The intention is to recruit AGYW who are already sexually active or likely to become sexually active, although this is not a strict eligibility criterion. In total, 1000 AGYW will be enrolled in each country (N=2000 total).

Recruitment will occur through a combination of community outreach activities, self-referral, and referral through invitations from other participants. Outreach workers will visit parts of the catchment area known to be high-risk. Through one-on-one conversations they will build rapport, assess sexual activity and past care-seeking behaviors, promote the services at their site, and invite them to participate. AGYW who enroll in the study will be provided with invitations to invite friends who they believe would also benefit.

Follow-up phone and physical tracing will be conducted for girls who miss their six or twelve month visits.

Data Collection and Management

The two primary sources of data collection are a detailed behavioral survey and service uptake data. The behavioral survey is administered at three time points—at study enrollment, month six, and month 12. The behavioral survey contains questions about demographics, socio-economic status, past and current care-seeking behaviors, sexual history, depression, intimate partner violence, and alcohol consumption. The twelve-month assessment also includes assessments of the BI and the CCT. The behavioral survey will be self-administered in South Africa, except among illiterate participants. It will be interviewer-administered by young female research assistants in Malawi. Surveys will be administered on encrypted password-protected Android tablets using Open Data Kit software and stored on secure servers.

In both countries, we will document delivery of HTC, family planning, and STI services. Due to the unique clinical contexts, data collection will occur differently in the two countries. In Malawi, a clinic

card that contains all clinical information has been developed and will be used by clinical staff. In South Africa, research assistants will transcribe clinical activities in existing clinical records onto a study-specific form. In both countries, these data will then be entered into secure databases by trained research assistants.

In both countries, each participant will be identified through a unique identifier. In South Africa, participants' identities will be verified through biometric data.

Study outcomes, analytic methods, and sample size

The first set of primary outcomes are care-seeking behaviors. We will compare the proportion of participants who receive HTC, male and female condoms, contraception, and STI services. We will also look at the proportion of participants who engage in dual protection. For all of these services, we will assess the proportion of participants who use each method ever, continuously, and for the first time during their year in Girl Power. The primary outcome of interest is uptake of dual protection defined as simultaneous uptake of male or female condoms and another modern method of contraception. These data are available both through the behavioral survey and clinical abstraction.

HIV risk behaviors collected on the behavioral survey are also key outcomes of interest. Questions of particular interest are the proportion of AGYW who have multiple sexual partners, have a considerably older male partner, engage in transactional sex, and experience IPV. We will assess how these indicators change between enrollment and each follow-up time point and compare these changes between clinics.

For all of these key outcomes of interest, we will conduct an intention to treat analysis, analyzing each participant in her assigned clinic. We will use generalized estimating equations to account for correlated records between each participant. A log or identity link, binomial distribution, and robust variance estimates will be used to estimate risk ratios and risk differences and ninety-five percent confidence intervals. We will compare absolute differences at each time point, as well as changes over time.

For the primary outcome of interest (uptake of dual protection) using two-sided tests; an alpha level of 0.05; and uptake levels of 10% (model 1), 20% (model 2), 35% (model 3) and 50% (model 4), we will have ≥85% power to detect differences between any two arms in each country.

Qualitative Sub-study

A qualitative sub-study will be conducted to better understand participant experiences with each service delivery model. Twelve to 15 in-depth interviews (IDIs) will be conducted at each site in each country (N=96-120 IDIs total). IDIs will focus on individual experiences with SOC, YFHS, BI, and CCT. At each clinic we will purposively select a mixture of good care-seekers, poor-care-seekers, and HIV-infected young women. Focus group discussions (FGDs) (N=2-3/site) will address norms surrounding these same topics and strategies for improving or enhancing these services. At each site, we will have at least one FGD with adolescent girls 15-19 years old and one with young women 20-24 years old. IDIs and FGDs will be conducted in Chichewa in Malawi and in isiXhosa or English in South Africa. All IDIs and FGDs will be transcribed and translated into English. They will be coded and analyzed using a thematic approach.

Limitations

The Girl Power study has several limitations. First, we are not powered to observe differences in biologic outcomes, such as HIV, STI, or pregnancy incidence. Rather, we are only observing behavioral intermediates. Second, due to budget constraints, we are not conducting a cluster randomized control trial which would be the ideal design to assess our research question. As such, it may be difficult to determine whether observed outcomes are due to our interventions or natural differences between clinics. Finally, due to the important contextual differences between countries, our interventions are similar but not identical. This may make it difficult to determine if different findings across countries are due to the context or the variations in the interventions themselves.

Ethics and Dissemination

This study was approved by the University of North Carolina Institutional Review Board (IRBIS 15-2901) and two local regulatory bodies: the Malawi National Health Sciences Research Committee (15/7/1447) and the University of Cape Town Human Research Ethics Committee (815/2015). In South Africa, all AGYW 15-24 years can decide whether to provide informed consent for themselves or seek optional parental consent. In Malawi, AGYW 18-24 years will provide informed consent for themselves. AGYW 15-17 years will provide assent and have a parent, guardian, or authorized representative provide informed consent. At each site, a community club will identify individuals ≥18 years who could serve as authorized representatives.

Dissemination activities will occur at all stages of the study: prior to implementation, at intermediate points during implementation, and at study culmination. Prior to study implementation, meetings were held with key local stakeholders, such as local health leadership (e.g. district, province, or city managers), clinical supervisors, and clinical staff. These meetings were designed to seek permission for study implementation, orient these stakeholders to study goals, and work together on implementation questions. Sensitization activities were also conducted with key community stakeholders, such as local chiefs and religious leaders, school headmasters, and library managers. These sensitizations were designed to inform key local leaders about the study, elicit buy-in and support, and facilitate recruitment. During study implementation, these same stakeholders will be engaged to report on study progress and discuss challenges. At the end of the study, results will be disseminated so that stakeholders are aware of the study's primary findings. Additionally, results will be disseminated in peer-reviewed journals and at national and international meetings and conferences. Dissemination of final results is expected in 2018.

Conclusion

Implementing combination interventions for AGYW in SSA has become a major focus of governments and donors over the last several years. In most cases however, programs have not been

rigorously evaluated for impact. Girl Power is expected to address this important gap in understanding and provide greater insights into how to support vulnerable AGYW in SSA.

Author Contributions

NER, AEP, and LGB designed the study. Other co-authors are responsible for study coordination, implementation, and analysis. All authors either wrote or made substantial edits to the draft, approved the final version and take responsibility for the work.

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Competing Interests Statement

We have no competing interests to declare.

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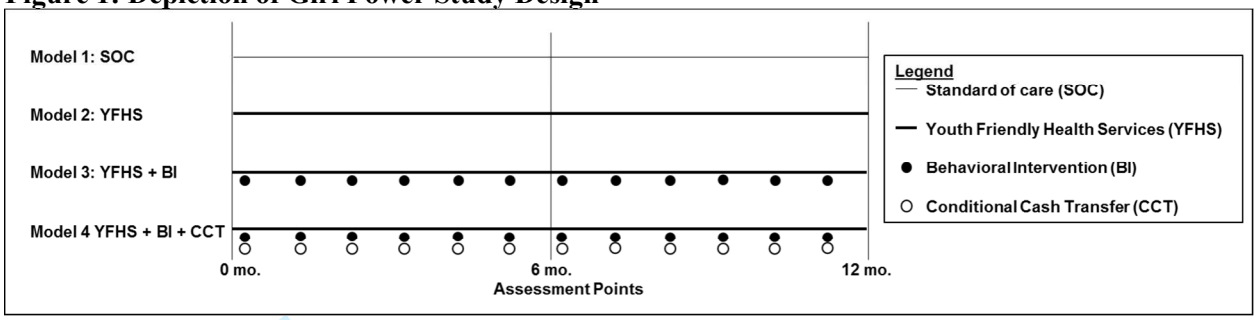
Figure 1: Depiction of Girl Power Study Design



STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any pre-specified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	10
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-12
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	10-12
Bias	9	Describe any efforts to address potential sources of bias	12
Study size	10	Explain how the study size was arrived at	12
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	11
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	11
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) If applicable, explain how loss to follow-up was addressed	NA
		(*e*) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
NA		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	NA
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Comparing Four Service Delivery Models for Adolescent Girls and Young Women through the "Girl Power" study: Protocol for a Multisite Quasi-experimental Cohort Study

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Comparing Four Service Delivery Models for Adolescent Girls and Young Women through the "Girl Power" study: Protocol for a Multisite Quasi-experimental Cohort Study

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The "Girl Power" protocol

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Abstract

Introduction: In sub-Saharan Africa, adolescent girls and young women (AGYW) face a range of sexual and reproductive health challenges. Clinical, behavioral, and structural interventions have each reduced these risks and improved health outcomes. However, combinations of these interventions have not been compared to each other or to no intervention at all. The "Girl Power" study is designed to systematically make these comparisons.

Methods and Analysis: Four comparable health facilities in Malawi and South Africa (N=8) were selected and assigned to one of the following models of care:

1) Standard of care: AGYW can receive family planning, HIV testing and counseling (HTC), and STI syndromic management in 3 separate locations with 3 separate queues with the general population. No youth-friendly spaces, clinic modifications or trainings are offered.
2) Youth-Friendly Health Services (YFHS): AGYW are meant to receive integrated family planning, HTC, and STI services in dedicated youth spaces with youth-friendly modifications and providers trained in YFHS.
3) YFHS + behavioral intervention (BI): In addition to YFHS, AGYW can attend twelve monthly theory-driven, facilitator-led, interactive sessions on health, finance, and relationships.
4) YFHS + BI + conditional cash transfer (CCT): In addition to YFHS and BI, AGYW receive up to twelve CCTs conditional on monthly BI session attendance.

At each clinic, 250 AGYW 15-24 years old (N=2000 total) will be consented, enrolled, and followed for one year. Each participant will complete a behavioral survey at enrollment, 6-months, and 12-months. All clinical, behavioral, and CCT services will be captured. Outcomes of interest include uptake of each package element and reduction in HIV risk behaviors. A qualitative sub-study will be conducted.

Ethics/Dissemination: This study has received ethical approval from the University of North Carolina, the University of Cape Town, and Malawi's National Health Science Research Committee. Study plans, processes, and findings will be disseminated to stakeholders, in peer-reviewed journals, and at conferences.

Strengths and Limitations of the this study

- Within each country, the selection of four comparable clinics and random assignment of each to one of the four models of service delivery is a key strength. However, each model is being implemented in only one clinic in each country. A cluster randomized controlled trial, with multiple clinics in each model in each country would be a next step.
- In spite of implementing four different models of care, efforts are being made to ensure comparable recruitment, retention, and data ascertainment procedures across sites, and to minimize contamination.
- The ability to triangulate these behavioral outcomes from both clinical and self-reported data is a strength. However, the study is not powered to detect differences in biologic outcomes, especially HIV incidence.
- Implementing a similar set of models in two distinct sub-Saharan contexts enhances generalizability. However, findings may not generalize to every sub-Saharan context.

Introduction

In sub-Saharan Africa (SSA), adolescent girls and young women (AGYW) 15-24 years old are vulnerable to a wide range of sexual and reproductive health (SRH) challenges, including acquisition of HIV and sexually transmitted infections (STI), unintended and unwanted pregnancies, and intimate partner violence (IPV). These challenges have many common underlying health system, behavioral, and structural drivers that have not, to our knowledge, been addressed and assessed in combination—in a youth friendly service delivery environment, with behavioral interventions, and with socio-economic support.

AGYW in SSA typically experience a service delivery environment characterized by judgmental provider attitudes, a lack of privacy, inconvenient hours, and non-integrated services.[1] As a result, service utilization by AGYW for SRH remains low. Youth-friendly health services (YFHS) that include provider training, clinic modifications, and community-based demand creation are promising approaches for increasing uptake of such services.[1-6] Eight out of nine randomized or quasi-experimental studies in SSA assessing YHFS models with these components increased service uptake by AGYW.[3] However, to our knowledge, such a platform has never been tested in combination with behavioral and structural interventions.

Offering behavioral interventions (BIs) within a YFHS platform could further enhance service uptake and address other behavioral risks and psychosocial outcomes. The social context of intimate relationships in SSA is characterized by severe gender inequality. Gender norms favor male control over sexual intercourse, often leaving young women with less power in sexual decision-making.[7-10] Additionally, many young women have older male partners, frequently with a transactional dimension, who are more likely to be HIV-infected.[11-15] BIs based on the theory of gender and power,[16,17] and social cognitive theory[18] have been shown to address these power imbalances and reduce multiple partnerships, HSV-2 incidence, and IPV.[19-21] All of these evidence-based interventions address gender norms and involve participatory activities for groups of young women. Synthesizing the most effective elements of these "empowerment" interventions and offering them within a YFHS service delivery platform could

help reduce behavioral sources of risk, improve psychosocial outcomes, and generate demand for health services. Assessing evidence-based clinical and behavioral interventions is a critical next step.

Cash transfers are also a promising tool for preventing HIV among AGYW.[22-24] In Malawi, when cash payments were given to girls and their guardians they were more likely to remain in school, less likely to report age-disparate relationships, and have lower HIV and HSV-2 prevalence.[22] In South Africa, adolescents living in homes receiving a national child grant reported half the incidence of transactional sex and much less age-disparate sex than those in homes not receiving it.[23] In a South African trial, cash transfers conditioned on schooling did not lead to lowered HIV incidence, but did lead to reductions in intimate partner violence and sexual risk.[25] However, to our knowledge, a cash transfer program has not been evaluated for AGYW in a clinical environment, nor has it been implemented in combination with a behavioral intervention. Understanding whether a cash transfer provides benefits in combination with a YFHS service delivery platform and empowerment-based BI is not known.

It is becoming widely acknowledged that combination HIV prevention packages that include effective, acceptable, and scalable clinical, socio-behavioral and structural interventions may have the greatest impact.[26-29] However, it is not known how best to combine different intervention levels for maximal effectiveness for multiple outcomes. The Girl Power study is designed to compare three different combinations of evidence-based interventions to one another and to a standard of care and to assess their impact on a range of care-seeking and sexual risk behaviors in two sub-Saharan African countries.

Methods and Analysis

Study Setting

The Girl Power study is an ongoing study (February 2016-November 2017) being conducted in Malawi and South Africa. These countries represent two prototypical, yet distinct sub-Saharan African contexts. In Malawi, based on nationally representative household data, first births often occur early, at a median age of 19 years, and within the context of marriage.[30] In South Africa, sexual activity tends to be

outside of the context of marriage, with a somewhat later age of first birth.[31,32] Malawi is characterized by extreme poverty with the majority of the population living on less than $1 per day, whereas South Africa has extreme wealth disparities. In spite of these socio-economic differences, both countries have high HIV prevalence levels—6% of women 20-24 years old are HIV-infected in Malawi and 17% in South Africa, rates considerably higher than their male counterparts.[30] Sexual violence is also a serious problem in both countries, with high rates of non-consensual sex reported by young women.[33-35] Additionally, both have public sector health facilities with human resource shortages, stock-outs of pharmaceuticals and supplies, long queues, and providers who exhibit negative attitudes towards AGYW. It was within these contexts that the Girl Power study was conceptualized.

Four comparable public sector health facilities were selected in each country. In Malawi, the four sites are public-sector health centers in Lilongwe. All sites are on a main road, have antenatal volumes >200 clients per month, and have antenatal HIV prevalence ≥5%. These sites have higher HIV prevalence than the surrounding rural areas where antenatal HIV prevalence is <5%. In South Africa, the four sites are in the Klipfontein and Mitchell's Plain areas in the Western Cape, which serve primarily black and coloured populations. These are high-density, low socioeconomic peri-urban townships comprised predominantly of informal dwellings. Antenatal prevalence in the Western Cape is 17%. In both countries, each clinic serves distinct communities. In South Africa, biometric identification is being used to ensure the same people do not enroll in more than one site. In Malawi, all sites are at least 7km apart.

Prior to the study, all sites in both countries offered free HIV testing and counseling (HTC), contraception, and STI services in separate locations within each clinic with separate queues. Condoms were also available for free at all sites—in the pharmacy at the Malawian sites and throughout the clinic at the South African sites. At all sites in both countries AGYW could receive general health services with the general population. However, there were no distinct YFHS spaces, times, or providers, no behavioral interventions (BIs), and no opportunities for CCTs within the clinic.

Study Design and Interventions

Girl Power is a quasi-experimental prospective cohort study comparing four different models of service delivery and their impacts on care-seeking and sexual risk behaviors among AGYW (Figure 1). The primary outcomes of interest are service uptake and behavioral risks. Participants enrolled at all sites will complete behavioral surveys at baseline, six, and twelve months and have their clinical data ascertained over a one-year period. In each country, each clinic was randomly assigned to one of the following models of care:

- Model 1: Standard of care (SOC): The SOC offers HTC, contraception, STI syndromic management and condoms to AGYW. However, health care providers have not been trained in YFHS and clinics have not made YFHS modifications, regarding hours, clinic navigation, integration, cost, or space.
- Model 2: YFHS: HTC, contraception, and STI services are offered by health providers who have been trained in YFHS. YFHS modifications have been made to the clinics, including clinic navigation (both countries), a youth-only space with integrated service provision (Malawi), and longer hours (Malawi).
- Model 3: YFHS + BI: In addition to the YFHS package, participants can attend twelve monthly facilitator-led, small-group interactive sessions. They are based on other evidence-based interventions from the region,[17,19,21] and are motivated by the theory of gender and power and Social Cognitive Theory. These sessions address sexual health topics (e.g. HIV, reproductive health), social issues (e.g. partner communication, peer pressure, and intimate partner violence), financial literacy (e.g. budgeting, saving, and investing), and general topics (e.g. self-esteem, goal-setting, and decision-making). Each session includes an activity to do at home after the session in order to encourage behavior change. Each country adapted curricula in a culturally-responsive manner; although sessions were not identical across countries, they explore similar themes. We expect sessions will be delivered to groups of 10-20 girls at once.

- Model 4: YFHS + BI + conditional cash transfer (CCT): In addition to the YFHS package and empowerment sessions, AGYW received a monthly CCT (approximately $6) conditional on attending the monthly empowerment session. Each young woman could receive up to 12 CCTs (one per month). In Malawi, the CCT is being provided in physical cash and in South Africa the CCT is provided electronically.

Study and clinical personnel, training activities, and clinical modifications by country and model are described in greater detail in Table 1.

Study Population

At each of the eight sites, 250 AGYW will be recruited and followed for one year. Eligibility criteria include being female, 15-24 years old, residing in the clinic's catchment area, and willing to be enrolled for a one-year period. The intention is to recruit AGYW who are already sexually active or likely to become sexually active, although this is not a strict eligibility criterion. In total, 1000 AGYW will be enrolled in each country (N=2000 total).

Recruitment will occur through comparably at each site through a combination of community outreach activities, self-referral, and referral through invitations from other participants. Outreach workers will visit parts of the catchment area known to be high-risk. Through one-on-one conversations they will build rapport, assess sexual activity and past care-seeking behaviors, promote the services at their site, and invite them to participate. AGYW who enroll in the study will be provided with invitations to invite friends who they believe would also benefit.

Follow-up phone and physical tracing will be conducted for girls who miss their six or twelve month visits. We will make comparable attempts to trace participants at all four clinics to avoid differential loss-to-follow-up and provide the same transport reimbursement for the three research visits across all four sites. These efforts are designed to minimize differential loss-to-follow-up.

Table 1. Girl Power Personnel, Training and Clinical Modifications by Clinic and Country

	Malawi				South Africa			
	Model 1	Model 2	Model 3	Model 4	Model 1	Model 2	Model 3	Model 4
Clinical model	SOC	YFHS	YFHS+BI	YFHS+BI+CCT	SOC	YFHS	YFHS+BI	YFHS+BI+CCT
Personnel								
Research	Research assistant: Young (≤29) female full-time staff responsible for all consenting, screening, enrolment, and behavioral surveys (1/clinic)				Research assistant: Female full-time staff responsible for all consenting, screening, enrolment, and behavioral surveys (1/clinic)			
Outreach	Peer outreach workers: Young full-time lay staff responsible for recruitment and retention activities. (2/clinic)	Peer outreach workers/navigators: Young full-time lay staff responsible for recruitment and retention activities (outreach roles). They also welcome participants, assess their sexual and reproductive health needs, and help with clinic navigation. (2/clinic)			Peer Outreach workers: Temporary staff responsible for community outreach and recruitment at study initiation (2/clinic)			
Navigation	-				Peer navigator: Full-time staff who welcome participants, discuss sexual and reproductive health needs, fetch patient files, and help with clinic navigation (1/clinic)			
Family planning and STI services	-	Nurses: 4-5 government nurses from these sites were assigned to rotate through a youth-focused Girl Power clinic.			-	Nurses: 1-3 government nurses provide SRH services to Girl Power participants		
HIV counseling and testing		Counselor: 1 young female HIV counselor was assigned to the Girl Power clinic.				Counselor: 1-3 government HTC counselors are available to attend to Girl Power participants		
Workshop facilitation	-	-	Facilitators: Young females lead empowerment sessions (1/facility).		-	-	Facilitators: Females lead empowerment sessions (1/facility)	
Training								
Protocol training		Study overview and design, clinical data collection, Good Clinical Practice (3 days) (all staff)			Study overview and design, data collection, sexual and reproductive health refresher, values clarification (1-2 days)			
YFHS training		Medical and psychosocial support for adolescents (2 day) (all staff)			-	Medical and psychosocial support for adolescents (1 day) (all staff)		
Clinical training		Nurses trained on long-acting reversible contraception (5 days) and STI syndromic management (5 days)			All nurses expected to be familiar with these provision of all contraceptive methods and STI syndromic management. Provided on-the-job training.			
Clinical Modifications								
Space	-	Dedicated space for AGYW service delivery in a separate area from general clinic to ensure privacy from adults			-	Dedicated waiting and/or welcome area for AGYW		
Hours	Typically morning hours	AGYW can come in the morning or afternoon			AGYW can come in the morning or afternoon			
Cost	STI medications require payment	All services are free			All services are free			

Data Collection and Management

The two primary sources of data collection are a detailed behavioral survey and clinical service records. The behavioral survey is administered at three time points—at study enrollment, month six, and month 12. The behavioral survey contains questions about demographics, socio-economic status, past and current care-seeking behaviors, sexual history, depression (10-item Center for Epidemiologic Studies of Depression scale), intimate partner violence (Modified Conflict Tactic Scale), alcohol consumption (NIAAA brief alcohol screening tool). The twelve-month assessment also includes assessments of the BI and the CCT. The behavioral survey will be self-administered in South Africa, except among illiterate participants; for these participants it will be interviewer-administered. In Malawi it will be interviewer-administered to all participants by young female research assistants. All surveys will be administered on encrypted password-protected Android tablets using Open Data Kit software and stored on secure servers.

In both countries, we will document delivery of HTC, family planning, and STI services. Due to the unique clinical contexts, data collection will occur differently in the two countries. In Malawi, a clinic card that contains all clinical information has been developed for the study and will be used by clinical staff at each patient encounter and housed at the clinic. In South Africa, clinical staff will record clinical activities in existing clinical records and study staff will transcribe this information onto a study-specific form. In both countries, these data will then be entered into tablets in ODK by trained research assistants. In all clinics, study staff will systematically examine clinical records to ensure consistent ascertainment.

In both countries, each participant will be identified through a unique identifier. In South Africa, participants' identities will be verified through biometric data.

Study outcomes, analytic methods, and sample size

The primary clinical outcomes are care-seeking behaviors using clinical data. Within each quarter, we will compare the proportion of participants who received HTC, male and/or female condoms, hormonal or long-acting contraception, and both condoms and another form of contraception. We will also explore the proportion of participants who receive STI services. For all of these services, we will

assess the proportion of participants who use each method ever, in each quarter, and in all quarters. These data are available both through clinical abstraction, the primary measure of clinical effectiveness. Details are reported in Table 2.

HIV risk behaviors collected on the behavioral survey are primary behavioral outcomes of interest. Questions of particular interest are the proportion of AGYW who have multiple sexual partners, have a considerably older male partner, and experience IPV. We will compare these indicators between participants in each country in each model.

Table 2. Primary outcome measures

	Data source	Time period	Numerator	Denominator
Primary clinical outcomes				
HIV testing uptake	Clinical record	Quarter 1, 2, 3,4, ever, all	Number with an HIV test recorded in each period	Persons HIV-negative or HIV-unknown in that period
Condom uptake	Clinical record	Quarter 1, 2, 3,4, ever, all	Number who received condoms in each period	Full cohort
Contraceptive uptake	Clinical record	Quarter 1, 2, 3,4, ever, all 4	Number who received contraceptive pills or injections or received/continued long-acting contraception in each period	Full cohort
Dual method uptake	Clinical record	Quarter 1, 2, 3,4, ever, all	Number with condom and contraceptive uptake in each period	Full cohort
Primary sexual behavior outcomes				
Age disparate sex	Behavioral survey	12 months	Number reporting at least one current partner ≥10 years older	Number who took 12 month behavioral survey
Multiple partners in the last year	Behavioral survey	12 months	Number reporting >1 sexual partner in the last year	Number who took 12 month behavioral survey
Physical IPV	Behavioral survey	6 and 12 months	Number reporting physical IPV in that period	Number who took 6, 12 month behavioral surveys
Sexual IPV	Behavioral survey	6 and 12 months	Number reporting physical IPV in that period	Number who took 6, 12 month behavioral surveys
Emotional IPV	Behavioral survey	6 and 12 months	Number reporting physical IPV in that period	Number who took 6, 12 month behavioral surveys

For all primary clinical outcomes, we will conduct an intention to treat analysis, analyzing each participant in her assigned clinic and assessing whether she received services in that clinic. We will use generalized estimating equations to account for correlated records between each participant at each time point. A log or identity link, binomial distribution, and robust variance estimates will be used to estimate

risk ratios and risk differences and ninety-five percent confidence intervals. We will compare absolute differences at each time point, as well as changes over time.

In Stata 12.0, we conducted two-sample tests of proportions to determine how much statistical power would be available to detect differences between any two arms at any time point within each country. Using an alpha level of 0.05 and a sample size of 250 participants per model we have >80% power to detect differences ≥13% between any two models at any time point.

Qualitative Sub-study

A qualitative sub-study will be conducted to better understand participant experiences with each service delivery model. Twelve to 15 in-depth interviews (IDIs) will be conducted at each site in each country (N=96-120 IDIs total). IDIs will focus on individual experiences with SOC, YFHS, BI, and CCT. At each clinic we will purposively select a mixture of good care-seekers, poor-care-seekers, and HIV-infected young women. Focus group discussions (FGDs) (N=2-3/site) will address norms surrounding these same topics and strategies for improving or enhancing these services. At each site, we will have at least one FGD with adolescent girls 15-19 years old and one with young women 20-24 years old. IDIs and FGDs will be conducted in Chichewa in Malawi and in isiXhosa or English in South Africa. All IDIs and FGDs will be transcribed and translated into English. They will be coded and analyzed using a thematic approach.

Ethics and Dissemination

This study was approved by the University of North Carolina Institutional Review Board (IRBIS 15-2901) and two local regulatory bodies: the Malawi National Health Sciences Research Committee (15/7/1447) and the University of Cape Town Human Research Ethics Committee (815/2015). In South Africa, all AGYW 15-24 years could decide whether to provide informed consent for themselves; those 15-17 years could seek optional parental consent. We requested that minors 15-17 years be able to consent for themselves because they are able to receive all of these clinical services without parental

consent. In a study designed to reduce barriers to care-seeking, obtaining parental consent could pose an undue barrier. In Malawi, AGYW 18-24 years will provide informed consent for themselves. AGYW 15-17 years will provide assent and have a parent, guardian, or authorized representative provide informed consent. We requested that minors be able to consent as adults, but this provision was denied. At each site, a community club of individuals ≥18 years who could serve as authorized representatives will be established.

Dissemination activities will occur at all stages of the study: prior to implementation, at intermediate points during implementation, and at study culmination. Prior to study implementation, meetings were held with key local stakeholders, such as local health leadership (e.g. district, province, or city managers), clinical supervisors, and clinical staff. These meetings were designed to seek permission for study implementation, orient these stakeholders to study goals, and work together on implementation questions. Sensitization activities were also conducted with key community stakeholders, such as local chiefs and religious leaders, school headmasters, and library managers. These sensitizations were designed to inform key local leaders about the study, elicit buy-in and support, and facilitate recruitment. During study implementation, these same stakeholders will be engaged to report on study progress and discuss challenges. At the end of the study, results will be disseminated so that stakeholders and participants are aware of the study's primary findings. Additionally, in both countries, we have oriented policy-makers and implementing partners to study goals and progress. Results will be disseminated in peer-reviewed journals and at national and international meetings and conferences. Dissemination of final results is expected in 2018.

Conclusion

Implementing combination interventions for HIV prevention among AGYW in SSA has become a major focus of governments and donors over the last several years. In most cases however, programs have not been rigorously evaluated for impact. Girl Power is expected to address this important gap in

understanding and provide greater insights into how to support vulnerable AGYW related to SRH and HIV in SSA.

Author Contributions

NER, AEP, LGB, and LM designed the study. Other co-authors are responsible for study coordination, implementation, and analysis. All authors either wrote or made substantial edits to the draft, approved the final version and take responsibility for the work.

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Competing Interests Statement

We have no competing interests to declare.

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Figure 1 Legend: Figure 1 depicts the study design.

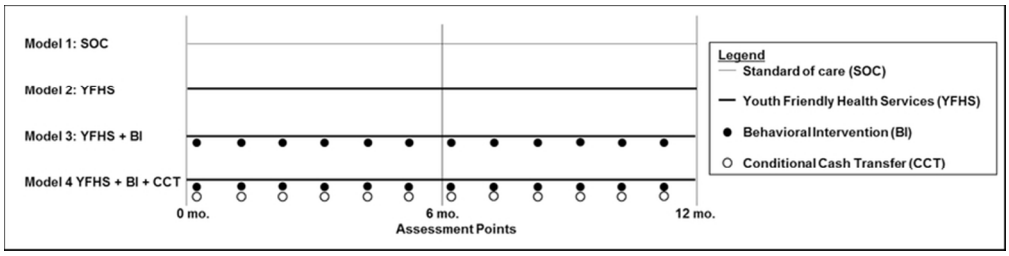

Figure 1 depicts the study design.

73x18mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any pre-specified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	10
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-12
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	10-12
Bias	9	Describe any efforts to address potential sources of bias	12
Study size	10	Explain how the study size was arrived at	12
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	11
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	11
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) If applicable, explain how loss to follow-up was addressed	NA
		(*e*) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
NA		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	NA
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Comparing Four Service Delivery Models for Adolescent Girls and Young Women through the "Girl Power" study: Protocol for a Multisite Quasi-experimental Cohort Study

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Comparing Four Service Delivery Models for Adolescent Girls and Young Women through the "Girl Power" study: Protocol for a Multisite Quasi-experimental Cohort Study

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The "Girl Power" protocol

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Abstract

Introduction: In sub-Saharan Africa, adolescent girls and young women (AGYW) face a range of sexual and reproductive health challenges. Clinical, behavioral, and structural interventions have each reduced these risks and improved health outcomes. However, combinations of these interventions have not been compared to each other or to no intervention at all. The "Girl Power" study is designed to systematically make these comparisons.

Methods and Analysis: Four comparable health facilities in Malawi and South Africa (N=8) were selected and assigned to one of the following models of care:

1) Standard of care: AGYW can receive family planning, HIV testing and counseling (HTC), and STI syndromic management in 3 separate locations with 3 separate queues with the general population. No youth-friendly spaces, clinic modifications or trainings are offered.
2) Youth-Friendly Health Services (YFHS): AGYW are meant to receive integrated family planning, HTC, and STI services in dedicated youth spaces with youth-friendly modifications and providers trained in YFHS.
3) YFHS + behavioral intervention (BI): In addition to YFHS, AGYW can attend twelve monthly theory-driven, facilitator-led, interactive sessions on health, finance, and relationships.
4) YFHS + BI + conditional cash transfer (CCT): In addition to YFHS and BI, AGYW receive up to twelve CCTs conditional on monthly BI session attendance.

At each clinic, 250 AGYW 15-24 years old (N=2000 total) will be consented, enrolled, and followed for one year. Each participant will complete a behavioral survey at enrollment, 6-months, and 12-months. All clinical, behavioral, and CCT services will be captured. Outcomes of interest include uptake of each package element and reduction in HIV risk behaviors. A qualitative sub-study will be conducted.

Ethics/Dissemination: This study has received ethical approval from the University of North Carolina, the University of Cape Town, and Malawi's National Health Science Research Committee. Study plans, processes, and findings will be disseminated to stakeholders, in peer-reviewed journals, and at conferences.

Strengths and Limitations of the this study

- Within each country, the selection of four comparable clinics and random assignment of each to one of the four models of service delivery is a key strength.
- The potential for differential recruitment, retention, and data ascertainment across sites are limitations.
- The study is not powered to detect differences in biologic outcomes, especially HIV incidence, a limitation.
- Implementing a similar set of models in two distinct sub-Saharan contexts enhances generalizability, a key strength.

Introduction

In sub-Saharan Africa (SSA), adolescent girls and young women (AGYW) 15-24 years old are vulnerable to a wide range of sexual and reproductive health (SRH) challenges, including acquisition of HIV and sexually transmitted infections (STI), unintended and unwanted pregnancies, and intimate partner violence (IPV). These challenges have many common underlying health system, behavioral, and structural drivers that have not, to our knowledge, been addressed and assessed in combination—in a youth friendly service delivery environment, with behavioral interventions, and with socio-economic support.

AGYW in SSA typically experience a service delivery environment characterized by judgmental provider attitudes, a lack of privacy, inconvenient hours, and non-integrated services.[1] As a result, service utilization by AGYW for SRH remains low. Youth-friendly health services (YFHS) that include provider training, clinic modifications, and community-based demand creation are promising approaches for increasing uptake of such services.[1-6] Eight out of nine randomized or quasi-experimental studies in SSA assessing YHFS models with these components increased service uptake by AGYW.[3] However, to our knowledge, such a platform has never been tested in combination with behavioral and structural interventions.

Offering behavioral interventions (BIs) within a YFHS platform could further enhance service uptake and address other behavioral risks and psychosocial outcomes. The social context of intimate relationships in SSA is characterized by severe gender inequality. Gender norms favor male control over sexual intercourse, often leaving young women with less power in sexual decision-making.[7-10] Additionally, many young women have older male partners, frequently with a transactional dimension, who are more likely to be HIV-infected.[11-15] BIs based on the theory of gender and power,[16,17] and social cognitive theory[18] have been shown to address these power imbalances and reduce multiple partnerships, HSV-2 incidence, and IPV.[19-21] All of these evidence-based interventions address gender norms and involve participatory activities for groups of young women. Synthesizing the most effective elements of these "empowerment" interventions and offering them within a YFHS service delivery platform could

help reduce behavioral sources of risk, improve psychosocial outcomes, and generate demand for health services. Assessing evidence-based clinical and behavioral interventions is a critical next step.

Cash transfers are also a promising tool for preventing HIV among AGYW.[22-24] In Malawi, when cash payments were given to girls and their guardians they were more likely to remain in school, less likely to report age-disparate relationships, and have lower HIV and HSV-2 prevalence.[22] In South Africa, adolescents living in homes receiving a national child grant reported half the incidence of transactional sex and much less age-disparate sex than those in homes not receiving it.[23] In a South African trial, cash transfers conditioned on schooling did not lead to lowered HIV incidence, but did lead to reductions in intimate partner violence and sexual risk.[25] However, to our knowledge, a cash transfer program has not been evaluated for AGYW in a clinical environment, nor has it been implemented in combination with a behavioral intervention. Understanding whether a cash transfer provides benefits in combination with a YFHS service delivery platform and empowerment-based BI is not known.

It is becoming widely acknowledged that combination HIV prevention packages that include effective, acceptable, and scalable clinical, socio-behavioral and structural interventions may have the greatest impact.[26-29] However, it is not known how best to combine different intervention levels for maximal effectiveness for multiple outcomes. The Girl Power study is designed to compare three different combinations of evidence-based interventions to one another and to a standard of care and to assess their impact on a range of care-seeking and sexual risk behaviors in two sub-Saharan African countries.

Methods and Analysis

Study Setting

The Girl Power study is an ongoing study (February 2016-November 2017) being conducted in Malawi and South Africa. These countries represent two prototypical, yet distinct sub-Saharan African contexts. In Malawi, based on nationally representative household data, first births often occur early, at a median age of 19 years, and within the context of marriage.[30] In South Africa, sexual activity tends to be

outside of the context of marriage, with a somewhat later age of first birth.[31,32] Malawi is characterized by extreme poverty with the majority of the population living on less than $1 per day, whereas South Africa has extreme wealth disparities. In spite of these socio-economic differences, both countries have high HIV prevalence levels—6% of women 20-24 years old are HIV-infected in Malawi and 17% in South Africa, rates considerably higher than their male counterparts.[30] Sexual violence is also a serious problem in both countries, with high rates of non-consensual sex reported by young women.[33-35] Additionally, both have public sector health facilities with human resource shortages, stock-outs of pharmaceuticals and supplies, long queues, and providers who exhibit negative attitudes towards AGYW. It was within these contexts that the Girl Power study was conceptualized.

Four comparable public sector health facilities were selected in each country. In Malawi, the four sites are public-sector health centers in Lilongwe. All sites are on a main road, have antenatal volumes >200 clients per month, and have antenatal HIV prevalence ≥5%. These sites have higher HIV prevalence than the surrounding rural areas where antenatal HIV prevalence is <5%. In South Africa, the four sites are in the Klipfontein and Mitchell's Plain areas in the Western Cape, which serve primarily black and coloured populations. These are high-density, low socioeconomic peri-urban townships comprised predominantly of informal dwellings. Antenatal prevalence in the Western Cape is 17%. In both countries, each clinic serves distinct communities. In South Africa, biometric identification is being used to ensure the same people do not enroll in more than one site. In Malawi, all sites are at least 7km apart.

Prior to the study, all sites in both countries offered free HIV testing and counseling (HTC), contraception, and STI services in separate locations within each clinic with separate queues. Condoms were also available for free at all sites—in the pharmacy at the Malawian sites and throughout the clinic at the South African sites. At all sites in both countries AGYW could receive general health services with the general population. However, there were no distinct YFHS spaces, times, or providers, no behavioral interventions (BIs), and no opportunities for CCTs within the clinic.

Study Design and Interventions

Girl Power is a quasi-experimental prospective cohort study comparing four different models of service delivery and their impacts on care-seeking and sexual risk behaviors among AGYW (Figure 1). The primary outcomes of interest are service uptake and behavioral risks. Participants enrolled at all sites will complete behavioral surveys at baseline, six, and twelve months and have their clinical data ascertained over a one-year period. In each country, each clinic was randomly assigned to one of the following models of care:

- Model 1: Standard of care (SOC): The SOC offers HTC, contraception, STI syndromic management and condoms to AGYW. However, health care providers have not been trained in YFHS and clinics have not made YFHS modifications, regarding hours, clinic navigation, integration, cost, or space.
- Model 2: YFHS: HTC, contraception, and STI services are offered by health providers who have been trained in YFHS. YFHS modifications have been made to the clinics, including clinic navigation (both countries), a youth-only space with integrated service provision (Malawi), and longer hours (Malawi).
- Model 3: YFHS + BI: In addition to the YFHS package, participants can attend twelve monthly facilitator-led, small-group interactive sessions. They are based on other evidence-based interventions from the region,[17,19,21] and are motivated by the theory of gender and power and Social Cognitive Theory. These sessions address sexual health topics (e.g. HIV, reproductive health), social issues (e.g. partner communication, peer pressure, and intimate partner violence), financial literacy (e.g. budgeting, saving, and investing), and general topics (e.g. self-esteem, goal-setting, and decision-making). Each session includes an activity to do at home after the session in order to encourage behavior change. Each country adapted curricula in a culturally-responsive manner; although sessions were not identical across countries, they explore similar themes. We expect sessions will be delivered to groups of 10-20 girls at once.

- Model 4: YFHS + BI + conditional cash transfer (CCT): In addition to the YFHS package and empowerment sessions, AGYW received a monthly CCT (approximately $6) conditional on attending the monthly empowerment session. Each young woman could receive up to 12 CCTs (one per month). In Malawi, the CCT is being provided in physical cash and in South Africa the CCT is provided electronically.

Study and clinical personnel, training activities, and clinical modifications by country and model are described in greater detail in Table 1.

Study Population

At each of the eight sites, 250 AGYW will be recruited and followed for one year. Eligibility criteria include being female, 15-24 years old, residing in the clinic's catchment area, and willing to be enrolled for a one-year period. The intention is to recruit AGYW who are already sexually active or likely to become sexually active, although this is not a strict eligibility criterion. In total, 1000 AGYW will be enrolled in each country (N=2000 total).

Recruitment will occur comparably at each site through a combination of community outreach activities, self-referral, and referral through invitations from other participants. Outreach workers will visit parts of the catchment area known to be high-risk. Through one-on-one conversations they will build rapport, assess sexual activity and past care-seeking behaviors, promote the services at their site, and invite them to participate. AGYW who enroll in the study will be provided with invitations to invite friends who they believe would also benefit.

Follow-up phone and physical tracing will be conducted for girls who miss their six or twelve month visits. We will make comparable attempts to trace participants at all four clinics to avoid differential loss-to-follow-up and provide the same transport reimbursement for the three research visits across all four sites. These efforts are designed to minimize differential loss-to-follow-up.

Table 1. Girl Power Personnel, Training and Clinical Modifications by Clinic and Country

	Malawi				South Africa			
	Model 1	Model 2	Model 3	Model 4	Model 1	Model 2	Model 3	Model 4
Clinical model	SOC	YFHS	YFHS+BI	YFHS+BI+CCT	SOC	YFHS	YFHS+BI	YFHS+BI+CCT
Personnel								
Research	Research assistant: Young (≤29) female full-time staff responsible for all consenting, screening, enrolment, and behavioral surveys (1/clinic)				Research assistant: Female full-time staff responsible for all consenting, screening, enrolment, and behavioral surveys (1/clinic)			
Outreach	Peer outreach workers: Young full-time lay staff responsible for recruitment and retention activities. (2/clinic)	Peer outreach workers/navigators: Young full-time lay staff responsible for recruitment and retention activities (outreach roles). They also welcome participants, assess their sexual and reproductive health needs, and help with clinic navigation. (2/clinic)			Peer Outreach workers: Temporary staff responsible for community outreach and recruitment at study initiation (2/clinic)			
Navigation	-				Peer navigator: Full-time staff who welcome participants, discuss sexual and reproductive health needs, fetch patient files, and help with clinic navigation (1/clinic)			
Family planning and STI services	-	Nurses: 4-5 government nurses from these sites were assigned to rotate through a youth-focused Girl Power clinic.			-	Nurses: 1-3 government nurses provide SRH services to Girl Power participants		
HIV counseling and testing		Counselor: 1 young female HIV counselor was assigned to the Girl Power clinic.				Counselor: 1-3 government HTC counselors are available to attend to Girl Power participants		
Workshop facilitation	-	-	Facilitators: Young females lead empowerment sessions (1/facility).		-	-	Facilitators: Females lead empowerment sessions (1/facility)	
Training								
Protocol training		Study overview and design, clinical data collection, Good Clinical Practice (3 days) (all staff)			Study overview and design, data collection, sexual and reproductive health refresher, values clarification (1-2 days)			
YFHS training		Medical and psychosocial support for adolescents (2 day) (all staff)			-	Medical and psychosocial support for adolescents (1 day) (all staff)		
Clinical training		Nurses trained on long-acting reversible contraception (5 days) and STI syndromic management (5 days)			All nurses expected to be familiar with these provision of all contraceptive methods and STI syndromic management. Provided on-the-job training.			
Clinical Modifications								
Space	-	Dedicated space for AGYW service delivery in a separate area from general clinic to ensure privacy from adults			-	Dedicated waiting and/or welcome area for AGYW		
Hours	Typically morning hours	AGYW can come in the morning or afternoon			AGYW can come in the morning or afternoon			
Cost	STI medications require payment	All services are free			All services are free			

Data Collection and Management

The two primary sources of data collection are a detailed behavioral survey and clinical service records. The behavioral survey is administered at three time points—at study enrollment, month six, and month 12. The behavioral survey contains questions about demographics, socio-economic status, past and current care-seeking behaviors, sexual history, depression (10-item Center for Epidemiologic Studies of Depression scale), intimate partner violence (Modified Conflict Tactic Scale), alcohol consumption (NIAAA brief alcohol screening tool). The twelve-month assessment also includes assessments of the BI and the CCT. The behavioral survey will be self-administered in South Africa, except among illiterate participants; for these participants it will be interviewer-administered. In Malawi it will be interviewer-administered to all participants by young female research assistants. All surveys will be administered on encrypted password-protected Android tablets using Open Data Kit software and stored on secure servers.

In both countries, we will document delivery of HTC, family planning, and STI services. Due to the unique clinical contexts, data collection will occur differently in the two countries. In Malawi, a clinic card that contains all clinical information has been developed for the study and will be used by clinical staff at each patient encounter and housed at the clinic. In South Africa, clinical staff will record clinical activities in existing clinical records and study staff will transcribe this information onto a study-specific form. In both countries, these data will then be entered into tablets in ODK by trained research assistants. In all clinics, study staff will systematically examine clinical records to ensure consistent ascertainment.

In both countries, each participant will be identified through a unique identifier. In South Africa, participants' identities will be verified through biometric fingerprinting.

Study outcomes, analytic methods, and sample size

The primary clinical outcomes are care-seeking behaviors using clinical data. Within each quarter, we will compare the proportion of participants who received HTC, male and/or female condoms, hormonal or long-acting contraception, and both condoms and another form of contraception. We will also explore the proportion of participants who receive STI services. For all of these services, we will

assess the proportion of participants who use each method ever, in each quarter, and in all quarters. These data are available both through clinical abstraction, the primary measure of clinical effectiveness. Details are reported in Table 2.

HIV risk behaviors collected on the behavioral survey are primary behavioral outcomes of interest. Questions of particular interest are the proportion of AGYW who have multiple sexual partners, have a considerably older male partner, and experience IPV. We will compare these indicators between participants in each country in each model.

Table 2. Primary outcome measures

	Data source	Time period	Numerator	Denominator
Primary clinical outcomes				
HIV testing uptake	Clinical record	Quarter 1, 2, 3,4, ever, all	Number with an HIV test recorded in each period	Persons HIV-negative or HIV-unknown in that period
Condom uptake	Clinical record	Quarter 1, 2, 3,4, ever, all	Number who received condoms in each period	Full cohort
Contraceptive uptake	Clinical record	Quarter 1, 2, 3,4, ever, all 4	Number who received contraceptive pills or injections or received/continued long-acting contraception in each period	Full cohort
Dual method uptake	Clinical record	Quarter 1, 2, 3,4, ever, all	Number with condom and contraceptive uptake in each period	Full cohort
Primary sexual behavior outcomes				
Age disparate sex	Behavioral survey	12 months	Number reporting at least one current partner ≥10 years older	Number who took 12 month behavioral survey
Multiple partners in the last year	Behavioral survey	12 months	Number reporting >1 sexual partner in the last year	Number who took 12 month behavioral survey
Physical IPV	Behavioral survey	6 and 12 months	Number reporting physical IPV in that period	Number who took 6, 12 month behavioral surveys
Sexual IPV	Behavioral survey	6 and 12 months	Number reporting physical IPV in that period	Number who took 6, 12 month behavioral surveys
Emotional IPV	Behavioral survey	6 and 12 months	Number reporting physical IPV in that period	Number who took 6, 12 month behavioral surveys

For all primary clinical outcomes, we will conduct an intention to treat analysis, analyzing each participant in her assigned clinic and assessing whether she received services in that clinic. We will use generalized estimating equations to account for correlated records between each participant at each time point. A log or identity link, binomial distribution, and robust variance estimates will be used to estimate

risk ratios and risk differences and ninety-five percent confidence intervals. We will compare absolute differences at each time point, as well as changes over time.

In Stata 12.0, we conducted two-sample tests of proportions to determine how much statistical power would be available to detect differences between any two arms at any time point within each country. Using an alpha level of 0.05 and a sample size of 250 participants per model we have >80% power to detect differences ≥13% between any two models at any time point.

Qualitative Sub-study

A qualitative sub-study will be conducted to better understand participant experiences with each service delivery model. Twelve to 15 in-depth interviews (IDIs) will be conducted at each site in each country (N=96-120 IDIs total). IDIs will focus on individual experiences with SOC, YFHS, BI, and CCT. At each clinic we will purposively select a mixture of good care-seekers, poor-care-seekers, and HIV-infected young women. Focus group discussions (FGDs) (N=2-3/site) will address norms surrounding these same topics and strategies for improving or enhancing these services. At each site, we will have at least one FGD with adolescent girls 15-19 years old and one with young women 20-24 years old. IDIs and FGDs will be conducted in Chichewa in Malawi and in isiXhosa or English in South Africa. All IDIs and FGDs will be transcribed and translated into English. They will be coded and analyzed using a thematic approach.

Ethics and Dissemination

This study was approved by the University of North Carolina Institutional Review Board (IRBIS 15-2901) and two local regulatory bodies: the Malawi National Health Sciences Research Committee (NHSRC) (15/7/1447) and the University of Cape Town Human Research Ethics Committee (815/2015). In South Africa, all AGYW 15-24 years could decide whether to provide informed consent for themselves; those 15-17 years could seek optional parental consent. We requested that minors 15-17 years be able to consent for themselves because they are able to receive all of these clinical services without

parental consent. In a study designed to reduce barriers to care-seeking, obtaining parental consent could pose an undue barrier; the ethics committee agreed. In Malawi, AGYW 18-24 years will provide informed consent for themselves. AGYW 15-17 years will provide assent and have a parent, guardian, or authorized representative provide informed consent. We requested that minors be able to consent as adults, but this provision was denied. At each site, a community club of individuals ≥18 years who could serve as authorized representatives will be established, a suggestion made by the NHSRC.

Dissemination activities will occur at all stages of the study: prior to implementation, at intermediate points during implementation, and at study culmination. Prior to study implementation, meetings were held with key local stakeholders, such as local health leadership (e.g. district, province, or city managers), clinical supervisors, and clinical staff. These meetings were designed to seek permission for study implementation, orient these stakeholders to study goals, and work together on implementation questions. Sensitization activities were also conducted with key community stakeholders, such as local chiefs and religious leaders, school headmasters, and library managers. These sensitizations were designed to inform key local leaders about the study, elicit buy-in and support, and facilitate recruitment. During study implementation, these same stakeholders will be engaged to report on study progress and discuss challenges. At the end of the study, results will be disseminated so that stakeholders and participants are aware of the study's primary findings. Additionally, in both countries, we have oriented policy-makers and implementing partners to study goals and progress. Results will be disseminated in peer-reviewed journals and at national and international meetings and conferences. Dissemination of final results is expected in 2018.

Discussion

Our findings will need to be interpreted in light of potential biases. First, each model may preferentially recruit persons who are interested in the services at that clinic. For example, the absence of services in model 1 may lead to recruitment of persons who do not need any services and the presence of a cash transfer in model 4 may lead to recruitment of persons in need of cash. We will explore whether baseline behavioral and socio-economic characteristics differ by model, and if so conduct adjusted

analyses as needed. Second, it is possible that retention will be differential across arms. Different retention is precisely what we are trying to measure in clinical outcomes, but is problematic with respect to behavioral survey outcomes. To mitigate this risk, identical research incentives will be offered in all models at the three behavioral survey visits. We will explore the magnitude and nature of loss by clinic and use multiple imputation techniques and sensitivity analyses to address the loss that does occur. Differential ascertainment of clinical outcomes is a third potential source of bias: clinical staff trained in models 2, 3, and 4 may capture services more consistently than staff in clinic 1: apparent differences in service uptake could in fact be differences in data capture. Observing whether clinical records are consistent with self-report will allow us to explore this potential bias. Finally, enrollment in more than one model is possible in the Malawi sites, which do not have biometric identification. If such contamination were to occur at a large scale, behavioral survey results would biased towards the null, as response options from the same participant at multiple clinics would be similar. In spite of these potential limitations, we believe Girl Power makes an important and unique contribution.

Conclusion

Implementing combination interventions for HIV prevention among AGYW in SSA has become a major focus of governments and donors over the last several years. In most cases however, programs have not been rigorously evaluated for impact. Girl Power is expected to address this important gap in understanding and provide greater insights into how to support vulnerable AGYW related to SRH and HIV in SSA.

Author Contributions

NER, AEP, LGB, RM, JT, MH, AK, and LM1 designed the study. TP, NM, NB, DV, AM, BM, and LM2 were responsible for study coordination and data acquisition. All authors either wrote or made substantial edits to the draft, approved the final version and take responsibility for the work.

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Competing Interests Statement

We have no competing interests to declare.

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Figure 1 Legend: Figure 1 depicts the study design.

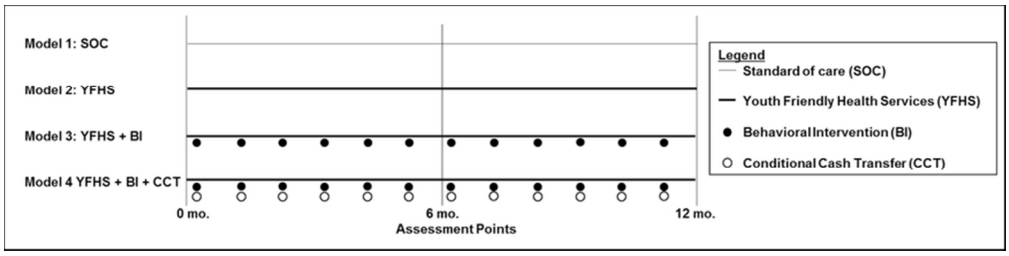

Figure 1 depicts the study design.

73x18mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any pre-specified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	10
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-12
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	10-12
Bias	9	Describe any efforts to address potential sources of bias	12
Study size	10	Explain how the study size was arrived at	12
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	11
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	11
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) If applicable, explain how loss to follow-up was addressed	NA
		(*e*) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
NA		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	NA
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.