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## Todurujo na Kadurok (Empowering Youth): study design of an HIV self-testing and edutainment comic cluster randomized trial among refugee youth in a humanitarian setting in Uganda

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Complete List of Authors:	Logie, Carmen; University of Toronto, Factor-Inwentash Faculty of Social Work; University of Toronto, Women's College Research Institute Okumu, Moses ; University of Illinois at Urbana-Champaign, School of Social Work; Uganda Christian University, Department of Social Work Loutet, Miranda; University of Toronto Dalla Lana School of Public Health Coelho, Madelaine; University of Toronto Berry, Isha ; University of Toronto Dalla Lana School of Public Health, Gittings, Lesley; University of Cape Town, ; University of Toronto, Odong Lukone, Simon; Uganda Refugee and Disaster Management Council Kisubi, Nelson; Uganda Refugee and Disaster Management Council Malon, Atama; Yumbe Hospital Kyambadde, Peter ; Mulago Hospital, Most at Risk Population Initiative
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# Todurujo na Kadurok (Empowering Youth): study design of an HIV self-testing and edutainment comic cluster randomized trial among refugee youth in a humanitarian setting in Uganda

Carmen H Logie<sup>1,2,3,4</sup>, Moses Okumu<sup>5</sup>, Miranda Loutet<sup>6</sup>, Madelaine Coelho<sup>4,7</sup>, Isha Berry<sup>6</sup>, Lesley Gittings<sup>1,8</sup>, Simon Odong Lukone<sup>9</sup>, Nelson Kisubi<sup>9</sup>, Malon Atama<sup>10</sup>, Peter Kyambadde<sup>11,12</sup>

<sup>1</sup>Factor-Inwentash Faculty of Social Work, University of Toronto, Toronto, ON, Canada

<sup>2</sup>United Nations University Institute for Water, Environment, and Health, Hamilton, ON, Canada

<sup>3</sup>Centre for Gender & Sexual Health Equity, Vancouver, BC, Canada

<sup>4</sup>Women's College Research Institute, Women's College Hospital, Toronto, ON, Canada

<sup>5</sup>School of Social Work, University of North Carolina Chapel Hill, Chapel Hill, NC, USA

<sup>6</sup>Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

<sup>7</sup>Department of Sociology, University of Toronto, Toronto, ON, Canada

<sup>8</sup>Centre for Social Science Research, University of Cape Town, South Africa

<sup>9</sup>Uganda Refugee and Disaster Management Council, Yumbe, Uganda

<sup>10</sup>Yumbe General Hospital, Yumbe, Uganda

<sup>11</sup>National AIDS Coordinating Program, Ugandan Ministry of Health, Kampala, Uganda

<sup>12</sup>Most at Risk Population Initiative (MARPI), Mulago Hospital, Kampala, Uganda

Co-authors' ORCID iDs:

Carmen H Logie <http://orcid.org/0000-0002-8035-433X>

Moses Okumu <https://orcid.org/0000-0003-2555-3077>

Miranda Loutet <https://orcid.org/0000-0002-6293-3047>

Isha Berry <https://orcid.org/0000-0003-3138-664X>

Lesley Gittings <https://orcid.org/0000-0002-0463-0478>

Odong Simon Lukone <https://orcid.org/0000-0002-6780-1705>

Nelson Kisubi <https://orcid.org/0000-0002-0260-4620>

Malon Atama <https://orcid.org/0000-0003-1409-1970>

Peter Kymbadde <https://orcid.org/0000-0002-9606-218X>

\*Corresponding Author: Dr. Carmen Logie, University of Toronto, Factor-Inwentash Faculty of Social Work, 246 Bloor St W, Toronto, ON M5S 1V4, [carmen.logie@utoronto.ca](mailto:carmen.logie@utoronto.ca)

## Abstract

**Introduction:** Refugees experience HIV vulnerabilities due to the confluence of displacement, violence, and poverty. HIV self-testing, understudied in refugee settlements, is a promising method to increase testing uptake, yet challenges remain linking persons to confirmatory testing following a positive HIV self-test. This study aims to evaluate the effectiveness of HIV self-testing kits and “edutainment” comics in increasing HIV testing and HIV status knowledge among refugee youth aged 16-24 years in Bidi Bidi Refugee Settlement, Uganda.

**Methods and analysis:** This study will be conducted in Bidi Bidi. We conducted a qualitative formative phase with focus groups to generate knowledge of contextually-specific barriers and facilitators of HIV prevention, testing and care among refugee youth (aged 16-24) in Bidi Bidi. These findings were then used to create comic scenarios aligning with edutainment approaches to health promotion. We will conduct a four-arm cluster randomized controlled trial in Bidi Bidi using a 2 x 2 factorial design: 1) HIV self-testing alongside edutainment comics, 2) HIV self-testing alone, 3) edutainment comic alone, and 4) standard of care. Approximately 120 youth (30 per arm) will be enrolled and followed for 3 months. Data will be collected at baseline and 3-months after enrolment. The primary outcomes (HIV testing frequency, HIV status knowledge) and secondary outcomes (linkage to confirmatory HIV testing, HIV care linkage, HIV self-test kit use, HIV-related stigma, HIV knowledge, safer sex efficacy, condom-use, adolescent sexual and reproductive health stigma, sexual relationship power, access to SRH services) will be evaluated using descriptive statistics and regression analyses.

**Ethics and dissemination:** This study has been approved by the University of Toronto Research Ethics Board, the Mildmay Uganda Research Ethics Committee, and the Uganda National Council for Science and Technology. This trial is registered at ClinicalTrials.gov (#NCT05213689). Results will be published in peer-reviewed journals and findings communicated through community forums.

### Strengths and limitations of this study:

- *Todurujo na Kadurok* (Empowering Youth) study is unique in exploring the use of edutainment comic books as a form of graphic medicine in addition to a clinical intervention (HIV self-testing kits) for improving HIV testing uptake and status knowledge among youth living in a humanitarian context in Uganda.
- This study will advance knowledge of HIV self-testing implementation in a refugee settlement context.
- The primary study limitations are potential loss to follow-up.
- This research will produce new information on the potential benefits of low-cost graphic medicine approaches on increasing HIV self-testing benefits among refugee youth, with implications for scaling-up HIV self-testing in humanitarian contexts.

## 80 BACKGROUND

81  
82 HIV vulnerabilities among displaced and refugee adolescents are shaped by a complex interplay  
83 of factors including poverty, violence, host community HIV prevalence, HIV urbanization, HIV  
84 testing and care access, and living conditions [1–3]. Uganda is the largest refugee hosting nation  
85 in Africa with over 1.4 million refugees in 2020, with more than 240,000 living in Bidi Bidi  
86 settlement near the South Sudan border [4]. Youth represent 44.4% of all new HIV infections in  
87 Uganda, with most infections sexually transmitted [5]. HIV prevalence among adolescents and  
88 young people in Uganda is 10.8% and is markedly higher among women (15.4%) compared with  
89 men (4.8%)[6]. Less is known of HIV prevalence, testing and prevention engagement among  
90 youth living in refugee settlements in Uganda, including in Bidi Bidi [7].

91 There is limited inclusion of refugee adolescents and youth in sexual and reproductive  
92 health research and programming [8–10] that may result in a lack of age, gender, culturally  
93 tailored programs, which in turn may contribute to low engagement with HIV testing and  
94 prevention services in humanitarian contexts [11]. Research findings suggest that inequitable  
95 gender norms and intersecting forms of stigma, including HIV-related stigma and refugee  
96 stigma, may also limit HIV testing and prevention engagement among refugee youth [12–15].  
97 Social network breakdown, poverty and travel distance to clinics, confidentiality concerns,  
98 language barriers and other logistic hurdles may also present obstacles to HIV testing [16,17].

99 HIV self-testing (HIVST) is a promising approach documented across systematic reviews  
100 to increasing HIV testing access and uptake [18–20]. This approach may mitigate confidentiality  
101 concerns, increase convenience, and reduce the risk of stigmatization, particularly important  
102 considerations for HIV testing with adolescents and youth [21–24]. HIVST involves an  
103 individual collecting their own oral specimen, conducting the test, and interpreting the results

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2  
3 104 independently with support from pictorial and written instructions. There is also a dearth of  
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5 105 information regarding advances in HIV testing, such as HIV self-testing, among youth in  
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7 106 humanitarian contexts [25], including countries with a high HIV prevalence and large number of  
8  
9 107 refugees such as Uganda.

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11  
12 108       There remain gaps in linkage to care following a positive HIV self-test when compared  
13  
14 109 with standard HIV testing services, and addressing these gaps requires innovative approaches  
15  
16 110 [26]. Comics—a form of graphic medicine—integrate text and visual images and are a promising  
17  
18 111 health promotion tool used to address a variety of health conditions such as HIV, sexually  
19  
20 112 transmitted infections, vaccines, and dementia [27–32]. Edutainment comics have been used to  
21  
22 113 educate both the general population and healthcare providers [33,34]. Comics align with the  
23  
24 114 entertainment-education (‘edutainment’) approach to improve health knowledge, attitudes and  
25  
26 115 practices applied in HIV prevention research [35,36]. In the field of HIV, comics have been used  
27  
28 116 in an HIV adherence intervention in the United States as well as in PrEP research, as well as in  
29  
30 117 HIV education in schools in Kenya [37–39]. Among refugees, comics have been used in mental  
31  
32 118 health research in Greece and Lebanon [40,41]. We did not locate research using comics for HIV  
33  
34 119 testing interventions at large, or with refugees on HIV research.

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40 120       HIV prevention cascade conceptual frameworks can inform research addressing gaps in  
41  
42 121 linkage to care following HIV self-testing [42,43]. Three key domains of the HIV prevention  
43  
44 122 cascade include motivation, access, and effective use, and these dimensions can be tailored to  
45  
46 123 identify population specific needs [43,44]. For instance, Moorhouse et al. applied the HIV  
47  
48 124 prevention cascade framework to develop community-based HIV prevention interventions and  
49  
50 125 noted dimensions of motivation (knowledge, risk perception, consequence of use, social norms),  
51  
52 126 access (availability, acceptable provision, affordability), and effective use (skills, self-efficacy,  
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3 127 partner) [42]. Identifying gaps in these prevention cascade dimensions can inform intervention  
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5 128 development and evaluation.  
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8 129 This cluster-randomized study, *Todurujo na Kadurok* (loosely translated to ‘Empowering  
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10 130 Youth’ in Bari), aims to conduct an HIV self-testing and edutainment comic intervention and  
11  
12 131 evaluate its effectiveness in increasing HIV testing and HIV status knowledge among refugee  
13  
14 132 youth in Bidi Bidi refugee settlement, Uganda. The comic intervention will be theoretically  
15  
16 133 informed by the HIV prevention cascade [42] to address gaps in motivation, access and effective  
17  
18 134 use identified in formative research. Study findings can inform local and global responses to  
19  
20 135 increase HIV testing engagement with youth in humanitarian contexts.  
21  
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## 25 26 137 **METHODS**

### 27 28 138 **Study aims and objectives**

29  
30 139 The overarching study goal is to evaluate the effectiveness of HIV self-testing, edutainment  
31  
32 140 comic, or a combination of both interventions on increasing HIV testing, HIV status knowledge  
33  
34 141 and linkage to confirmatory testing and care among refugee youth aged 16 to 24 years living in  
35  
36 142 Bidi Bidi refugee settlement, Uganda. The primary objectives are to evaluate the effectiveness of  
37  
38 143 the interventions on participants (1) HIV status knowledge and (2) HIV testing frequency.  
39  
40 144 Secondary objectives include examining the impact of the intervention on: (1) HIV self-testing  
41  
42 145 kit use, (2) linkage to confirmatory HIV testing for those testing positive on the HIVST, and (3)  
43  
44 146 linkage to HIV care for those testing positive, (4) HIV-related stigma, (5) adolescent sexual and  
45  
46 147 reproductive health stigma, (6) HIV knowledge, (7) safer sex efficacy, (8) condom use, (9)  
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48 148 sexual relationship power, and (10) access to other sexual and reproductive health services (e.g.,  
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50 149 contraception, post-exposure prophylaxis).  
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## 150 **Study Design**

151 We are conducting a cluster-randomized study using a 2 x 2 factorial design (see Figure 1) [45].  
152 This approach will specifically test the effectiveness of offering: 1) HIV self-testing alongside  
153 the edutainment comic, 2) HIV self-testing alone, 3) edutainment comic alone, and 4) standard of  
154 care, on defined primary and secondary outcomes. Factorial designs are an appropriate and  
155 efficient approach to understand synergies between interventions. As HIV self-testing is an  
156 established testing approach that is feasible and acceptable [26,45–47], we are particularly  
157 interested to see if the benefits of HIV self-testing with youth in a humanitarian context are  
158 increased with accompanying edutainment comics that are theoretically designed to address  
159 barriers to testing and care across the HIV cascade. This design can help with identifying  
160 effective strategies to reach study aims and in turn can inform intervention design to include the  
161 most effective components [48]. Data will be collected from all participants directly before  
162 providing the intervention (baseline: time 1), and again at 3-month follow-up (time 2).

## 164 **Study setting**

165 This trial will be conducted in four villages located in two zones in Bidi Bidi Refugee Settlement  
166 within the Yumbe district in Northwestern Uganda. With over 245,000 refugees largely (99.9%)  
167 from South Sudan, Bidi Bidi is the world's second-largest refugee settlement with one-quarter of  
168 the population (25%; n=61,036) youth aged 15 to 24 years [49]. In Bidi Bidi, health centers offer  
169 free regular testing for HIV and comprehensive HIV care services including adult and pediatric  
170 antiretroviral therapy (ART) and cotrimoxazole prophylaxis. However, only a few facilities in  
171 the settlement offer comprehensive HIV care such as Prevention of Mother to Child  
172 Transmission (PMTCT) services. Moreover, there are reported challenges including lack of



173 facility accreditation to offer HIV care, drug and test kits stock out and poor adherence to ART  
174 by the refugees [50,51].

175 The clinical trial study setting includes two villages in Zone 3, with more than 58,000  
176 residents, and two villages in Zone 4 annex, with more than 52,000 residents [49]. To ensure  
177 anonymity of participants, the village numbers are not included in this protocol. The zones and  
178 villages were selected due to large geographical separation to avoid contamination of  
179 intervention arms, eagerness of youth in these areas to learn more about HIV testing, and to fill a  
180 void of HIV research in these particular areas. In Zone 3 there are the following participating  
181 health centres: Jomorogo Health Centre 3, Kongbe Health Centre 3, Yoyo Health Centre 3,  
182 Luzira Health Centre 3. In Zone 4 annex the following health centres will participate: Igamara  
183 Health Centre 3, Bolomoni Health Centre 3, Bangatuti Health Centre, and Kulikulinga  
184 Government Centre. All participants are able to access these health centres throughout the study  
185 for HIV testing and treatment.

### 187 **Participants and recruitment**

188 We will use convenience sampling methods, including peer driven recruitment supported by  
189 collaborators at Uganda Refugee and Disaster Management Council (URDMC) and eight peer  
190 navigators. Peer navigators are self-identified young refugees aged 20-24 years living in Bidi  
191 Bidi, specifically Zone 3 and Zone 4 annex, who received training from the study team in  
192 research methods and confidentiality and are supervised by URDMC. Inclusion criteria for  
193 participants in the *Todurujo na Kadurok* study include: (1) living in one of the four selected  
194 villages in Zone 3 and Zone 4 annex in Bidi Bidi; (2) identifying as a refugee or displaced  
195 person; (3) aged 16-24 years; and (4) speaking and reading one of the study languages (English,

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3 196 Bari, Juba Arabic). The same recruitment methods and eligibility criteria will be used for the  
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5 197 focus groups in Phase 1 and the cluster-randomized study in Phase 2.  
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7  
8 198 For Phase 2, participants will be randomized by the village they live in. We will recruit a  
9  
10 199 total of 120 participants, with 30 participants in each of the four arms. The arms will be  
11  
12 200 geographically separated into four different villages from two zones to avoid contamination of  
13  
14 201 the intervention effects. The villages will be randomly assigned to a study arm. Youth will be  
15  
16 202 approached by peer navigators and study staff at URDMC to be recruited to the study. At the  
17  
18 203 baseline visit (time 1) the youth will be provided a written consent form, which will be available  
19  
20 204 in English, Bari and Juba Arabic. Once the youth have provided informed written consent they  
21  
22 205 will be enrolled into the study, assigned to a study arm based on the village that they live in, and  
23  
24 206 baseline data will be collected by a URDMC research assistant. Peer navigators will use multiple  
25  
26 207 study reminder strategies (e.g., texts, private messages over social media) to maintain  
27  
28 208 engagement until the follow-up visit at 3-months after enrolment. These efforts will be  
29  
30 209 supplemented with existing outreach services to youth by URDMC.  
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### 38 211 **Patient and public involvement**

39  
40 212 The study protocol was developed after a formative qualitative research phase (Phase 1). As  
41  
42 213 depicted in Figure 1, this formative research in Phase 1 included four focus groups (2 with young  
43  
44 214 women, 2 with young men) with refugee youth in Bidi Bidi (n=10 in each focus group; n=40 in  
45  
46 215 total) aged 16-24 years to collect information on knowledge of current HIV testing opportunities  
47  
48 216 and experiences in Bidi Bidi and perspectives on HIV self-testing. The qualitative findings were  
49  
50 217 used to identify key themes for the development of the edutainment comics (see Table 1), in this  
51  
52 218 way the study responds to the health needs and priorities of refugee youth in this humanitarian  
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219 context. These focus groups were followed by a 3-day human-centered design workshop with  
 220 eight peer navigators to adapt and develop HIV self-testing edutainment materials to enhance  
 221 cultural, gender, age, and contextual relevance (see Figure 1). The study is conducted as a  
 222 collaboration with local physicians, clinics, and the implementing partner is a refugee agency  
 223 based in Bidi Bidi. These study collaborators have been involved since the study inception and  
 224 will lead implementation. Peer navigators (n=8) who share with participants refugee lived  
 225 experiences, and include youth living with HIV, have meaningfully contributed to the study  
 226 design through the human centered design workshops, feedback into edutainment comic  
 227 development, pilot testing of study tools, and will support implementation through actively  
 228 contributing to participant recruitment, engagement, and retention.

229 **Table 1.** Scenarios on the HIV prevention cascade included in the edutainment comic

Domain of prevention cascade	Stage of the prevention cascade	Description
Motivation	Risk perception	Discussion explores perceived risk for HIV and a) misinformation (e.g., sharing body lotion is not as an HIV risk factor) and b) provides information about condom breakage and post-exposure prophylaxis.
	Consequence of use	Discussion between healthcare provider and youth of how to manage a positive HIV test result, including the ability to manage confidentiality and access support services.
	Social norms	Discussion of experiences of HIV stigma and discrimination, as well as an example of receiving support from a friend.
	Knowledge	Discussion of knowledge as power, including benefits of knowing one's HIV positive and HIV negative serostatus.
Access	Access and availability	Parallel conversations between youth around testing barriers, including travel costs, and stockouts of HIV testing kits, with a discussion of locations for testing and support in Bidi Bidi.
	Acceptable provision	Discussions of a) the possibility of receiving an HIV test while accessing other health services such as contraception and condoms; b) accessing HIV testing from a healthcare provider of a different gender; c) feeling empowered to find a doctor one feels comfortable talking with about sexual health
Effective use	Partner	Discussion of HIV testing with partner to assess partner perspectives on HIV testing and evaluate concerns (e.g.,

		negative partner reaction, violence, consequence of positive test result). Healthcare provider discussion of partner testing with a couple, including possible sero-discordant results. Decision making considerations for engaging in partner testing, including motivations (empowerment, support, open communication, stronger relationship) and barriers (loss of trust, violence, conflict, break up).
	Skills	Discussion of disclosure process and decision making regarding who to disclose an HIV positive test result with.
	Self-efficacy	Discussion of how knowledge of HIV testing benefits, HIV positive serostatus, and available resources increase empowerment to take care of oneself and support others.

230

231 **Intervention description**

232 *Todurujo na Kadurok* is a 2 x 2 factorial cluster-randomized trial, with clusters randomized to  
233 one of the following four arms: (1) HIV self-testing and edutainment comic, (2) HIV self-testing  
234 only, (3) edutainment comic only, and (4) standard of care.

235 Participants in the HIV self-testing arms (arm 1; arm 2) will each receive two HIV self-  
236 testing kits (OraQuick Rapid HIV-1/2 Antibody Test, OraSure Technologies) at baseline along  
237 with verbal, written and visual instructions (in their choice of study language), as well as  
238 linkages to peer navigators and URDMC for support accessing confirmatory testing and care.

239 Participants in the edutainment comic arms (arm 1; arm 3) will receive a hard copy of the  
240 edutainment comic at baseline. They will meet with the peer navigator to review and discuss the  
241 comic themes and will be provided with a blank version to complete on their own. This approach  
242 to edutainment comics provides a participatory component whereby participants can  
243 contextualize the comic themes within their own lives and experiences [52]. In addition to the  
244 comic, the participants in arm 1 and 3 will also have linkages to peer navigators and URDMC for  
245 support accessing confirmatory testing and care.

246 Participants in the standard of care arm (arm 4) will receive verbal and written  
247 information and resources about HIV testing, care, and support services in Bidi Bidi and Yumbe  
248 Hospital from their peer navigator as well as contact information for URDMC and an overview  
249 of their programs offered. The existing standard of HIV care in Bidi Bidi is offered through  
250 clinics located in Bidi Bidi settlement and the hospital in Yumbe and includes pre- and post-test  
251 counselling for HIV, follow-up visits for HIV care in the community, intensive treatment  
252 adherence counselling for immunosuppressed and non-immunosuppressed patients in the  
253 community and facility, and community drug re-fills for people living with HIV.

254

## 255 **Outcomes**

256 The primary outcomes measured in this trial are:

- 257 1. Changes in HIV testing frequency: This is measured as participants' self-reported last HIV  
258 test. To capture changes, this measure is assessed at both study time points (baseline [Time  
259 1], 3 months [Time 2]).
- 260 2. Changes in HIV status knowledge: At the final 3-month visit, a clinician supported by trained  
261 peer navigators will offer all participants a completely voluntary rapid point-of-care HIV test  
262 (Alere Determine HIV-1/2) to measure HIV status knowledge. HIV status knowledge will be  
263 assessed as correct for participants that agree to take the rapid test and correctly report their  
264 HIV status before receiving the result.

265 The secondary outcomes include:

- 266 1. Changes in linkage to confirmatory HIV testing: Participants in arm 1 and arm 2 (e.g., those  
267 given a HIVST) will be asked at Time 2 if they used their HIV self-test kit. All participants  
268 who report using the test will be asked the result, and participants who self-report a positive

1  
2  
3 269 result will be asked if they received confirmatory testing, and if so, where they received the  
4  
5 270 test. Participants will also be provided study coupons (with only the name of the UDRMC  
6  
7 271 and their study ID#) that they can provide when receiving HIV or other sexual and  
8  
9 272 reproductive health services at collaborating health clinics; this clinic engagement will be  
10  
11 273 linked to the participant study ID#.

12  
13  
14 274 2. Changes in linkage to HIV care: At Time 2, participants who seroconvert in the study will be  
15  
16 275 asked if they received HIV care, including ART and counseling, since receiving an HIV-  
17  
18 276 positive diagnosis.

19  
20  
21 277 3. HIV self-test kit use: In order to understand the use of HIV self-test kits and to reduce social  
22  
23 278 desirability bias, one month after Time 2 the participants in arm 1 and arm 2 will be asked if  
24  
25 279 they have unused test kits. They will be informed this information is just to guide future  
26  
27 280 trials.

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29  
30 281 4. HIV-related stigma, assessed with the Reinius et al., 2017 12-item short HIV stigma  
31  
32 282 assessment [53] including vicarious and felt-normative HIV stigma dimensions through an  
33  
34 283 internalized AIDS-related scale from Kalichman et al. 2020 [54,55].

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36  
37 284 5. HIV knowledge assessed with the HIV knowledge questionnaire by Carey & Schroder [56].  
38  
39 285 6. Safer sex efficacy using the Condom Use Self-Efficacy Scale [57,58].

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41  
42 286 7. Condom use in past 3 -months (condom use at last sex; condom use at sex every time in last  
43  
44 287 3 months [dichotomous: yes/no]).

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46  
47 288 8. Adolescent sexual and reproductive health stigma, assessed with the Ugandan Adolescent  
48  
49 289 Sexual and Reproductive Health (SRH) Stigma scale (Logie et al. 2019) adapted from Hall et  
50  
51 290 al.'s Adolescent SRH Stigma scale [59]

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2  
3 291 9. Sexual relationship power (SRP) using the Relationship Control Sub-Scale from the Sexual  
4 & Relationship Power Scale [60]  
5  
6 292  
7  
8 293 10. Access to other SRH services will be assessed by asking if the participants went to any health  
9  
10 294 clinic/hospital or service provider in the past 3 months to access: condoms, lubricant,  
11  
12 295 contraception, post-exposure prophylaxis, pre-exposure prophylaxis, pregnancy test, sexual  
13  
14 296 and gender-based violence information, sexually transmitted infections testing, or other  
15  
16 297 services. Participants will be provided coupons with UDRMC logo and their study ID to  
17  
18 298 bring to participating clinics when accessing services, so this variable will be assessed by  
19  
20 299 self-report by participant as well as by collecting study coupons that will be attached to a list  
21  
22 300 of services accessed during the study timeframe.  
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26 301 All participants, regardless of study arm, will receive an HIV self-test at the end of the study  
27  
28 302 with accompanying instructions, information and resources to ensure the study arms without  
29  
30 303 access to HIV self-testing are made aware of this approach and can access its benefits.  
31  
32

33 304

### 35 305 **Sample size and power**

36  
37 306 We will recruit 120 refugee youth aged 16-24 years living in Bidi Bidi (60 adolescent girls, 60  
38  
39 307 adolescent boys) in the cluster-randomized trial. The recruited youth will come from four  
40  
41 308 villages in two zones (Zone 3 and Zone 4 annex) within Bidi Bidi, and each village will be  
42  
43 309 randomized to a study arm such that all youth living in the village are clustered to receive the  
44  
45 310 same intervention. Calculated using G\*Power 3.1, a sample size of 105 is sufficient for  
46  
47 311 multivariable regression analyses (effect size: 0.2, power: 0.95, number of tested predictors: 5,  
48  
49 312 critical F: 2.306) [61]. To account for 15% attrition, we have selected a sample size of 120.  
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## 314 **Data collection and management**

315 For the cluster-randomized trial (Phase 2), we will collect sociodemographic characteristics from  
316 participants at time 1, and exposures relevant to sexual and reproductive health and outcome data  
317 at both timepoints (time 1, time 2). Data will be collected using tablet-based structured surveys  
318 conducted by trained research assistants in all study languages. We will collect data using  
319 SurveyCTO (Dobility, Cambridge, USA), which is a secure platform whereby data collected is  
320 automatically encrypted and uploaded to a password-protected server using a Secure Sockets  
321 Layer (SSL) certificate. SurveyCTO allows for data to be collected offline and has branching  
322 logic, consistency checks, and facilitates multi-lingual data collection. No personal identifying  
323 information will be collected with the survey data, all participants will instead be given a unique  
324 participant ID to enhance confidentiality. Only study staff will have access to the dataset for the  
325 purpose of data management and outcome reporting, and all datasets will be saved on a  
326 password-protected server.

## 328 **Data analysis**

329 Analysis and reporting for the cluster-randomized trial (Phase 2) will be conducted in  
330 accordance with CONSORT (Consolidated Standards of Reporting Trials) guidelines [62]. The  
331 analyst will be blinded to group allocation. A flow diagram will be used to illustrate patient flow  
332 (consent/enrolment, randomization, baseline, and follow-up). Baseline data will be reported for  
333 all four arms and summarized as mean and standard deviations or median and interquartile range  
334 for continuous variables and as number and percentage for categorical variables. The primary  
335 analysis will involve intention-to-treat analysis (data from participants will be analyzed  
336 according to their allocation, irrespective of whether they received the intervention). Between-



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3 337 group comparisons will be performed using generalized estimating equations (GEE) logistic or  
4  
5 338 linear regression models – depending on which outcome is being evaluated - using unstructured  
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7 339 correlation matrix and robust standard errors to account for clustering. For these models, the  
8  
9 340 intervention effects across time (from baseline to 3-month follow-up) will be included as the  
10  
11 341 main effects of intervention arm, time, and an arm\*time interaction. The level of significance  
12  
13 342 will be set at  $\alpha=0.05$ . The results will be expressed as odds ratios or mean differences as  
14  
15 343 appropriate, accompanied by 95% confidence intervals and p-values. We will conduct an  
16  
17 344 adjusted analysis for the primary outcome (changes in HIV testing frequency, HIV self-test kit  
18  
19 345 use, HIV status knowledge, changes to linkage to confirmatory HIV testing and to HIV care) to  
20  
21 346 investigate the role of various covariates in the relative effect. Covariates, such as age and  
22  
23 347 gender, will be entered as a block. We will explore gender differences in primary and secondary  
24  
25 348 intervention outcomes. Given the outcomes of this study are related to behavior change and the  
26  
27 349 trial is of a short duration with minimal risks, a data monitoring committee was not deemed  
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29 350 necessary.  
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## 352 **DISCUSSION**

353 This study approach has the potential to inform research, practice, and policy surrounding  
354 measuring the efficacy of new programming and HIV-related testing. Study findings, therefore,  
355 have the potential to not only inform a larger, fully powered randomized controlled trial to test  
356 the effectiveness of an edutainment comic book intervention but can also inform policies on how  
357 strategies such as comic books can be integrated into school health curricula for HIV prevention.  
358 Our findings can also inform research, practice, and policy on HIV/AIDS among youth, to better  
359 meet the needs of refugee adolescents and youth. An edutainment comic book intervention

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3 360 approach holds promise for meaningfully engaging youth and healthcare providers in  
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5 361 humanitarian contexts in dialogue on STI prevention, care, and support.  
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## 9 10 363 **ETHICS AND DISSEMINATION**

### 11 12 364 **Ethical approval**

13  
14 365 Ethical approval for the study was provided through the Mildmay Uganda Research Ethics  
15 366 Committee (REC REF 0802-2021), UNCST (SS884ES), and the University of Toronto Research  
16  
17 367 Ethics Board (37496). This trial is registered at ClinicalTrials.gov (#NCT05213689). The  
18  
19 368 protocol for the study was developed in accordance with the SPIRIT Statement [63,64]. To  
20  
21 369 ensure the protection of human subjects, all participants in Phase 1 and 2 will be provided with  
22  
23 370 enough time to provide written voluntary consent to participate in the study. All informed written  
24  
25 371 consent processes will occur in a private room at a location provided by URDMC. The  
26  
27 372 participant will read the consent form themselves or a peer navigator will read aloud the  
28  
29 373 informed consent in a language comfortable to the participant (English, Bari or Juba Arabic) and  
30  
31 374 will ask if the participant has any questions and will answer their questions. Participants will be  
32  
33 375 asked to sign the consent form or provide a thumbprint to indicate their consent. The consent  
34  
35 376 form will in no way be connected with focus group transcripts or data collected during the  
36  
37 377 cluster-randomized trial and will be destroyed five years after data collection is completed. As  
38  
39 378 Uganda's HIV and AIDS Prevention and Control Act permits youth aged 12 years or above to  
40  
41 379 independently access HIV testing and counselling without parental permission, we received  
42  
43 380 ethics approval to allow youth aged 16-17 years to participate without parental consent; this is a  
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45 381 common approach to reduce barriers to youth participation in sexual and reproductive health  
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47 382 research [65–67].  
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384 **Dissemination plan**

385 We will employ participatory methods for knowledge dissemination, working with youth  
 386 peer navigators to develop strategies such as youth community forums and arts-based methods  
 387 (e.g., comic books) and brief videos. We will make findings available in English, Bari and Juba  
 388 Arabic. Findings will be disseminated through a variety of methods including the preparation of  
 389 community reports (disseminated to the Ugandan National AIDS Program, Ministry of Health,  
 390 and our collaborators [e.g., URDMC]) and peer-reviewed publications (e.g., Journal of the  
 391 International AIDS Society). Irrespective of study findings, results will be published in peer-  
 392 reviewed scientific journals following international authorship guidelines, and will be presented  
 393 to academics and researchers at key scientific conferences.

394

395 **Trial status**

396 The formative qualitative phase of the *Todurujo na Kadurok* (Empowering Youth) study was  
 397 launched in September 2021. The study team has been trained and ethics approval obtained. All  
 398 qualitative activities from phase 1 and the development of the comic book have been completed.  
 399 We anticipate for the intervention to begin in July 2022 along with baseline data collection, and  
 400 the final follow-up survey to be conducted in October 2022. Any important protocol  
 401 modifications will be included as amendments in REB and updated on the ClinicalTrials.gov  
 402 registry, as and when needed. Box 1 details the information on the ClinicalTrials.gov registry.

<b>Box 1. Items from the US National Institutes of Health Trial Registry</b>
<b>Data category information</b>
<b>Primary registry and trial identifying number:</b> ClinicalTrials.gov NCT05213689.
<b>Date of registration:</b> 28 January 2022.

**Source(s) of monetary support:** ViiV Healthcare (Grant#628520-1652450711)  
**Primary sponsor:** University of Toronto.  
**Primary sponsor:** University of Toronto.  
**Contact for public and scientific queries:** Carmen Logie, PhD (carmen.logie@utoronto.ca).  
**Public and scientific title:** HIV Self-Testing and Comic Intervention with Refugee Adolescents and Youth.  
**Countries of recruitment:** Uganda.  
**Health condition(s) or problem(s) studied:** HIV testing, status knowledge, linkage to confirmatory and care.  
**Intervention(s):** HIV self-testing kits and edutainment comic books.

**Key inclusion criteria:** living in one of the four selected villages in Zone 3 and Zone 4 annex in Bidi Bidi; identifying as a refugee or displaced person; aged 16-24 years; and speaking and reading one of the study languages (English, Bari, Juba Arabic).

**Study type:** interventional (clinical trial); cluster-randomized control trial with 4 study arms.  
**Date of first enrolment:** June 2022 (estimate)  
**Target sample size:** 120.

**Primary outcome(s):** HIV testing frequency, HIV status knowledge, linkage to confirmatory HIV testing, linkage to HIV care, HIV self-test kit use.  
**Key secondary outcomes:** HIV-related stigma, HIV knowledge, safer sex efficacy, condom-use, sexual and reproductive health (SRH) stigma, sexual relationship power and access to SRH services.

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**Contributors:** Study design – CHL, MO, IB. Data collection – SOL, ML, MC, IB, LG, NK, MA, CHL, MO. Data management – ML, MC, SOL, NK, CHL. Manuscript writing – MC, ML, CHL. Manuscript editing and critical review – CHL, MO, ML, MC, IB, LG, SOL, NK, MA, PK.

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**Competing interests:** The authors have declared that no competing interests exist.

**Patient and public involvement:** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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3 4244 425 **Patent consent for publication:** Not required.

5 426

6 427 **Provenance and peer review:** Not commissioned; peer reviewed for ethical and funding  
7 428 approval prior to submission.

8 429

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10 431 Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to  
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13 434 given, any changes made indicated, and the use is non-commercial. See:14 435 <http://creativecommons.org/licenses/by-nc/4.0/>.

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649 **Figure Legends:**

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651 **Figure 1: Flowchart of Study Phases and Participant Involvement**

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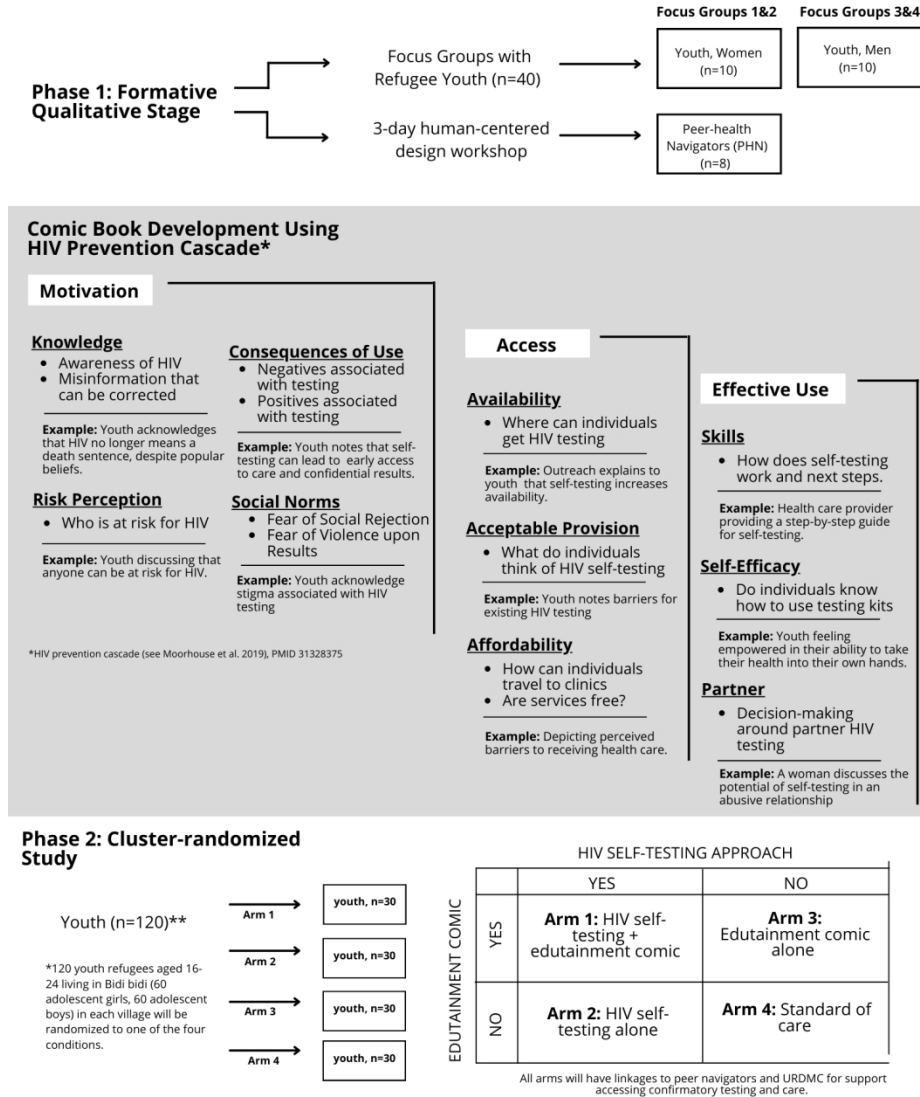


Figure 1: Flowchart of Study Phases and Participant Involvement

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	ItemNo	Description	Page (P); Line (L)
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1; L1-3
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	P2; L59-60
	2b	All items from the World Health Organization Trial Registration Data Set	Box 1
Protocol version	3	Date and version identifier	Box 1
Funding	4	Sources and types of financial, material, and other support	P17; L407-409
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	P17; L403-405
	5b	Name and contact information for the trial sponsor	P1; L29-30
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	P 17; L403-405 & 411
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	P 3-5
	6b	Explanation for choice of comparators	P9; L230-248
Objectives	7	Specific objectives or hypotheses	P5; L135-145

1				
2	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	P6; L147-158
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8	<b>Methods: Participants, interventions, and outcomes</b>			
9				
10	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P6-7; L161-181
11				
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14	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P7; L 188-193
15				
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19	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P9-10; L227-248 (Figure 1)
20				
21				
22		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A; low risk behaviour change intervention
23				
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28		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	P8; L202-205
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32		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A; low risk behaviour change intervention
33				
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38	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P 10-12; L 251-295
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46	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
47				
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50	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P 12-13; L301-307
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55	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	P 8; L197-205
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**Methods: Assignment of interventions (for controlled trials)**

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60**Allocation:**

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	P8; L194-197
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A; interventions cluster-randomized and not blinded
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	P8; L197-198
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	P13; L319-321, 326
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A; low risk behaviour change intervention so unblinding will not occur

**Methods: Data collection, management, and analysis**

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	P 13; L310-321
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P8; L202-205
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P13; L312-321

1				
2	Statistical	20a	Statistical methods for analysing primary and secondary	P 13-14;
3	methods		outcomes. Reference to where other details of the statistical	L324-345
4			analysis plan can be found, if not in the protocol	
5				
6		20b	Methods for any additional analyses (eg, subgroup and adjusted	P 14; L338-
7			analyses)	343
8				
9		20c	Definition of analysis population relating to protocol non-	P 14; L329-
10			adherence (eg, as randomised analysis), and any statistical	334
11			methods to handle missing data (eg, multiple imputation)	
12				
13				
14	<b>Methods: Monitoring</b>			
15				
16	Data	21a	Composition of data monitoring committee (DMC); summary of	P 14; L343-
17	monitoring		its role and reporting structure; statement of whether it is	345
18			independent from the sponsor and competing interests; and	
19			reference to where further details about its charter can be found,	
20			if not in the protocol. Alternatively, an explanation of why a DMC	
21			is not needed	
22				
23				
24		21b	Description of any interim analyses and stopping guidelines,	N/A; low risk
25			including who will have access to these interim results and	behaviour
26			make the final decision to terminate the trial	change
27				intervention
28				for a short
29				duration
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32	Harms	22	Plans for collecting, assessing, reporting, and managing	N/A; low risk
33			solicited and spontaneously reported adverse events and other	behaviour
34			unintended effects of trial interventions or trial conduct	change
35				intervention
36				for a short
37				duration
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40	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and	N/A; low risk
41			whether the process will be independent from investigators and	behaviour
42			the sponsor	change
43				intervention
44				for a short
45				duration
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49	<b>Ethics and dissemination</b>			
50				
51	Research	24	Plans for seeking research ethics committee/institutional review	P 15; L360-
52	ethics approval		board (REC/IRB) approval	362
53				
54	Protocol	25	Plans for communicating important protocol modifications (eg,	P 16; L395-
55	amendments		changes to eligibility criteria, outcomes, analyses) to relevant	397
56			parties (eg, investigators, REC/IRBs, trial participants, trial	
57			registries, journals, regulators)	
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1				
2	Consent or	26a	Who will obtain informed consent or assent from potential trial	P 15-16;
3	assent		participants or authorised surrogates, and how (see Item 32)	L363-377
4				
5		26b	Additional consent provisions for collection and use of	N/A; no
6			participant data and biological specimens in ancillary studies, if	ancillary
7			applicable	studies
8				
9	Confidentiality	27	How personal information about potential and enrolled	P 13; L317-
10			participants will be collected, shared, and maintained in order to	319
11			protect confidentiality before, during, and after the trial	
12				
13				
14	Declaration of	28	Financial and other competing interests for principal	P 17; L413
15	interests		investigators for the overall trial and each study site	
16				
17	Access to data	29	Statement of who will have access to the final trial dataset, and	P13; L319-321
18			disclosure of contractual agreements that limit such access for	
19			investigators	
20				
21	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and for	N/A; low risk
22	post-trial care		compensation to those who suffer harm from trial participation	behaviour
23				change
24				intervention
25				for a short
26				duration
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30	Dissemination	31a	Plans for investigators and sponsor to communicate trial results	P 16; L380-
31	policy		to participants, healthcare professionals, the public, and other	388
32			relevant groups (eg, via publication, reporting in results	
33			databases, or other data sharing arrangements), including any	
34			publication restrictions	
35				
36				
37		31b	Authorship eligibility guidelines and any intended use of	P 16; L386-
38			professional writers	388
39				
40		31c	Plans, if any, for granting public access to the full protocol,	P 17; L424-
41			participant-level dataset, and statistical code	429
42				
43				
44	<b>Appendices</b>			
45	Informed	32	Model consent form and other related documentation given to	Supplementar
46	consent		participants and authorised surrogates	y material
47	materials			
48				
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50	Biological	33	Plans for collection, laboratory evaluation, and storage of	N/A; no
51	specimens		biological specimens for genetic or molecular analysis in the	biological
52			current trial and for future use in ancillary studies, if applicable	specimens
53				collected
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\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT

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# BMJ Open

## Todurujo na Kadurok (Empowering Youth): study design of an HIV self-testing and edutainment comic cluster randomized trial among refugee youth in a humanitarian setting in Uganda

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<b>Primary Subject Heading</b>:	HIV/AIDS
Secondary Subject Heading:	Global health, Public health, Sexual health, Research methods
Keywords:	HIV & AIDS < INFECTIOUS DISEASES, Public health < INFECTIOUS DISEASES, PREVENTIVE MEDICINE, PUBLIC HEALTH

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## 1 Todurujo na Kadurok (Empowering Youth): study design of an HIV self-testing and edutainment comic cluster randomized trial among refugee youth in a humanitarian setting in Uganda

5 Carmen H Logie<sup>1, 2, 3, 4</sup>, Moses Okumu<sup>5</sup>, Miranda Loutet<sup>6</sup>, Madelaine Coelho<sup>4, 7</sup>, Isha Berry<sup>6</sup>,  
6 Lesley Gittings<sup>1, 8</sup>, Simon Odong Lukone<sup>9</sup>, Nelson Kisubi<sup>9</sup>, Malon Atama<sup>10</sup>, Peter  
7 Kyambadde<sup>11, 12</sup>

9 <sup>1</sup>Factor-Inwentash Faculty of Social Work, University of Toronto, Toronto, ON, Canada

10 <sup>2</sup>United Nations University Institute for Water, Environment, and Health, Hamilton, ON, Canada

11 <sup>3</sup>Centre for Gender & Sexual Health Equity, Vancouver, BC, Canada

12 <sup>4</sup>Women's College Research Institute, Women's College Hospital, Toronto, ON, Canada

13 <sup>5</sup>School of Social Work, University of North Carolina Chapel Hill, Chapel Hill, NC, USA

14 <sup>6</sup>Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

15 <sup>7</sup>Department of Sociology, University of Toronto, Toronto, ON, Canada

16 <sup>8</sup>Centre for Social Science Research, University of Cape Town, South Africa

17 <sup>9</sup>Uganda Refugee and Disaster Management Council, Yumbe, Uganda

18 <sup>10</sup>Yumbe General Hospital, Yumbe, Uganda

19 <sup>11</sup>National AIDS Coordinating Program, Ugandan Ministry of Health, Kampala, Uganda

20 <sup>12</sup>Most at Risk Population Initiative (MARPI), Mulago Hospital, Kampala, Uganda

21  
22 Co-authors' ORCID iDs:

23 Carmen H Logie <http://orcid.org/0000-0002-8035-433X>

24 Moses Okumu <https://orcid.org/0000-0003-2555-3077>

25 Miranda Loutet <https://orcid.org/0000-0002-6293-3047>

26 Isha Berry <https://orcid.org/0000-0003-3138-664X>

27 Lesley Gittings <https://orcid.org/0000-0002-0463-0478>

28 Odong Simon Lukone <https://orcid.org/0000-0002-6780-1705>

29 Nelson Kisubi <https://orcid.org/0000-0002-0260-4620>

30 Malon Atama <https://orcid.org/0000-0003-1409-1970>

31 Peter Kymbadde <https://orcid.org/0000-0002-9606-218X>

32  
33 \*Corresponding Author: Dr. Carmen Logie, University of Toronto, Factor-Inwentash Faculty of  
34 Social Work, 246 Bloor St W, Toronto, ON M5S 1V4, [carmen.logie@utoronto.ca](mailto:carmen.logie@utoronto.ca)

## Abstract

**Introduction:** Refugees experience HIV vulnerabilities due to the confluence of displacement, violence, and poverty. HIV self-testing, understudied in refugee settlements, is a promising method to increase testing uptake, yet challenges remain linking persons to confirmatory testing following a positive HIV self-test. This study aims to evaluate the effectiveness of HIV self-testing kits and “edutainment” comics in increasing HIV testing and HIV status knowledge among refugee youth aged 16-24 years in Bidi Bidi Refugee Settlement, Uganda.

**Methods and analysis:** This study will be conducted in Bidi Bidi. We conducted a qualitative formative phase to generate knowledge of contextually-specific barriers and facilitators of HIV prevention, testing and care among refugee youth (aged 16-24) in Bidi Bidi. These findings were then used to create comic scenarios aligning with health promotion edutainment approaches and inform a four-arm cluster randomized controlled trial in Bidi Bidi using a 2 x 2 factorial design: 1) HIV self-testing alongside edutainment comics, 2) HIV self-testing alone, 3) edutainment comic alone, and 4) standard of care. Approximately 120 youth (30 per arm) will be enrolled in the trial and followed for 3 months. Data will be collected at baseline and 3-months after enrolment. The primary outcomes (HIV testing frequency, HIV status knowledge) and secondary outcomes (linkage to confirmatory HIV testing, HIV care linkage, HIV self-test kit use, HIV-related stigma, HIV knowledge, safer sex efficacy, condom use, adolescent sexual and reproductive health stigma, sexual relationship power, SRH service access) will be evaluated using descriptive statistics and regression analyses.

**Ethics and dissemination:** This study has been approved by the University of Toronto Research Ethics Board, the Mildmay Uganda Research Ethics Committee, and the Uganda National Council for Science and Technology. This trial is registered at ClinicalTrials.gov (#NCT05213689). Results will be published in peer-reviewed journals and findings communicated through community forums.

### Strengths and limitations of this study:

- *Todurujo na Kadurok* (Empowering Youth) study is unique in exploring the use of edutainment comic books as a form of graphic medicine in addition to a clinical intervention (HIV self-testing kits) for improving HIV testing uptake and status knowledge among youth living in a humanitarian context in Uganda.
- This study will advance knowledge of HIV self-testing implementation in a refugee settlement context.
- The primary study limitations are potential loss to follow-up.
- This research will produce new information on the potential benefits of low-cost graphic medicine approaches on increasing HIV self-testing benefits among refugee youth, with implications for scaling-up HIV self-testing in humanitarian contexts.

## 80 BACKGROUND

81  
82 HIV vulnerabilities among displaced and refugee adolescents are shaped by a complex interplay  
83 of factors including poverty, violence, host community HIV prevalence, HIV urbanization, HIV  
84 testing and care access, and living conditions [1–3]. There is a dearth of data on HIV prevalence  
85 among refugee and displaced persons [1, 2]. Displaced and refugee populations often do not have  
86 the same access to HIV testing and treatment as host populations, and therefore, the United  
87 Nations has prioritized refugees as a key population for HIV policy and programming [2]. A  
88 systematic review of studies conducted among refugee, migrant and displaced girls and young  
89 women across the African continent found that information regarding STIs and HIV prevalence  
90 among this population is not well characterized, comprehensive HIV and STI knowledge is low,  
91 and access and availability of sexual health services is constrained due to distance, costs and  
92 stigma [3].

93 Uganda is the largest refugee hosting nation in Africa with over 1.4 million refugees in  
94 2020, with more than 240,000 living in Bidi Bidi settlement near the South Sudan border [4].  
95 Youth represent 44.4% of all new HIV infections in Uganda, with most infections sexually  
96 transmitted [5]. HIV prevalence among adolescents and young people in Uganda is 10.8% and is  
97 markedly higher among women (15.4%) compared with men (4.8%)[6]. Less is known of HIV  
98 prevalence, testing and prevention engagement among youth living in refugee settlements in  
99 Uganda, including in Bidi Bidi [7].

100 There is limited inclusion of refugee adolescents and youth in sexual and reproductive  
101 health research and programming [8–10] that may result in a lack of age, gender, culturally  
102 tailored programs, which in turn may contribute to low engagement with HIV testing and  
103 prevention services in humanitarian contexts [11]. Studies conducted among urban refugee youth

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3 104 in Kampala, Uganda have found that inequitable gender norms and intersecting forms of stigma,  
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5 105 including HIV-related stigma and refugee stigma, may also limit HIV testing and prevention  
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7 106 engagement among refugee youth [12–15]. Social network breakdown, poverty and travel  
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9 107 distance to clinics, confidentiality concerns, language barriers and other logistic hurdles may also  
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11 108 present obstacles to HIV testing [16,17].

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14 109 HIV self-testing (HIVST) is a promising approach documented across systematic reviews  
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16 110 to increasing HIV testing access and uptake [18–20]. This approach may mitigate confidentiality  
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18 111 concerns, increase convenience, and reduce the risk of stigmatization, particularly important  
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20 112 considerations for HIV testing with adolescents and youth [21–24]. HIVST involves an  
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22 113 individual collecting their own oral specimen, conducting the test, and interpreting the results  
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24 114 independently with support from pictorial and written instructions. There is also a dearth of  
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26 115 information regarding advances in HIV testing, such as HIV self-testing, among youth in  
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28 116 humanitarian contexts [25], including countries with a high HIV prevalence and large number of  
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30 117 refugees such as Uganda.

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33 118 There remain gaps in linkage to care following a positive HIV self-test when compared  
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35 119 with standard HIV testing services, and addressing these gaps requires innovative approaches  
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37 120 [26]. Innovative approaches can often be population-specific and community-driven, repurposing  
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39 121 tools that are used in other fields of work. Comics—a form of graphic medicine—integrate text  
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41 122 and visual images and are a promising health promotion tool used to address a variety of health  
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43 123 conditions such as HIV, sexually transmitted infections, vaccines, and dementia [27–32].  
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45 124 Edutainment comics have been used to educate both the general population and healthcare  
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47 125 providers [33,34]. Comics align with the entertainment-education (‘edutainment’) approach to  
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49 126 improve health knowledge, attitudes and practices applied in HIV prevention research [35,36]. In  
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3 127 the field of HIV, comics were used in the Undetectables Intervention for antiretroviral therapy  
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5 128 adherence in the United States, PrEP research in the United States, as well as in HIV education  
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8 129 in schools in Kenya that improved students' knowledge about HIV, reduced stigma towards  
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10 130 people living with HIV, and increased likelihood and intention of testing [37–39]. Among  
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12 131 refugees, comics have been used in mental health research in Greece and Lebanon [40,41]. We  
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15 132 did not locate research on HIV testing interventions applying comics in humanitarian settings.

16  
17 133 This cluster randomized trial, *Todurujo na Kadurok* (loosely translated to 'Empowering  
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19 134 Youth' in Bari), aims to conduct an HIV self-testing and edutainment comic intervention and  
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21 135 evaluate its effectiveness in increasing HIV testing and HIV status knowledge among refugee  
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23 136 youth in Bidi Bidi refugee settlement, Uganda. The comic intervention will be theoretically  
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25 137 informed by the HIV prevention cascade [42–44] to address gaps in motivation, access and  
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27 138 effective use identified in formative research. Study findings can inform local and global  
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29 139 responses to increase HIV testing engagement with youth in humanitarian contexts.  
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## 141 **METHODS**

### 142 **Study aims and objectives**

143 The overarching study goal is to evaluate the effectiveness of HIV self-testing, edutainment  
144 comic, or a combination of both interventions on increasing HIV testing, HIV status knowledge  
145 and linkage to confirmatory testing and care among refugee youth aged 16 to 24 years living in  
146 Bidi Bidi refugee settlement, Uganda. The primary objectives are to evaluate the effectiveness of  
147 the interventions on participants (1) HIV status knowledge and (2) HIV testing frequency.  
148 Secondary objectives include examining the impact of the intervention on: (1) HIV self-testing  
149 kit use, (2) linkage to confirmatory HIV testing for those testing positive on the HIVST, and (3)



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3 150 linkage to HIV care for those testing positive, (4) HIV-related stigma, (5) adolescent sexual and  
4  
5 151 reproductive health stigma, (6) HIV knowledge, (7) safer sex efficacy, (8) condom use, (9)  
6  
7 152 sexual relationship power, and (10) access to other sexual and reproductive health services (e.g.,  
8  
9 153 contraception, post-exposure prophylaxis).

## 12 154 **Study Design**

15 155 We are conducting a cluster randomized trial using a 2 x 2 factorial design (see Figure 1) [45].  
16  
17 156 This approach will specifically test the effectiveness of offering: 1) HIV self-testing alongside  
18  
19 157 the edutainment comic, 2) HIV self-testing alone, 3) edutainment comic alone, and 4) standard of  
20  
21 158 care, on defined primary and secondary outcomes. Factorial designs are an appropriate and  
22  
23 159 efficient approach to understand synergies between interventions. As HIV self-testing is an  
24  
25 160 established testing approach that is feasible and acceptable [26,45–47], we are particularly  
26  
27 161 interested to see if the benefits of HIV self-testing with youth in a humanitarian context are  
28  
29 162 increased with accompanying edutainment comics that are theoretically designed to address  
30  
31 163 barriers to testing and care across the HIV cascade. This design can help with identifying  
32  
33 164 effective strategies to reach study aims and in turn can inform intervention design to include the  
34  
35 165 most effective components [48]. Study design and research implementation was in collaboration  
36  
37 166 between the University of Toronto and a refugee agency based in Bidi Bidi called Uganda  
38  
39 167 Refugee and Disaster Management Council (URDMC). Data will be collected from all  
40  
41 168 participants directly before providing the intervention (baseline: time 1), and again at 3-month  
42  
43 169 follow-up (time 2).

## 49 170

## 51 171 **Study setting**

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2  
3 172 This trial will be conducted in four villages located in two zones in Bidi Bidi Refugee Settlement  
4  
5 173 within the Yumbe district in Northwestern Uganda. With over 245,000 refugees largely (99.9%)  
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7  
8 174 from South Sudan, Bidi Bidi is the world's second-largest refugee settlement with one-quarter of  
9  
10 175 the population (25%; n=61,036) youth aged 15 to 24 years [49]. In Bidi Bidi, health centers offer  
11  
12 176 free regular testing for HIV and comprehensive HIV care services including adult and pediatric  
13  
14 177 antiretroviral therapy (ART) and cotrimoxazole prophylaxis. However, only a few facilities in  
15  
16 178 the settlement offer comprehensive HIV care such as Prevention of Mother to Child  
17  
18 179 Transmission (PMTCT) services. Moreover, there are reported challenges including lack of  
19  
20 180 facility accreditation to offer HIV care, drug and test kits stock out and poor adherence to ART  
21  
22 181 by the refugees [50,51].  
23  
24  
25

26 182 The clinical trial study setting includes two villages in Zone 3, with more than 58,000  
27  
28 183 residents, and two villages in Zone 4 annex, with more than 52,000 residents [49]. To ensure  
29  
30 184 anonymity of participants, the village numbers are not included in this protocol. The zones and  
31  
32 185 villages were selected due to large geographical separation to avoid contamination of  
33  
34 186 intervention arms, eagerness of youth in these areas to learn more about HIV testing, and to fill a  
35  
36 187 void of HIV research in these particular areas. In Zone 3 there are the following participating  
37  
38 188 health centres: Jomorogo Health Centre 3, Kongbe Health Centre 3, Yoyo Health Centre 3,  
39  
40 189 Luzira Health Centre 3. In Zone 4 annex the following health centres will participate: Igamara  
41  
42 190 Health Centre 3, Bolomoni Health Centre 3, Bangatuti Health Centre, and Kulikulinga  
43  
44 191 Government Centre. All participants will be able to access these health centres throughout the  
45  
46 192 study for HIV testing and treatment.  
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## 194 **Participants and recruitment**

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3 195 We will use convenience sampling methods, including peer driven recruitment supported by  
4  
5 196 collaborators at URDMC and eight peer navigators. Peer navigators are self-identified young  
6  
7 197 refugees aged 20-24 years living in Bidi Bidi, specifically Zone 3 and Zone 4 annex, who  
8  
9 198 received training from the study team in research methods and confidentiality and are supervised  
10  
11 199 by URDMC. Inclusion criteria for participants in the *Todurujo na Kadurok* study include: (1)  
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13 200 living in one of the four selected villages in Zone 3 and Zone 4 annex in Bidi Bidi; (2)  
14  
15 201 identifying as a refugee or displaced person; (3) aged 16-24 years; and (4) speaking and reading  
16  
17 202 one of the study languages (English, Bari, Juba Arabic).  
18  
19  
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21 203 For the cluster randomized controlled trial, participants will be randomized by the village  
22  
23 204 they live in. URDMC and peer navigators will recruit a total of 120 participants, with 30  
24  
25 205 participants in each of the four arms. The arms will be geographically separated into four  
26  
27 206 different villages from two zones to avoid contamination of the intervention effects. The villages  
28  
29 207 will be randomly assigned to a study arm. Youth will be approached by peer navigators and  
30  
31 208 study staff at URDMC to be recruited to the study. At the baseline visit (time 1) the youth will be  
32  
33 209 provided a written consent form, which will be available in English, Bari and Juba Arabic. Once  
34  
35 210 the youth have provided informed written consent they will be enrolled into the study, assigned  
36  
37 211 to a study arm based on the village that they live in, and baseline data will be collected by a  
38  
39 212 URDMC research assistant. Peer navigators will use multiple study reminder strategies (e.g.,  
40  
41 213 texts, private messages over social media) to maintain engagement until the follow-up visit at 3-  
42  
43 214 months after enrolment. These efforts will be supplemented with existing outreach services to  
44  
45 215 youth by URDMC.  
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## 52 53 217 **Patient and public involvement**

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3 218 This study protocol was developed after a formative qualitative research phase. As depicted in  
4  
5 219 Figure 1, this formative research in Phase 1 included four focus groups conducted by two  
6  
7 220 URDMC research assistants (2 with young women, 2 with young men) with refugee youth in  
8  
9 221 Bidi Bidi (n=10 in each focus group; n=40 in total) aged 16-24 years to collect information on  
10  
11 222 knowledge of current HIV testing opportunities and experiences in Bidi Bidi and perspectives on  
12  
13 223 HIV self-testing. HIV prevention cascade conceptual frameworks were used by analysts at the  
14  
15 224 University of Toronto in the analysis of the qualitative data to inform the study to address gaps in  
16  
17 225 linkage to care following HIV self-testing [42,43]. Three key domains of the HIV prevention  
18  
19 226 cascade include motivation, access, and effective use, and these dimensions can be tailored to  
20  
21 227 identify population specific needs [43,44]. For instance, Moorhouse et al. applied the HIV  
22  
23 228 prevention cascade framework to develop community-based HIV prevention interventions and  
24  
25 229 noted dimensions of *motivation* (knowledge, risk perception, consequence of use, social norms),  
26  
27 230 *access* (availability, acceptable provision, affordability), and *effective use* (skills, self-efficacy,  
28  
29 231 partner) [42]. These qualitative findings were used to identify key themes for the development of  
30  
31 232 the edutainment comics (see Table 1); in this way the study responds to the health needs and  
32  
33 233 priorities of refugee youth in this humanitarian context.

34  
35 234 These focus groups were followed by a 3-day human-centered design workshop led by  
36  
37 235 URDMC research managers who engaged eight peer navigators to adapt and develop HIV self-  
38  
39 236 testing edutainment materials to enhance cultural, gender, age, and contextual relevance (see  
40  
41 237 Figure 1). The study was designed and will be conducted as a collaboration with local  
42  
43 238 physicians, clinics, and the implementing partner is a refugee agency based in Bidi Bidi. These  
44  
45 239 study collaborators have been involved since the study inception and will lead implementation.  
46  
47 240 Peer navigators (n=8) who share the participants' refugee lived experiences, and include youth  
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241 living with HIV, have meaningfully contributed to the study design through the human centered  
 242 design workshops, feedback into edutainment comic development, pilot testing of study tools,  
 243 and will support implementation of the cluster randomized controlled trial through actively  
 244 contributing to participant recruitment, engagement, and retention.

245 **Table 1.** Scenarios on the HIV prevention cascade included in the edutainment comic

Domain of prevention cascade	Stage of the prevention cascade	Description
Motivation	Risk perception	Discussion explores perceived risk for HIV and a) misinformation (e.g., sharing body lotion is not as an HIV risk factor) and b) provides information about condom breakage and post-exposure prophylaxis.
	Consequence of use	Discussion between healthcare provider and youth of how to manage a positive HIV test result, including the ability to manage confidentiality and access support services.
	Social norms	Discussion of experiences of HIV stigma and discrimination, as well as an example of receiving support from a friend.
	Knowledge	Discussion of knowledge as power, including benefits of knowing one's HIV positive and HIV negative serostatus.
Access	Access and availability	Parallel conversations between youth around testing barriers, including travel costs, and stockouts of HIV testing kits, with a discussion of locations for testing and support in Bidi Bidi.
	Acceptable provision	Discussions of a) the possibility of receiving an HIV test while accessing other health services such as contraception and condoms; b) accessing HIV testing from a healthcare provider of a different gender; c) feeling empowered to find a doctor one feels comfortable talking with about sexual health
Effective use	Partner	Discussion of HIV testing with partner to assess partner perspectives on HIV testing and evaluate concerns (e.g., negative partner reaction, violence, consequence of positive test result). Healthcare provider discussion of partner testing with a couple, including possible sero-discordant results. Decision making considerations for engaging in partner testing, including motivations (empowerment, support, open communication, stronger relationship) and barriers (loss of trust, violence, conflict, break up).
	Skills	Discussion of disclosure process and decision making regarding who to disclose an HIV positive test result with.
	Self-efficacy	Discussion of how knowledge of HIV testing benefits, HIV positive serostatus, and available resources increase empowerment to take care of oneself and support others.

246

## 247 **Intervention description**

248 *Todurujo na Kadurok* is a 2 x 2 factorial cluster randomized trial, with clusters randomized to  
249 one of the following four arms: (1) HIV self-testing and edutainment comic, (2) HIV self-testing  
250 only, (3) edutainment comic only, and (4) standard of care.

251 Participants in the HIV self-testing arms (arm 1; arm 2) will each receive two HIV self-  
252 testing kits (OraQuick Rapid HIV-1/2 Antibody Test, OraSure Technologies) at baseline along  
253 with verbal, written and visual instructions (in their choice of study language), as well as  
254 linkages to peer navigators and URDMC for support accessing confirmatory testing and care.

255 Participants in the edutainment comic arms (arm 1; arm 3) will receive a hard copy of the  
256 edutainment comic at baseline. They will meet with the peer navigator to review and discuss the  
257 comic themes and will be provided with a blank version to complete on their own. This approach  
258 to edutainment comics provides a participatory component whereby participants can  
259 contextualize the comic themes within their own lives and experiences [52]. In addition to the  
260 comic, the participants in arm 1 and 3 will also have linkages to peer navigators and URDMC for  
261 support accessing confirmatory testing and care.

262 Participants in the standard of care arm (arm 4) will receive verbal and written  
263 information and resources about HIV testing, care, and support services in Bidi Bidi and Yumbe  
264 Hospital from their peer navigator as well as contact information for URDMC and an overview  
265 of their programs offered. The existing standard of HIV care in Bidi Bidi is offered through  
266 clinics located in Bidi Bidi settlement and the hospital in Yumbe and includes pre- and post-test  
267 counselling for HIV, follow-up visits for HIV care in the community, intensive treatment  
268 adherence counselling for immunosuppressed and non-immunosuppressed patients in the  
269 community and facility, and community drug re-fills for people living with HIV.

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3 270  
45 271 **Outcomes**6  
7  
8 272 The primary outcomes measured in this trial will be:

- 9
- 10 273 1. Changes in HIV testing frequency: This is measured as participants' self-reported last HIV
- 11
- 12 274 test. To capture changes, this measure is assessed at both study time points (baseline [Time
- 13
- 14 275 1], 3 months [Time 2]).
- 15
- 16 276 2. Changes in HIV status knowledge: At the final 3-month visit, a clinician supported by trained
- 17
- 18 277 peer navigators will offer all participants a completely voluntary rapid point-of-care HIV test
- 19
- 20 278 (Alere Determine HIV-1/2) to measure HIV status knowledge. HIV status knowledge will be
- 21
- 22 279 assessed as correct for participants that agree to take the rapid test and correctly report their
- 23
- 24 280 HIV status before receiving the result.
- 25
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- 27

28 281 The secondary outcomes include:

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- 30 282 1. Changes in linkage to confirmatory HIV testing: Participants in arm 1 and arm 2 (e.g., those
- 31
- 32 283 given a HIVST) will be asked at Time 2 if they used their HIV self-test kit. All participants
- 33
- 34 284 who report using the test will be asked the result, and participants who self-report a positive
- 35
- 36 285 result will be asked if they received confirmatory testing, and if so, where they received the
- 37
- 38 286 test. Participants will also be provided study coupons (with only the name of the UDRMC
- 39
- 40 287 and their study ID#) that they can provide when receiving HIV or other sexual and
- 41
- 42 288 reproductive health services at collaborating health clinics; this clinic engagement will be
- 43
- 44 289 linked to the participant study ID#.
- 45
- 46 290 2. Changes in linkage to HIV care: At Time 2, participants who seroconvert in the study will be
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- 48 291 asked if they received HIV care, including ART and counseling, since receiving an HIV-
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- 50 292 positive diagnosis.
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3 293 3. HIV self-test kit use: In order to understand the use of HIV self-test kits and to reduce social  
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5 294 desirability bias, one month after Time 2 the participants in arm 1 and arm 2 will be asked if  
6  
7 295 they have unused test kits. They will be informed this information is just to guide future  
8  
9 296 trials.
- 10  
11  
12 297 4. HIV-related stigma, assessed with the Reinius et al., 2017 12-item short HIV stigma  
13  
14 298 assessment [53] including vicarious and felt-normative HIV stigma dimensions through an  
15  
16 299 internalized AIDS-related scale from Kalichman et al. 2020 [54,55].
- 17  
18  
19 300 5. HIV knowledge assessed with the HIV knowledge questionnaire by Carey & Schroder [56].  
20  
21 301 6. Safer sex efficacy using the Condom Use Self-Efficacy Scale [57,58].  
22  
23  
24 302 7. Condom use in past 3 -months (condom use at last sex; condom use at sex every time in last  
25  
26 303 3 months [dichotomous: yes/no]).
- 27  
28  
29 304 8. Adolescent sexual and reproductive health stigma, assessed with the Ugandan Adolescent  
30  
31 305 Sexual and Reproductive Health (SRH) Stigma scale (Logie et al. 2019) adapted from Hall et  
32  
33 306 al.'s Adolescent SRH Stigma scale [59]
- 34  
35 307 9. Sexual relationship power (SRP) using the Relationship Control Sub-Scale from the Sexual  
36  
37 308 & Relationship Power Scale [60]
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40 309 10. Access to other SRH services will be assessed by asking if the participants went to any health  
41  
42 310 clinic/hospital or service provider in the past 3 months to access: condoms, lubricant,  
43  
44 311 contraception, post-exposure prophylaxis, pre-exposure prophylaxis, pregnancy test, sexual  
45  
46 312 and gender-based violence information, sexually transmitted infections testing, or other  
47  
48 313 services. Participants will be provided coupons with UDRMC logo and their study ID to  
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50 314 bring to participating clinics when accessing services, so this variable will be assessed by  
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3 315 self-report by participant as well as by collecting study coupons that will be attached to a list  
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5 316 of services accessed during the study timeframe.  
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8 317 All participants, regardless of study arm, will receive an HIV self-test at the end of the study  
9  
10 318 with accompanying instructions, information and resources to ensure the study arms without  
11  
12 319 access to HIV self-testing are made aware of this approach and can access its benefits.  
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15 320

### 17 321 **Sample size and power**

18  
19 322 We will recruit 120 refugee youth aged 16-24 years living in Bidi Bidi (60 adolescent girls, 60  
20  
21 323 adolescent boys) in the cluster randomized trial. The recruited youth will come from four  
22  
23 324 villages in two zones (Zone 3 and Zone 4 annex) within Bidi Bidi, and each village will be  
24  
25 325 randomized to a study arm such that all youth living in the village are clustered to receive the  
26  
27 326 same intervention. Calculated using G\*Power 3.1, a sample size of 105 is sufficient for  
28  
29 327 multivariable regression analyses (effect size: 0.2, power: 0.95, number of tested predictors: 5,  
30  
31 328 critical F: 2.306) [61]. To account for 15% attrition, we have selected a sample size of 120.  
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35 329

### 38 330 **Data collection and management**

39  
40 331 For the cluster randomized trial, we will collect sociodemographic characteristics from  
41  
42 332 participants at time 1, and exposures relevant to sexual and reproductive health and outcome data  
43  
44 333 at both timepoints (time 1, time 2). Data will be collected using tablet-based structured surveys  
45  
46 334 conducted by trained URDMC research assistants in all study languages. Data will be collected  
47  
48 335 using SurveyCTO (Dobility, Cambridge, USA), which is a secure platform whereby data  
49  
50 336 collected is automatically encrypted and uploaded to a password-protected server using a Secure  
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52 337 Sockets Layer (SSL) certificate. SurveyCTO allows for data to be collected offline and has  
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3 338 branching logic, consistency checks, and facilitates multi-lingual data collection. No personal  
4  
5 339 identifying information will be collected with the survey data, all participants will instead be  
6  
7 340 given a unique participant ID to enhance confidentiality. Only study staff at URDMC and  
8  
9 341 University of Toronto will have access to the dataset for the purpose of data management and  
10  
11 342 outcome reporting, and all datasets will be saved on a password-protected server.  
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15 343

### 16 17 344 **Data analysis**

18  
19 345 Analysis and reporting for the cluster randomized trial will be conducted in accordance  
20  
21 346 with CONSORT (Consolidated Standards of Reporting Trials) guidelines [62]. The analyst at the  
22  
23 347 University of Toronto will be blinded to group allocation. A flow diagram will be used to  
24  
25 348 illustrate patient flow (consent/enrolment, randomization, baseline, and follow-up). Baseline data  
26  
27 349 will be reported for all four arms and summarized as mean and standard deviations or median  
28  
29 350 and interquartile range for continuous variables and as number and percentage for categorical  
30  
31 351 variables. The primary analysis will involve intention-to-treat analysis (data from participants  
32  
33 352 will be analyzed according to their allocation, irrespective of whether they received the  
34  
35 353 intervention). Between-group comparisons will be performed using generalized estimating  
36  
37 354 equations (GEE) logistic or linear regression models – depending on which outcome is being  
38  
39 355 evaluated - using unstructured correlation matrix and robust standard errors to account for  
40  
41 356 clustering. For these models, the intervention effects across time (from baseline to 3-month  
42  
43 357 follow-up) will be included as the main effects of intervention arm, time, and an arm\*time  
44  
45 358 interaction. The level of significance will be set at  $\alpha=0.05$ . The results will be expressed as  
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47 359 odds ratios or mean differences as appropriate, accompanied by 95% confidence intervals and p-  
48  
49 360 values. We will conduct an adjusted analysis for the primary outcome (changes in HIV testing  
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3 361 frequency, HIV self-test kit use, HIV status knowledge, changes to linkage to confirmatory HIV  
4  
5 362 testing and to HIV care) to investigate the role of various covariates in the relative effect.  
6  
7 363 Covariates, such as age and gender, will be entered as a block. We will explore gender  
8  
9 364 differences in primary and secondary intervention outcomes. Given the outcomes of this study  
10  
11 365 are related to behavior change and the trial is of a short duration with minimal risks, a data  
12  
13 366 monitoring committee was not deemed necessary.  
14  
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17 367

## 18 19 368 **DISCUSSION**

20  
21 369 This study approach has the potential to inform research, practice, and policy surrounding  
22  
23 370 measuring the efficacy of new programming and HIV-related testing. Study findings, therefore,  
24  
25 371 have the potential to not only inform a larger, fully powered randomized controlled trial to test  
26  
27 372 the effectiveness of an edutainment comic book intervention but can also inform policies on how  
28  
29 373 strategies such as comic books can be integrated into school health curricula for HIV prevention.  
30  
31 374 Our findings can also inform research, practice, and policy on HIV/AIDS among youth, to better  
32  
33 375 meet the needs of refugee adolescents and youth. An edutainment comic book intervention  
34  
35 376 approach holds promise for meaningfully engaging youth and healthcare providers in  
36  
37 377 humanitarian contexts in dialogue on STI prevention, care, and support.  
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### 43 44 379 **Strengths and limitations of this study**

45  
46 380 The Todurujo na Kadurok cluster randomized trial is unique in exploring HIV self-testing  
47  
48 381 feasibility and uptake among youth living in a large refugee settlement using innovative  
49  
50 382 community-based health promotion activities. The study design will allow us to assess if HIV  
51  
52 383 self-testing along, edutainment comics or HIV self-testing alongside the edutainment comics  
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3 384 increase HIV testing frequency and status knowledge compared to standard of care. By  
4  
5 385 clustering the interventions to areas within Bidi Bidi Refugee Settlement we aim to mitigate  
6  
7 386 threats to internal validity and contamination of the intervention effects. The study is subject to  
8  
9  
10 387 limitations commonly incurred by prospective longitudinal studies – loss to follow-up and  
11  
12 388 missing data. However, we will mitigate these limitations by using peer navigators to recruit and  
13  
14 389 follow-up on participants in the community, and will also conduct digital questionnaires on  
15  
16 390 tablets that are programmed to flag missing data.  
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## 392 **ETHICS AND DISSEMINATION**

### 393 **Ethical approval**

394 Ethical approval for the study was provided through the Mildmay Uganda Research  
395 Ethics Committee (REC REF 0802-2021), UNCST (SS884ES), and the University of Toronto  
396 Research Ethics Board (37496). This trial is registered at ClinicalTrials.gov (#NCT05213689).  
397 The protocol for the study was developed in accordance with the SPIRIT Statement [63,64]. To  
398 ensure the protection of human subjects, all participants in the formative phase and the cluster  
399 randomized controlled trial will be provided with enough time to provide written voluntary  
400 consent to participate in the study. All informed written consent processes will occur in a private  
401 room at a location provided by URDMC. The participant will read the consent form themselves  
402 or a peer navigator will read aloud the informed consent in a language comfortable to the  
403 participant (English, Bari or Juba Arabic) and will ask if the participant has any questions and  
404 will answer their questions. Participants will be asked to sign the consent form or provide a  
405 thumbprint to indicate their consent. The consent form will in no way be connected with focus  
406 group transcripts or data collected during the cluster randomized trial and will be destroyed five

1  
2  
3 407 years after data collection is completed. As Uganda's HIV and AIDS Prevention and Control Act  
4  
5 408 permits youth aged 12 years or above to independently access HIV testing and counselling  
6  
7 409 without parental permission, we received ethics approval to allow youth aged 16-17 years to  
8  
9 410 participate without parental consent; this is a common approach to reduce barriers to youth  
10  
11 411 participation in sexual and reproductive health research [65–67].  
12  
13

14 412 Emotional risks include that participants may feel uncomfortable, anxious, or upset  
15  
16 413 taking an HIV test, stigma due to accidental disclosure of HIV serostatus, psychosocial harm as a  
17  
18 414 result of learning HIV status, discussing HIV, STI, sexual risk factors, and social capital. The  
19  
20 415 study has been designed to minimize psychological/emotional risks of feeling uncomfortable,  
21  
22 416 anxious, or upset with study questions and topics of discussion through wellbeing-focussed  
23  
24 417 training for data collectors. URDMC will also collaborate with a local psychological aid  
25  
26 418 organization to support peer navigators and participants during any mental distress. Moreover,  
27  
28 419 we will ensure the confidentiality of all participants by not collecting identifying information  
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30  
31 420 (i.e., no full names, no date of birth).  
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35 421

## 36 422 **Dissemination plan**

37  
38 423 We will employ participatory methods for knowledge dissemination, working with youth  
39  
40 424 peer navigators to develop strategies such as youth community forums and arts-based methods  
41  
42 425 (e.g., comic books) and brief videos. We will make findings available in English, Bari and Juba  
43  
44 426 Arabic. Findings will be disseminated through a variety of methods including the preparation of  
45  
46 427 community reports (disseminated to the Ugandan National AIDS Program, Ministry of Health,  
47  
48 428 and our collaborators [e.g., URDMC]) and peer-reviewed publications (e.g., Journal of the  
49  
50 429 International AIDS Society). Irrespective of study findings, results will be published in peer-  
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430 reviewed scientific journals following international authorship guidelines, and will be presented  
 431 to academics and researchers at key scientific conferences.

432

### 433 **Trial status**

434 The formative qualitative phase of the *Todurujo na Kadurok* (Empowering Youth) study was  
 435 launched in September 2021. The study team has been trained and ethics approval obtained. All  
 436 qualitative activities from phase 1 and the development of the comic book have been completed.  
 437 We anticipate for the intervention to begin in Fall 2022 along with baseline data collection, and  
 438 the final follow-up survey to be conducted 3-months later in late 2022. Any important protocol  
 439 modifications will be included as amendments in REB and updated on the ClinicalTrials.gov  
 440 registry, as and when needed. Box 1 details the information on the ClinicalTrials.gov registry.

#### **Box 1. Items from the US National Institutes of Health Trial Registry**

##### **Data category information**

**Primary registry and trial identifying number:** ClinicalTrials.gov NCT05213689.

**Date of registration:** 28 January 2022.

**Source(s) of monetary support:** ViiV Healthcare (Grant#628520-1652450711)

**Primary sponsor:** University of Toronto.

**Primary sponsor:** University of Toronto.

**Contact for public and scientific queries:** Carmen Logie, PhD (carmen.logie@utoronto.ca).

**Public and scientific title:** HIV Self-Testing and Comic Intervention with Refugee Adolescents and Youth.

**Countries of recruitment:** Uganda.

**Health condition(s) or problem(s) studied:** HIV testing, status knowledge, linkage to confirmatory and care.

**Intervention(s):** HIV self-testing kits and edutainment comic books.

**Key inclusion criteria:** living in one of the four selected villages in Zone 3 and Zone 4 annex in Bidi Bidi; identifying as a refugee or displaced person; aged 16-24 years; and speaking and reading one of the study languages (English, Bari, Juba Arabic).

**Study type:** interventional (clinical trial); cluster randomized control trial with 4 study arms.

**Date of first enrolment:** June 2022 (estimate)

**Target sample size:** 120.

**Primary outcome(s):** HIV testing frequency, HIV status knowledge, linkage to confirmatory HIV testing, linkage to HIV care, HIV self-test kit use.

**Key secondary outcomes:** HIV-related stigma, HIV knowledge, safer sex efficacy, condom-use, sexual and reproductive health (SRH) stigma, sexual relationship power and access to SRH services.

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**Contributors:** Study design – CHL, MO, IB. Data collection – SOL, ML, MC, IB, LG, NK, MA, CHL, MO. Data management – ML, MC, SOL, NK, CHL. Manuscript writing – MC, ML, CHL. Manuscript editing and critical review – CHL, MO, ML, MC, IB, LG, SOL, NK, MA, PK.

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**Patient and public involvement:** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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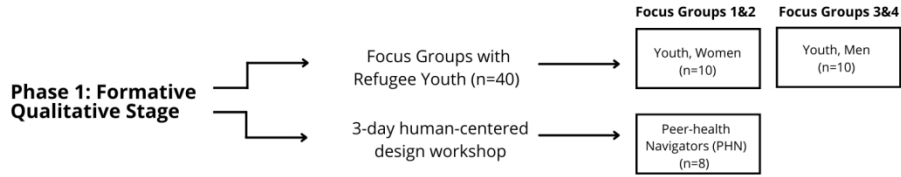
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3 684 **Figure Legends:**

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5 686 **Figure 1: Flowchart of Study Phases and Participant Involvement**

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For peer review only



### Comic Book Development Using HIV Prevention Cascade\*

**Motivation**

**Knowledge**

- Awareness of HIV
- Misinformation that can be corrected

**Example:** Youth acknowledges that HIV no longer means a death sentence, despite popular beliefs.

**Risk Perception**

- Who is at risk for HIV

**Example:** Youth discussing that anyone can be at risk for HIV.

**Consequences of Use**

- Negatives associated with testing
- Positives associated with testing

**Example:** Youth notes that self-testing can lead to early access to care and confidential results.

**Social Norms**

- Fear of Social Rejection
- Fear of Violence upon Results

**Example:** Youth acknowledge stigma associated with HIV testing

**Access**

**Availability**

- Where can individuals get HIV testing

**Example:** Outreach explains to youth that self-testing increases availability.

**Acceptable Provision**

- What do individuals think of HIV self-testing

**Example:** Youth notes barriers for existing HIV testing

**Affordability**

- How can individuals travel to clinics
- Are services free?

**Example:** Depicting perceived barriers to receiving health care.

**Effective Use**

**Skills**

- How does self-testing work and next steps.

**Example:** Health care provider providing a step-by-step guide for self-testing.

**Self-Efficacy**

- Do individuals know how to use testing kits

**Example:** Youth feeling empowered in their ability to take their health into their own hands.

**Partner**

- Decision-making around partner HIV testing

**Example:** A woman discusses the potential of self-testing in an abusive relationship

\*HIV prevention cascade (see Moorhouse et al. 2019), PMID 31328375

**Phase 2: Cluster-randomized Study**

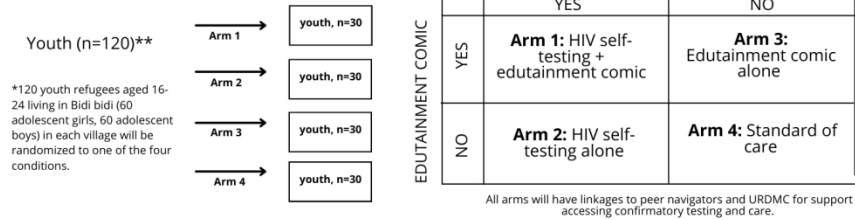


Figure 1: Flowchart of Study Phases and Participant Involvement

545x705mm (72 x 72 DPI)



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	ItemNo	Description	Page (P); Line (L)
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1; L1-3
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	P2; L59-60
	2b	All items from the World Health Organization Trial Registration Data Set	Box 1
Protocol version	3	Date and version identifier	Box 1
Funding	4	Sources and types of financial, material, and other support	P17; L407-409
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	P17; L403-405
	5b	Name and contact information for the trial sponsor	P1; L29-30
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	P 17; L403-405 & 411
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	P 3-5
	6b	Explanation for choice of comparators	P9; L230-248
Objectives	7	Specific objectives or hypotheses	P5; L135-145

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2	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	P6; L147-158
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8	<b>Methods: Participants, interventions, and outcomes</b>			
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10	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P6-7; L161-181
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14	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P7; L 188-193
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19	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P9-10; L227-248 (Figure 1)
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22		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A; low risk behaviour change intervention
23				
24				
25				
26				
27				
28		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	P8; L202-205
29				
30				
31				
32		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A; low risk behaviour change intervention
33				
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38	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P 10-12; L 251-295
39				
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46	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
47				
48				
49				
50	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P 12-13; L301-307
51				
52				
53				
54				
55	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	P 8; L197-205
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57				

58 **Methods: Assignment of interventions (for controlled trials)**

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60



## Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	P8; L194-197
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A; interventions cluster-randomized and not blinded
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	P8; L197-198
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	P13; L319-321, 326
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A; low risk behaviour change intervention so unblinding will not occur

**Methods: Data collection, management, and analysis**

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	P 13; L310-321
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P8; L202-205
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P13; L312-321

1				
2	Statistical	20a	Statistical methods for analysing primary and secondary	P 13-14;
3	methods		outcomes. Reference to where other details of the statistical	L324-345
4			analysis plan can be found, if not in the protocol	
5				
6		20b	Methods for any additional analyses (eg, subgroup and adjusted	P 14; L338-
7			analyses)	343
8				
9		20c	Definition of analysis population relating to protocol non-	P 14; L329-
10			adherence (eg, as randomised analysis), and any statistical	334
11			methods to handle missing data (eg, multiple imputation)	
12				
13				
14	<b>Methods: Monitoring</b>			
15				
16	Data	21a	Composition of data monitoring committee (DMC); summary of	P 14; L343-
17	monitoring		its role and reporting structure; statement of whether it is	345
18			independent from the sponsor and competing interests; and	
19			reference to where further details about its charter can be found,	
20			if not in the protocol. Alternatively, an explanation of why a DMC	
21			is not needed	
22				
23				
24		21b	Description of any interim analyses and stopping guidelines,	N/A; low risk
25			including who will have access to these interim results and	behaviour
26			make the final decision to terminate the trial	change
27				intervention
28				for a short
29				duration
30				
31				
32	Harms	22	Plans for collecting, assessing, reporting, and managing	N/A; low risk
33			solicited and spontaneously reported adverse events and other	behaviour
34			unintended effects of trial interventions or trial conduct	change
35				intervention
36				for a short
37				duration
38				
39				
40	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and	N/A; low risk
41			whether the process will be independent from investigators and	behaviour
42			the sponsor	change
43				intervention
44				for a short
45				duration
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49	<b>Ethics and dissemination</b>			
50				
51	Research	24	Plans for seeking research ethics committee/institutional review	P 15; L360-
52	ethics approval		board (REC/IRB) approval	362
53				
54	Protocol	25	Plans for communicating important protocol modifications (eg,	P 16; L395-
55	amendments		changes to eligibility criteria, outcomes, analyses) to relevant	397
56			parties (eg, investigators, REC/IRBs, trial participants, trial	
57			registries, journals, regulators)	
58				
59				
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1				
2	Consent or	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P 15-16; L363-377
3	assent			
4				
5		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A; no ancillary studies
6				
7				
8				
9	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	P 13; L317-319
10				
11				
12				
13				
14	Declaration of	28	Financial and other competing interests for principal investigators for the overall trial and each study site	P 17; L413
15	interests			
16				
17	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	P13; L319-321
18				
19				
20				
21	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A; low risk behaviour change intervention for a short duration
22	post-trial care			
23				
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30	Dissemination	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P 16; L380-388
31	policy			
32				
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37		31b	Authorship eligibility guidelines and any intended use of professional writers	P 16; L386-388
38				
39				
40		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P 17; L424-429
41				
42				
43				
44	<b>Appendices</b>			
45	Informed	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary material
46	consent			
47	materials			
48				
49				
50	Biological	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A; no biological specimens collected
51	specimens			
52				
53				
54				

\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT

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# BMJ Open

## Todurujo na Kadurok (Empowering Youth): study protocol of an HIV self-testing and edutainment comic cluster randomized trial among refugee youth in a humanitarian setting in Uganda

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Manuscripts

# **Todurujo na Kadurok (Empowering Youth): study protocol of an HIV self-testing and edutainment comic cluster randomized trial among refugee youth in a humanitarian setting in Uganda**

Carmen H Logie<sup>1,2,3,4</sup>, Moses Okumu<sup>5</sup>, Miranda Loutet<sup>6</sup>, Madelaine Coelho<sup>4,7</sup>, Isha Berry<sup>6</sup>, Lesley Gittings<sup>1,8</sup>, Simon Odong Lukone<sup>9</sup>, Nelson Kisubi<sup>9</sup>, Malon Atama<sup>10</sup>, Peter Kyambadde<sup>11,12</sup>

<sup>1</sup>Factor-Inwentash Faculty of Social Work, University of Toronto, Toronto, ON, Canada

<sup>2</sup>United Nations University Institute for Water, Environment, and Health, Hamilton, ON, Canada

<sup>3</sup>Centre for Gender & Sexual Health Equity, Vancouver, BC, Canada

<sup>4</sup>Women's College Research Institute, Women's College Hospital, Toronto, ON, Canada

<sup>5</sup>School of Social Work, University of North Carolina Chapel Hill, Chapel Hill, NC, USA

<sup>6</sup>Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

<sup>7</sup>Department of Sociology, University of Toronto, Toronto, ON, Canada

<sup>8</sup>Centre for Social Science Research, University of Cape Town, South Africa

<sup>9</sup>Uganda Refugee and Disaster Management Council, Yumbe, Uganda

<sup>10</sup>Yumbe General Hospital, Yumbe, Uganda

<sup>11</sup>National AIDS Coordinating Program, Ugandan Ministry of Health, Kampala, Uganda

<sup>12</sup>Most at Risk Population Initiative (MARPI), Mulago Hospital, Kampala, Uganda

Co-authors' ORCID iDs:

Carmen H Logie <http://orcid.org/0000-0002-8035-433X>

Moses Okumu <https://orcid.org/0000-0003-2555-3077>

Miranda Loutet <https://orcid.org/0000-0002-6293-3047>

Isha Berry <https://orcid.org/0000-0003-3138-664X>

Lesley Gittings <https://orcid.org/0000-0002-0463-0478>

Odong Simon Lukone <https://orcid.org/0000-0002-6780-1705>

Nelson Kisubi <https://orcid.org/0000-0002-0260-4620>

Malon Atama <https://orcid.org/0000-0003-1409-1970>

Peter Kymbadde <https://orcid.org/0000-0002-9606-218X>

\*Corresponding Author: Dr. Carmen Logie, University of Toronto, Factor-Inwentash Faculty of Social Work, 246 Bloor St W, Toronto, ON M5S 1V4, [carmen.logie@utoronto.ca](mailto:carmen.logie@utoronto.ca)

## Abstract

**Introduction:** Refugees experience HIV vulnerabilities due to the confluence of displacement, violence, and poverty. HIV self-testing, understudied with refugees, is a promising method to increase testing uptake, yet challenges remain with linkages to confirmatory testing following a positive HIV self-test. This study aims to evaluate the effectiveness of HIV self-testing kits and “edutainment” comics in increasing HIV testing and HIV status knowledge among refugee youth aged 16-24 years in Bidi Bidi Refugee Settlement, Uganda.

**Methods and analysis:** This study will be conducted in Bidi Bidi. We conducted a qualitative formative phase with focus groups (n=40) to generate knowledge of barriers and facilitators of HIV prevention, testing and care among refugee youth (aged 16-24) in Bidi Bidi. These findings were used to create comic scenarios aligning with edutainment approaches to health promotion and inform a four-arm cluster randomized controlled trial in Bidi Bidi using a 2x2 factorial design: 1) HIV self-testing alongside edutainment comics, 2) HIV self-testing alone, 3) edutainment comic alone, and 4) standard of care. The target sample size will be 120 youth (30 per arm), who will be enrolled in the trial and followed for 3 months. Data will be collected at baseline and 3-months after enrolment. The primary outcomes (HIV testing frequency, HIV status knowledge) and secondary outcomes (linkage to confirmatory HIV testing, HIV care linkage, HIV self-test kit use, HIV-related stigma, HIV knowledge, safer sex efficacy, condom-use, adolescent sexual and reproductive health stigma, sexual relationship power, access to SRH services) will be evaluated using descriptive statistics and regression analyses.

**Ethics and dissemination:** This study was approved by the University of Toronto Research Ethics Board, Mildmay Uganda Research Ethics Committee, and the Uganda National Council for Science and Technology. This trial is registered at ClinicalTrials.gov (#NCT05213689). Results will be shared in peer-reviewed publications and community knowledge sharing.

### Strengths and limitations of this study:

- The formative qualitative phase informed intervention design (edutainment comics, HIV self-testing) to ensure they are tailored to youth in a humanitarian context.
- Applying community-based research approaches in study design can improve the implementation and sustainability of HIV testing, prevention, and care.
- The study setting will allow for multiple interventions to be tested with sufficient sample size among youth living in a humanitarian context.
- The primary study limitations are potential loss to follow-up.
- Knowledge translation will be an important aspect of this study protocol, with implications for scaling-up HIV self-testing in humanitarian contexts.

## 78 BACKGROUND

79  
80 HIV vulnerabilities among displaced and refugee adolescents are shaped by a complex interplay  
81 of factors including poverty, violence, host community HIV prevalence, HIV urbanization, HIV  
82 testing and care access, and living conditions [1–3]. There is a dearth of data on HIV rates  
83 among displaced and refugees, but globally in 2006 5.4% of people and 7.2% of children living  
84 with HIV were affected by conflict, humanitarian crises and/or displacement [1]. Displaced and  
85 refugee populations often do not have the same access to HIV testing and treatment as host  
86 populations, and therefore, the United Nations has prioritized refugees as a key population for  
87 HIV policy and programming in their 2022 report [2]. A systematic review of studies conducted  
88 among refugee, migrant and displaced girls and young women across the African continent  
89 reported limited knowledge regarding HIV and other sexually transmitted infections among this  
90 population and that access and availability of sexual health services is constrained by distance,  
91 costs and stigma [3].

92 Uganda is the largest refugee hosting nation in Africa with over 1.4 million refugees in  
93 2020, with more than 240,000 living in Bidi Bidi settlement near the South Sudan border [4].  
94 Youth represent 44.4% of all new HIV infections in Uganda, with most infections sexually  
95 transmitted [5]. HIV prevalence among adolescents and young people in Uganda is 10.8% and is  
96 markedly higher among women (15.4%) compared with men (4.8%)[6]. Less is known of HIV  
97 prevalence, testing and prevention engagement among youth living in refugee settlements in  
98 Uganda, including in Bidi Bidi [7].

99 There is limited inclusion of refugee adolescents and youth in sexual and reproductive  
100 health research and programming [8–10] that may result in a lack of age, gender, culturally  
101 tailored programs, which in turn may contribute to low engagement with HIV testing and



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2  
3 102 prevention services in humanitarian contexts [11]. Studies conducted among urban refugee youth  
4  
5 103 in Kampala, Uganda have found that inequitable gender norms and intersecting forms of stigma,  
6  
7 104 including HIV-related stigma and refugee stigma, may also limit HIV testing and prevention  
8  
9 105 engagement among refugee youth [12–15]. Social network breakdown, poverty and travel  
10  
11 106 distance to clinics, confidentiality concerns, language barriers and other logistic hurdles may also  
12  
13 107 present obstacles to HIV testing [16,17].

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16  
17 108 HIV self-testing (HIVST) is a promising approach documented across systematic reviews  
18  
19 109 to increasing HIV testing access and uptake [18–20]. This approach may mitigate confidentiality  
20  
21 110 concerns, increase convenience, and reduce the risk of stigmatization, particularly important  
22  
23 111 considerations for HIV testing with adolescents and youth [21–24]. HIVST involves an  
24  
25 112 individual collecting their own oral specimen, conducting the test, and interpreting the results  
26  
27 113 independently with support from pictorial and written instructions. There is also a dearth of  
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29 114 information regarding advances in HIV testing, such as HIV self-testing, among youth in  
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31 115 humanitarian contexts [25], including countries with a high HIV prevalence and large number of  
32  
33 116 refugees such as Uganda.

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36  
37 117 There remain gaps in linkage to care following a positive HIV self-test when compared  
38  
39 118 with standard HIV testing services, and addressing these gaps requires innovative approaches  
40  
41 119 [26]. Innovative approaches will often be population-specific and community-driven,  
42  
43 120 repurposing tools that are used in other fields of work. Comics—a form of graphic medicine—  
44  
45 121 integrate text and visual images and are a promising health promotion tool used to address a  
46  
47 122 variety of health conditions such as HIV, sexually transmitted infections, vaccines, and dementia  
48  
49 123 [27–32]. Edutainment comics have been used to educate both the general population and  
50  
51 124 healthcare providers [33,34]. Comics align with the entertainment-education (‘edutainment’)  
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3 125 approach to improve health knowledge, attitudes and practices applied in HIV prevention  
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5 126 research [35,36]. In the field of HIV, comics have been used in an HIV adherence intervention in  
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7 127 the United States, PrEP research, as well as in HIV education in schools in Kenya that improved  
8  
9 128 students' knowledge about HIV, reduced stigma towards people living with HIV, and increased  
10  
11 129 likelihood and intention of testing [37–39]. Among refugees, comics have been used in mental  
12  
13 130 health research in Greece and Lebanon [40,41]. We did not locate research using comics  
14  
15 131 focussed on HIV testing interventions at large, or with refugees on HIV research. |

16  
17 132 This cluster randomized trial, *Todurujo na Kadurok* (loosely translated to 'Empowering  
18  
19 133 Youth' in Bari), aims to conduct an HIV self-testing and edutainment comic intervention and  
20  
21 134 evaluate its effectiveness in increasing HIV testing and HIV status knowledge among refugee  
22  
23 135 youth in Bidi Bidi refugee settlement, Uganda. The comic intervention will be theoretically  
24  
25 136 informed by the HIV prevention cascade [42-44] to address gaps in motivation, access and  
26  
27 137 effective use identified in formative research. Study findings can inform local and global  
28  
29 138 responses to increase HIV testing engagement with youth in humanitarian contexts.  
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31 139

## 32 33 140 **METHODS**

### 34 35 141 **Study aims and objectives**

36  
37 142 The overarching study goal is to evaluate the effectiveness of HIV self-testing, edutainment  
38  
39 143 comic, or a combination of both interventions on increasing HIV testing, HIV status knowledge  
40  
41 144 and linkage to confirmatory testing and care among refugee youth aged 16 to 24 years living in  
42  
43 145 Bidi Bidi refugee settlement, Uganda. The primary objectives are to evaluate the effectiveness of  
44  
45 146 the interventions on participants (1) HIV status knowledge and (2) HIV testing frequency.  
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47 147 Secondary objectives include examining the impact of the intervention on: (1) HIV self-testing  
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3 148 kit use, (2) linkage to confirmatory HIV testing for those testing positive on the HIVST, and (3)  
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5 149 linkage to HIV care for those testing positive, (4) HIV-related stigma, (5) adolescent sexual and  
6  
7 150 reproductive health stigma, (6) HIV knowledge, (7) safer sex efficacy, (8) condom use, (9)  
8  
9 151 sexual relationship power, and (10) access to other sexual and reproductive health services (e.g.,  
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11 152 contraception, post-exposure prophylaxis).

### 14 153 **Study Design**

16  
17 154 We are conducting a cluster randomized trial using a 2 x 2 factorial design (see Figure 1) [45].  
18  
19 155 This approach will specifically test the effectiveness of offering: 1) HIV self-testing alongside  
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21 156 the edutainment comic, 2) HIV self-testing alone, 3) edutainment comic alone, and 4) standard of  
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23 157 care, on defined primary and secondary outcomes. Factorial designs are an appropriate and  
24  
25 158 efficient approach to understand synergies between interventions. As HIV self-testing is an  
26  
27 159 established testing approach that is feasible and acceptable [26,45–47], we are particularly  
28  
29 160 interested to see if the benefits of HIV self-testing with youth in a humanitarian context are  
30  
31 161 increased with accompanying edutainment comics that are theoretically designed to address  
32  
33 162 barriers to testing and care across the HIV cascade. This design can help with identifying  
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35 163 effective strategies to reach study aims and in turn can inform intervention design to include the  
36  
37 164 most effective components [48]. Study design and research implementation was in collaboration  
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39 165 between the University of Toronto and Uganda Refugee and Disaster Management Council  
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41 166 (URDMC), a refugee agency based in Bidi Bidi. Data will be collected from all participants  
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43 167 directly before providing the intervention (baseline: time 1), and again at 3-month follow-up  
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45 168 (time 2).  
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### 54 170 **Study setting**

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3 171 This trial will be conducted in four villages located in two zones in Bidi Bidi Refugee Settlement  
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5 172 within the Yumbe district in Northwestern Uganda. With over 245,000 refugees largely (99.9%)  
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7 173 from South Sudan, Bidi Bidi is the world's second-largest refugee settlement with one-quarter of  
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9 174 the population (25%; n=61,036) youth aged 15 to 24 years [49]. In Bidi Bidi, health centers offer  
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11 175 free regular testing for HIV and comprehensive HIV care services including adult and pediatric  
12  
13 176 antiretroviral therapy (ART) and cotrimoxazole prophylaxis. However, only a few facilities in  
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15 177 the settlement offer comprehensive HIV care such as Prevention of Mother to Child  
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17 178 Transmission (PMTCT) services. Moreover, there are reported challenges including lack of  
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19 179 facility accreditation to offer HIV care, drug and test kits stock out and poor adherence to ART  
20  
21 180 by the refugees [50,51].  
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25

26 181 The clinical trial study setting includes two villages in Zone 3, with more than 58,000  
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28 182 residents, and two villages in Zone 4 annex, with more than 52,000 residents [49]. To ensure  
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30 183 anonymity of participants, the village numbers are not included in this protocol. The zones and  
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32 184 villages were selected due to large geographical separation to avoid contamination of  
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34 185 intervention arms, eagerness of youth in these areas to learn more about HIV testing, and to fill a  
35  
36 186 void of HIV research in these particular areas. In Zone 3 there are the following participating  
37  
38 187 health centres: Jomorogo Health Centre 3, Kongbe Health Centre 3, Yoyo Health Centre 3,  
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40 188 Luzira Health Centre 3. In Zone 4 annex the following health centres will participate: Igamara  
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42 189 Health Centre 3, Bolomoni Health Centre 3, Bangatuti Health Centre, and Kulikulinga  
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44 190 Government Centre. All participants will be able to access these health centres throughout the  
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46 191 study for HIV testing and treatment.  
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### 53 193 **Participants and recruitment**

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3 194 We will use convenience sampling methods, including peer driven recruitment supported by  
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5 195 collaborators at URDMC and eight peer navigators. Peer navigators are self-identified young  
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7 196 refugees aged 20-24 years living in Bidi Bidi, specifically Zone 3 and Zone 4 annex, who  
8  
9 197 received training from the study team in research methods and confidentiality and are supervised  
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11 198 by URDMC. Inclusion criteria for participants in the *Todurujo na Kadurok* study include: (1)  
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13 199 living in one of the four selected villages in Zone 3 and Zone 4 annex in Bidi Bidi; (2)  
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15 200 identifying as a refugee or displaced person; (3) aged 16-24 years; and (4) speaking and reading  
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17 201 one of the study languages (English, Bari, Juba Arabic).  
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22 202 For the cluster randomized controlled trial, participants will be randomized by the village  
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24 203 they live in. URDMC and peer navigators will recruit a total of 120 participants, with 30  
25  
26 204 participants in each of the four arms. The arms will be geographically separated into four  
27  
28 205 different villages from two zones to avoid contamination of the intervention effects. The villages  
29  
30 206 will be randomly assigned to a study arm. Youth will be approached by peer navigators and  
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32 207 study staff at URDMC to be recruited to the study. At the baseline visit (time 1) the youth will be  
33  
34 208 provided a written consent form, which will be available in English, Bari and Juba Arabic. Once  
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36 209 the youth have provided informed written consent they will be enrolled into the study, assigned  
37  
38 210 to a study arm based on the village that they live in, and baseline data will be collected by a  
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40 211 URDMC research assistant. Peer navigators will use multiple study reminder strategies (e.g.,  
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42 212 texts, private messages over social media) to maintain engagement until the follow-up visit at 3-  
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44 213 months after enrolment. These efforts will be supplemented with existing outreach services to  
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46 214 youth by URDMC.  
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## 52 216 **Patient and public involvement**

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3 217 This study protocol was developed after a formative qualitative research phase. As depicted in  
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5 218 Figure 1, this formative research in Phase 1 included four focus groups conducted by two  
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7 219 URDMC research assistants (2 with young women, 2 with young men) with refugee youth in  
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9 220 Bidi Bidi (n=10 in each focus group; n=40 in total) aged 16-24 years to collect information on  
10  
11 221 knowledge of current HIV testing opportunities and experiences in Bidi Bidi and perspectives on  
12  
13 222 HIV self-testing. HIV prevention cascade conceptual frameworks were used by analysts at the  
14  
15 223 University of Toronto in the analysis of the qualitative data to inform the study to address gaps in  
16  
17 224 linkage to care following HIV self-testing [42,43]. Three key domains of the HIV prevention  
18  
19 225 cascade include motivation, access, and effective use, and these dimensions can be tailored to  
20  
21 226 identify population specific needs [43,44]. For instance, Moorhouse et al. applied the HIV  
22  
23 227 prevention cascade framework to develop community-based HIV prevention interventions and  
24  
25 228 noted dimensions of motivation (knowledge, risk perception, consequence of use, social norms),  
26  
27 229 access (availability, acceptable provision, affordability), and effective use (skills, self-efficacy,  
28  
29 230 partner) [42]. The qualitative findings were used to identify key themes for the development of  
30  
31 231 the edutainment comics (see Table 1), in this way the study responds to the health needs and  
32  
33 232 priorities of refugee youth in this humanitarian context.

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39 233 These focus groups were followed by a 3-day human-centered design workshop led by  
40  
41 234 URDMC research managers who engaged eight peer navigators to adapt and develop HIV self-  
42  
43 235 testing edutainment materials to enhance cultural, gender, age, and contextual relevance (see  
44  
45 236 Figure 1). The study was designed and will be conducted as a collaboration with local  
46  
47 237 physicians, clinics, and the implementing partner is a refugee agency based in Bidi Bidi. These  
48  
49 238 study collaborators have been involved since the study inception and will lead implementation.  
50  
51 239 Peer navigators (n=8) who share the participants' refugee lived experiences, and include youth  
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240 living with HIV, have meaningfully contributed to the study design through the human centered  
 241 design workshops, feedback into edutainment comic development, pilot testing of study tools,  
 242 and will support implementation of the cluster randomized controlled trial through actively  
 243 contributing to participant recruitment, engagement, and retention.

244 **Table 1.** Scenarios on the HIV prevention cascade included in the edutainment comic

Domain of prevention cascade	Stage of the prevention cascade	Description
Motivation	Risk perception	Discussion explores perceived risk for HIV and a) misinformation (e.g., sharing body lotion is not as an HIV risk factor) and b) provides information about condom breakage and post-exposure prophylaxis.
	Consequence of use	Discussion between healthcare provider and youth of how to manage a positive HIV test result, including the ability to manage confidentiality and access support services.
	Social norms	Discussion of experiences of HIV stigma and discrimination, as well as an example of receiving support from a friend.
	Knowledge	Discussion of knowledge as power, including benefits of knowing one's HIV positive and HIV negative serostatus.
Access	Access and availability	Parallel conversations between youth around testing barriers, including travel costs, and stockouts of HIV testing kits, with a discussion of locations for testing and support in Bidi Bidi.
	Acceptable provision	Discussions of a) the possibility of receiving an HIV test while accessing other health services such as contraception and condoms; b) accessing HIV testing from a healthcare provider of a different gender; c) feeling empowered to find a doctor one feels comfortable talking with about sexual health
Effective use	Partner	Discussion of HIV testing with partner to assess partner perspectives on HIV testing and evaluate concerns (e.g., negative partner reaction, violence, consequence of positive test result). Healthcare provider discussion of partner testing with a couple, including possible sero-discordant results. Decision making considerations for engaging in partner testing, including motivations (empowerment, support, open communication, stronger relationship) and barriers (loss of trust, violence, conflict, break up).
	Skills	Discussion of disclosure process and decision making regarding who to disclose an HIV positive test result with.
	Self-efficacy	Discussion of how knowledge of HIV testing benefits, HIV positive serostatus, and available resources increase empowerment to take care of oneself and support others.

245

## 246 **Intervention description**

247 *Todurujo na Kadurok* is a 2 x 2 factorial cluster randomized trial, with clusters randomized to  
248 one of the following four arms: (1) HIV self-testing and edutainment comic, (2) HIV self-testing  
249 only, (3) edutainment comic only, and (4) standard of care.

250 Participants in the HIV self-testing arms (arm 1; arm 2) will each receive two HIV self-  
251 testing kits (OraQuick Rapid HIV-1/2 Antibody Test, OraSure Technologies) at baseline along  
252 with verbal, written and visual instructions (in their choice of study language), as well as  
253 linkages to peer navigators and URDMC for support accessing confirmatory testing and care.

254 Participants in the edutainment comic arms (arm 1; arm 3) will receive a hard copy of the  
255 edutainment comic at baseline. They will meet with the peer navigator to review and discuss the  
256 comic themes and will be provided with a blank version to complete on their own. This approach  
257 to edutainment comics provides a participatory component whereby participants can  
258 contextualize the comic themes within their own lives and experiences [52]. In addition to the  
259 comic, the participants in arms 1 and 3 will also have linkages to peer navigators and URDMC  
260 for support accessing confirmatory testing and care.

261 Participants in the standard of care arm (arm 4) will receive verbal and written  
262 information and resources about HIV testing, care, and support services in Bidi Bidi and Yumbe  
263 Hospital from their peer navigator as well as contact information for URDMC and an overview  
264 of their programs offered. The existing standard of HIV care in Bidi Bidi is offered through  
265 clinics located in Bidi Bidi settlement and the hospital in Yumbe and includes pre- and post-test  
266 counselling for HIV, follow-up visits for HIV care in the community, intensive treatment  
267 adherence counselling for immunosuppressed and non-immunosuppressed patients in the  
268 community and facility, and community drug re-fills for people living with HIV.



269

**270 Outcomes**

271 The primary outcomes measured in this trial will be:

- 272 1. Changes in HIV testing frequency: This is measured as participants' self-reported last HIV  
273 test. To capture changes, this measure is assessed at both study time points (baseline [Time  
274 1], 3 months [Time 2]).
- 275 2. Changes in HIV status knowledge: At the final 3-month visit, a clinician supported by trained  
276 peer navigators will offer all participants a completely voluntary rapid point-of-care HIV test  
277 (Alere Determine HIV-1/2) to measure HIV status knowledge. HIV status knowledge will be  
278 assessed as correct for participants that agree to take the rapid test and correctly report their  
279 HIV status before receiving the result.

280 The secondary outcomes include:

- 281 1. Changes in linkage to confirmatory HIV testing: Participants in arm 1 and arm 2 (e.g., those  
282 given a HIVST) will be asked at Time 2 if they used their HIV self-test kit. All participants  
283 who report using the test will be asked the result, and participants who self-report a positive  
284 result will be asked if they received confirmatory testing, and if so, where they received the  
285 test. Participants will also be provided study coupons (with only the name of the UDRMC  
286 and their study ID#) that they can provide when receiving HIV or other sexual and  
287 reproductive health services at collaborating health clinics; this clinic engagement will be  
288 linked to the participant study ID#.
- 289 2. Changes in linkage to HIV care: At Time 2, participants who seroconvert in the study will be  
290 asked if they received HIV care, including ART and counseling, since receiving an HIV-  
291 positive diagnosis.

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3 292 3. HIV self-test kit use: In order to understand the use of HIV self-test kits and to reduce social  
4  
5 293 desirability bias, one month after Time 2 the participants in arm 1 and arm 2 will be asked if  
6  
7 294 they have unused test kits. They will be informed this information is just to guide future  
8  
9 295 trials.
- 10  
11  
12 296 4. HIV-related stigma, assessed with the Reinius et al., 2017 12-item short HIV stigma  
13  
14 297 assessment [53] including vicarious and felt-normative HIV stigma dimensions through an  
15  
16 298 internalized AIDS-related scale from Kalichman et al. 2020 [54,55].
- 17  
18  
19 299 5. HIV knowledge assessed with the HIV knowledge questionnaire by Carey & Schroder [56].  
20  
21 300 6. Safer sex efficacy using the Condom Use Self-Efficacy Scale [57,58].  
22  
23  
24 301 7. Condom use in past 3 -months (condom use at last sex; condom use at sex every time in last  
25  
26 302 3 months [dichotomous: yes/no]).  
27  
28  
29 303 8. Adolescent sexual and reproductive health stigma, assessed with the Ugandan Adolescent  
30  
31 304 Sexual and Reproductive Health (SRH) Stigma scale (Logie et al. 2019) adapted from Hall et  
32  
33 305 al.'s Adolescent SRH Stigma scale [59]  
34  
35 306 9. Sexual relationship power (SRP) using the Relationship Control Sub-Scale from the Sexual  
36  
37 307 & Relationship Power Scale [60]  
38  
39  
40 308 10. Access to other SRH services will be assessed by asking if the participants went to any health  
41  
42 309 clinic/hospital or service provider in the past 3 months to access: condoms, lubricant,  
43  
44 310 contraception, post-exposure prophylaxis, pre-exposure prophylaxis, pregnancy test, sexual  
45  
46 311 and gender-based violence information, sexually transmitted infections testing, or other  
47  
48 312 services. Participants will be provided coupons with UDRMC logo and their study ID to  
49  
50 313 bring to participating clinics when accessing services, so this variable will be assessed by  
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3 314 self-report by participant as well as by collecting study coupons that will be attached to a list  
4  
5 315 of services accessed during the study timeframe.  
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8 316 All participants, regardless of study arm, will receive an HIV self-test at the end of the study  
9  
10 317 with accompanying instructions, information and resources to ensure the study arms without  
11  
12 318 access to HIV self-testing are made aware of this approach and can access its benefits.  
13  
14

15 319

### 16 17 320 **Sample size and power**

18  
19 321 We will recruit 120 refugee youth aged 16-24 years living in Bidi Bidi (60 adolescent girls, 60  
20  
21 322 adolescent boys) in the cluster randomized trial. The recruited youth will come from four  
22  
23 323 villages in two zones (Zone 3 and Zone 4 annex) within Bidi Bidi, and each village will be  
24  
25 324 randomized to a study arm such that all youth living in the village are clustered to receive the  
26  
27 325 same intervention. Calculated using G\*Power 3.1, a sample size of 105 is sufficient for  
28  
29 326 multivariable regression analyses (effect size: 0.2, power: 0.95, number of tested predictors: 5,  
30  
31 327 critical F: 2.306) [61]. To account for 15% attrition, we have selected a sample size of 120.  
32  
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34

35 328

### 36 37 38 329 **Data collection and management**

39  
40 330 For the cluster randomized trial, we will collect sociodemographic characteristics from  
41  
42 331 participants at time 1, and exposures relevant to sexual and reproductive health and outcome data  
43  
44 332 at both timepoints (time 1, time 2). Data will be collected using tablet-based structured surveys  
45  
46 333 conducted by trained URDMC research assistants in all study languages. Data will be collected  
47  
48 334 using SurveyCTO (Dobility, Cambridge, USA), which is a secure platform whereby data  
49  
50 335 collected is automatically encrypted and uploaded to a password-protected server using a Secure  
51  
52 336 Sockets Layer (SSL) certificate. SurveyCTO allows for data to be collected offline and has  
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3 337 branching logic, consistency checks, and facilitates multi-lingual data collection. No personal  
4  
5 338 identifying information will be collected with the survey data, all participants will instead be  
6  
7 339 given a unique participant ID to enhance confidentiality. Only study staff at URDMC and  
8  
9  
10 340 University of Toronto will have access to the dataset for the purpose of data management and  
11  
12 341 outcome reporting, and all datasets will be saved on a password-protected server.  
13  
14  
15 342

### 17 343 **Data analysis**

19 344 Analysis and reporting for the cluster randomized trial will be conducted in accordance  
20  
21 345 with CONSORT (Consolidated Standards of Reporting Trials) guidelines [62]. The analyst at the  
22  
23 346 University of Toronto will be blinded to group allocation. A flow diagram will be used to  
24  
25 347 illustrate patient flow (consent/enrolment, randomization, baseline, and follow-up). Baseline data  
26  
27 348 will be reported for all four arms and summarized as mean and standard deviations or median  
28  
29 349 and interquartile range for continuous variables and as number and percentage for categorical  
30  
31 350 variables. The primary analysis will involve intention-to-treat analysis (data from participants  
32  
33 351 will be analyzed according to their allocation, irrespective of whether they received the  
34  
35 352 intervention). Between-group comparisons will be performed using generalized estimating  
36  
37 353 equations (GEE) logistic or linear regression models – depending on which outcome is being  
38  
39 354 evaluated - using unstructured correlation matrix and robust standard errors to account for  
40  
41 355 clustering. For these models, the intervention effects across time (from baseline to 3-month  
42  
43 356 follow-up) will be included as the main effects of intervention arm, time, and an arm\*time  
44  
45 357 interaction. The level of significance will be set at  $\alpha=0.05$ . The results will be expressed as  
46  
47 358 odds ratios or mean differences as appropriate, accompanied by 95% confidence intervals and p-  
48  
49 359 values. We will conduct an adjusted analysis for the primary outcome (changes in HIV testing  
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3 360 frequency, HIV self-test kit use, HIV status knowledge, changes to linkage to confirmatory HIV  
4  
5 361 testing and to HIV care) to investigate the role of various covariates in the relative effect.  
6  
7 362 Covariates, such as age and gender, will be entered as a block. We will explore gender  
8  
9 363 differences in primary and secondary intervention outcomes. Given the outcomes of this study  
10  
11 364 are related to behavior change and the trial is of a short duration with minimal risks, a data  
12  
13 365 monitoring committee was not deemed necessary.  
14  
15  
16  
17 366

## 18 19 367 **DISCUSSION**

20  
21 368 This study approach has the potential to inform research, practice, and policy surrounding  
22  
23 369 measuring the efficacy of new programming and HIV-related testing. Study findings, therefore,  
24  
25 370 have the potential to not only inform a larger, fully powered randomized controlled trial to test  
26  
27 371 the effectiveness of an edutainment comic book intervention but can also inform policies on how  
28  
29 372 strategies such as comic books can be integrated into school health curricula for HIV prevention.  
30  
31 373 Our findings can also inform research, practice, and policy on HIV/AIDS among youth, to better  
32  
33 374 meet the needs of refugee adolescents and youth. An edutainment comic book intervention  
34  
35 375 approach holds promise for meaningfully engaging youth and healthcare providers in  
36  
37 376 humanitarian contexts in dialogue on STI prevention, care, and support.  
38  
39  
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41

### 42 377 **Strengths and limitations of this study**

43  
44 378 The Todurujo na Kadurok cluster randomized trial is unique in exploring HIV self-testing  
45  
46 379 feasibility and uptake among youth living in a large refugee settlement using innovative  
47  
48 380 community-based health promotion activities. The study design will allow us to assess if HIV  
49  
50 381 self-testing along, edutainment comics or HIV self-testing alongside the edutainment comics  
51  
52 382 increase HIV testing frequency and status knowledge compared to standard of care. By  
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3 383 clustering the interventions to areas within Bidi Bidi Refugee Settlement we aim to mitigate  
4  
5 384 threats to internal validity and contamination of the intervention effects.  
6  
7  
8 385 The study is subject to limitations commonly incurred by prospective longitudinal studies – loss  
9  
10 386 to follow-up and missing data. However, we will mitigate these limitations by using peer  
11  
12 387 navigators to recruit and follow-up on participants in the community and also by using digital  
13  
14 388 questionnaires on tablets that are programmed to flag missing data.  
15  
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17 389

## 19 390 **ETHICS AND DISSEMINATION**

### 21 391 **Ethical approval**

23  
24 392 Ethical approval for the study was provided through the Mildmay Uganda Research  
25  
26 393 Ethics Committee (REC REF 0802-2021), UNCST (SS884ES), and the University of Toronto  
27  
28 394 Research Ethics Board (37496). This trial is registered at ClinicalTrials.gov (#NCT05213689).  
29  
30  
31 395 The protocol for the study was developed in accordance with the SPIRIT Statement [63,64]. To  
32  
33 396 ensure the protection of human subjects, all participants in the formative phase and the cluster  
34  
35 397 randomized controlled trial will be provided with enough time to provide written voluntary  
36  
37 398 consent to participate in the study. All informed written consent processes will occur in a private  
38  
39 399 room at a location provided by URDMC. The participant will read the consent form themselves  
40  
41  
42 400 or a peer navigator will read aloud the informed consent in a language comfortable to the  
43  
44 401 participant (English, Bari or Juba Arabic) and will ask if the participant has any questions and  
45  
46 402 will answer their questions. Participants will be asked to sign the consent form or provide a  
47  
48 403 thumbprint to indicate their consent. The consent form will in no way be connected with focus  
49  
50 404 group transcripts or data collected during the cluster randomized trial and will be destroyed five  
51  
52  
53 405 years after data collection is completed. As Uganda's HIV and AIDS Prevention and Control Act  
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3 406 permits youth aged 12 years or above to independently access HIV testing and counselling  
4  
5 407 without parental permission, we received ethics approval to allow youth aged 16-17 years to  
6  
7 408 participate without parental consent; this is a common approach to reduce barriers to youth  
8  
9  
10 409 participation in sexual and reproductive health research [65–67].

11  
12 410 Emotional risks include that participants may feel uncomfortable, anxious, or upset  
13  
14 411 taking an HIV test, stigma due to accidental disclosure of HIV serostatus, psychosocial harm as a  
15  
16 412 result of learning HIV status, discussing HIV, STI, sexual risk factors, and social capital. The  
17  
18 413 study has been designed to minimize psychological/emotional risks of feeling uncomfortable,  
19  
20 414 anxious, or upset with study questions and topics of discussion through wellbeing-focussed  
21  
22 415 training for data collectors. URDMC will also collaborate with a local psychological aid  
23  
24 416 organization to support peer navigators and participants during any mental distress. Moreover,  
25  
26 417 we will ensure the confidentiality of all participants by not collecting identifying information  
27  
28  
29 418 (i.e., no full names, no date of birth).

30  
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### 34 35 420 **Dissemination plan**

36  
37 421 We will employ participatory methods for knowledge dissemination, working with youth  
38  
39 422 peer navigators to develop strategies such as youth community forums and arts-based methods  
40  
41 423 (e.g., comic books) and brief videos. We will make findings available in English, Bari and Juba  
42  
43 424 Arabic. Findings will be disseminated through a variety of methods including the preparation of  
44  
45 425 community reports (disseminated to the Ugandan National AIDS Program, Ministry of Health,  
46  
47 426 and our collaborators [e.g., URDMC]) and peer-reviewed publications (e.g., Journal of the  
48  
49  
50 427 International AIDS Society). Irrespective of study findings, results will be published in peer-

428 reviewed scientific journals following international authorship guidelines, and will be presented  
 429 to academics and researchers at key scientific conferences.

430

### 431 **Trial status**

432 The formative qualitative phase of the *Todurujo na Kadurok* (Empowering Youth) study was  
 433 launched in September 2021. The study team has been trained and ethics approval obtained. All  
 434 qualitative activities from phase 1 and the development of the comic book have been completed.  
 435 We anticipate for the intervention to begin in Fall 2022 along with baseline data collection, and  
 436 the final follow-up survey to be conducted 3-months later in late 2022. Any important protocol  
 437 modifications will be included as amendments in REB and updated on the ClinicalTrials.gov  
 438 registry, as and when needed. Box 1 details the information on the ClinicalTrials.gov registry.

#### **Box 1. Items from the US National Institutes of Health Trial Registry**

##### **Data category information**

**Primary registry and trial identifying number:** ClinicalTrials.gov NCT05213689.

**Date of registration:** 28 January 2022.

**Source(s) of monetary support:** ViiV Healthcare (Grant#628520-1652450711)

**Primary sponsor:** University of Toronto.

**Primary sponsor:** University of Toronto.

**Contact for public and scientific queries:** Carmen Logie, PhD (carmen.logie@utoronto.ca).

**Public and scientific title:** HIV Self-Testing and Comic Intervention with Refugee Adolescents and Youth.

**Countries of recruitment:** Uganda.

**Health condition(s) or problem(s) studied:** HIV testing, status knowledge, linkage to confirmatory and care.

**Intervention(s):** HIV self-testing kits and edutainment comic books.

**Key inclusion criteria:** living in one of the four selected villages in Zone 3 and Zone 4 annex in Bidi Bidi; identifying as a refugee or displaced person; aged 16-24 years; and speaking and reading one of the study languages (English, Bari, Juba Arabic).

**Study type:** interventional (clinical trial); cluster randomized control trial with 4 study arms.

**Date of first enrolment:** June 2022 (estimate)

**Target sample size:** 120.



**Primary outcome(s):** HIV testing frequency, HIV status knowledge, linkage to confirmatory HIV testing, linkage to HIV care, HIV self-test kit use.

**Key secondary outcomes:** HIV-related stigma, HIV knowledge, safer sex efficacy, condom-use, sexual and reproductive health (SRH) stigma, sexual relationship power and access to SRH services.

439

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444

**Contributors:** Study design – CHL, MO, IB. Data collection – SOL, ML, MC, IB, LG, NK, MA, CHL, MO. Data management – ML, MC, SOL, NK, CHL. Manuscript writing – MC, ML, CHL. Manuscript editing and critical review – CHL, MO, ML, MC, IB, LG, SOL, NK, MA, PK.

448

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452

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454

**Competing interests:** The authors have declared that no competing interests exist.

456

**Patient and public involvement:** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

460

**Patent consent for publication:** Not required.

462

**Provenance and peer review:** Not commissioned; peer reviewed for ethical and funding approval prior to submission.

465

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470

<http://creativecommons.org/licenses/by-nc/4.0/>.

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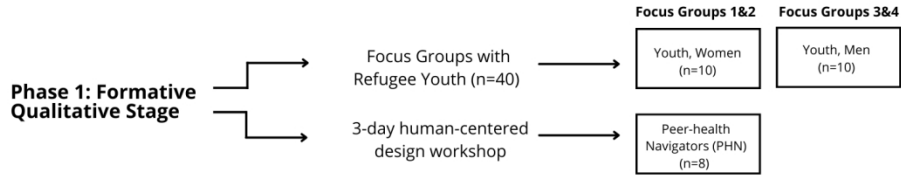
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3 685 **Figure Legends:**

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5 687 **Figure 1: Flowchart of Study Phases and Participant Involvement**

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For peer review only



### Comic Book Development Using HIV Prevention Cascade\*

**Motivation**

**Knowledge**

- Awareness of HIV
- Misinformation that can be corrected

**Example:** Youth acknowledges that HIV no longer means a death sentence, despite popular beliefs.

**Risk Perception**

- Who is at risk for HIV

**Example:** Youth discussing that anyone can be at risk for HIV.

**Consequences of Use**

- Negatives associated with testing
- Positives associated with testing

**Example:** Youth notes that self-testing can lead to early access to care and confidential results.

**Social Norms**

- Fear of Social Rejection
- Fear of Violence upon Results

**Example:** Youth acknowledge stigma associated with HIV testing

**Access**

**Availability**

- Where can individuals get HIV testing

**Example:** Outreach explains to youth that self-testing increases availability.

**Acceptable Provision**

- What do individuals think of HIV self-testing

**Example:** Youth notes barriers for existing HIV testing

**Affordability**

- How can individuals travel to clinics
- Are services free?

**Example:** Depicting perceived barriers to receiving health care.

**Effective Use**

**Skills**

- How does self-testing work and next steps.

**Example:** Health care provider providing a step-by-step guide for self-testing.

**Self-Efficacy**

- Do individuals know how to use testing kits

**Example:** Youth feeling empowered in their ability to take their health into their own hands.

**Partner**

- Decision-making around partner HIV testing

**Example:** A woman discusses the potential of self-testing in an abusive relationship

\*HIV prevention cascade (see Moorhouse et al. 2019), PMID 31328375

### Phase 2: Cluster-randomized Study

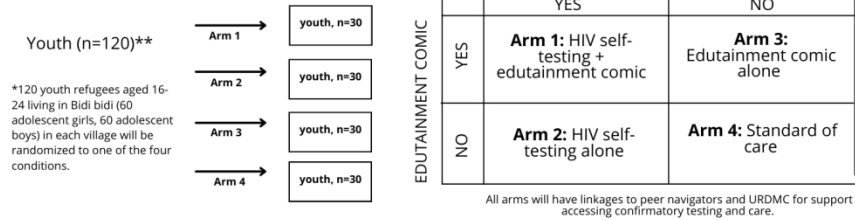


Figure 1: Flowchart of Study Phases and Participant Involvement

545x705mm (72 x 72 DPI)





SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	ItemNo	Description	Page (P); Line (L)
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1; L1-3
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	P2; L59-60
	2b	All items from the World Health Organization Trial Registration Data Set	Box 1
Protocol version	3	Date and version identifier	Box 1
Funding	4	Sources and types of financial, material, and other support	P17; L407-409
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	P17; L403-405
	5b	Name and contact information for the trial sponsor	P1; L29-30
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	P 17; L403-405 & 411
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	P 3-5
	6b	Explanation for choice of comparators	P9; L230-248
Objectives	7	Specific objectives or hypotheses	P5; L135-145

1				
2	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	P6; L147-158
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8	<b>Methods: Participants, interventions, and outcomes</b>			
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10	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P6-7; L161-181
11				
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14	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P7; L 188-193
15				
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19	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P9-10; L227-248 (Figure 1)
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22		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A; low risk behaviour change intervention
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28		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	P8; L202-205
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32		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A; low risk behaviour change intervention
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38	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P 10-12; L 251-295
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46	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
47				
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50	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P 12-13; L301-307
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55	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	P 8; L197-205
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58 **Methods: Assignment of interventions (for controlled trials)**

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## Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	P8; L194-197
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A; interventions cluster-randomized and not blinded
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	P8; L197-198
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	P13; L319-321, 326
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A; low risk behaviour change intervention so unblinding will not occur

**Methods: Data collection, management, and analysis**

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	P 13; L310-321
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P8; L202-205
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P13; L312-321

1				
2	Statistical	20a	Statistical methods for analysing primary and secondary	P 13-14;
3	methods		outcomes. Reference to where other details of the statistical	L324-345
4			analysis plan can be found, if not in the protocol	
5				
6		20b	Methods for any additional analyses (eg, subgroup and adjusted	P 14; L338-
7			analyses)	343
8				
9		20c	Definition of analysis population relating to protocol non-	P 14; L329-
10			adherence (eg, as randomised analysis), and any statistical	334
11			methods to handle missing data (eg, multiple imputation)	
12				
13				
14	<b>Methods: Monitoring</b>			
15				
16	Data	21a	Composition of data monitoring committee (DMC); summary of	P 14; L343-
17	monitoring		its role and reporting structure; statement of whether it is	345
18			independent from the sponsor and competing interests; and	
19			reference to where further details about its charter can be found,	
20			if not in the protocol. Alternatively, an explanation of why a DMC	
21			is not needed	
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24		21b	Description of any interim analyses and stopping guidelines,	N/A; low risk
25			including who will have access to these interim results and	behaviour
26			make the final decision to terminate the trial	change
27				intervention
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29				duration
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32	Harms	22	Plans for collecting, assessing, reporting, and managing	N/A; low risk
33			solicited and spontaneously reported adverse events and other	behaviour
34			unintended effects of trial interventions or trial conduct	change
35				intervention
36				for a short
37				duration
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40	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and	N/A; low risk
41			whether the process will be independent from investigators and	behaviour
42			the sponsor	change
43				intervention
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49	<b>Ethics and dissemination</b>			
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51	Research	24	Plans for seeking research ethics committee/institutional review	P 15; L360-
52	ethics approval		board (REC/IRB) approval	362
53				
54	Protocol	25	Plans for communicating important protocol modifications (eg,	P 16; L395-
55	amendments		changes to eligibility criteria, outcomes, analyses) to relevant	397
56			parties (eg, investigators, REC/IRBs, trial participants, trial	
57			registries, journals, regulators)	
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2	Consent or	26a	Who will obtain informed consent or assent from potential trial	P 15-16;
3	assent		participants or authorised surrogates, and how (see Item 32)	L363-377
4				
5		26b	Additional consent provisions for collection and use of	N/A; no
6			participant data and biological specimens in ancillary studies, if	ancillary
7			applicable	studies
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9	Confidentiality	27	How personal information about potential and enrolled	P 13; L317-
10			participants will be collected, shared, and maintained in order to	319
11			protect confidentiality before, during, and after the trial	
12				
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14	Declaration of	28	Financial and other competing interests for principal	P 17; L413
15	interests		investigators for the overall trial and each study site	
16				
17	Access to data	29	Statement of who will have access to the final trial dataset, and	P13; L319-321
18			disclosure of contractual agreements that limit such access for	
19			investigators	
20				
21	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and for	N/A; low risk
22	post-trial care		compensation to those who suffer harm from trial participation	behaviour
23				change
24				intervention
25				for a short
26				duration
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28				
29				
30	Dissemination	31a	Plans for investigators and sponsor to communicate trial results	P 16; L380-
31	policy		to participants, healthcare professionals, the public, and other	388
32			relevant groups (eg, via publication, reporting in results	
33			databases, or other data sharing arrangements), including any	
34			publication restrictions	
35				
36				
37		31b	Authorship eligibility guidelines and any intended use of	P 16; L386-
38			professional writers	388
39				
40		31c	Plans, if any, for granting public access to the full protocol,	P 17; L424-
41			participant-level dataset, and statistical code	429
42				
43				
44	<b>Appendices</b>			
45	Informed	32	Model consent form and other related documentation given to	Supplementar
46	consent		participants and authorised surrogates	y material
47	materials			
48				
49				
50	Biological	33	Plans for collection, laboratory evaluation, and storage of	N/A; no
51	specimens		biological specimens for genetic or molecular analysis in the	biological
52			current trial and for future use in ancillary studies, if applicable	specimens
53				collected
54				

\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT

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