Feasibility of Recruiting Adolescent Women into a Mock HIV Prevention Trial

Elizabeth E. Tolley[1], Sylvia Kaaya[2], Doreen Bangapi[2], Anna Minja[2], Jennifer Headley[1], Anna Kaale[2], Joy Noel Baumgartner[3]

BACKGROUND

Recent clinical trial successes have accelerated the need to evaluate the safety, acceptability, and effectiveness of new HIV prevention technologies, including oral and vaginal microbicides, among adolescents. However, few data exist on the ability to recruit and retain adolescents below the age of 18 in clinical trial research. In Tanzania, we conducted a mock HIV prevention clinical trial to evaluate the opportunities and challenges of recruitment among adolescents as compared to young adult women.

OBJECTIVES

1. To describe the recruitment of adolescents (aged 15-17) versus young adult women (aged 18-21).
2. To determine whether adolescents are more likely than adult women to miss study visits.
3. To identify baseline socio-demographic or other factors that may account for differences in retention between age groups.

METHODS

The mock HIV prevention clinical trial compared the feasibility of recruiting HIV-negative, non-pregnant, recently sexually active adolescents aged 15-17 with young adult women aged 18-21. After community information meetings, potential participants were invited to visit the study clinic for baseline screening and enrollment, which usually took place on the same day.

Screening involved provision of informed consent, followed by verification of age (through specified documentation or a series of time-related questions) and recent sexual activity. Potential participants were then tested for HIV and pregnancy before considered to be enrolled. Additional baseline questionnaires and a physical exam were conducted only after enrollment. Follow-up was conducted at 2, 4, and 6 months. An optional sub-study with a microbicide proxy product took place between 4 and 6 months.

We examined differences in the status of missed visits between age groups using chi-square tests. We also examined differences in baseline socio-demographic and other factors between age groups using two-sample t-tests and chi-square or Fisher's exact tests . Finally, we examined the relationship between each baseline factor and the status of missed visits, controlling for age group, using the Cochran-Mantel-Haenszel test for association. Any differences in these relationships by age group were noted descriptively.

The study was reviewed and approved by the ethics committees of Muhimbili University Health and Allied Sciences (MUHAS), the National Institute for Medical Research (NIMR), and FHI 360's Protection of Human Subjects Committee (PHSC). As stipulated by the three ethics committees, participants aged 16-21 could provide their own informed consent to join the mock trial. Adolescents aged 15 required additional consent from a parent or guardian.

AUTHOR AFFILIATIONS

[1] FHI 360, Research Triangle Park, Durham, North Carolina, United States

[2] Muhimbili University Health and Allied Sciences (MUHAS), Dar es Salaam, Tanzania

[3] FHI 360, Washington, D.C., United States

RESULTS

Between May 30, 2011, and May 15, 2012, we screened 147 adolescents and young women and enrolled 127. Follow-up is ongoing through December 2012.

SOCIO-DEMOGRAPHICS

Most adolescents and young women in this study lived with one or both parents (80% and 59%, respectively). Almost all adolescents (97%) and most young adult women (79%) were single but had a regular partner. Almost half of the adolescents (46%) and just under two-thirds of the adult participants (59%) had some secondary education.

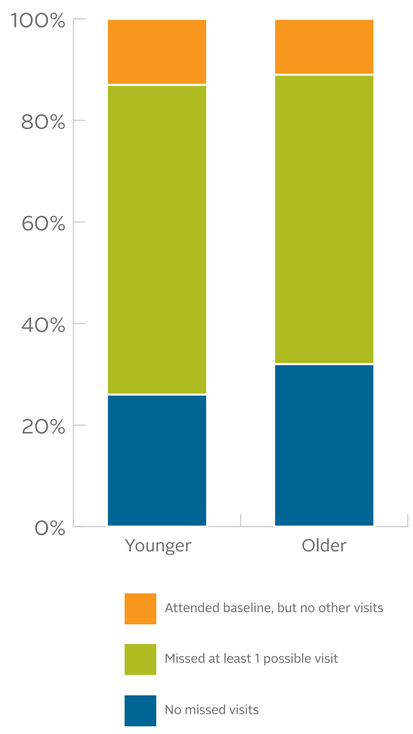
RECRUITMENT

Young adult women were more than twice as likely as adolescents to make a clinic visit for study screening (Table 1). Similar proportions of adolescents and young women were found to be ineligible. The main reasons for non-enrollment related to testing positive for pregnancy or HIV at screening.

TABLE 1. STUDY ELIGIBILITY, BY AGE GROUP

	Adolescents (aged 15-17)	Young Women (aged 18-21)	P-Value
	(N=40)	(N=101)	
Screened but not enrolled	12.5%	8.9%	0.54
Enrolled	87.5%	91.1%	
Reasons for non-enrollment	N=5	N=9	
HIV positive or pregnant	40.0%	77.8%	
Not sexually active	40.0%	0.0%	
Parental consent not obtained	20.0%	n/a	
Consented, but no baseline	0.0%	22.2%	
Not fully screened or missing age verification	N=6		

FIGURE 1. MISSED VISIT STATUS, BY AGE GROUP



MISSED VISITS

Based on data from the 127 participants enrolled thus far, less than a third fully adhered to their follow-up schedule (Figure 1). Adolescents were less likely than young adults to attend all visits, although this difference was not statistically significant.

Study staff conducted telephone calls and home visits to encourage participants to return for visits or to determine if they intended to drop out. Several issues contributed to missed visits, including lack of reliable cell phone numbers, high participant mobility, and local transport difficulties. About two-thirds of participants who returned for their 4-month visit agreed to participate in the sub-study. Seven participants declined participation, and six others were found pregnant at the visit and were thus ineligible to participate.

AFFECT OF BASELINE RISK FACTORS ON RETENTION

Overall, adolescents differed from young adult women in several important ways. They were significantly less likely to have ever been pregnant (14% versus 43%), more likely to have NO perceived risk of HIV (37% versus 15%), and less likely to have ever been tested for HIV (42% versus 76%) (data not shown). Table 2 examines whether these and other baseline risk factors accounted for differences in the status of missed visits.

Participants who did not return after baseline were more likely to be employed and less likely to have ever been pregnant. In addition, they were less likely to have ever been diagnosed with or experienced a reproductive tract infection (RTI) or to have been tested for HIV.

Lack of prior exposure to SRH services was significantly associated with having missed some or all visits post-baseline. This was especially true for adolescents. Almost all adolescents who attended only baseline were never tested for HIV (80%), compared to just less than half of the older group who attended only baseline (42%).

TABLE 2. BASELINE FACTORS BY MISSED VISIT STATUS, WITHOUT AND WITH CONTROLLING FOR AGE GROUP

Factor	No Missed Visits	Missed Some Follow-up Visits	Missed All Post-Baseline Visits	P-Value	Mantel-Haenszel P-Value
	(N=35)	(N=72)	(N=20)	(w/o Controlling for Age)	(Controlling for Age)
Socio-Demographic Factors					
Employed	28.6%	25.0%	45.0%	0.22	0.22
Does not live with either parent	48.6%	26.4%	45.0%	0.18	0.21
Away from home for more than 2 weeks	39.4%	31.9%	35.0%	0.76	0.20
Ever Pregnant	45.7%	34.7%	20.0%	0.16	0.19
Baseline Risk Perception					
No perceived HIV risk	11.4%	26.4%	20.0%	0.28	0.30
Perceived a little HIV risk	77.1%	55.6%	60.0%		
Perceived a lot of HIV risk	11.4%	18.1%	20.0%		
Prior Use of SRH Services					
	N=35	N=64	N=16		
Never diagnosed/experienced RTIs	60.0%	84.4%	93.8%	0.005*	0.007*
	N=35	N=68	N=17		
Never tested for HIV	11.4%	38.2%	52.9%	0.003*	0.005*
	N=35	N=68	N=17		
Never had a pelvic exam	82.9%	86.8%	94.1%	0.53	0.57

Abbreviations: RTI = reproductive tract infection; SRH = sexual and reproductive health.

Column 5 of the table presents the significance level for independent comparisons of baseline socio-demographic, risk-perception, and sexual and reproductive health (SRH) service-utilization variables by missed visit status, without controlling for age. Column 6 (the last column) indicates the significance of each independent variable when controlling for age group.

STUDY LIMITATIONS

OUR ANALYSIS WAS LIMITED DUE TO A SMALL SAMPLE SIZE. THE INTENDED SAMPLE SIZE WAS 300: 150 PARTICIPANTS EACH FROM PUNE, INDIA, AND DAR ES SALAAM, TANZANIA. HOWEVER, THE INDIA SITE WAS CLOSED AFTER A COMMUNITY FORMATIVE RESEARCH PHASE. ENROLLMENT IN TANZANIA WAS CLOSED JUST AFTER THIS ANALYSIS WAS CONDUCTED, AND FOLLOW-UP IS STILL IN PROGRESS, LIMITING OUR ABILITY TO FURTHER REPORT ON WILLINGNESS TO JOIN THE PRODUCT SUB-STUDY AND ON OVERALL RETENTION IN THE MAIN STUDY.

CONCLUSIONS

It is feasible to recruit adolescent women to HIV prevention trials, although they may face special challenges in accessing clinic sites. Our participants tended to be highly mobile and difficult to follow-up through mobile phones or home visits. In addition, young women's lack of prior exposure to SRH services may create barriers to participation. Those who did not return after their baseline visit were less likely to have ever been pregnant, or to have accessed HIV testing or other services. In particular, recruitment strategies that include logistical support for follow-up visits and ongoing community informational activities that create demand for adolescent SRH visits may be needed, especially for adolescents aged 15-17.

ACKNOWLEDGEMENTS

We would like to thank the young women who participated in this study, as well as the Youth Interactive Group (YIG) that assisted with recruitment. The clinical staff at the Infectious Disease Center (IDC) in Dar es Salaam, Tanzania, took on additional responsibilities to make this study happen. We thank Dr. Mario Chen and Ms. Lisa Albert for their statistical support and review of this poster. Finally, we would like to acknowledge the National Institute for Mental Health (NIMH) for funding this study (RO1 MH086160).

fhi360 THE SCIENCE OF IMPROVING LIVES

PEPFAR U.S. President's Emergency Plan for AIDS Relief

NIMH National Institute of Mental Health

ELIMU TIBA UTAFITI

www.fhi360.org