BMJ Open

Assessing a norming intervention to promote acceptance of HIV testing and reduce stigma during household tuberculosis contact investigation: protocol for a cluster-randomised trial

Mari Armstrong-Hough,[1,2] Joseph Ggita,[2] Amanda J Gupta ,[2,3,4] Tyler Shelby,[3] Joanita Nangendo,[2] Daniel Okello Ayen,[5] J L Davis ,[2,3,6,7] Achilles Katamba [2,8]

To cite: Armstrong-Hough M, Ggita J, Gupta AJ, *et al*. Assessing a norming intervention to promote acceptance of HIV testing and reduce stigma during household tuberculosis contact investigation: protocol for a cluster-randomised trial. *BMJ Open* 2022;**12**:e061508. doi:10.1136/bmjopen-2022-061508

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-061508).

MA-H, JG and AJG contributed equally.
JLD and AK contributed equally.

Received 28 January 2022
Accepted 27 April 2022

For numbered affiliations see end of article.

Correspondence to
Dr Mari Armstrong-Hough; mah842@nyu.edu

ABSTRACT

Introduction HIV status awareness is important for household contacts of patients with tuberculosis (TB). Home HIV testing during TB contact investigation increases HIV status awareness. Social interactions during home visits may influence perceived stigma and uptake of HIV testing. We designed an intervention to normalise and facilitate uptake of home HIV testing with five components: guided selection of first tester; prosocial invitation scripts; opt-out framing; optional sharing of decisions to test; and masking of decisions not to test.

Methods and analysis We will evaluate the intervention effect in a household-randomised controlled trial. The primary aim is to assess whether contacts offered HIV testing using the norming strategy will accept HIV testing more often than those offered testing using standard strategies. Approximately 198 households will be enrolled through three public health facilities in Kampala, Uganda. Households will be randomised to receive the norming or standard strategy and visited by a community health worker (CHW) assigned to that strategy. Eligible contacts ≥15 years will be offered optional, free, home HIV testing. The primary outcome, proportion of contacts accepting HIV testing, will be assessed by CHWs and analysed using an intention-to-treat approach. Secondary outcomes will be changes in perceived HIV stigma, changes in perceived TB stigma, effects of perceived HIV stigma on HIV test uptake, effects of perceived TB stigma on HIV test uptake and proportions of first-invited contacts who accept HIV testing. Results will inform new, scalable strategies for delivering HIV testing.

Ethics and dissemination This study was approved by the Yale Human Investigation Committee (2000024852), Makerere University School of Public Health Institutional Review Board (661) and Uganda National Council on Science and Technology (HS2567). All participants, including patients and their household contacts, will provide verbal informed consent. Results will be submitted to a peer-reviewed journal and disseminated to national stakeholders, including policy-makers and representatives of affected communities.

Trial registration number ClinicalTrials.gov Identifier: NCT05124665.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This trial will evaluate an intervention designed to increase uptake of HIV testing among household contacts of patients with tuberculosis using a household-randomised, controlled design.
⇒ The intervention is based on a strong foundation of longstanding research on social decision-making and could be widely scaled to improve HIV status awareness if effective.
⇒ The cluster-randomised design will allow us to evaluate both individual-level and household-level effects of the intervention.
⇒ The cluster-randomised design and use of separate teams of community health workers for each arm reduce the risk of contamination across arms.
⇒ This study design is limited by the short follow-up period of the trial, which will evaluate uptake of HIV testing (primary outcome) and record linkage to HIV care, but not initiation of antiretroviral therapy.

INTRODUCTION

Background and rationale

An estimated 37 million people worldwide are living with HIV, and more than 15%[1] do not know their status because they are unaware that they are at risk, unable to access counselling and testing, or unwilling to test because of stigma and fear. Layered on to the stigma of HIV is stigma for tuberculosis (TB),[2] the leading cause of death among persons living with HIV (PLWH). Approximately 40% of those with TB worldwide are unaware of their TB status.[3] Like HIV-related stigma, TB-related stigma is common and reduces the willingness of at-risk individuals to test for TB and engage in care.

Testing for HIV is particularly important for close contacts of patients with TB. However, layered HIV–TB stigma introduces social and psychological barriers to testing for HIV and

TB during TB contact investigation. Acceptance of home HIV test offers is lower among TB contacts compared with the general population.[4 5] There is a critical need for targeted interventions to address layered stigma, reduce the fear of HIV and TB testing and increase uptake of testing for HIV and/or TB among individuals at high risk.

Offering testing at home is a promising approach to increase testing and linkage to care for HIV and TB. Home-based HIV testing can reach individuals outside the health system, eliminate the costs of attending clinics for testing and offer testing in a familiar environment. Nevertheless, many individuals offered home HIV testing in sub-Saharan Africa decline. We have previously shown that when HIV testing is offered during TB home visits, social interactions among household members influence perceived stigma and test uptake.[6] Specifically, when household members discern that others have declined, they say that they fear that testing will be socially discrediting. In adjusted analyses, individuals were four times as likely to decline testing when the first member of their home declined testing as when that individual accepted.[4 6] Others have shown that misperceived norms influence HIV-related health behaviours.[7 8] A 'norming' intervention[9] to facilitate re-evaluation of norms related to HIV testing may increase uptake of testing by exposing individuals to the attitudes, values and behaviours of household members who support HIV testing.

Objectives

Nearly a century of research demonstrates that observing the decision-making behaviours of peers profoundly influences perceptions, judgments and subsequent behaviours.[10–14] Moreover, status and social ties among group members modify their influences on one another. We designed an intervention using established principles from social and behavioural science to facilitate household interactions that reduce stigma and promote uptake of HIV testing. This study will evaluate a novel approach to destigmatising home HIV testing that optimises the social opportunity to test and link to care for HIV. We plan to evaluate this strategy in a randomised controlled trial, and hypothesise that offering and delivering HIV testing in this manner will increase the proportion of TB contacts completing HIV testing and linking to care. The results will inform new, scalable strategies for delivering HIV counselling and testing to key populations. These data will also inform a future factorial experiment and scale-up study to evaluate the effectiveness of each intervention component in increasing uptake of HIV testing and decreasing perceived stigma related to HIV testing in household settings.

METHODS AND ANALYSIS

Trial design

We will carry out a prospective, household cluster-randomised controlled implementation trial evaluating a multicomponent, social and behavioural intervention to reduce household HIV stigma and promote uptake of HIV testing among household members undergoing TB contact investigation. We will recruit multiple-contact households undergoing routine contact investigation for TB, and randomise them to one of two study arms. Households in both arms will receive routine TB contact investigation services, with optional oral HIV testing at no cost to the patient. Offers in the control arm will be presented using a standard approach and offers in the intervention arm presented using a social–behavioural norming strategy.

Intervention description

The intervention is designed to normalise the use of HIV testing in the household and increase detection of HIV. Community health workers (CHWs) will employ acceptance-optimised sequencing of invitations and a prosocial invitation script to offer salivary testing for HIV to household members. We will measure HIV-related and TB-related stigma using standardised, locally validated instruments before invitation and after completion of post-test counselling. We will measure the proportion consenting to HIV testing, the yield of HIV diagnoses and the proportion of new PLWH linked to HIV care. We will also reassess household HIV and TB stigma at 3 months in a subset of participating households. A subset of participants will be contacted at a later point for interviews, focus-group discussions or surveys to better understand the implementation, mechanisms and impact of the intervention.

Study setting

The study will take place in Kampala, Uganda. Uganda is a high HIV/TB burden country, with estimated HIV prevalence of 5.4% and TB incidence of 200 per 100,000.[15 16] More than 25% of PLWH are unaware of their HIV status.[17] Uptake of door-to-door home HIV testing ranges from 69% to 95%,[18–20] but uptake of home HIV testing among household contacts of patients with TB is only 53%–61%.[6 21 22] The Uganda PLWH Stigma Index Survey found that >30% of Ugandan PLWH had experienced malicious gossip in their family or community in the prior year.[23] TB stigma may be even more common than HIV stigma; nearly 50% of survey respondents in Uganda held stigmatising attitudes toward persons with TB, compared with only 26% of respondents who held stigmatising attitudes toward PLWH.[24] Participants will be recruited from public health facilities administered by the Kampala Capital City Authority (KCCA). Patients diagnosed with TB at KCCA health facilities are offered routine TB contact investigation services led by trained CHWs.

Eligibility criteria

We will enroll index patients and their household contacts from three public-sector, primary care facilities: Kiswa, Kawaala and Kisenyi Health Centres, all in Kampala, Uganda. For the purposes of this study, household

contacts are defined as those individuals 'sleeping under the same roof' as the index patient for one or more days or nights within the past 3 months.[25]

Index patient eligibility criteria include (1) being an adult or child recorded as a TB case in the site's National TB and Leprosy Programme TB Treatment Register, (2) residing within the boundaries of the KCCA, (3) not diagnosed with multidrug resistant TB, (4) reporting ≥2 household contacts, age 15 or above and (5) agreeing to study procedures in addition to routine contact investigation. Eligibility criteria for household contacts include (1) being ≥15 years of age and (2) agreeing to study procedures in addition to routine contact investigation.

Informed consent

In accordance with National TB guidelines, CHWs will verbally invite eligible index patients and their household contacts to participate in contact investigation. Willing index patients and their household contacts will be asked to review the research study information sheet and verbal informed consent document outlining all study-related activities before providing formal verbal consent to participate in the study. Because the primary risk to trial participants is a breach of confidentiality, we will use verbal informed consent to minimise the risk of disclosure of TB or HIV status from signatures on consent forms.

CHWs trained in Human Subjects' Protection, Good Clinical Practice and informed consent procedures will carry out and document all verbal informed consent encounters. For participants under age 18 who are not emancipated minors, permission to participate will be obtained from a parent or legal guardian. Among index patients and contacts, children aged 15–17 must subsequently assent to participate. Among contacts, only household members 15 years of age or older will be eligible for HIV testing.

Additional consent provisions—collection and use of participant data

After deidentification, participant data (but no specimens) will be stored for at least 7 years. As outlined during informed consent, we will not require reconsenting of participants when data are used for a purpose beyond the originally proposed aims, provided the purpose is approved by relevant institutional review boards (IRBs).

Interventions

Choice of comparators

We will compare a standard, provider-initiated approach to offering HIV counselling and testing during household TB contact investigation, as recommended in the Uganda National TB and Leprosy Programme (NTLP) guidelines, to our interventional approach, a novel, social–behavioural norming strategy. In both arms, CHWs screen contacts for TB symptoms and offers HIV testing to all individuals age ≥15 who do not report themselves to be already living with HIV. In the control arm, CHWs will use the standard, 'opt-in' framing. Those who agree to test will then be taken to a private area within the home and provided HIV counselling and oral testing (OraQuick, OraSure Technologies, Bethlehem, Pennsylvania, USA), in accordance with Uganda Ministry of Health guidelines.[26] The order in which household contacts are offered HIV testing will be at the discretion of the CHW, and household members will not be informed of each other's decisions. Those testing positive will be referred to a nearby health facility for confirmatory testing and treatment initiation.

Intervention descriptions

The trial intervention is a sociobehavioural norming strategy to address misperceived norms related to HIV testing in the household. It consists of five components, each designed to influence household dynamics to promote acceptance of HIV counselling and testing. The components include[1] guided selection of the first tester[2]; use of a prosocial script[3]; opt-out framing of the test offer[4]; optional sharing of decisions to test and[5] masking decisions not to test, as further outlined below. Each of these components is delivered by a CHW during a single home visit, guided by decision support prompts and scripts integrated into an electronic case record application.

Selection of first tester

CHWs are trained to make the first HIV testing invitation to the individual most likely to accept testing, as nominated by the index patient during the household intake interview. If this person is not present, CHWs are trained to invite whomever they deem most likely to accept testing. In all cases, the order of subsequent testers will be at the discretion of the CHW.

Prosocial invitation script

When inviting contacts to test, CHWs will employ a standardised script to encourage testing: 'Knowing your status sets a good example for your household'. This script is labelled as 'prosocial'—meaning 'for the group'—because it features language that frames HIV testing as an activity that benefits the entire household by protecting it from the risks that undiagnosed HIV poses to any of its members.[27]

Opt-out framing of the test offer

CHWs will employ an 'opt-out' framing for offering HIV testing rather than the standard opt-in framing: 'This oral test kit is approved by the Ministry of Health and used in KCCA health facilities. I'm going to test you for HIV now. Is that ok?'

Sharing decision to test

If the household contact offered HIV testing agrees to test, the CHW will privately invite the contact to disclose his/her decision to test (although *not* the test results) with other household members. After delivering the HIV testing results, the CHW will use the following script: 'Would you like to share your decision to test with the others? Sharing is completely optional. However, learning

that someone else in their household decided to test sometimes gives people the strength to test themselves. Sharing your decision might help another person find the strength to test. This does *not* mean sharing your test results, just that you were tested for HIV. Learning that someone else in their household decided to test sometimes gives people the strength to test themselves.'

Masking household members decision not to test

To ensure that testing decisions cannot be inferred from the length of the private counselling session (eg, <2 min for those who decline testing, vs 20–30 min for those who accept and undergo testing), CHWs will standardise the length of time before an individual is returned to the group. For those declining testing, CHWs will administer a survey about their attitudes towards HIV testing for approximately 15 min.

Criteria for discontinuing or modifying intervention

Because this is a minimal-risk social and behavioural intervention, the primary risk to participants is a loss of privacy or confidentiality, as may occasionally occur in routine practice. While we do not anticipate the need to discontinue the intervention, we will notify the relevant IRBs about these events if they occur.

Strategies to improve adherence to intervention

To prevent cross-contamination between trial arms, three separate teams of CHWs will deliver services: a clinic-based team enrolling patients with TB and randomly allocating interventions, a field-based team trained to deliver the intervention strategy, and a field-based team trained to deliver the standard strategy. The two field-based teams will not share training materials or have access to electronic case records or forms for the arm to which they are not assigned. To improve CHW adherence to the intervention, decision support, invitation scripts and intervention components are integrated into the electronic case record forms (CommCare, Dimagi, Boston, Massachusetts, USA). CHWs will only have access to training, procedures, forms and contact information related to their assigned allocation within the electronic case record forms. All CHWs participated in training emphasising the design and purpose of randomised controlled trials.

Relevant concomitant care permitted or prohibited during trial

Concomitant care is permitted during the trial.

Provisions for post-trial care

Any participant diagnosed with HIV will be referred to antiretroviral therapy clinics at the participating health centres, free of charge.

Outcomes

Our primary outcome is the uptake of HIV testing, defined as the number of eligible contacts who undergo HIV testing divided by the total number of contacts offered testing. We will also examine several secondary outcomes: change in perceived stigma for HIV, change in perceived stigma for TB, effect of perceived stigma for HIV on HIV test uptake, effect of perceived stigma for TB on HIV test uptake and proportions of first-invited contacts who accept HIV testing.

Participant measures

We will collect baseline clinical and demographic variables from cases and contacts. At enrolment, we will also ask cases to predict which household contacts are most likely to accept testing, and to share whom they and their household contacts go to within the household for health-specific advice, knowledge and/or approval. We will also record if CHWs observe contacts openly sharing their testing decisions with household members.

Participant timeline

The schedule of participant procedures for both study arms can be found in table 1.

Sample size and recruitment

Sample size

Approximately 152 households including about 304 household contacts are needed to power the primary analysis. For recruitment and randomisation, we will inflate this number by 30% to 198 households to account for non-completion of household visits (ie, losses to follow-up). We analysed power for a two-arm household-randomised controlled trial using mixed model tests for two proportions in a two-level hierarchical design (household, contact). Based on our previous randomised controlled trial of household contact investigation for TB, we assume an average of two household contacts will be eligible for HIV testing per household, the intraclass correlation coefficient (ICC) within households will be 0.59, the proportion consenting to testing in the control group will be 0.85, and proportion consenting to testing in the intervention group will be 0.98.[21] With these assumptions, this sample size target will provide 90% power to detect an effect of +0.13 at α=0.05.

Recruitment

Clinic-based CHWs will approach consecutive patients presenting with TB at the three participating health centres. Those identified as eligible for both contact investigation and this study will be offered a home visit by the CHW. During the home visit, CHWs will assess all encountered household contacts aged ≥15 for study eligibility and subsequently offer HIV testing. Those not eligible for the study will be offered routine TB contact investigation services per NTLP guidelines.

Assignment of interventions: allocation

Sequence generation

Households will be assigned to a study arm using variable block randomisation, with block sizes of 2, 4 or 8 to mask the end of a block. We will use Study Randomizer,[28] a web-based randomisation service with concealed allocation, to generate the allocation sequence.

Table 1 Participant schedule of procedures

Activity	Participant type	Study arm	Location	Approximate time to complete	Prestudy screening consent	Study initial clinic visit	Study community visit	Study follow-up clinic visit	Study follow-up 3 month visit
Timing					**–1**	**0**	**T1**	**T2**	**T3**
Screening for contact investigation eligibility	Patient with TB	Both	Clinic	3 min	X				
Consent to contact investigation and study participation	Patient with TB	Both	Clinic	3–5 min	X				
Index patient interview	Patient with TB	Both	Clinic	10 min		X			
Routine TB education	Patient with TB	Both	Clinic	20 min		X			
Screening for study eligibility	Contact	Both	Community	3 min			X		
Consent to study participation	Contact	Both	Community	3–5 min			X		
Contact interview on TB symptoms, HIV test eligibility and HIV–TB stigma scale administration	Contact	Both	Community	20 min			X		
Invitation to HIV testing—standard*	Contact	Standard	Community	2 min			X		
Invitation to HIV testing—socionormative script*	Contact	Intervention	Community	2 min			X		
HIV testing†	Contact	Both	Community	20 min			X		
Disclose decision to test to other household members†	Contact	Intervention	Community	3 min			X		
Evaluation by clinician and initiation of ART‡	Contact	Both	Clinic	~10–60 min				X	
HIV–TB stigma scale readministration	Contact	Both	Community	15 min					X

*Only for those age 15 or above who are not self-reported as living with HIV.
†Only for those who accept offer of HIV testing.
‡Only for those who test positive for HIV.
ART, antiretroviral therapy; TB, tuberculosis.

Concealment mechanism

The allocation sequence will be predetermined by Study Randomizer and accessible only to the study coordinators and only at the time of enrollment, with adherence to the release sequence verifiable by comparison of time-stamps in Study Randomizer and separate electronic case record forms.

Implementation

On determining that a patient is eligible for the study and obtaining verbal informed consent, the clinic-based CHW will telephone the study coordinator, who will communicate the assigned allocation after enrolling the household using the Study Randomizer tool. The CHW will record the allocation and unique randomisation identifier in the case record form and connect the index patient with the appropriate CHW team to arrange the household visit.

Assignment of interventions: blinding

Blinding

Although CHWs will be blinded to the allocation procedures, blinding them to the assigned strategy is not feasible because the two approaches to test offers are easily distinguishable. CHWs will record the outcome of test acceptance, but CHWs assigned to each arm will be blinded to the outcomes recorded in the other arm. Participants will not be informed about whether they are assigned to the intervention or the standard invitation strategy. Neither the investigators nor the onsite study coordinators managing randomisation will be blinded to allocation, but all will remain blinded to study outcomes until data cleaning is completed after the trial and the database are locked.

Procedure for unblinding if needed

Coordinators and investigators may be unblinded to the outcomes for a participant if needed to investigate a severe adverse event.

Data collection and management

Plans for assessment and collection of outcomes

All outcomes will be collected through direct interview of study participants and/or review of health centre registers.

Plans to promote participant retention and complete follow-up

CHWs in both study arms will telephone the index patient or treatment supporter ahead of the household visit. If the visit does not take place within 2 weeks, CHWs will repeat the invitation at the index patient's 2 week TB treatment follow-up visit at the clinic. If a community visit has not occurred within 7 days of the 2 week clinic visit, that patient will be considered lost to follow-up.

Data management

CHWs will enter all data into a customised CommCare application (Dimagi, Boston, Massachusetts, USA) on password-protected Android tablets. Once submitted, data will be automatically uploaded to a secure server. Uploaded data are stored on a Health Insurance Portability and Accountability Act (HIPAA)-certified, password protected, encrypted server. In addition to built-in data checks for out-of-range or impossible values, a data manager will review all data weekly for missing or impossible values. All CHWs will receive data management reports at regular intervals with data queries, which will be resolved in consultation with the CHW who initially entered the data.

Confidentiality

The CommCare application and server are password-protected and HIPAA-certified and use encryption to ensure patient confidentiality. Only those with study-approved logins can access participant data, with the data manager and principal investigators retaining centralised control over access.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use

No biological specimens will be collected for purposes beyond routine TB and HIV evaluation, nor will any be stored for future use.

Statistical methods

Statistical methods for primary and secondary outcomes

We will describe enrollment and report baseline characteristics by study arm using simple proportions for categorical variables and measures of central tendency for discrete variables. We will estimate primary and secondary outcomes using simple proportions or probabilities using mixed effects logistic models. We will assess the correlation of outcomes within households by calculating the ICC for test uptake by household. We will compare uptake among intervention households by fitting a multivariable mixed effects logistic regression model with two levels (household, contact), including covariates for characteristics of contacts (age, sex). First, we will compare proportions of first-invited contacts who accept HIV testing between study arms. We will estimate the reliability of the TB case's nomination of the household contact most likely to test by calculating the proportion of nominated contacts who accept HIV testing offers in each study arm. We will estimate the influence of the first-tester's decision on subsequent testers' decisions to test by study arm. For the intervention arm only, we will estimate the effect of the first testers' disclosure of their decision to test on subsequent testers' decisions to test. Finally, we will assess the effect of the intervention on HIV and TB stigma by comparing stigma scores between study arms. We will carry out secondary analyses of the association between HIV and TB stigma scores and decision to test for HIV. We will construct models adjusted for imbalances in baseline confounders as needed.

Interim analyses

After 100 unique household visits have occurred, we will conduct an interim analysis for the purposes of evaluating

the sample size target. We will not examine trial outcomes during the interim analysis. Rather, we will calculate the household ICC and mean cluster size for contact HIV test uptake across study arms by fitting a null multilevel model. If the ICC is meaningfully different from our initial sample size calculations (>10% difference higher or lower than our initial estimate of 0.59), or mean cluster size differs by ≥1 participant, we will recalculate sample size and adjust the final sample size accordingly.

Methods for additional analyses (subgroup)

Stratified analyses will be carried out by age group and gender of household contacts, and HIV status of the household index patient.

Methods in analysis to handle protocol non-adherence and missing data

The primary analysis will consider the intent-to-treat population, which will include all contacts enrolled and eligible at all sites. Intervention contacts in the intent-to-treat population will be those enrolled and assigned to the intervention arm through Study Randomizer, regardless of allocation listed in the electronic data record. Control contacts in the intent-to-treat population will be those enrolled and assigned to the control arm through Study Randomizer, regardless of allocation listed in the electronic data record. Participants with missing HIV testing decisions will be eliminated from the final study analysis. In secondary analyses, we will perform a per protocol analysis for participants for whom there is a randomisation mismatch between data recorded in case record forms and Study Randomizer records.

Plans for granting public access to full protocol, participant data, statistical code

The full trial protocol is contained with the ClinicalTrials.gov registry (NCT05124665).

Oversight and monitoring

Composition of coordinating centre and trial steering committee

Because this is a small, investigator-initiated trial of a minimal risk behavioural intervention, we did not appoint a steering committee.

Composition of data monitoring committee, role and reporting structure

Because this is a small, investigator-initiated trial of a minimal risk behavioural intervention, we did not appoint a monitoring committee.

Adverse event reporting and harms

CHWs are responsible for reporting any adverse events occurring after enrollment to the study team within 24 hours, regardless of causality. The study team will immediately notify the principal investigators on learning of an adverse event, and together they will investigate and prepare a formal report to the IRBs within 48 hours. The IRBs will determine if the trial needs to be paused or terminated based on these reports, and the principal investigators will take immediate action based on the IRBs' determination.

Frequency and plans for auditing trial conduct

The principal investigators will conduct periodic audits of trial conduct. We will also adhere to all audit requirements of the IRBs and the funder, including monitoring visits.

Plans for communicating important protocol amendments to relevant parties (participants, ethical committees, etc)

We will immediately notify the IRBs if an amendment is needed for safety or if we need to revise the target sample size, and we will notify all CHWs and all active participants on approval of the amendment.

Patient and public involvement

We first involved patients and the public in the research by interviewing participants from 56 households undergoing TB contact investigation to obtain feedback on the proposed intervention components and the implementation strategy. We used these data on participant experiences and preferences to modify CHW invitation scripts, improve CHW training and decision support and optimise the client-centeredness of the intervention. We also used these data to inform the design of interview guides to assess implementation fidelity and context during the trial.

ETHICS AND DISSEMINATION

The study protocol and consent forms (online supplemental appendices 1 and 2) have been approved by the Yale Human Investigation Committee (2000024852), the Makerere University School of Public Health Institutional Review Board (IRB) (661) and the Uganda National Council for Science and Technology (HS2567). Study progress will be reviewed annually by the Makerere University School of Public Health IRB. All participants, including patients and their household contacts, will provide verbal informed consent.

Trial results will be published using the outcome definition presented here. We will disseminate our findings to stakeholders, including local communities and policymakers, and the global research community, through public and private meetings, scientific presentations and open-access publications in peer-reviewed journals. We will follow the International Committee of Medical Journal Editors guidelines for authorship and include a statement of measures employed to ensure equitable recognition of all members of the research team in published reports of the trial results.

Trial status

Recruitment of study participants began on 25 October 2021. We anticipate recruitment of participants to end in May 2023, or whenever the target sample size is reached.

Author affiliations
[1]Departments of Social and Behavioral Sciences and Epidemiology, New York University, New YorkUSA
[2]Uganda Tuberculosis Implementation Research Consortium, Kampala, Uganda
[3]Epideimology of Microbial Diseases, Yale University School of Public Health, New Haven, Connecticut, USA
[4]Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA
[5]Kampala Capital City Authority, Kampala, Uganda
[6]Pulmonary, Critical Care, and Sleep Medicine Section, Yale School of Medicine, New Haven, Connecticut, USA
[7]Center for Methods in Implementation and Prevetion Science, Yale School of Public Health, New Haven, Connecticut, USA
[8]Clinical Epidemiology and Biostatistics Unit, Makerere University College of Health Sciences, Kampala, Kampala, Uganda

Twitter J L Davis @LDavisMD

Acknowledgements The authors wish to acknowledge all study participants, including index patients, contacts, community health workers, and other health workers and administrators at the participating Kampala Capital City Authority (KCCA) sites. We also wish to thank the staff and administration at the Uganda TB Implementation Research Consortium and at Walimu, who are responsible for conducting the trial.

Contributors MAH, JLD and AK devised the study procedures. MAH, JG, AJG and TS wrote the first draft of this manuscript. JN and DOA critically revised the manuscript for intellectual content. All authors reviewed and revised the final manuscript before submission.

Funding This project is funded by the Fogarty International Center and the National Institute of Mental Health through grant R21TW011270 (JLD). The funder has no role and will not have any role in study design, data collection, analysis or preparation of any manuscripts relating to this research.

Competing interests None declared.

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.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Amanda J Gupta http://orcid.org/0000-0003-2318-1783
J L Davis http://orcid.org/0000-0002-8629-9992
Achilles Katamba http://orcid.org/0000-0002-2347-4183

REFERENCES

1 UNAIDS. Fact Sheet - World AIDS Day 2021 Global HIV Statistics. UNAIDS 2021.
2 Daftary A. Hiv and tuberculosis: the construction and management of double stigma. *Soc Sci Med* 2012;74:1512–9.
3 World Health Organization. *Global tuberculosis control: WHO report 2021*. Geneva, Switzerland: World Health Organization, 2021.
4 Armstrong-Hough M, Ggita J, Ayakaka I, *et al*. Brief Report: "Give Me Some Time": Facilitators of and Barriers to Uptake of Home-Based HIV Testing During Household Contact Investigation for Tuberculosis in Kampala, Uganda. *J Acquir Immune Defic Syndr* 2018;77:400–4.
5 Velen K, Lewis JJ, Charalambous S, *et al*. Household HIV testing uptake among contacts of TB patients in South Africa. *PLoS One* 2016;11:e0155688.
6 Armstrong-hough M, Meyer AJ, Katamba A. Conformity and communal decision-making: First-tester effects on acceptance of home-based HIV counseling and testing in Uganda. *Peer J Preprints* 2018;6:e27006v2.
7 Perkins JM, Kakuhikire B, Baguma C, *et al*. Perceptions about local art adherence norms and personal adherence behavior among adults living with HIV in rural Uganda. *AIDS Behav* 2022;26:1892–904.
8 Perkins JM, Nyakato VN, Kakuhikire B, *et al*. Actual versus perceived HIV testing norms, and personal HIV testing uptake: a cross-sectional, population-based study in rural Uganda. *AIDS Behav* 2018;22:616–28.
9 Yamin P, Fei M, Lahlou S. Using social norms to change behavior and increase sustainability in the real world: a systematic review of the literature. *Sustainability* 2019;11:5847.
10 Asch SE. *Effects of group pressure upon the modification and distortion of judgments*. Oxford, England: Carnegie Press, 1951: 177–90.
11 Campbell JD, Fairey PJ. Informational and normative routes to conformity: the effect of faction size as a function of norm extremity and attention to the stimulus. *J Pers Soc Psychol* 1989;57:457–68.
12 Cialdini RB, Goldstein NJ. Social influence: compliance and conformity. *Annu Rev Psychol* 2004;55:591–621.
13 Pachucki MA, Jacques PF, Christakis NA. Social network concordance in food choice among spouses, friends, and siblings. *Am J Public Health* 2011;101:2170–7.
14 Christakis NA, Fowler JH. Social contagion theory: examining dynamic social networks and human behavior. *Stat Med* 2013;32:556–77.
15 UNAIDS. *Country Factsheets - Uganda 2020*. UNAIDS, 2021.
16 CDC. Uganda country profile. centers for disease control and prevention 2021.
17 World Health Organization. *Uganda: HIV country profile*. Geneva, Switzerland: WHO, 2017.
18 Tumwesigye E, Wana G, Kasasa S, *et al*. High uptake of home-based, district-wide, HIV counseling and testing in Uganda. *AIDS Patient Care STDS* 2010;24:735–41.
19 Kyaddondo D, Wanyenze RK, Kinsman J, *et al*. Home-Based HIV counseling and testing: client experiences and perceptions in eastern Uganda. *BMC Public Health* 2012;12:966.
20 Sekandi JN, Sempeera H, List J, *et al*. High acceptance of home-based HIV counseling and testing in an urban community setting in Uganda. *BMC Public Health* 2011;11:730.
21 Davis JL, Turimumahoro P, Meyer AJ, *et al*. Home-Based tuberculosis contact investigation in Uganda: a household randomised trial. *ERJ Open Res* 2019;5. doi:10.1183/23120541.00112-2019. [Epub ahead of print: 29 07 2019].
22 Ochom E, Meyer AJ, Armstrong-Hough M, *et al*. Integrating home HIV counselling and testing into household TB contact investigation: a mixed-methods study. *Public Health Action* 2018;8:72–8.
23 Uganda Country Assessment Report. *The National forum of people living with HIV networks in Uganda*. Uganda: The people living with HIV stigma index, 2019. stigmaindex.org
24 Wynne A, Richter S, Jhangri GS, *et al*. Tuberculosis and human immunodeficiency virus: exploring stigma in a community in Western Uganda. *AIDS Care* 2014;26:940–6.
25 World Health Organization. *Who operational Handbook on tuberculosis. module 2: screening. systematic screening for tuberculosis disease*. Geneva, Switzerland: WHO, 2021.
26 Ministry of Health. *Uganda national policy guidelines for HIV voluntary counselling and testing*. Kampala, Uganda: Uganda Ministry of Health, 2005.
27 Kraft-Todd G, Yoeli E, Bhanot S, *et al*. Promoting cooperation in the field. *Curr Opin Behav Sci* 2015;3:96–101.
28 Study Randomizer [Software Application], 2017. Available: https://www.studyrandomizer.com