

Title: A Mobile Phone Game to Prevent HIV among Young Africans

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1.0 LAY SUMMARY

A Mobile Phone Game to Prevent HIV among Young Africans

Rationale and Objectives: This project, funded by the National Institute of Mental Health, will design, develop and pilot test an electronic game to prevent HIV among African preadolescents (aged 11-14), delivered via inexpensive Android smart phones. In order to collect feasibility data for a future randomized controlled trial, this study involves the development and subsequent pilot-testing of the intervention with a sample of young people in Nyanza region, Kenya, where 11.4% of young women ages 15-24 are HIV-infected. This feasibility study will be carried out with the Kenya Medical Research Institute (KEMRI).

Population: The population to be studied are minors, male and female, aged 11-14 (n = 108; 48 participating in formative research and 60 in intervention), their older siblings and friends, and their parents or caregivers.

Recruitment and Informed Consent/Assent: Participants will be recruited by KEMRI via schools and community-based organizations (CBOs). Parents/caregivers will be invited to attend an informational meeting at which study staff will describe the nature of the study and ask for volunteers. Written informed consent/assent will be required. Study enrollment will take place at the homes of participants.

Data collection:

1. Formative Research: Focus Group Discussions (FGDs) will be held with preadolescents and their parents/caregivers at KEMRI offices or those of a local CBO. FGD participants will provide feedback on game design documents and successive modules; they will also review the behavioral survey to establish face validity and acceptability. Respondent burden will be approximately 1 hour (preadolescent) or 1.5 hours (adult) per FGD.

2. Intervention: Preadolescents in the intervention and control group will complete 3 behavioral surveys over a 12-week period via audio computer-assisted self-interview (ACASI) technology. Respondent burden per survey will be approximately 45 minutes. Participants in the intervention arm and their parents will also take part in post-intervention FGDs. Respondent burden will be approximately 1 hour (preadolescent) or 1.5 hours (adult) per FGD. Participants enrolled in the intervention arm will engage in 10 hours of game play over a two-week period. The game will automatically collect for analysis data related to all of participants' in-game behavior, e.g. time spent playing, scores on knowledge-based mini-games, decisions made in role-playing games.

Confidentiality: Identification numbers will be the sole identifier included on the survey, FGD transcripts, and in analysis datasets. Only consent/assent forms and the participant list will have participant names. The participant list that links participant names and study identification numbers will be kept in a locked file drawer, and only authorized study team members will have access to that list.

The game will address issues related to sexual and reproductive health. The behavioral survey will assess behaviors and behavioral mediators that we propose will be influenced by the game. These include sexual behavior and intent and perceived readiness to have sex; knowledge, attitudes, perceived social norms, and self-efficacy related to targeted behaviors. Using ACASI technology, we will ask “gate” questions (“Have you ever had sex?”) that introduce skip patterns

determining whether study participants are asked more detailed questions. Participants who answer “no” to the gate question will not be asked more detailed questions about their sexual behavior. These safeguards will protect participants from questions that could cause discomfort.

2.0 BACKGROUND

In sub-Saharan Africa, around 45% of new HIV infections occur in young people between the ages of 15 and 24.¹ Youth need information and skills prior to sexual debut to protect themselves from HIV. Reaching preadolescents ages 11-14 with the knowledge and skills to support healthy behaviors prior to sexual debut may help establish lifelong patterns of safer sexual behavior and avert high-risk behaviors in the future.²⁻⁵

New mobile technologies provide unprecedented opportunities to deliver culturally-relevant skills-building interventions at scale.⁶ Increasingly ubiquitous mobile phone technologies in Africa will, with time, make it possible to engage youth – at scale and at low cost – in culturally-adapted prevention interventions that require little manpower to implement with consistent quality, have high entertainment and motivation appeal, and incorporate automated data collection. If appropriately grounded in behavioral theory and evidence-based practice, electronic games delivered via mobile phones have the potential to become valuable tools in HIV prevention efforts.

This project, funded by the National Institute of Mental Health, will design, develop and pilot test *Tumaini*, an electronic game for preadolescents, delivered via inexpensive Android smart phones. The game will be informed by socio-behavioral and pedagogical theories, evidence-based practice, and Dr. Winskell’s unique formative research on youth sexual culture in sub-Saharan Africa. It will be designed to: educate young players, ages 11-14, about sexual health and HIV/AIDS; build risk-reduction skills and related self-efficacy for prevention of HIV/STIs and unintended pregnancy; challenge harmful gender norms and HIV stigma; and foster dialogue with parents and caregivers.

In order to collect feasibility data for a future randomized controlled trial (RCT), this study involves the development of the electronic game intervention and pilot-testing of the intervention with a sample of 60 young people in Kisumu town and in a rural site in Nyanza region, Kenya, where 11.4% of young women ages 15-24 are HIV-infected.⁷ Males and females ages 11-14 enrolled in the intervention arm will engage in 10 hours of game play over a two-week period.

The feasibility study will be carried out with the Kenya Medical Research Institute (KEMRI), Kisumu, Kenya.

2.1 Aims of the feasibility study

The specific aims for our proposed 3-year study are:

Aim 1: To design and develop a theory-based, empirically grounded mobile phone game for young Kenyans aged 11-14 focused on increasing age at sexual debut and condom use at first sex;

Aim 2: To pilot test the game with a sample of 60 preadolescents aged 11-14 in rural and urban Western Kenya focusing on data needed for a larger efficacy trial, including assessments of feasibility, acceptability, willingness, and safety.

We also have the following secondary aim:

Secondary Aim 1: To provide preliminary data on the impact of the game on mediators of behaviors (knowledge, attitudes, perceived social norms, behavioral intentions, and related self-efficacy) to inform the development of an R01 focused on establishing efficacy of the game.

2.2 Preliminary studies that support this stage of the research

The proposed project draws on several years of formative research conducted by Dr. Kate Winskell on young Africans’ – including young Kenyans’ – HIV-related narratives. The narratives were submitted by tens of thousands of young Africans to Global Dialogues/Scenarios from Africa⁸ (GD/SfA) scriptwriting competitions. Analysis of this data has provided insights into youth sexual culture and youth sense-making⁹ around subjects including condoms,¹⁰ stigma,^{11,12} abstinence,¹³ testing,¹⁴ gender norms, sexual violence, relationships, peer influence, and antiretroviral therapy (ART). The narratives also provide a goldmine of authentic and relevant storylines, dialogue, characters and environments, which are essential to the development of culturally adapted curricula focusing on skills-building. Research findings and narratives are currently being applied in the enhancement and cultural adaptation of evidence-based youth prevention curricula for CDC’s Division of Global HIV/AIDS (DGHA).¹⁵⁻¹⁷ The game will be tailored to 11-14 year-old males and females, drawing on the youth-authored narratives and based on concept- and pre-testing data.

In 2013, additional preliminary research was conducted with funding from Emory’s Hubert Department of Global Health to inform the development of the current proposal. Anonymous online surveys were launched via Facebook with young people aged 15-19 in Nigeria and Kenya and four Focus Group Discussions (FGDs), segmented by sex and by time spent playing games, were conducted with young people in Imo State, South-East Nigeria. Although clearly not representative of the youth population, our online survey data revealed high levels of game-playing and broad enthusiasm for the game concept in both countries. FGDs likewise revealed great enthusiasm for games from male and female participants and “game-players” and “non-game-players” (determined by hours of weekly game-play) alike, and was also reported among their younger siblings. Participants expressed particular enthusiasm for the idea of a role-playing game framed in terms of protecting one’s future and preparing for life challenges.

A developmental R03 award from the Emory Center for AIDS Research (CFAR) allowed us to conceptualize the proposed project in dialogue with a range of partners; identify and engage in regular dialogue around game design with our game development partner; and review relevant literature and curricula of youth prevention evidence-based interventions (EBIs), including EBIs culturally adapted for Kenyan youth. This unique combination of preliminary data sources ensures the proposed intervention and feasibility trial are grounded in the realities of African youth experience.

2.3 Significance/justification for current study

Recent meta-analyses have noted the need for more effective behavioral prevention interventions

for African youth, highlighting the stark mismatch between the HIV burden in youth and efforts to conceptualize and rigorously evaluate interventions targeting this population.⁵ There is a pressing need in youth HIV prevention to develop and test approaches that show potential for increased size and sustainability of effects. Youth prevention interventions have focused on young people ages 15-19, many of whom are already sexually active, despite the well-documented challenges of trying to change established risk behaviors.^{4,5} Reaching preadolescents ages 11-14 with the knowledge, adolescents and skills to support healthy behaviors prior to sexual debut may help establish lifelong patterns of safer sexual behavior and avert high-risk behaviors in the future.²⁻⁵

While many youth HIV prevention programs are successful in increasing awareness and knowledge, they have shown little effect on sexual risk behavior.⁵ They often lack skills-building or practice activities and have too often provided information that is decontextualized from young people's lived reality and which fails to engage with the structural and normative factors that constrain individual agency.¹⁸ Future interventions must promote skills for preventing HIV infection that are relevant to the prevailing socio-cultural context^{6,18-21} and grounded in scenarios which young people perceive as authentic and relevant.

There is a need to pursue approaches characterized by catalytic innovation,²² i.e. that are more affordable, easier to deliver, and have superior scalability, and that thereby have the potential to dramatically increase reach, while ensuring fidelity to intervention design. Such approaches can help meet the ethical obligation to ensure that youth in high HIV-prevalence settings are optimally prepared for a safe sexual debut in the most cost-effective way.

New mobile technologies provide unprecedented opportunities to deliver culturally relevant skills-building interventions at scale. Increasingly affordable basic Chinese-manufactured smartphones offer the possibility to engage youth in culturally-relevant skills-building interventions that require little manpower to implement with consistent quality, have high entertainment and motivation appeal, and incorporate automated data collection, facilitating monitoring, evaluation and theory-building.

Electronic games are extremely popular among young people. They have potential to impact youth HIV prevention in sub-Saharan Africa if they are (a) appropriately grounded in behavioral and instructional theory^{23,24} and informed by evidence-based practice and (b) use technologies that will be accessible to players at the time of future dissemination.²⁵ Clinical²⁶⁻²⁹ and military³⁰ training provide examples of the benefits of video game technology for learning and skills development, while a small but growing body of evidence³¹⁻³⁷ supports the effectiveness of games for health outcomes related to diabetes³⁸ and asthma³⁹ management, diet⁴⁰ and physical activity,⁴¹ and adherence to medication.⁴² In addition to health outcomes, studies report positive effects on a range of mediators of health behaviors, including knowledge, self-efficacy, and health-related dialogue. To date, few games have been designed with solid theoretical grounding and rigorously evaluated.³¹⁻³⁷ There is therefore a pressing need to expand our understanding of and the evidence base for the use of game technology for health and to assess their feasibility in low-resource settings. If proved efficacious in the eventual trial, the proposed intervention has the potential to be highly scalable, cost-effective, and culturally adaptable to individual sub-Saharan countries.

2.4 Sample

Population:

- Preadolescents, male and female, aged 11-14, in Nyanza region, Kenya (n = 108)
- Parents of preadolescents aged 11-14, in Nyanza region, Kenya (n = 54)
- Adolescents, including older siblings of enrolled intervention arm preadolescents, **aged 15-25, in Nyanza region, Kenya (n=75)**

Vulnerable population: A proportion of this population will be minors (<18 years old). Safeguards to protect this vulnerable population are described in detail below.

Inclusion criteria (preadolescents):

- Aged 11-14 at time of recruitment
- Resident in Nyanza region, Kenya
- Having basic literacy in English (Grade 3-4 on the Flesch-Kincaid Reading Scale). This criteria is not expected to greatly limit generalizability of findings for our 11-14 year-old target audience as primary school education (ages 6/7 through 13/14+) has been free and compulsory in Kenya since 2003; all school subjects are taught in English from Standard Year 4 (age 10+) onwards.
- Only one child per family

Exclusion criteria (preadolescents):

- Aged <11 or >14
- Not resident in Nyanza region, Kenya
- Without basic literacy in English
- Sibling to a child already enrolled in the study
- Participant in formative research to inform the study

Inclusion criteria (parents):

- Parent/primary caregiver of child aged 11-14 at time of recruitment
- Resident in Nyanza region, Kenya

Exclusion criteria:

- Not parent/primary caregiver of child aged 11-14 at time of recruitment
- Not resident in Nyanza region, Kenya
- Participant in formative research to inform the study

Inclusion criteria (siblings):

- Older sibling of intervention arm child aged 11-14 at time of recruitment, **currently aged 15-25**
- Resident in Nyanza region, Kenya
- With basic English literacy

Exclusion criteria (siblings):

- Not older sibling of intervention arm child aged 11-14 at time of recruitment

- Older than **25**
- Not resident in Nyanza region, Kenya
- Without basic English literacy

Inclusion criteria (other adolescents):

- **Currently** aged 15-25
- Resident in Nyanza region, Kenya
- With basic English literacy

Exclusion criteria (other adolescents):

- Older than **25**
- Not resident in Nyanza region, Kenya
- Without basic English literacy

2.5 Setting

The proposed pilot test will be conducted in rural Western Kenya, where the Kenyan Medical Research Institute (KEMRI)/CDC Health and Demographic Surveillance System (HDSS) is located, and in Kisumu town, Kenya's third largest city. KEMRI has established community advisory boards (CABs) in the HDSS sites and in Kisumu town, which will be available to the proposed study.

Data collection will take place at KEMRI offices, health clinics, or in the meeting room of a local community-based organization (CBO). In addition, data on game-play will be automatically collected on mobile phones given to preadolescent study participants.

2.6 Recruitment

Site of and/or procedures for recruitment: Participants will be recruited through schools, CBOs, clinics, churches and social events in Kisumu town and rural communities. KEMRI will provide a list of all schools, CBOs, clinics, churches and upcoming social events in each area. Research staff will arrange meetings with leaders of these venues to describe the nature of the research.

Description of recruitment methods: In schools, information will be sent out to parents describing the study and inviting them to an informational meeting. At the informational meeting, study staff will describe the nature of the study and answer questions from attendees. The meetings will ask for parents/ caregivers to volunteer for participation. We expect to hold around 10 of these informational meetings. Contact information will be collected from parents/caregivers selected and a research assistant will then arrange to meet interested families at their homes or another preferred location, provide a brief description of the project, answer any remaining questions, and screen for eligibility, prior to securing parental consent and preadolescent assent. Siblings will be recruited through phone contact with previously enrolled families. Additional adolescents will be recruited through snowball sampling, by asking previously enrolled families to distribute letters describing the study to friends and family, and having interested individuals contact the study team directly; **by asking secondary school teachers to distribute these letters to creative and engaged students, and having interested individuals contract the study team directly; and by asking CAB and YAB (youth advisory board) members and local youth-friendly clinics and CBOs to distribute these same letters**

to young people and having interested individuals contact the study team Consent and assent for additional participants under age 18 will be carried out in the same way as for preadolescent participants. Participants aged 18 and over will meet with a research assistant at home or another preferred location, receive a brief description of the project, ask any remaining questions, and be screened for eligibility prior to providing consent for participation.

Equitable recruitment of subjects: The youth sample will be gender-balanced and efforts will be made to ensure that participation is evenly distributed across the 11-14 age range. No more than 8 volunteers will be recruited from each informational meeting to avoid overrepresentation by site. If more than 8 parents/caregivers volunteer, they will be selected randomly from names placed in a bowl. If there is more than one eligible child in the household, study staff will randomly select a child for enrollment by placing the children's names in a bowl. Recruitment materials and consent/assent forms will be available in English and Luo to ensure comprehension (these will be translated into Luo and Swahili and back translated to English by two groups of in-house translators at KEMRI to ensure accuracy). Parents choosing not to enroll will be asked to complete a brief questionnaire identifying reasons for non-participation.

The sibling sample will not be held to the same even gender and age distribution. The additional adolescents recruited through snowball sampling will be selected in order to ensure age and gender balance the group of 15-25 year old participants.

2.7 Procedures

Study Design and Data Collection Procedures:

The study design falls into four parts. Data collection procedures and total respondent burden for each part are specified below:

i) Game Development and Validation of Behavioral Measures

- a. Focus Group Discussions with preadolescents [34 FGDs x 6-8 participants; there will be overlap in participants in the focus groups, i.e. the same individual may take part in several different rounds of focus groups]. Total respondent burden: 1 hour per FGD and/or Cognitive Interviews with preadolescents [9 Interviews; participants will be the same individuals as those involved in FGDs]. Total respondent burden: 1 hour per interview
- b. Focus Group Discussions with parents/caregivers [14 FGDs x 6-8 participants; ; there will be overlap in participants in the focus groups, i.e. the same individual may take part in more than one round of focus groups]. Total respondent burden: 1.5 hours per FGD.

ii) Intervention

- c. Intervention: Independent game-play [30 preadolescents]. Total respondent burden: 10 hours of game-play over 2-3 weeks.

iii) Behavioral Survey

- d. Survey of preadolescents [60 preadolescents]. Total respondent burden: 45 minutes x 3 (at baseline, post-intervention, and endline)

iv) Follow-up Evaluation

- e. Focus Group Discussions with preadolescents [14 FGDs x 6-8 participants]. Total respondent burden per FGD: 1 hour and/or In-Depth Interview (IDI) with preadolescents [12 Interviews; participants may be the same individuals as those involved in FGDs]. Total respondent burden: 1 hour per interview
- f. Focus Group Discussions with parents [8 FGDs x 6-8 participants]. Total respondent burden: 1.5 hours. and/or In-Depth Interview (IDI) with parents [8 Interviews; participants may be the same individuals as those involved in FGDs]. Total respondent burden: 1 hour per interview
- g. Focus Group Discussions with adolescents [16 FGDs x 6-8 participants]. Total respondent burden: 1 hour and/or In-Depth Interview (IDI) with siblings [16 Interviews; participants may be the same individuals as those involved in FGDs]. Total respondent burden: 1 hour per interview
- h. Survey on social networks with preadolescents and adolescents [1 survey x 120 participants]. Total respondent burden: 15 minutes.
- i. Cognitive interviews with preadolescents and adolescents [12 interviews]. Total respondent burden: 1 hour
- j. Cognitive interviews with parents [9 interviews]. Total respondent burden: 1 hour
- k. Survey of adolescents [20 preadolescents and adolescents]. Total respondent burden: 1 hour
- l. Survey of parents [20 parents]. Total respondent burden: 1 hour

2.8 Measures

i) Game Development and Validation of Behavioral Measures

A draft game design document and successive modules will be reviewed by young people and their parents in Kenya via FGDs. Game development will be iterative, with ten rounds of FGDs with preadolescents and parents/caregivers staggered across the 8-month process. A total of 48 preadolescents and 24 parents will be recruited to participate in the FGDs. There will be overlap in participants in the focus groups, i.e. the same individual may take part in several different rounds of focus groups. The first two rounds will comprise 3 FGDs with preadolescents (6-8 per FGD) and 3 FGDs with parents (6-8 per FGD). Their purpose will be to fine-tune the game concept and design, graphic design elements, and narrative. Rounds 3-10 will pre-test successive modules of the game in FGDs with preadolescents. FGD questions will focus on perceived acceptability (liking, appropriateness), usability (ease of play), comprehension of concepts, relevance to their daily lives, entertainment and immersive appeal of the game. In addition, suggestions will be elicited on how to improve the game design. The same participants will not participate in every round of FGD.

FGDs will be conducted to establish face validity and comprehension of the behavioral survey questions among preadolescents and their acceptability among parents. In cognitive interviews and FGDs, preadolescent participants will be asked questions relating to specific survey items and what specific survey questions mean to them. Parents will be asked to read the survey and identify questions they consider unacceptable.

ii) Intervention

The 60 pilot study participants (youth ages 11-14) will be randomized to the intervention or control arm upon completion of the baseline survey. The assignments will be generated with the use of a pseudo-random-number generator with permuted blocks, used to ensure balance between the numbers of participants assigned to each arm. Those randomized to the intervention arm will be given a low-cost (<\$50) Android phone on which the game is programmed and invited to play the game for one hour each day for 10 days over a two-week period. While we anticipate that access to smartphones will be widespread at time of roll-out of an efficacious game, this is not yet the case: for the purposes of the feasibility test, phones need to be provided in order to ensure consistency of technology and avoid SES bias. All other phone functions will be disabled for safety reasons. The phone will be programmed to issue regular reminders to encourage game-play. The game will automatically record the time spent playing and the choices made in the context of game play. Those randomized to the control arm will receive the current standard of care i.e. no intervention beyond routine exposure to local community-based and mass media interventions and exposure to life skills education for those in school.

The game, *Tumaini*, will be a scenario-based role-playing game, optimized for use on low-cost Android smartphones that uses comic book-style graphics. It will be downloaded onto the phone as an app so that it can be played without Internet access. The game will be tailored to 11-14 year-old males and females, drawing on the youth-authored narratives and based on concept- and pre-testing data.

The game will be available first in English, produced with locally-sourced voice talent. A Luo version would follow if feasibility for conducting an efficacy trial in Nyanza were established. In order to maximize access to the game for those with limited literacy levels (and increase its youth entertainment appeal), all game content will be delivered via both audio and text. Eligible participants in the feasibility study will need to demonstrate basic literacy in English (Grade 3-4 on the Flesch-Kincaid Reading Scale) to ensure that they are able to link response options that are heard in English with the same response options shown in text format on screen (for example, “Option 1: Leave. Option 2: Stay and see what happens...”). Audio effects will be used to maximize immersion.

The proposed game will be designed to: educate young players, ages 11-14, about sexual health and HIV/AIDS; build risk-reduction skills and related self-efficacy for prevention of HIV/STIs and unintended pregnancy; challenge HIV stigma and harmful gender norms; nurture awareness of and positive attitudes towards health services; and promote parent-child dialogue. The Information-Motivation-Behavioral Skills (IMB) model⁴³ elucidates the triple-layered structure of the game:

1. **Information – mini-games.** Information that is relevant to HIV transmission and prevention will be conveyed by a series of mini-games, i.e. short, simple electronic games contained within the larger, more complex game.
2. **Behavioral skills and related self-efficacy – scenarios.** Built around GD/SfA data, the central role-playing element of the game invites the player to take over male and female avatars and navigate through a series of scenarios in which s/he makes decisions and develops skills and related self-efficacy. The game will include skills-building scenarios from

preadolescence through the teen years addressing subjects including: realizing future plans and dreams; healthy romantic relationships; puberty; harmful gender norms and expectations; gender-based violence, including sexual violence, child sexual abuse, and early marriage; positive and negative peer influence; alcohol and drugs; peer, partner and adult pressure to have sex; intergenerational and transactional sex; unintended pregnancy; STIs; living with HIV - testing, treatment and disclosure; and parent/caregiver-child communication.

3. **Motivation – meta-narrative linking virtual and real worlds.** A motivational meta-narrative will also link the virtual world with the player’s real world.

iii) Behavioral Survey

A survey will be implemented with the preadolescents at baseline (1-2 weeks prior to the intervention), post-intervention (1-2 weeks after the intervention), and follow-up (6 weeks after the intervention), assessing mediators of sexual behavior. We anticipate that the assessment will take no more than 45 minutes to complete. All assessments will be conducted via audio computer-assisted self-interview (ACASI) technology in which the computer will read questions to the participants. Previous research has successfully used the ACASI system in Kenya.⁴⁴ Prior to using the ACASI system, its feasibility and acceptability will be pilot tested with a sample of 10 preadolescents. Each participant will wear headphones to ensure privacy while answering the questions. Study staff will be available to orient participants to the computer system and to answer any questions that arise during the interview. Research assistants will administer the questionnaire face to face for those participants who are not comfortable using the computer. The data will be directly entered into the computer. Surveys will be conducted using ACASI with a view to protecting participant confidentiality and reducing social desirability bias.

The survey measures will focus on behaviors and behavioral mediators that we propose will be influenced by the game. The proposed measures reflect Social Cognitive Theory⁴⁵ and the Information-Motivation-Behavioral Skills model in which the intervention is grounded. We will measure sexual behavior, intent to have sex and readiness to have sex. We will also assess parent-child dialogue about sex. These primary behavioral mediators have already been validated and used with this a similar youth population in the Nyanza region HDSS site as part of the evaluation of the Families Matter! Program (FMP) and/or with a similar youth population in Botswana as part of an RCT of Project AIM⁴⁶ conducted by CDC’s DGHA.⁴⁷ FMP is a CDC-sponsored intervention for parents and caregivers of 9-12 year-olds that promotes effective parent-child communication about sexuality and sexual risk reduction.² In addition, the validity and reliability of many of the questions had been established in prior research with US populations.^{48,49} The FMP measures will be supplemented with additional measures drawn from existing literature and adapted to be culturally and age-appropriate.⁵⁰ The survey will assess knowledge, attitudes, perceived social norms, along with self-efficacy related to targeted behaviors (e.g. rejection of peer, partner and adult pressure to have sex).⁵¹ Attitudinal measures and measures of perceived social norms will address HIV stigma, gender norms, violence against women, intergenerational sex and transactional sex, alcohol and drugs, and condoms. Examples of source literature for these measures include: the questionnaire from the Guttmacher Institute’s Protecting the Next Generation Project, used with

adolescents in Uganda; Kalichman et al.'s brief HIV stigma scale, validated in South Africa;⁵² IMB sub-scales (including, for example, the Perceived Effectiveness of AIDS Preventive Behavior sub-scale),⁵³ used with adolescents in South Africa;⁵⁴ the Gender Equitable Men Scale,⁵⁵ and CARE's Gender Equity Index (modeled after the GEM scale for 10-14 year-olds and tested and implemented in Kenya).⁵⁶

ACASI allows us to introduce "gate" questions ("Have you ever had sex?") that introduce skip patterns determining whether study participants are asked more detailed questions. Participants who answer "no" to the gate question will not be asked the more detailed questions about their sexual behavior. These safeguards will protect participants from questions that could cause discomfort and should help allay unease parents may feel about their children being asked questions about sexual behaviors. The survey will collect demographic data (age, sex, years in school, residency, etc) and include questions about computer access, hours of game play per week, personal phone ownership, household phone ownership. The follow-up surveys will be identical to the baseline, with the exception that those exposed to the intervention arm will also be asked questions on how long and how they used the game. They will also be asked to rate individual modules, the game's usability, entertainment appeal, etc.

iv) Follow-up Evaluation

Following the intervention, four FGDs will be conducted with the 30 preadolescents in the intervention arm, and four FGDs will be conducted with their parents/caregivers, for a total of 8 FGDs, each with 6-8 participants. Equal numbers of FGDs will take place at the two locations (Kisumu town and the rural site). The FGDs will be held at KEMRI offices or a CBO meeting room and will be conducted in Luo and/or English. The purpose of the FGD will be to provide deeper contextual data on the experience of exposure to the game. Questions will focus on: acceptability; dose received; barriers to playing the game as instructed; usability; appeal; immersion; relevance; safety; and suggestions for improving the experience.

Additional FGDs and/or IDIs will be conducted with the preadolescents, with some of their older siblings, other older adolescents, and with parents, for a total of 30 additional FGDs, each with 6-8 participants, and/or 36 IDIs. These will also be held at KEMRI offices or a CBO meeting room and conducted in DhoLuo, Swahili, and/or English. The purpose of these additional FGDs will be to provide additional data on particular aspects of game appeal, recommendations for revisions, and suggestions for future game expansions.

An additional short survey will be conducted with control and intervention arm participant preadolescents, their siblings, and other older adolescents. For those who attend FGDs, these surveys will be done in person. For others, they can be carried out by phone. The purpose of this survey is to provide additional data on social networks and information sharing networks among youths in our target demographic.

Parents will be invited to review and provide feedback on the acceptability of edits to the behavioral survey questions. Further cognitive interviews and pilot tests will be conducted with preadolescents, their older siblings and other older adolescents to assist revisions to the behavioral survey, for a total of 12 interviews and 20 pilot tests. Parents will also participate in 9 cognitive interviews and 20 pilot tests to assist with the development of an additional parental survey.

Unlike feasibility test behavioral surveys, these modified surveys are intended to be delivered via ODK (Open Data Kit), using mobile devices. Piloting of the survey will include piloting the new platform for usability and for feasibility of this form of survey delivery.

2.9 Risks to participation

Potential risks consist of being uncomfortable or emotionally upset as a result of the questions asked in the FGDs or the assessment survey, or topics addressed in intervention sessions. It is possible that certain assessment questions regarding sexual behavior may make participants feel uncomfortable. In addition, participants may have concerns about their personal safety associated with being in possession of the mobile phone.

Procedures to reduce risk: Questions will be vetted by the KEMRI community advisory board, by parents/guardians, and by preadolescent participants in focus group discussions **and cognitive interviews** prior to being administered. Participants are free to refuse to answer any question and may terminate participation in the study at any time. To minimize the risk of participants feeling uncomfortable about answering personal questions, we will use a self-administered ACASI survey. We will make every effort to create a secure environment (ensuring privacy) prior to conducting baseline, post-intervention, and endline assessments. One objective of the feasibility study will be to ensure that providing participants with low-cost smartphones will not result in risks to their safety. Non-game-related functions on the phone will be disabled in the interests of participants' safety. In addition, participants will be instructed not to tell others about the phone or to use it in public. Because of these risk reduction procedures, we expect there would be minimal psychological harm to participants. In the event any participant experiences psychological harm due to study participation, participant will be evaluated, adequate psychological support including referral for further management will be provided by the study team.

2.10 Benefits to subject or future benefits

Participants in the intervention arm will have the opportunity to experience the use of an electronic game to promote safer sexual health for youth in Africa. Others will benefit because the study will result in increased knowledge about how video games could be used for HIV prevention efforts in Africa. The study will provide important new information to inform the development of an efficacy trial of an electronic game and its impact on sexual health among youth in Africa. Given the very high burden of HIV among youth in Africa, this has the potential to offer an exciting new opportunity for intervention.

2.11 Data analysis

Rationale for proposed number of subjects: We propose to enroll a total of 168 Kenyan preadolescents. Forty eight children will participate in concept-testing and pre-testing of the game and in fine-tuning and ensuring face validity of the survey instrument. Sixty of the remaining 90 will participate in the pilot intervention, 30 in the study arm, and 30 in the control group. The last 75 will be recruited after the intervention is tested, and only participate in focus group discussions and review of survey instruments.

Twenty-four parents or caregivers of 11-14 year-olds will participate in concept-testing and pre-testing of the game and in determining acceptability of the survey instrument. In addition, one

parent or guardian of each study participant in the intervention arm (n = 30) will be recruited to participate in post-intervention focus group discussions.

We propose, then, to consent and enroll a sample of 60 youth for the intervention component of the study. Previous KEMRI based studies suggest approximately 15% loss to follow-up (LFU) in cohort studies. We allow for 20% LFU in our sample, producing a sample of 48 youth with complete data. As with most pilot studies, we are not adequately powered to show efficacy of the game in the study population. The purpose of the proposed pilot study is to collect data on the feasibility of conducting a larger efficacy trial of the game. However, we are interested in showing that the game “trends” in the correct direction.

Formal sample calculations: We found that our study design (30 participants using the game versus 30 control participants, yielding data on 48 participants) would have 77% statistical power to detect a 32% change in a binary attitude measure using a two-sided level-0.1 test of two independent binomial proportions. If we use a level-0.2 test, then we have 77% statistical power to detect a change in attitudes of about 26%.

Based on prior pre-testing experience, we are confident that this number of FGDs is sufficient to achieve data saturation for our purposes.

Plans for data management and statistical analysis: For each measure we will examine univariate properties (frequency and range) and compare prevalence/ mean (range) by age, gender, urban/rural location and study arm using appropriate statistical tests for significance. We will conduct additional analysis to the prevalence and mean (ranges) of these variables across control and experimental arms, focusing on identifying significant differences in changes in these variables pre and post intervention. Although the pilot study is not powered to detect changes, this analysis will provide more data on the context of behaviors in this population and will suggest the possible directions of effects for a larger efficacy trial.

The game will automatically collect data related to all of participants’ in-game behavior, including but not limited to: time they spend playing; their scores on knowledge-based mini-games; the decisions they make in the role-playing games, including how they solve problems, accomplish tasks, and overcome obstacles; and the life goals they choose in the meta-narrative component. We will generate descriptive statistics from the in-game data. Analysis will present descriptive statistics of time spent playing the game (times per week, minutes per session, minutes per week), time devoted to different game components, number of players using each phone, scores on knowledge-based mini-games, and choices made during game play. Using appropriate tests for significance, we will examine differences in these outcomes by age, gender, urban/ rural location, and in relation to other survey measures.

Data from the FGDs and IDIs will be audio-recorded, transcribed and entered into MaxQDA software. A codebook of deductive themes, focusing on domains addressed in discussion guide, and inductive themes emerging from the transcripts, will be used to label the data. We will conduct grounded theory-based, thematic analysis of the transcripts with particular focus on linkages between thematic domains, patterns by age and gender, and issues that could inform the successful design of a future efficacy trial.

Inclusion of stopping rules as appropriate: Not applicable.

3.0 TRAINING

3.1 Description of training for research personnel

All research personnel have completed CITI training. The PIs (Winskell, Mudhune) or one of the Co-Is (Stephenson, Breiman) will hold a pre-training preparation meeting at the individual sites with local staff to cover the goals, purpose and design of the study and briefly introduce the intervention and underlying philosophy of the intervention. Staff will receive study-specific training on data collection procedures (including ACASI and ODK data collection) and related confidentiality issue ethics. They will be trained to be sensitive to preadolescent and parent/caregiver discomfort with certain themes or questions, and to people's differing opinions about sexual education for children. Additionally, all staff will be trained on recognition and documentation of any unusual events or circumstances that occur during data collection. Staff will be monitored closely by the PIs and Kenya-based Project Coordinator. Staff deficient in any aspect of performance will be re-trained, closely monitored for proficiency, and if not adhering to established protocols and procedures, will be terminated.

4.0 PLANS FOR DATA MANAGEMENT AND MONITORING

4.1 Description of data safety and monitoring plan

In accordance with the National Institutes of Health (NIH) requirements, we will adopt a Data and Safety Monitoring Plan to ensure participants' safety as well as the data's validity and integrity. The PIs will provide close monitoring and oversight of all study procedures and quality assurance checks. All records pertaining to the study and all of the original and electronic files containing collected data will be securely stored by the PIs. Paper copies will be stored in a locked metal file cabinet housed in an off-site office location while electronic files will have encryption and strong password protection. Completed and signed consent forms will be stored in a different locked file cabinet also off-site.

Because there are minimal risks involved in this study, the chances of adverse events are low. The most likely adverse event is participant discomfort with some of the subject matter in the intervention or the assessments. Interventionists and assessment staff will be trained to be sensitive to this discomfort, and to people's differing opinions about sexual education for children. Participants who are not comfortable with the content of the intervention or the assessment questionnaires will be reminded that they can choose not to participate for any reason.

A second area of discomfort is that parents may be uncomfortable with their child being asked questions about sexual behaviors and attitudes. The consent form will indicate that children will be asked questions about sex. Parents will be invited to review the child's assessment instrument, and paper forms will be available for parents' review. We will point out to parents that for questions about sexual behavior, there is a "gate" question that determines whether children are asked more detailed questions about sexual intercourse, condom use, and sex partners. Children who answer "no" to the gate question will not be asked the more detailed questions about their sexual behavior. Parents who object to their children being asked these questions can choose not to participate. Parents who accept their children to participate in the study will have reviewed the questions their children will be asked. However, the parents will not be able to identify their children's specific choices.

In the event that a minor reports neglect and/ or sexual abuse, the study team (in line with conventional best practices) plans to document such cases, report to the local IRB and most importantly, refer the victim to the nearest gender based violence center (GBV) for psycho-social counseling, medical care and paralegal advice. Interviewers will be trained to offer referrals for counseling or social services, trained to discuss sensitively the adolescent's disclosed experience and to monitor for emotional upset or anxiety during or as a result of the interview among any of the participants (adolescent or parent) and to offer support and referrals for counseling and other services to those participants. Additionally, interviewers will receive training in protection of human subjects.

Staff will be trained to report any adverse events that concern them immediately to the Project Coordinator at the local field site, via telephone. Should a serious adverse event occur, the Project Coordinator will immediately inform Drs. Winskell and Mudhune who, in turn, will immediately inform the Emory University IRB and KEMRI IRB. If an adverse event appears to be research-related, it will be reported to the OHRP and the NIMH project officer, along with summaries of discussions concerning the event. The funding institution project officer will be informed of any IRB action taken concerning any adverse event.

Dr. Winskell's Program Officer at NIMH has indicated that a Data Safety and Monitoring Board is not required for this study.

5.0 CONFIDENTIALITY

5.1 Plans to protect privacy of subjects and confidentiality of data

Study surveys will be self-administered via ACASI and will be completed by preadolescents in a private space. Access to data collected through these surveys (without associated identifiers) will be limited to Drs. Winskell and Mudhune, and relevant staff, all of whom will be training in the importance of data privacy. No PHI will be collected. At enrollment, we will collect at least 2 forms of information to facilitate re-contact of participants, including a home address and a cell phone number. Re-contact information will be stored in the study's retention database and will only be accessible to study staff with a study-related need for access to these identifiers. Re-contact information will not be linked to the survey data.

The Principal Investigators and Co-Investigators will be responsible for dissemination of study findings through presentations and publications. Dr. Winskell will also be solely responsible for handling any requests from other investigators to examine the data collected during this study.

To minimize risks to confidentiality, we will provide study data with all appropriate physical and operational security protections. Data will be stored in a physically secure environment, and all electronic data files will have encryption and strong password protection. Only those study staff who require access to identifying data to complete their study-related roles will be allowed access. All study staff will be trained in security and confidentiality procedures, and will sign a confidentiality agreement before receiving access to any participant data. Focus group participants will be reminded that the confidentiality of any information they provide cannot be guaranteed and that they should not say anything that they do not want others outside the group to hear.

5.2 Description of plans to link data to identifiers

Identification numbers will be developed for participants and noted on study identification cards handed out to participants. These will be the sole identifiers included on the survey, FGD transcripts, and in analysis datasets. A list will be kept linking the study identification numbers to the identifying participant information. Only consent/assent forms and the participant list will have participant names.

5.3 Description of how linkage will be protected

The participant list that links participant names and study identification numbers will be kept in a locked file drawer, and only authorized study team members will have access to that list.

6.0 INFORMED CONSENT

6.1 How and where will informed consent be obtained? Oral or written?

Informed consent/assent will consist of a written document, which the participant may read himself, or which can be read to the participant by study staff. Written documentation of informed consent/assent will be required. Recruitment materials and consent/assent forms will be available in English, Swahili and DhoLuo to ensure comprehension (these will be translated into Swahili and Luo and back translated to English by two groups of in-house translators at KEMRI to ensure accuracy). Parents choosing not to enroll will be asked to complete a brief questionnaire identifying reasons for non-participation.

Parents/ primary caregivers will provide informed consent for their child's participation **if the child is under 18**; in order to avoid any pressure to participate, children will simultaneously be invited to provide informed assent in a separate room. **Siblings and other adolescents over 18 will provide informed consent for participation in follow-up FGDs on their own behalf.** Children and parents will be informed that participation is voluntary, that they do not have to answer questions that make them uncomfortable, and that all information will be kept private. Information on participants' experimenting with sex will not be made available to parents for participants' to maintain participants' own privacy. The game is however meant to promote safer sexual health for youth in Africa and for participants.

Unless another location is preferred by participants, study enrollment will take place at the home of participants so that they can be easily located in the event of potential attrition. To encourage retention, study staff will make regular house calls to the parents/ caregivers of the enrolled youth (once per week), and reminders for follow-up study assessments will be made – via phone calls – one week and the day before study assessments.

6.2 Plans to inform participants of new findings or research results that might affect health

This preliminary study is unlikely to uncover information that would directly impact participants' health.

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APPENDICES

Appendix 1: Study Budget

Redacted

Appendix 2A: Assent Formative Research - English

ASSENT FORM FOR MINOR SUBJECTS

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators: Kate Winskell, PhD, and Victor Mudhune, MBA MPH

This page to be filled in by research team at the time assent is obtained:

Subject's Age: _____ years (If the child is **younger than 6 years old**, assent is not required.)

Subject's Name: _____

Check one box:

This child is 6 to 10 years old — must obtain subject's verbal assent (subject's signature not required)

Signature of person soliciting assent of 6 to 10-year-old subject _____ _____
Date Time

This child is 11 to 17 years old — must obtain subject's signature on assent form to document assent

In my opinion, this child is unable to provide informed assent for non-age-related reasons, and the PI for this study has been informed of this determination.

- Reason(s):

Signature of person soliciting assent (if above box is checked) _____ _____
Date Time

ASSENT FORM FOR MINOR SUBJECTS

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators: Kate Winskell, PhD and Victor Mudhune, MBA MPH

INFORMATION ABOUT THIS STUDY:

Introduction

You are being invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for children to learn about HIV using a game on a mobile phone.

You only have to take part in the study if you want to. The purpose of this form is to help you decide if you want to be in the study. If you are going to be in the study, your parent/caregiver also has to agree. But if you do not wish to be in the study, you do not have to, even if your parent/caregiver has agreed. Your parent/caregiver cannot force you.

You can leave the study at any time. If you join the study and then change your mind, it is okay for you to leave the study. No one will be upset with you. You can skip any questions that you do not wish to answer.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to develop a new way for children to learn about HIV using a game on a mobile phone. We would like you to tell us what you think of their ideas, plans, and designs. We would also like you to help us decide what questions to ask children in order to find out if the game is helping them learn about HIV.

What will happen if I take part in this study?

If you agree to be in the study, here is what will happen:

Focus Group Discussion: We will show you our ideas, plans and designs for the game and ask you to discuss them with a group of 6-10 children of about your age. We will also ask you to tell us what you think about certain topic areas and about certain questions that we plan to ask other children who play the game. We will ask you to take part in these discussion groups around 3-5 times over a period of 8 months, but you can refuse to participate in any of these discussion groups you don't want to take part in. The group discussions will be recorded to make sure we do not miss anything that participants say. Each group discussion will last about an hour.

What are the good (benefits) and bad (risks) things that could happen to me if I agree to be in the study?

Benefits: You will not receive direct benefit by taking part. However, when you take part, you are helping us to make a game about HIV that you like and would like to play. You are also

helping us learn if the questions we plan to ask children make sense. You will not be offered payment for being in this study. However, you will be reimbursed Kshs 500 for your time and transport costs and refreshments provided as per standard requirements during FGDs.

Risks: Parts of the game and some of the questions may embarrass you or make you feel uncomfortable. If you feel uncomfortable with any questions you are asked, you may refuse to answer them.

What about my confidentiality?

You are being asked to take part in a group discussion. We cannot promise that children in the group will not share what you say with others. You shouldn't say anything in the discussion group that you would not want others outside the group to hear.

Your information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your answers to you.

This assent form will be kept in a safe locked cabinet. We will use a study number in place of your name on all study forms. Your name will never be shared with others. Your name will never be used for analysis.

Disclosure of Child Sexual Abuse and Neglect

Your privacy is very important to us, but so is your health and safety. In cases where abuse, neglect or a child's desire to harm themselves or others is suspected or disclosed during the study, our staff are required to report this information.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor **Mudhune**, Principal Investigator, KEMRI

Email: VMudhune@kemricdc.org

Phone: 057 2022929/02

If you have any questions about your rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the secretary, KEMRI Scientific and Ethics Review Unit (SERU), (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003 or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Email: SMunga@kemri.org

Phone: 057 2022929/02

Or

Name: Emory University Institutional Review Board

Email: irb@emory.edu

Phone: +1 404 712 0720

Appendix 2B: Assent Formative Research - Swahili

Informed Consent Forms

ASSENT FORM FOR MINOR SUBJECTS

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators: Kate Winskell, PhD, and Victor Mudhune, MBA MPH

This page to be filled in by research team at the time assent is obtained:

Subject's Age: _____years (If the child is **younger than 6 years old**, assent is not required.)

Subject's Name: _____

Check one box:

This child is 6 to 10 years old — must obtain subject's verbal assent (subject's signature not required)

Signature of person soliciting assent of 6 to 10-year-old subject Date _____ / /
Time

This child is 11 to 17 years old — must obtain subject's signature on page 2 of assent form to document assent

In my opinion, this child is unable to provide informed assent for non-age-related reasons, and the PI for this study has been informed of this determination.

- Reason(s):

- _____

Signature of person soliciting assent (if above box is checked) Date _____ / /
Time

ASSENT FORM FOR MINOR SUBJECTS

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators: Kate Winskell, PhD and Victor Mudhune, MBA MPH

MAELEZO/HABARI KUHUSU UTAFITI HUU

Utangulizi

Unakaribishwa ushiriki katika utafiti unaofanywa na chuo kikuu cha Emory Atlanta na Kenya Medical Research Institute (KEMRI). utafiti huu utatusaidia kuunda njia mpya ya watoto kujifunza kuhusu Virusi Vya Ukimwi kwa kutumia mchezo kwenye simu ya mkono.

Utashiriki tu kwa utafiti ikiwa unataka. Sababu ya hii karatasi/fomu ni kukusaidia kuamua kama unataka kuwa katika utafiti. kama unaenda kushiriki katika utafiti, mzazi wako /mlezi pia lazima akubali. Lakini kama hutaki kushiriki kwenye utafiti, si lazima hata kama mzazi/mlezi wako amekubali. Mzazi /mlezi wako hawezi kukulazimisha.

Unaweza kuacha utafiti wakati wowote. Kama umejiunga na utafiti kisha ubadili fikira zako, ni sawa kuacha utafiti. Hakuna atakaye kasirika na wewe. Unaweza ruka maswali yoyote ambayo hutaki kujibu.

Fomu hii inaweza kuwa na maneno ambayo huelewi. Tafadhali uliza mfanyikazi wa utafiti aeleze neno lolote au maelezo ambayo si wazi kwako. Unaweza kuuliza maswali wakati wowote.

Ni kwa nini tunafanya utafiti huu?

Timu ya utafiti inataka kuunda njia mpya ya watoto kujifunza kuhusu virusi vya ukimwi kwa kutumia mchezo kwenye simu ya mkono/rununu. Tungependa utuambie kile ambacho unafikiria kuhusu mawazo, mipango na miundo yao. Tungependa pia utusaidie kuamua maswali ya kuuliza watoto ili kujua kama mchezo inawasaidia kujifunza kuhusu virusi vya ukimwi,

Ni nini itafanyika kama nimeshiriki katika utafiti huu?

kama umekubali kushiriki katika utafiti, haya ndiyo yatakayofanyika/yatakayotendeka:

Mahojiano/majadiliano ya kikundi: tutakuonyesha mawazo, mipango na miundo yetu ya mchezo na kukuuliza uzijadili na kundi la watoto 6-10 ambao wanakaribia umri sawa na wako. Tutakuuliza pia utuambie unachofikiria kuhusu mada nyingine na kuhusu maswali fulani ambayo tunapanga kuuliza watoto wengine wanaocheza mchezo. Tutakuuliza ushiriki katika makundi ya majadiliano karibu mara 3-5 kwa kipindi cha miezi 8, lakini unaweza kukataa kushiriki kwenye makundi ya majadiliano yoyote ambayo hutaki kushiriki. Majadiliano ya makundi yatarekodiwa ili kuhakikisha hatujakosa chochote ambacho mshiriki atasema. kila majadiliano ya kikundi itakaa karibu saa moja.

Ni nini manufaa na hatari ambayo inaweza kunifanyikia kama nimekubali kushiriki kwenye utafiti?

Manufaa: hutapata manufaa ya moja kwa moja kwa kushiriki. Hata hivyo, ukishiriki, unatusaidia kuunda mchezo kuhusu virusi vya ukimwi ambayo unapenda na ungependa kucheza. Unatusaidia pia kujifunza kama maswali tunayopanga kuuliza watoto ni ya maana/mantiki. Hutapewa malipo kwa kushiriki katika utafiti huu. Utapewe pesa kiasi cha \$6 za kugaramia wakati na nauli yako pamoja na vinyuaji kulingana na kanuni inayo kubaliwa saa ya mazungumzo ya vikundi.

Hatari: Sehemu ya mchezo na baadhi ya maswali yanaweza kukuaibisha au kukufanya usihisi kuwa huru. Kama unahisi huko huru na maswali yoyote umeulizwa, unaweza kukataa kuyajibu

Ni nini kuhusu siri yangu?

Unaulizwa ushiriki katika majadiliano ya kikundi. Hatuwezi kuahidi kwamba watoto katika kikundi hawataeleza wengine utakachosema. Hufai kusema chochote katika maadiliano ya kikundi ambayo hungetaka wengine nje ya kikundi wasikie.

Maelezo yako yatawekwa siri. Maelezo/taarifa yote yatahifadhiwa kwa salama kwenye tarakilishi/kompyuta ambayo imelindwa na neno la siri. Hakuna atakayeweza fuatilia majibu yako kwako

Fomu hii ya afikio itawekwa salama kwenye kabati iliyofungwa. Tutatumia nambari ya utafiti badala ya jina lako kwenye fomu zote za utafiti. Jina lako kamwe halitaelezwa wengine. Jina lako kamwe halitatumika kwa uchambuzi

Kutoa taarifa ya unyanyasaji wa watoto kimapenzi na Kutelekezwa

Siri yako ni muhimu sana kwetu lakini pia, afya na usalama yako katika hali ambapo unyanyasaji, kutelekezwa au hamu ya mtoto kujiumiza au wengi imeshukiwa au kusemwa wakati wa utafiti, wafanyi kazi wa utafiti wetu wanahitajika kuripoti taarifa/habari hii.

Je, kama nina maswali ?

Unaweza kuuliza maswali yoyote ambayo uko nayo wakati wowote. Kama uko na maswali yoyote kuhusu utafiti saa hii au baadaye, unaweza wasiliana:

Jina: Dr. Victor **Mudhune**, Principal Investigator, KEMRI

Barua pepe: VMudhune@kemricdc.org

Nambari ya simu: 057 2022929/02

Kama uko na maswali yoyote kuhusu haki zako kama mshiriki wa utafiti au uko na wasiwasi wowote au malalamishi, au kama unahisi umeumizwa kwa kushiriki katika utafiti huu. Tafadhali wasiliana na:

Katibu, KEMRI Scientific and Ethics Review Unit (SERU), (sanduku la posta 54840-00200, Nairobi) kwenye nambari ya simu 020-2722541 au simu ya rununu 0722205901 au 0733400003 au

Jina: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Barua pepe: SMunga@kemri.org

:Simu :057 2022929/02

au

Jina: Emory University Institutional Review Board

Barua pepe: irb@emory.edu

Simu: +1 404 712 0720

Nambari hapo juu si ya dharura. Kama uko na dharura, tafadhali enda kwenye kliniki /pahali karibu ambapo unaweza pata usaidizi.

Je uko na maswali yoyote?

Kauli ya idhini/Kukubali

Nimesoma (au nimeelezewa) na naelewa hii fomu. Naelewa sababu ya utafiti na kile ambacho kitatendeka kwa utafiti. Naelewa hatari na manufaa kwangu. Nimepewa nafasi ya kufikiria uamuzi wangu na maswali yangu yote yamejibiwa. Naelewa kwamba:

- a) Ninaweza chagua kujiunga na huu utafiti au la . ni juu yangu.
- b) Mzazi /mlezi wangu lazima pia akubali ili niweze kushiriki katika utafiti. Siwezi kushiriki katika utafiti kama mzazi/mlezi wangu hajakubali.
- c) Hata kama mzazi/mlezi wangu amekubali, si lazima nishiriki kwa utafiti kama sitaki.
- d)
- e) kama nimekataa kujiunga na utafiti, hakuna atakaye kasirika na mzazi/mlezi wangu na mimi.
- f) Ninaweza amua kuacha kuwa katika utafiti wakati wowote.
- g) Mzazi/mlezi anaweza nichagulia ili niache kuwa/kushiriki katika utafiti wakati wowote.

Afikio

Kwa kuweka sahihi katika karatasi, nakubali kushiriki katika huu utafiti kama ilivyoelezwa katika fomu hii ya afikio.

Sahihi ya mshiriki wa umri 11-17

Tarehe

Saa

Sahihi ya mtu anayekusanya/kuchukua
afikio ya mshiriki wa umri 11-17

Tarehe

Saa

Appendix 2C: Assent Formative Research - Luo

Oboke Mar Ayie Mar Nonro ma Dwaro Wach

Informed Consent Forms

Oboke Mag Ayie

ASSENT FORM FOR MINOR SUBJECTS

OBOKE MAR AYIE MAR NYITHINDO MATINDO MA JOCHIWRE

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Nying Nonro: Tugo mani e simb ong'we yamo mar gengo landruok mar kute mag ayaki kuom joma tindo ma jorotenge.

Jochung ne Nonro: Kate Winskell, PhD, and Victor Mudhune, MBA MPH

Oboke ibiro pog gi jatij nonro sama ikao ayie:

Hik jachiwre: _____ higni (ka nyathi tin ne higni 6, oboke mar ayie ok dwarre)

Nying Jachiwre: _____

Rwak/go tik achiel kuom box gi:

Nyathini en jahigni 6 nyaka 10- nyaka ochiw ayie gi dhoge (seyi mar jachiwre)

Seyi mar jalno ma kao ayie kuom nyathi ma jahigni 6-10. _____ Tarik _____ /
Saa

Nyathini en jahigni 11-17- nyaka seyi mar jachiwre kau e oboke mar 2 mar oboke mar ayie

Gi pacha, nyathini ok nyal chiwo ayie nikech gigo ma ok otenore gi hike, to jachung mar nonroni onyis wachni/duokoni.

- Gigomomiyo:

Seyi mar jalno ma kao ayie (ka orwak/ogo tik box) _____ Tarik _____ /
Saa

**ASSENT FORM FOR MINOR SUBJECTS
OBOKE MAR AYIE NE NYITHINDO MA JOCHIWRE**

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Nying Nonro: Tugo mani e simb ong'we yamo mar gengo landruok mar kute mag ayaki kuom joma tindo ma jorotenge.

Jochung ne Nonro: Kate Winskell, PhD and Victor Mudhune, MBA MPH

WECHE KUOM/E WI NONRO:

Chakruok

Waruaki donjo e nonro ma itimo gi mbalariany mar Emory, Atlanta gi migao mar Kenya Medical Research Institute (KEMRI). Nonroni biro konyowa loso yoo manyien ne nyithindo mondo opunjore kuom kute mag ayaki e yor tugo man e simb ongwe yamo.

Ibiro mana donjo e nonro ka idwaro/diher. Fomni biro konyi ng'ado paro ka idwaro bedo e nonro. Ka ibiro bedo e nonro, janyuolni/jaritni nyaka bende yie/chiw thuolo. To ka ok idwar bedo e nonro, ok ochuno ibedie, kata ka janyuolni/jaritni oyie/ochiwo thuolo. Janyuolni /Jaritni ok nyal chuni.

Inyalo wuok e nonro e saa asaya. Ka idonjo e nonro to kendo iloko paro, en kare mondo iwuogi e nonro. Onge ng'ato ma biro chuanyore kodi. Inyalo kadho penjo ma ok idwar duoko.

Fomni nyalo tigo weche ma ok winjireni. Bed thuolo mar penjo jatij nonro mondo olermi wach kata weche mak ok winjireni. Inyalo penjo saa a saya.

Ang'o momiyo watimo nonro?

Jononro dwaro loso yoo manyien ne nyithindo mondo puonjore e wi kute mag ayaki e yor tugo mani e simb ong'we yamo. Dwar mondo unyiswa gima uparo kuom wachni, chenro gi kido gi.

Ang'o ma biro timore ka adonjo a nonro?

Ka iyie bedo e nonro, mae e gima biro timore:

Wuoyo/Twak ma kanyakla/grup: Wabiro nyisi paro ma wan go, chenro gi kido mag tugo kaeto wakwayi mondo wawuoye e kanyakla/grup mar nyithindo 6-10 ma uromgo e higni/ ma mbaseni. Bende wabiro penji mondo inyiswa gima iparo kuom wuoyowa gi e wi penjo moko ma wachano penjo nyithindo mamoko ma biro tugo tugoni. Wabiro kwayi mondo idonjo e twag mar kanyakla ndalo 3-5 kuom thuolo ma dweche 8, to inyalo tamori chiwruok e wuoyo/twak moro amora ma ok idwar donjoe. Twak mar kanyakla/grup ibiro mak gi nyakalondo.

Ang'o maber (ber) gi marach (rach) manyalo timore ne an ka ayie bedo e nonro?

Ohala/ber: Ok ibi yudo ohala/ ber moriere kuom donjo e nonroni. To, ka idonjo, ikonyowa loso tugo e kuom kute mag ayaki ma ihero kendo diher tugo. Bende ikonyowa puonjore ka penjo ma wachano penjo nyithindo bende winjore. Ok bi miyi chudo ne bedo e nonro. Kata kamano wabiro miyi Kshs 500 ne secheni, gi pes wuoth gi math ibiro chiw kaka chick dware seche twak.

Hinyruok/ Rach: Moko kuom tukegi gi penjo moko nyalo miyo ine wichkuot kata mi ibed ma ok ini thuolo. Ka iwinjo ka ok ini thuolo gi penjo moro amora ma openji, inyalo tamori duoko penjogo.

Ang'o kuom kano weche mopondo/maling ling

Ikwayi mondo idonji e wuoyo/ twak mar kanyakla/grup.Ok wanyal singo ni nyithindo mani e wuoyo/twak mar grup/kanyakla ok nyal wacho weche ma owach gi joma moko. Ok onego iwach wach moro e wuoyo/ twak mar kanyakla/grup ma ok idwar joma moko oko mar grup owinji/ong'e.

Wecheni ibiro kan mopondo. Weche duto ibiro kan mopondo e komputa mag gi nying ma aling ling. Onge ng'ato ma biro luu duokogi

Oboke mar ayieni ibiro kan mopondo e kabat ma olor. Wabiro tiyo gi namba kar nying e foms duto mag nonro.Nyingi ok bi mi joma moko. Nyingi ok bi ti godo e yudo duoko mag nonro.

Wacho ka ng'ato ojang'w'o kata omulo, oterore gi nyathi e yo ma ok owinjore

Ritni en gima duong ne wan, bende ngimani gi ritni. E thuolo ma ng'ato omul, oterore gi nyathi kata ojwange mondo ohinye, jotijwa onego ochiw wachni.

Ang'o ma timore ka an gi penjo?

Inyalo penjo penjo mora ma ingo saa a saya. Ka ini gi penjo e wi nonro sani kata bange, inyalo tudori gi:

Nying: Dr. Victor **Mudhune**, Principal Investigator, KEMRI

Oboke mar mbui: VMudhune@kemricdc.org

Simu: 057 2022929/02

Ka eni gi penjo mora mora e wi ratiro mari kaka jachiwre e nonro, kata ini gi ngur kata ywagruok, kata iwinjo ka iyudo hinyruok kuom chiwruok e nonro, yie itudri gi: jagoro KEMRI Scientific and Ethics Review Unit (SERU), (P. O. Box 54840-00200, Nairobi) simu 020-2722541 kata ong'we yamo 0722205901 kata 0733400003 kata

Nying: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Oboke mar mbui: SMunga@kemri.org

Simu: 057 2022929/02

Kata

Nying: Emory University Institutional Review Board
: Oboke mar mbui:irb@emory.edu
Phone: simu: +1 404 712 0720

Nembni mani malo ka ok gini mag dwaro kony mapiyo piyo . Ka in gi chandruok ma dwaro kony mapiyo piyo, wakwayi mondo idhi e klinik/kama chiegni kodi mondoiyud kony.
Be eni gi penjo?

Wach mar Chiwo Thuolo

Asesomo(kata oselerna) kendo owinjo gima fomni wacho. Ang'eyo gima omiyo itimo nonro gi gima biro timore e nonro. Ang'eyo hinyruok/ rach gi ohala/ber ne an. Omiya thuolo mar ng'ado paro kendo penjo ga duto oseduoki. Ang'eyo ni:

- 7) Anyalo yiero donjo e nonro kata ok tamora. En herona.
- 8) Jonyuolna/jaritna nyaka bende yie mondo achiwra e nonro. Ok anyal chiwra ka jonyuol/jarit odagi.
- 9) Kata ka janyuolna/jaritna oyie. Ok ochuno ni nyaka achiwra e nonro ka ok adwar.
- 10) Ka adagi donjo e nonro, onge ng'ato ma biro chwanyore gi janyuolna/jaritna kendo koda.
- 11) Anyalo wuok bedo e nonroni e saa a saya.
- 12) Janyuolna/jaritna nyalo yiero mondo awe bedo e nonro e saa a saya.

Ayie

Ka agoyo seyi obokeni, ayie donjo e nonro kaka oler e form mar ayie.

_____	_____	____/____
Seyi mar jachiwre ma jahigni 11-17	Tarik	Saa

_____	_____	____/____
Seyi mar jalno ma kao ayie mar Jachiwre ma jahigni 11-17	Tarik	Saa

Appendix 3A: Parental Consent Formative Research - English

Consent for Child to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction

Your child is being invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for children to learn about HIV using a game on a mobile phone. We plan to recruit a total of 162 people for this study.

This form is to help you decide if you want to allow your child to be in the study. Your child can only take part in the study if you agree. Your child will also be asked if they want to take part in the study. Nothing bad will happen to you or your child if you or they say ‘no’.

If you decide to allow your child to join the study and then change your mind, it is okay for him/her to leave the study. You can remove him/her from the study at any time. No one will be upset with you or your child.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to develop a new way for children to learn about HIV using a game on a mobile phone. We would like your child to tell us what he or she thinks of the research team’s ideas, plans, and designs. We would also like your child to help us decide what questions to ask children in order to find out if the game is helping them learn about HIV.

What will happen if my child takes part in this study?

If both you and your child agree for your child to take part in the study, here is what will happen:

Focus Group Discussion: We will show your child our ideas, plans and designs for the game and ask him or her to discuss them with a group of 6-10 children of about the same age. We will also ask your child to tell us what they think about certain topic areas and about certain questions that we plan to ask other children who play the game. We will ask your child to take part in these discussion groups 3-5 times over a period of 8 months. He or she can refuse to participate in any of these discussion groups. The group discussions will be recorded to make sure we do not miss anything that participants say. Each group discussion will last about 1 hour.

What are the good (benefits) and bad (risks) things that could happen to my child if I agree for him/her to be in this study?

Benefits: Your child will not receive direct benefit by taking part. However, when your child takes part, he or she is helping us to make a game about HIV that children like him or her like and would like to play. He or she is also helping us learn if the questions we plan to ask children are clear and relevant. You will not be offered payment for being in this study. However, you will be reimbursed Kshs 500 for your time and transport costs and refreshments.

Risks: Parts of the game and some of the questions may embarrass your child or make him or her feel uncomfortable. If your child feels uncomfortable with any questions, he or she may refuse to answer them.

What about my child's confidentiality?

Your child is being asked to take part in a group discussion. We cannot promise that children in the group will not share what he or she say with others. Your child shouldn't say anything in the discussion group that he or she would not want others outside the group to hear.

Your child's information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your child's answers to him or her.

This consent form will be kept in a safe locked cabinet. We will use a study number in place of your child's name on all study forms. Your child's name will never be shared with others. Your child's name will never be used for analysis.

Does my child have to participate? What will happen if we change our minds?

You can choose for your child to not be in this study. Your child can choose not to be in the study. If you and your child agree for him/her to be in the study, he/she can still refuse to answer any question. You or your child can stop their participation in the study at any time. Nothing bad will happen to you or your child if they refuse to answer questions or want to stop taking part in the study.

Disclosure of Child Sexual Abuse and Neglect

Your child's privacy is very important to us, but so are his/her health and safety. In cases where abuse, neglect or the desire to harm themselves or others is suspected or disclosed during the study, our staff are required to report this information.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune

Email: VMudhune@kemricdc.org

Phone: 057 2022929/02

If you have any questions about your or your child's rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the secretary, KEMRI Scientific and Ethics Review Unit (SERU), (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003 or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Email: SMunga@kemri.org

Phone: 057 2022929/02

Or

Name: Emory University Institutional Review Board

Email: irb@emory.edu

Phone: +1-404-712-0720

The above numbers are not for emergencies. If you are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for my child. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 1) I can choose to allow my child to join this study or not. It is up to me.
- 2) My child can choose to join the study or not. It is up to him or her.
- 3) Even if I agree, my child does not have to participate in the study if he/she does not want to.
- 4) If I refuse or my child chooses not to join the study, nothing bad will happen to me or my child as a result.
- 5) I can decide to stop my child from being in this study at any time.
- 6) My child can stop being in the study at any time.

Consent

By signing this document, I agree to let my child participate in the study as explained in this form.

Date

Signature of Parent/Guardian

Printed Name of Parent/Guardian

Child's Name

Date

Signature of Project Staff

Printed Name of Project Staff

Appendix 3B: Parental Consent Formative Research - Swahili

Consent for Child to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Utangulizi

Mtoto wako anakaribishwa kushiriki katika utafiti unaofanywa na chuo kikuu cha Emory Atlanta na Kenya Medical Research Institute (KEMRI). utafiti huu utatusaidia kuunda njia mpya ya watoto kujifunza kuhusu Virusi Vya Ukimwi kwa kutumia mchezo kwenye simu ya mkono. tuko na mpango wa kusajili jumla ya watu 162 kwa hii utafiti.

Fomu hii ni ya kukusaidia kuamua kama unataka kukubalia mtoto wako ashiriki katika utafiti. Mtoto wako anaweza shiriki katika utafiti kama umekubali tu. Mtoto wako pia ataulizwa kama unataka kushiriki katika utafiti. Hakuna kitu kibaya kitakachokufanyikia au mtoto wako kama wewe au mtoto wako amesema la

Kama umeamua kukubalia mtoto wako ajiunge na utafiti na kisha ubadilishe fikira, ni sawa kuacha utafiti. unaweza kumtoa kwenye utafiti wakati wowote. hakuna atakaye kasirika na wewe au mtoto wako.

Hii fomu inaweza kuwa na maneno ambayo huelewi. Tafadhali uliza mfanyikazi wa utafiti aeleze neno lolote au taarifa/maelezo ambayo si wazi kwako. Unaweza kuuliza maswali wakati wowote.

Ni kwa nini tunafanya utafiti huu?

Timu ya utafiti inataka kuunda njia mpya ya watoto kujifunza kuhusu virusi vya ukimwi kwa kutumia mchezo kwenye simu ya mkono/rununu. Tungependa mtoto wako atuambie kile ambacho anafikiria kuhusu mawazo, mipango na miundo yao. Tungependa pia mtoto wako atusaidie kuamua maswali ya kuuliza watoto ili kujua kama mchezo inawasaidia kujifunza kuhusu virusi vya ukimwi,

Ni nini itafanyika/tendeka kama mtoto wangu ameshiriki katika utafiti huu?

Kama wewe na mtoto wako mmekubali ili mtoto wako ashiriki katika utafiti,

Mahojiano/majadiliano ya kikundi: tutaonyesha mtoto wako mawazo, mipango na miundo yetu ya mchezo na kumuuliza azijadili na kundi la watoto 6-10 ambao wanakaribia umri sawa na yake. Tutauliza mtoto wako pia atuambie anachofikiria kuhusu mada Fulani na kuhusu maswali fulani ambayo tunapanga kuuliza watoto wengine wanaocheza mchezo. Tutauliza mtoto wako ashiriki katika mahojiano ya kikundi karibu mara 3-5 kwa kipindi cha miezi 8. Anaweza kukataa kushiriki kwenye mahojiano/majadiliano ya kikundi. Majadiliano ya makundi yatarekodiwa ili

kuhakikisha hatujakosa chochote ambacho mshiriki amesema.kila mahojiano ya kikundi itakaa karibu saa moja.

Ni nini manufaa na hatari ambayo inaweza kufanyikia mtoto wangu kama nimekubali ashiriki kwenye utafiti?

Manufaa: mtoto wako hatapata manufaa ya moja kwa moja kwa kushiriki. hata hivyo,mtoto wako akishiriki, anatusaidia kuunda mchezo kuhusu virusi vya ukimwi ambayo watoto kama yeye wanapenda na wangependa kucheza.anatusaidia pia kujifunza kama maswali tunayopanga kuuliza watoto ni wazi na ya maana/mantiki. Hutapewa malipo kwa kushiriki katika utafiti huu. Utapewe pesa kiasi cha Kshs 500 za kugaramia wakati na nauli yako pamoja na vinyuaji kulingana na kanuni inayo kubaliwa saa ya mazungumzo ya vikundi.

Hatari: sehemu ya mchezo na baadhi ya maswali yanaweza kuaibisha mtoto wako au kumfanya asihisi kuwa huru. Kama mtoto wako anahisi hako huru na maswali yoyote, anaweza kukataa kuyajibu

Ni nini kuhusu siri ya mtoto wangu?

Mtoto wako anaulizwa ashiriki katika mahojiano/majadiliano ya kikundi. Hatuwezi kuahidi kwamba watoto katika kikundi hawataeleza wengine atakachosema. Mtoto wako hafai kusema chochote katika mahojiano/majadiliano ya kikundi ambayo hangetaka wengine nje ya kikundi wasikie.

Maelezo ya mtoto wako yatawekwa siri. Maelezo/taarifa yote yatahifadhiwa kwa salama kwenye tarakilishi/kompyuta ambayo imelindwa na neno la siri. Hakuna atakayeweza fuatilia majibu ya mtoto wako kwake.

Fomu hii ya afikio itawekwa salama kwenye kabati iliyofungwa. Tutatumia nambari ya utafiti badala ya jina la mtoto kwenye fomu zote za utafiti. Jina la mtoto wako kamwe halitaelezwa wengine. Jina la mtoto wako kamwe halitatumika kwa uchambuzi

Ni lazima mtoto wangu ashiriki? Ni nini itafanyika/itatendeka kama tumebadili fikira?

Unaweza kuchagua kama mtoto wako atashiriki katika utafiti. Mtoto wako anaweza kuchagua kushiriki katika utafiti. Kama wewe na mtoto wako mmekubali akuwe katika utafiti, bado anaweza kukataa kujibu swali lolote. Wewe na mtoto wako mnaweza kushiriki katika utafiti wakati wowote. Hakuna kitu kibaya ambacho kitafanyika /kitatendeka kama amekataa kujibu maswali au kupeana damu au anataka kuacha kushiriki kwenye utafiti.

Kutoa taarifa ya unyanyasaji wa watoto kimapenzi na Kutelekezwa

Siri ya mtoto wako ni muhimu sana kwetu lakini pia, afya na usalama wake.katika hali ambapo unyanyasaji, kutelekezwa au hamu ya kujiumiza au wengine imeshukiwa au kusemwa wakati wa utafiti,wafanyi kazi wa utafiti wetu wanahitajika kuripoti taarifa hii.

Je, kama nina maswali yoyote?

Unaweza kuuliza maswali yoyote ambayo uko nayo wakati wowote. Kama uko na maswali yoyote kuhusu utafiti saa hii au baadaye, unaweza wasiliana:

Jina: Dr. Victor Mudhune
Barua pepe VMudhune@kemricdc.org
Simu 057 2022929/02

Kama uko na maswali yoyote kuhusu haki zako kama mshiriki wa utafiti au uko na wasiwasi wowote au malalamishi, au kama unahisi umeumizwa kwa kushiriki katika utafiti huu. Tafadhali wasiliana:

Katibu, KEMRI Scientific and Ethics Review Unit (SERU), (sanduku la posta 54840-00200, Nairobi) kwenye nambari ya simu 020-2722541 au simu ya rununu 0722205901 au 0733400003 au

Jina Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research
Barua pepe SMunga@kemri.org
Simu 057 2022929/02
Jina: Emory University Institutional Review Board
Barua pepe irb@emory.edu
Simu +1-404-712-0720

Nambari hapo juu si ya dharura. Kama uko na dharura, tafadhali enda kwenye kliniki /pahali karibu ambapo unaweza pata usaidizi.
Je uko na maswali yoyote?

Kauli ya idhini/kukubali

Nimesoma (au nimeelezwa) na naelewa hii fomu. Naelewa sababu ya utafiti na kile ambacho kitatendeka kwa utafiti. Naelewa hatari na manufaa kwa mtoto wangu. Nimepewa nafasi ya kufikiria uamuzi wangu na maswali yangu yote yamejibiwa. Naelewa kwamba:

Ninaweza chagua kukubalia mtoto wangu ajiunge na utafiti huu au la, ni juu yangu.
Mtoto wangu anaweza kuchagua kujiunga na utafiti au la. Ni juu yake.

1. Hata kama nimekubali, si lazima mtoto wangu ashiriki katika utafiti kama hataki
2. Kama nimekataa na mtoto wangu amechagua kutojiunga na utafiti, hakuna kitu kibaya ambacho kitanifanyikia au mtoto wangu juu ya hii.
2. Ninaweza amua kukataza mtoto wangu kushiriki katika huu utafiti wakati wowote.
3. Mtoto wangu anaweza kataa kushiriki kwenye utafiti wakati wowote.

Afikio

Kwa kusahihi karatasi hii, nakubali kuacha mtoto wangu ashiriki katika utafiti vile imeelezwa kwa hii fomu.

Tarehe

Sahihi ya mzazi/msimamizi/mlezi

Jina la mtoto

Jina chapisho la mzazi /msimamizi/mlezi

Tarehe

Sahihi ya afisa wa mradi.

Jina chapisho la afisa wa mradi

Appendix 3C: Parental Consent Formative Research - Luo

Consent for Child to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Nying Nonro: Tugo mani e simb ong'we yamo mar gengo landruok mar kute mag ayaki kuom joma tindo ma jorotenge.

Jochung ne Nonro:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Omuom Owuok: U.S. National Institute of Mental Health

Chakruok

Nyathini iruako mondo odonji e nonro ma itimo gi Mbalariany mar Emory, Atlanta gi migawo mar Kenya Medical Research Institute (KEMRI). Nonroni biro konyowa loso yoo manyien ne nyithindo puonjore kuom kute mag ayaki e yor tugo e simb ong'we yamo. Wachano rwako madirom ji 162 e nonroni.

Fomni biro konyi ng'ado paro ka idwaro yiene nyathini mondo odonj e nonro. Nyathini nyalo mana donjo e nonro ka iyie. Nyathini bende ibiro penj ka odwaro donjo e nonro. Onge gima rach ma biro timore ne ini kata nyathini ka ini kata nyathini owacho 'ooyo'.

Ka ing'ado yiene nyathini donjo e nonro kendo bange iloko paro, en kare ne en wuok e nonro. Inyalo golo nyathini e nonro saa a saya. Onge ng'ato ma biro chwanyore kodi kata gi nyathini.

Fomni nyalo bedo gi weche ma ok winjire. Yie ipenj jotij nonro olermi wach kata weche ma ok winjire ne ini. Inyalo penjo penjo saa a saya.

Ang'o momiyo watimo nonroni?

Jotij nonro dwaro loso yoo manyien ma nyithindo nyalo puonjore e wi kute mag ayaki e yor tugo ma e simb ong'we yamo. Dwaher nyathini onyiswa gima oparo kuom paro, chenro gi kido mag tugo mag jotij nonro. Bende dwaher nyathini okonywa ng'ado paro e wi penjo ma wapenjo nyithindo mondo wang'e ka tugoni konyogi puonjore e wi kute mag ayaki.

Ang'o ma biro timore ka nyathini ochiwore e nonroni?

Ka ute, ini gi nyathini uyie nyathini odonji e nonro, mae e gima biro timo:

Twak mar kanyakla/grup: Wabiro nyiso nyathini pachwa, chenrowa gi kit tuke kendo penje/wuoyo kanyakla/grup mar nyithindo 6-10 manigi higni ma rom kode/mbesene. Bende wabiro penjo nyathini mondo onyiswa gima giparo e wi wuoyowa gi penjo moko ma wachano miyo nyithindo moko ma tugo tugo. Wabiro kwayo nyathini mondo odonji e wuoyo/ twak mag kanyakla /grup ndalo 3-5 kuom thuolo mar dweche 8. Nyathini nyalo tamore chiwre e wuoyo/twak mag kanyakla/grup. Wuoyo/Twak mag kanyakla/grup ibiro mak gi nyakalondo

mondo kik gimoro obawa ma jachiwre owacho. Twak mag kanyakla/grup biro kao ma dirom saa 1.

Ang'o maber (ohala) gi rach (hinyruok) gigo ma nyalo timore ka nyathini oyie donjo e nonro?

Ohala/ Ber: Nyathini ok bi yudo ohala/ber moriere kuom donjo e nonro. To, ka nyathini odonjo, obiro konyowa loso tugo e wi kute mag ayaki ma nyithindo ka en kata machal kode diher tugo. Nyathini bende konyowa puonjore ka penjo ma wachano penjo winjore kendo ni kare. Ok bi miyi chudo kuom bedo e nonro. Kata kamano wabiro miyi Kshs 500 ne secheni, gi pes wuoth gi math ibiro chiw kaka chick dwaro seche twak

Hinyruok/rach

Moko kuom tugo gi penjo moko nyalo kuodo wiy nyathini kata mi obedi ma ok thuolo. Ka nyathini obedo ma ok thuolo gi penjo moko, nyathini nyalo tamore duoko penjo.

Ang'o kuom kano mopondo/maling ling weche nyathina?

Ikwayi nyathini mondo idonji e twak mar kanyakla/grup.Ok wanyalo singo ni nyithindo manie twak mar grup/kanyakla ok nyalo wacho/pimo weche ma owach gi joma moko. Ok onego iwach wach moro e twak mar kanyakla/grup ma ok idwar joma moko oko mar grup owinji/onge.

Wecheni mag nyathini ibiro kan mopondo. Weche duto ibiro kan mopondo e komputa mag gi nying ma aling ling. Onge ng'ato ma biro luo duoko mag nyathini

Oboke mar ayieni ibiro kan mopondo e kabat ma olor. Wabiro tiyo gi namba kar nying nyathini e foms duto mag nonro.Nying nyathini ok bi miyi joma moko. Nying nyathini ok bi ti godo e yudo duoko mag nonro.

Bende nyathina nyaka chiwre? Ang'o ma biro timore ka waloko paro?

Inyalo yiero mondo nyathini kik donj e nonro. Nyathini nyalo yiero mondo kik odonj e nonro. Ka ini gi nyathini uyie mondo odonj e nonro nyathini podi nyalo tamore duoko penjo. Ini kata nyathini nyalo weyo chiwruok e nonro e saa a saya. Onge gima rach ma nyalo timore ne ini kata nyathini ka gi otamore duoko penjo kata tamore donjo e nonro.

Wacho ka ng'ato ojwang'o kata omulo, oterore gi nyathi e yo ma ok owinjore

Ritni en gima duong ne wan, bende ngimani gi ritni. E thuolo ma ng'ato omul, oterore gi nyathi kata ojwange mondo ohinye, jotijwa onego ochiw wachni.

Ang'o ma timore ka an gi penjo?

Inyalo penjo penjo mora ma ingo saa a saya. Ka ini gi penjo e wiy nonro sani kata bange, inyalo tudori gi:

Nying: Dr. Victor Mudhune, Principal Investigator, KEMRI

Oboke mar mbui: VMudhune@kemricdc.org
Simu: 057 2022929/02

Ka eni gi penjo mora mora e wi ratiro mari kaka jachiwre e nonro, kata ini gi ngur kata ywagruok, kata iwinjo ka iyudo hinyruok kuom chiwruok e nonro, yie itudri gi: jagoro KEMRI Scientific and Ethics Review Unit (SERU), (P. O. Box 54840-00200, Nairobi) simu 020-2722541 kata ong'we yamo 0722205901 kata 0733400003 kata

Nying: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research
Oboke mar mbui: SMunga@kemri.org
Simu: 057 2022929/02

Kata
Nying: Emory University Institutional Review Board
Oboke mar mbui: irb@emory.edu
Simu: +1 404 712 0720

Nembni mani malo ka ok gini mag dwaro kony ma piyo piyo. Ka eni gi chandruok ma dwaro kony ma piyo piyo. Wakwayi idhi e klinik/kama chiegni kodi mondo iyudi kony. Be eni gi penjo?

Wach mar Chiwo Thuolo

Asesomo (kata oselerna) kendo owinjo gima fomni wacho. Ang'eyo gima omiyo itimo nonro gi gima biro timore e nonro. Ang'eyo hinyruok/ rach gi ber ne an. Omiya thuolo mar ng'ado paro kendo penjo g a duto oseduoki. Ang'eyo ni:

1. Anyalo yiero mondo nyathina odonji e nonro kata atamora. En herona
2. Nyathina nyalo yiero donjo e nonro kata tamruok. En herone
3. Kata ka ayie, nyathina ok onego odonji e nonro ka ok idwar.
4. Ka atamora kata ka nyathina otamore donjo e nonro, onge gima rach ma biro timore ne an kata ne nyathina nikech mano.
5. Anyalo chungo nyathina kik ibed e nonro saa asaya
6. Nyathina nyalo weyo bedo e nonro saa asaya

Ayie

Ka agoyo seyi obokeni. Ayie mondo nyathina ochiwre e nonroni kaka oler e fomni

Tarik

Seyi mar janyuol/jarit

Ndik Nying janyuol/jarit

Nying Nyathi

Tarik

Seyi mar Jatij Nonro

Ndik Nying Jatij Nonro

Appendix 4A: Assent Intervention - English

ASSENT FORM FOR MINOR SUBJECTS

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators: Kate Winskell, PhD, and Victor Mudhune, MBA MPH

This page to be filled in by research team at the time assent is obtained:

Subject's Age: _____ years (If the child is **younger than 6 years old**, assent is not required.)

Subject's Name: _____

Check one box:

This child is 6 to 10 years old — must obtain subject's verbal assent (subject's signature not required)

Signature of person soliciting assent of 6 to 10-year-old subject Date _____ / /
Time

This child is 11 to 17 years old — must obtain subject's signature on assent form to document assent

In my opinion, this child is unable to provide informed assent for non-age-related reasons, and the PI for this study has been informed of this determination.

- Reason(s):

Signature of person soliciting assent (if above box is checked) Date _____ / /
Time

ASSENT FORM FOR MINOR SUBJECTS

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD

Victor Mudhune, MBA MPH

INFORMATION ABOUT THIS STUDY:

Introduction

You are being invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for children to learn about HIV using a game on a mobile phone. About 108 preadolescents, male and female will be asked to join the study.

You only have to take part in the study if you want to. The purpose of this form is to help you decide if you want to be in the study. If you are going to be in the study, your parent/caregiver also has to agree. But if you do not wish to be in the study, you do not have to, even if your parent/caregiver has agreed. Your parent/caregiver cannot force you.

You can leave the study at any time. If you join the study and then change your mind, it is okay for you to leave the study. No one will be upset with you. You can skip any questions that you do not wish to answer.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to find out how a game about HIV that children play on a mobile phone may affect their behavior. The study will help us understand whether the game helps children learn about HIV and helps keep them healthy.

What will happen if I take part in this study?

If both you and your parent/caregiver agree for you to take part in the study, here is what will happen:

Survey: You will sit in front of a computer wearing headphones. You will hear questions through the headphones and will enter your answers on the computer (this is called a survey). You will complete the survey three times (about 12 weeks apart). Each survey will take about 45 minutes. Some questions will be about you, your health, and your goals. Other questions will be about sexual behavior and alcohol use. If you feel uncomfortable with any of the questions, you may refuse to answer them. You can also stop taking part in the survey at any time.

Game: You may or may not be selected to complete this part of the study. If you are selected, we will lend you a mobile phone. The only thing you will be able to do on the phone is play the game: all other functions of the phone will be disabled. We will ask you to play the game for 10

hours over a 2-3 week period. At the end of this time, we will collect the phone from you. We will be able to see from the phone how you played the game.

Focus Group Discussion: After we have collected the phone, we will ask you to take part in a group discussion to tell us about your experiences playing the game. The group discussion will be recorded to make sure we do not miss anything that participants say. The group discussion will last about 1 hour.

What are the good (benefits) and bad (risks) things that could happen to me if I agree to be in the study?

Benefits: You will not get direct benefit by taking part. However, when you take part, you are helping us to find out if the game helps children learn about HIV and stay healthy. You will not be offered payment for being in this study. However, you will be reimbursed Kshs 500 for your time and transport costs and refreshments.

Risks: Parts of the game and some of the questions may embarrass you or make you feel uncomfortable. If you feel uncomfortable with any questions, you may refuse to answer them. You can return the phone to us and stop being in the study at any time.

What about my confidentiality?

Your information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your answers to you.

This assent form will be kept in a safe locked cabinet. We will use a study number in place of your name on all study forms. Your name will never be shared with others. Your name will never be used for analysis.

You are being asked to take part in a group discussion. We cannot promise that children in the group will not share what you say with others. You shouldn't say anything in the discussion group that you would not want others outside the group to hear.

Disclosure of Child Sexual Abuse and Neglect

Your privacy is very important to us, but so is your health and safety. In cases where abuse, neglect or a child's desire to harm themselves or others is suspected or disclosed during the study, our staff are required to report this information.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune

Email: VMudhune@kemricdc.org

Phone: 057 2022929/02

If you have any questions about your rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the

Appendix 4B: Assent Intervention - Swahili

ASSENT FORM FOR MINOR SUBJECTS

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators: Kate Winskell, PhD, and Victor Mudhune, MBA MPH

This page to be filled in by research team at the time assent is obtained:

Subject's Age: _____ years (If the child is **younger than 6 years old**, assent is not required.)

Subject's Name: _____

Check one box:

This child is 6 to 10 years old — must obtain subject's verbal assent (subject's signature not required)

Signature of person soliciting assent of 6 to 10-year-old subject _____ /
Date Time

This child is 11 to 17 years old — must obtain subject's signature on page 2 of assent form to document assent

In my opinion, this child is unable to provide informed assent for non-age-related reasons, and the PI for this study has been informed of this determination.

- Reason(s):

Signature of person soliciting assent (if above box is checked) _____ /
Date Time

ASSENT FORM FOR MINOR SUBJECTS

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD

Victor Mudhune, MBA MPH

MAELEZO KUHUSU UTAFITI HUU

Utangulizi

Unakaribishwa ushiriki katika utafiti unaofanywa na chuo kikuu cha Emory Atlanta na Kenya Medical Research Institute (KEMRI). utafiti huu utatusaidia kuunda njia mpya ya watoto kujifunza kuhusu Virusi Vya Ukimwi kwa kutumia mchezo kwenye simu ya mkono. Karibu vijana 108 ,wa kiume na kike wataulizwa wajiunge na utafiti.

Utashiriki tu kwa utafiti ikiwa unataka. Sababu ya hii karatasi/fomu ni kukusaidia kuamua kama unataka kuwa katika utafiti.kama unaenda kushiriki katika utafiti, mzazi wako /mlezi pia lazima akubali. Lakini kama hutaki kushiriki kwenye utafiti,si lazima hata kama mzazi/mlezi wako amekubali. Mzazi /mlezi wako hawezi kukulazimisha.

Unaweza kuacha utafiti wakati wowote. Kama umejiunga na utafiti kisha ubadili fikira zako, ni sawa kuacha utafiti.Hakuna atakaye kasirika na wewe. Unaweza ruka maswali yoyote ambayo hutaki kujibu.

Fomu hii inaweza kuwa ma maneno ambayo huelewi. Tafadhali uliza mfanyikazi wa utafiti aeleze neno lolote au maelezo ambayo si wazi kwako. Unaweza kuuliza maswali wakati wowote.

Ni kwa nini tunafanya huu utafiti

Timu ya utafiti inataka kujua ni vipi mchezo kuhusu virusi vya ukimwi ambayo watoto wanacheza kwenye simu ya mkono inaweza athiri tabia yao.utafiti utatusaidia kuelewa kama mchezo inasaidia watoto kujifunza kuhusu virusu vya ukimwi na inawasaidia kuendelea kuwa na afya bora.

Ni nini itafanyika kama nimeshiriki katika utafiti huu?

Kama umekubali pamoja na mzazi/mlezi kushiriki kwenye utafiti ,haya ndiyo yatakayofanyika/yatakayotendeka:

Uchunguzi: utakaa mbele ya kompyuta ukiwa umevaa vifaa vya kusikiza sauti. Utasikia maswali kupitia vifaa vya kusikiza sauti na utaweka majibu kwa kompyuta (hii inaitwa uchunguzi) utakamilisha utafiti mara tatu (kama tofauti ya wiki 12). Kila uchunguzi utachukua karibu dakika 45. Maswali mengine yatakuwa kukuhusu, afya yako na malengo yako. Maswali mengine

yatakuwa kuhusu tabia ya kingono na matumizi ya pombe. Kama unahisi huko huru na maswali yoyote, unaweza kataa kuzijibu. Unaweza pia kuacha kushiriki katika uchunguzi wakati wowote.

Mchezo: unaweza au huwezi kuchaguliwa kushiriki katika utafiti. Kama umechaguliwa, tutakusaidia na simu ya mkono. Kile ambacho utaweza kufanya kwenye simu ni kucheza mchezo pekee: sehemu nyingine yote ya simu itafungwa isifanye kazi. tutakuuliza ucheze mchezo kwa masaa 10 kwa muda wa wiki 2-3. mwisho wa wakati huu, tutakusanya simu kutoka kwako. Tutaweza kuona kwenye simu vile ambavyo ulicheza mchezo

Mahojiano /majadiliano ya kikundi: baada ya kukusanya simu, tutakuuliza ushiriki katika mahojiano ya kikundi ili utuambie kuhusu uliyoyapitia kucheza mchezo. Mahojiano ya kikundi yatarekodiwa ili kuhakikisha katujakosa chochote ambacho mshiriki amesema. Mahojiano ya kikundi itakaa karibu saa moja.

Ni nini manufaa na hatari ambayo inaweza kunifanyikia kama nimekubali kushiriki kwenye utafiti?

Manufaa: hutapata manufaa ya moja kwa moja kwa kushiriki. Hata hivyo, ukishiriki, unatusaidia kujua kama mchezo inasaidia watoto kujifunza kuhusu virusi vya ukimwi na kukuwa na afya bora. hutapewa malipo kwa kushiriki katika utafiti huu. Utapewe pesa kiasi cha Kshs 500 za kugaramia wakati na nauli yako pamoja na vinyuaji kulingana na kanuni inayo kubaliwa saa ya mazungumzo ya vikundi.

Hatari: sehemu ya mchezo na baadhi ya maswali yanaweza kukuaibisha au kukufanya usihisi kuwa huru. Kama unahisi huko huru na maswali yoyote umeulizwa, unaweza kukataa kuyajibu. Unaweza rudisha simu kwetu na kuacha kushiriki kwenye utafiti wakati wowote.

Ni nini kuhusu siri yangu?

Maelezo yako yatawekwa siri. Maelezo/taarifa yote yatahifadhiwa kwa salama kwenye tarakilishi/kompyuta ambayo imelindwa na neno la siri. Hakuna atakayeweza kufuatilia majabu yako kwako

Fomu hii ya afikio itawekwa salama kwenye kabati iliyofungwa. Tutatumia nambari ya utafiti badala ya jina lako kwenye fomu zote za utafiti. Jina lako kamwe halitaelezwa wengine. Jina lako kamwe halitatumika kwa uchambuzi

Unaulizwa ushiriki katika majadiliano ya kikundi. Hatuwezi kuahidi kwamba watoto katika kikundi hawataeleza wengine utakachosema. Hufai kusema chochote katika majadiliano ya kikundi ambayo hungetaka wengine nje ya kikundi wasikie.

Kutoa taarifa ya unyanyasaji wa watoto kimapenzi na Kutelekezwa

Siri yako ni muhimu sana kwetu lakini pia, afya na usalama yako. katika hali ambapo unyanyasaji, kutelekezwa au hamu ya mtoto kujiumiza au wengi imeshukiwa au kusemwa wakati wa utafiti, wafanyi kazi wa utafiti wetu wanahitajika kuripoti taarifa hii.

Je, kama nina maswali?

Unaweza kuuliza maswali yoyote ambayo uko nayo wakati wowote. Kama uko na maswali yoyote kuhusu utafiti saa hii au baadaye, unaweza wasiliana na:

Jina: Dr. Victor Mudhune
Barua pepe: VMudhune@kemricdc.org
Simu: 057 2022929/02

Kama uko na maswali yoyote kuhusu haki zako kama mshiriki wa utafiti au uko na wasiwasi wowote au malalamishi, au kama unahisi umeumizwa kwa kushiriki katika utafiti huu. Tafadhali wasiliana na:

Katibu, KEMRI Scientific and Ethics Review Unit (SERU), (sanduku la posta 54840-00200, Nairobi) kwenye nambari ya simu 020-2722541 au simu ya rununu 0722205901 au 0733400003 au

Jina: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research
Barua pepe: SMunga@kemri.org
Simu: 057 2022929/02

au
Jina: Emory University Institutional Review Board
Barua pepe: irb@emory.edu
Simu: +1-404-712-0720

Nambari hapo juu si ya dharura. Kama uko na dharura, tafadhali enda kwenye kliniki /pahali karibu ambapo unaweza pata usaidizi.

Je uko na maswali yoyote?

Kauli ya idhini/kukubali

Nimesoma (au nimeelezwa) na naelewa hii fomu. Naelewa sababu ya utafiti na kile ambacho kitatendeka kwa utafiti. Naelewa hatari na manufaa kwangu. Nimepewa nafasi ya kufikiria uamuzi wangu na maswali yangu yote yamejibiwa. Naelewa kwamba:

1. Ninaweza chagua kujiunga na huu utafiti au la . ni juu yangu
2. Mzazi /mlezi wangu lazima pia akubali ili niweze kushiriki katika utafiti. Siwezi kushiriki katika utafiti kama mzazi/mlezi wangu hajakubali.
3. Hata kama mzazi/mlezi wangu amekubali, si lazima nishiriki kwa utafiti kama sitaki.
4. Kama nimekataa kujiunga na utafiti, hakuna atakaye kasirika na mzazi/mlezi wangu na mimi.
5. Ninaweza amua kuacha kuwa katika utafiti wakati wowote
6. Mzazi/mlezi anaweza nichagulia ili niache kuwa/kushiriki katika utafiti wakati wowote.

Afikio

Kwa kuweka sahihi katika hii karatasi, nakubali kushiriki katika huu utafiti kama ilivyoelezwa katika fomu hii ya afikio.

_____ Tarehe _____ /
Sahihi ya mshiriki wa umri 11 hadi 17 Saa _____

_____ Tarehe _____ /
Sahihi ya mtu anayekusanya/kuchukua Saa _____
afikio ya mshiriki wa umri 11-17

Appendix 4C: Assent Intervention - Luo

ASSENT FORM FOR MINOR SUBJECTS

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Nying Nonro: Tugo mani e simb ong'we yamo mar gengo landruok mar kute mag ayaki kuom joma tindo ma jorotenge.

Jochung ne nonro: Kate Winskell, PhD, and Victor Mudhune, MBA MPH

Oboke ibiro pog gi jatij nonro sama ikao ayie:

Hik jachiwre: _____ higni (ka **nyathi tin ne higni 6**, oboke mar ayie ok dware)

Nying jachiwre: _____

Rwak/go tik achiel kuom box gi:

Nyathini en jahigni 6 nyaka 10- nyaka chiw ayie gi dhoge (seyi mar jachiwre)

Seyi mar jalno ma kao ayie kuom nyathi ma jahigni 6-10. _____ Tarik _____ /
Saa

Nyathini en jahigni 11-17- nyaka sey mar jachiwre kau e oboke mar 2 mar oboke mar ayie

Gi pacha, nyathini ok nyal chiwo ayie nitech gigo ma ok otenore gi hike, to jachung mar nonroni onyis wachni/duokoni.

Gigo momiyio:

Seyi mar jalno ma kao ayie (ka orwak/go tik box) _____ Tarik _____ /
Saa

ASSENT FORM FOR MINOR SUBJECTS

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Nying Nonro: Tugo mani e simb ong'we yamo mar gengo landruok mar kute mag ayaki kuom joma tindo ma jorotenge.

Jochung ne Nonro

Kate Winskell, PhD

Victor Mudhune, MBA MPH

WECHE KUOM/E WI NONRO

Chakruok

Iruaki mondo idonj e nonro mitimo gi Mbalariany mar Emory, Atlanta gi migawo mar Kenya Medical Research Institute (KEMRI). Nonroni biro konyowa loso yoo manyien ma nyithindo nyalo puonjore e wi kute mag ayaki ka gi tugo man e simb ong'we yamo. Ma dirom nyithindo 108, machuo gi nyiri ibiro kwa mondo odonj e nonro.

Ibiri mana donjo e nonro ka idwaro. Fomni ichiwo mondo okonyi ng'ado paro ka idwaro donjo e nonro. Ka ibiro bet the nonro, janyuolni/jaritni nyaka yie. To ka ok idwar bet e nonro, ok ochuno, kata ka janyuolni/jaritni oyie. Janyuolni/jaritni ok nyal chuni.

Inyalo wuok e nonro saa asaya. Ka idonjo e nonro to bange iloko paro, en kare mondo iwuog e nonro. Onge ng'ato ma ibiro chwanyo. Inyalo kadho penjo ma ok idwar duoko.

Fomni nyalo bedo gi weche ma ok winjire. Wakwayi mondo ipenj jatij nonro mondo olerni wach kata weche ma ok winjireni. Inyalo penjo penjo saa a saya.

Ang'o momiyo watimo nonro?

Jotij Nonro dwaro ng'eyo kaka tugo e wi kute mag ayaki ma nyithindo tugo e simb ong'we yamo nyalo chocho/loko timbegi. Nonroni biro konyowa ng'eyo kaponono tugoni konyo nyithindo puonjore e wi kute mag ayaki kendo konyogi bedo mangima.

Ang'o ma biro timore ka adonjo e nonroni?

Ka ute ini gi janyuolni/jaritni oyie mondo idonji e nonro, mae e gima biro timore:

Survey/Penjo: Ibiri bet mbele/ e nyim komputa ka iruako gir winjo wach/headphones. Ibiri winjo penjo kokalo e gir winjo wach/headphones kendo ibiro ruako duoko e komputa (mae iluongo survey/ penjo). Ibiri tieko penjo/survey ndalo adek (kuom wige 12 mopogore). Penji/survey ka penji/survey biro kao dakika maromo 45. Penjo moko biro bedo kuomi iwuon, ngimani gi dwareni. Penjo moko biro bedo e timbeni mag terruok gi tiyo gi kongo. Ka iwinjo k ok ini thuolo gi penjo moro amora, inyalo tamori duokogi. Inyalo wuok e penjini/survey saa asaya.

Tugo: Inyalo yieri kata ok nyal yieri tieko bath nonroni. Ka oyier wabiro miyi simb ong'we yamo. Gima ibiro nyalo timo e simb ong'we yamo en mana tugo tugo: tije mamoko mag simb ong'we yamo ibiro ket mondo kik tii. Wabiro kwayi mondo itug tugo kuom seche 10 kuom thuolo mar wige 2-3. E giko mar thuoloni, wabiro choko simb ong'we koa kuomi. Wabiro neno e yie simb ong'we yamo kaka ne itugo tugo.

Wuoyo/Twak mar kanyakla/grup: Ka wasechoko simbe mag ong'we yamo, wabiro kwayi mondo idonj e twak mar kanyakla/grup mondo inyiswa e wiy gig wa iparo kata ikadhe sama ne itugo tugo. Wuoyo mar kanyakla/grup ibiro mak gi nyakalondo mondo mi kik wawe wach moro oko ma jachiwre owacho. Twak mar kanyakla/grup biro kao madirom saa 1.

Ang'o maber (ohala) gi rach (hinyruok) gigo ma nyalo timore ka nyathini oyie donjo e nonro?

Ohala/ Ber: Ok ibi yudo ber moriere kuom donjo e nonroni. To, ka idonjo, ikonyowa loso tugo e kuom kute mag ayaki ma ihero kendo diher tugo. Bende ikonyowa puonjuok ka penjo ma wachano penjo nyithindo bende winjore. Ok bi miyi chudo ne bedo e nonro. Kata kamano wabiro miyi Kshs 500 ne secheni, gi pes wuoth gi math ibiro chiw kaka chick dware seche twak

Hinyruok/ Rach: Moko kuom tukegi gi penjo moko nyalo miyo ine wichkuot kata mi ibed ma ok ini thuolo. Ka iwinjo ka ok ini thuolo gi penjo moro amora ma openji, inyalo tamori duoko penjogo.

Ang'o kuom kano mopondo/maling ling?

Wecheni ibiro kan mopondo. Weche duto ibiro kan mopondo e komputa mag gi nying ma aling ling. Onge ng'ato ma biro luo duokogi.

Oboke mar ayieni ibiro kan mopondo e kabat ma olor. Wabiro tiyo gi namba kar nying nyath e foms duto mag nonro. Nyingi ok bi mi joma moko. Nyingi ok be ti godo e yudo duoko mag nonro.

Ikwayi nyathini mondo idonji e wuoyo/ twak mar kanyakla/grup. Ok wanyalo singo ni nyithindo manie wuoyo/twak mar grup/kanyakla ok nyalo wacho/pimo weche ma owach gi joma moko.

Ok onego iwach wach moro e wuoyo/twak mar kanyakla/grup ma ok idwar joma moko oko mar grup owinji/ong'e.

Wacho ka ng'ato ojwang'o kata omulo, oterore gi nyathi e yo ma ok owinjore

Ritni en gima duong ne wan, bende ngimani gi ritni. E thuolo ma ng'ato omul, oterore gi nyathi kata ojwange mondo ohinye, jotijwa onego ochiw wachni.

Ang'o ma timore ka an gi penjo?

Inyalo penjo penjo mora ma ingo saa asaya. Ka ini gi penjo e wiy nonro sani kata bange, inyalo tudori gi:

Nying: Dr. Victor Mudhune, Principal Investigator, KEMRI

Oboke mar mbui: VMudhune@kemricdc.org

Simu: 057 2022929/02

Ka ini gi penjo mora mora e wi ratiro mari kaka jachiwre e nonro, kata ini gi ngur kata ywagruok, kata iwinjo ka iyudo hinyruok kuom chiwruok e nonro, yie itudri gi: jagoro KEMRI Scientific and Ethics Review Unit (SERU), (P. O. Box 54840-00200, Nairobi) simu 020-2722541 kata ong'we yamo 0722205901 kata 0733400003 kata

Nying: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Oboke mar mbui: SMunga@kemri.org

Simu: 057 2022929/02

Or Kata

Nying: Emory University Institutional Review Board

Oboke mar mbui: irb@emory.edu

Simu: +1 404 712 0720

Nembni mani malo ka ok gini mag dwaro kony ma piyo piyo. Ka ini gi chandruok ma dwaro kony ma piyo piyo. Wakwayi idhi e klinik/kama chiegni kodi mondo iyudi kony. Be ini gi penjo?

Wach mar Chiwo Thuolo

Asesomo (kata oselerna) kendo owinjogima fomuni wacho. Ang'eyo gima omiyo itimo nonro gi gima biro timore e nonro. Ang'eyo hinyruok/ rach gi ber/ohala ne an. Omiya thuolo mar ng'ado paro kendo penjo ga duto oseduoki. Ang'eyo ni:

- 1) Anyalo yiero donjo e nonro kata ok adonj. En herona.
- 2) Jonyuolna/jaritna nyaka bende yie mondo achiwra e nonro. Ok anyal chiwora ka jonyuol/jarit odagi.
- 3) Kata ka janyuolna/jaritna oyie. Ok ochuno ni nyaka achiwra e nonro ka ok adwar.
- 4) Ka adagi donjo e nonro, onge ng'ato ma biro chwanyore gi janyuolna/jaritna kendo koda.
- 5) Anyalo weyo bedo e nonroni e saa a saya.
- 6) Janyuolna/jaritna nyalo yiero mondo awe bedo e nonro e saa a saya.

Ayie

Ka agoyo seyi obokeni, ayie donjo e nonro kaka oler e form mar ayie.

Seyi mar jachiwre ma jahigni 11-17 Tarik Saa

Appendix 5A: Parental Consent Intervention - English

Consent for Child to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction

Your child is being invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for children to learn about HIV using a game on a mobile phone. We plan to recruit a total of 162 people for this study.

This form is to help you decide if you want to allow your child to be in the study. Your child can only take part in the study if you agree. Your child will also be asked if they want to take part in the study. Nothing bad will happen to you or your child if you or they say ‘no’.

If you decide to allow your child to join the study and then change your mind, it is okay for him/her to leave the study. You can remove him/her from the study at any time. No one will be upset with you or your child.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to find out how a game about HIV that children play on a mobile phone may affect their behavior. The study will help us understand whether the game helps children learn about HIV and helps keep them healthy.

What will happen if my child takes part in this study?

If both you and your child agree for your child to take part in the study, here is what will happen:

Survey: Your child will sit in front of a computer wearing headphones. She or he will hear questions through the headphones and will enter his or her answers on the computer (this is called a survey). Your child will complete the survey three times (about 12 weeks apart).

Each survey will take about 45 minutes. Some questions will be about your child, his or her health, and goals. Other questions will be about sexual behavior and alcohol use.

If your child feels uncomfortable with any of the questions, he or she may refuse to answer them. Your child can also stop taking part in the survey at any time.

Game: Your child may or may not be selected to complete this part of the study. If your child is selected, we will lend him or her a mobile phone. The only thing your child will be able to do on the phone is play the game: all other functions of the phone will be disabled. We will ask your child to play the game for 10 hours over a 2-3 week period. At the end of this time, we will collect the phone from your child. We will be able to see from the phone how your child played the game.

Focus Group Discussion: After we have collected the phones, we will ask your child to take part in a group discussion to tell us about his or her experiences playing the game. The group discussion will be recorded to make sure we do not miss anything that participants say. The group discussion will last about 1 hour.

What are the good (benefits) and bad (risks) things that could happen to my child if I agree for him/her to be in this study?

Benefits: Your child may not get direct benefits by taking part. However, when your child takes part, he or she is helping us to find out if the game helps children learn about HIV and stay healthy. You will not be offered payment for being in this study. However, you will be reimbursed Kshs 500 for your time and transport costs and refreshments.

Risks: Parts of the game and some of the questions may embarrass your child or make him or her feel uncomfortable. If your child feels uncomfortable with any questions, he or she may refuse to answer them. Your child can return the phone to us and stop being in the study at any time.

What about my child's confidentiality?

Your child's information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your child's answers to him or her.

This consent form will be kept in a safe locked cabinet. We will use a study number in place of your child's name on all study forms. Your child's name will never be shared with others. Your child's name will never be used for analysis.

Your child is being asked to take part in a group discussion. We cannot promise that children in the group will not share what he or she say with others. Your child shouldn't say anything in the discussion group that he or she would not want others outside the group to hear. We will remind him or her about this.

Does my child have to participate? What will happen if we change our minds?

You can choose for your child to not be in this study. Your child can choose not to be in the study. If you and your child agree for him/her to be in the study, he/she can still refuse to answer any question. You or your child can stop their participation in the study at any time. Nothing bad

will happen to you or your child if they refuse to answer questions or want to stop taking part in the study.

Disclosure of Child Sexual Abuse and Neglect

Your child's privacy is very important to us, but so are his/her health and safety. In cases where abuse, neglect or the desire to harm themselves or others is suspected or disclosed during the study, our staff are required to report this information.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune
Email: VMudhune@kemricdc.org
Phone: 057 2022929/02

If you have any questions about your or your child's rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the secretary, KEMRI Scientific and Ethics Review Unit (SERU), (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003 or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research
Email: SMunga@kemri.org
Phone: 057 2022929/02

Or

Name: Emory University Institutional Review Board
Email: irb@emory.edu
Phone: +1-404-712-0720

The above numbers are not for emergencies. If you are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for my child. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 1) I can choose to allow my child to join this study or not. It is up to me.
- 2) My child can choose to join the study or not. It is up to him or her.
- 3) Even if I agree, my child does not have to participate in the study if he/she does not want to.
- 4) If I refuse or my child chooses not to join the study, nothing bad will happen to me or my child as a result.

- 5) I can decide to stop my child from being in this study at any time.
- 6) My child can stop being in the study at any time.

Consent

By signing this document, I agree to let my child participate in the study as explained in this form.

Date

Signature of Parent/Guardian

Printed Name of Parent/Guardian

Child's Name

Date

Signature of Project Staff

Printed Name of Project Staff

Appendix 5B: Parental Consent Intervention - Swahili

Consent for Child to be a Research Subject

Mada: Mchezo wa simu ya rununu ili kuzuia virusi vya ukimwi kwa vijana wa Afrika

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Utangulizi

Mtoto wako anakaribishwa kushiriki katika utafiti unaofanywa na chuo kikuu cha Emory Atlanta na Kenya Medical Research Institute (KEMRI). utafiti huu utatusaidia kuunda njia mpya ya watoto kujifunza kuhusu Virusi Vya Ukimwi kwa kutumia mchezo kwenye simu ya mkono. tuko na mpango wa kusajili jumla ya watu 162 kwa hii utafiti.

Fomu hii ni ya kukusaidia kuamua kama unataka kukubalia mtoto wako ashiriki katika utafiti. Mtoto wako anaweza shiriki katika utafiti kama umekubali tu. Mtoto wako pia ataulizwa kama unataka kushiriki katika utafiti. hakuna kitu kibaya kitakachokufanyikia au mtoto wako kama wewe au mtoto wako amesema la

Kama umeamua kukubalia mtoto wako ajiunge na utafiti na kisha ubadilishe fikira, ni sawa kuacha utafiti. unaweza kumtoa kwenye utafiti wakati wowote. hakuna atakaye kasirika na wewe au mtoto wako.

Hii fomu inaweza kuwa na maneno ambayo huelewi. Tafadhali uliza mfanyikazi wa utafiti aeleze neno lolote au taarifa/maelezo ambayo si wazi kwako. Unaweza kuuliza maswali wakati wowote.

Ni kwa nini tunafanya utafiti huu?

Timu ya utafiti inataka kujua jinsi mchezo kuhusu virusi vya ukimwi ambayo watoto wanacheza kwa simu ya mkono inaweza kuathiri tabia yao. utafiti utatusaidia kuelewa kama michezo inasaidia watoto kujifunza kuhusu virusi vya ukimwi na inawasadia kuendelea kuwa na afya bora.

Ni nini itafanyika/tendeka kama mtoto wangu ameshiriki katika utafiti huu

Kama umekubali pamoja na mtoto wako kushiriki kwenye utafiti, haya ndiyo yatakayofanyika/yatakayotendeka:

Uchunguzi: mtoto wako atakaa mbele ya kompyuta akiwa umevaa vifaa vya kusikiza sauti. atasikia maswali kupitia vifaa vya kusikiza sauti na ataweka majibu kwa kompyuta (hii inaitwa uchunguzi) mtoto wako atakamilisha uchunguzi mara tatu (kama tofauti ya wiki 12). Kila uchunguzi utachukua karibu dakika 45. Maswali mengine yatakuwa kuhusu mtoto wako, afya yake na malengo yake. Maswali mengine yatakuwa kuhusu tabia ya kingono na matumizi ya

pombe. Kama mtoto wako anahisi hayuko huru na maswali yoyote, anaweza kataa kuzijibu. Mtoto wako anaweza pia kuacha kushiriki katika uchunguzi wakati wowote.

Mchezo: mtoto wako anaweza au hawezi kuchaguliwa kushiriki katika utafiti. Kama mtoto wako amechaguliwa, tutamsaidia na simu ya mkono. Kile ambacho mtoto wako ataweza kufanya kwenye simu ni kucheza mchezo pekee: sehemu nyingine yote ya simu itafungwa isifanye kazi. tutauliza mtoto wako acheze mchezo kwa masaa 10 kwa muda wa wiki 2-3. mwisho wa wakati huu, tutakusanya simu kutoka kwa mtoto wako.. Tutaweza kuona kwenye simu vile ambavyo mtoto wako alicheza mchezo.

Mahojiano/majadiliano ya kikundi: baada ya kukusanya simu, tutauliza mtoto wako ashiriki katika mahojiano ya kikundi ili atuambie kuhusu aliyoyapitia kucheza mchezo. Mahojiano ya kikundi yatarekodiwa ili kuhakikisha katujakosa chochote ambacho mshiriki amesema. Mahojiano ya kikundi itakaa karibu saa moja.

Ni nini manufaa na hatari ambayo inaweza fanyikia mtoto wangu kama nimekubali ashiriki kwenye utafiti?

Manufaa: hutapata manufaa ya moja kwa moja kwa kushiriki. Hata hivyo, ukishiriki, unatusaidia kukua kama mchezo inasaidia watoto kujifunza kuhusu virusi vya ukimwi na kukuwa na afya bora. hutapewa malipo kwa kushiriki katika utafiti huu. Utapewe pesa kiasi cha Kshs 500 za kugaramia wakati na nauli yako pamoja na vinyuaji kulingana na kanuni inayo kubaliwa saa ya mazungumzo ya vikundi.

Hatari: sehemu ya mchezo na baadhi ya maswali yanaweza kukuaibisha au kukufanya usihisi kuwa huru. Kama unahisi huko huru na maswali yoyote umeulizwa, unaweza kukataa kuyajibu. Unaweza rudisha simu kwetu na kuacha kushiriki kwenye utafiti wakati wowote.

Ni nini kuhusu siri ya mtoto wangu?

Maelezo ya mtoto wako yatawekwa siri. Maelezo/taarifa yote yatahifadhiwa kwa salama kwenye tarakilishi/kompyuta ambayo imelindwa na neno la siri. Hakuna atakayeweza kufuatilia majibu ya mtoto wako yake

Fomu hii ya afikio itawekwa salama kwenye kabati iliyofungwa. Tutatumia nambari ya utafiti badala ya jina la mtoto wako kwenye fomu zote za utafiti. Jina la mtoto wako kamwe halitaelezwa wengine. Jina lako kamwe halitatumika kwa uchambuzi

Mtoto wako anaulizwa ashiriki katika majadiliano ya kikundi. Hatuwezi kuahidi kwamba watoto katika kikundi hawataeleza wengine atakachosema. Hufai kusema chochote katika mahojiano ya kikundi ambayo hangetaka wengine nje ya kikundi waskie. Tutamkumbusha kuhusu hii.

Ni lazima mtoto wangu ashiriki? Ni nini itafanyika/itatendeka kama tumebadili fikira?

Unaweza kuchagua kama mtoto wako atashiriki katika utafiti. Mtoto wako anaweza kuchagua kushiriki katika utafiti. Kama wewe na mtoto wako mmekubali akuwe katika utafiti, bado anaweza kukataa kujibu swali lolote. Wewe na mtoto wako mnaweza kushiriki katika utafiti

wakati wowote. Hakuna kitu kibaya ambacho kitafanyika /kitatendeka kama amekataa kujibu maswali au kupeana damu au anataka kuacha kushiriki kwenye utafiti.

Kutoa taarifa ya unyanyasaji wa watoto kimapenzi na Kutelekezwa

Siri ya mtoto wako ni muhimu sana kwetu lakini pia, afya na usalama yake. Katika hali ambapo unyanyasaji, kutelekezwa au hamu ya kujiumiza au wengine imeshukiwa au kusemwa wakati wa utafiti, wafanyi kazi wa utafiti wetu wanahitajika kuripoti taarifa hii.

Je, kama nina maswali ?

Unaweza kuuliza maswali yoyote ambayo uko nayo wakati wowote. Kama uko na maswali yoyote kuhusu utafiti saa hii au baadaye, unaweza wasiliana na :

Name: Dr. Victor Mudhune

Barua pepe: VMudhune@kemricdc.org

Simu: 057 2022929/02

Kama uko na maswali yoyote kuhusu haki zako kama mshiriki wa utafiti au uko na wasiwasi wowote au malalamishi, au kama unahisi umeumizwa kwa kushiriki katika utafiti huu. Tafadhali wasiliana na:

Katibu, KEMRI Scientific and Ethics Review Unit (SERU), (sanduku la posta 54840-00200, Nairobi) kwenye nambari ya simu 020-2722541 au simu ya rununu 0722205901 au 0733400003 au

Jina: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Barua pepe: SMunga@kemri.org

Simu: 057 2022929/02

au

Name: Emory University Institutional Review Board

irb@emory.edu

+1-404-712-0720

Nambari hapo juu si ya dharura. Kama uko na dharura, tafadhali enda kwenye kliniki /pahali karibu ambapo unaweza pata usaidizi.

Je uko na maswali yoyote?

kauli ya idhini/kukubali

Nimesoma (au nimeelezwa) na naelewa hii fomu. Naelewa sababu ya utafiti na kile ambacho kitatendeka kwa utafiti. Naelewa hatari na manufaa kwa mtoto wangu. Nimepewa nafasi ya kufikiria uamuzi wangu na maswali yangu yote yamejibiwa. Naelewa kwamba:

1. Ninaweza chagua kukubalia mtoto wangu ajiunge na utafiti huu au la . ni juu yangu
2. Mtoto wangu anaweza kuchagua kujiunga na utafiti au la. Ni juu yake.
3. hata kama nimekubali, si lazima mtoto wangu ashiriki katika utafiti kama hataki
4. Kama nimekataa na mtoto wangu amechagua kutojiunga na utafiti, hakuna kitu kibaya ambacho kitanifanyikia au mtoto wangu juu ya hii.

5. Ninaweza amua kukataza mtoto wangu kushiriki katika huu utafiti wakati wowote.
6. Mtoto wangu anaweza kata kushiriki kwenye utafiti wakati wowote.

Afikio

Kwa kusahihi karatasi hii, nakubali kuacha mtoto wangu ashiriki katika utafiti vile imeelezwa kwa hii fomu.

Tarehe

Sahihi ya mzazi/msimamizi/mlezi

Jina chapisho la mzazi /msimamizi/mlezi

Jina la mtoto

Tarehe

Sahihi ya afisa wa mradi.

Jina chapisho la afisa wa mradi

Appendix 5C: Parental Consent Intervention - Luo Consent for Child to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Nying Nonro: Tugo mani e simb ong'we yamo mar gengo landruok mar kute mag ayaki kuom joma tindo ma jorotenge.

Jochung ne Nonro:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Omuom Owuok: U.S. National Institute of Mental Health

Chakruok

Iruako nyathini mondo odonji e nonro ma itimo gi Mbalariany mar Emory, Atlanta gi migawo ma Kenya Medical Research Institute (KEMRI).

Nonroni biro konyowa loso yoo manyien ma nyithindo puonjore e wi kute mag ayaki e yor tugo e simb ong'we yamo. Wachano ruako ji 162 e nonroni.

Fomni en mar konyi ng'ado paro ka idwar yieni nyathini donjo e nonroni. Nyathini nyalo donjo e nonro mana ka iyiene. Nyathini bende ibiro penj ka odwaro donjo e nonro. Onge gima rach ma biro timore ne ini kata nyathini ka ini kata nyathini owacho 'ooyo'

Ka ing'ado yiene nyathini donjo e nonro to iloko paro, en kare ne en weyo nonro. Inyalo gole e nonro saa asaya. Onge ng'ato ma biro chwanyore gi ini kata nyathini.

Fomni otingo weche moko ma ok winjre. Wakwayi ipenji jotij nonro mondo olerni wach kat weche ma ok winjreni. Inyalo penjo penjo saa a saya.

Ang'o ma watimo e nonroni?

Jotij nonro dwaro ng'eyo kaka tugo e wi kute mag ayaki ma nyithindo tugo e simb ong'we yamo nyalo chocho timbe gi. Nonroni biro konyowa ng'eyo kaponono tugo gi konyo nyithindo puonjore e wi kute mag ayaki kendo konyo gi bedo mangima.

Ang'o ma biro timore ka nyathina odonjo e nonroni?

Ka ute ini gi nyathini oyie ne nyathini donjo e nonro, mae e gima biro timore:

Survey/Penjo: Ibiro bet e mbele/nyim komputa ka iruako gir winjo wach/ headphones. Ibiro winjo penjo kokalo e gir winjo wach/ headphones kendo ibiro ruako duoko e komputa(mae iluongo survey/ penjo). Ibiro tieko penjo/survey ndalo adek(kuom wige 12 mopogore). Penji/survey ka penji/survey biro kao dakika maromo 45. Penjo moko biro bedo kuomi iwuon, ngimani gi dwareni. Penjo moko biro bedo e timbeni mag terruok gi tiyo gi kongo. Ka iwinjo ka ok ini thuolo gi penjo moro amora, inyalo tamori duokogi. Inyalo wuok e penjini/survey saa a saya.

Tugo: Inyalo yieri kata ok nyal yieri tieko bath nonroni. Ka oyier wabiro miyi simb ong'we yamo. Gima ibiro nyalo timo e simb ong'we yamo en mana tugo tugo: tije mamoko mag simb ong'we yamo ibiro ket mondo kik tii. Wabiro kwayi mondo itug tugo kuom seche 10 kuom thuolo mar wige 2-3. E giko mar thuoloni, wabiro choko simb ong'we koa kuomi. Wabiro neno e simb ong'we yamo kaka ne itugo tugo.

Wuoyo/Twak mar kanyakla/grup: Ka wasechoko simbe mag ong'we yamo, wabiro kwayi mondo idonj e twak mar kanyakla/grup mondo inyiswa e wiy gig wa iparo kata ikadhe sama ne itugo tugo. Wuoyo mar kanyakla/grup ibiro mak gi nyakalondo mondo mi kik wawe wach moro oko ma jachiwre owacho. Twak mar kanyakla/grup biro kao madirom saa 1.

Ang'o maber (ohala) gi rach (hinyruok) gigo ma nyalo timore ka nyathini oyie donjo e nonro?

Ohala/ ber: Ok ibi yudo ber moriere kuom donjo e nonroni. To, ka idonjo, ikonyowa loso tugo e kuom kute mag ayaki ma ihero kendo diher tugo. Bende ikonyowa puonjuok ka penjo ma wachano penjo nyithindo bende winjore. Ok bi miyi chudo ne bedo e nonro. Kata kamano wabiro miyi Kshs 500 ne secheni, gi pes wuoth gi math ibiro chiw kaka chick dware seche twak.

Hinyruok/rach: Moko kuom tukegi gi penjo moko nyalo miyo ine wichkuot kata mi ibedi ma ok ini thuolo. Ka iwinjo ka ok eni thuolo gi penjo moro amora ma openji, inyalo tamori duoko penjogo.

Ang'o kuom kano mopondo/maling ling weche nyathina?

Wecheni nyathini ibiro kan mopondo. Weche duto ibiro kan mopondo e komputa mag gi nying ma aling ling. Onge ng'at ma biro luo duokogi

Oboke mar ayieni ibiro kan mopondo e kabat ma olor. Wabiro tiyo gi namba kar nying e fomus duto mag nonro. Nying ok bi miyi joma moko. Nying ok bi ti godo e yudo duoko mag nonro.

Ikwayi nyathini mondo idonj e wuoyo/twak mar kanyakla/grup. Ok wanyal singo ni nyithindo mantie e wuoyo/ twak mar grup/kanyakla ok nyal wacho weche ma owach gi joma moko. Ok oneg iwach wach moro e wuoyo/twak mar kanyakla/grup ma ok idwar joma moko oko mar grup owinji/ong'e. Wabiro parone mano.

Bende nyathina nyaka chiwre? Ang'o ma biro timore ka waloko paro?

Inyalo yiero mondo nyathini kik donj e nonro. Nyathini nyalo yiero mondo kik odonj e nonro. Ka ini gi nyathini uyie mondo odonj e nonro nyathini podi nyalo tamore duoko penjo. Ini kata nyathini nyalo wuok chiwruok e nonro e saa a saya. Onge gima rach ma nyalo timore ne ini kata nyathini ka gi tamore duoko penjo kata chiwo remo kata tamore donjo e nonro.

Wacho ka ng'ato ojang'w'o kata omulo, oterore gi nyathi e yo ma ok owinjore

Ritni en gima duong ne wan, bende ngimani gi ritni. E thuolo ma ng'ato omul, oterore gi nyathi kata ojwange mondo ohinye, jotijwa onego ochiw wachni.

Ang'o ma timore ka an gi penjo?

Inyalo penjo penjo mora ma ingo saa asaya. Ka ini gi penjo e wiy nonro sani kata bange, inyalo tudori gi:

Nying: Dr. Victor Mudhune, Principal Investigator, KEMRI

Oboke mar mbui: VMudhune@kemricdc.org

Simu: 057 2022929/02

Ka eni gi penjo mora mora e wi ratiro mari kaka jachiwre e nonro, kata ini gi ngur kata ywagruok, kata iwinjo ka iyudo hinyruok kuom chiwruok e nonro, yie itudri gi: jagoro KEMRI Scientific and Ethics Review Unit (SERU), (P. O. Box 54840-00200, Nairobi) simu 020-2722541 kata ong'we yamo 0722205901 kata 0733400003 kata

Nying: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Oboke mar mbui: SMunga@kemri.org

Simu: 057 2022929/02

Or Kata

Nying: Emory University Institutional Review Board

Oboke mar mbui: irb@emory.edu

Simu: +1 404 712 0720

Nembni mani malo ka ok gini mag dwaro kony ma piyo piyo. Ka eni gi chandruok ma dwaro kony ma piyo piyo. Wakwayi idhi e klinik/kama chiegni kodi mondo iyudi kony.

Be eni gi penjo?

Wach mar chiwo thuolo

Asesomo(kata oselerna) kendo owinjo gima fomni wacho. Ang'eyo gima omiyo itimo nonro gi gima biro timore e nonro. Ang'eyo hinyruok/ rach gi ber/ohala ne an. Omiya thuolo mar ng'ado paro kendo penjo ga duto oseduoki. Ang'eyo ni:

- 1) Anyalo yiero mondo nyathina odonji e nonro kata atamora. En herona
- 2) Nyathina nyalo yiero donjo e nonro kata tamruok. En herone
- 3) Kata ka ayie, nyathina ok onego odonji e nonro ka ok idwar.
- 4) Ka atamora kata ka nyathina otamore donjo e nonro, onge gima rach ma biro timore ne an kata ne nyathina nikech mano.
- 5) Anyalo chungo nyathina kik ibed e nonro saa a saya
- 6) Nyathina nyalo weyo bedo e nonro saa a saya

Ayie

Ka agoyo seyi obokeni. Ayie mondo nyathina ochiwre e nonroni kaka oler e fomni

Tarik

Seyi mar janyuol/jarit

Ndik Nying janyuol/jarit

Nying Nyathi

Tarik

Seyi mar Jatij Nonro

Ndik Nying Jatij Nonro

Appendix 6A: Parent Consent Formative Research- English

Consent to Be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction

You are being invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for children to learn about HIV using a game on a mobile phone. We plan to recruit a total of 162 people for this study.

You only have to take part in the study if you want to. The purpose of this form is to help you decide if you want to be in the study. If you do not wish to be in the study, you do not have to. If you join the study and then change your mind, it is okay for you to leave the study. No one will be upset with you.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to develop a new way for children to learn about HIV using a game on a mobile phone. We would like you to tell us what you think of their ideas, plans, and designs. We would also like you to help us decide what questions to ask children in order to find out if the game is helping them learn about HIV.

What will happen if I take part in this study?

If you agree to be in the study, here is what will happen:

Focus Group Discussion: We will show you our ideas, plans and designs for the game and ask you to discuss them with a group of 6-10 other parents. We will also read to you or ask you to look at questions we plan to ask children who play the game. We will ask you to tell us how you feel about these questions and to discuss them with a group of other parents. We will ask you to take part in these discussion groups up to 4 times over a period of 8 months. Each group discussion will last about 90 minutes. The group discussions will be recorded to make sure we do not miss anything that participants say.

What are the good (benefits) and bad (risks) things that could happen to me if I agree to be in the study?

Benefits: You will not receive direct benefit by taking part. However, when you take part, you are helping us to make a game about HIV that you like and would feel comfortable with your child playing. You are also helping us learn if the questions we plan to ask children are acceptable to you. You will not be offered payment for being in this study. However, you will be reimbursed Kshs 500 for your time and transport costs and refreshments.

Risks: Parts of the game and some of the questions may embarrass you or make you feel uncomfortable. If you feel uncomfortable with any questions you are asked, you may refuse to answer them.

What about my confidentiality?

You are being asked to take part in a group discussion. We cannot promise that others in the group will not share what you say with others. You shouldn't say anything in the discussion group that you would not want others outside the group to hear.

Your information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your answers to you.

This consent form will be kept in a safe locked cabinet. We will use a study number in place of your name on all study forms. Your name will never be shared with others. Your name will never be used for analysis.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune, Principal Investigator, Kenya Medical Research Institute

Email: VMudhune@kemricdc.org

Phone: 057 2022929/02

If you have any questions about your rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the secretary, KEMRI Scientific and Ethics Review Unit (SERU), (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003 or

Name: Dr. Stephen Munga, Center Director, Kenya Medical Research Institute, Center for Global Health Research

Email: SMunga@kemri.org

Phone: 057 2022929/02

Or

Name: Emory University Institutional Review Board

Email: irb@emory.edu

Phone: +1-404-712-0720

The above numbers are not for emergencies. If you are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for me. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 1) I can choose to join this study or not. It is up to me.
- 2) If I refuse to join the study, no one will be upset with me or my child.
- 3) I can decide to stop being in this study at any time.
- 4) I can refuse to answer any questions I choose.

Consent

By signing this document, I agree to take part in this study as explained in this assent form.

Date

Signature of Adult

Printed Name of Adult

Date

Signature of Project Staff

Printed Name of Project Staff

Appendix 6B: Parent Consent Formative Research - Swahili

Consent to Be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction Utangulizi

Unakaribishwa kushiriki katika utafiti unaofanywa na chuo kikuu cha Emory Atlanta na Kenya Medical Research Institute (KEMRI). utafiti huu utatusaidia kuunda njia mpya ya watoto kujifunza kuhusu Virusi Vya Ukimwi kwa kutumia mchezo kwenye simu ya mkono.tuko na mpango wa kusajili jumla ya watu 162 kwa hii utafiti.

Unafaa ushiriki katika huu utafiti kama unataka tu. Sababu ya hii fomu ni kukusaidia amua kama unataka kushiriki katika utafiti.kama hutaki kushiriki kwenye utafiti, si lazima. Kama umejiunga na utafiti na kasha ubadilishe fikira, ni sawa kuacha utafiti.hakuna atakaye kasirika nawe.

Fomu hii inaweza kuwa na maneno ambayo huelewi. Tafadhali uliza mfanyikazi wa utafiti akueleza neno lolote au maelezo ambayo si wazi kwako. Unaweza uliza maswali wakati wowote.

Ni kwa nini tunafanya utafiti?

Timu ya utafiti inataka kuunda njia mpya ya watoto kujifunza kuhusu virusi vya ukimwi kwa kutumia mchezo kwenye simu ya mkono.tungependa utuambie kile ambacho unafikiria kuhusu mawazo, mipango na miundo yao, tungependa pia utusaidie kuamua ni maswali gani ya kuiliza watoto ili tuweze kujua kama mchezo inawasaidia kujifunza kuhusu virusi vya ukimwi.

Ni nini itatendeka kama nimeshiriki katika utafiti?

Kama umekubali kushiriki katika utafiti, haya ndio yatatendeka:

Mahojiano/majadiliano ya kikundi: tutakuonyesha mawazo, mipango na miundo yetu ya mchezo na kukuuliza uzijadili na kundi la wazazi 6-10 . Tutakusomea pia au kukuuliza uangalie maswali ambayo tunapanga kuuliza watoto ambao wanacheza mchezo.tutakuuliza utuambie jinsi unavyohisi kuhusu maswali haya na kuzijadili na kundi la wazazi wengine. Tutakuuliza ushiriki katika makundi ya mahojiano karibu mara 4 kwa kipindi cha miezi 8. Kila mahojiano ya kikundi itakaa karibu dakika 90.Mahojiano ya kikundi yatarekodiwa ili kuhakikisha hatujakosa chochote ambacho washiriki watasema.

Ni nini manufaa na hatari ambayo inaweza kunifanyikia kama nimekubali kushiriki kwenye utafiti?

Manufaa: hutapata manufaa ya moja kwa moja kwa kushiriki. Hata hivyo, ukishiriki, unatusaidia kuunda mchezo kuhusu virusi vya ukimwi ambayo unapenda na ungehisi huru mtoto wako

akicheza.unatusaidia pia kujifunza kama maswali tunayopanga kuuliza watoto yanakubalika na wewe. Hutapewa malipo kwa kushiriki katika utafiti huu. Utapewe pesa kiasi cha Kshs 500 za kugaramia wakati na nauli yako pamoja na vinyuaji kulingana na kanuni inayo kubaliwa saa ya mazungumzo ya vikundi.

Hatari: sehemu ya mchezo na baadhi ya maswali yanaweza kukuaibisha au kukufanya usihisi kuwa huru. Kama unahisi huko huru na maswali yoyote umeulizwa, unaweza kukataa kuyajibu

Ni nini kuhusu siri yangu?

Unaulizwa ushiriki katika majadiliano ya kikundi. Hatuwezi kuahidi kwamba wengine katika kikundi hawataeleza wengine utakachosema. Hufai ku sema chochote katika maadiliano ya kikundi ambayo hungetaka wengine nje ya kikundi waskie.

Maelezo yako yatawekwa siri. Maelezo/taarifa yote yatahifadhiwa kwa salama kwenye tarakilishi/kompyuta ambayo imelindwa na neno la siri. Hakuna atakayeweza fuatilia majibu yako kwako

Fomu hii ya afikio itawekwa salama kwenye kabati iliyofungwa. Tutatumia nambari ya utafiti badala ya jina lako kwenye fomu zote za utafiti. Jina lako kamwe halitaelezwa wengine. Jina lako kamwe halitatumika kwa uchambuzi

Je Kama nina maswali?

Unaweza kuuliza maswali yoyote ambayo uko nayo wakati wowote. Kama uko na maswali yoyote kuhusu utafiti saa hii au baadaye, unaweza wasiliana na :

Jina: Dr. Victor Mudhune, Principal Investigator, Kenya Medical Research Institute

Barua pepe: VMudhune@kemricdc.org

Simu: 057 2022929/02

Kama uko na maswali yoyote kuhusu haki zako kama mshiriki wa utafiti au uko na wasiwasi wowote au malalamishi, au kama unahisi umeumizwa kwa kushiriki katika utafiti huu. Tafadhali wasiliana na :

Katibu, KEMRI Scientific and Ethics Review Unit (SERU), (sanduku la posta 54840-00200, Nairobi) kwenye nambari ya simu 020-2722541 au simu ya rununu 0722205901 au 0733400003 au

Jina: Dr. Stephen Munga, Center Director, Kenya Medical Research Institute, Center for Global Health Research

Barua pepe: SMunga@kemri.org

Simu:057 2022929/02

au

Jina: Emory University Institutional Review Board

Barua pepe: irb@emory.edu

Simu: +1-404-712-0720

Nambari hapo juu si ya dharura. Kama uko na dharura, tafadhali enda kwenye kliniki /pahali karibu ambapo unaweza pata usaidizi ko na maswali yoyote?

Kauli ya idhini/kukubali

Nimesoma (au nimeelezwa) na naelewa hii fomu. Naelewa sababu ya utafiti na kile ambacho kitatendeka kwa utafiti. Naelewa hatari na manufaa kwangu. Nimepewa nafasi ya kufikiria uamuzi wangu na maswali yangu yote yamejibiwa. Naelewa kwamba:

1. Ninaweza chagua kujiunga na huu utafiti au la . Ni juu yangu.
2. Kama nimekataa kujiunga na utafiti, hakuna atakaye kasirika nami au mtoto wangu.
3. Ninaweza kuamua kuacha kuwa katika utafiti wakati wowote.
4. Ninaweza kata kujibu maswali yoyote ambayo nimechagua.

Afikio

Kwa kuweka sahihi katika karatasi, nakubali kushiriki katika huu utafiti kama ilivyoelezwa katika fomu hii ya afikio.

Tarehe

sahihi ya mtu mzima

Jina chapisho la mtu mzima

Tarehe

Sahihi ya mfanyikazi wa mradi

Jina chapisho la mfanyi kazi wa mradi.

Appendix 6C: Parent Consent Formative Research - Luo

Consent to Be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Nying Nonro: Tugo mani e simb ong'we yamo mar gengo landruok mar kute mag ayaki kuom joma tindo ma jorotenge.

Jochung ne nonro:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Omuom Owuok:U.S. National Institute of Mental Health

Chakruok

Iruaki mondo idonji e nonro ma itimo gi Mbalariany mar Emory, Atlanta gi migawo ma Kenya Medical Research Institute(KEMRI). Nonroni biro konyowa loso yoo manyien ma nyithindo puonjore e wi kute mag ayaki e yor tugo e simb ong'we yamo. Wachano ruako koriwore ji 162 e nonroni.

Oneg idonj e nonroni mana ka idwaro.Fomni en mar konyi ng'ado paro ka idwar donjo e nonroni. Fomni biro konyi ng'ado paro ka idwaro donjo nonro. Ka ok idwaro donjo e nonro, ok ochuno ibedie. Ka idonjo e nonro kendo iloko pachi, en kare mondo iwuog e nonro. Onge ng'ama biro chwanyoreFomni otingo weche moko ma ok winjre. Wakwayi ipenji jotij nonro mondo olerni wach kata weche ma ok winjreni. Inyalo penjo penjo saa a saya.

Ang'o momiyo watimo nonroni?

Jotij nonro dwaro loso yoo manyien ma nyithindo nyalo puonjore e wi kute mag ayaki e yor tugo man e simb ong'we yamo. Dwaher nyathini onyiswa gima oparo kuom pache, chenro gi kido mag tugo mag jotij nonro. Bende dwaher nyathini okonywa ng'ado paro e wi penjo ma wapenjo nyithindo mondo wang'e ka tugoni konyogi puonjore e wi kute mag ayaki.

Ang'o ma biro timore ka adonjo enonroni?

Ka iyie donjo e nonro, mae e gima biro timore:

Wuoyo/Twak ma Kanyakla/grup: Wabiro nyisou pachwa, chenrowa gi kit tuke kendo penji wuoye kanyakla/grup mar jonyuol 6-10. Bende wabiro somou kendo kwayou mondo ung'I penjo ma wachano penjo nyithindu mondo otugie. Wabiro kwayou mondo unyiswa gima uparo e wi weche ma wawuoye gi, gi penjo moko ma wachano miyo nyithindu moko ma tugo tugo. Kendo wuoye gi jonyuol ma moko.Wabiro kwayou mondo udonji e twak mag kanyakla /grup ndalo 4 kuom thuolo mar dweche 8. Twak mag kanyakla/group ibiro kao dakika 90. Wuoyo/Twak ibiro mak gi nyakalondo mondo kik gimoro obawa ma jochiwre owacho.

Ang' o maber (ohala) gi rach (hinyruok) gigo ma nyalo timore ka nyathini oyie donjo e nonro?

Ohala/ber: Ok ibi yudo ohala/ber moriere kuom donjo e nonroni. To, ka idonjo, ikonyowa loso tugo e kuom kute mag ayaki ma ihero kendo diher tugo. Bende ikonyowa puonjruok ka penjo ma wachano penjo nyithindo bende winjore. Ok bi miyi chudo ne bedo e nonro. Kata kamano wabiro miyi Kshs 500 ne secheni, gi pes wuoth gi math ibiro chiw kaka chick dwaro seche twak.

Hinyruok/rach: Moko kuom tukegi gi penjo moko nyalo miyo ine wichkuot kata mi ibedi ma ok ini thuolo. Ka iwinjo ka ok ini thuolo gi penjo moro amora ma openji, inyalo tamori duoko penjogo.

Ang' o kuom kano mopondo/maling ling?

Ikwayi mondo idonji e twak mar kanyakla/grup. Ok wanyalo singo ni jomoko mantie e twak mar grup/kanyakla ok nyalo wacho/pimo weche ma owach gi joma moko. Ok onego iwach wach moro e twak mar kanyakla/grup ma ok idwar joma moko oko mar grup owinji/ong'e.

Wecheni ibiro kan mopondo. Weche duto ibiro kan mopondo e komputa mag gi nying ma aling ling. Onge ng'ato ma biro luo duokogi.

Oboke mar ayieni ibiro kan mopondo e kabat ma olor. Wabiro tiyo gi namba e foms duto mag nonro. Nyingi ok bi mi joma moko. Nyingi ok bi ti godo e yudo duoko mag nonro.

Ang' o ma timore ka an gi penjo? Inyalo penjo penjo mora ma ingo saa asaya. Ka ini gi penjo e wiy nonro sani kata bange, inyalo tudori gi:

Nying: Dr. Victor Mudhune, Principal Investigator, KEMRI

Oboke mar mbui: VMudhune@kemricdc.org

Simu: 057 2022929/02

Ka ini gi penjo mora mora e wi ratiro mari kaka jachiwre e nonro, kata ini gi ngur kata ywagruok, kata iwinjo ka iyudo hinyruok kuom chiwruok e nonro, yie itudri gi: jagoro

KEMRI Scientific and Ethics Review Unit (SERU), (P. O. Box 54840-00200, Nairobi) simu 020-2722541 kata ong'we yamo 0722205901 kata 0733400003 kata

Nying: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Oboke mar mbui: SMunga@kemri.org

Simu: 057 2022929/02

Or Kata

Nying: Emory University Institutional Review Board

Oboke mar mbui: irb@emory.edu

Phone: simu: +1 404 712 0720

Nembni mani malo ka ok gini mag dwaro kony ma piyo piyo. Ka eni gi chandruok ma dwaro kony ma piyo piyo. Wakwayi idhi e klinik/kama chiegni kodi mondo iyudi kony.

Be eni gi penjo?

Wach mar Chiwo Thuolo

Asesomo (kata oselerna) kendo owinjo gima fomni wacho. Ang'eyo gima omyo itimo nonro gi gima biro timore e nonro. Ang'eyo hinyruok/ rach gi ber/ohala ne an. Omya thuolo mar ng'ado paro kendo penjo g a duto oseduoki. Ang'eyo ni:

1. Anyalo yiero donjo e nonroni kata tamora ma ok adonjo
2. Ka atamora donjo e nonroni, onge ng'ato ma biro chwanyore koda kata gi nyathina
3. Anyalo ng'ado mondo awuog enonroni saa asaya
4. Anyalo tamora duoko penjo ka ayiero.

Ayie

Ka agoyo seyi obokeni. Ayie mondo adonji e nonroni kaka olerna e fom mar ayie

Tarik

Seyi mar Janyuol

Ndik nying janyuol

Tarik

Seyi mar Jatij Nonro

Ndik Nying Jatij Nonro

Appendix 7A: Parent Consent Self Post-Intervention FGD - English

Consent to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction

You are being invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for children to learn about HIV using a game on a mobile phone. We plan to recruit a total of 162 people for this study.

You only have to take part in the study if you want to. The purpose of this form is to help you decide if you want to be in the study. If you do not wish to be in the study, you do not have to. If you join the study and then change your mind, it is okay for you to leave the study. No one will be upset with you.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to develop a new way for children to learn about HIV using a game on a mobile phone. Your child is participating or has participated in a study in which he or she was invited to play a game on a mobile phone for 10 hours over a 2-3 week period. We would like you to tell us about your family's experience with this study.

What will happen if I take part in this study?

If you agree to be in the study, here is what will happen:

Focus Group Discussion: After your child has played the game and returned the phone, we will ask you to take part in a group discussion to tell us about your experiences as the parent of a child taking part in this study. The group discussion will be recorded to make sure we do not miss anything that participants say. The group discussion will last about 90 minutes.

What are the good (benefits) and bad (risks) things that could happen to me if I agree to be in the study?

Benefits: You will not receive direct benefit by taking part. However, when you take part, you are helping us to learn how we can make the game as valuable as possible for children and their parents. You will not be offered payment for being in this study. You will not be offered

payment for being in this study. However, you will be reimbursed Kshs 500 for your time and transport costs and refreshments provided as per standard requirements during FGDs.

Risks: Some of the questions may embarrass you or make you feel uncomfortable. If you feel uncomfortable with any questions you are asked, you may refuse to answer them.

What about my confidentiality?

You are being asked to take part in a group discussion. We cannot promise that others in the group will not share what you say with others. You shouldn't say anything in the discussion group that you would not want others outside the group to hear.

Your information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your answers to you.

This consent form will be kept in a safe locked cabinet. We will use a study number in place of your name on all study forms. Your name will never be shared with others. Your name will never be used for analysis.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune, Principal Investigator, KEMRI

Email: VMudhune@kemricdc.org

Phone: 057 2022929/02

If you have any questions about your rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the secretary, KEMRI Scientific and Ethics Review Unit (SERU), (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003.

Or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Email: SMunga@kemri.org

Phone: 057 2022929/02

Or

Name: Emory University Institutional Review Board

Email: irb@emory.edu

Phone: +1 404 712 0720

The above numbers are not for emergencies. If you are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for me. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 1) I can choose to join this study or not. It is up to me.
- 2) If I refuse to join the study, no one will be upset with me or my child.
- 3) I can decide to stop being in this study at any time.
- 4) I can refuse to answer any questions I choose.

Consent

By signing this document, I agree to take part in this study as explained in this assent form.

Date

Signature of Adult

Printed Name of Adult

Date

Signature of Project Staff

Printed Name of Project Staff

Appendix 7B: Parent Consent Self Post-Intervention FGD - Swahili

Consent to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Utangulizi

Unakaribishwa kushiriki katika utafiti unaofanywa na chuo kikuu cha Emory Atlanta na Kenya Medical Research Institute (KEMRI). utafiti huu utatusaidia kuunda njia mpya ya watoto kujifunza kuhusu Virusi Vya Ukimwi kwa kutumia mchezo kwenye simu ya mkono. tuko na mpango wa kusajili jumla ya watu 162 kwa hii utafiti.

Unafaa ushiriki katika huu utafiti kama unataka tu. Sababu ya hii fomu ni kukusaidia amua kama unataka kushiriki katika utafiti. kama hutaki kushiriki kwenye utafiti, si lazima. Kama umejiunga na utafiti na kasha ubadilishe fikira, ni sawa kuacha utafiti. hakuna atakaye kasirika nawe.

Fomu hii inaweza kuwa na maneno ambayo huelewi. Tafadhali uliza mfanyikazi wa utafiti akueleza neno lolote au maelezo ambayo si wazi kwako. Unaweza uliza maswali wakati wowote.

Ni kwa nini tunafanya huu utafiti?

Timu ya utafiti inataka kuunda njia mpya ya watoto kujifunza kuhusu virusi vya ukimwi kwa kutumia mchezo kwenye simu ya mkono. Mtoto wako anashiriki au ameshiriki katika utafiti ambayo alikaribishwa achezze mchezo kwa simu ya mkono kwa masaa 10 kwa muda wa wiki 2-3. Tungependa utuambie kuhusu vitu ambavyo familia yako wamepitia/kuona kwa hii utafiti.

Ni nini itatendeka kama nimeshiriki katika utafiti?

Kama umekubali kushiriki katika utafiti, haya ndio yatatendeka:

Mahojiano/majadiliano ya kikundi: baada ya mtoto wako amecheza mchezo na kurudisha simu, tutakuuliza ushiriki kwa mahojiano ya kikundi na utuambie kuhusu uliyoyapitia kama mzazi wa mtoto anayeshiriki katika huu utafiti. Mahojiano ya kikundi itakaa karibu dakika 90.

Ni nini manufaa na hatari ambayo inaweza kunifanyikia kama nimekubali kushiriki kwenye utafiti?

Manufaa: hutapata manufaa ya moja kwa moja kwa kushiriki. Hata hivyo, ukishiriki, unatusaidia kujifunza jinsi ya kuunda mchezo ikuwe ya thamani iwezekanavyo kwa watoto na wazazi wao. Hutapewa malipo kwa kushiriki katika utafiti huu. Utapewe pesa kiasi cha Kshs 500 za

kugaramia wakati na nauli yako pamoja na vinyuaji kulingana na kanuni inayo kubaliwa saa ya mazungumzo ya vikundi.

Hatari: sehemu ya mchezo na baadhi ya maswali yanaweza kukuaibisha au kukufanya usihisi kuwa huru. Kama unahisi huko huru na maswali yoyote umeulizwa, unaweza kukataa kuyajibu

Ni nini kuhusu siri yangu?

Unaulizwa ushiriki katika majadiliano ya kikundi. Hatuwezi kuahidi kwamba wengine katika kikundi hawataeleza wengine utakachosema. Hufai kusema chochote katika maadiliano ya kikundi ambayo hungetaka wengine nje ya kikundi waskie.

Maelezo yako yatawekwa siri. Maelezo/taarifa yote yatahifadhiwa kwa salama kwenye tarakilishi/kompyuta ambayo imelindwa na neno la siri. Hakuna atakayeweza fuatilia majibu yako kwako

Fomu hii ya afikio itawekwa salama kwenye kabati iliyofungwa. Tutatumia nambari ya utafiti badala ya jina lako kwenye fomu zote za utafiti. Jina lako kamwe halitaelezwa wengine. Jina lako kamwe halitatumika kwa uchambuzi

Je kama nina maswali?

Unaweza kuuliza maswali yoyote ambayo uko nayo wakati wowote. Kama uko na maswali yoyote kuhusu utafiti saa hii au baadaye, unaweza wasiliana na:

Jina: Dr. Victor Mudhune, Principal Investigator, KEMRI
Barua pepe: VMudhune@kemricdc.org
Simu: 057 2022929/02

Kama uko na maswali yoyote kuhusu haki zako kama mshiriki wa utafiti au uko na wasiwasi wowote au malalamishi, au kama unahisi umeumizwa kwa kushiriki katika utafiti huu. Tafadhali wasiliana na:

Katibu, KEMRI Scientific and Ethics Review Unit (SERU), (sanduku la posta 54840-00200, Nairobi) kwenye nambari ya simu 020-2722541 au simu ya rununu 0722205901 au 0733400003

au

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research
Barua Pepe: SMunga@kemri.org

Simu: 057 2022929/02

Au

Jina: Emory University Institutional Review Board
Barua pepe: irb@emory.edu

Simu: +1 404 712 0720

Nambari hapo juu si ya dharura. Kama uko na dharura, tafadhali enda kwenye kliniki /pahali karibu ambapo unaweza pata usaidizi

Uko na maswali yoyote?

Kauli ya idhini/kukubali

Nimesoma (au nimeelezewa) na naelewa hii fomu. Naelewa sababu ya utafiti na kile ambacho kitatendeka kwa utafiti. Naelewa hatari na manufaa kwangu. Nimepewa nafasi ya kufikiria uamuzi wangu na maswali yangu yote yamejibiwa. Naelewa kwamba:

1. Ninawza chagua kujiunga na utafiti au la. Ni juu yangu
2. Kama nimekataa kujiunga na utafiti, hakuna atakaye kasirika na mimi au mtoto wangi
3. Ninaweza amua kuacha kuwa katika huu utafiti wakati wowote.
4. Ninaweza kukataa kujibu maswali yoyote nimechagua.

Afikio

Kwa kutia sahihi kwenye hii karatasi, nakubali kushiriki katika utafiti hii kama ilivyoelezwa katika fomu hii ya afikio.

Tarehe

Sahihi ya mtu mzima

Jina chapisho la mtu mzima

Tarehe

sahihi ya mfanyikazi wa mradi

Jina chapisho la mfanyi kazi wa mradi

Appendix 7C: Parent Consent Self Post-Intervention FGD - Luo Consent to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Nying Nonro: Tugo mani e simb ong'we yamo mar gengo landruok mar kute mag ayaki kuom joma tindo ma jorotenge.

Jochung ne Nonro:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Omuom Owuok: U.S. National Institute of Mental Health

Chakruok

Iruaki mondo idonji e nonro ma itimo gi Mbalariany mar Emory, Atlanta gi migawo ma Kenya Medical Research Institute(KEMRI). Nonroni biro konyowa loso yoo manyien ma nyithindo puonjore e wi kute mag ayaki e yor tugo e simb ong'we yamo. Wachano ruako koriwore ji 162 e nonroni.

Oneg idonj e nonroni mana ka idwaro. Fomni en mar konyi ng'ado paro ka idwar donjo e nonroni. Fomni biro konyi ng'ado paro ka idwaro donjo nonro. Ka ok idwaro donjo e nonro, ok ochuno ibedie. Ka idonjo e nonro kendo iloko pachi, en kare mondo iwuog e nonro. Onge ng'ama biro chwanyore.

Fomni otingo weche moko ma ok winjre. Wakwayi ipenji jotij nonro mondo olerni wach kata weche ma ok winjreni. Inyalo penjo penjo saa a saya.

Ang'o momiyo watimo nonroni?

Jotij Nonro dwaro loso yoo ma nyithindo nyalo puonjore e wi kute mag ayaki ka tiyo gi simb ong'we yamo. Nyathini ochiwre kata chiwre e nonroni ma oruake mondo otug tugo mar simb ong'we yamo kuom seche 10 kuom thuolo mar wige 2-3. Dwaher mondo inyiswa kaka family mar paro e wi nonroni.

Ang'o ma biro timore ka adonjo e nonroni?

Ka iyie donjo e nonroni, mae e gima biro timore:

Tugo: Bang ka nyathini osetugo ma oduoko simb ong'we yamo, wabiro kwayi mondo ibedie e wuoyo/twak mar kanyakla/grup mondo inyiswa pachi kuom mae kaka janyuol mar nyathi mantie e nonro. Wuoyoni/twak mag kanyakla/grup ibiro mak gi nyakalondo ok wadwak gimoro obawa ma jachiwre owacho. Wuoyoni/twakni mar kanyakla/grup biro kao dakika 90.

Ang'o maber (ohala) gi rach (hinyruok) gigo ma nyalo timore ka nyathini oyie donjo e nonro?

Ohala/ ber: Ok ibi yudo ohala/ber moriere kuom donjo e nonroni. To, ka idonjo, ikonyowa loso tugo e kuom kute mag ayaki ma ihero kendo diher tugo. Bende ikonyowa puonjruok ka penjo

ma wachano penjo nyithindo bende winjore. Ok bi miyi chudo ne bedo e nonro. Kata kamano wabiro miyi Kshs 500 ne secheni, gi pes wuoth gi math ibiro chiw kaka chick dwaro seche twak.

Hinyruok/rach:Moko kuom tukegi gi penjo moko nyalo miyo ine wichkuot kata mi ibedi ma ok ini thuolo. Ka iwinjo ka ok ini thuolo gi penjo moro amora ma openji, inyalo tamori duoko penjogo.

Ang'o kuom kano mopondo/maling ling?

Ikwayi mondo idonji e twak mar kanyakla/grup.Ok wanyalo singo ni jomoko mantie e wuoyo/twak mar grup/kanyakla ok nyalo wacho/pimo weche ma owach gi joma moko. Ok onego iwach wach moro e twak mar kanyakla/grup ma ok idwar joma moko oko mar grup owinji/ong'e.

Wecheni ibiro kan mopondo. Weche duto ibiro kan mopondo e komputa mag gi nying ma aling ling. Onge ng'ato ma biro luo duokogi.

Oboke mar ayieni ibiro kan mopondo e kabat ma olor. Wabiro tiyo gi namba kar nying e fomus duto mag nonro.Nying ok bi miyi joma moko. Nying ok be ti godo e yudo duoko mag nonro.

Ang'o ma timore ka an gi penjo?

Inyalo penjo penjo mora ma ingo saa a saya. Ka ini gi penjo e wi nonro sani kata bange, inyalo tudori gi:

Nying: Dr. Victor Mudhune, Principal Investigator, KEMRI

Oboke mar mbui: VMudhune@kemricdc.org

Simu: 057 2022929/02

Ka ini gi penjo mora mora e wi ratiro mari kaka jachiwre e nonro, kata ini gi ngur kata ywagruok, kata iwinjo ka iyudo hinyruok kuom chiwruok e nonro, yie itudri gi: jagoro KEMRI Scientific and Ethics Review Unit (SERU), (P. O. Box 54840-00200, Nairobi) simu 020-2722541 kata ong'we yamo 0722205901 kata 0733400003 kata

Nying: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Oboke mar mbui: SMunga@kemri.org

Simu: 057 2022929/02

Kata

Nying: Emory University Institutional Review Board

Oboke mar mbui: irb@emory.edu

Simu: +1 404 712 0720

Nembni mani malo ka ok gini mag dwaro kony ma piyo piyo. Ka ini gi candruok ma dwaro kony ma piyo piyo, wakwayi mondo idhi e klinik/kama chiegni kodi mondo iyud kony.

Be ini gi penjo?

Wach mar chiwo thuolo

Asesomo (kata oselerna) kendo owinjo gima fomni wacho. Ang'eyo gima omiyo itimo nonro gi gima biro timore e nonro. Ang'eyo hinyruok/ rach gi ber/ohala ne an. Omiya thuolo mar ng'ado paro kendo penjo ga duto oseduoki. Ang'eyo ni:

- 1) Anyalo yiero donjo e nonroni kata tamora ma ok adonjo
- 2) Ka atamora donjo e nonroni, onge ng'ato ma biro chwanyore koda kata gi nyathina
- 3) Anyalo ng'ado mondo awuoK e nonroni saa a saya
- 4) Anyalo tamora duoko penjo ka ayiero.

Ayie

Ka agoyo seyi obokeni. Ayie mondo adonji e nonroni kaka olerna e fom mar ayie

Tarik

Seyi mar Janyuol

Ndik Nying Janyuol

Tarik

Seyi mar Jatij Nonro

Ndik Nying Jatij Nonro

Appendix 8A through Appendix 21 redacted

Appendix 22: Assent Followup= English

EMORY UNIVERSITY ASSENT FORM FOR MINOR SUBJECTS

Study Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

**Kate Winskell, PhD, Emory University Rollins School of Public Health
Victor Mudhune, MBA, MPH, KEMRI Center for Global Health Research**

INFORMATION ABOUT THIS STUDY:

Introduction

You were invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for children to learn about HIV using a game on a mobile phone. We have recruited 162 people for this study (108 young people, and 54 of their parents) and are recruiting an additional 45 people.

You only have to take part in the study if you want to. The purpose of this form is to help you decide if you want to continue to be in the study. If you are going to be in the study, your parent/caregiver also has to agree. But if you do not wish to be in the study anymore, you do not have to, even if your parent/caregiver has agreed. Your parent/caregiver cannot force you.

You can leave the study at any time. If you join the study and then change your mind, it is okay for you to leave the study. No one will be upset with you. You can skip any questions that you do not wish to answer.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to find out how a game about HIV that children play on a mobile phone may affect their behavior. The study will help us understand whether the game helps children learn about HIV and helps keep them healthy.

What will happen if I take part in this study?

If both you and your parent/caregiver agree for you to take part in the study, here is what will happen:

Focus Group Discussion: After we collected the phone, we asked those who played to take part in a group discussion to tell us about their experiences playing the game. For this stage of the study, we are asking you to take part in another group discussion to give additional information about your experience and to share your suggestions on what topics and stories this kind of game could be about. The group discussion will be recorded to make sure we do not miss anything that participants say. The group discussion will last about 1 hour.

In-Depth Interview: We may ask you to take part in a one-on-one interview to tell us about your experience playing the game, and your suggestions on what other topics and stories this game could be

about. The interview will be recorded to make sure we do not miss anything you say. It will last about 60 minutes.

Game Play: We may ask you to play an updated version of the game and to give your feedback about the changes that have been made since last year during a focus group discussion. The discussion will last no more than 2 hours.

Cognitive Interview/ Discussion: We may ask you to read questions we plan to ask children who play the game in the future. This interview/ discussion will last no more than 1 hour.

Survey Pilot: We may ask you to answer the questions we plan to ask children who play the game in the future so we can test the questions. This will last no more than 1 hour.

Survey: We will ask you to answer a few questions about how you share information with others and who you share information with. This survey will take no more than 15 minutes.

What are the good (benefits) and bad (risks) things that could happen to me if I agree to be in the study?

Benefits: You will not get direct benefit by taking part. However, when you take part, you are helping us to find out if the game helps children learn about HIV and stay healthy. You will not be offered payment for being in this study.

Risks: Some of the questions may embarrass you or make you feel uncomfortable. If you feel uncomfortable with any questions, you may refuse to answer them. You can stop being in the study at any time.

What about my confidentiality?

Your information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your answers to you.

This assent form will be kept in a safe locked cabinet. We will use a study number in place of your name on all study forms. Your name will never be shared with others. Your name will never be used for analysis.

You are being asked to take part in a group discussion. We cannot promise that children in the group will not share what you say with others. You shouldn't say anything in the discussion group that you would not want others outside the group to hear.

Disclosure of Child Sexual Abuse and Neglect

Your privacy is very important to us, but so is your health and safety. In cases where abuse, neglect or a child's desire to harm themselves or others is suspected or disclosed during the study, our staff are required to report this information.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune, Principal Investigator, KEMRI
Email: vmudhune@kemricdc.org
Phone: 0722-687430

If you have any questions about your rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the secretary, KEMRI Ethical Review Committee, (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003 or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research
Email: SMunga@kemri.org
Phone: 057 22923/24

Or

Name: Emory University Institutional Review Board
Email: irb@emory.edu
Phone: +1-404-712-0720

The above numbers are not for emergencies. If you are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for me. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 1) I can choose to join this study or not. It is up to me.
- 2) My parent/caregiver must also agree for me to participate in the study. I cannot participate in the study if my parent/caregiver does not agree.
- 3) Even if my parent/caregiver agrees, I do not have to participate in the study if I do not want to.
- 4) If I refuse to join the study, no one will be upset with my parent/caregiver and me.
- 5) I can decide to stop being in this study at any time.
- 6) My parent/guardian can choose for me to stop being in the study at any time.

Assent

By signing this document, I agree to take part in this study as explained in this assent form.

Signature of 11 to 17-year-old Subject

Date

Time

Signature of person soliciting assent of 11-17 year old Subject

Date

Time

Appendix 23: Parental Consent Followup= English

Emory University Consent for Child to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Emory University Rollins School of Public Health
Victor Mudhune, MBA, MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction

Your child was invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study is helping us develop a new way for children to learn about HIV using a game on a mobile phone. We have recruited 162 people for this study (108 young people, and 54 of their parents) and are recruiting an additional 45 people.

This form is to help you decide if you want to allow your child to be in the next step of the study. Your child can only take part if you agree. Your child will also be asked if they want to take part in the study. Nothing bad will happen to you or your child if you or they say 'no'.

If you decide to allow your child to join the study and then change your mind, it is okay for him/her to leave the study. You can remove him/her from the study at any time. No one will be upset with you or your child.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to find out how a game about HIV that children play on a mobile phone may affect their behavior. The study is helping us understand whether the game helps children learn about HIV and helps keep them healthy.

What will happen if my child takes part in this study?

If both you and your child agree for your child to take part in the study, here is what will happen:

Focus Group Discussion: After we collected the phones, we may have asked your child to take part in a group discussion to tell us about his or her experiences playing the game. For this stage of the study we may ask your child to take part in another group discussion to give additional information about his or her experience, and his or her suggestions on what other topics and stories this kind of game could be about. The group discussion will be recorded to make sure we do not miss anything that participants say. The group discussion will last about 1 hour.

In-Depth Interview: We may ask your child to take part in a one-on-one interview to tell us about his or her experience playing the game, and his or her suggestions on what other topics and stories this game could be about. The interview will be recorded to make sure we do not miss anything you say. It will last about 60 minutes.

Game Play: We may ask your child to play an updated version of the game and to give his or her feedback about the changes that have been made since last year during a focus group discussion. The discussion will last no more than 2 hours.

Cognitive Interview/Discussion: We may ask your child to read questions we plan to ask children who play the game in the future so we can make sure the questions are understandable for young people. This interview or group discussion will last no more than 1 hour.

Survey Pilot: We may ask your child to answer the questions we plan to ask children who play the game in the future so we can test the questions. This will last no more than 1 hour.

Survey: We will ask your child to answer a few questions about how he or she shares information with others and who he or she shares information with. This survey will take no more than 15 minutes.

What are the good (benefits) and bad (risks) things that could happen to my child if I agree for him/her to be in this study?

Benefits: Your child may not get direct benefits by taking part. However, when your child takes part, he or she is helping us to find out if the game helps children learn about HIV and stay healthy. You will not be offered payment for being in this study.

Risks: Parts of the game and some of the questions may have embarrassed your child or made him or her feel uncomfortable. If your child feels uncomfortable with any questions now, he or she may refuse to answer them. Your child can stop being in the study at any time.

What about my child's confidentiality?

Your child's information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your child's answers to him or her.

This consent form will be kept in a safe locked cabinet. We will use a study number in place of your child's name on all study forms. Your child's name will never be shared with others. Your child's name will never be used for analysis.

Your child is being asked to take part in a group discussion. We cannot promise that children in the group will not share what he or she say with others. Your child shouldn't say anything in the discussion group that he or she would not want others outside the group to hear. We will remind him or her about this.

Does my child have to participate? What will happen if we change our minds?

You can choose for your child to not be in this study. Your child can choose not to be in the study. If you and your child agree for him/her to be in the study, he/she can still refuse to answer any question. You or your child can stop their participation in the study at any time. Nothing bad will happen to you or your child if they refuse to answer questions or want to stop taking part in the study.

Disclosure of Child Sexual Abuse and Neglect

Your child's privacy is very important to us, but so are his/her health and safety. In cases where abuse, neglect or the desire to harm themselves or others is suspected or disclosed during the study, our staff are required to report this information.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune, Principal Investigator, KEMRI

Email: vmudhune@kemricdc.org

Phone: 0722-687430

If you have any questions about your or your child's rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the secretary, KEMRI Ethical Review Committee, (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003 or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Email: SMunga@kemri.org

Phone: 057 22923/24

Or

Name: Emory University Institutional Review Board

Email: irb@emory.edu

Phone: +1-404-712-0720

The above numbers are not for emergencies. If you are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for my child. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 1) I can choose to allow my child to join this study or not. It is up to me.
- 2) My child can choose to join the study or not. It is up to him or her.
- 3) Even if I agree, my child does not have to participate in the study if he/she does not want to.
- 4) If I refuse or my child chooses not to join the study, no one will be upset with me or my child as a result.
- 5) I can decide to stop my child from being in this study at any time.
- 6) My child can stop being in the study at any time.

Consent

By signing this document, I agree to let my child participate in the study as explained in this form.

Date

Signature of Adult

Printed Name of Adult

Date

Signature of Project Staff

Printed Name of Project Staff

Appendix 24: Assent Followup (Siblings)= English

Emory University Assent to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction

You are being invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for children to learn about HIV using a game on a mobile phone. We have recruited 162 people for this study (108 young people, and 54 of their parents) and are recruiting an additional 45 people.

You only have to take part in the study if you want to. The purpose of this form is to help you decide if you want to be in the study. If you do not wish to be in the study, you do not have to. If you join the study and then change your mind, it is okay for you to leave the study. No one will be upset with you.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to develop a new way for children to learn about HIV using a game on a mobile phone. Your brother or sister participated in a study in which he or she was invited to play a game on a mobile phone for 10 hours over a 2-3 week period. We would like you to tell us about your experience with this study.

What will happen if I take part in this study?

If you agree to be in the study, here is what may happen:

Focus Group Discussion: We may ask you to take part in a group discussion to tell us about your experiences as the brother or sister of a child taking part in this study, any experience you had playing the game, and your suggestions on what other topics and stories this kind of game could be about. The group discussion will be recorded to make sure we do not miss anything that participants say. The group discussion will last about 60 minutes.

In-Depth Interview: We may ask you to take part in a one-on-one interview to tell us about your experience playing the game, and your suggestions on what other topics and stories this game could be about. The interview will be recorded to make sure we do not miss anything you say. It will last about 60 minutes.

Game Play: We may ask you to play an updated version of the game and to give your feedback about the changes that have been made since last year during a focus group discussion. The discussion will last no more than 2 hours.

Cognitive Interview/ Discussion: We may ask you to read questions we plan to ask children who play the game in the future. This interview or discussion will last no more than 1 hour.

Survey Pilot: We may ask you to answer the questions we plan to ask children who play the game in the future so we can test the questions. This will last no more than 1 hour.

Survey: We will ask you to answer a few questions about how you share information with others and who you share information with. This survey will take you no more than 15 minutes.

What are the good (benefits) and bad (risks) things that could happen to me if I agree to be in the study?

Benefits: You will not receive direct benefit by taking part. However, when you take part, you are helping us to learn how we can make the game as valuable as possible for children and their parents. You will not be offered payment for being in this study.

Risks: Some of the questions may embarrass you or make you feel uncomfortable. If you feel uncomfortable with any questions you are asked, you may refuse to answer them.

What about my confidentiality?

You are being asked to take part in a group discussion. We cannot promise that others in the group will not share what you say with others. You shouldn't say anything in the discussion group that you would not want others outside the group to hear.

Your information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your answers to you.

This consent form will be kept in a safe locked cabinet. We will use a study number in place of your name on all study forms. Your name will never be shared with others. Your name will never be used for analysis.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune, Principal Investigator, KEMRI

Email: VMudhune@kemricdc.org

Phone: 0722-687430

If you have any questions about your rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the secretary, KEMRI Ethical Review Committee, (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003.

Or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Email: SMunga@kemri.org

Phone: 057 22923/24

Or

Name: Emory University Institutional Review Board

Email: irb@emory.edu

Phone: +1 404 712 0720

The above numbers are not for emergencies. If you are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for me. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 1) I can choose to join this study or not. It is up to me.
- 2) My parent/ caregiver must also agree for me to participate in the study. I cannot participate in the study if my parent/caregiver does not agree.
- 3) Even if my parent/caregiver agrees. I do not have to participate in the study if I do not want to.
- 4) If I refuse to join the study, no one will be upset with me.
- 5) I can decide to stop being in this study at any time.
- 6) My parent/ guardian can choose for me to stop being in the study at any time.
- 7) I can refuse to answer any questions I choose.

Consent

By signing this document, I agree to take part in this study as explained in this assent form.

Date

Signature of 15-17 year old subject

Date
subject

Signature of person soliciting assent of 15-17 year old

Appendix 25: Parental Consent Followup (Sibling) - English

Emory University Consent to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction

Your child is being invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for children to learn about HIV using a game on a mobile phone. We have recruited 162 people for this study (108 young people, and 54 of their parents) and are recruiting an additional 45 people.

The purpose of this form is to help you decide if you want allow your child to be in the study. Your child can only take part in the study if you agree. Your child will also be asked if they want to take part in the study. Nothing bad will happen to you or your child if you or they say “no”.

If you decide to allow your child to join the study and then you or your child change your mind, it is okay for him/her to leave the study. No one will be upset with you or your child.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to develop a new way for children to learn about HIV using a game on a mobile phone. Your younger child has participated in a study in which he or she was invited to play a game on a mobile phone for 10 hours over a 2-3 week period. Your older child may also have played this game while the younger child was in the study. We would like your older child to tell us about his or her experience with this game, and to give us advice about future games we may develop, even if he or she has not played.

What will happen if your child takes part in this study?

If both you and your child agree to be in the study, here is what will happen:

Focus Group Discussion: We may ask your child to take part in a group discussion to tell us about his/her experience playing the game that was part of our study in April, and his or her suggestions on what other topics and stories this kind of game could be about. The group discussion will be recorded to make sure we do not miss anything that participants say. The group discussion will last about 60 minutes.

In-Depth Interview: We may ask your child to take part in a one-on-one interview to tell us about his or her experience playing the game, and his or her suggestions on what other topics and stories this game could be about. The interview will be recorded to make sure we do not miss anything you say. It will last about 60 minutes.

Game Play: We may ask your child to play an updated version of the game and to give his or her feedback about the changes that have been made since last year during a focus group discussion. The discussion will last no more than 2 hours.

Cognitive Interview/ Discussion: We may ask your child to read questions we plan to ask children who play the game in the future. This interview or discussion will last no more than 1 hour.

Survey Pilot: We may ask your child to answer the questions we plan to ask children who play the game in the future so we can test the questions. This will last no more than 1 hour.

Survey: We will ask your child to answer a few questions about how he or she shares information with others and who he or she shares information with. This survey will take no more than 15 minutes.

What are the good (benefits) and bad (risks) things that could happen to me if I agree to be in the study?

Benefits: Your child will not receive direct benefit by taking part. However, when your child takes part, he or she is helping us to learn how we can make the game as valuable as possible for children of their age. You will not be offered payment for being in this study.

Risks: Some of the questions may embarrass your child or make him or her feel uncomfortable. If they feel uncomfortable with any questions they are asked, they may refuse to answer them.

What about my child's confidentiality?

Your child is being asked to take part in a group discussion. We cannot promise that others in the group will not share what he or she says with others. He or she shouldn't say anything in the discussion group that he or she would not want others outside the group to hear.

Your child's information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace their answers to your child.

This consent form will be kept in a safe locked cabinet. We will use a study number in place of your child's name on all study forms. Your child's name will never be shared with others. Your child's name will never be used for analysis.

Does my child have to participate? What will happen if we change our minds?

You can choose for your child to not be in this study. Your child can choose not to be in the study. If you and your child agree for him or her to be in the study, he or she can still refuse to answer any question. You or your child can stop their participation in the study at any time. Nothing bad will happen to you or your child if they refuse to answer questions or want to stop taking part in the study.

Disclosure of Child Sexual Abuse and Neglect

Your child's privacy is very important to us, but so are his/her health and safety. In cases where abuse, neglect or the desire to harm themselves or others is suspected or disclosed during the study, our staff are required to report this information.

What if I have questions?

You or your child can ask any questions you have at any time. If you or your child have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune, Principal Investigator, KEMRI
Email: vmudhune@kemricdc.org
Phone: 0722-687430

If you have any questions about your child's rights as a research participant, or have concerns or complaints, or if you feel your child has been harmed by taking part in this study, please contact: the secretary, KEMRI Ethical Review Committee, (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003.

Or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research
Email: SMunga@kemri.org
Phone: 057 22923/24

Or

Name: Emory University Institutional Review Board
Email: irb@emory.edu
Phone: +1 404 712 0720

The above numbers are not for emergencies. If you or your child are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for my child. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 1) I can choose to allow my child to join this study or not. It is up to me.
- 2) My child can choose to join the study or not. It is up to him or her.
- 3) Even if I agree, my child does not have to participate in the study if he/she does not want to.
- 4) If I refuse or my child chooses not to join the study, no one will be upset with me or my child as a result.
- 5) I can decide to stop my child from being in this study at any time.
- 6) My child can stop being in the study at any time.

Consent

By signing this document, I agree to take part in this study as explained in this assent form.

Date

Signature of Adult

Printed Name of Adult

Date

Signature of Project Staff

Printed Name of Project Staff

Appendix 26: Assent Followup (Adolescents)= English

Emory University Assent to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction

You are being invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for children to learn about HIV using a game on a mobile phone. We have recruited 162 people for this study (108 young people, and 54 of their parents) and are recruiting an additional 45 people.

You only have to take part in the study if you want to. The purpose of this form is to help you decide if you want to be in the study. If you do not wish to be in the study, you do not have to. If you join the study and then change your mind, it is okay for you to leave the study. No one will be upset with you.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to develop a new way for children to learn about HIV using a game on a mobile phone. Young people participated in a study in which they were invited to play a game on a mobile phone for 10 hours over a 2-3 week period. One of the families involved in this study has suggested that you had some experience with this study. We would like to know more about any experience you had with the game, and to ask your advice about future games we may develop, even if you have not played.

What will happen if I take part in this study?

If you agree to be in the study, here is what may happen:

Focus Group Discussion: We may ask you to take part in a group discussion to tell us about any experience you had playing the game, and your suggestions on what other topics and stories this kind of game could be about. The group discussion will be recorded to make sure we do not miss anything that participants say. The group discussion will last about 60 minutes.

In-Depth Interview: We may ask you to take part in a one-on-one interview to tell us about your experience playing the game, and your suggestions on what other topics and stories this game could be about. The interview will be recorded to make sure we do not miss anything you say. It will last about 60 minutes.

Game Play: We may ask you to play an updated version of the game and to give your feedback about the changes that have been made since last year during a focus group discussion. The discussion will last no more than 2 hours.

Cognitive Interview/Discussion: We may ask you to read questions we plan to ask children who play the game in the future. This interview or discussion will last no more than 1 hour.

Survey Pilot: We may ask you to answer the questions we plan to ask children who play the game in the future so we can test the questions. This will last no more than 1 hour.

Survey: We will ask you to answer a few questions about how you share information with others and who you share information with. This survey will take you no more than 15 minutes.

What are the good (benefits) and bad (risks) things that could happen to me if I agree to be in the study?

Benefits: You will not receive direct benefit by taking part. However, when you take part, you are helping us to learn how we can make the game as valuable as possible for children and their parents. You will not be offered payment for being in this study.

Risks: Some of the questions may embarrass you or make you feel uncomfortable. If you feel uncomfortable with any questions you are asked, you may refuse to answer them.

What about my confidentiality?

You are being asked to take part in a group discussion. We cannot promise that others in the group will not share what you say with others. You shouldn't say anything in the discussion group that you would not want others outside the group to hear.

Your information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your answers to you.

This consent form will be kept in a safe locked cabinet. We will use a study number in place of your name on all study forms. Your name will never be shared with others. Your name will never be used for analysis.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune, Principal Investigator, KEMRI

Email: VMudhune@kemricdc.org

Phone: 0722-687430

If you have any questions about your rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the secretary, KEMRI Ethical Review Committee, (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003.

Or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Email: SMunga@kemri.org

Phone: 057 22923/24

Or

Name: Emory University Institutional Review Board

Email: irb@emory.edu

Phone: +1 404 712 0720

The above numbers are not for emergencies. If you are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for me. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 1) I can choose to join this study or not. It is up to me.
- 2) My parent/ caregiver must also agree for me to participate in the study. I cannot participate in the study if my parent/caregiver does not agree.
- 3) Even if my parent/caregiver agrees. I do not have to participate in the study if I do not want to.
- 4) If I refuse to join the study, no one will be upset with me.
- 5) I can decide to stop being in this study at any time.
- 6) My parent/ guardian can choose for me to stop being in the study at any time.
- 7) I can refuse to answer any questions I choose.

Consent

By signing this document, I agree to take part in this study as explained in this assent form.

Date

Signature of 15-17 year old subject

Date
subject

Signature of person soliciting assent of 15-17 year old

Appendix 27: Parental Consent Followup (Adolescent) - English

Emory University Consent to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction

Your child is being invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for children to learn about HIV using a game on a mobile phone. We have recruited 162 people for this study (108 young people, and 54 of their parents) and are recruiting an additional 45 people.

The purpose of this form is to help you decide if you want allow your child to be in the study. Your child can only take part in the study if you agree. Your child will also be asked if they want to take part in the study. Nothing bad will happen to you or your child if you or they say “no”.

If you decide to allow your child to join the study and then you or your child change your mind, it is okay for him/her to leave the study. No one will be upset with you or your child.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to develop a new way for children to learn about HIV using a game on a mobile phone. Young people participated in a study in which they were invited to play a game on a mobile phone for 10 hours over a 2-3 week period. One of the families involved in the study has suggested that your child had some experience with the study. We would like your child to tell us about any experience he or she had with the game, and to give us advice about future games we may develop, even if he or she has not played.

What will happen if your child takes part in this study?

If both you and your child agree to be in the study, here is what will happen:

Focus Group Discussion: We may ask your child to take part in a group discussion to tell us about any experience he or she had playing the game that was part of our study in April, and his or her suggestions on what other topics and stories this kind of game could be about. The group discussion will be recorded to make sure we do not miss anything that participants say. The group discussion will last about 60 minutes.

In-Depth Interview: We may ask your child to take part in a one-on-one interview to tell us about any experience playing the game, and his or her suggestions on what other topics and stories this game could be about. The interview will be recorded to make sure we do not miss anything you say. It will last about 60 minutes.

Cognitive Interview/ Discussion: We may ask your child to read questions we plan to ask children who play the game in the future. This interview or discussion will last no more than 1 hour.

Game Play: We may ask your child to play an updated version of the game and to give his or her feedback about the changes that have been made since last year during a focus group discussion. The discussion will last no more than 2 hours.

Survey Pilot: We may ask your child to answer the questions we plan to ask children who play the game in the future so we can test the questions. This will last no more than 1 hour.

Survey: We will ask your child to answer a few questions about how he or she shares information with others and who he or she shares information with. This survey will take no more than 15 minutes.

What are the good (benefits) and bad (risks) things that could happen to me if I agree to be in the study?

Benefits: Your child will not receive direct benefit by taking part. However, when your child takes part, he or she is helping us to learn how we can make the game as valuable as possible for children of their age. You will not be offered payment for being in this study.

Risks: Some of the questions may embarrass your child or make him or her feel uncomfortable. If they feel uncomfortable with any questions they are asked, they may refuse to answer them.

What about my child's confidentiality?

Your child is being asked to take part in a group discussion. We cannot promise that others in the group will not share what he or she says with others. He or she shouldn't say anything in the discussion group that he or she would not want others outside the group to hear.

Your child's information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace their answers to your child.

This consent form will be kept in a safe locked cabinet. We will use a study number in place of your child's name on all study forms. Your child's name will never be shared with others. Your child's name will never be used for analysis.

Does my child have to participate? What will happen if we change our minds?

You can choose for your child to not be in this study. Your child can choose not to be in the study. If you and your child agree for him or her to be in the study, he or she can still refuse to answer any question. You or your child can stop their participation in the study at any time. Nothing bad will happen to you or your child if they refuse to answer questions or want to stop taking part in the study.

Disclosure of Child Sexual Abuse and Neglect

Your child's privacy is very important to us, but so are his/her health and safety. In cases where abuse, neglect or the desire to harm themselves or others is suspected or disclosed during the study, our staff are required to report this information.

What if I have questions?

You or your child can ask any questions you have at any time. If you or your child have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune, Principal Investigator, KEMRI
Email: vmudhune@kemricdc.org
Phone: 0722-687430

If you have any questions about your child's rights as a research participant, or have concerns or complaints, or if you feel your child has been harmed by taking part in this study, please contact: the secretary, KEMRI Ethical Review Committee, (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003.

Or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research
Email: SMunga@kemri.org
Phone: 057 22923/24

Or

Name: Emory University Institutional Review Board
Email: irb@emory.edu
Phone: +1 404 712 0720

The above numbers are not for emergencies. If you or your child are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for my child. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 7) I can choose to allow my child to join this study or not. It is up to me.
- 8) My child can choose to join the study or not. It is up to him or her.
- 9) Even if I agree, my child does not have to participate in the study if he/she does not want to.
- 10) If I refuse or my child chooses not to join the study, no one will be upset with me or my child as a result.
- 11) I can decide to stop my child from being in this study at any time.
- 12) My child can stop being in the study at any time.

Consent

By signing this document, I agree to take part in this study as explained in this assent form.

Date

Signature of Adult

Printed Name of Adult

Date

Signature of Project Staff

Printed Name of Project Staff

Appendix 28: Parent Consent Self Additional Evaluation - English

Consent to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction

You and your child were invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI) last year. The study is helping us develop a new way for children to learn about HIV using a game on a mobile phone. We recruited a total of 162 people for this study and are recruiting an additional 45 people.

You only have to take part in the study if you want to. The purpose of this form is to help you decide if you want to be in the study. If you do not wish to be in the study, you do not have to. If you join the study and then change your mind, it is okay for you to leave the study. No one will be upset with you.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to develop a new way for children to learn about HIV using a game on a mobile phone. Your child is participating or has participated in a study in which he or she may have been invited to play a game on a mobile phone for 10 hours over a 2-3 week period. We would like you to tell us more about your experience with this study and your recommendations for future games we may develop for children and their parents.

What will happen if I take part in this study?

If you agree to be in the study, here is what will happen:

Focus Group Discussion: After children played the game and returned the phones, we asked you to tell us about your experiences as the parent of a child taking part in this study. For this stage of the study, we are asking you to take part in another group discussion to provide additional information about your experience and to share your ideas on future games we may develop for children and their parents. The group discussion will be recorded to make sure we do not miss anything that participants say. The group discussion will last about 90 minutes.

In-Depth Interview: We may ask you to take part in a one-on-one interview to tell us about your experiences with your children playing the game, and your recommendations for future games for parents and children. The interview will be recorded to make sure we do not miss anything you say. It will last about 60 minutes.

Cognitive Interview/ Discussion: We may ask you to read questions we plan to ask parents who play games or whose children play the games in the future. This interview or discussion will last no more than 1 hour.

Survey Pilot: We may ask you to answer the questions we plan to ask parents who play games or whose children play the games in the future so we can test the questions. This will last no more than 1 hour.

What are the good (benefits) and bad (risks) things that could happen to me if I agree to be in the study?

Benefits: You will not receive direct benefit by taking part. However, when you take part, you are helping us to learn how we can make games as valuable as possible for children and their parents. You will not be offered payment for being in this study. You will not be offered payment for being in this study. However, you will be reimbursed Kshs 500 for your time and transport costs and refreshments provided as per standard requirements during FGDs.

Risks: Some of the questions may embarrass you or make you feel uncomfortable. If you feel uncomfortable with any questions you are asked, you may refuse to answer them.

What about my confidentiality?

You are being asked to take part in a group discussion. We cannot promise that others in the group will not share what you say with others. You shouldn't say anything in the discussion group that you would not want others outside the group to hear.

Your information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your answers to you.

This consent form will be kept in a safe locked cabinet. We will use a study number in place of your name on all study forms. Your name will never be shared with others. Your name will never be used for analysis.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune, Principal Investigator, KEMRI

Email: VMudhune@kemricdc.org

Phone: 057 2022929/02

If you have any questions about your rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the secretary, KEMRI Scientific and Ethics Review Unit (SERU), (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003.

Or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Email: SMunga@kemri.org

Phone: 057 2022929/02

Or

Name: Emory University Institutional Review Board
Email: irb@emory.edu
Phone: +1 404 712 0720

The above numbers are not for emergencies. If you are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for me. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 5) I can choose to join this study or not. It is up to me.
- 6) If I refuse to join the study, no one will be upset with me or my child.
- 7) I can decide to stop being in this study at any time.
- 8) I can refuse to answer any questions I choose.

Consent

By signing this document, I agree to take part in this study as explained in this assent form.

Date

Signature of Adult

Printed Name of Adult

Date

Signature of Project Staff

Printed Name of Project Staff

Appendix 29: Consent Followup Activities (Sibling) - English

Emory University Consent to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction

You are invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for young people to learn about HIV using a game on a smartphone. We have recruited 174 people for this study (120 young people, and 54 of their parents) and are recruiting an additional 63 people.

The purpose of this form is to help you decide if you want to be in the study. Nothing bad will happen to you if you say “no”. If you decide to join the study and then you change your mind, it is okay for you to leave the study. No one will be upset with you.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to develop a new way for children to learn about HIV using a game on a smartphone. Your younger brother or sister participated in a study in which he or she was invited to play a game on a smartphone for 10 hours over a 2-3 week period. You may also have played this game while your brother or sister was in the study. We would like you to tell us about your experience with this game, and to give us advice about future games we may develop, even if you have not played.

What will happen if you takes part in this study?

If you agree to be in the study, here is what will happen:

Focus Group Discussion: We may ask you to take part in a group discussion to tell us about any experience you had playing the game, and your suggestions on what other topics and stories this kind of game could be about. The group discussion will be recorded to make sure we do not miss anything that you say. The group discussion will last about 60 minutes.

In-Depth Interview: We may ask you to take part in a one-on-one interview to tell us about any experience you had playing the game, and your suggestions on what other topics and stories this game could be about. The interview will be recorded to make sure we do not miss anything you say. It will last about 60 minutes.

Cognitive Interview/ Discussion: We may ask you to read questions we plan to ask young people who play the game in the future. This interview or discussion will last no more than 1 hour.

Game Play: We may ask you to play an updated version of the game and to give your feedback about the changes that have been made in a focus group discussion. The discussion will last no more than 2 hours.

Survey Pilot: We may ask you to answer the questions we plan to ask young people who play the game in the future so we can test the questions. This will last no more than 1 hour.

Survey: We will ask you to answer a few questions about how you share information with others and who you share information with. This survey will take no more than 15 minutes.

What are the good (benefits) and bad (risks) things that could happen to me if I agree to be in the study?

Benefits: You will not receive direct benefit by taking part. However, when you take part, you are helping us to learn how we can make the game as valuable as possible for young people and their parents. You will not be offered payment for being in this study.

Risks: Some of the questions may embarrass you or make you feel uncomfortable. If you feel uncomfortable with any questions you are asked, you may refuse to answer them.

What about my confidentiality?

You may be asked to take part in a group discussion. We cannot promise that others in the group will not share what you say with others. You shouldn't say anything in the discussion group that you would not want others outside the group to hear.

Your information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your answers to you.

This consent form will be kept in a safe locked cabinet. We will use a study number in place of your name on all study forms. Your name will never be shared with others. Your name will never be used for analysis.

Do I have to participate? What will happen if I change my mind?

You can choose to not be in this study. If you agree to be in the study, you can still refuse to answer any question. You can stop your participation in the study at any time. Nothing bad will happen to you if you refuse to answer questions or want to stop taking part in the study.

Disclosure of Child Sexual Abuse and Neglect

Your privacy is very important to us, but so is your health and safety. In cases where abuse, neglect or the desire to harm yourself or others is suspected or disclosed during the study, our staff are required to report this information.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune, Principal Investigator, KEMRI
Email: vmudhune@kemricdc.org
Phone: 0722-687430

If you have any questions about your rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the secretary, KEMRI Ethical Review Committee, (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003.

Or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research
Email: SMunga@kemri.org
Phone: 057 22923/24

Or

Name: Emory University Institutional Review Board
Email: irb@emory.edu
Phone: +1 404 712 0720

The above numbers are not for emergencies. If you are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for myself. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 1) I can choose to join this study or not. It is up to me.
- 2) If I refuse to join the study, no one will be upset with me as a result.
- 3) I can decide to stop being in this study at any time.
- 4) I can refuse to answer any questions I choose.

Consent

By signing this document, I agree to take part in this study as explained in this assent form.

Date

Signature of Adult

Printed Name of Adult

Date

Signature of Project Staff

Printed Name of Project Staff

Appendix 30: Consent Followup Activities (Other Adolescents) - English

Emory University Consent to be a Research Subject

Title: A Mobile Phone Game to Prevent HIV among Young Africans

Principal Investigators:

Kate Winskell, PhD, Rollins School of Public Health

Victor Mudhune, MBA MPH, KEMRI Center for Global Health Research

Funding Source: U.S. National Institute of Mental Health

Introduction

You are invited to take part in a research study conducted by Emory University in Atlanta and the Kenya Medical Research Institute (KEMRI). The study will help us develop a new way for young people to learn about HIV using a game on a smartphone. We have recruited 174 people for this study (120 young people, and 54 of their parents) and are recruiting an additional 63 people.

The purpose of this form is to help you decide if you want to be in the study. Nothing bad will happen to you if you say “no”. If you decide to join the study and then you change your mind, it is okay for you to leave the study. No one will be upset with you.

This form may contain words that you do not understand. Please ask the study staff to explain any word or information that is not clear to you. You can ask questions at any time.

Why are we doing this research?

The research team wants to develop a new way for children to learn about HIV using a game on a smartphone. Young people participated in a study in which they were invited to play a game on a smartphone for 10 hours over a 2-3 week period. One of the families involved in this study has suggested that you had some experience with the study. We would like to know more about any experience you had with the game, and to ask your advice about future games we may develop, even if you have not played.

What will happen if you takes part in this study?

If you agree to be in the study, here is what will happen:

Focus Group Discussion: We may ask you to take part in a group discussion to tell us about any experience you had playing the game, and your suggestions on what other topics and stories this kind of game could be about. The group discussion will be recorded to make sure we do not miss anything that you say. The group discussion will last about 60 minutes.

In-Depth Interview: We may ask you to take part in a one-on-one interview to tell us about any experience you had playing the game, and your suggestions on what other topics and stories this game could be about. The interview will be recorded to make sure we do not miss anything you say. It will last about 60 minutes.

Cognitive Interview/ Discussion: We may ask you to read questions we plan to ask young people who play the game in the future. This interview or discussion will last no more than 1 hour.

Game Play: We may ask you to play an updated version of the game and to give your feedback about the changes that have been made in a focus group discussion. The discussion will last no more than 2 hours.

Survey Pilot: We may ask you to answer the questions we plan to ask young people who play the game in the future so we can test the questions. This will last no more than 1 hour.

Survey: We will ask you to answer a few questions about how you share information with others and who you share information with. This survey will take no more than 15 minutes.

What are the good (benefits) and bad (risks) things that could happen to me if I agree to be in the study?

Benefits: You will not receive direct benefit by taking part. However, when you take part, you are helping us to learn how we can make the game as valuable as possible for young people and their parents. You will not be offered payment for being in this study.

Risks: Some of the questions may embarrass you or make you feel uncomfortable. If you feel uncomfortable with any questions you are asked, you may refuse to answer them.

What about my confidentiality?

You may be asked to take part in a group discussion. We cannot promise that others in the group will not share what you say with others. You shouldn't say anything in the discussion group that you would not want others outside the group to hear.

Your information will be kept private. All information will be stored safely on a computer protected by passwords. No one will be able to trace your answers to you.

This consent form will be kept in a safe locked cabinet. We will use a study number in place of your name on all study forms. Your name will never be shared with others. Your name will never be used for analysis.

Do I have to participate? What will happen if I change my mind?

You can choose to not be in this study. If you agree to be in the study, you can still refuse to answer any question. You can stop your participation in the study at any time. Nothing bad will happen to you if you refuse to answer questions or want to stop taking part in the study.

Disclosure of Child Sexual Abuse and Neglect

Your privacy is very important to us, but so is your health and safety. In cases where abuse, neglect or the desire to harm yourself or others is suspected or disclosed during the study, our staff are required to report this information.

What if I have questions?

You can ask any questions you have at any time. If you have any questions about the study now or later, you may contact:

Name: Dr. Victor Mudhune, Principal Investigator, KEMRI

Email: vmudhune@kemricdc.org

Phone: 0722-687430

If you have any questions about your rights as a research participant, or have concerns or complaints, or if you feel you have been harmed by taking part in this study, please contact: the secretary, KEMRI Ethical Review Committee, (P. O. Box 54840-00200, Nairobi) at telephone 020-2722541 or cell phone 0722205901 or 0733400003.

Or

Name: Dr. Stephen Munga, Center Director, KEMRI, Center for Global Health Research

Email: SMunga@kemri.org

Phone: 057 22923/24

Or

Name: Emory University Institutional Review Board

Email: irb@emory.edu

Phone: +1 404 712 0720

The above numbers are not for emergencies. If you are having an emergency, please go to the nearest clinic/place you can get help.

Do you have any questions?

Statement of Permission

I have read (or have been explained) and understand this form. I understand the reason for the study and what will happen in the study. I understand the risks and benefits for myself. I have been given the opportunity to consider my decision and have had all my questions answered. I understand that:

- 13) I can choose to join this study or not. It is up to me.
- 14) If I refuse to join the study, no one will be upset with me as a result.
- 15) I can decide to stop being in this study at any time.
- 16) I can refuse to answer any questions I choose.

Consent

By signing this document, I agree to take part in this study as explained in this assent form.

Date

Signature of Adult

Printed Name of Adult

Date

Signature of Project Staff

Printed Name of Project Staff

Appendix 31 and Appendix 32 redacted