HOSENG trial – Effect of the provision of oral self-testing for absent and refusing individuals during a door-to-door HIV testing campaign on testing coverage: protocol of a cluster randomized clinical trial in rural Lesotho

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Abstract

BACKGROUND HIV testing coverage remains below the targeted 90% despite efforts and resources invested. Home-based HIV testing is a key approach endorsed by the World Health Organization (WHO), especially to reach individuals who might not seek testing otherwise. Although acceptance of test-ing during such campaigns is high, coverage remains low due to absent household members. This cluster-randomized trial aims to assess increase in testing coverage using oral HIV self-testing (HIVST) among individuals who are absent or decline testing during home-based HIV testing. METHODS The HOSENG (HOme-based SElf-testiNG) trial is a cluster-randomized, parallel group, superiority trial in two districts of Lesotho, Southern Africa. Clusters are stratified by district, village size, and village access to the nearest health facility. Cluster eligibility criteria include: village is in catchment area of one of the study facilities, village authority provides consent, and village has a registered, capable and consenting village health worker (VHW). In intervention clusters, HIV self-tests are provided for eligible household members who are absent or decline HIV testing in presence of the campaign team. In control clusters, standard of care for absent and refusing individuals applies, i.e. referral to health facility. The primary outcome is HIV testing coverage among individuals 12 years and older within 120 days after enrolment. Secondary objectives include HIV testing coverage among other age groups, and uptake of the different testing modalities. Statistical analyses will be conducted and reported in line with CONSORT guidelines. HOSENG trial is linked to VIBRA (Vil-lage-Based Refill of ART) trial. Together, they constitute the GET ON (GETting tOwards Ninety) research project. DISCUSSION The HOSENG trial tests if oral HIVST may be an add-on during door-to-door testing campaigns towards achieving optimal testing coverage. The provision of oral self-test kits, followed up by VHWs, requires little additional human resources, finances and logistics. If cost-effective, this approach will inform home-based HIV testing policies not only in Lesotho, but in similar high-prevalence settings. TRIAL REGISTRATION This trial has been registered at clinicaltrials.gov (NCT03598686) on July 25, 2018. More information under www.getonproject.wordpress.com.

Background

The United Nations Programme on HIV/AIDS (UNAIDS) has shown a way forward in controlling and finally ending the deadly AIDS epidemic by launching the 90-90-90 strategy.1 The first target is to ensure that 90% of all people living with HIV are aware of their status. The second target is that 90% of those diagnosed receive sustained antiretroviral therapy (ART). And the third target stands for 90% of those receiving ART achieving viral suppression. Globally, in 2017, progress towards the first UNAIDS target, i.e. that 90% of people living with HIV are aware of their status, was lower than other stages of the HIV care cascade.2 The most recent data from Eastern and Southern Africa show that the percentage of people living with HIV who know their HIV status has steadily improved in the last few years, currently at a level of 81% (64%-95%), but still leaving a gap of approximately 1.7 million HIV-positive people to reach the target of 90% knowing their HIV status.3,4 In order to reach the first UNAIDS target, home-/community-based testing, i.e. HIV testing close to where people live or work, is a key strategy endorsed by World Health Organization.5,6 Many studies from Southern Africa, including Lesotho, have shown that home-based HIV testing is highly promising for closing the crucial gap to achieve the first 90.7 Yet, it is critical to distinguish between the principal acceptance (uptake) of HIV testing and the HIV testing coverage. While in most cases the former is above 90%, the coverage often remains below 90% due to household members that are absent at the time of the campaign, mainly men and young adults.8

HIVST proved to be an accurate diagnostic tool that increases uptake of HIV testing, facilitates linkage to care among target-populations, and may be more cost-effective than provider-delivered HIV testing.9–17 Thus, WHO strongly endorses oral HIVST.18 In a WHO review, 16 countries reported having a policy supportive of HIVST, including Lesotho.19,20

However, to date only limited data are available, assessing the effect of oral HIVST in increasing HIV testing coverage. This randomized controlled trial thus aims to determine the added effect of distributing oral HIVST to individuals absent or refusing to test during a home-based HIV testing campaign on HIV testing coverage.

Methods

Methods

Setting

The HOSENG trial will be conducted in the districts of Butha-Buthe and Mokhotlong, in northern Lesotho, Southern Africa, in the catchment areas of 22 health facilities. Both districts are characterized by mostly rural settings with an estimated population of 220,000, mainly subsistence farmers and mine workers as well as construction or domestic labourers who work in neighbouring South Africa. Each district has only one mid-size town: Buthe-Buthe with ca. 25,000 inhabitants, and Mokhotlong with ca. 10,000 inhabitants. The remaining population lives in villages scattered over a mountainous area of 5,842 km2. According to the recent household-based national survey from 2016-2017 the adult HIV prevalence is 17.8% in Butha-Buthe and 26.1% in Mokhotlong.21

Design

The HOSENG trial is a cluster-randomized controlled, superiority trial in a resource-limited setting. The rationale for a cluster-randomized design at village level is a) the reliance of the trial on the VHWs and b) the high risk of cross-contamination between the study arms if randomization would be done at individual or household level. The HOSENG trial with its home-based HIV testing campaign provides a recruitment platform for another trial, the VIBRA trial, and thus they are based on the same cluster-randomization and run in parallel. Together, HOSENG and VIBRA constitute the GET ON research project. To ensure a balance in the exposure to the HOSENG intervention in the two VIBRA arms, the clusters (villages) will be randomized into 4 potential groups in a 1:1:1:1 allocation.

Cluster sampling and randomization

Figure 1 summarizes the cluster sampling and randomization process. A list of all villages with their corresponding VHWs in the study districts was provided by the Ministry of Health and the local District Health Management Teams. Two local members of the research team cross-checked the village list for accuracy. They defined the village size (≥30 versus <30 households) and access to the nearest health facility (easy versus hard to reach, defined by needing to cross a mountain or river or >10 km away from health facility) by contacting the relevant VHW coordinators. Each village was considered a cluster, except villages which do not have their own VHW and therefore form one cluster with neighbouring villages served by the same VHW. It is not feasible to visit all clusters (358 villages in Butha-Buthe and 290 villages in Mokhotlong) nor to include >2 VHWs per cluster. Therefore, a random sample of 180 clusters, stratified by district, village size and access, was taken. If a cluster had more than two VHWs, randomly two VHWs were selected. After excluding clusters who did not meet the eligibility criteria (see next section), the remaining 159 clusters were randomized into the 4 groups in a 1:1:1:1 allocation ratio with block sizes of 4, stratified by the same stratification factors. All random sampling processes as well as the randomization were performed by an independent statistician. The first 103 clusters were provided to the research team and will all be enrolled for the campaign. If needed, further clusters will be released from the randomization list.

Eligibility criteria

Table 1 outlines the eligibility criteria for clusters and households. No individual eligibility criteria apply for the HOSENG trial as HIV testing coverage is a population-level outcome including every individual in the surveyed area.

Before randomization, all VHWs from the 175 randomly selected villages attend a one-day refresher training focusing on HIV testing and counseling (HTC). Every VHW takes a short pre- and post-training assessment. The assessment includes questions about a) HIV knowledge and HIV stigma using a validated questionnaire22, b) HIV testing knowledge, and c) one open question (“What are important qualities of a counselor?”). The assessment will be used to evaluate the baseline HIV/AIDS-related knowledge and stigma of the involved VHWs and to evaluate their eligibility for participation in the trial (Table 1).

Prior to trial start, the research team met with all relevant village chief councils in order to inform them about the trial and to obtain their consent.

Procedure

Two to three specifically trained teams, each consisting of 5-6 lay-counsellors, 1 campaign organizer and 1 supervising study nurse will visit all households in selected villages, going from door to door. The teams will propose HTC and multi-disease screenings and prevention. The population of the selected areas are informed about the campaign beforehand by their village chief. Specifically, the campaign team will arrive in the village in the morning, meet with the village chief and then start systematically visiting all households in the pre-defined area by going from door to door. At the household, the teams will proceed as follows:

The counselor will introduce him-/herself and the purpose of the testing/screening campaign

The counselor will ask the head of household or their representative (aged 18 years and older) for written informed consent to the testing/screening campaign, and to obtaining data about present and absent household members for study purpose

If the head of household or the representative refuses his/her household participation, the team will leave the house, record the refusal reason, and proceed to the next household

The counselor will assess the total number of present and absent household members

Definition of household member: 1) is acknowledged by the household head or the representative as part of the household and 2) sleeps in the household regularly (at least once a month) and 3) if absent during the campaign: returns to the household no later than three months after the date of home-visit

The counselor will provide information about HIV and testing, prevention aspects, and the other disease screenings (see below)

The counselor will assess the HIV status of all household members and screen the patients' health booklets ("bukana")

Household members who are eligible for and consent to testing (by filling in the Lesotho national informed consent form for HIV testing) undergo HIV testing by the counselor according to specific cluster arm allocation procedure and according to national HIV testing guidelines.20 For absent or declining household members, the specific procedures differs between the two cluster arms, and are described in detail below in the section on intervention clusters. Figure 2 presents all possible HIV testing scenarios during the campaign.

Once the HIV test is done, the counselor documents the result in the patients' health booklet and provides post-test counseling. If the HIV test is confirmed positive, the counselor contacts the study nurse, who then provides further counseling and assesses the participant for enrolment into the inter-linked follow-up study (VIBRA trial).

The HIV testing campaign is combined with additional multi-disease screening. The campaign screens for tuberculosis (TB) according to national guidelines using the clinical symptom screening tool.23 If TB is suspected, one sputum sample is collected on the spot, transported to the health facility the same day by the campaign team for testing with GeneXpert. Another sputum bottle for collecting a morning sample is left behind, the individual is instructed how to use it and a follow-up plan for collection (i.e. collection by VHW) is agreed upon. Further campaign services include alcohol abuse screening using the CAGE questionnaire24, information and referral of males aged 15-50 years old (HIV-negative and -positive due to stigma reasons) for voluntary medical male circumcision (VMMC) according to WHO recommendations25, and promotion and provision of male condoms. Figure 3 presents the overview of the HIV and multi-disease campaign and its algorithm.

Intervention clusters

Figure 4 summarizes the procedures in the HOSENG clusters and Figure 5 the SPIRIT flow diagram. In the intervention clusters, the campaign team will leave an oral HIVST kit (OraQuick® ADVANCE HIV I/II, second generation serology assay with a sensitivity of >93%, a specificity of >9926–29) for every household member 12 years or older who is absent or declined HIV testing on the day of the campaign. We chose 12 years as threshold because adolescents are an important risk group and this is the legal age for providing HIV testing consent in Lesotho.23 The household can refuse to have an oral HIVST left behind for their absent household members. The oral HIVST kit is prepacked, includes a written and pictoral instruction for use in the local language, Sesotho, and the package is labelled with a written request to consult the VHW within 2 weeks after use of the test – irrespective of the result. In cases where more than one trained VHW serves the village, the household will be asked for the VHW of choice. The team will label the kit with the name of the absent member before dispensation.
One household member – the one with the closest relation to the absent person(s) – will be tested and trained using the oral HIVST. All other present household members are tested using the standard blood-based point-of-care HIV test according to Lesotho national guidelines.20

The VHWs in the intervention custers will receive a list of all household members for whom an oral HIVST was dispensed. The VHW will visit all households 2-4 weeks after the campaign to collect the oral HIVST in case the oral HIVST is not returned to him/her. If

an oral HIVST is reactive, the VHW will either provide further blood-based testing on the spot or organize referral to the nearby health facility for confirmatory testing. All VHWs from intervention clusters will receive a second extensive training session about oral HIVST, handling disclosure and stigma, and data entering on paper-based study forms and the patients health booklet.

Control clusters

Following standard of care during home-based HIV testing, every absent household member or those declining HIV testing will be encouraged to get an HIV test done by the VHW or the nearby health facility. The research team will screen the registers at the health facilities in order to assess if these individuals came for testing in the timeframe of the primary endpoint window.

Endpoints

The primary endpoint is HIV testing coverage among individuals aged 12 years or older in the surveyed area within 120 days after the home visit, defined as the proportion of all individuals 12 years or older living in a household of the surveyed area with a confirmed HIV test result.

We define a confirmed HIV-negative result as either being tested HIV-negative as per the algorithm defined in Figure 2, or being tested HIV-negative within the last 4 weeks with proof of documentation (i.e. documentation in patients' health booklets). We define a confirmed HIV-positive result as a) tested HIV-positive as per the algorithm defined in Figure 2, or b) being tested HIV-positive but not yet on ART with proof of documentation, or c) being on ART with proof of documentation.

The rationale for the time-point of 120 days is that we leave oral HIVST kits at the households for all absent household members aged 12 years or older who return within a maximum of 3 months (see definition of household member above in section Procedure). An interval of 120 days after home visit allows sufficient time for absent members to return to their households, conduct self-testing, and be followed up by the VHW.

The secondary endpoints are outlined in Table 2.

Additional research within the project

For the entire GET ON project we will collect cost data, see more details in the VIBRA trial protocol published elsewhere. Specifically for HOSENG trial, first, direct costs of the intervention will be assessed: Staff costs (campaign team, VHWs, clinic staff), personnel training costs (VHWs), cost of equipment (HIV tests, consumables, logistics), as well as non-medical costs to the participant (i.e. cost of transportation to ART service). These data will provide the cost per participant achieving the primary endpoint within 120 days in each cluster arm ('per participant tested cost'). Secondly, a cost-effectiveness analysis will be performed with respect to the primary endpoint. The cost-effectiveness ratio will be presented as incremental cost per additional confirmed HIV test result. Data to assess patient level costs will be collected from a randomly selected sub-sample of study participants from each cluster arm. Costs will be reported in local currencies and US dollars and International Dollars. The robustness of results will be tested with probabilistic sensitivity analysis and deriving cost-effectiveness acceptability curves to capture the uncertainty around the probability that the intervention is below the relevant cost-effectiveness thresholds.

A nested study (ADORE study: "ADolescent ORal sElf-testing") will explore the effectiveness and acceptability of oral HIVST among adolescents and young adults with quantitative methods (see secondary endpoint) and qualitative methods: A qualitative case-control study. Cases are those who refused testing through oral HIVST and controls are those who accepted testing through oral HIVST. We plan to conduct at least 10 interviews per group, stratified by two pre-defined factors (male vs female; age 12-15 vs age 16-24), following the concept of saturation. Data will be collected by a trained study member, who was part of the HIV testing campaign, using a piloted interview questionnaire (KoboToolbox; www.kobotoolbox.org), conducted in the local language (Sesotho). Qualitative data will be recorded, transcribed, translated into English and coded and analyzed using the Framework Method30.

Data collection and management

The campaign team will capture all data collected during the campaign using a tablet-based application and platform (MACRO, Elsevier). The randomization assignment of the villages is pre-loaded into the program and a unique household identifier is automatically generated. Before leaving the household, the completed questionnaire will be checked for mistakes and completeness.

Data from the tablet devices will be uploaded regularly via secure electronic transfer and stored on a secure server at the Swiss Tropical and Public Health Institute (Swiss TPH). After the follow-up period, all confidential information of the study participants (i.e. names) will be deleted from the database and only the anonymous study-ID will be kept. The informed consent forms will be stored in a secure way in the headquarter of the study center (SolidarMed Office in Butha-Buthe, Lesotho). Participant files will be maintained in storage for a period of at least 10 years after completion of the trial.

The VHWs enter data for following up the dispensed oral HIVST kits on standardized paper study forms (Case Report Forms), that act as source documents. These data will be collected regularly by the study team and entered into the above mentioned platform. A study data manager will monitor data quality and completeness on a weekly basis. Queries about the data will be sent to the local principal investigators for follow-up and correction, as needed. Data integrity checks will be written into the database to limit missing fields or the entry of incorrect data. The type of activity that an individual user in the online study database may undertake, will be regulated by the privileges associated with his/her user identification code and password.

Sample-size

The sample size is driven by the VIBRA trial. We assume to achieve the VIBRA trial sample size (minimum 262 HIV-positive individuals not on ART) by testing about 10'000 individuals in 100 villages, based on a previous trial.31 According to a previous home-based HIV testing campaign32, we estimate an HIV testing coverage rate of individuals 12 years or older in rural villages of 63%. We consider a 15% increase in coverage as relevant from a policy perspective. Using an intra-cluster correlation of 0.028, with a sample of 100 clusters, we will have >90% power to detect an increase in coverage rates to 78% or higher.

Analyses

Analyses will be reported following CONSORT guidelines for cluster-randomized trials.33 Clusters will be set as unit of randomization (stratified by district, size of village, and village access to the nearest health facility), whereas individuals are set as unit of analysis. An intention-to-treat set will be used, i.e. all study participants will be evaluated according to arm assignment at randomization. The primary analysis will use a multi-level random effects logistic regression model to assess the difference between HIV testing coverage in the intervention versus control arm, adjusted for a) the pre-specified randomization stratification factors, b) clustering according to the household and the village and c) relevant baseline factors (age groups, gender, education status, employment status, HIV testing history) if found to be randomly unbalanced between intervention and control clusters.34

Baseline characteristics will be presented according to randomized groups; no formal testing will be performed. Categorical variables will be described with absolute and relative frequencies and continuous variables with medians and interquartile ranges. As with the primary analysis, secondary endpoints will be analyzed with multi-level random effects logistic regression models. All results will be presented as odds ratios and 95% confidence intervals. The potential effect modification of sociodemographic determinants (age groups, gender, education status, employment status, HIV testing history) on all endpoints will be assessed by including interaction terms in the models. Sensitivity analyses will be conducted in order to provide evidence that the result seen from the primary analysis are robust. These analyses will focus on the deviations in model assumptions. All analyses will be done using Stata (version 14, Stata Corporation, Austin/Texas, USA). For all tests, we will use 2-sided p-values with alpha 0.05 level of significance.

Monitoring, auditing, and data safety and monitoring board

At least one external monitoring visit will assess adherence to the approved trial protocol, accuracy of completed study forms, and the electronic dataset. The Principal Investigator agrees to allow inspectors from regulatory agencies to review records and will assist the inspectors in their duties, if requested.

The HOSENG trial represents implementation research and the oral HIVST is a well-established diagnostic tool. Thus, we do not expect serious adverse effects (SAE) on patients' health from this intervention. However, for the purpose of this trial, we will try to capture the following SAEs: a) Death due to any reason (especially within 30 days of a positive HIVST results), b) Hospitalisation due to self-inflicted injuries within 30 days of a positive HIVST results, and c) Hospitalisation resulting from violent assault by others (intimate partner violence, assault by family or community members) within 30 days of a positive HIVST result. The campaign team members all have several years of experience in HTC and received an additional study-specific one-week training in order to handle

adverse events related to testing stigma. A separate, detailed safety monitoring plan has been developed to handle these SAEs in line with Swiss and Basotho ethics regulations. It is not planned to establish a data safety and monitoring board.

Discussion

HIV testing constitutes the front door to reach the UNAIDS 90-90-90 targets.35 Currently, UNITAID invests $23 million into a four-year research initiative, called STAR, to gather evidence and catalyse the market for HIVST, and eventually improve testing coverage through HIVST in three African countries (Malawi, Zambia, and Zimbabwe).36 Whereas the STAR trials assess HIVST on a large scale, the HOSENG trial will focus on the use of oral HIVST during home-based HIV testing campaigns. As such, its result will be complementary to the findings of the STAR project.

Home-based HIV testing campaigns have been shown to be very effective in achieving high testing uptake, especially in resource-limited countries.7 However, one major question is still unanswered: How to reach the absent people during these campaigns in a cost-effective way? The HOSENG trial tests if oral HIVST may be an effective add-on during door-to-door testing campaigns towards achieving optimal testing coverage. Linkage to further testing and care after usage of oral HIVST will be provided by the VHWs, a trusted and long-standing public-sector cadre. VHW programs exist in all countries of Southern Africa and are being expanded.37 If cost-effective, the HOSENG approach could easily be scaled up in the region, as the provision of oral self-test kits, followed up by VHWs, requires little additional human resources, finances and logistics. HOSENG trial will inform home-based HTC policies not only in Lesotho, but in similar in sub-Saharan Africa. However, we will have to closely monitor the linkage after testing and the additional burden of work for the VHWs.

Trial status and recruitment

The trial has been launched on July 26, 2018 in both study districts. The recruitment time is driven by VIBRA trial, as HOSENG trial is the main recruitment platform for the VIBRA trial. We assume a recruitment period of 6-8 months.

Abbreviations

ART	Antiretroviral Therapy
HIV	Human Immune Deficiency Virus
HIVST	HIV self-test/ing
HOSENG	HOme-based SElftestiNG
HTC	HIV Testing and Counseling
GET ON	GETting tOwards Ninety
ICMJE	International Committee of Medical Journal Editors
VIBRA	Village-Based Refill of ART
ADORE	ADolescent ORal sElf-testing
SAE	Serious Adverse Events
Swiss TPH	Swiss Tropical and Public Health Institute
TB	Tuberculosis
UNAIDS	United Nations Programme on HIV/AIDS
VHW	Village Health Worker
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

Declarations

Ethics approval and consent to participate

Before cluster-randomization and trial start, the study team obtains verbal consent from all involved village chiefs by attending the village chiefs' councils and presenting the project. On the day of the HIV testing campaign, the counsellors obtain a written consent from the household head (or representative aged 18 years or older), to collect household data and to propose HIV testing to all household members. Allocation to cluster arm is concealed at the household level in order to keep the risk of selection bias as low as possible. Illiterate participants will provide a thumb print and a witness (independent to the trial and >21 years old), chosen by the participant, will co-sign the form. The informed consent is provided in the local language, Sesotho, and the participant will receive a copy of the consent forms. The household head has the right to withdraw consent at any time without giving reasons. In case of withdrawal, only data collected until the time of withdrawal will be used for research purposes (fully anonymized, identifier removed).

If the household consents to participate, then the counselors obtain from each household member written informed consent for HIV testing, following national HIV testing guidelines and using the national HIV testing form.20 According to national guidelines individuals aged 12 years or older can consent to HIV testing. For younger individuals a witness has to sign the national testing form. For HIVST no written consent will be obtained as the act of self-testing itself represents consent. Individual consent for interventions/screenings other than HIV testing, such as referral for VMMC, is obtained using standard procedures according to national guidelines as these are considered part of the routine delivery of HIV prevention services and not specifically study-related.

This trial has been approved by the National Health Research and Ethics Committee of the Ministry of Health of Lesotho (ID06-2018) and the Ethics committee in Switzerland (Ethikkomission Nordwest- und Zentralschweiz; 2018-00283).

Results of this research project will be shared at three levels: At district level, national level, and on an international level, by presenting at conferences and publication in peer-reviewed journals. The current version of the International Committee of Medical Journal Editors (ICMJE) recommendations38 is applicable regarding authorship eligibility and the use of professional writers is not intended.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the study will be available from the corresponding author on reasonable request.

Competing interests

The Division of Infectious Diseases and Hospital Epidemiology, University Hospital Basel, under the lead of MB receives unrestricted education and research grants from Gilead, MSD, Janssen, and ViiV. All other authors declare that they have no competing interests.

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The funding sources have no role in the design of the study, and will not be involved in data collection, data analysis, interpretation of the results and writing of the manuscript.

Author's contribution

TRG is the Principal Investigator of this trial. AA, JM, LK, NDL, TIL and TRG conceived and designed the trial. BLN, FV, MB, MBa, MK, MKa were involved in critical revision of the article for important intellectual content. TK and KT provide laboratory expertise. All authors read, revised, and approved the final manuscript.

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Tables

Tables

Table 1. Cluster and household eligibility criteria for HOSENG trial

		Inclusion Criteria	*Exclusion Criteria*
	Cluster eligibility		
1		The cluster is rural and clearly confined to the catchment area of one of the study clinics Note: one cluster usually consists of one village, but could include several small villages if serviced by the same VHW	The village authority (=village chief) is opposed to trial participation
2		The cluster has at least one registered VHW who is willing to participate and fulfills the following criteria: is at least 18 years of age has adequate reading and writing skills successfully passes the training assessment evaluated by a local person independent to the research project and the research team, by checking if the VHW: is able to fill in the assessment (ticking boxes, writing in correct fields) is able to give an adequate answer regarding the open question, which implies adequate reading and writing skills and a basic logical thinking	The VHW is not willing to attend the training or opposed to trial participation or not fulfilling the criteria: Note: if a cluster entails several VHWs, then the cluster can still participate if there is at least one VHW in the cluster who is willing to participate and fulfills the criteria
	Household eligibility		
1		Signed informed consent from household head or representative aged 18 years or older	No signed informed consent from household head or representative aged 18 years or older

Table 2. Secondary endpoints of HOSENG trial

	Endpoint	*Definition*	*Time point following enrolment*
1	Testing coverage irrespective of age	Proportion of all individuals living in a household of the surveyed area with a confirmed HIV test result	Within 120 days
2	Blood-based HIV testing uptake	Proportion of all present individuals living in a household of the surveyed area, being eligible for blood-based HIV testing and accepting to be tested using blood-based point-of-care HIV test	On the day of the campaign
3	Oral-based HIV testing uptake	Proportion of all individuals living in a household of the surveyed area for whom an oral HIVST was left behind and who performed the oral HIVST.	Within 120 days
4	Adolescent and young adult HIV testing coverage *(ADORE nested study outcome)*	Proportion of all 12-24 years old individuals living in a household of the surveyed area with a confirmed HIV test result	Within 120 days

Figures

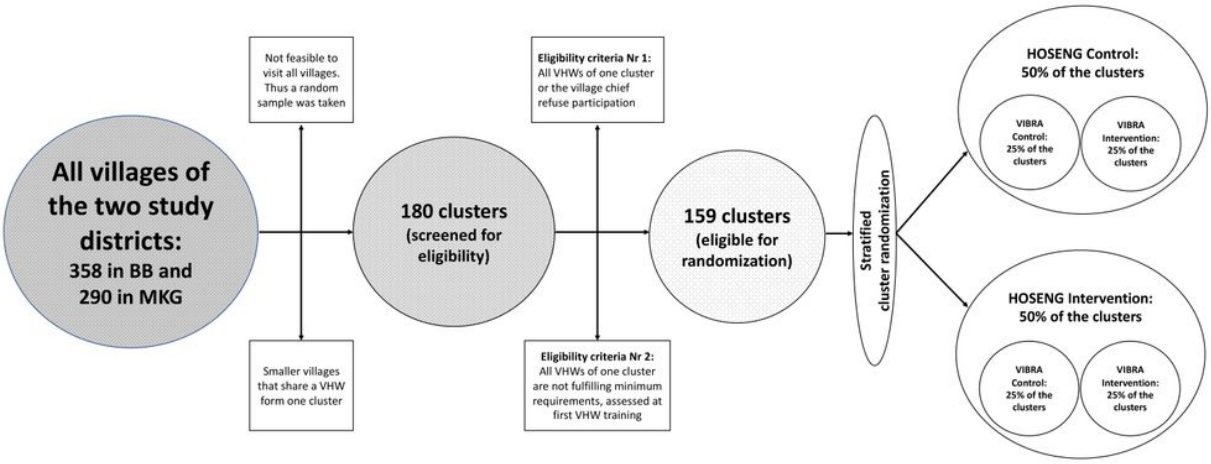

Figure 1

Cluster sampling and randomization - Abbreviations: BB (Butha-Buthe), MKG (Mokhotlong), VHW (Village Health Worker).

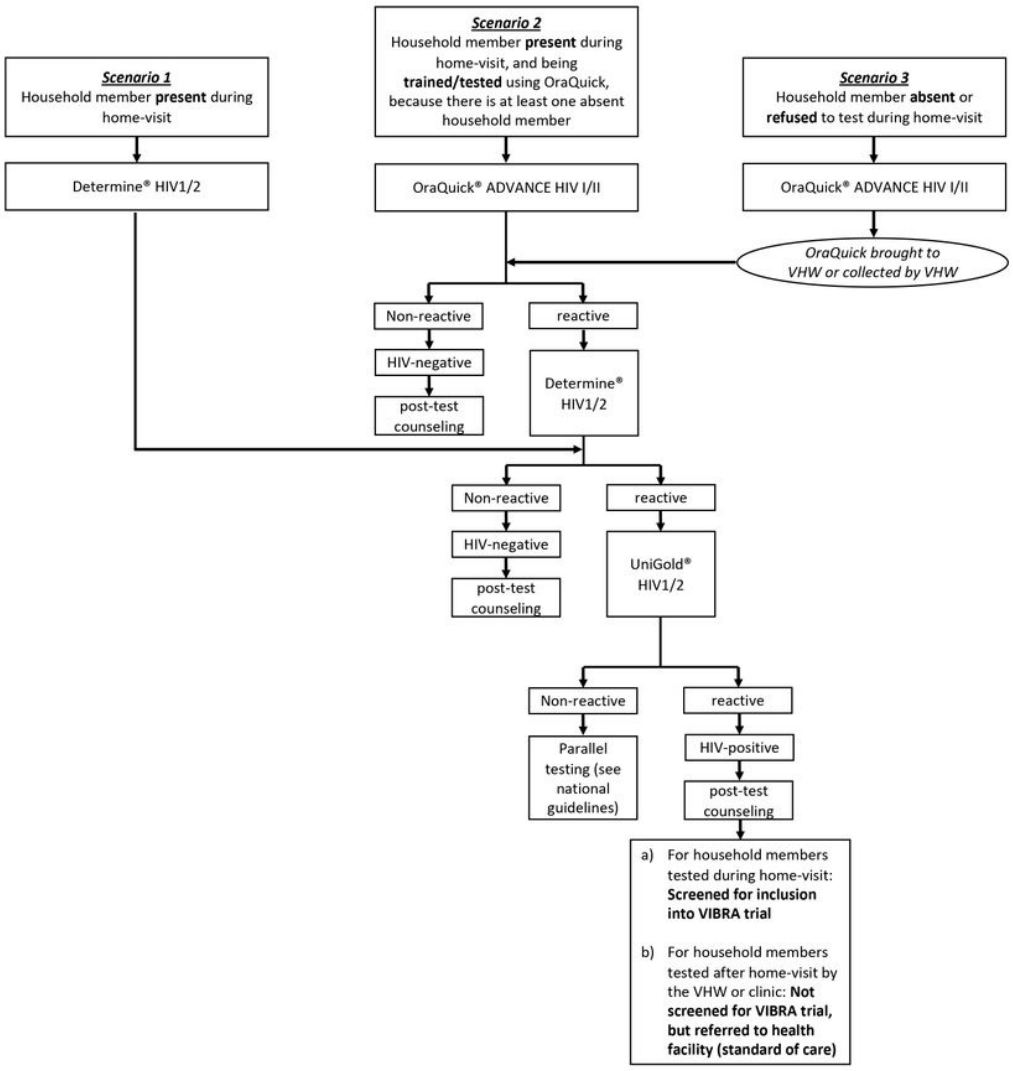

Figure 2

HIV testing scenarios in HOSENG trial - Scenario 2 and 3 only occur in HOSENG intervention clusters.

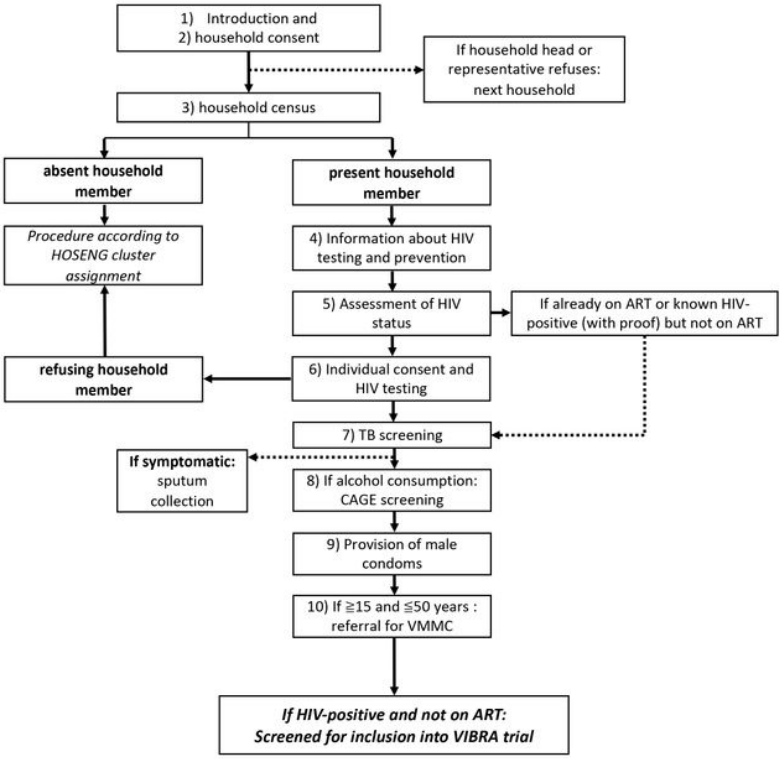

Figure 3

Algorithm of HIV and multi-disease screening/prevention campaign.

HOSENG Control	HOSENG Intervention
Home-based HIV testing campaign	**Home-based HIV testing campaign**
WHEN: June until November, full day	WHEN: June until November, full day
WHERE: In the village, door to door	WHERE: In the village, door to door
WHO: Campaign team, consisting of counselors, 1 campaign organizer and 1 nurse or physician	WHO: Campaign team, consisting of counselors, 1 campaign organizer and 1 nurse or physician
WHAT: a) For present household members: *blood-based HIV testing* b) For absent household members or household members who refuse testing: *Encouraged to get tested by the VHW or the nearby health facility. Linkage to care via VHW.* Linking if present household member is HIV-positive: *Referring to nurse on spot, screening for inclusion into VIBRA trial (that includes retesting and same-day ART initiation)*	WHAT: a) For present household members: *blood-based HIV testing* If any absent person in this household: One of the household members is tested and trained using OraQuick b) For absent household members or household members who refuse testing: *One OraQuick is left behind and has to be brought back to VHW after usage. Otherwise it will be collected by the VHW after two weeks. Linkage to care via VHW.* Linking if present household member is HIV-positive: *Referring to nurse on spot, screening for inclusion into VIBRA trial (that includes retesting and same-day ART initiation)*

Figure 4

Description of procedure in HOSENG intervention and control clusters - - Mobilizing: Through village chief before the campaign date, and through the campaign team on the day of the campaign by going from door to door - Further services include: Screening for tuberculosis, screening for alcohol abuse, voluntary medical male circumcision and condom provision.

	Enrolment	Post-allocation
TIMEPOINT	0	Within 120 days
ENROLMENT:		
allocation (pre-set by cluster)	X	
INTERVENTIONS:		
Distribution of OraQuick (HOSENG Intervention) and follow-up through VHW	X	♦----------♦
No distribution of OraQuick (HOSENG Control) and follow-up through clinic	X	♦----------♦
ASSESSMENTS:		
Socio-demographic factors	X	
tuberculosis screening	X	
CAGE screening	X	
Voluntary male medical circumcision info	X	
Condom distribution	X	

Figure 5

SPIRIT Flow Diagram of HOSENG trial.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- supplement1.pdf