

Longitudinal Effects of a Smartphone Game (Tumaini) to Prevent HIV among Young Africans: 45-Month Trajectories of Proximal Outcomes related to Condom Use in a Randomized Controlled Trial

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Abstract

Background: African adolescents and young adults account for a disproportionate number of new HIV infections. There is an urgent need to identify scalable and cost-effective behavioral HIV prevention strategies for this population. Using a condom at first sex is associated with higher likelihood of consistent use later. Tumaini ("Hope for the Future" in Swahili) is a choose-your-own-adventure smartphone game that has been shown to reduce risk of unprotected first sex by endline in a 45-month randomized controlled trial in Western Kenya.

Objective: We sought to assess the impact of Tumaini on proximal outcomes related to condom use at first sex, specifically, behavioral intentions, self-efficacy, attitudes, and knowledge, longitudinally across mid-adolescence in the above trial.

Methods: Adolescent participants (n=996, mean baseline age 14.0 years) were randomized 1:1 to receive either a smartphone loaded with Tumaini or an attention-control Math game for 5-7 weeks at three timepoints (mean ages 14.0, 15.3, and 16.0 years). They completed a behavioral survey at 13 timepoints through mean age 17.7 years. Using generalized estimating equations and controlling for age at baseline, we modeled mean scores (overall and stratified by gender) on a range of condom-related survey items over time to assess mean differences at specific timepoints. We applied appropriate Bonferroni corrections ($\alpha = 0.05/4$ and $\alpha = 0.05/12$) to inferences about cross-arm differences in mean changes relative to baseline at four time points (after each intervention period and at endline) and within-arm mean changes relative to baseline at each of the 12 post-baseline timepoints. Analyses were conducted as intent-to-treat.

Results: At endline, 97.8% of the sample (n=974) had been retained. Participants in both arms dedicated a mean total >30 hours to their assigned game. There was significant improvement across all condom-related proximal outcomes in the intervention arm relative to the control arm immediately after initial intervention exposure. For almost all outcomes, a significant cross-arm difference was also present at endline, and for most outcomes at the two intervening comparison timepoints. Some outcomes saw stronger intervention effects on female participants (e.g., self-efficacy to refuse unprotected sex) or male participants (e.g., knowledge that condoms are an effective way to prevent HIV). In each arm, intention to use a condom at first sex was consistently higher among male participants; however, female intervention-arm scores overtook male control-arm scores following initial intervention exposure.

Conclusions: Tumaini significantly improved theory-based proximal outcomes related to condom use, with effects sustained 45 months post-initial exposure and 16 months post-most recent exposure. Adolescents benefited from even short-term exposure,

though repeated exposure generally sustained and reinforced intervention effects. In the context of increasing access to smartphones, Tumaini has potential for high scalability and impact on condom-related outcomes. Clinical Trial: ClinicalTrials.gov, NCT04437667

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Original Manuscript

Original Paper

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Keywords: Adolescents, HIV, prevention, sub-Saharan Africa, Kenya, serious game, narrative, smartphone, randomized controlled trial, mHealth

Abstract

Background: African adolescents and young adults account for a disproportionate number of new HIV infections. There is an urgent need to identify scalable and cost-effective behavioral HIV prevention strategies

for this population. Using a condom at first sex is associated with higher likelihood of consistent use later. *Tumaini* (“Hope for the Future” in Swahili) is a choose-your-own-adventure smartphone game that has been shown to reduce risk of unprotected first sex by endline in a 45-month randomized controlled trial in Western Kenya.

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Results: At endline, 97.8% of the sample (n=974) had been retained. Participants in both arms dedicated a mean total >30 hours to their assigned game. There was significant improvement across all condom-related proximal outcomes in the intervention arm relative to the control arm immediately after initial intervention exposure. For almost all outcomes, a significant cross-arm difference was also present at endline, and for most outcomes at the two intervening comparison timepoints. Some outcomes saw stronger intervention effects on female participants (e.g., *self-efficacy to refuse unprotected sex*) or male participants (e.g., *knowledge that condoms are an effective way to prevent HIV*). In each arm, *intention to use a condom at first sex* was consistently higher among male participants; however, female intervention-arm scores overtook male control-arm scores following initial intervention exposure.

Conclusions: *Tumaini* significantly improved theory-based proximal outcomes related to condom use, with effects sustained 45 months post-initial exposure and 16 months post-most recent exposure. Adolescents benefited from even short-term exposure, though repeated exposure generally sustained and reinforced intervention effects. In the context of increasing access to smartphones, *Tumaini* has potential for high scalability and impact on condom-related outcomes.

Trial Registration: ClinicalTrials.gov, NCT04437667

Introduction

Worldwide, a third of all new adult (ages 15-49) HIV infections occur in eastern and southern Africa and over a third of these infections occur in young people aged 15-24 [1]. HIV-related morbidity and mortality in this age group is disproportionately high. In addition, as the largest ever generation of young Africans is now entering adolescence, it is feared that a resurgence in the global epidemic could ensue unless more is done to prevent HIV in this demographic [2]. There is an urgent need to develop and rigorously test scalable and cost-effective behavioral interventions to prevent HIV among African adolescents and young adults, particularly adolescent girls and young women who are disproportionately affected [1].

Reaching adolescents with information and skills before sexual debut may help establish long-term patterns of safer sexual behavior [3]. For example, studies have shown that those who use condoms at first sex are more likely to use them consistently in the future [4]. However, there is a need for a stronger evidence base on the longitudinal effects of early and ongoing intervention, as few studies evaluating any HIV prevention interventions for adolescents and young adults include long-term follow-up [5].

Scaling up in-person, group-based HIV prevention interventions is challenging [6]. Digital behavioral interventions are likely to be easier to deliver at scale with consistent quality than those delivered in person. As smartphone penetration grows across sub-Saharan Africa, especially among young people, digital HIV prevention interventions are becoming increasingly viable. Across the continent, 81% of mobile phone connections will be smartphones by 2030 [7].

Electronic games are a promising sub-set of digital behavioral interventions [8]. However, few have been rigorously designed and evaluated [9]. Specifically, games leveraging interactive narrative can provide a level of experiential learning unparalleled by most other interventions by allowing players to experience real agency in a virtual and safe environment.

Tumaini (“hope for the future” in Swahili) is a “choose-your-own-adventure” game app for inexpensive Android smartphones. It was developed by specialists in adolescent sexual health in collaboration with a commercial game developer with input from Kenyan adolescents and their parents. The game’s theoretical framework [10] draws on: Social Cognitive Theory [11], existing evidence-based interventions for youth HIV prevention, and literature on games for health and Entertainment-Education [12, 13]. It is grounded in research on HIV-themed narratives written by thousands of young Africans [14-16].

Tumaini uses interactive narrative to promote observational learning, cognitive and behavioral rehearsal, and problem-solving [10]. It provides over 12 hours of discrete gameplay and comprises: (1) an engaging role-playing narrative in which players make choices for six characters (3 female, 3 male) as they proceed through adolescence, and observe short- and long-term consequences in the characters’ lives; (2) mini-games to reinforce knowledge and skills; and (3) *My Story*, in which players set life goals, reflect on how the game relates to their lives, customize a personal avatar, and collect rewards. The narrative uses branching logic for 40 possible long-term outcomes (“epilogues”) across the 6 characters and is designed to be replayed, allowing players to experience different outcomes based on their in-game decisions. Players must assume the role of characters different from themselves in terms of sex and serostatus, thereby challenging stigma and harmful gender norms.

In a randomized feasibility study with 60 adolescents in Kenya, the intervention arm showed significant gains in sexual health-related knowledge and self-efficacy and behavioral intention for risk avoidance strategies and sexual risk communication when compared with the control arm six weeks post-intervention [17]. Intervention-arm participants spent on average over 50% longer playing the game than instructed, while quantitative and qualitative data on user engagement and on game appeal, relevance, and acceptability among adolescents and parents were extremely positive.

A randomized controlled trial with a larger sample size (n=996) and longer duration of follow-up (45

months) was undertaken to evaluate the efficacy of *Tumaini* in reducing high-risk sexual debut at endline by increasing age and condom use at first sex. At endline *Tumaini* demonstrated significant impact on the primary trial outcome (high-risk sexual debut vs. low-risk or no sexual debut), attributable to increased condom use at first sex, in intent-to-treat analyses [18]. Among participants who had not yet reached sexual debut, exposure to *Tumaini* halved their intention to have unprotected first sex.

Participants completed a behavioral survey at 13 timepoints over the 45-month duration of the trial. This manuscript leverages this data to evaluate *Tumaini*'s impact on proximal outcomes related to condom use from ages 14.0 to 17.7 years (mean ages at baseline and endline, respectively), i.e., across mid-adolescence, a key developmental phase, and to assess differential effects by gender. These theory-based proximal outcomes are of particular importance given that the primary behavioral outcomes in this trial, being related to sexual debut, are developmentally influenced and analyses statistically underpowered prior to endline, 16 months after participants' most recent exposure to *Tumaini*.

Methods

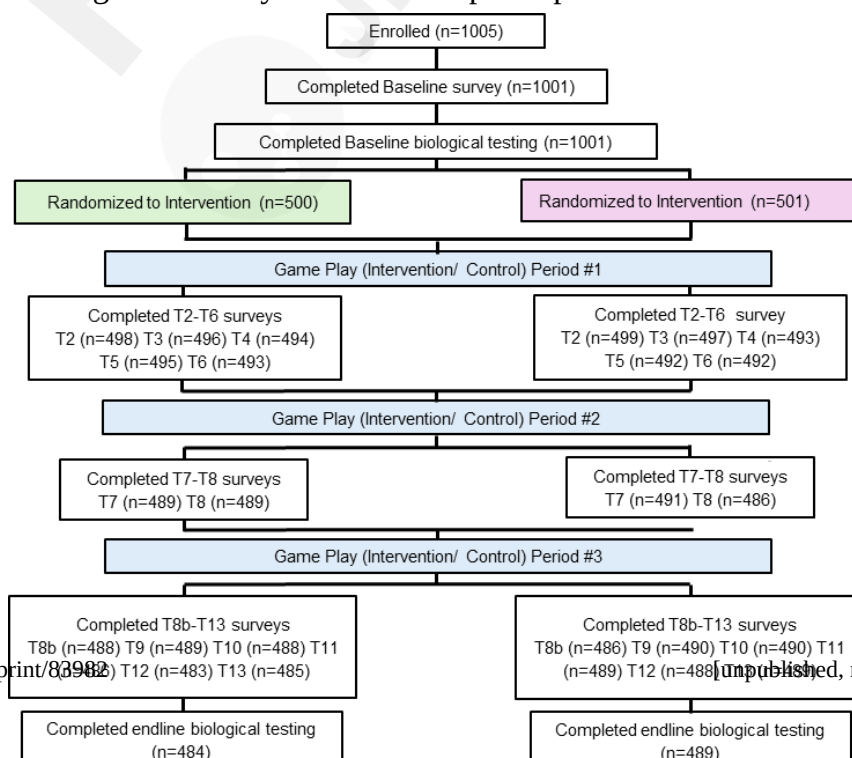
Study Setting

Kenya has the 7th largest HIV burden globally and an HIV epidemic that is generalized throughout the population. Kisumu County has Kenya's second highest prevalence (15.5%) and annual number of new infections [19]. The study took place in Kisumu Town, Kenya's third largest city, where youth aged 15-24 comprise 48% of new HIV infections [20].

Study design

This was a 45-month, 2-arm individually randomized controlled trial with 996 participants, mean age 14.0 (SD 0.6) years [21]. The study took place from October 2020 (start of enrollment) to August 2024 (last quantitative data collection). Participants were randomized 1:1 to play either *Tumaini* or a commercially available attention-control Math game, *Brainilis*. They were provided with a low-cost Android smartphone loaded with their assigned game at mean participant ages 14.0, 15.3, and 16.0 years, i.e., between T1 and T2, T6 and T7, and T8 and T9 (Figure 1). Gameplay periods lasted 5-7 weeks and took place during school holidays; they were unevenly spaced due to COVID-related disruptions to the school calendar. Participants completed behavioral surveys at 13 timepoints (baseline plus 12 follow-up surveys).

Figure 1. CONSORT diagram of study activities and participant totals for *Tumaini* efficacy trial



Recruitment and Randomization

Participant recruitment was conducted through a combination of school- and community-based strategies in urban and peri-urban Kisumu. Eligibility criteria for participation were: aged 12-14 at time of enrolment, resident in Kisumu Town, basic English literacy (Grade 3-4 on the Flesch-Kincaid Reading Scale), and no prior exposure to *Tumaini*-related activities. Written informed consent was secured from one parent or guardian and the participant provided their written assent prior to study baseline.

Recruitment slots were used to balance participant gender, age, and residence (in the 16 wards that comprise Kisumu East, West, and Central). Randomization to the study arms was conducted by a blinded member of the data analysis team with no contact with participants. Success of randomization was confirmed through calculation and cross-arm comparison of descriptive statistics for adolescent demographics.

Due to the nature of the intervention, participants were not blinded to group assignment, which was revealed following completion of all baseline activities. Data analysts remained blinded to study arm assignment until completion of all primary outcome data analysis.

Data Collection and Analysis

Behavioral surveys were self-administered at 13 timepoints (T1-T13), via tablet-based Open Data Kit. Participants completed surveys with headphones in a private space. Access to audio of all questions was provided to maximize understandability. Survey items were designed to evaluate the impact of exposure to the intervention on a range of primary and secondary outcomes. The study's primary outcomes assessed experience of sexual debut and condom use at first sex separately and also combined them in a composite binary variable of high-risk sexual debut (no condom use or "I don't know") vs. low-risk sexual debut (condom use)/no risk (not yet initiated sex). Sex was defined as penile-vaginal ("when a boy or man puts his penis inside a girl or woman's vagina"). It was specified that condoms were understood to be male condoms, defined as "a thin rubber covering worn by a man on his erect penis when he has sex"; due to low availability of female condoms (or "internal condoms"), the intervention and study elected to focus on the more widely known and available male condoms. Endline outcome analyses are presented elsewhere [18].

Survey items also assessed theory-based and intervention-targeted proximal influences, namely knowledge, attitudes, self-efficacy, and behavioral intentions, of these primary outcomes. The behavioral survey instrument was adapted from the version used in the *Tumaini* feasibility study [17]. Individual measures were drawn from existing instruments, with priority given to those previously used with sub-Saharan African youth populations [22-24]. The chosen items were adapted for age, linguistic, and cultural appropriateness and consistency of formatting, and supplemented with additional measures where necessary. In the interest of age appropriateness, some questions were framed as hypothetical risk scenarios ("*Imagine that...*").

Here, we focus on the longitudinal trajectories of the proximal outcomes related to condom-use behavior. These outcomes, their exact wording, and response options (binary and 3 or 4-point Likert scales) are presented in Table 1 (additional items are detailed in Supplemental Table 1). Each item was scored on a 0-1 scale, with higher values indicating more desirable or, in the case of knowledge, correct answers. This standardization of scores facilitated comparison across items. Mean scores were calculated for individual items at each timepoint. Only participants who had responded to the question at that timepoint were included in mean score calculations; missing values were not imputed. Only those participants reporting never having had sex were asked about their intention to use a condom at first sex.

Table 1: Condom-related proximal outcomes, question wording, and response options

Proximal outcome	Condom-related proximal outcome	Question wording	Response options
Behavioral intention	Intention to use a condom at first sex	"When you have sex for the first time, do you plan to use a condom?"	Definitely yes, maybe yes, maybe no, definitely no
	Intention to talk to a partner about HIV prevention	"Imagine that either in the future or now you are thinking about having sex with someone and you are not ready to become a parent. [...] Would you talk with him/her about preventing HIV?"	Definitely yes, maybe yes, maybe no, definitely no
Self-efficacy	Self-efficacy to use a condom correctly	"I am sure that I could use a condom correctly."	I strongly agree, I agree, I disagree, I strongly agree
	Self-efficacy to refuse unprotected sex	"Imagine that, either in the future or now, you are in a relationship. He/ She says she wants to have sex with you but she does not want to use a condom. [...] If I did not want to have sex with him/her without a condom, I am sure that I could say no firmly."	I strongly agree, I agree, I disagree, I strongly agree
Attitudes	Endorsement that condom use is a sign of respect	"Using a condom is a sign that you respect your partner"	I strongly agree, I agree, I disagree, I strongly agree
	Endorsement of gender parity in condom initiation	"A woman can suggest using condoms just like a man can"	I strongly agree, I agree, I disagree, I strongly agree
Knowledge	Knowledge of how to use a condom correctly	"Do you know how to use a condom correctly?"	Yes, no
	Knowledge that condoms are effective for HIV prevention	"Are condoms an effective way to prevent HIV?"	Yes, no, I don't know

We used generalized estimating equations (GEE) [25] to model these proximal outcome variables measured repeatedly over time and to facilitate statistical inferences about cross-arm (intervention vs. control) mean differences at specific time points. Specifically, the GEE model controlled for participants' baseline age (centered at the average value) and included indicator variables for arm (intervention as reference) and time (T1–T13, with T1 as reference), together with the 12 group-by-time interaction terms. This approach accounts for the correlated nature of the data, utilizing an exchangeable working correlation structure that was selected via initial comparisons of alternatives based on the quasi-likelihood information criterion [26]. The granular nature of the model provides a close fit to the sample means of the outcome for each arm at each time, while facilitating direct inferences about the change in the mean outcome relative to baseline for the intervention arm at each timepoint (T2–T13) and the cross-arm differences in these mean changes. Of primary interest in these analyses are Bonferroni-corrected (significance level .05/4) inferences about the cross-arm differences in mean changes relative to baseline at four specific time points (T2, T7, T9, and T13).

The inferences at T2 and T13 compare the average early and late (endline) change in the mean response relative to baseline for the intervention and control arms. The inferences at T7 and T9 are designed to investigate potential enhancements in the cross-arm differences in change relative to baseline at the two timepoints following reintroduction of the intervention. Secondary to these cross-arm comparisons, we also report Bonferroni-corrected (significance level 0.05/12) inferences to assess mean within-arm changes relative to baseline at each of the twelve subsequent timepoints (T2–T13). These analyses were conducted overall and separately for female and male participants.

In the plots presented below, solid lines track estimated mean responses (marked with triangles) for the intervention group over time; dashed lines (with circles) track estimated means for the control group. Solid markers (triangles for the intervention arm, circles for the control arm) indicate the within-arm difference in mean response relative to baseline at that timepoint is significant after Bonferroni correction (i.e., at $\alpha=.00042$ level); open symbols indicate lack of significance relative to baseline. Inferences addressing the four primary cross-arm comparisons of mean change relative to baseline are indicated with *p*-values at the top of the plot. Asterisks after the *P*-value indicate significance after Bonferroni correction (i.e., at $\alpha=.0125$ level).

All analyses were conducted as intent-to-treat and were completed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

The Institutional Review Board of Emory University (STUDY00002974) and the Scientific and Ethics Review Unit of the Kenya Medical Research Institute (KEMRI) (SERU: KEMRI/SERU/CGHR/11/3812) approved this study.

Results

Baseline characteristics of the sample are presented in Table 2. Participants represented a range of socio-economic and food security profiles. At endline, 97.8% of the sample ($n=974$) had been retained. There were no adverse events associated with study participation.

Table 2: Baseline characteristics of the intent-to-treat population

	Intervention ($n=499$)	Control ($n=497$)
Sex		
Female, n (%)	249 (50%)	250 (50%)
Male, n (%)	250 (50%)	247 (50%)
Age (years), mean (SD)	13.99 (0.57)	13.97 (0.54)
Enrolled in school, n (%)	499 (100%)	493 (99%)
Socioeconomic status		
Lower SES, n (%)	241 (49%)	241 (49%)
Higher SES, n (%)	254 (51%)	251 (51%)
Food insecurity		
None, n (%)	270 (54%)	260 (52%)
Low, n (%)	138 (28%)	149 (30%)
Medium, n (%)	73 (15%)	73 (15%)
High, n (%)	18 (4%)	15 (3%)
Living with HIV, n (%)	8 (2%)	8 (2%)
Experienced sexual debut, n (%)	76 (15%)	76 (15%)

At the end of each of the three intervention periods, self-reported engagement in both intervention and control games was high, with 100% exposure of each arm to their allocated game by T2. Participants in each arm dedicated comparable amounts of time to their assigned game across the three intervention periods, totaling 33.43 hours (SD 17.84) to *Tumaini* and 32.37 hours (SD 18.41) to the Math game, indicating that the latter functioned as a highly effective attention-control condition. Fifty-eight percent of the control arm reported having played some of *Tumaini* by T9 (mean hours for those exposed: 19.77 (SD 15.03)) [18], with 35% exposed at T2, and 52% at T7.

We provide an overview of cross-arm differences in change since baseline at four timepoints (Table 3) and, for each outcome, within-arm change since baseline at 12 timepoints and longitudinal plotlines over time, for all participants and stratified by gender. Mean scores for each outcome at each timepoint and associated *P*-values for within-arm change are presented in Supplemental Tables 2-9.

Table 3: Cross-arm difference in mean change in proximal outcomes relative to baseline and associated *P*-values at four timepoints

Timepoint	T2		T7		T9		T13	
Mean age (years)	14.1		15.6		16.4		17.7	
	Difference in change in mean score	<i>P</i> -value	Difference in change in mean score	<i>P</i> -value	Difference in change in mean score	<i>P</i> -value	Difference in change in mean score	<i>P</i> -value
Behavioral intentions								
<i>Intention to use a condom at first sex</i>								
All	0.118	.0053 [†]	0.200	.008 [†]	0.201	.0127	0.164	.0065 [†]
Female	0.083	.0202	0.088	.0299	0.099	.0182	0.103	.0189
Male	0.055	.1052	0.059	.1125	0.045	.2533	0.059	.1375
<i>Intention to talk to a partner about HIV prevention</i>								
All	0.107	<.0001 [†]	0.085	<.0001 [†]	0.081	.0002 [†]	0.076	.0004 [†]
Female	0.115	.0002	0.047	.1061	0.048	.1043	0.057	.0543
Male	0.099	.0008	0.123	<.0001 [†]	0.115	.0003 [†]	0.095	.0024 [†]
Self-efficacy								
<i>Self-efficacy to use a condom correctly</i>								
All	0.215	<.0001 [†]	0.283	<.0001 [†]	0.273	<.0001 [†]	0.254	<.0001 [†]
Female	0.216	<.0001 [†]	0.278	<.0001 [†]	0.263	<.0001 [†]	0.283	<.0001 [†]
Male	0.213	<.0001 [†]	0.287	<.0001 [†]	0.282	<.0001 [†]	0.224	<.0001 [†]
<i>Self-efficacy to refuse unprotected sex</i>								
All	0.072	.0061 [†]	0.039	.1262	0.042	.1083	-0.037	.4054
Female	0.107	.0044 [†]	0.028	.4302	0.063	.0861	0.040	.2784
Male	0.037	.3176	0.051	.1709	0.021	.5683	0.002	.9569
Attitudes								
<i>Endorsement that condom use is a sign of respect</i>								
All	0.218	<.0001 [†]	0.201	<.0001 [†]	0.201	<.0001 [†]	0.164	<.0001 [†]
Female	0.234	<.0001 [†]	0.187	<.0001 [†]	0.201	<.0001 [†]	0.191	<.0001 [†]
Male	0.203	<.0001 [†]	0.214	<.0001 [†]	0.202	<.0001 [†]	0.138	<.0001 [†]
<i>Endorsement of gender parity in condom initiation</i>								
All	0.151	<.0001 [†]	0.205	<.0001 [†]	0.221	<.0001 [†]	0.192	<.0001 [†]
Female	0.146	<.0001 [†]	0.220	<.0001 [†]	0.218	<.0001 [†]	0.203	<.0001 [†]
Male	0.156	<.0001 [†]	0.189	<.0001 [†]	0.224	<.0001 [†]	0.181	<.0001 [†]
Knowledge								
<i>Knowledge of how to use a condom correctly</i>								
All	0.372	<.0001 [†]	0.429	<.0001 [†]	0.464	<.0001 [†]	0.458	<.0001 [†]
Female	0.376	<.0001 [†]	0.440	<.0001 [†]	0.462	<.0001 [†]	0.462	<.0001 [†]

Male	0.367	<.0001 [†]	0.417	<.0001 [†]	0.465	<.0001 [†]	0.453	<.0001 [†]
<i>Knowledge that condoms are effective for HIV prevention</i>								
All	0.096	.0012 [†]	0.093	.0105 [†]	0.085	.0188	0.110	.0032 [†]
Female	0.116	.0061 [†]	0.123	.0133	0.097	.0504	0.158	.0022 [†]
Male	0.076	.0674	0.059	.2508	0.072	.1687	0.062	.2463

[†] Indicates significance after Bonferroni correction (significance level .05/4, i.e. .0125)

Behavioral Intentions

Intention to use a condom at first sex

Figure 2: Intention to use a condom at first sex

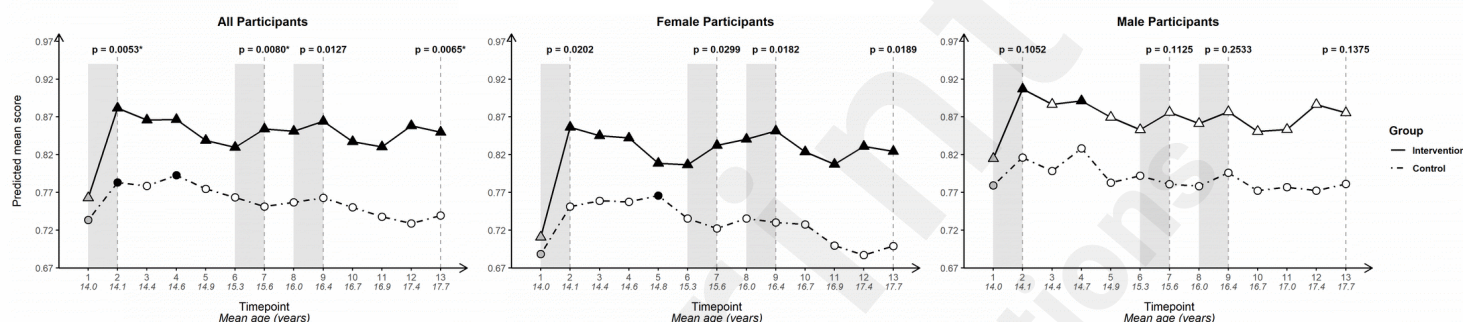


Figure 2 summarizes results of the longitudinal analysis of the *condom use at first sex behavioral intention* outcome.

Cross-arm difference: When all participants were included in the analysis, there was significantly greater improvement in the intervention arm than the control arm immediately after initial intervention exposure ($P=.0053$), following the second intervention period, (i.e. at T7; $P=.0080$), and at endline ($P=.0065$). Significance was marginal after Bonferroni correction following the third intervention period at T9 ($P=.0127$) and not present when participants were stratified by gender, suggesting insufficient power once the sample was halved.

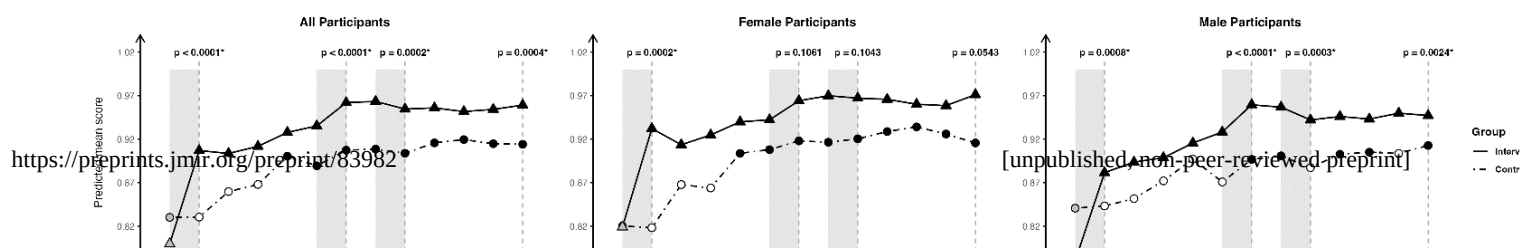
Within-arm change: Solid triangles at T2-T13 for all participants indicate a Bonferroni-corrected statistically significant difference in the mean relative to baseline for the intervention arm at every subsequent timepoint. In addition to the steep uptick in mean score following initial intervention exposure, the intervention arm showed an uptick following the second and third intervention periods. In contrast, significant within-arm differences from baseline were present only occasionally in the control arm, with mean scores at endline closely resembling those at baseline.

Difference by gender: *Intention to use a condom at first sex* was higher from baseline among male than female participants in both arms. Female intervention-arm participants saw a steeper uptick at T2 and significant improvement relative to baseline for all subsequent timepoints, such that it overtook the male control arm. After an initial upward trajectory, the control-arm plot trended downwards for female participants from T5 (age 14.8).

Intention to talk to a partner about HIV prevention

Cross-arm difference: Significant cross-arm differences in increased *intention to talk to a partner about HIV prevention* (Figure 3) were present at all four timepoints for all participants and for male participants.

Figure 3: Intention to talk to a partner about HIV prevention



Despite an uptick in the intervention arm during the second intervention period, cross-arm differences were not significant at T7, T9, and endline for female participants. The plots suggest that this may be due to a combination of ceiling effects (mean scores in the intervention arm were extremely high from T7 (age 15.6) onwards, limiting scope for improvement) and developmental gains in the control arm.

Within-arm change: For intervention-arm participants, within-arm change since baseline was significant for all timepoints for all, female, and male participants. For control-arm participants, difference relative to baseline mean became significant from T5 (age 14.9) onwards for all and female participants. Male control-arm participants saw sporadic significant change since baseline from T7 (age 15.6) onwards. Unlike *intention to use a condom at first sex*, mean scores followed an upward trajectory over time for both arms, suggesting a developmental effect.

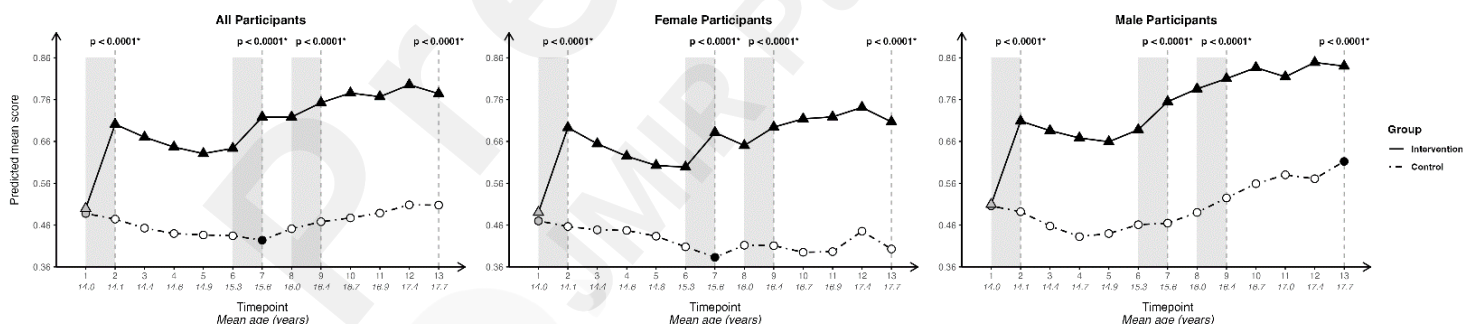
A related outcome, *self-efficacy to talk to a partner about HIV prevention* (Supplemental Figure 1, Supplemental Table 5), showed a similar trajectory to *intention to talk to a partner about HIV prevention*, with control-arm change since baseline for male participants achieving significance from mean at age 14.9 and endline values approximating those of the intervention arm.

Self-Efficacy

Self-efficacy to use a condom correctly

Cross-arm difference: Baseline mean scores on *self-efficacy to use a condom correctly* (Figure 4) were lower and intervention-arm gains greater than for all other condom-related behavioral determinants except *knowledge of correct condom use* (which shows a similar trajectory, particularly in the intervention arm). Cross-arm differences in change since baseline were highly significant ($P < .0001$) for all four timepoints for all participants and when stratified by gender.

Figure 4: Self-efficacy to use a condom correctly



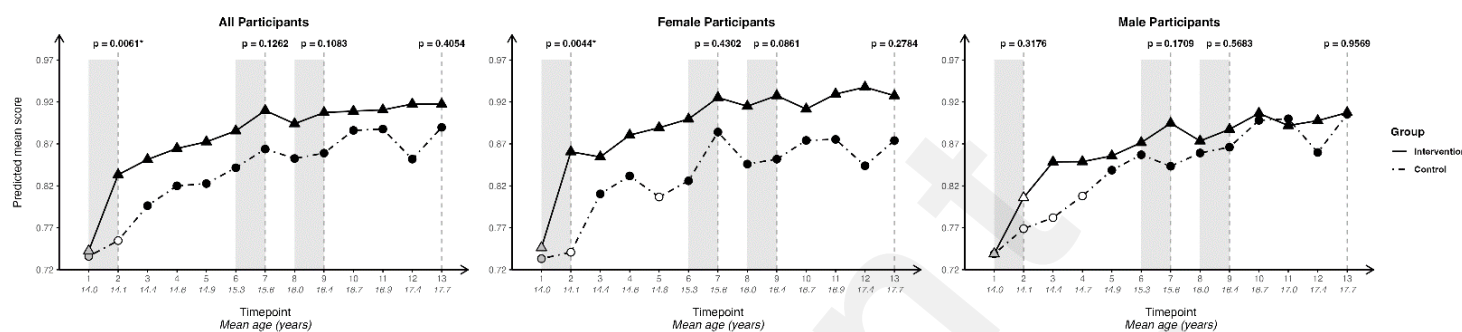
Within-arm change from baseline was significant for intervention-arm participants at all subsequent timepoints, following a sharp uptick in mean score after the first intervention period, and smaller upticks after the other intervention periods. For control-arm participants significant difference relative to baseline only occurred at one timepoint for each group: negatively at T7 (age 15.6) for all and for female participants and positively at endline for male participants.

Difference by gender: The overall upward trajectory among intervention-arm participants from T6 (age 15.4) was steeper for male than for female participants. A similar upward trajectory was observed for male participants in the control arm, though at a much lower level, suggesting a developmental influence. The trajectory for female control-arm participants, by contrast, trended downwards.

Self-efficacy to refuse unprotected sex

Cross-arm difference in increased self-efficacy to refuse unprotected sex (Figure 5) was significant following initial exposure to the intervention for all participants ($P=.0061$) and for female participants ($P=.0044$), but not for male participants ($P=.3176$).

Figure 5: Self-efficacy to refuse unprotected sex



It was not significant at subsequent timepoints for any of the population groupings, despite upticks in the intervention arm following the second and third intervention periods. The upward trend in the intervention arm was mirrored by a similar trajectory, albeit at a generally lower level, in the control arm, suggesting a positive developmental influence for this outcome.

For the intervention arm, *within-arm change* since baseline was significant across all timepoints for all participants and when stratified by gender except for at T2 for male participants. Within-arm difference was significant for all control-arm participants from T3 (age 14.4) onwards and for male participants from T5 onwards. For female participants, it was generally significant from T3 onwards. *Difference by gender:* For male participants, the intervention-arm plotline was crossed by the control-arm plotline at T11 (age 17.0; across all determinants this was the only instance of this happening). Endline values for both arms were near-identical among male participants.

Attitudes

Endorsement of “Using a condom is a sign you respect your partner” and “A woman can suggest using condoms just like a man can”.

The survey included two condom-related attitude items, asking participants to indicate degree of agreement with: *using a condom is a sign that you respect your partner* (Figure 6) and *a woman can suggest using a condom just like a man can* (Figure 7).

Figure 6: Endorsement of “Using a condom is a sign that you respect your partner”

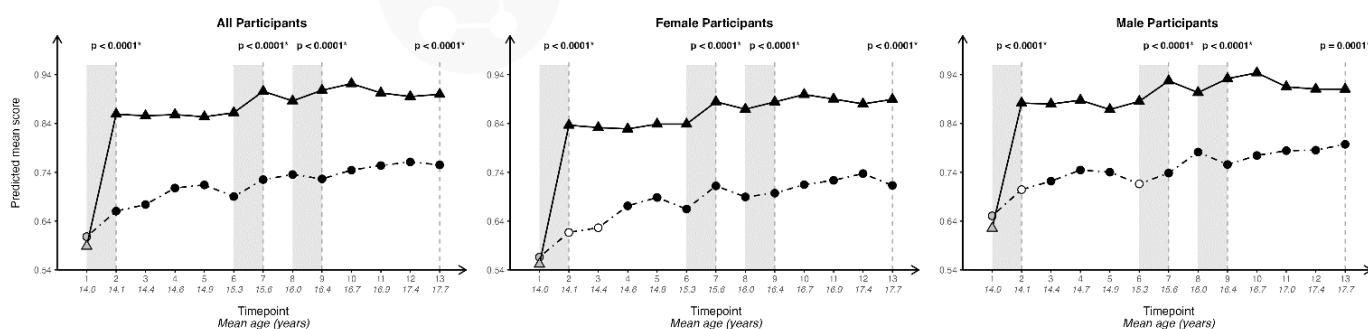
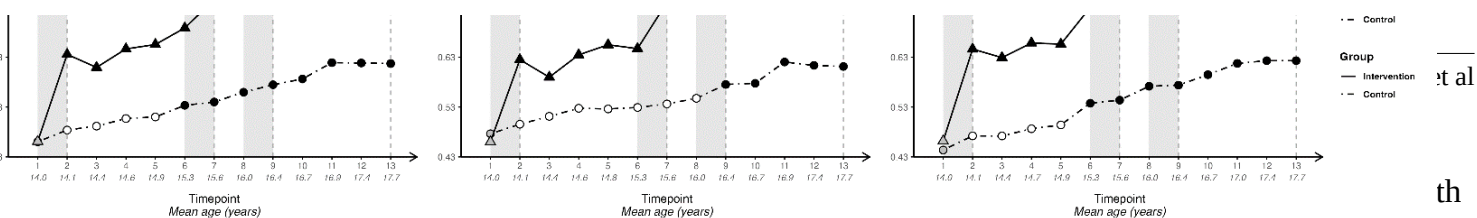


Figure 7: Endorsement of “A woman can suggest using condoms just like a man can”

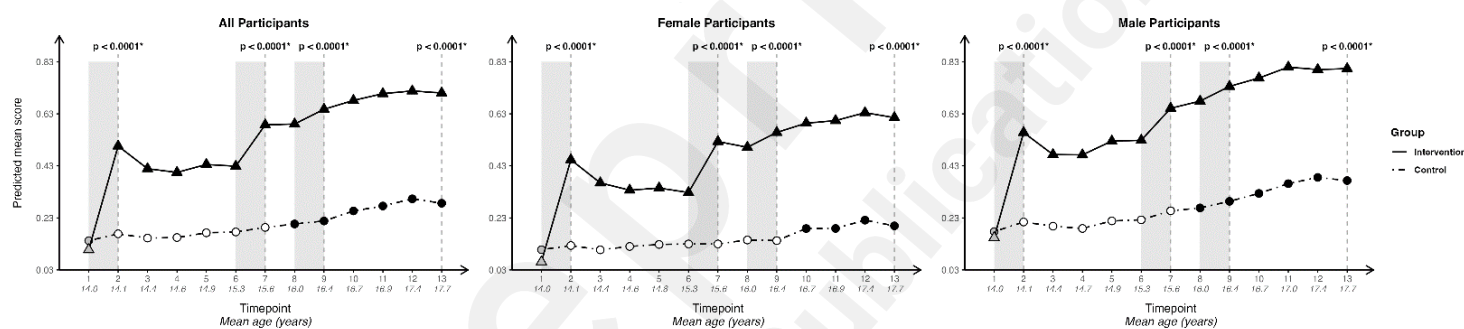


Significant *within-arm change* since baseline was present in the intervention arm at every timepoint for both questions and for all population groupings. The intervention-arm uptake following initial exposure to *Tumaini* was more pronounced for the first, gender-neutral question, with moderate increases across subsequent timepoints. For the second question, which challenged traditional cultural norms around women initiating condom use, the longitudinal trajectory for the intervention arm showed a steady rise from T2 that was reflected at lower mean scores but a similar slope in the control arm, suggesting a more pronounced intersection of intervention and developmental influences. Both questions saw an uptick in intervention-arm scores following the second and third intervention periods.

Knowledge

Knowledge of how to use a condom correctly

Figure 8: Knowledge of correct condom use



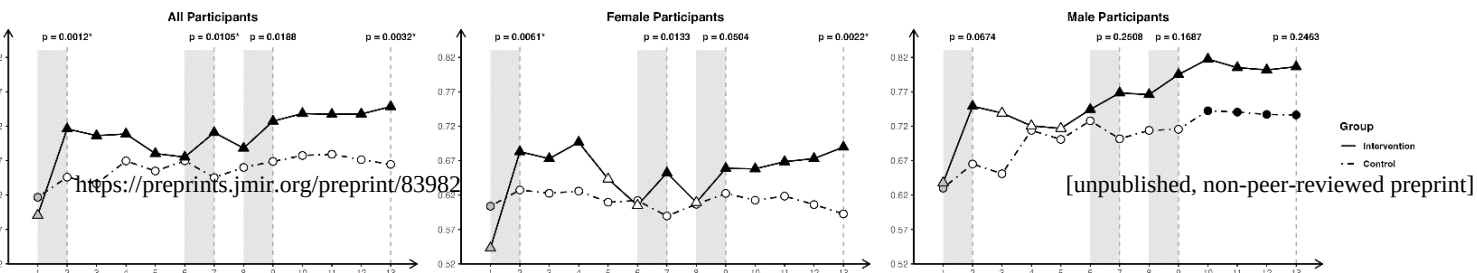
The two condom-related knowledge questions show variations in trajectory. For *knowledge of correct condom use* (Figure 8), *cross-arm change* in score since baseline differed highly significantly ($P < .0001$) at all four timepoints and across all population groupings. Baseline scores were the lowest for any condom-use determinant, particularly among female participants, but saw a spike in the intervention arm following initial exposure that was built upon at the second and third intervention periods.

Within-arm difference since baseline in the intervention arm was significant at all twelve post-baseline timepoints across all population groupings. The control arm only saw significance from T8 (age 16.0; T10, age 16.7, for female participants) onwards, with the slight upward trend at later ages suggesting a mild developmental influence.

Knowledge that condoms are effective at preventing HIV

Cross-arm difference in change in *knowledge that condoms are an effective way to prevent HIV* (Figure 9) was significant following Bonferroni correction immediately after initial intervention exposure and at endline for all participants and for female participants, and at T7 for all participants. It was not significant at any timepoint for male participants, who had higher scores throughout than

Figure 9: Knowledge that condoms are effective at preventing HIV



female participants.

Within-arm change since baseline was significant for the intervention arm at all timepoints for all participants. This was true when stratifying by gender except for at T5 and T6 for female participants and T3-5 for male participants. In addition to a steep uptick after initial intervention exposure, the intervention arm saw upticks for the two subsequent intervention periods. This is particularly striking for female participants whose mean scores dip between intervention periods but recover following re-exposure to the intervention. Mean scores then stabilize with a slight upward trajectory from this point forward while the control dips, indicating the value of repeated intervention exposure across mid-adolescence for female participants for this outcome. The control arm was non-significant for within-arm change since baseline at all timepoints except for male participants from T10 (age 16.7) onwards.

Discussion

We evaluated the longitudinal impact of a theory-based choose-your-own-adventure smartphone game on proximal outcomes related to condom use across 45 months of mid-adolescence. These proximal outcomes are of particular importance given that assessment of primary *behavioral* outcomes, related to sexual debut, was not powered until endline, 45 months after participants' initial exposure to *Tumaini* and 16 months after their most recent exposure. Intervention-arm participants devoted over 30 hours in total to playing *Tumaini*, while the control-arm game attracted similar levels of engagement, thereby functioning as an effective attention-control condition.

Cross-arm difference: Despite cross-arm contamination, *Tumaini* significantly improved all intervention-targeted proximal influences of condom use relative to the control arm immediately after initial exposure. For almost all proximal outcomes, a significant cross-arm difference was also present at endline and, for most outcomes, at the two intervening timepoints when cross-arm comparison was undertaken, following re-exposure to the intervention.

Within-arm difference: For the intervention arm, when all participants were included in the analysis, within-arm mean change since baseline was significant for every outcome at every timepoint. All outcomes saw a spike in intervention-arm mean score immediately after initial exposure to *Tumaini*. Repeat exposure to the intervention at ages 15.3 and 16.0 reinforced these effects in almost every case.

These significant findings and their timing relative to the intervention periods provide compelling evidence of *Tumaini*'s impact and suggest that adolescents may benefit from even short-term exposure, though repeated exposure frequently sustained and strengthened effects. They are also consistent with our primary behavioral outcomes at endline: among participants reporting sexual debut between baseline and endline, 50% (41/82) of control-arm participants had unprotected first sex compared to 28% (23/81) of intervention-arm participants (RR 0.57, 95% CI 0.38-0.85) [18].

Multiple frameworks across health communication, social psychology, and behavioral science support a hierarchy of effects in behavioral interventions, e.g. [27], whereby knowledge is least resistant to change, followed by attitudes, self-efficacy, behavioral intentions, and finally behavior itself. In line with this hierarchy, while behavioral HIV prevention interventions for younger adolescents in sub-Saharan Africa have improved condom-related knowledge, attitudes, and even self-efficacy, relatively few have been shown in rigorous studies to reduce sexual risk by increasing condom use [5, 28-30]. Our own findings are positive across the hierarchy of effects, from knowledge through attitudes, self-efficacy, and intentions, to behavior.

Findings from the present analyses indicate that *Tumaini*'s condom-related content was most effective at strengthening *self-efficacy to use a condom* (especially among male participants), which is highly dependent on *knowledge of how to use a condom correctly*, and at informing positive condom-related attitudes. While findings are extremely positive across the board, they also highlight

areas where the intervention could potentially be revised to achieve even stronger effects. For example, they suggest that *Tumaini* could do more to strengthen male participants' *self-efficacy to refuse unprotected sex*. Trajectories for *knowledge that condoms are an effective way to prevent HIV* also differ substantially by gender. However, lower scores for female participants may relate less to condom efficacy, which is strongly emphasized throughout the intervention, than to the different levels of agency exercised by female versus male adolescents in condom use. *Tumaini* must strike a balance between building adolescents' self-efficacy while also nurturing awareness of the challenges of real-life operationalization of condom use. This is both particularly important and especially difficult where younger adolescents are concerned and hence delaying first sex is a primary goal.

In addition to being the main strategy for HIV prevention for the population addressed in our trial, condoms are also the primary method of contraception [31]. *Tumaini* emphasizes the advantages of condoms for preventing pregnancy in addition to HIV. Pregnancy is an outcome that is a more immediate, and hence often more resonant, threat for adolescents – especially girls and young women – than HIV, even in high-prevalence parts of sub-Saharan Africa. Leveraging the long-term consequences of unplanned pregnancy for adolescents' future plans and dreams has the added benefit of being less likely to contribute to HIV stigma. It is notable that trajectories for pregnancy-related proximal outcomes (Supplemental Figures 2-4) were very similar to those for HIV prevention.

In their 2010 systematic review and meta-analysis of HIV prevention for sub-Saharan African youth [32], Michielsen et al. found that effects on condom use were larger in male participants in almost all studies where these were reported as significant. Gender-stratification of our primary behavioral outcomes at endline, in contrast, revealed a stronger impact on female participants, for whom risk of unprotected first sex was reduced significantly from 57% (21/37) in the control arm to 21% (7/33) in the intervention arm (RR 0.37, 95% CI 0.18-0.76) [18]. Male participants also saw a reduction, but it was non-significant, from 44% (20/45) in the control arm to 33% (16/48) in the intervention arm (RR 0.75, 95% CI 0.45-1.26) despite them scoring higher at every timepoint for *intention to use condom at first sex*. Intention may be lower for many Kenyan adolescent girls and young women because they envisage their sexual debut happening within marriage, a context in which they foresee less need to rely on a condom. Lower intervention impact on male participants' condom use at first sex suggests that the translation of intention into behavior may operate differently for male than for female adolescents. It is possible that lower *self-efficacy to refuse unprotected sex* may be a factor and/or that male participants struggle in the emotionally charged context of first sex when performance anxiety may be exacerbated by condom use.

Alongside those referenced above, multiple structural and contextual factors have been identified as potentially militating against translation of condom-use proximal outcomes up the hierarchy of effects, from knowledge to behavior. Sociocultural factors include, for example: the association of condoms with immorality; gender norms promoting "submissiveness" in adolescent girls and young women; perceptions among young men that condoms reduce sexual pleasure; and a range of myths and misconceptions [15, 16, 33, 34]. Among behavioral theories, Social Cognitive Theory, in which *Tumaini* is grounded, has the advantage of foregrounding the role played by the social environment in individual behavior. *Tumaini*'s narrative-based approach, drawing on research on thousands of stories contributed by young Africans to scriptwriting competitions [15, 16, 35], ensures that contextual and structural factors are extensively engaged with.

In addition, although delivered at the individual level, *Tumaini* either does – or has the potential to – catalyze engagement at higher socioecological levels of analysis. It catalyzes considerable household, including parent-child, interaction [36], which is modeled and nurtured in the game by the presence of parent, other adult, and older peer characters who function as "virtual mentors". Further, the high levels of engagement it causes and sustains suggest that, when widely disseminated, its effects could extend to the community level with the potential to support normative change. Depending on population needs, moreover, its effects could be enhanced through dissemination in combination with structural or biomedical programming, alongside anticipated direct-to-consumer

dissemination via an app store.

Strengths and Limitations

Some longitudinal observational studies have followed cohorts of young Africans through adolescence tracking sexual and reproductive health outcomes [37] [38]. However, longitudinal intervention evaluations are rare. An exception is Let Us Protect Our Future!, with follow-ups at 3, 6, 12, 42, and 54 months [39, 40]. Our efficacy trial is notable for the length and frequency of follow-up (13 surveys over 45 months), in addition to its extremely high levels of participant retention (97.5% at endline), its effective attention-control condition, and its high and sustained intervention engagement.

The longitudinal trajectories presented here allow us to observe *Tumaini*'s influence on a range of theory-based, condom-related proximal outcomes across mid-adolescence and across the three intervention periods. The within-arm comparison, with plotlines incorporating intervention periods, provide invaluable contextualization for the cross-arm comparative data and facilitate identification of gender-specific and developmental influences. These analyses thus provide richer insights into the effects of *Tumaini*, including how these may be optimized, than endline estimates of relative risk alone.

In addition to these strengths, the study has limitations. First, there is a risk that repeated participant exposure to the same survey items over time might blunt the sensitivity of those questions. However, cross-arm differences, upticks in intervention-arm mean scores at each intervention period, and diversity in longitudinal trajectory by outcome, suggest that this was not a major concern in this study. Second, while we drew our survey items from scales that had been used and/or validated with similar populations, we were unable to use the complete validated scales due to the age of our participants (some as young as 12 at baseline) and the risk of overburdening them with an extensive questionnaire or exposing them to non-age-appropriate content. Third, by their nature, our proximal outcomes are self-reported. Specifically, *self-efficacy to use a condom correctly* and *knowledge of how to use a condom correctly* are self-assessments and it is possible that these measures may not ultimately mediate correct condom use in real-life circumstances. Fourth, the study provided participants with smartphones with parental restrictions blocking internet access; additional research is needed to assess *Tumaini*'s effectiveness under more "real-world" conditions. We are planning a Hybrid Type 2 Effectiveness/Implementation study and anticipate that end-users will ultimately play *Tumaini* on their parents', older siblings', friends' or own phones. Finally, cross-arm contamination may have reduced our ability to detect some intervention effects.

Future research

Ongoing qualitative research with this cohort may shed additional light on contextual factors informing these trajectories. Mediation analysis currently underway will allow us to pinpoint which proximal outcomes mediated our behavioral outcomes for those who had reached sexual debut by endline, and which lower-level proximal outcomes mediated behavioral intentions for those who had not. Through this additional research, we will seek to optimize *Tumaini* prior to our planned Hybrid Type 2 Effectiveness/ Implementation trial.

Conclusions

Tumaini significantly improved theory-based proximal influences of condom use, with effects sustained 45 months post-initial exposure and 16 months post-most recent exposure. Spikes in intervention-arm scores immediately after initial exposure suggest that adolescents may benefit from even short-term exposure, though repeated exposure frequently sustained and reinforced effects. At a time when threats to global HIV funding highlight the necessity of preventing new infections among young people, study findings support the promise of reaching adolescents at an early age with

information and skills. In the context of rapidly increasing access to smartphones in sub-Saharan Africa and at a time when cost-effectiveness is at a premium, *Tumaini* has potential for high scalability and impact on condom-related outcomes.

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Data Availability

Data underlying these analyses is not publicly available as analyses are ongoing. Data are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Author Contributions

KW led the design of the study, and GS, KK, RB, RL, VM, and KO contributed to the design of the study. VM, KO, JA and CM contributed to protocol implementation and data collection and management. SG, HWQ, and GS conducted data analyses, guided by RL, RB, and KK. KW drafted the manuscript; all other authors edited and reviewed the manuscript. KW is overall principal investigator, while VM is the site principal investigator for this study.

Abbreviations

T1- baseline data collection

T2- second data collection timepoint

T7- 7th data collection timepoint

T9- 9th data collection timepoint

T13- 13th data collection timepoint (endline)

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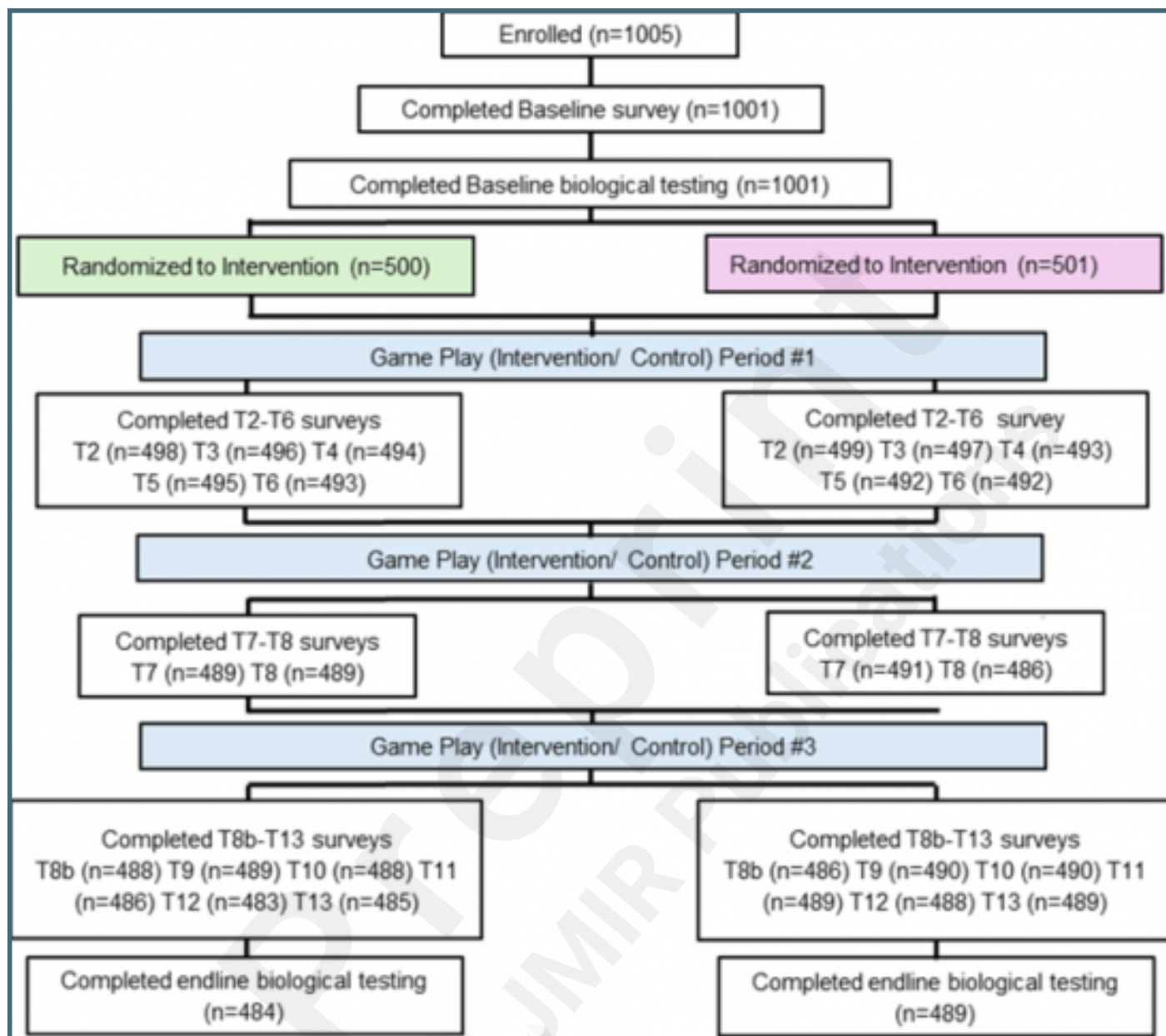
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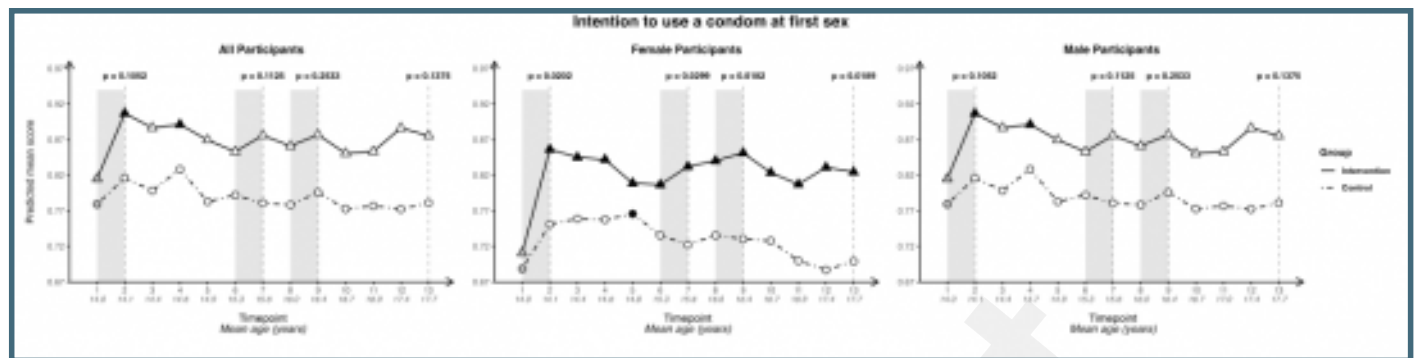
Supplementary Files

Figures

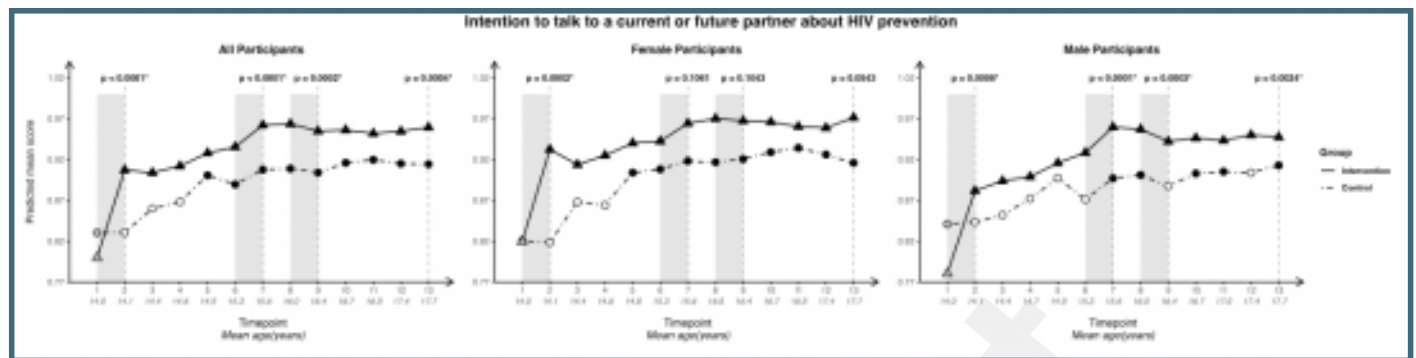
CONSORT diagram.



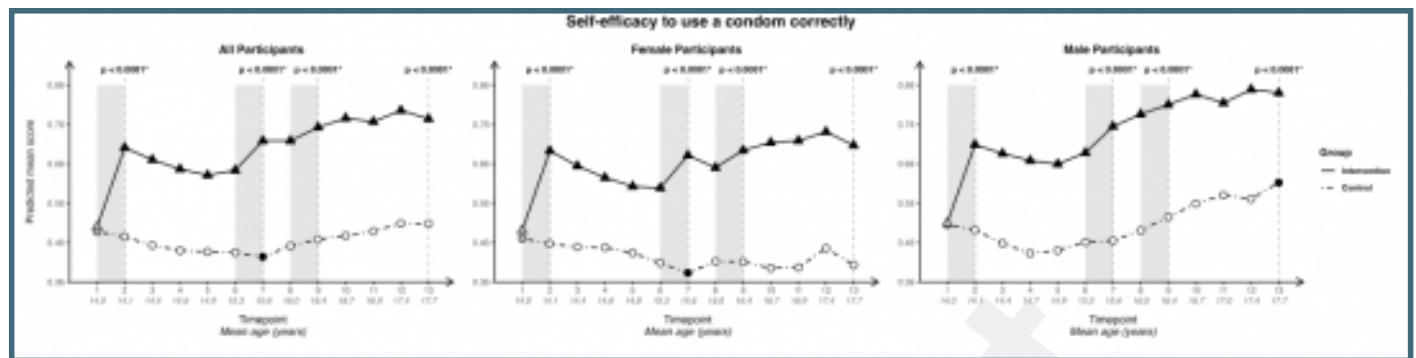
Intention to use a condom at first sex.



Intention to talk to a partner about HIV prevention.



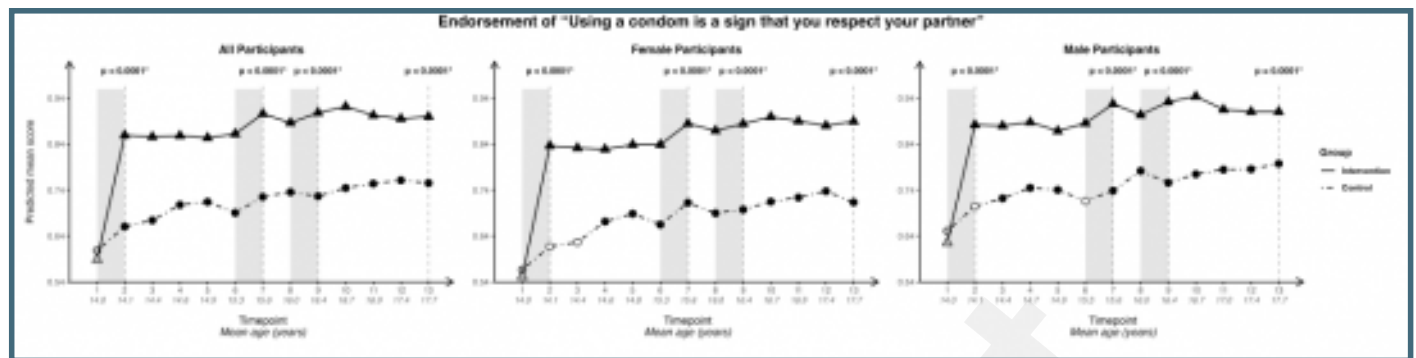
Self-efficacy to use a condom correctly.



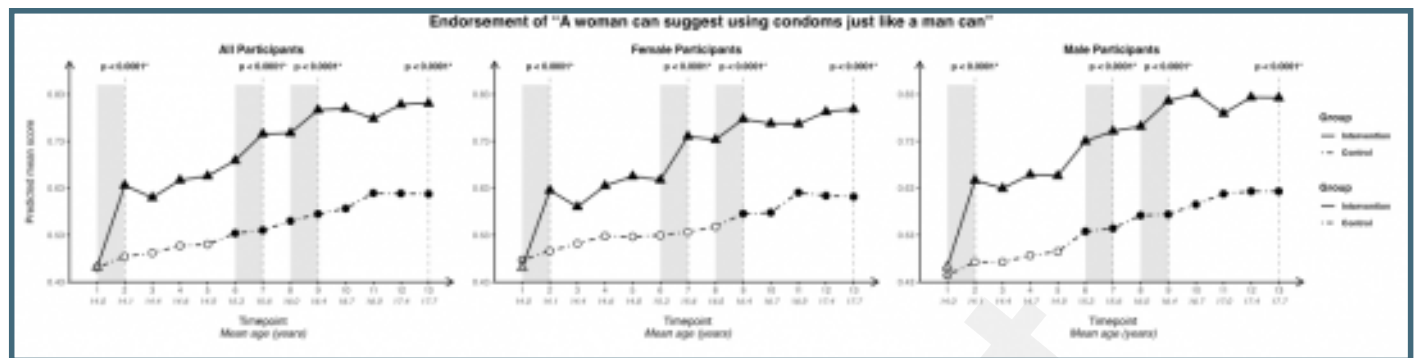
Self-efficacy to refuse unprotected sex.



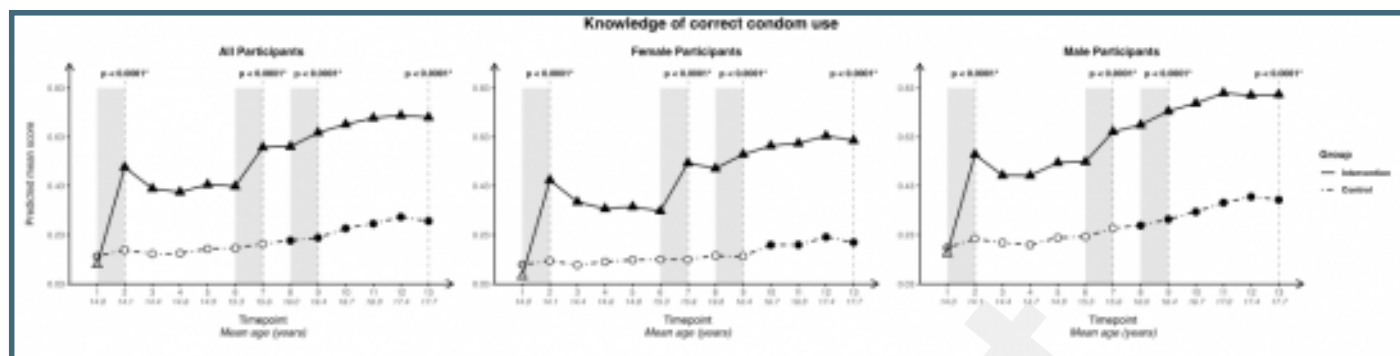
Endorsement condom is a sign of respect.



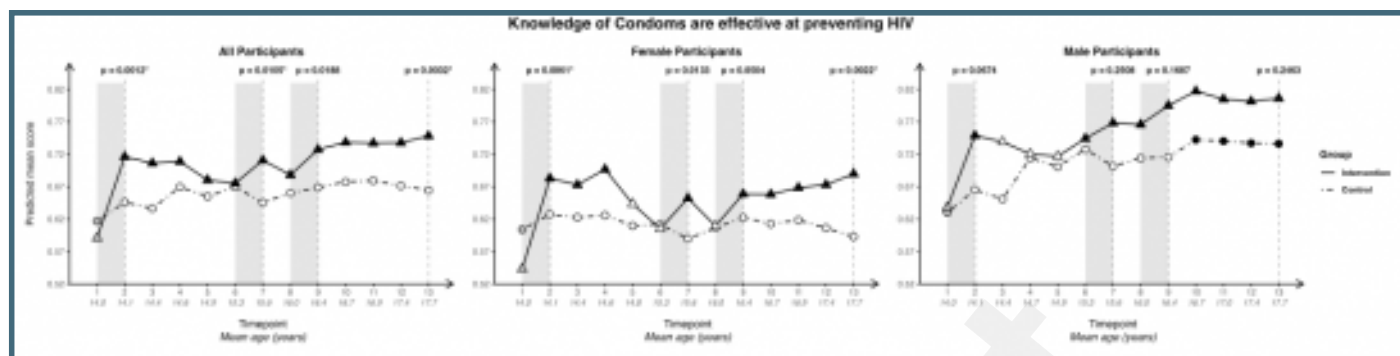
Endorsement women can suggest condom use.



Knowledge of correct condom use.



Knowledge that condoms are effective at preventing HIV.



Multimedia Appendixes

Supplemental tables.

URL: <http://asset.jmir.pub/assets/1b26353d4b5b620df4f52ce695aa51b9.docx>

Supplemental figures.

URL: <http://asset.jmir.pub/assets/e2bbdc0a566f19cf8c4e3c63ada010cb.docx>



CONSORT (or other) checklists

E-CONSORT checklist.

URL: <http://asset.jmir.pub/assets/7dcbc492131b06a5f00857c25d4d8507.pdf>