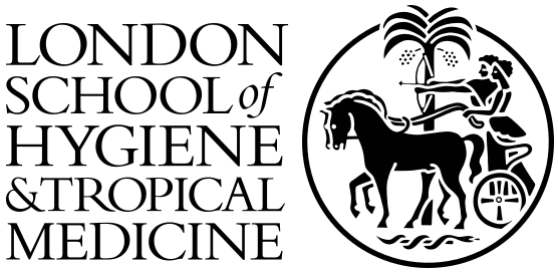

Evaluation of community-led delivery of HIV self-testing in Malawi

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Declaration

I, Pitchaya Peach Indravudh, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Abstract

Response to the HIV epidemic is a global health priority, with HIV a leading cause of morbidity and mortality in sub-Saharan Africa. The United Nations Fast-Track Strategy sets to accelerate reductions in incidence and AIDS-related deaths by 2030. Undiagnosed infection, especially among underserved population subgroups, continues to drive ongoing transmission and poorer outcomes from late diagnosis.

This thesis evaluates the health, social, and economic impact of an alternative approach for providing HIV testing using community-led delivery of HIV self-testing. First, it includes a mixed-methods systematic review and shows that community-led responses for communicable disease control can improve health behaviours, including for disease prevention, screening, and management. Second, a cluster-randomised trial was conducted to evaluate the effectiveness of community-led delivery of HIV self-testing in Malawi. The community-led HIV self-testing intervention was shown to increase HIV testing in adolescents, older adults, and men as well as population-level antiretroviral therapy initiation immediately following implementation. Additionally, the intervention was safe and associated with high uptake. Third, the economic costs and effects on HIV testing positivity were measured using a trial-based economic evaluation. The intervention was found to provide testing at a low additional cost but was unlikely to be cost-effective in contexts with low prevalence of undiagnosed HIV. Lastly, pathways to impact were examined using causal mediation analysis. The intervention was reported to increase uptake of HIV testing directly through community contributions to service delivery rather than indirectly by modifying social and structural determinants.

Collectively, this thesis shows that community-led delivery of HIV self-testing is an effective and cost-efficient strategy that enables communities to lead solutions for disease control. This thesis also provides insights on the value of community participation in public health and approaches to support their application in the delivery of novel self-care technologies.

Acknowledgements

I am very grateful to many people: to the study participants of Mangochi district, Malawi, whose contributions have been instrumental to my learning and hopefully to our understanding of improving health and welfare; to Prof. Fern Terris-Prestholt and Prof. Katherine Fielding, for their excellent supervision, which have contributed substantially to my academic growth, and kindness; to Prof. Liz Corbett, for this opportunity, her mentorship, and welcoming me in Malawi; to members of the HIV Self-Testing Africa consortium, for their collaboration and importantly camaraderie; to the Malawi Ministry of Health and Mangochi District Health Office, for their support of this research; to my family, for their dedication and encouragement throughout my education; and to Andrew McCallum, for coffees in the morning, teas at night, and everything in between.

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Acronyms and abbreviations

AIDS	Acquired immunodeficiency syndrome
aRR	Adjusted risk ratio
ART	Antiretroviral therapy
BCG	Bacillus Calmette-Guérin
C	Control
CD	Communicable disease
CE	Cost-effectiveness
CHAG	Community health action group
CHW	Community health worker
CL-HIVST	Community-led HIV self-testing
CLTS	Community-led total sanitation
CRT	Cluster-randomised trial
CV	Community volunteer
DALY	Disability-adjusted life year
DPT	Diphtheria, pertussis, and tetanus
FGD	Focus group discussion
GM	Geometric mean
HI	House improvement
HIV	Human immunodeficiency virus
HIVST	HIV self-testing
HTS	HIV testing services
HW	Handwashing
IDI	In-depth interview
IPV	Intimate partner violence
ICER	Incremental cost-effectiveness ratio
LL	Lower limit
LSHTM	London School of Hygiene & Tropical Medicine
LSM	Larval source management
LSTM	Liverpool School of Tropical Medicine
M&E	Monitoring and evaluation
MD	Mean difference
MLW	Malawi-Liverpool-Wellcome Trust Clinical Research Programme
MoH	Ministry of Health
NCD	Non-communicable disease
NGO	Non-governmental organization

OPV	Oral polio vaccine
PSI	Population Services International
RDT	Rapid diagnostic test
RCT	Randomised controlled trial
RD	Risk difference
RR	Risk ratio
SDG	Sustainable development goals
SOC	Standard of care
STAR	HIV Self-Testing Africa Initiative
TAG	Technical advisory group
UL	Upper limit
VMMC	Voluntary medical male circumcision
WASH	Water, sanitation, and hygiene
WHO	World Health Organisation
UNAIDS	Joint United Nations Programme on HIV/AIDS
USD	United States dollars

Chapter 1.
Introduction

1.1 Background

Global HIV epidemic and response

In 2018, 37.9 million people were living with human immunodeficiency virus globally, with 1.7 million people newly infected and 770,000 deaths from AIDS-related illnesses [1]. Sub-Saharan Africa contributed an estimated two-thirds of new infections and AIDS-related deaths, with infections highly concentrated among young women aged 15 to 24 years and key populations and their sexual partners [1]. In eastern and southern Africa, HIV incidence and AIDS-related mortality have respectively declined by 44% and 28% in the past decade, but recent progress has stagnated (**Figure 1.1**) [1]. Factors driving incidence in adults include frequent casual and transactional sex, suboptimal condom use, low uptake of preexposure prophylaxis and voluntary medical male circumcision, and undiagnosed and untreated infection [2].

The United Nations Fast-Track Strategy sets to accelerate reductions in HIV incidence and deaths from AIDS-related illnesses and end the AIDS epidemic by 2030 [3]. Global strategies aim to maximise early diagnosis, treatment, and viral suppression of people living with HIV as well as adoption of key preventive services [3]. Diagnosis is often ascertained through antibody tests, which can be used at the point-of-care for rapid diagnosis by lay health care workers [4]. Following diagnosis, antiretroviral therapy (ART) is used for treatment. Adherence to ART can reduce the amount of virus to undetectable levels, which is important for managing HIV-related morbidity and mortality as well as preventing onward transmission [5, 6].

To maximise the preventive effect of treatment, the Fast Track targets aims to diagnose 95% of people living with HIV, provide ART for 95% of those diagnosed, and achieve viral suppression for 95% of those treated by 2025 [3]. In 2018, almost one-fifth of people living with HIV in southern and eastern Africa were unaware of their status, with undiagnosed infection driving ongoing transmission [1].

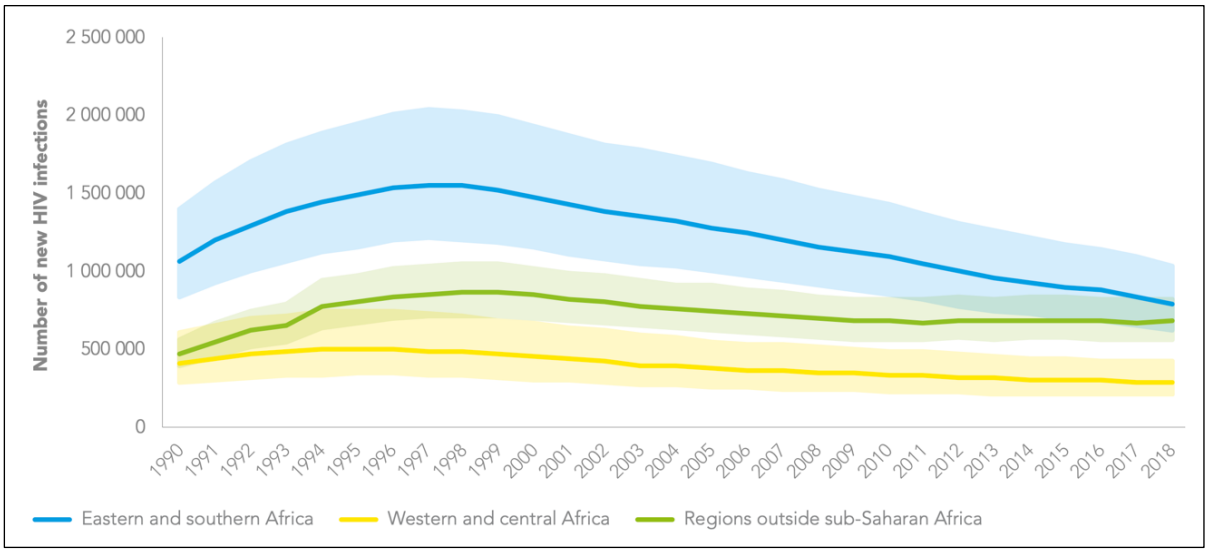


Figure 1.1. New HIV infections. Number of new HIV infections from 1990 to 2018 by region. Source: UNAIDS.

HIV epidemic in Malawi

HIV prevalence in Malawi is among the highest in the world. In 2016, 11% of people aged 15 to 64 years were living with HIV, with 28,000 new infections [7]. Further, a projected 77% of people living with HIV were aware of their status, of whom 91% were on ART, of whom 91% were virally suppressed [7], highlighting progress made towards achieving the Fast Track targets [1]. Diagnosis remains the biggest gap, especially among certain population subgroups including adolescents, older adults, and men.

In 2016, HIV prevalence was lower among men compared with women (9% vs. 13%), but fewer HIV-positive men were diagnosed (72% vs. 80%) [7]. According to the 2015–16 Malawi Demographic and Health Survey, men had lower coverage of lifetime HIV testing (51% vs. 70%) as well as recent testing (25% vs. 49%) compared with women [8]. In terms of age groups, prevalence was lowest in young people aged 15 to 24 years (3%) and highest in adults aged 40 to 49 years (22%) [7]. However, diagnosis among young people living with HIV was lowest across age groups at 54% [7]. Coverage of lifetime and recent testing was respectively 51% and 34% in young men and 70% and 42% in young women [8]. Men and young adults were also less likely to start on ART following a positive diagnosis and often initiated ART at more advanced stages of disease [7]. Undiagnosed infection in these key subgroups contribute to ongoing transmission and poorer outcomes from late diagnosis, impeding achievement of elimination goals [9, 10].

HIV testing services

Routine HIV testing is important for early diagnosis and treatment to reduce HIV-related morbidity and mortality and maximise prevention benefits [11]. In Malawi, HIV testing services (HTS) are

primarily facility-based and include client and provider-initiated testing, with periodic community-based testing in high prevalence areas or populations [12]. Following diagnosis, people living with HIV are universally eligible for treatment [12]. Expanded access to HTS by the national HIV programme has contributed to declines in new infections by 30% from 2010 to 2018 [1].

Multiple factors influence access and utilisation of HTS in adolescents, older adults, and men (**Figure 1.2**). Qualitative studies have described the influence of masculine norms on stigmatisation of HIV service use and undervaluation of HIV risk or symptoms of disease [13-15]. Men also have less exposure to health care services while women often engage through maternal and child health services [15]. For instance, pregnant women are routinely tested for HIV through antenatal care [16]. Further, men have higher levels of participation in the workforce and subsequently experience larger opportunity costs from accessing health care services during work hours [14, 15].

For young people, their status as minors and dependents can complicate their ability to consent or finance associated service costs, or prompt fears that a positive diagnosis might diminish social and economic protections received from their families [17-21]. Concerns around implicit revelation of sexual debut and stigma and discrimination from health care providers can also hinder uptake [17-21]. Factors impeding testing in older adults include low risk perception and age norms that associate testing with sexual risk or lack of wisdom, which is seen as a threat to social status [22]. Further, conventional HIV services often do not consider the unique experiences of adolescents, older adults, and men, and how to tailor service delivery accordingly [14, 17, 20].

Alternatives strategies for HIV testing

Aimed at addressing barriers to access, community-based HTS can extend coverage of HIV testing,

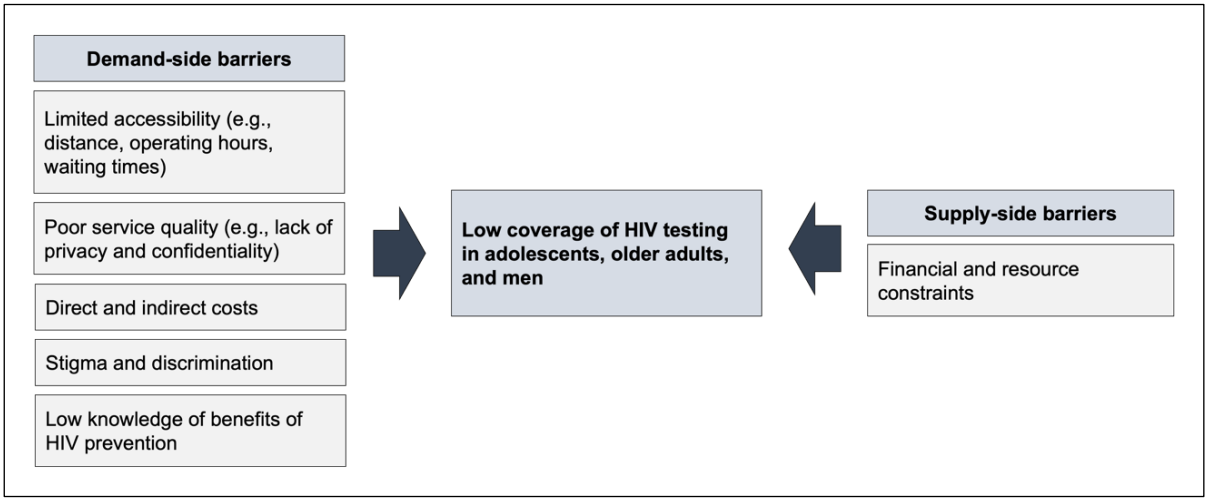


Figure 1.2. Barriers to HIV testing services. Demand and supply-side barriers to access and utilisation of HIV testing services.

including among underserved population subgroups [23, 24]. Evidence also supports earlier diagnosis of people living with HIV and improved treatment and viral suppression when combined with convenient ART services [23-25]. Randomised trials of community-based "universal test-and-treat" reported more than 90% diagnosis of people living with HIV [26-29]. Target coverage of ART initiation and viral suppression was also achieved with provision of comprehensive linkage to care, though outcome attainment among young people was relatively low [26, 28, 29]. Studies also measured some reductions in HIV incidence [29], with implementation beyond the trial period cost-effective at thresholds greater than US$800 per disability-adjusted life year averted [30].

Alternative strategies using HIV self-testing (HIVST) have also shown promise. HIVST involves individuals collecting their specimen, performing their test, and interpreting their results [4]. HIVST is used as a test for triage. Reactive results need to be confirmed through additional testing by a health care provider, while non-reactive results should prompt linkage to prevention services [4]. Products use either oral-fluid or finger-prick blood samples and take between five to seven steps and 1 to 45 minutes to provide results [31]. In 2016, HIVST was recommended WHO as an additional approach to providing HTS based on evidence of high acceptability, feasibility, accuracy, and uptake [4], with many countries since adopting supportive policies [32].

Randomised trials in sub-Saharan Africa have demonstrated increased coverage of testing through facility and community-based provision of HIVST. In Malawi, distribution of HIVST kits by community volunteers achieved high uptake, with increased demand for ART initiation with offer of home-based care [33, 34]. Introduction of home-based HIVST improved testing coverage in rural populations, including among men and adolescents [35]. Provision of HIVST in addition to testing by community health workers in urban Zambia increased knowledge of HIV status, especially in men [36]. Accuracy and low adverse events were reported [33-36]. Further, societal costs of community-based HIVST were reported to be lower than facility-based testing, but provider costs were consistently higher, especially the cost per new diagnosis [37, 38].

While community-based testing and self-testing can extend testing coverage to underserved populations, availability remains limited by financial and resources constraints within national HIV programmes. Population-based surveys have reported low coverage of testing through community-based strategies [39]. Meeting and maintaining high awareness of HIV status is dependent on identifying sustainable approaches for providing testing outside of health facilities, especially with declining global funding for community health programmes [40]. Moreover, as countries successfully scale-up testing and treatment services, the cost per new diagnosis is increasing due to decreasing prevalence of undiagnosed HIV [41]. To remain cost-effective, community-based

programmes must further minimise costs and maximise the proportion diagnosed, treated, or linked to prevention [41].

Community-led strategies for population health

The Alma-Alta Declaration of 1978 established community participation as a key principle of primary health care, asserting "people have the right and duty to participate individually and collectively in the planning and implementation of their health care" [42]. Community-led strategies involve underserved communities identifying problems contributing to poor health, planning and implementing solutions to improve health, and evaluating implementation of solutions [43-46]. Community-led approaches are founded on principles of empowerment. Most practice is influenced by Freirean conscientisation [47], whereby groups of individuals with shared circumstances undergo critical reflection to understand root causes of ill health and identify actions to address their determinants [48, 49].

Community-led strategies are hypothesised to have multiple benefits. From an organisational and service delivery perspective, community involvement through knowledge, time, and resource contributions could enhance the coverage and efficiency of health programmes [50, 51]. Control of decision making and resource mobilisation by communities could align programmes with the needs and preferences of communities. Delivery through community-driven systems could increase the pool of available resources. Community empowerment could also improve equity in health care [50, 51]. Devolvement of power, decision making, and control to marginalised populations could enable more equitable access to health care and equitable relationships between health care providers and beneficiaries. Further, participation could facilitate a sense of community and community competence, which are valued as endpoints in addition to mechanisms through which health is improved [52, 53].

Systematic reviews of community participation in health programmes have reported some evidence of improvements in health consequences and behaviours across disease areas [54-58]. Studies have also described gains in psychosocial benefits at individual level as well as improvements in community and social outcomes [55, 58]. While studies have broadly examined the role of community participation in HIV prevention and management [59, 60], few randomised trials have assessed the effectiveness of community-led strategies, with none involving HTS provision [61, 62]. In Uganda, a feasibility study of community-led multi-disease campaigns reported high uptake of HIV testing [61]. Campaigns involved community leaders designing and implementing demand creation activities and working with nearby health facilities to deliver services based on local health

priorities. HIVST could be introduced within a similar community-led framework to enable provision of HTS.

1.2 Rationale

High HIV-burden populations will have ongoing need for HTS to meet and sustain global Fast Track targets. Facility-based HTS does not fully meet the testing needs of all population subgroups in the general population, with insufficient coverage of adolescents, older adults, and men. Meanwhile, knowledge of HIV status remains in high demand, as evidenced by high uptake of community-based testing in controlled settings, with financial and resource constraints a limiting factor. Community-led approaches for HTS could be an alternative to providing periodic community-based services in high prevalence areas or to underserved subgroups. Recent innovations in self-care technologies are now expanding the breadth of services that could be delivered by communities. While previous studies have established the impact of HIVST delivery through community-based models, it is uncertain whether similar outcomes and costs could be achieved if provision is decentralised to communities. Community-led delivery of HIVST could potentially address demand-side barriers to increase uptake of testing and linkage to care and prevention and supply-side constraints to service provision, while facilitating sustained community engagement in HIV prevention and management.

1.3 Thesis aims and objectives

The broad aim of the thesis was to evaluate the health, social, and economic impact of community-led delivery of HIV self-testing compared with the standard of care among rural populations in Malawi.

The specific objectives were:

1. To summarise evidence on the health, social, and economic impact of community-led strategies for communicable disease control.
2. To evaluate the effectiveness of community-led delivery of HIVST on HIV testing, ART initiation, and HIV-related attitudes and norms.
3. To measure the economic costs and effects on HIV testing positivity of the community-led HIVST intervention.
4. To examine pathways to impact from the community-led HIVST intervention.

1.4 Intellectual ownership and collaborations contributing to thesis

Conceptualisation of the research presented in the thesis began in 2017. I was based at the Malawi-Liverpool-Wellcome Trust Clinical Research Programme (MLW) as part of the HIV Self-Testing Africa Initiative (STAR). STAR was a consortium funded by Unitaid and led by Population Services International (PSI) in partnership with the London School of Hygiene and Tropical Medicine (LSHTM) and WHO. STAR conducted multi-country studies of HIVST from 2015 to 2017, with PSI leading implementation and LSHTM leading evaluation with in-country research institutions including MLW. In 2017, STAR was awarded additional funding for the evaluation of community-led models of HIVST under LSHTM chief investigator Prof. Elizabeth Corbett.

I had a leading role in the conceptualisation of research contributing to the thesis. I supported the application for funding renewal as a member of STAR. I developed, piloted, and finalised the intervention design in collaboration with MLW and PSI colleagues. I also led the design of the randomised trial and sub-studies, with advisory support from Prof. Corbett as well as my thesis supervisors Prof. Fern Terris-Prestholt and Prof. Katherine Fielding. Specifically, I wrote the study protocol and submitted applications for ethical approval from the University of Malawi College of Medicine, LSHTM, and WHO. I also developed the standard operating procedures and data collection tools, and trained colleagues on the materials. Further, I managed the conduct of the trial, monitored procedures, and reviewed data with the technical advisory group. I developed the statistical analysis plan and analysed the data. Lastly, I prepared the drafts of all manuscripts included in the thesis. My role was supported by a wider team at MLW, LSHTM, PSI, and other institutions, with the list of contributors outlined in **Table 1.1**.

Table 1.1. List of contributors to thesis

Role	Name (Institution)
Data management	MLW: Japhet Banda, Mphatso Kadzanja, Rebecca Nzawa; PSI: Phillip Mkandawire, Edward Nyondo
Economics	MLW: Saviour Mphande, Linda Sande; LSHTM: Fern Terris-Prestholt
Epidemiology and statistics	LSHTM: Elizabeth Corbett, Katherine Fielding, Melissa Neuman
Implementation	PSI: Patrick Chibota, Richard Chilongosi, Khumbo Chinemba, Marcpoly Chiwanda, Karin Hatzold, Ian Khruza, Lovemore Magombo, Anganile Mwenifumbo, Keith Pondani, Brian Satha
Social science	LSTM: Nicola Desmond; MLW: Moses Kumwenda, Henry Sambakunsi, Mwiza Sambo, Wakumanya Sibande
Policy	MoH Malawi: Rose Nyirenda; WHO: Cheryl Johnson

LSTM, Liverpool School of Tropical Medicine; LSHTM, London School of Hygiene & Tropical Medicine; MoH, Ministry of Health; MLW, Malawi-Liverpool-Wellcome Trust Clinical Research Programme; PSI, Population Services International; WHO, World Health Organisation.

1.5 Ethical considerations

Ethical approvals were granted by the University of Malawi College of Medicine (P.01/18/2332), LSHTM (14761), and WHO (STAR-comm led CRT-Malawi).

1.6 Structure of thesis

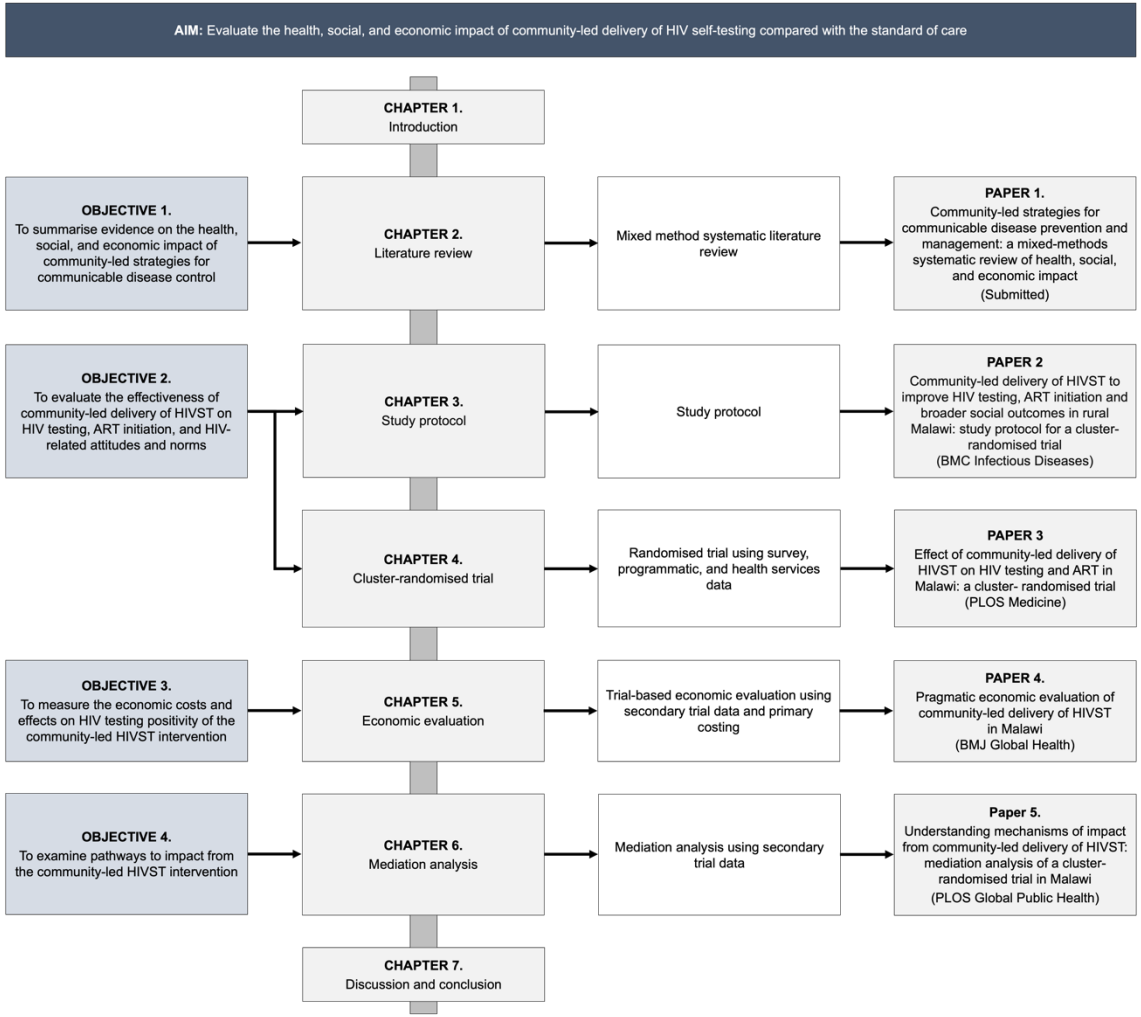
The thesis is organised in a research paper style (**Figure 1.3**). Each chapter with a research paper includes the supplementary material for the paper at the end of the chapter. Appendices for the thesis are included at the end of the thesis.

Chapter 2 systematically reviews the literature on the health, social, and economic impact of community-led strategies for communicable disease prevention and management. The nature and extent of community participation are also summarised, along with implementation, mechanisms of impact, and contexts. Chapter 3 is a methodological chapter and describes the design of the main cluster-randomised trial in addition to substudies including the economic evaluation [63].

The thesis includes three results chapters. Chapter 4 uses a cluster-randomised trial to measure the effect of community-led delivery of HIV self-testing on HIV testing among adolescents, adults 40 years and above, and men [64]. Impact on secondary outcomes, including ART initiation and HIV-related attitudes and norms, as well as process outcomes are explored. Chapter 5 is a trial-based economic evaluation of the community-led HIVST intervention that estimates the incremental cost per additional person tested HIV positive and models potential cost-effectiveness [65]. Chapter 6 uses mediation analysis to investigate the extent to which community and social outcomes mediate the impact of the community-led HIVST intervention on HIV testing [66].

Chapter 7 presents a summary of the main results and situates the findings in the wider context. The strengths and limitations of the thesis are appraised. The chapter concludes with discussion on the contributions of the thesis and reflection on research and policy implications.

Figure 1.3. Structure of thesis.



ART, antiretroviral therapy; HIVST, HIV self-testing. Mapping of thesis aims, objectives, chapters, and methods.

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Chapter 2.
Literature review

2.1. Summary

This chapter includes Paper 1, "Community-led strategies for communicable disease prevention and management: a mixed-methods systematic review of health, social, and economic impact". Addressing Objective 1, the paper consists of a systematic literature review that aims to understand the impact of community-led strategies for communicable disease control. The paper outlines the methods of the systematic review and then summarises evidence on the impact, costs, and cost-effectiveness of community-led approaches. The nature and extent of community participation are described along with implementation, mechanisms of impact, and contexts. An earlier version of this paper informed Objectives 2, 3, and 4 and was later updated to include the papers presented in Chapters 4, 5, and 6.

This paper has been submitted for publication.

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Student ID Number	1701865	**Title**	Ms
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Thesis Title	Evaluation of community-led delivery of HIV self-testing		
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If the Research Paper has previously been published please complete Section B, if not please move to Section C.

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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I led the conceptualisation and design of the study. I performed the screening, data extraction, and quality appraisal in collaboration with a co-author. I conducted the data analysis. I also wrote the first draft of the manuscript. Co-authors contributed to the study conceptualisation and design as well as read and approved the final manuscript.

SECTION E

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Date	2nd April 2023

Community-led strategies for communicable disease prevention and management: a mixed-methods systematic review of health, social, and economic impact

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Abstract

Introduction

Control of infectious diseases is a global health priority and a target of the 2015-2030 Sustainable Development Goals (SDGs). Advancement of primary health care is critical to meeting SDGs, with community participation a fundamental component. We conducted a mixed-methods systematic review to understand the health, social, and economic impact of community-led strategies for communicable disease prevention and management.

Methods

We searched seven electronic databases through 31 December, 2022 and included cluster-randomised trials and economic evaluations of community-led strategies for communicable disease control in low- and middle- income countries. Reference searches additionally identified process evaluations associated with eligible database records. Data extraction and narrative synthesis aimed to (i) summarise evidence on impact, costs, and cost-effectiveness, (ii) describe the nature and extent of community participation, and (iii) examine implementation, mechanisms of impact, and contexts. Risk of bias of was assessed using standard guidelines.

Results

Our search strategy yielded 12,023 articles from databases. Following database and reference screening, we included 48 records from 16 cluster-randomised trials, with the majority based in sub-Saharan Africa. Communicable disease strategies included provision of biomedical products, environmental modifications, and education and outreach. Based on moderate-risk evidence, we found that community-led approaches can improve health behaviours, including for diarrhoeal diseases, HIV, malaria, and neglected tropical diseases. Evidence for impact on mortality and morbidity, health care access and utilisation, and community and social outcomes was captured among fewer studies and less consistent. Impact appeared to depend on achieving sufficient intensity of implementation by community actors. Factors facilitating implementation included motivation to engage and implement communicable disease strategies, trust between community actors and the wider community, and engagement with stakeholders including health care providers. Contextual influences included demographic and social factors, such as attitudes and norms around communicable diseases. Economic studies were few and many omitted societal costs and consequences.

Discussion

This review supports community-led communicable disease control as a potentially effective strategy to positively impact health behaviours and contribute to SDGs. Operational guidance on how to define and identify strategies for meaningful community participation and capture relevant outcomes, costs, and processes will be critical to support rapid evidence generation in this important area.

Introduction

Control of infectious diseases is a global health priority and a target of the 2015-2030 Sustainable Development Goals (SDGs) [1]. Major communicable diseases, including HIV, tuberculosis, and malaria, are leading contributors to the global burden of disease, especially in low-and-middle-income countries [2]. While their impact on morbidity and mortality has been declining in recent decades, endemic and epidemic communicable diseases continue to pose significant threats to public health [2]. Advancing primary health care is critical to universal health coverage and to meeting SDGs, with community participation a fundamental component of primary health care [3].

Community-led health prioritisation and action has been advocated for decades but with limited implementation [4]. Responses that are driven by communities have potential to increase uptake and coverage of health programmes, improve health outcomes, and impact sustainability [5, 6]. Empowerment of communities is suggested to enhance programme delivery through community-centred design and implementation and impact social determinants of health through power decentralisation, community systems strengthening, and collective engagement [7]. Calls for increased investment in community-led initiatives are based on the recognition that community participation is essential for meeting SDG targets [8]. Further, communicable diseases have spillover properties, making them amenable to a collective approach for their prevention, screening and management, and surveillance [9].

There is an urgent need to consolidate evidence on community-led responses to support SDGs targeting communicable diseases. However, synthesising evidence on whether community participation improves health and, if so, through which mechanisms has been challenging [10, 11]. Definitions of community participation are not standardised, leading to inconsistencies in their use and practice [12]. The scope of community participation is highly heterogeneous, and frameworks characterising participation lack agreement [13-19]. Further, community participation is a multicomponent process that interacts with many variables, including context, to improve outcomes. Complex interventions and systems can be difficult to capture through relatively simplified cause-effect frameworks [11], underscoring the importance of explaining and contextualising findings in evidence synthesis to identify common attributes and themes across studies [20].

The main aim of this systematic literature review was to summarise and synthesise evidence on community-led strategies for communicable disease prevention and management in low-and-middle- income countries, specifically on attributes contributing to impact, costs, and cost-effectiveness. Previous reviews have examined community participation more broadly [10, 21-24]

or have been disease specific [25-27]. The novel aspects of this review were that we aimed to focus on studies involving communities leading decision making and resource allocation in health programmes and to assess evidence across a range of diseases and disease syndemics [28]. The specific objectives were to: (i) summarise the impact, costs, and cost-effectiveness of community-led approaches, (ii) describe the nature and extent of community participation, and (iii) examine implementation, the mechanisms through which community-led approaches affect outcomes, and interactions with contexts.

Methods

The review was registered with PROSPERO (CRD42021281164) and followed the Cochrane handbook for systematic reviews and PRISMA guidelines (**Supplementary Text 2.A**) [29, 30].

Defining 'community-led'

UNAIDS defines community-led responses as "actions and strategies that…are specifically informed and implemented by and for communities and the organisations, groups, and networks that represent them" [31]. However, definitions and applications of 'community' and 'participation' have varied widely in public health [12]. Community refers to a group of people with shared spatial or social characteristics or collective interests [32]. Community participation encapsulates a continuum of increasing empowerment, as outlined by frameworks summarised in **Supplementary Text 2.B**. These frameworks characterise the nature and extent of participation by external actors (e.g., governmental and non-governmental organisations) and community actors in health programmes. At the lowest end of the continuum, health is defined as the absence of disease [14]; external actors are perceived as experts who are best positioned to identify health problems and solutions, with the community acting as a setting or target of externally prescribed agendas [13-15, 17-19]. The highest end defines health broadly as the human condition [14]; the community is an agent for change, supported by external actors to prioritise and solve health problems [13-15, 17-19]. Community-led responses, which have adopted a range of terminology, are founded on principles of empowerment [31, 33-35].

Eligibility criteria

Database searches included cluster-randomised trials and economic evaluations in low-and-middle-income countries that compared community-led strategies for communicable disease control against facility-based, community-based, or community-led alternatives (**Supplementary Text 2.C**). Interventions qualified as community-led if communities were leading decision making and

resource mobilisation for communicable disease strategies during any stage of design, implementation, monitoring and evaluation, or post-implementation. The framework used to define and categorise studies is summarised in **Figure 2.1** and mainly adapted from Rifkin and Pridmore (2001) and Draper (2010) [14, 16]. Outcomes included morbidity and mortality, health care access and 39tilization, health behaviours, community and social outcomes, environmental outcomes, and costs and cost-effectiveness. Reference searches identified process evaluations related to records included from database searches. Additional criteria were studies published in peer-reviewed journals and in English, with no limitations on date of publication.

Search strategy, screening, and data extraction

We searched seven electronic databases (Cochrane Trials, Econlit, Embase, Global Health, Medline, Pubmed, Web of Science) on 11 October, 2021, updated through 31 December, 2022. Searches were based on terms for community-led strategies and communicable diseases, as described in **Supplementary Text 2.C**. References from eligible studies were also screened. Database searches were calibrated to yield impact and economic evaluations, while reference searches aimed to identify process evaluations associated with eligible records from database searches. Following automated removal of duplicates, PPI screened titles and abstracts for initial inclusion and PPI and KM independently reviewed full texts for final inclusion, with disagreements resolved by consensus.

PPI extracted data using standardised forms on study characteristics; intervention and comparator characteristics, including the nature and extent of community participation; results on effects, costs,

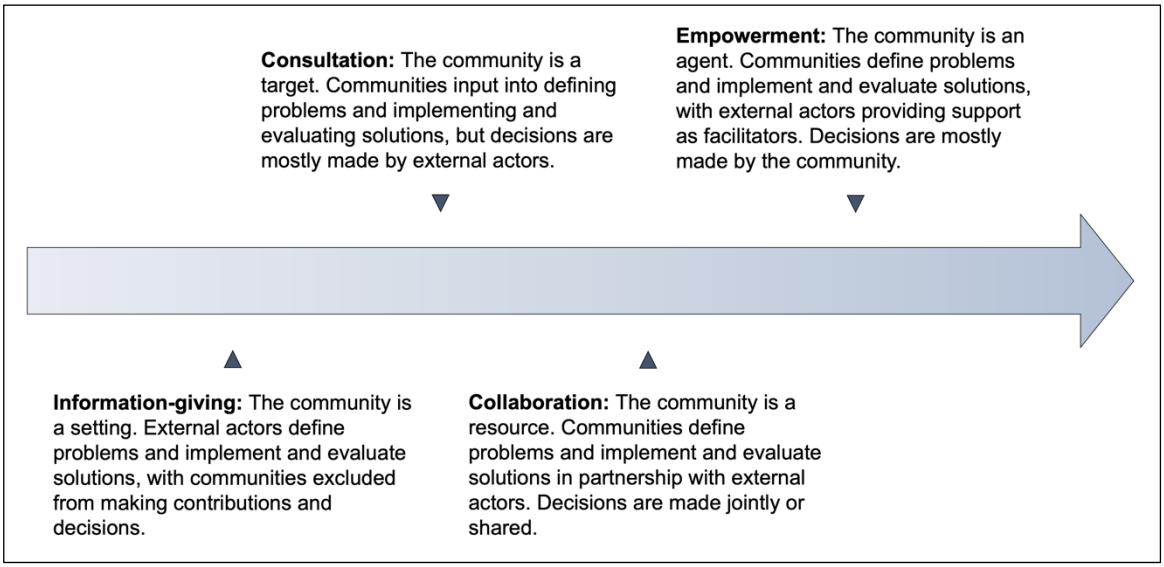


Figure 2.1. Framework for community participation. Continuum of community participation indicating increasing levels of empowerment. Adapted from Rifkin and Pridmore (2001) and Draper (2010) [14, 16].

and cost-effectiveness; results on implementation, mechanisms of impact, and contexts; and details for quality appraisal (**Supplementary Text 2.D**). Effect estimates were extracted for all outcomes and time points from adjusted analyses, if reported. Estimates from subgroup analysis were extracted if outcomes were only assessed for subgroups. Risk of bias assessment used the Revised Cochrane Risk-of-Bias Tool for Cluster-Randomised Trials and the Drummond checklist [36, 37]. Certainty of evidence for each outcome was not assessed due to heterogeneity. KM independently extracted data and conducted quality appraisal for a random sample of records to evaluate consistency.

Data synthesis

We followed narrative reporting based on synthesis without meta-analysis guidelines, since meta-analysis was not appropriate given variation in outcomes [38]. All included studies were eligible for synthesis and are described with their risk of bias, if relevant. Reporting on impact was grouped by disease area and outcome domain, which included mortality and morbidity, health care access and utilisation, health behaviours, community and social outcomes, and environmental outcomes. Reporting was prioritised based on relevance of outcomes to communicable diseases and their determinants. We also aimed to identify common attributes and themes to draw conclusions across subgroups.

Synthesis addressed each of our objectives. We summarised the direction of effect from outcomes reported in cluster-randomised trials and used harvest plots to present summaries by subgroup [39]. Cost and cost-effectiveness estimates were standardised to 2022 US Dollars [40] and summarised. To measure community participation, we categorised interventions into domains using a scoring method [14, 16, 21, 24] from 0 to 4 (0=no information, 1=information giving, 2=consultation, 3=collaboration, 4=empowerment) that was applied to design, implementation, monitoring and evaluation, and post-implementation stages (**Supplementary Text 2.E**). Overall scores ranged from 0 to 16, indicating low to high community participation. Radar graphs were used to illustrate scores. Finally, we mapped evidence on implementation, mechanisms of impact, and context [41], with quantitative and qualitative data analysed separately and subsequently combined [42].

Results

Our search strategy yielded 12,023 records from databases (**Figure 2.2**). After removing duplicate articles, we screened titles and abstracts of 6,713 records, of which 287 records were eligible for full-text review. We included 27 records and identified an additional 21 records from reference searches. Overall, we included 48 records from 16 cluster-randomised trials [43-58], of which 29

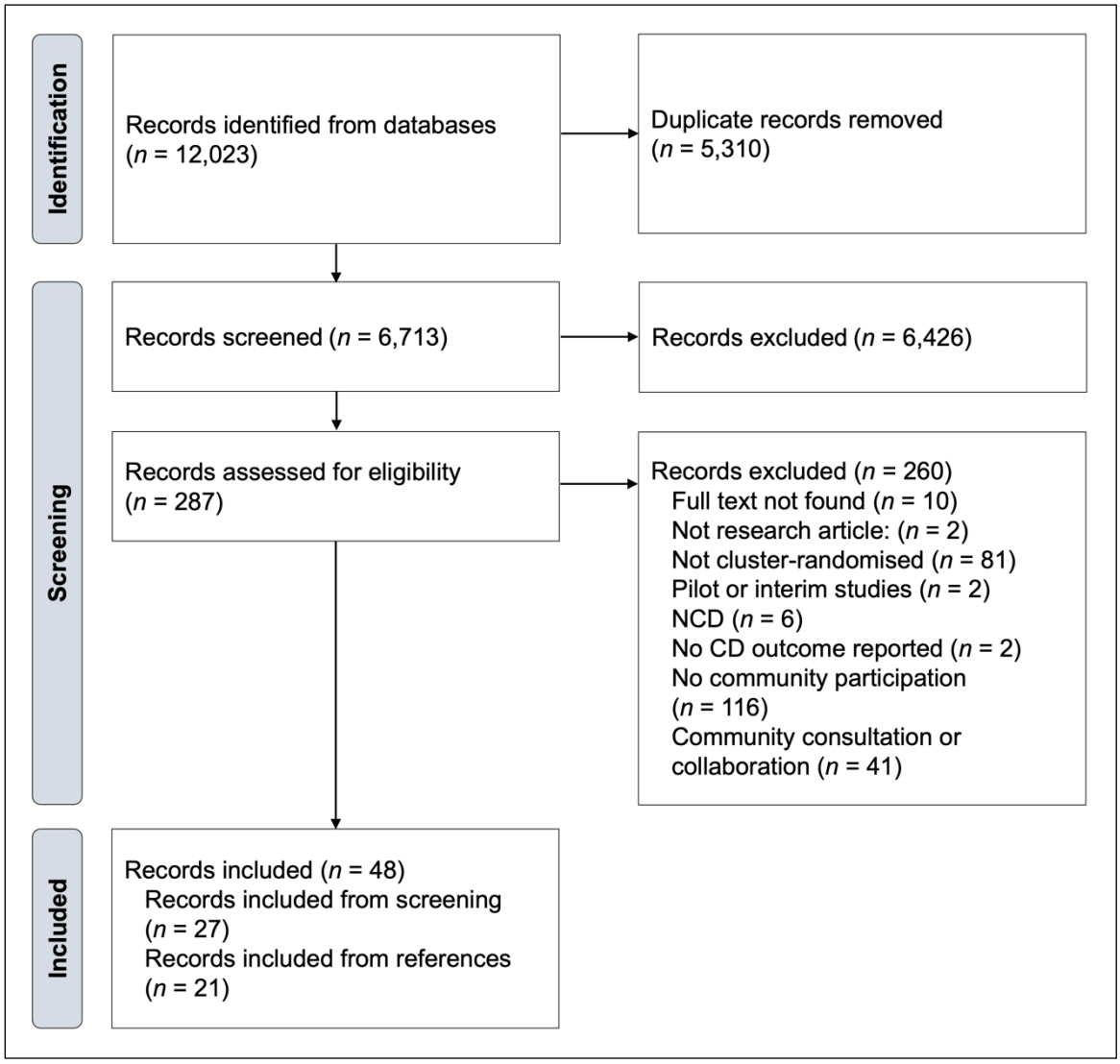


Figure 2.2. Flow diagram. CD, communicable disease; NCD, non-communicable disease. Flow diagram of record identification, screening, and inclusion.

records reported on impact outcomes [43-71]; 12 records reported on economic outcomes (eight economic evaluations, four costing studies) [51, 52, 55, 58, 72-79]; and 26 records reported on process outcomes (15 quantitative studies, eight qualitative studies, three mixed-methods studies) [45, 47, 49-52, 55, 56, 58-61, 67, 68, 71, 80-90]. **Table 2.1** describes the characteristics and main results of included cluster-randomised trials and lists their substudies.

Characteristics of included studies

Disease areas included diarrhoeal diseases, HIV, malaria, and neglected tropical diseases, with three cluster-randomised trials including strategies targeting multiple diseases [51, 52, 55]. Most trials were in sub-Saharan Africa, with 10 trials in eastern and southern Africa [45, 46, 48, 50-54, 58, 59] and three trials in western and central Africa [49, 56, 57]. All trials were directed towards the general population, except for one trial, which focussed on people with disabilities [45]. In all trials,

Table 2.1. Study characteristics of cluster-randomised trials

Article	Study design	Setting	Population	Intervention	Control	Main results	Related studies
Diarrhoeal diseases							
Biran (2018) [45]	CRT of group village head units	Malawi	People with disabilities	CLTS inclusive of people with disabilities. External actors and health surveillance assistants facilitated 'triggering' exercises (e.g., community mapping, action planning), aiming to include people with disabilities. Sanitation committees led improved sanitation activities inclusive of people with disabilities in their villages, with some monitoring from external actors and community health workers.	CLTS. External actors and health surveillance assistants facilitated 'triggering' exercises (e.g., community mapping, action planning). Sanitation committees led improved sanitation activities in their villages, with some monitoring from external actors and community health workers.	No difference between arms in primary outcome of latrine construction. No differences between arms in sanitation outcomes, including improved latrine access and use.	
Briceño (2017) [46]	Factorial CRT of wards	Tanzania	General population (adults and children)	CLTS. External actors, including district and ward officers, facilitated 'triggering' exercises (e.g., community mapping, action planning), trained local masons, and conducted mass media activities. Sanitation committees led and monitored improved sanitation activities in their villages.	Handwashing promotion. Trained community activists provided handwashing promotion activities to households alongside mass media activities and infrastructure building. No intervention.	No differences in primary outcome of 7-day child diarrhoeal prevalence between both intervention arms vs. control arm. Lower 14-day diarrhoeal prevalence, haemoglobin levels, and weight-for-age among children in CLTS and handwashing promotion arm vs. control arm. No	‡ Briceño (2015) [78]

Article	Study design	Setting	Population	Intervention	Control	Main results	Related studies
				CLTS and handwashing promotion.		differences in morbidity outcomes between CLTS arm vs. control arm. Higher coverage of most sanitation outcomes, including improved latrine access and use and absence of open defection, in both intervention arms vs. control arm.	
Cameron (2019) [47]	CRT of villages	Indonesia	General population (adults and children)	CLTS. External actors, including government officers, facilitated 'triggering' exercises, including community mapping and action planning. Community members led improved sanitation activities in their villages, with some monitoring from external actors.	No intervention.	Lower roundworm density among children in intervention arm vs. control arm. No differences in haemoglobin levels, height, weight, and health index. Higher latrine construction and absence of open defection in intervention arm vs. control arm. No difference in diarrhoeal knowledge.	* Borja-Vega (2014) [86]
Cha (2021) [48]	CRT of villages	Ethiopia	General population (adults and children)	CLTS. External actors, including district health officers, health care providers, and health extension workers, facilitated 'triggering' exercises (e.g., community mapping) and identified and	SOC. Government sanitation services provided by health extension workers.	For primary outcomes, lower diarrhoeal incidence and 100-day diarrhoeal prevalence among children in intervention arm vs. control arm. No differences in diarrhoeal duration and	‡ Cha (2020) [75]

Article	Study design	Setting	Population	Intervention	Control	Main results	Related studies
				trained WASH promoters on sanitation management. WASH promoters led improved sanitation activities in their villages, with monitoring from external actors, and received compensation.		7-day diarrhoeal prevalence. Higher coverage of most sanitation outcomes, including improved latrine access, in intervention arm vs. control arm.	
Crocker (2016) [49]	CRT of villages	Ghana	General population (adults and children)	CLTS with training of natural leaders. External actors facilitated 'triggering' exercises (e.g., community mapping) and trained natural leaders, including on action planning. Natural leaders led improved sanitation activities in their villages.	CLTS. External actors facilitated 'triggering' exercises, including community mapping. Community members led improved sanitation activities in their villages.	Higher improved latrine access and use and lower open defecation in intervention arm vs. control arm.	* Crocker (2017) [69] ‡ Crocker (2017) [77] ‡ Crocker (2021) [76]
Pickering (2015) [56]	CRT of villages	Mali	General population (adults and children)	CLTS. External actors, including Sanitation Department officers, facilitated 'triggering' exercises, including community mapping. Sanitation committees led improved sanitation activities in their villages, with monitoring from external actors.	No intervention.	For primary outcomes, no differences between arms in 2-day diarrhoeal prevalence and 2-week diarrhoeal prevalence among children. Differences between arms in most development outcomes among children, including height-for age, weight-for-age, stunting, and wasting.	

Article	Study design	Setting	Population	Intervention	Control	Main results	Related studies
						Lower diarrhoea-related mortality in intervention arm vs. control arm. No differences in diarrhoeal symptoms. Differences between arms in most sanitation outcomes, including latrine access and use and open defecation. No difference between arms in E. coli level.	
Quattrochi (2018) [57]	CRT of village groups	Democratic Republic of Congo	General population (adults and children)	Community-led WASH. External actors, including Health Zone officers, trained WASH committees, including on problem solving and assessment, action planning, and WASH management. WASH committees and volunteers decided on and led improved WASH activities in their villages, with monitoring from Health Zone officers, and received compensation and material support.	No intervention.	For primary outcomes, higher coverage of improved water and sanitation infrastructure in intervention arm vs. control arm. No differences in water access and availability. No differences between arms in child diarrhoea symptoms and health care use. Higher coverage of WASH outcomes, including improved water and sanitation indices, in intervention arm vs. control arm.	* Crocke (2022) [68]
HIV							
Abramsky (2014) [59]	Pair-matched CRT of administrative parishes	Uganda	General population (adults)	Community mobilisation for HIV and IPV prevention. External actors	Enhanced SOC. Community activists provided with basic health training.	For primary outcomes, higher acceptance of refusal to have sex among women and	*† Kyegombe (2014) [80] † Kyegombe (2014) [81] * Abramsky (2016) [43] * Abramsky (2016) [60]

Article	Study design	Setting	Population	Intervention	Control	Main results	Related studies
				facilitated a four-phase cycle (start, awareness, support, and action), which included training of community activists on strategies for local activism. Community activists led mobilisation activities, with support from external actors. Mass media and advocacy, communications, and ongoing trainings and mentoring to community activists, leaders, and stakeholders were also provided by external actors.		men in intervention arm vs. control arm. Lower acceptance of physical IPV among women and concurrency of sexual partners among men. No differences in physical IPV, sexual IPV, acceptance of physical IPV among men, and community response to IPV. Higher HIV testing among men in intervention arm vs. control arm. Differences between arms in some IPV outcomes, including emotional IPV, and outcomes on gender attitudes and norms, including gender roles.	‡ Michaels-Igbokwe (2016) [72] † Starmann (2017) [83] * Abramsky (2018) [82] *† Starmann (2018) [84]
Indravudh (2021) [50]	CRT of group village head units	Malawi	General population (adults)	Community-led HIVST. External actors trained community groups and volunteers, including on problem solving and assessment, action planning, and HIVST. Community groups and volunteers decided on, led, and monitored HIVST activities in their villages and received compensation and material support.	SOC. Standard HIV testing services provided through government health facilities.	For primary outcome, higher lifetime HIV testing among adolescents in intervention arm vs. control arm. Higher HIV testing among adults ≥40 years and HIV testing among men in intervention arm vs. control arm. No difference in antiretroviral therapy	‡ Indravudh (2021) [73] * Indravudh (2022) [61]

Article	Study design	Setting	Population	Intervention	Control	Main results	Related studies
						initiation. Higher social cohesion and shared concern for HIV in intervention arm vs. control arm. No differences in knowledge of HIV treatment benefits, HIV testing stigma, community HIV stigma, and critical consciousness.	
Sibanda (2021) [58]	CRT of village headman units	Zimbabwe	General population (adults)	Community-led HIVST. External actors engaged community leaders and members, who decided on HIVST activities. Community distributors received trainings and led HIVST activities in their villages, with monitoring from health facilities, and received material support.	Community-based HIVST. Trained community distributors implemented door-to-door HIVST delivery.	No differences between arms in primary outcomes of new HIV diagnosis and linkage to confirmatory HIV testing and prevention.	
Malaria							
McCann (2021) [54]	Factorial CRT of village groups	Malawi	General population (adults and children)	Community-driven larval source management. External actors trained village committees and health animators on malaria control. Village committees and health animators led and monitored activities for larval source management activities in their villages.	SOC. Government malaria control programmes.	No difference in primary outcome of entomological inoculation rate between intervention arms vs. control arm. No differences in malaria prevalence and haemoglobin levels between intervention arms vs. control arm.	*† Malenga (2017) [89] † Kaunda-Khangamwa (2019) [88] † Gowelo (2020) [90] ‡ Phiri (2021) [79] * Gowelo (2023) [71]

Article	Study design	Setting	Population	Intervention	Control	Main results	Related studies
				Community-driven house improvement. External actors trained village committees and health animators on malaria control. Village committees and health animators led and monitored activities for house improvement activities in their villages. Community-driven larval source management and house improvement.		Almost no differences in mosquito densities between intervention arms vs. control arm.	
Neglected tropical diseases							
Andersson (2015) [44]	CRT of census enumeration areas	Mexico, Nicaragua	General population (adults and children)	Community-led dengue control. External actors trained community groups and volunteers on dengue control. Community groups and volunteers decided on and led dengue control activities at community level, with monitoring from neighbouring peers. Community volunteers also implemented household activities.	SOC. Government dengue control programmes, including distribution of temephos sachets and space spraying.	For primary outcome, lower dengue infection in intervention arm vs. control arm. Differences between arms in some dengue control outcomes, including pesticide use. Almost no differences in community attitudes and norms on dengue control. Lower larvae and pupae density in intervention arm vs. control arm.	* Carcamo (2017) [62] * Jimenez-Alejo (2017) [63] * Legorreta-Soberanis (2017) [64] * Legorreta-Soberanis (2017) [65] * Legorreta-Soberanis (2017) [66] * Alvarado-Castro (2019) [67] ‡ Tschampl (2020) [74]
Massa (2009) [53]	CRT of school catchment areas	Tanzania	General population (children)	Community-directed distribution of treatment for schistosomiasis and soil-transmitted	School-based treatment for schistosomiasis and soil-transmitted	For primary outcomes, some differences between arms in parasitological	* Massa (2009) [70] † Massa (2009) [87]

Article	Study design	Setting	Population	Intervention	Control	Main results	Related studies
				helminthiasis. External actors engaged community leaders and members, who decided on parasitological treatment activities. Community drug distributors received trainings and led parasitological treatment activities in their villages and received material support.	helminthiasis. Teachers distributed drugs to school-age children.	prevalence outcomes. Some differences between arms in treatment coverage outcomes.	
Multiple diseases							
Lewycka (2013) [51]	Factorial CRT of census enumeration areas	Malawi	General population (women and children)	Participatory women's groups for maternal and child health, including for HIV, malaria, and immunisation. External actors and community facilitators guided a four-phase cycle (identifying and prioritising problems, planning, implementation, and evaluation). Women's groups prioritised problems and decided on, led, and evaluated maternal and child health activities. Participatory women's groups and peer counselling.	Peer counselling for pregnant women. Trained peer counsellors provided health education to pregnant women through scheduled antenatal and postnatal visits at home. Enhanced SOC. Standard services provided through government health facilities, with health systems strengthening.	No differences in primary outcomes of maternal, perinatal, neonatal, and infant mortality rates between intervention arms vs. control arm. Some differences in outcomes on access of antenatal and infant care, including infant immunisation, between intervention arms vs. control arm. Almost no differences in use of insecticide treated bed nets and breastfeeding practices between intervention arms vs. control arm.	† Rosato (2012) [85]
Makaula (2019) [52]	CRT of health facility	Malawi	General population	Community-directed primary health care.	SOC. Standard services provided	No differences between arms in use of	

Article	Study design	Setting	Population	Intervention	Control	Main results	Related studies
	catchment areas		(adults and children)	External actors, including health care providers, engaged community members, who decided on primary health care activities. Community volunteers received trainings and led primary health care activities in their villages, with monitoring from external actors.	through government health facilities.	antimalarial drugs, vitamin A, and praziquantel. Higher use of long-lasting insecticide treated bed nets among women and children in intervention arm vs. control arm.	
Nair (2017) [55]	CRT of villages and adjoining hamlets	India	General population (women and children)	Participatory women's groups for maternal and child health, including for immunisation. External actors and community-based workers guided a four-phase cycle (identifying and prioritising problems, planning, implementation, and evaluation). Women's groups prioritised problems and decided on, led, and evaluated maternal and child health activities.	Enhanced SOC. Capacity strengthening of village health and sanitation committees and standard government health services.	For primary outcome, lower child length-for-age in intervention arm vs. control arm. Almost no differences between arms in infant mortality and child development outcomes, including wasting and stunting. No differences in infant care outcomes, including immunisation. Differences between arms in most outcomes on child nutrition and hygiene, including handwashing.	

CLTS, community-led total sanitation; CRT, cluster randomised trial; HIVST, HIV self-testing; IPV, intimate partner violence; SOC, standard of care; WASH, water, sanitation, and hygiene.

* Quantitative studies.

† Qualitative studies.

‡ Economic studies.

'community' was defined geographically (**Supplementary Table 2.A**). Strategies for engaging community actors were varied and included problem solving and assessment, action planning, skills development, and goal setting and review. Communicable disease strategies included provision of biomedical products, environmental modifications, and education and outreach. Periods of implementation spanned from 2 weeks to 4 years. Overall scores for community participation had a mean of 10.8 out of 16, indicating upper moderate levels of participation. Scores were highest for the implementation stage and lowest for the post-implementation stage (**Supplementary Figure 2.A**).

Of the 16 trials, one study had low risk of bias and 10 studies had moderate risk of bias (**Supplementary Table 2.B**). Five studies were found to have high risk of bias, mostly due to lack of reporting of missing outcome data. Among the eight economic evaluations, all except one study reported high risk of bias (**Supplementary Table 2.C**), with the most common reason being exclusion of important costs and consequences, namely societal.

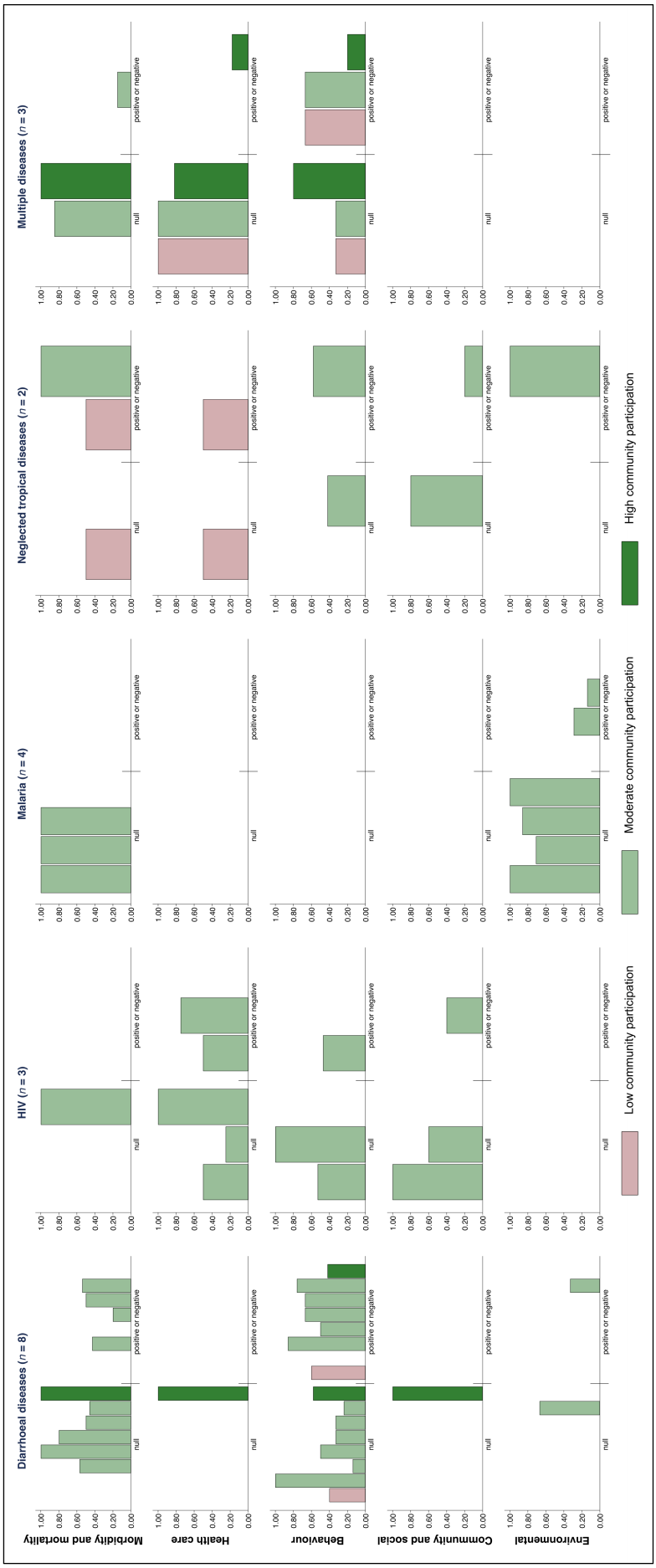
Impact

Supplementary Table 2.D summarises evidence of intervention effects for each cluster-randomised trial. Most studies evaluated outcomes related to health, health care access and utilisation, and health behaviours, while few studies assessed community and social outcomes. Some studies also assessed environmental outcomes, such as parasitological and entomological measures. **Figure 2.3** includes a harvest plot that illustrates the category of effect, either a null effect or a positive or negative effect, by disease area, outcome domain, and community participation domain. Some impact on health behaviours was observed, especially for studies targeting diarrhoeal diseases.

Diarrhoeal diseases

Seven cluster-randomised trials focussed on diarrhoeal diseases, mainly through community-led total sanitation (CLTS) [45-49, 56, 69]. CLTS involved external actors initiating a situational assessment or 'triggering' with community actors, who subsequently devised and enacted action plans to meet goals for improved sanitation. The implementation period ranged from less than 1 year to 2 years. Communicable disease strategies, such as latrine construction, were often predefined by external actors. Another trial evaluated a community-driven water, sanitation, and hygiene (WASH) strategy across 6 months in the Democratic Republic of Congo [57, 68]. Administrative health zones facilitated problem assessment and solving, and village committees designed and implemented action plans with health zones supporting monitoring and evaluation.

Figure 2.3. Evidence of intervention effects by disease area



Harvest plot with outcome domains indicated in rows and disease areas indicated in columns. Each bar represents a single study, or if a single study included more than two comparison arms, each bar represents a single comparison (*N* = 20). The height of the bar indicates the number of outcomes that reported a null effect or a positive or negative effect as a proportion of the number of outcomes reported for the domain. Evidence of an intervention effect was determined based on the effect estimate and confidence interval for each outcome. The color of the bar indicates categorical levels of community participation.

Three moderate-risk trials evaluated the impact of CLTS on child diarrhoeal prevalence and incidence compared with the standard of care (SOC) [46, 48, 56]. In Ethiopia, Cha et al. reported evidence of a decrease in diarrhoeal incidence (adjusted incidence ratio 0.66, 95% CI 0.45 to 0.97) and 100-day diarrhoeal prevalence (adjusted prevalence ratio 0.70, 95% CI 0.52 to 0.95) [48]. A factorial trial reported weak evidence of reductions in diarrhoeal prevalence at 14-days when CLTS was combined with handwashing promotion, with no differences measured for other diarrhoeal and child development outcomes [46]. No differences in morbidity outcomes were measured when evaluating CLTS alone against the SOC. A Malian trial of CLTS found no evidence of changes in diarrhoeal prevalence but reported improvements in outcomes for diarrhoea-related mortality and child development [56]. In Indonesia, a high-risk trial of CLTS demonstrated reductions in roundworm infection but reported no differences in child development outcomes [47]. Impact on child health from community-driven WASH was also not observed, with moderate risk of bias reported [57, 68].

Most trials observed improvements in terms of preventive health behaviours. Positive changes were reported for sanitation practices, including improved latrine access and use and open defecation [46-49, 56, 57]. There was strong evidence of an increase in ownership of improved latrines following the introduction of CLTS in Ethiopia [48]. A moderate-risk trial also reported strong evidence of changes in improved latrine ownership and open defecation when training of opinion leaders was added to CLTS in Ghana [49]. Improvements in water and hygiene practices, such as handwashing, were also reported [46, 48, 56, 57]. An exception was a high-risk trial in Malawi that compared CLTS inclusive of people with disabilities against standard CLTS [45]. The study did not report an effect on any WASH behaviours, citing poor engagement of people with disabilities as a target population.

HIV

Three cluster-randomised trials targeted HIV, with all reporting moderate risk of bias [43, 50, 58, 59, 61, 80]. Two trials evaluated community-led HIV testing. In Malawi, community groups and volunteers participated in workshops and trainings to prepare for 7-day HIV self-testing (HIVST) campaigns [50, 61]. Provision of HIVST was fixed by external actors, but approaches for demand creation, distribution, and linkage to care were decided on by community actors. Compared with the SOC, the study reported strong evidence of improved testing coverage, including a 15.2% (95% CI 7.5% to 22.9%) increase in the primary outcome of lifetime testing among adolescents [50]. The study also reported weak evidence of an intervention effect on social cohesion and collective HIV concern [61]. A Zimbabwean trial, which compared 6-week community-led HIVST campaigns by unpaid community volunteers versus community-based implementation by externally supported

and paid distributors, found no differences in new HIV diagnosis and linkage to HIV prevention and care [58].

Another trial in Uganda assessed the impact of community mobilisation for HIV and intimate partner violence (IPV) prevention against the SOC [43, 59, 80]. Groups of community activists led implementation of education and outreach activities across 4 years, with mobilisation done in tandem with externally planned activities, including mass media and health and social systems strengthening [59]. The study reported improvements in HIV testing for men (adjusted risk ratio 1.50, 95% CI 1.13 to 2.00) but not women [80]. In terms of behavioural outcomes, the study reported no differences between arms in the primary outcomes of physical and sexual IPV, but did detect reductions in other forms of IPV as well as changes in gender roles and norms, interpersonal dynamics, and HIV risk behaviours, including partner concurrency and condom use among men [43, 59, 80].

Malaria

McCann et al. conducted a factorial cluster-randomised trial comparing community-driven strategies for larval source management and house improvements with the SOC, with the study showing high risk of bias [54, 71]. For two years, village committees and health animators led community workshops and oversaw implementation of externally defined vector control activities, which were mostly self-monitored but involved reporting to government community health workers. For the primary outcome of entomological inoculation rate and most secondary outcomes, including malaria prevalence, the study did not demonstrate evidence of an effect for any of the interventions.

Neglected tropical diseases

Two cluster-randomised trials evaluated strategies for neglected tropical diseases [44, 53, 62-67, 70]. Anderson et al. conducted a low-risk trial of community-led strategies for dengue control compared with the SOC in Mexico and Nicaragua [44, 62-67]. Community groups and volunteers designed and implemented community-wide education and outreach activities across 1 year. Volunteers also conducted household education, which was fixed by external actors. The study reported reductions in the primary outcome of dengue infection (relative risk reduction 29.5%, 95% CI 3.8% to 55.3%) as well as changes in dengue-related vectors [44, 62, 63, 67]. Preventive health behaviours, including knowledge and practice of dengue control, also improved [44, 64]. Changes in community-level outcomes, such as collective action and social capital, were not detected [67].

Massa et al. compared community-directed distribution of treatment for schistosomiasis and soil-transmitted helminthiasis with school-based delivery in Tanzania [53, 70]. Community leaders and members decided on distribution activities in their villages and elected drug distributors, who implemented activities across 1 year. The trial, which had high risk of bias, found some evidence of reductions in parasitological outcomes and improvements in treatment coverage.

Multiple diseases

Two cluster-randomised trials evaluated participatory women's groups for maternal and child health [51, 55]. Women's groups were guided through a participatory learning and action cycle where they prioritised disease areas, decided on actions to address health priorities, and implemented and evaluated identified actions. In Malawi, a factorial trial compared 3-year participatory women's groups with peer counselling for pregnant women and an enhanced SOC, with moderate risk of bias reported [51]. The study did not observe evidence of an intervention effect on the primary outcomes of maternal and infant mortality [51]. In India, a moderate-risk trial comparing participatory women's groups against an enhanced SOC found improvements in the primary outcome of infant length-for-age but no changes in other child development outcomes [55].

In terms of health care access and utilisation, the Malawian study reported an increase in uptake of infant immunisation but no changes in other outcomes including HIV testing at antenatal care [51]. The study in India also observed changes in immunisation uptake as well as WASH behaviours for infants [55]. Makaula et al. evaluated provision of community-directed primary care compared with the SOC in Malawi [52]. The high-risk trial did not measure differences in uptake of treatment for malaria and schistosomiasis but found strong evidence of an increase in use of insecticide treated bed nets among women and children.

Costs and cost-effectiveness

Supplementary Table 2.E and **Supplementary Table 2.F** summarise estimates for costs and cost-effectiveness for each cluster-randomised trial. Almost all eight economic evaluations were trial based. All studies measured full economic costs, with seven studies adopting a provider perspective [51, 52, 55, 58, 72-74] and five studies adopting a societal perspective [75-79]. Community costs, including valuation of community time use and in-kind contributions, were captured in most studies, though were often incomplete in measurement.

Three studies assessed the economic impact of CLTS. Using cost-benefit modelling, Cha et al. found that provision of CLTS yielded net societal benefits against the SOC in Ethiopia, with moderate risk-of-bias reported [75]. Benefits, which were valued based on premature diarrheal

deaths and illness from diarrhoea cases averted, substantially outweighed costs over a 10-year period, including across different levels of uncertainty. Two high-risk trial-based economic evaluations of CLTS were also conducted from a societal perspective [76-78]. Crocker et al. evaluated the addition of opinion leaders to CLTS and reported an incremental cost of $1,205 per household with an improved latrine [76, 77]. Household time and resource use was included in cost estimations [76, 77]. Comparing CLTS with the SOC, Briceño et al. estimated an incremental cost of $194 per household with an improved latrine [78]. While household resource contributions were included in cost estimations, time use was excluded [78].

HIV studies included a trial-based economic evaluation of community-led HIVST compared with the SOC [73]. The study reported an incremental cost per additional person tested HIV positive of $351 from a provider perspective, with 45% probability of cost-effectiveness against a recommended threshold for diagnostics [73]. Results were highly sensitive to variation in the outcome estimate. In Zimbabwe, unit costs of community-led HIVST were lower compared with early costs of the community-based alternative but higher compared with later implementation costs [58]. In a trial-based comparison of community mobilisation for HIV and IPV prevention against the SOC, Michaels-Igbokwe et al. estimated a provider incremental cost per physical IPV case averted of $560 [72]. Cost measurements included time use associated with community implementation.

Tschampl et al. conducted a high-risk trial-based economic evaluation, which evaluated community-led dengue control against the SOC from a provider perspective [74]. The analysis reported an incremental cost per disability-adjusted life year averted of $35,393 in Mexico and $34,888 in Nicaragua, with respectively 51% and 0% cost-effectiveness probability against a threshold based on gross domestic product per capita. Low likelihood of cost-effectiveness was attributed to exclusion of societal benefits and costs and high costs of implementation within a randomised trial. Phiri et al. evaluated the societal costs of community-driven larval source management and house improvement for malaria and observed similar costs for both strategies, with costs sensitive to personnel costs and population coverage [79].

For multi-disease studies, two trial-based economic evaluations assessed participatory women's groups against an enhanced SOC, with a high risk of bias determined [51, 55]. Provider incremental cost per life-year lost averted was $142 in Malawi and provider incremental cost per life-year saved was $1,082 in India. Determinants of costs and cost-effectiveness were not discussed. Makaula et al. assessed total costs of community-directed primary care, which had higher costs than the SOC due to community-level costs including volunteer allowance [52].

Implementation, mechanisms of impact, and context

Table 2.2 and **Supplementary Table 2.G** summarises results on facilitators and barriers related to implementation, mechanisms of impact, and context.

Implementation

Studies reported high levels of involvement by community actors in participatory activities initiated by external actors [50, 51, 55, 56, 59]. Community actors were motivated by their desire to gain knowledge and skills in delivering communicable disease strategies and to act as change agents [88, 90]. In some studies, community actors were elected by the wider community, ensuring that trusted individuals acted as representatives [52, 87]. Communicable disease strategies varied and were either externally defined and adapted by community actors or identified by community actors through participatory exercises. For example, dengue control strategies in Mexico and Nicaragua included activities, such as household education, that were predetermined by external actors [44]. Other studies involved strategies that were completely decided on by community actors. In Malawi, women's groups prioritised disease areas and identified a range of maternal and child health activities, including health education, bicycle ambulances, distribution of health commodities, mobile clinics, garden cultivation, and income generation, through participatory meetings [85].

Support from health care providers and other stakeholders facilitated implementation and created an enabling environment for delivering communicable disease strategies [52, 85, 89]. In Malawi, women's groups established linkages with nearby health facilities and collaborated on provision of mobile antenatal and under-5 clinics [85]. Another reported facilitator was trust between community actors and the wider community [81, 87]. Abramsky et al. described the established relationship between community activists and community members, which was critical for building trust and facilitating uptake of knowledge and practices for HIV and IPV prevention [81]. Availability and support of community activists and their use of participatory activities were also important for engaging with community members [80, 81, 83, 84]. Externally set targets and rewards were sometimes used to support community implementation. Pickering et al. included implementation targets for CLTS activities, with communities receiving certification upon achievement [56].

Communicable disease strategies that were costly, time consuming, or labour intensive, such as latrine construction or larval source management, were barriers to implementation [45, 89, 90]. Further, strategies that did not take into consideration the different needs of population subgroups also acted as barriers. Despite its aims, CLTS with inclusivity training had poor engagement of

Table 2.2. Summary of implementation, mechanisms of impact, and context

	Implementation		Mechanisms of impact	Context
	Community participation strategies	**Communicable disease strategies**		
Facilitators	Motivation by community actors to gain knowledge and skills [88, 90] Nomination of community actors by wider community [52, 87]	Variety of identified activities [55, 85] Established trust with wider community [81, 87] Availability, support, and influence of community actors [81, 83, 88, 90] Proximity [84] Use of participatory and collective approaches [80, 81, 83, 84] Availability, support, and influence of community leaders [52, 89] Availability, support, and influence of health care providers [52, 85, 89] Monitoring and evaluation of outcomes [89, 90] Targets and rewards for implementation [56]	Sufficient exposure to CD strategies [49, 50, 56, 59, 84, 87, 88] Sufficient coverage of CD strategies [50, 56] Repeated engagement with CD strategies [45, 82, 84, 89] Motivation to address CDs [89, 90] Awareness of the benefits of CD strategies [87, 90] Diffusion of messages and adoption of CD strategies through social networks [84] Attitudes and norms related to CDs and risk factors [60, 61, 80, 81, 83] Social capital [47, 67] Community empowerment [61]	Male [50, 58, 59] Younger age group [50] Female head of household [86] Willingness to change [81] Personal experience related to CDs or risk factors [83]
Barriers	Exclusion of marginalised and vulnerable groups [45]	Exclusion of marginalised and vulnerable groups [45] Inadequate engagement of subgroups [89] Labour, time, and costs of CD strategies [45, 89, 90]	Poor coverage of CD strategies [58]	Attitudes and norms around CDs [90]

CD, communicable disease.

people with disabilities, meaning marginalised and vulnerable groups were less likely to be considered in sanitation strategies [45]. In Malawi, men were less likely to participate in malaria control activities due to time lost from income-generating activities as well as the perception that women were responsible for health care-related activities [89].

Mechanisms of impact

Sufficient exposure to and uptake of communicable disease strategies led by community actors were necessary to influence outcomes [49, 50, 56, 59, 84, 87, 88]. Community-led provision of HIVST in Malawi achieved 75% uptake, which had a subsequent impact on HIV testing outcomes [50]. In contrast, a similar study in Zimbabwe reported HIVST uptake of 22%, which was lower than uptake in the comparison arm, and thus did not measure an effect on HIV diagnosis and care [58]. Further, repeated exposure to communicable disease strategies was found to be an important mechanism of change [45, 82, 84, 89]. In Uganda, a dose-response relationship was observed between increasing exposure to community mobilisation activities and positive changes in interpersonal relationships [84]. Other factors influencing outcomes included motivation to address communicable diseases [89, 90] and awareness of the benefits of implemented strategies [87, 90]. A Malawian study reported that malaria was considered to be the largest threat to health and acted as a motivation for community members to engage in prevention activities [89].

Mediators of the impact of community-led approaches included attitudes and norms related to communicable diseases and their risk factors [60, 61, 80, 81, 83]. In Uganda, community mobilisation, including participatory community and household-level activities for HIV and IPV prevention, contributed to shifting gender norms and power dynamics and enhancing communication and nonviolent conflict resolution between partners, which strengthened interpersonal relationships and reduced IPV risk [60, 80, 81, 83]. There was also some evidence that changes in community and social-level measures had an impact on downstream outcomes [47, 60, 61, 67]. For example, physical IPV was found to be mediated by gender attitudes and norms at community level [60]. Alvarado-Castro et al. reported associations between higher levels of social capital and reductions in dengue vectors in communities exposed to community-led dengue prevention [67]. In Malawi, associations between measures of community empowerment and HIV testing were detected following introduction of community-led HIVST, though there was no evidence of a mediation effect through community-level variables [61].

Context

At an individual level, studies reported differences in the intervention effect by sex. Community-led HIVST resulted in greater improvements in coverage of HIV testing and linkage to HIV

prevention and care among men compared with women [50, 58]. In Indonesia, the effect of CLTS on diarrhoeal prevalence was larger among female heads of households than male household heads [86]. Qualitative evidence from Uganda found that community members exposed to community mobilisation activities were more likely change their behaviours based on personal experience with HIV and IPV [83]. Other factors that impacted the intervention effect included prevailing attitudes and norms around communicable diseases. For example, the perception that larvicide posed health risks contributed to initial lack of trust in malaria control strategies in Malawi [90].

Discussion

The main findings of this systematic review were that community-led approaches can improve health behaviours including for diarrhoeal diseases, HIV, malaria, and neglected tropical diseases, based on evidence with moderate risk of bias. Evidence was strongest for diarrhoeal diseases, with multiple cluster-randomised trials reporting consistent improvements in water, hygiene, and sanitation practices. However, evidence for impact on mortality and morbidity, health care access and utilisation, and community and social outcomes was less conclusive, with fewer trials measuring these outcomes and results inconsistent among these studies. We also aimed to summarise evidence on pathways to impact and contexts as well as costs and cost-effectiveness. Process evaluations suggested that impact was dependent on achieving sufficient intensity of implementation by community actors, and that factors facilitating implementation included motivation to engage and implement communicable disease strategies, trust between community actors and the wider community, and engagement with stakeholders including health care providers. Contextual influences included demographic and social factors, such as attitudes and norms around communicable diseases. Economic studies were few and many omitted societal costs and consequences. Providing clearer operational guidance on how to define and identify strategies for meaningful community participation and capture relevant outcomes, costs, and processes will be critical to support rapid evidence generation in this important and promising area.

Our findings contribute to previous reviews that highlight the potential value of community participation in public health [10, 21-27], but underscore difficulties in synthesis due to variability concerning the nature and extent of community participation and the adaptation and implementation of strategies by communities. We found more consistent evidence for positive impact on health behaviours in contrast with other outcome domains, including morbidity and mortality and health care. For example, most trials on diarrhoeal diseases reported consistent improvements in sanitation practices, water infrastructure, and hygiene behaviours, but showed weaker evidence for diarrhoeal disease burden and child development. Positive changes in health behaviours, such as gender roles and norms [59, 80], sexual behaviours [59, 80], and vector control measures [44], were reported for

other disease areas but included fewer studies. Evidence on health care outcomes was difficult to interpret without understanding service-related barriers to provision and use of care. For instance, availability of HIVST was important for addressing supply and demand-side barriers to care and therefore increasing HIV testing coverage [50]. To impact morbidity and mortality, some trials integrated more vertical elements to improve intensity of implementation. Reduction of dengue infection in Mexico and Nicaragua was achieved through a combination of community-driven mobilisation and externally prescribed household education [44]. However, we recognise that drawing conclusions on drivers of effect heterogeneity is challenging with limited studies.

Interventions included in our review varied in terms of the scope of community participation and communicable disease strategies. For example, some studies involved external actors predetermining the remit of disease strategies, such as latrine construction [45-49, 56]. In other studies, community actors had broader input, such as women's groups identifying prioritised disease areas and strategies for maternal and child health [51, 55]. Choice of approach may vary according to the intended aims of the intervention. For example, biomedical and environmental strategies requiring immediate attention may be more amenable to community-driven implementation of solutions set by external actors. A review of community engagement approaches in high-income countries found that community-based implementation had larger effect sizes than empowerment-based approaches, potentially due to higher intervention intensity [24]. Alternatively, strategies aimed at addressing social and structural determinants of diseases might require more extensive engagement of community actors to impact upstream outcomes.

Our synthesis aimed to understand processes underlying the effects of community-led approaches, which are characterised by multicomponent inputs and implementation, nonlinear mechanisms of impact, interactions with contexts, and synergies between outcomes [24]. Included studies reported high levels of community involvement, underscoring the acceptability of community-led strategies for communicable disease control. Desire to gain knowledge and skills and act collectively as change agents motivated implementation by community actors and has previously been described as important for community participation [91]. Other key implementation factors included support from health care providers and other stakeholders as well as trust between community actors and the wider population. In Malawi, collaborations between women's groups and nearby health facilities were integral to providing antenatal care and under-5 services through mobile clinics [85].

Reaching sufficient intensity of implementation by community actors was important to meet intended outcomes. For example, high levels of exposure to CLTS events likely facilitated improvements in latrine ownership in Mali [56]. Another hypothesised pathway for improving health outcomes is by modifying social and structural determinants of health [5, 6, 92]. Some studies

reported quantitative and qualitative evidence for indirect effects through community and social outcomes, but data were limited. In Uganda, impact on physical IPV was found to be mediated by gender attitudes and norms at community level [60]. Our review also reported some evidence of population-level impact on community and social outcomes, but with few studies included and inconsistent findings among studies. While impact on upstream determinants of health has been reported in previous reviews [24], our inconclusive findings are not surprising given that community and social outcomes are products of complex systems, difficult to measure, and rarely included in evaluations [27]. Studies are also not often powered to measure these outcomes [27]. Further, impact might be more difficult to achieve if studies are targeting downstream health determinants, with direct intervention on community empowerment likely needed to impact community and social outcomes [93]. For example, changes in collective action and social capital were not observed following community-led environmental management for dengue prevention in Mexico and Nicaragua [67].

Evidence for costs and relative cost-effectiveness against facility and community alternatives was varied, largely due to differences in measurement of costs and outcomes. For example, economic costing of CLTS in Tanzania accounted for in-kind contributions but not volunteer time [78]. Most studies used a provider rather than societal perspective, meaning that direct and indirect costs incurred by communities were largely excluded from cost estimations. Few studies also measured generic or non-health consequences as well as long-term costs and outcomes, potentially underestimating benefits from community participation. When broader costs and benefits were modelled, interventions were found to generate net benefits [75]. These gaps underscore the need for standardised guidance for measuring costs and benefits in this methodologically challenging area [94]. Systematic capture of community costs is especially important given the potential for the benefits of community engagement to be offset by the time and financial burden of involvement [21]. Further, there is a risk that decentralisation of resource use will be exploited as an alternative to the substantial investment required for community-based strategies [22]. Therefore, it is important that funding for community-led responses appropriately account for community costs with systems in place to support financial sustainability, such as integrating social contracting into national and global health financing structures.

Reviews of community participation have previously highlighted the challenges of evidence synthesis. Interventions involving participatory approaches consist of multiple independent and interdependent components that seek to influence a complex system [95, 96]. Community participation is fluid and can evolve over time, and implementation will differ based on the needs, resources, and conditions of communities [94, 97]. Participation by communities can generate both health and non-health effects that can occur at individual and community levels, immediate and

extended time horizons and through direct and indirect exposure that differ by context [94-96]. To address heterogeneity concerning community participation, we restricted our eligibility criteria to community-led approaches. However, there was still substantial variation in terms of the degree of community ownership. Ascertaining study eligibility required subjective interpretations and judgements due to differences in terminology for community participation used by authors. Not all studies reported implementation procedures in sufficient detail to understand how community actors were engaged and how strategies were developed by community actors. Mechanisms of impact and contextual factors that might support or hinder impact were also not consistently described and should be prioritised in reporting.

Our review had additional limitations, including the broad scope of disease areas and strategies for communicable diseases. We attempted to address study variability by grouping studies by outcome domains and interventions to assess evidence across disease areas. To improve methodological quality of effectiveness studies, we restricted our review to cluster-randomised trials, which have well-known limitations in terms of their application to complex interventions [96]. As a result, our conclusions are based on interventions done in controlled settings, with external actors potentially having a greater role than in real-world contexts. Comparators within trials varied, meaning the intervention effect may have captured other differences between arms besides community participation. For example, trials on HIVST used different facility and community comparators [50, 58]. Lastly, our search was based on broad terms for 'community', potentially excluding studies that referred to specific population subgroups. As a result, most studies in our review included communities defined by spatial rather than social characteristics.

This systematic literature review of community-led communicable disease control strategies showed stronger evidence for positive impact on health behaviours, but less conclusive data for morbidity and mortality, health care access and utilisation, and community and social outcomes. Impact appeared to depend on the intensity of community implementation, with factors facilitating implementation including motivation by community actors, trust between community actors and the wider population, and engagement with the health system. Our synthesis highlights the need for consensus on and use of an operational framework for community-led approaches to define key concepts and practices, support more complete and consistent reporting, including on costs and processes, and enable lessons to be learned across health and development. Further, this review supports community-led communicable disease control as a potentially effective strategy to improve health behaviours and contribute to SDGs. Given the current global context of disruptive shocks to health, social, and economic systems, greater focus on generating evidence and establishing systems to support design and scale-up of community-led health responses should be considered a global priority.

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Supplementary materials

Contents

Supplementary Text 2.A. PRISMA checklist of information to include when reporting a systematic review

Section/Item	Item #	Standard checklist item	Page #
Title and abstract			
Title	1	Identify the report as a systematic review.	Title
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Abstract
Introduction			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Introduction
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Introduction
Methods			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Methods: Eligibility criteria Supplementary text C
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Methods: Search strategy, screening, and extraction Supplementary text C
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Methods: Search strategy, screening, and data extraction Supplementary text C
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Methods: Search strategy, screening, and data extraction Supplementary text C
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Methods: Search strategy, screening, and data extraction Supplementary text D
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Methods: Search strategy, screening, and data extraction Supplementary text D
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Methods: Search strategy, screening, and data extraction Supplementary text D
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Methods: Search strategy, screening, and data extraction Supplementary text D
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Methods: Data synthesis
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Methods: Data synthesis
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as	Methods: Data synthesis

Section/Item	Item #	Standard checklist item	Page #
		handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Methods: Data synthesis
	13d	Describe any methods used to synthesise results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Methods: Data synthesis
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Methods: Data synthesis
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Not applicable
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Not applicable
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Not applicable
Results			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Results Figure 2
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Figure 2
Study characteristics	17	Cite each included study and present its characteristics.	Results: Characteristics of included studies Table 1
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Results: Characteristics of included studies Supplementary table B Supplementary table C
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Supplementary table D Supplementary table E Supplementary table F
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Results
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Results: Impact Figure 3
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Results Figure 3
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Not applicable
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Not applicable

Section/Item	Item #	Standard checklist item	Page #
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Not applicable
Discussion			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Discussion
	23b	Discuss any limitations of the evidence included in the review.	Discussion
	23c	Discuss any limitations of the review processes used.	Discussion
	23d	Discuss implications of the results for practice, policy, and future research.	Discussion
Other information			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Methods
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Methods
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Not applicable

Supplementary Text 2.B. Frameworks for community participation

Author	Description
Arnstein[1]	Ranks citizen participation in public planning based on the level of power held by citizens. **'Non-participation'** excludes citizens from planning and includes sub-categories 'manipulation' and 'therapy'. In **'tokenism'**, the have-nots "hear and have a voice" but lack the power to ensure meaningful adoption by the haves. Sub-categories including 'informing', 'consultation', and 'placation'. In **'citizen power'**, citizens have increasing decision making power in planning, from 'partnership' to 'delegated power' to 'citizen control'.
Labonte[2]	Differentiates between community-based and community development approaches based on "who sets the agenda and who names the issue or problem". **'Community-based'** involves external actors defining community problems and solutions, with assistance from the community. **'Community development'** involves the process of supporting the community to identify priority concerns and issues and plan and implement strategies in response, aiming to shift power relations between external actors and the community towards greater equity.
Laverack and Labonte[3]	Describes frameworks for community participation in health promotion. A **'top-down'** approach involves external actors following a predetermined cycle of programme design, implementation, and evaluation. In a **'bottom-up'** approach, programme cycles are negotiated, with external actors supporting the community "in the identification of issues which are important and relevant to their lives and enable them to develop strategies to resolve these issues".
McLeroy et al.[4]	Conceptualises the community as either a 'setting', 'target', 'resource', or 'agent' of community-based health interventions. As a **'setting'**, the community is the geographic location in which interventions are implemented by external actors. The community as a **'target'** refers to externally led interventions that aim to change behaviours at the community level rather than the individual level. Interventions with the community as a **'resource'** aim to channel resources from the community towards priority health strategies, with external actors working through community institutions and resources. As an **'agent'**, the community is a 'unit of solution' that functions to meet the needs of community members. The role of the external actor is to strengthen the capacity of the community to respond to these needs.
Rothman et al.[5]	Specifies three models of community organisation. **'Planning and policy'** is task oriented, whereby empirical data are used to understand and solve community problems, often by an external actor. **'Community capacity development'** is process oriented. External actors aim to enable the community to understand their own problems and implement their own solutions. **'Social advocacy'** is task and process oriented, with external actors further galvanising the community to redress systematic power imbalances in pursuit of equity and justice.
Rifkin and Pridmore[6] Draper et al.[7]	Differentiates community participation based on the perspective on health and respective role of the community in health programmes. **'Information giving'** and **'consultation'** or **'mobilisation'** views health as the absence of disease and external actors provide advice to the community as experts. **'Collaboration'** incorporates a broader perspective of health as physical, mental, and social wellbeing, with the community contributing time and resources towards externally defined health programmes. **'Empowerment'** further defines health as the human condition. The community plans and implements health programmes and external actors function as facilitators.

[1] Arnstein SR. A ladder of citizen participation. *JAPA.* 1969; 35(4):216-224.
[2] Labonte R. Health Promotion and Empowerment: Practice Frameworks. Toronto: Centre for Health Promotion, University of Toronto; 1993.
[3] Laverack G, Labonte R. A planning framework for community empowerment goals within health promotion. *Health Policy Plann.* 2000; 15(3):255-262.
[4] McLeroy KR, Norton BL, Kegler MC, Burdine JN, Sumaya CV. Community-based interventions. *Am J Public Health.* 2003; 93(4):529-533.
[5] Rothman J, Erlich J, Tropman JE. Strategies of Community Intervention, 1st edn. Itasca: F.E. Peacock Publishers; 2001.
[6] Rifkin SB, Pridmore P. Partners in Planning: Information, Participation and Empowerment, 1st edn. London: Macmillan Education Ltd; 2001.
[7] Draper AK, Hewitt G, Rifkin S. Chasing the dragon: developing indicators for the assessment of community participation in health programmes. *Soc Sci Med.* 2010; 71(6):1102-1109.

Supplementary Text 2.C. Eligibility criteria and search strategy for database searches

Eligibility criteria

Table. Inclusion and exclusion criteria

	Inclusion	Exclusion
Article	Full text, peer-reviewed articles	Abstracts
Language	English	Non-English
Study design	Cluster RCT or economic evaluations using RCT data	Commentaries, meta-analyses, observational studies, non-randomised intervention studies, economic evaluations using observational data, protocols, reviews, meta-analyses Interim or pilot RCTs, individual RCTs, RCTs with 1 group per arm, RCTs with interventions added post-randomisation
Disease area	CDs or determinants of CDs	Other diseases (e.g., non-CDs, diseases caused by infectious agents but not spread from person-to-person) Other diseases among people living with chronic CDs Determinants of CDs but disease not described or described generally (e.g., infection)
Outcome	Effects, costs, and cost-effectiveness related to CDs or determinants of CDs	Effects, costs, and cost-effectiveness related to other diseases
Population	Any population	Not applicable
Intervention, setting	Outside of standard health facilities	Standard health facilities, laboratories, pharmacies
Intervention, group	Groups, organisations, or networks with shared spatial or social characteristics or collective interests	Non-groups, organisations, or networks Groups, organisations, or networks without shared spatial or social characteristics or collective interests, or not specified
Intervention, participation	The community is an agent. Communities define problems and implement and evaluate solutions, with external actors providing support as facilitators. Decisions are mostly made by the community.	The community is a setting. External actors define problems and implement and evaluate solutions, with communities excluded from making contributions and decisions. The community is a target. Communities input into defining problems and implementing and evaluating solutions, but decisions are mostly made by external actors. The community is a resource. Communities define problems and implement and evaluate solutions in partnership with external actors. Decisions are made jointly or shared.
Comparator	Any comparator	Not applicable

CD, communicable disease; RCT, randomised controlled trial.

Search strategy

Seven electronic databases were searched on 11 October, 2021. Searches were updated on 31 December, 2022.

Cochrane Trials

	Search	N
1	(community consultation OR community collaboration OR community directed OR community-directed OR community driven OR community-driven OR community empowerment OR community led OR community-led OR community mobili$ation OR community action OR community capacity building OR community development OR community engagement OR community initiative OR community involvement OR community organi$ation OR community outreach OR community participation):af	19,707
2	(coronavirus OR covid OR hepatitis OR human immunodeficiency virus OR HIV OR sexually transmitted OR sexually-transmitted OR STIs OR STDs OR tuberculosis OR TB OR vector* OR parasit* OR malaria OR dengue OR chikungunya OR zika OR neglected tropical diseases OR NTDs OR lymphatic filariasis OR onchocerciasis OR schistosomiasis OR trachoma OR soil transmitted helminth* OR soil-transmitted helminth* OR STHs OR immuni$ation OR infect* OR transmit* or communicable or viral or virus* or bacteri*):af	226,093
3	(random* OR trial* OR experiment* OR cost*):ab	1,157,012
4	#1 AND #2 AND #3	3,210

Econlit

	Search	N
1	(community consultation or community collaboration or community directed or community-directed or community driven or community-driven or community empowerment or community led or community-led or community mobilisation or community action or community capacity building or community development or community engagement or community initiative or community involvement or community organi$ation or community outreach or community participation).af.	2,842
2	(coronavirus or covid or hepatitis or human immunodeficiency virus or HIV or sexually transmitted or sexually-transmitted or STIs or STDs or tuberculosis or TB or vector* or parasit* or malaria or dengue or chikungunya or zika or neglected tropical diseases or NTDs or lymphatic filariasis or onchocerciasis or schistosomiasis or trachoma or soil transmitted helminth* or soil-transmitted helminth* or STHs or immuni$ation or infect* or transmit* or communicable or viral or virus* or bacteri*).af.	35,590
3	(random* or trial* or experiment* or cost*).ab.	221,878
4	1 and 2 and 3	7

EMBASE

	Search	N
1	(community consultation or community collaboration or community directed or community-directed or community driven or community-driven or community empowerment or community led or community-led or community mobili$ation or community action or community capacity building or community development or community engagement or community initiative or community involvement or community organi$ation or community outreach or community participation).af.	27,465
2	(coronavirus or covid or hepatitis or human immunodeficiency virus or HIV or sexually transmitted or sexually-transmitted or STIs or STDs or tuberculosis or TB or vector* or parasit* or malaria or dengue or chikungunya or zika or neglected tropical diseases or NTDs or lymphatic filariasis or onchocerciasis or schistosomiasis or trachoma or soil transmitted helminth* or soil-transmitted helminth* or STHs or immuni$ation or infect* or transmit* or communicable or viral or virus* or bacteri*).af.	6,941,390
3	(random* or trial* or experiment* or cost*).ab.	5,957,502
4	1 and 2 and 3	2,299

Global Health

	Search	N
1	(community consultation or community collaboration or community directed or community-directed or community driven or community-driven or community empowerment or community led or community-led or community mobili$ation or community action or community capacity building or community development or community engagement or community initiative or community involvement or community organi$ation or community outreach or community participation).af.	20,439
2	(coronavirus or covid or hepatitis or human immunodeficiency virus or HIV or sexually transmitted or sexually-transmitted or STIs or STDs or tuberculosis or TB or vector* or parasit* or malaria or dengue or chikungunya or zika or neglected tropical diseases or NTDs or lymphatic filariasis or onchocerciasis or schistosomiasis or trachoma or soil transmitted helminth* or soil-transmitted helminth* or STHs or immuni$ation or infect* or transmit* or communicable or viral or virus* or bacteri*).af.	3,058,202
3	(random* or trial* or experiment* or cost*).ab.	806,976
4	1 and 2 and 3	1,814

Medline

	Search	N
1	(community consultation or community collaboration or community directed or community-directed or community driven or community-driven or community empowerment or community led or community-led or community mobili$ation or community action or community capacity building or community development or community engagement or community initiative or community involvement or community organi$ation or community outreach or community participation).af.	35,728
2	(coronavirus or covid or hepatitis or human immunodeficiency virus or HIV or sexually transmitted or sexually-transmitted or STIs or STDs or tuberculosis or TB or vector* or parasit* or malaria or dengue or chikungunya or zika or neglected tropical diseases or NTDs or lymphatic filariasis or onchocerciasis or schistosomiasis or trachoma or soil transmitted helminth* or soil-transmitted helminth* or STHs or immuni$ation or infect* or transmit* or communicable or viral or virus* or bacteri*).af.	5,435,897
3	(random* or trial* or experiment* or cost*).ab.	4,490,370
4	1 and 2 and 3	1,439

Pub Med

	Search	N
1	(“community consultation” OR “community collaboration” OR “community directed” OR “community-directed” OR “community driven” OR “community-driven” OR “community empowerment” OR “community led” OR “community-led” OR “community mobilization” OR “community mobilisation” OR “community action” OR “community capacity building” OR “community development” OR “community engagement” OR “community initiative” OR “community involvement” OR “community organization” OR “community organisation” OR “community outreach” OR “community participation”) in All Fields	40,110
2	(coronavirus OR covid OR hepatitis OR “human immunodeficiency virus” OR HIV OR “sexually transmitted” OR “sexually-transmitted” OR STIs OR STDs OR tuberculosis OR TB OR vector* OR parasit* OR malaria OR dengue OR chikungunya OR zika OR “neglected tropical diseases” OR NTDs OR “lymphatic filariasis” OR onchocerciasis OR schistosomiasis OR trachoma OR “soil transmitted helminth*” OR “soil-transmitted helminth*” OR STHs OR immunization OR immunisation OR infect* OR transmit* OR communicable OR viral OR virus* OR bacteri*) in All Fields	6,291,933
3	(random* OR trial* OR experiment* OR cost*) in Title/Abstract	4,967,995
4	#1 AND #2 AND #3	1,793

Web of Science

	Search	N
1	ALL=(“community consultation” OR “community collaboration” OR “community directed” OR “community-directed” OR “community driven” OR “community-driven” OR “community empowerment” OR “community led” OR “community-led” OR “community mobilisation” OR “community action” OR “community capacity	47,592

	Search	N
	building" OR "community development" OR "community engagement" OR "community initiative" OR "community involvement" OR "community organi?ation" OR "community outreach" OR "community participation")	
2	ALL=(coronavirus OR covid OR hepatitis OR "human immunodeficiency virus" OR HIV OR "sexually transmitted" OR "sexually-transmitted" OR STIs OR STDs OR tuberculosis OR TB OR vector* OR parasit* OR malaria OR dengue OR chikungunya OR zika OR "neglected tropical diseases" OR NTDs OR "lymphatic filariasis" OR onchocerciasis OR schistosomiasis OR trachoma OR "soil transmitted helminth*" OR "soil-transmitted helminth*" OR STHs OR immuni?ation OR infect* OR transmit* OR communicable OR viral OR virus* OR bacteri*)	6,349,300
3	AB=(random* OR trial* OR experiment* OR cost*)	9,822,733
4	#1 AND #2 AND #3	1,461

Supplementary Text 2.D. Data extraction form

Group	Category	Field
Record information	Record characteristics	Author
		Year
		Record category (primary/secondary/economic)
		Record title
Parent	Parent characteristics	Country
		Region
		Population
		Disease areas – communicable diseases
		Disease areas – other
	Parent design	Randomised trial design
		Randomisation unit
		Number of units
		Unit eligibility
		Intervention details
		Control details
Intervention	Intervention and control characteristics	External actors
		Community actors
		Other actors
		Intervention setting
		Intervention eligibility
		Intervention period
		Strategies for community participation
		Strategies for communicable diseases
	Community participation	Design – score (information giving / consultation / collaboration / empowerment)
		Design – details
		Implementation – score (information giving / consultation / collaboration / empowerment)
		Implementation – details
		Monitoring and evaluation – score (information giving / consultation / collaboration / empowerment)
		Monitoring and evaluation – details
		Post-implementation – score (information giving / consultation / collaboration / empowerment)
		Post-implementation – details
Outcome evaluation	Study design	Data sources
		Measurement timepoints
		Measurement period
		Sampling approach
		Sample
		Sample size
		Analytical approach
	Results	Primary outcomes – summary
		Primary outcomes – measure
		Primary outcomes – estimate
		Secondary health / health care outcomes – summary
		Secondary health / health care outcomes – measure
		Secondary health / health care outcomes – estimate
		Other secondary outcomes – summary
		Other secondary outcomes – measure
		Other secondary outcomes – estimate
Economic evaluation	Study design	Study design
		Perspective
		Time horizon
		Analytical approach
		Sensitivity analysis
		Discount rate
		Inflation rate
	Results	Currency
		Currency year
		Incremental cost-effectiveness ratio estimate
		Incremental cost-effectiveness ratio estimate (adjusted)
		Cost-effectiveness probability
Cost	Study design	Study design

Group	Category	Field
		Perspective
		Prospective or retrospective
		Economic or financial
		Real world or per protocol
		Full or incremental
		Scope (above service delivery / service delivery / community / patient)
		Inputs
		Data sources
		Measurement period
		Sampling approach
		Sample size
	Results	Currency
		Currency year
		Total cost estimate
		Output estimate
		Unit cost estimate
		Unit cost estimate (adjusted)
		Direct costs (%)
		Indirect costs (%)
		Start-up (%)
		Capital (%)
		Personnel (%)
		Other recurrent (%)
		Other (%)
Process evaluation	Study design	Study design
		Sampling approach
		Sample
		Sample size
		Analytical approach
	Results	Implementation details
		Mechanism of impact details
		Context details
Risk of bias	Risk of bias tool for cluster randomised trials[1]	Randomisation
		Timing of identification or recruitment of participants
		Deviations from intended interventions (assignment)
		Missing outcome data
		Measurement of the outcome
		Selection of the reported result
		Overall (low / moderate / high)
	Drummond checklist for critique of economic evaluations[2]	Was a well-defined question posed in answerable form?
		Was a comprehensive description of the competing alternatives given (i.e., can you tell who did what to whom, where, and how often)?
		Was the effectiveness of the programme or services established?
		Were all the important and relevant costs and consequences for each alternative identified?
		Were costs and consequences measured accurately in appropriate physical units (e.g., hours of nursing time, number of physician visits, lost workdays, gained life years)?
		Were the costs and consequences valued credibly?
		Were costs and consequences adjusted for differential timing?
		Was an incremental analysis of costs and consequences of alternatives performed?
		Was allowance made for uncertainty in the estimates of costs and consequences?
		Did the presentation and discussion of study results include all issues of concern to users?

[1] Higgins J, Thomas J, Chandler J, Cumpston M, Li T, Page M *et al*. Cochrane handbook for systematic reviews of interventions. [www.training.cochrane.org/handbook].

[2] Drummond MF, Jefferson TO. Guidelines for authors and peer reviewers of economic submissions to the BMJ. *BMJ.* 1996; 313(7052):275-283.

Group	Category	Field
		Overall (low / moderate / high)

Supplementary Text 2.E. Adapted framework for community participation

	Information giving	Consultation	Collaboration	Empowerment
Overall	The community is a setting. External actors define problems and implement and evaluate solutions, with communities excluded from making contributions and decisions.	The community is a target. Communities input into defining problems and implementing and evaluating solutions, but decisions are mostly made by external actors.	The community is a resource. Communities define problems and implement and evaluate solutions in partnership with external actors. Decisions are made jointly or shared.	The community is an agent. Communities define problems and implement and evaluate solutions, with external actors providing support as facilitators. Decisions are mostly made by the community.
Design	External actors identify priorities, design strategies, and prepare funds and resources, with communities excluded from making contributions and decisions.	Communities input into identifying priorities, designing strategies, and preparing funds and resources, but decisions are mostly made by external actors.	Communities identify priorities, design strategies, and prepare funds and resources in partnership with external actors. Decisions are made jointly or shared.	Communities identify priorities, design strategies, and prepare funds and resources, with external actors providing support as facilitators. Decisions are mostly made by the community.
Implementation	External actors mobilise funds and resources and implement strategies, with communities excluded from making contributions and decisions.	Communities contribute towards mobilising funds and resources and implementing strategies, but decisions are mostly made by external actors.	Communities mobilise funds and resources and implement strategies in partnership with external actors. Decisions are made jointly or shared.	Communities mobilise funds and resources and implement strategies, with external actors providing support as facilitators. Decisions are mostly made by the community.
Monitoring and evaluation	External actors define data indicators, collect and analyse data, and discuss learnings, with communities excluded from making contributions and decisions.	Communities contribute towards defining data indicators, collecting and analysing data, and discussing learnings, but decisions are mostly made by external actors.	Communities define data indicators, collect and analyse data, and discuss learnings in partnership with external actors. Decisions are made jointly or shared.	Communities define data indicators, collect and analyse data, and discuss learnings, with external actors providing support as facilitators. Decisions are mostly made by the community.
Post-implementation	External actors define long-term priorities, strategies, and funds and resources, with communities excluded from making contributions and decisions.	Communities contribute towards defining long-term priorities, strategies, and funds and resources, but decisions are mostly made by external actors.	Communities define long-term priorities, strategies, and funds and resources in partnership with external actors. Decisions are made jointly or shared.	Communities define long-term priorities, strategies, and funds and resources, with external actors providing support as facilitators. Decisions are mostly made by the community.

Framework adapted from Rifkin and Pridmore (2001) and Draper (2010) [1,2].

[1] Rifkin SB, Pridmore P. Partners in Planning: Information, Participation and Empowerment, 1st edn. London: Macmillan Education Ltd; 2001.
[2] Draper AK, Hewitt G, Rifkin S. Chasing the dragon: developing indicators for the assessment of community participation in health programmes. *Soc Sci Med.* 2010; 71(6):1102-1109.

Supplementary Table 2.A. Results for community participation scores

Article	Setting	Intervention	Community unit	Main strategies for community participation	Main strategies for communicable diseases	Intervention period	Design	Implementation	M&E	Post-implementation	Overall
Diarrhoeal diseases											
Biran (2018)	Malawi	CLTS inclusive of people with disabilities	Sanitation committees	Coalition building Situational assessment Action planning	Awareness raising Education Environmental alterations	7 months	3	4	3	0	10
Briceño (2017)	Tanzania	CLTS	Sanitation committees	Coalition building Situational assessment Action planning	Awareness raising Education Environmental alterations	2 years	3	4	4	0	11
Cameron (2019)	Indonesia	CLTS	Community members	Coalition building Situational assessment Action planning	Awareness raising Education Environmental alterations	NR	3	4	3	0	10
Cha (2021)	Ethiopia	CLTS	WASH promoters	Coalition building Situational assessment Action planning Skills development	Awareness raising Education Environmental alterations	1 year	3	4	3	0	10
Crocker (2016)	Ghana	CLTS with training of natural leaders	Natural leaders, community members	Coalition building Situational assessment Action planning Skills development	Awareness raising Education Environmental alterations	1.5 years	3	4	0	0	7
Pickering (2015)	Mali	CLTS	Sanitation committees	Coalition building Situational assessment Action planning	Awareness raising Education Environmental alterations	2 years	3	4	3	0	10

Article	Setting	Intervention	Community unit	Main strategies for community participation	Main strategies for communicable diseases	Intervention period	Design	Implementation	M&E	Post-implementation	Overall
Quattrochi (2018)	Democratic Republic of Congo	Community-led WASH	WASH committees, WASH volunteers	Coalition building Problem assessment and solving Action planning Skills development	Awareness raising Education Environmental alterations	6 months	4	4	3	3	14
HIV											
Abramsky (2014)	Uganda	Community mobilisation for HIV and IPV prevention	Community activists	Coalition building Problem assessment and solving Action planning Skills development	Awareness raising Education Peer support	4 years	4	4	0	3	11
Indravudh (2021)	Malawi	Community-led HIVST	Community health action groups and volunteers	Coalition building Problem assessment and solving Action planning Goal setting and review Skills development	Demand creation Diagnostic testing	2 weeks	4	4	4	0	12
Sibanda (2021)	Malawi	Community-led HIVST	Community leaders, distributors, and members	Coalition building Problem assessment and solving Action planning Skills development	Demand creation Diagnostic testing	6 weeks	4	4	3	0	11
Malaria											
McCann (2021)	Malawi	Community-driven larval source management and house improvement.	Village committees, health animators	Coalition building Action planning Goal setting and review Skills development	Vector control	2.5 years	3	4	4	0	11

Article	Setting	Intervention	Community unit	Main strategies for community participation	Main strategies for communicable diseases	Intervention period	Design	Implementation	M&E	Post-implementation	Overall
Neglected tropical diseases											
Andersson (2015)	Mexico, Nicaragua	Community-led dengue control	Community groups, volunteers	Coalition building Problem assessment and solving Action planning Skills development	Education Environmental alterations Vector control	1.5 years	4	4	3	0	11
Massa (2009)	Tanzania	Community-directed distribution of treatment for schistosomiasis and soil-transmitted helminthiasis	Community drug distributors, members	Coalition building Action planning Skills development	Treatment	1 year	4	4	0	0	8
Multiple diseases											
Lewycka (2013)	Malawi	Participatory women's groups for maternal and child health	Women's groups	Coalition building Problem assessment and solving Action planning Goal setting and review Skills development	Education Access to services Income generation Nutrition Vector control	3.5 years	4	4	4	4	16
Makaula (2019)	Malawi	Community-directed primary health care	Community volunteers, members	Coalition building Problem assessment and solving Action planning Skills development	Vector control Drugs for prevention Drugs for treatment Nutrition	1 year	3	3	2	0	8
Nair (2017)	India	Participatory women's groups for	Women's groups	Coalition building Problem assessment and solving	Education Peer support Advocacy	2 years	4	4	4	0	12

Article	Setting	Intervention	Community unit	Main strategies for community participation	Main strategies for communicable diseases	Intervention period	Design	Implementation	M&E	Post-implementation	Overall
		maternal and child health		Action planning Goal setting and review Skills development	Access to services Nutrition						

CLTS, community-led total sanitation; HIVST, HIV self-testing; IPV, intimate partner violence; NR, not reported; WASH, water, sanitation, and hygiene. Scores use a 0–4 scale: 0=not reported, 1=information giving, 2=consultation, 3=collaboration, 4=empowerment.

Supplementary Table 2.B. Risk of bias assessment for cluster-randomised trials

	1a. Randomisation	1b. Timing of identification or recruitment of participants	2. Deviations from intended interventions	3. Missing outcome data	4. Measurement of outcome	5. Selection of reported result	Overall
Diarrhoeal diseases							
Biran (2018)	×	+	–	×	+	–	×
Briceño (2017)	–	+	–	+	–	+	–
Cameron (2019)	–	+	–	×	–	–	×
Cha (2021)	–	+	–	+	–	+	–
Crocker (2016)	+	+	–	+	–	–	–
Pickering (2015)	–	+	–	+	–	+	–
Quattrochi (2018)	+	+	–	+	–	+	–
HIV							
Abramsky (2014)	+	+	–	+	–	+	–
Indravudh (2021)	+	+	–	+	–	+	–
Sibanda (2021)	+	+	–	+	–	+	–
Malaria							
McCann (2021)	–	+	–	×	+	+	×
Neglected tropical diseases							
Andersson (2015)	+	+	+	+	+	+	+
Massa (2009)	–	+	–	×	+	–	×
Multiple diseases							
Lewycka (2013)	+	+	–	+	+	+	–
Makaula (2019)	–	+	–	×	–	–	×
Nair (2017)	+	+	–	+	+	+	–

+, low risk; –, moderate risk; ×, high risk. Risk of bias assessment used the Revised Cochrane Risk-of-Bias Tool for Cluster-Randomised Trials[1].

[1] Higgins J, Thomas J, Chandler J, Cumpston M, Li T, Page M *et al*. Cochrane handbook for systematic reviews of interventions. [www.training.cochrane.org/handbook].

Supplementary Table 2.C. Risk of bias assessment for economic evaluations

	1. Was a well-defined question posed in answerable form?	2. Was a comprehensive description of the competing alternatives given?	3. Was the effectiveness of the programme or services established?	4. Were all the important and relevant costs and consequences for each alternative identified?	5. Were costs and consequences measured accurately in appropriate .physical units?	6. Were the cost and consequences valued credibly?	7. Were costs and consequences adjusted for differential timing?	8. Was an incremental analysis of costs and consequences of alternatives performed?	9. Was allowance made for uncertainty in the estimates of costs and consequences?	10. Did the presentation and discussion of study results include all issues of concern to users?	Overall
Diarrhoeal diseases											
Briceño (2017)	+	+	+	+	+	–	–	+	×	×	×
Cha (2021)	+	+	+	+	–	+	–	+	+	–	–
Crocker (2016)	+	+	+	+	+	×	+	+	–	–	×
HIV											
Indravudh (2021)	+	+	+	×	+	–	–	+	–	–	×
Neglected tropical diseases											
Andersson (2015)	+	–	+	×	+	–	–	+	–	–	×
Multiple diseases											
Lewycka (2013)	+	–	+	×	–	+	–	+	×	×	×
Nair (2017)	+	–	+	×	+	–	–	+	×	×	×

+, low risk; –, moderate risk; ×, high risk. Risk of bias assessment used the Drummond checklist for economic evaluations[1].

[1] Drummond MF, Jefferson TO. Guidelines for authors and peer reviewers of economic submissions to the BMJ. *BMJ.* 1996; 313(7052):275-283.

Supplementary Table 2.D. Results from cluster-randomised trials

Article	Study design	Setting	Intervention	Control	Sample size	Effect estimates
Diarrhoeal diseases						
Biran (2018)	CRT of group village head units	Malawi	CLTS inclusive of people with disabilities	CLTS	Household, with people with disabilities, *N* = 171	**Behaviour** **Null:** latrine construction*, improved latrine construction, time to travel to latrine, able to use latrine as required, able to use latrine without assistance, water near latrine for handwashing, able to use latrine without coming into contact with faeces, improved latrine access for people with disabilities, easy latrine access, wants changes to latrine **Other** **Positive:** meeting attendance, meeting attendance among people with disabilities, discussed sanitation, discussed sanitation among people with disabilities, discussed how to make latrine access easier, discussed how to make latrine access easier among people with disabilities, invited to participate in sanitation activities
Briceño (2017)	Factorial CRT of wards	Tanzania	CLTS CLTS and handwashing promotion	Handwashing promotion No intervention	Household, with children <5 years, *N* = 3,619	**Mortality and morbidity** **Negative:** 14-day diarrhoeal prevalence (CLTS+HW vs. C), haemoglobin levels (CLTS+HW vs. C), weight-for-age (CLTS+HW vs. C) **Null:** 7-day diarrhoeal prevalence (CLTS vs. C)*, 7-day diarrhoeal prevalence (CLTS+HW vs. C)*, 14-day diarrhoeal prevalence (CLTS vs. C), health index (CLTS vs. C), health index (CLTS+HW vs. C), haemoglobin levels (CLTS vs. C), weight-for-age (CLTS vs. C), height-for-age (CLTS vs. C), height-for-age (CLTS+HW vs. C), head circumference (CLTS vs. C), head circumference (CLTS+HW vs. C) **Behaviour** **Positive:** sanitation index (CLTS vs. C), sanitation index (CLTS+HW vs. C), latrine construction (CLTS vs. C), latrine construction (CLTS+HW vs. C), improved latrine use (CLTS vs. C), improved latrine use (CLTS+HW vs. C), safe removal of child faeces (CLTS vs. C), safe removal of child faeces (CLTS+HW vs. C), open defecation free village (CLTS vs. C), open defecation free village (CLTS+HW vs. C), hygiene index (CLTS+HW vs. C), knowledge of handwashing (CLTS+HW vs. C), has a fixed handwashing device (CLTS+HW vs. C), handwashing before

Article	Study design	Setting	Intervention	Control	Sample size	Effect estimates
						handling food (CLTS+HW vs. C), caregiver hand cleanliness index (CLTS+HW vs. C), child cleanliness index (CLTS+HW vs. C) **Negative:** open defecation (CLTS vs. C), open defecation (CLTS+HW vs. C), handwashing after faecal contact (CLTS vs. C) **Null:** hygiene index (CLTS vs. C), knowledge of handwashing (CLTS vs. C), has a handwashing device (CLTS vs. C), has a handwashing device (CLTS+HW vs. C), has a fixed handwashing device (CLTS vs. C), handwashing after faecal contact (CLTS+HW vs. C), handwashing before handling food (CLTS vs. C), caregiver hand cleanliness index (CLTS vs. C), child cleanliness index (CLTS vs. C)
Cameron (2019)	CRT of villages	Indonesia	CLTS	No intervention	Household, *N* = 1,858	**Mortality and morbidity** **Negative:** roundworm density **Null:** haemoglobin levels, weight z-score, height z-score, health index **Behaviour** **Positive:** latrine construction, open defecation intolerance **Null:** diarrhoeal knowledge
Cha (2021)	CRT of villages	Ethiopia	CLTS	SOC	Household, with children <5 years, *N* = 842	**Mortality and morbidity** **Negative:** diarrhoeal incidence*,100-day diarrhoeal prevalence* **Null:** diarrhoeal duration*, 7-day diarrhoeal prevalence* **Behaviour** **Positive:** own toilet, own improved toilet, own partially improved toilet or better, own hand washing facility, self-reported toilet use **Negative:** faeces in compound, faeces outside compound, presence of flies **Null:** observed toilet use, faeces around pit hole, child faeces disposal, handwashing
Crocker (2016)	CRT of villages	Ghana	CLTS with training of natural leaders	CLTS	Households, *N* = 1,708	**Behaviour** **Positive:** shared latrine ownership*, private latrine ownership*, latrine use **Negative:** open defecation* **Null:** communal latrine ownership*
Pickering (2015)	CRT of villages	Mali	CLTS	No intervention	Household, with children <10 years, *N*	**Mortality and morbidity** **Positive:** height-for-age z-score among children <5 years, height-for-age z-score among children <2 years, height-for-age z-

Article	Study design	Setting	Intervention	Control	Sample size	Effect estimates
					= 4,031	score among children <1 year, weight-for-age z-score among children <2 years, weight-for-age z-score among children <1 year **Negative:** stunted among children <5 years, stunted among children <2 years, stunted among children <1 year, severely stunted among children <5 years, severely stunted among children <2 years, severely stunted among children <1 year, underweight among children <2 years, underweight among children <1 year, severely underweight among children <5 years, severely underweight among children <2 years, severely underweight among children <1 year, blood in stool at 2-week recall, difficulty breathing at 2-day recall, difficulty breathing at 2-week recall, diarrhoea-related mortality **Null:** diarrhoea at 2-day recall*, diarrhoea at 2-week recall*, weight-for-age z-score among children <5 years, underweight among children <5 years, loose stool at 2-day recall, loose stool at 2-week recall, blood in stool at 2-day recall, vomiting at 2-day recall, vomiting at 2-week recall, fever at 2-day recall, fever at 2-week recall, congestion at 2-day recall, congestion at 2-week recall, cough at 2-day recall, cough at 2-week recall, earache at 2-day recall, bruising at 2-day recall, mortality **Behaviour** **Positive:** access to own latrine, child uses potty, satisfied with sanitation, women have privacy, women feel safe at night, potty in latrine, soap in latrine, water in latrine, latrine hole covered, stored water reported treated, daily handwashes with soap, reports handwashing important after using toilet **Negative:** share latrine with other households, flies in latrine, human faeces in compound, animal faeces in compound, open defecation among women, open defecation among men, open defecation among children 5–10 years, open defecation among children <5 years **Null:** latrine has concrete slab, faeces on latrine floor, water or urine on latrine floor, clear path to latrine, latrine appears used, mother has clean palms **Environment** **Null:** E. coli per 100 mL in stored water, E. coli per 100 mL in source water

Article	Study design	Setting	Intervention	Control	Sample size	Effect estimates
Quattrochi (2018)	CRT of village groups	Democratic Republic of Congo	Community-led WASH	No intervention	Individual, women, *N* = 1,312	**Mortality and morbidity** **Null:** child health index, people with COVID-19 symptoms, people with non COVID-19 symptoms, psychological well-being index, quantity of household members with illnesses **Health care access and utilisation** **Null:** quantity of hospital visits, forgone visits for health care **Behaviour** **Positive:** improved water source*, improved sanitation facility*, handwashing index, sanitation index, water satisfaction index, vaccine acceptance, household COVID prevention index, perception of COVID prevention index, COVID knowledge index **Null:** time to collect water*, quantity of water collected*, water storage index **Community and social** **Positive:** village COVID prevention index, vaccine acceptance by village leaders, vaccine advice by village leader **Other** **Null:** school attendance index, financial cost of water, water quality and access index, water governance index, governance index, livelihood index, food insecurity, approval of President, approval of National Assembly, approval of National Ministry of Health, approval of Provincial Government, approval of international NGOs, approval of local NGOs, approval of traditional leaders, approval of Health Zone officials, approval of Health Area officials, approval of village chief
HIV						
Abramsky (2014)	Pair-matched CRT of administrative parishes	Uganda	Community mobilisation for HIV and IPV prevention	Enhanced SOC	Individual, 18–49 years, *N* = 2,532	**Health care access and utilisation** **Positive:** HIV testing among men **Null:** HIV testing among women **Behaviour** **Positive:** acceptance of refusal to have sex among women*, acceptance of refusal to have sex among men*, discussed HIV testing with partner among men, ability to refuse sex with partner, discussed condom use among men, condom use at last sex among men, joint decision making with partner among women,

Article	Study design	Setting	Intervention	Control	Sample size	Effect estimates
						joint decision making with partner among men, helps partner with housework among men, helps partner look after children among men, appreciation for work partner does inside home among men, appreciation for work partner does outside home among men, discussed planning for children with partner among men, discussed partner's sexual preferences among men, discussed sexual preferences with partner among men, discussed feelings with partner among men **Negative:** acceptance of physical IPV among women*, concurrency of sexual partners among men*, continued physical IPV, continued sexual IPV, continued physical/sexual IPV, any emotional IPV, high intensity emotional IPV, continued emotional aggression, high-intensity controlling behaviours, new controlling behaviours, continued fear of partner **Null:** acceptance of physical IPV among men*, physical IPV*, sexual IPV*, discussed condom use among women, condom use among women, condom use among men, condom use at last sex among women, concurrency of sexual partners among women, discussed HIV testing with partner among women, partner helps with housework among women, partner helps look after children among women, appreciation for work partner does inside home among women, appreciation for work partner does outside home among women, discussed planning for children with partner among women, discussed partner's sexual preferences among women, discussed sexual preferences with partner among women, discussed day with partner among women, discussed day with partner among men, discussed feelings with partner among women, at least one episode of severe physical IPV or more than one occurrence of less severe act, new onset physical IPV, new sexual IPV, physical/sexual IPV, injury from physical/sexual IPV, new physical/sexual IPV, new emotional aggression, any controlling behaviours, continued controlling behaviours, fear of partner, new fear of partner **Community and social** **Null:** community response to women experiencing IPV*
Indravudh (2021)	CRT of group village head units	Malawi	Community-led HIVST	SOC	Individual, ≥15 years, *N* = 7,880	**Health care access and utilisation** **Positive:** lifetime HIV testing among adolescents*, HIV testing among adults ≥40 years, HIV testing among men **Null:** antiretroviral therapy initiation

Article	Study design	Setting	Intervention	Control	Sample size	Effect estimates
					Population, ≥15 years, *N* = 84,349	**Behaviour** **Null:** knowledge of HIV treatment benefits **Community and social** **Positive:** social cohesion, shared concern for HIV **Null:** HIV testing stigma, community HIV stigma, critical consciousness
Sibanda (2021)	CRT of village headman units	Zimbabwe	Community-led HIVST	Community-based HIVST	Individual, ≥16 years, *N* = 11,510	**Mortality and morbidity** **Null:** New HIV diagnosis* **Health care access and utilisation** **Null:** Linkage to confirmatory testing, pre-exposure prophylaxis, and voluntary medical male circumcision*,
Malaria						
McCann (2021)	Factorial CRT of village groups	Malawi	Community-driven house improvement Community-driven larval source management Community-driven house improvement and larval source management	SOC	Household, *N* = 1,844	**Mortality and morbidity** **Null:** malaria prevalence without symptoms among women (HI vs. C), malaria prevalence without symptoms among women (LSM vs. C), malaria prevalence without symptoms among women (HI+LSM vs. C), malaria prevalence without symptoms among children 6–23 months (HI vs. C), malaria prevalence without symptoms among children 6–23 months (LSM vs. C), malaria prevalence without symptoms among children 6–23 months (HI+LSM vs. C), malaria prevalence without symptoms among children 6–59 months (HI vs. C), malaria prevalence without symptoms among children 6–59 months (LSM vs. C), malaria prevalence without symptoms among children 6–59 months (HI+LSM vs. C), malaria prevalence with symptoms among women (HI vs. C), malaria prevalence with symptoms among women (LSM vs. C), malaria prevalence with symptoms among women (HI+LSM vs. C), malaria prevalence with symptoms among children 6–23 months (HI vs. C), malaria prevalence with symptoms among children 6–23 months (LSM vs. C), malaria prevalence with symptoms among children 6–23 months (HI+LSM vs. C), malaria prevalence with symptoms among children 6–59 months (HI vs. C), malaria prevalence with symptoms among children 6–59 months (LSM vs. C), malaria prevalence with symptoms among children 6–59 months (HI+LSM vs. C), haemoglobin levels among women (HI vs. C), haemoglobin levels among women (LSM vs. C), haemoglobin levels among women (HI+LSM vs. C), haemoglobin levels among

Article	Study design	Setting	Intervention	Control	Sample size	Effect estimates
						children 6–23 months (HI vs. C), haemoglobin levels among children 6–23 months (LSM vs. C), haemoglobin levels among children 6–23 months (HI+LSM vs. C), haemoglobin levels among children 6–59 months (HI vs. C), haemoglobin levels among children 6–59 months (LSM vs. C), haemoglobin levels among children 6–59 months (HI+LSM vs. C) **Environment** **Positive:** indoor A.arabiensis mosquito density (LSM vs. C), indoor A.arabiensis mosquito density (HI+LSM vs. C) **Negative:** outdoor A.arabiensis mosquito density (HI+LSM vs. C) **Null:** entomological inoculation rate (HI vs. C)*, entomological inoculation rate (LSM vs. C)*, entomological inoculation rate (LSM+HI vs. C)*, indoor anopheles mosquito density (HI vs. C), indoor anopheles mosquito density (LSM vs. C), indoor anopheles mosquito density (HI+LSM vs. C), indoor A.arabiensis mosquito density (HI vs. C), indoor A.funestus mosquito density (HI vs. C), indoor A.funestus mosquito density (LSM vs. C), indoor A.funestus mosquito density (HI+LSM vs. C), outdoor anopheles mosquito density (HI vs. C), outdoor anopheles mosquito density (LSM vs. C), outdoor anopheles mosquito density (HI+LSM vs. C), outdoor A.arabiensis mosquito density (HI vs. C), outdoor A.arabiensis mosquito density (LSM vs. C), outdoor A.funestus mosquito density (HI vs. C), outdoor A.funestus mosquito density (LSM vs. C), outdoor A.funestus mosquito density (HI+LSM vs. C), anopheles larval density (LSM vs. non-LSM)
Neglected tropical diseases						
Andersson (2015)	CRT of census enumeration areas	Mexico, Nicaragua	Community-led dengue control	SOC	Household, *N* = 18,838	**Mortality and morbidity** **Negative:** self-reported dengue infection*, dengue infection based on serology* **Behaviour** **Positive:** agree bathing in water with temephos is harmful **Negative:** agree with pesticide use, agree temephos and fumigation is the best way to control mosquitos, purchased pesticide, temephos present in at least one water container, households that purchased anti-mosquito products, households that spent >USD 3.25 on anti-mosquito products

Article	Study design	Setting	Intervention	Control	Sample size	Effect estimates
						Null: recognise larvae and know its relevance, intention to eliminate breeding sites, agree drinking or cooking with water with temephos is harmful, temephos placed in water, temephos removed after 1 month or no temephos **Community and social** **Positive:** agree communities can control dengue **Null:** neighbours agree it is worthwhile to eliminate breeding site, discuss with neighbours about dengue control, agree neighbours help one another, social capital **Environment** **Positive:** absence of larvae or pupae in households, absence of pupae in households **Negative:** households with larvae or pupae*, containers with larvae or purpae*, containers with larvae or pupae (among households)*, pupae per person*, larvae or pupae among households with regular water supply, larvae or pupae among households with irregular water supply, pupae among households with regular water supply, pupae among households with irregular water supply, pupal productivity in rainy season, pupal productivity in dry season, pupae per household in rainy season, pupae per household in dry season, pupae per person in rainy season, pupae per person in dry season, households with larvae or pupae in rainy season, households with larvae or pupae in dry season, containers with larvae or pupae in rainy season, containers with larvae or pupae in dry season **Other** **Null:** visits by temephos government programme, work/school days lost by the dengue patients, work/school days lost by caregivers of dengue patients
Massa (2009)	CRT of school catchment areas	Tanzania	Community-directed distribution of treatment for schistosomiasis and soil-transmitted helminthiasis	School-based treatment for schistosomiasis and soil-transmitted helminthiasis	Individual, 6–15 years, *N* = 1,143	**Mortality and morbidity** **Negative:** S. haematobium prevalence*, ascaris lumbricoides prevalence*, hookworm prevalence*, ascaris lumbricoides intensity, hookworm intensity **Null:** S. mansoni prevalence*, trichuris trichiura prevalence*, S. mansoni intensity, S. haematobium intensity, trichuris trichiura intensity

Article	Study design	Setting	Intervention	Control	Sample size	Effect estimates
						Health care access and utilisation **Positive:** treatment coverage among non-enrolled children at first round **Null:** treatment coverage among enrolled children at first round
Multiple diseases						
Lewycka (2013)	Factorial CRT of census enumeration areas	Malawi	Participatory women's groups for maternal and child health Participatory women's groups and peer counselling	Peer counselling Enhanced SOC	Individual, pregnant women, *N* = 3,033	**Mortality and morbidity**† **Null:** maternal mortality rate*, perinatal mortality rate*, neonatal mortality rate*, infant mortality rate*, any perceived antenatal, delivery, or postnatal maternal problem, any perceived infant problem (cough, fever, or diarrhoea) **Health care access and utilisation**† **Positive:** any antenatal care at a health facility, infant received BCG, OPV3, and DTP3 by 6 months **Negative:** birth attended by a traditional birth attendant **Null:** four or more antenatal care visits, any iron and folate, iron or folate given for more than 90 days, any tetanus toxoid immunisation, adequate tetanus toxoid immunisation, any sulfadoxine-pyrimethamine, two or more doses of sulfadoxine-pyrimethamine, any HIV testing at antenatal care, institutional delivery, birth attended by skilled provider, attendant washed hands or wore gloves, infant wrapped within 30 minutes, infant bathed after 24 hours, postnatal care at a health facility, **Behaviour**† **Positive:** infant exclusively breastfed to 6 months **Null:** bed net used every night during pregnancy, breastfeeding initiated within 1 hour of birth, use of prelacteal feeds, any breastfeeding problem
Makaula (2019)	CRT of health facility catchment areas	Malawi	Community-directed primary health care	SOC	Household, *N* = 4,511	**Health care access and utilisation** **Null:** antimalarial drug use, vitamin A use, praziquantel use **Behaviour** **Positive:** long-lasting insecticide treated net use among pregnant women, long-lasting insecticide treated net use among children **Null:** long-lasting insecticide treated bed net use among households
Nair (2017)	CRT of villages and adjoining	India	Participatory women's groups	Enhanced SOC	Individual, pregnant women,	**Mortality and morbidity** **Positive:** length-for-age z-score* **Negative:** underweight at 18 months

Article	Study design	Setting	Intervention	Control	Sample size	Effect estimates
	hamlets		for maternal and child health		*N* = 3,001	**Null:** maternal mid-upper arm circumference in third trimester of pregnancy, maternal body mass index at 9 months postpartum, birthweight, change in length-for-age from birth to 18 months, weight-for-height at 18 months, weight-for-age at 18 months, mid-upper arm circumference at 18 months, stunting at 18 months, wasting at 18 months, infant diarrhoea, cough, fever in past 2 weeks, infant mortality **Health care access and utilisation** **Null:** infant received appropriate home care during illness episode, care sought for infant from a nurse or doctor, infant received BCG, OPV3, DTP3, measles, hepatitis B vaccine **Behaviour** **Positive:** minimum dietary diversity, infant with minimum dietary diversity, infant given minimum meal frequency, infant hand washed before feeding, infant hand washed after helping with defecation, infant hand washed after defecation **Null:** ate more than three times in last day, infant exclusively breastfed until 6 months, infant started complementary foods at 6 months

BCG, Bacillus Calmette-Guérin; C, control; CLTS, community-led total sanitation; CRT, cluster randomised trial; DPT, diphtheria, pertussis, and tetanus; HI, house improvement; HIVST, HIV self-testing; HW, handwashing; IPV, intimate partner violence; LSM, larval source management; NGO; non-governmental organisation; OPV, oral polio vaccine; SOC, standard of care; USD, US dollars.

* Primary outcomes.

† Comparison of participatory women's groups (alone and combined with peer counselling) versus the SOC (alone and combined with peer counselling).

Supplementary Table 2.E. Results from costing studies

Article	Study design	Setting	Intervention	Perspective	Economic or financial	Full or incremental	Cost scope	Unit cost estimates
Diarrhoeal diseases								
Briceño (2017)	Micro-costing	Tanzania	CLTS	Societal	Economic	Full	Above service delivery Service delivery Community	Cost of sanitation per person reached, $6.74 (*N* = NR) Cost of sanitation and handwashing per person reached, $11.24 (*N* = NR)
Cha (2021)	Gross and micro-costing	Ethiopia	CLTS	Societal	Economic	Full	Above service delivery Service delivery Community	NR
Crocker (2016)	Micro-costing	Ghana	CLTS with training of natural leaders	Societal	Economic	Full	Above service delivery Service delivery Community	Cost of sanitation with natural leaders per household*, $103.92 (*N* = NR) Cost of sanitation per household*, $38.28 (*N* = NR)
HIV								
Abramsky (2014)	Gross and micro-costing	Uganda	Community mobilisation for HIV and IPV prevention	Provider	Economic	Full	Above service delivery Service delivery Community	Cost per person reached, $26 (*N* = 10,333) Cost per activist supported, $1,919 (*N* = 351) Cost per activity, $57 (*N* = 11,877)
Indravudh (2021)	Gross and micro-costing	Malawi	Community-led HIVST	Provider	Economic	Full	Above service delivery Service delivery Community	Cost per HIV self-test distributed, $6.17 (*N* = 24,316) Cost per person HIV self-tested, $6.20 (*N* = 24,219)
Sibanda (2021)	Gross and micro-costing	Zimbabwe	Community-led HIVST	Provider	Economic	Full	Above service delivery Service delivery Community	Cost per HIV self-test distributed, $10.68 (*N* = 27,812)
Malaria								

Article	Study design	Setting	Intervention	Perspective	Economic or financial	Full or incremental	Cost scope	Unit cost estimates
McCann (2021)	Gross and micro-costing	Malawi	Community-driven larval source management and house improvement	Societal	Economic	Full	Above service delivery Service delivery Community	Annual cost of larval source management per household, $124.09 (*N* = 1,520) Annual cost of larval source management per person, $27.74 (*N* = 6,801) Annual cost of house improvement per household, $132.74 (*N* = 1,030) Annual cost of house improvement per person, $29.93 (*N* = 4,568)
Neglected tropical diseases								
Andersson (2015)	Micro-costing	Mexico, Nicaragua	Community-led dengue control	Provider	Economic	Full	Above service delivery Service delivery	Annual cost per capita in Mexico, $19.98 (*N* = NR) Annual cost per capita in Nicaragua, $8.93 (*N* = NR)
Multiple diseases								
Lewycka (2013)	Gross and micro-costing	Malawi	Participatory women's groups for maternal and child health	Provider	Economic	Full	Above service delivery Service delivery Community	Cost per year per woman of childbearing age, $6.82 (*N* = NR) Cost per year per infant, $20.22 (*N* = NR)
Makaula (2019)	Micro-costing	Malawi	Community-directed primary health care	Provider	Economic	Full	Service delivery Community	NR
Nair (2017)	Gross and micro-costing	India	Participatory women's groups for maternal and child health	Provider	Economic	Full	Above service delivery Service delivery	Annual cost per live birth, $327 (*N* = NR) Annual cost per pregnant woman, 17 (*N* = NR)

CLTS, community-led total sanitation; HIVST, HIV self-testing; IPV, intimate partner violence; NR, not reported. Costs are reported in 2022 US dollars.
* Costs not reported in 2022 US dollars due to unknown currency year.

Supplementary Table 2.F. Results from economic evaluations

Article	Study design	Setting	Intervention	Control	Perspective	Time horizon	CE estimate	CE probability
Diarrhoeal diseases								
Briceño (2017)	Trial-based	Tanzania	CLTS CLTS and handwashing promotion	Handwashing promotion No intervention	Societal	4 years	Incremental cost per household accessed improved latrine, CLTS vs. C: $241 (95% CI $169–$419) Incremental cost per household accessed improved latrine, CLTS+HW vs. C: $611 (95% CI $384–$1,491) Incremental cost per person accessed improved latrine, CLTS vs. C: $44 (95% CI $30–$75) Incremental cost per person accessed improved latrine, CLTS+HW vs. C: $109 (95% CI $68–$266)	NR
Cha (2021)	Modelled	Ethiopia	CLTS	SOC	Societal	10 years	Benefit-cost ratio, 3.7 Net present value, $1,193,786	100%
Crocker (2016)	Trial-based	Ghana	CLTS with training of natural leaders	CLTS	Societal	2.5 years	Incremental cost per household stopped open defecation*, $505 Incremental cost per household accessed improved latrine*, $1,205	NR
HIV								
Abramsky (2014)	Trial-based	Uganda	Community mobilisation for HIV and IPV prevention	Enhanced SOC	Provider	1 year	Incremental cost per physical IPV case averted, $560	NR
Indravudh (2021)	Trial-based	Malawi	Community-led HIV self-testing	SOC	Provider	1 year	Incremental cost per additional person tested HIV positive, $351	45%
Neglected tropical diseases								

Article	Study design	Setting	Intervention	Control	Perspective	Time horizon	CE estimate	CE probability
Andersson (2015)	Trial-based	Mexico, Nicaragua	Community-led dengue control	SOC	Provider	1 year	Incremental cost per DALY averted in Mexico, $35,393 (95% CI $16,573–$79,941) Incremental cost per DALY averted in Nicaragua, $34,888 (95% CI $17,081–$86,254)	Mexico, 51% Nicaragua, 0%
Multiple diseases								
Lewycka (2013)	Trial-based	Malawi	Participatory women's groups for maternal and child health Participatory women's groups and peer counselling	Peer counselling Enhanced SOC	Provider	4.5 years	Incremental cost per life-year lost averted†, $142	NR
Nair (2017)	Trial-based	India	Participatory women's groups for maternal and child health	Enhanced SOC	Provider	NR	Incremental cost per infant death averted, $33,346 Incremental cost per life-year saved, $1,082	NR

C, control; CE, cost-effectiveness; CLTS, community-led total sanitation; DALY, disability-adjusted life years, HW, handwashing, ICER, incremental cost-effectiveness ratio; NR, not reported; SOC, standard of care. Costs are reported in 2022 US dollars.

* Costs not reported in 2022 US dollars due to unknown currency year.

† Comparison of participatory women's groups (alone and combined with peer counselling) versus the SOC (alone and combined with peer counselling).

Supplementary Table 2.G. Results from process evaluations

Article	Study design	Setting	Intervention	Implementation	Mechanisms of impact	Context
Diarrhoeal diseases						
Biran (2018)	IDIs	Malawi	CLTS inclusive of people with disabilities	External actors and community health workers inconsistently conveyed messages on inclusive sanitation and promotion of constructing or adapting latrines. Activities did not achieve full participation from people with disabilities, including attendance at community participation due to accessibility of meetings and representation on sanitation committees. Barriers to change included the perceived cost and physical ability to construct or adapt a latrine.	Community members were more likely to change sanitation behaviours if they were exposed to more activities.	NR
Cameron (2019)	Panel surveys	Indonesia	CLTS	Intervention villages exposed to resource agencies compared with government agencies were more likely to have greater engagement with community health officers, intensity of implementation, and participation by community members.	In the intervention arm, households in villages with higher levels of social capital were more likely to have constructed a toilet, potentially by imposing social sanctions.	The intervention effect on diarrhoeal prevalence varied by sex of the head of household, with further reductions among female household heads, and ethnic groups.
Crocker (2016)	Cross-sectional surveys	Ghana	CLTS	Participation from community members was similar across arms, with one-third attending any WASH meetings and one-third discussing WASH topics with a neighbour.	The intensity of WASH activities, including time spent by natural leaders and community members, was higher in the intervention arm.	NR
Pickering (2015)	Panel surveys	Mali	CLTS	Among households, 85% attended triggering events.	Among households, 95% were exposed to promotion of latrine building. Open defecation free certification was achieved in 97% of intervention villages,	NR

Article	Study design	Setting	Intervention	Implementation	Mechanisms of impact	Context
					with implementation targets set by external actors.	
Quattrochi (2018)	Panel surveys	Democratic Republic of Congo	Community-led WASH	NR	The intervention effect on water and sanitation outcomes persisted over time, but confidence in government and traditional leaders was not found to be a mechanism of impact.	NR
HIV						
Abramsky (2014)	Cross-sectional surveys, monitoring forms, IDIs	Uganda	Community mobilisation for HIV and IPV prevention	External actors supported over 400 community activists, who led more than 11,000 activities that reached 260,000 community members. Factors facilitating implementation and uptake included participatory and collective activities, proximity of activities, established trust between community activists and community members, and availability and support of community activists.	In quantitative analysis, the intervention achieved high coverage, with 91% of men and 68% of women reporting exposure to activities, communication materials or multi-media. A dose-response relationship was observed between intervention exposure and changes in interpersonal relationships and willingness to intervene to prevent IPV. Norms related to IPV were the most important mediators of the intervention effect on physical IPV at the community level, followed by norms related to gender roles and power dynamics. Trust and attitudes around violence mediated the intervention effect at the relationship and individual levels, respectively. In qualitative analysis, participatory community activities facilitated a strong sense of collective engagement and contributed to changing norms and perceptions around IPV. Community and household	Men compared with women reported higher intervention exposure. Changes in outcomes also varied based on willingness to change gender norms and relationship dynamics and personal experience with IPV.

Article	Study design	Setting	Intervention	Implementation	Mechanisms of impact	Context
					conversations contributed to shifting gender norms and power dynamics, enhancing communication, and introducing skills for conflict resolution, which strengthened interpersonal relationships and reduced IPV and HIV risk. Ongoing availability and support by community activists bolstered change by establishing trust, reinforcing messages, and providing accountability. Social networks facilitated diffusion of intervention messages and encouraged participation in activities.	
Indravudh (2021)	Cross-sectional surveys, monitoring forms	Malawi	Community-led HIVST	External actors supported 157 community health group members and 190 community volunteers, who distributed 24,316 HIV self-tests. Implementation strategies involved sensitisation and distribution of HIVST kits at village head-led community meetings, homes, and fixed locations and social hotspots. Strategies to support linkage to routine HIV services included active post-test follow-up, phone referrals to health facilities, and material assistance.	HIVST awareness and uptake was 95% and 75%, respectively. In the intervention arm, social cohesion, community concern, and critical consciousness had a non-linear association with HIV testing. However, community measures were not found to be mediators of impact.	The intervention effect on HIV testing among adolescents was higher among younger age groups and boys.
Sibanda (2021)	Cross-sectional surveys, monitoring forms	Zimbabwe	Community-led HIVST	Community distributors provided 27,812 HIV self-tests.	HIVST uptake was 21.6%.	The intervention effect on linkage to HIV care was higher among men.

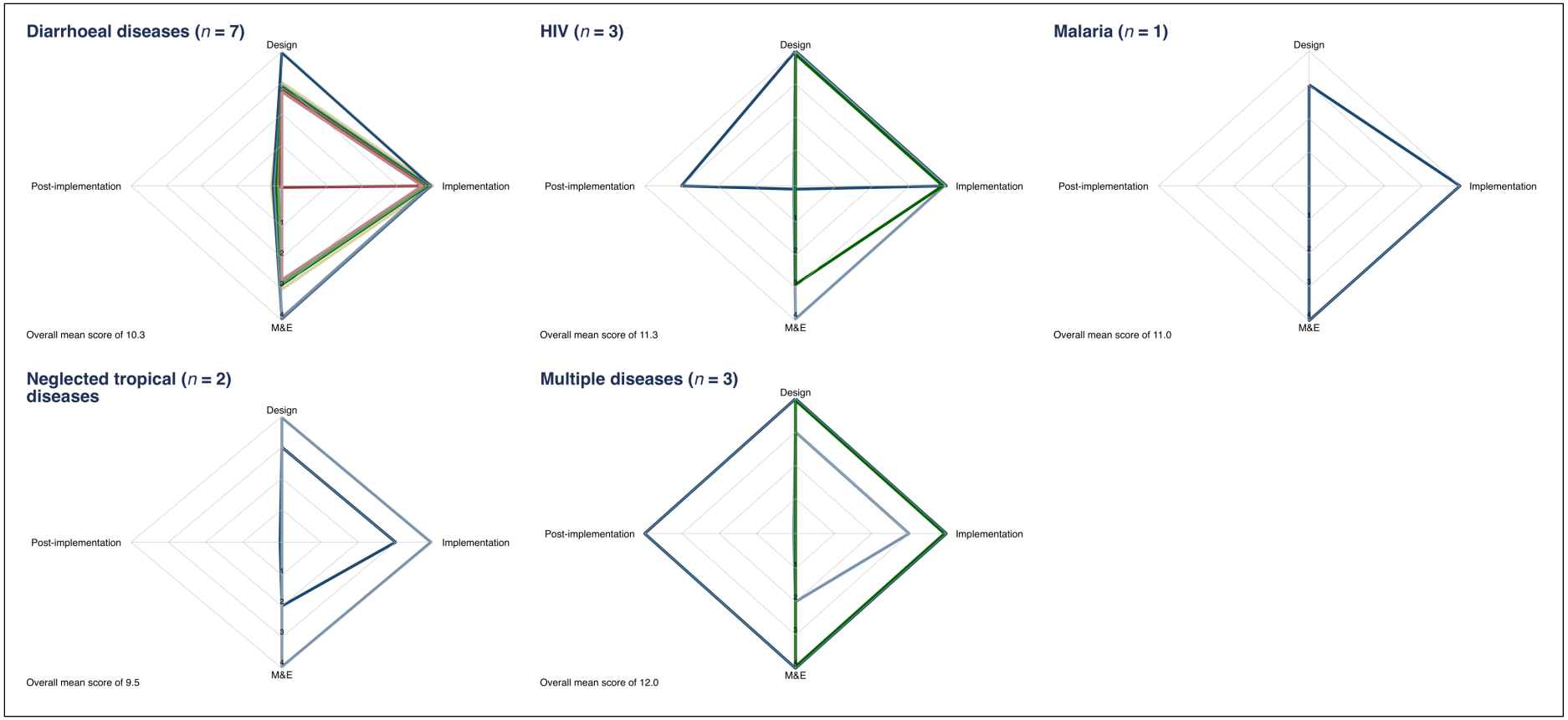
Article	Study design	Setting	Intervention	Implementation	Mechanisms of impact	Context
Malaria						
McCann (2021)	Monitoring forms, IDIs, FGDs	Malawi	Community-driven larval source management and house improvement	Village committees and health animators valued knowledge and skills gained from trainings, which they were able to transfer to community members through group workshops. Health animators and village committee members conducted 172 group workshops, with factors facilitating attendance including the presence of community leaders and community health workers. Implementation factors facilitating uptake included observing and evaluating changes in malaria outcomes. Barriers included labour intensiveness, time requirements, and lack of financial incentives or material support.	Community members were aware of the role and work of village committees and health animators. Through group workshops, community members were aware of malaria as a health problem, its sources of transmission, and methods of control, which motivated actions to prevent malaria. Attendance at group workshops was varied. Motivation to manage malaria acted as a facilitator, while time availability acted as a barrier, with attendance lower among men and young people. Factors facilitating individual behaviour change included repeat attendance at workshops. Engagement with village committees and health animators also facilitated attitudes and practices for malaria prevention, especially for novel strategies such as larval source management.	Barriers included lack of trust in larvicides.
Neglected tropical diseases						
Andersson (2015)	Cross-sectional surveys	Mexico, Nicaragua	Community-led dengue control	NR	In the intervention arm, households with higher social capital were more likely to have larvae and/or pupae absent.	NR
Massa (2009)	IDIs, FGDs	Tanzania	Community-directed distribution of treatment for schistosomiasis and soil-transmitted	Community leaders and members selected community drug distributors based on their reputation and level of education. Sensitisation was done at village meetings. Community distributors	Community members were aware of drug distribution and the importance of treatment.	NR

Article	Study design	Setting	Intervention	Implementation	Mechanisms of impact	Context
			helminthiasis	delivered drugs at homes and fixed locations. Factors facilitating implementation included trust between community drug distributors and community members.		
Multiple diseases						
Lewycka (2013)	Cross-sectional surveys, monitoring forms	Malawi	Participatory women's groups for maternal and child health	Community facilitators established 207 women's groups, with more than 12,000 people attending at least once. Among women, 59% attended 1–5 times, 30% attended 6–10 times, and 11% attended more than 10 times. Women's groups identified a breadth of strategies, which were implemented by groups alone or in collaboration with health care providers. Strategies included health education, bicycle ambulances, distribution of health commodities, mobile clinics, garden cultivation, and income generation. Resources were raised through advocacy, fundraising, or partnerships with stakeholders.	NR	NR
Makaula (2019)	IDIs, FGDs	Malawi	Community-directed primary health care	Selection of qualified community volunteers and engagement with multi-level stakeholders facilitated implementation.	NR	NR
Nair (2017)	Cross-sectional surveys, monitoring forms	India	Participatory women's groups for maternal and child health	Community-based workers established 163 women's groups, with common strategies including a combination of home-based preventive actions, care-seeking, and community-	NR	NR

Article	Study design	Setting	Intervention	Implementation	Mechanisms of impact	Context
				level activities (e.g., kitchen gardens, campaigning). Among women, 56% attended meetings at least once and 80% received visits from community-based workers.		

CLTS, community-led total sanitation; FGD, focus group discussion, HIVST, HIV self-testing; IDI, in-depth interview, IPV, intimate partner violence; NR, not reported; WASH, water, sanitation, and hygiene.

Supplementary Figure 2.A. Radar graph of community participation scores



Radar graph illustrating the level of community participation for stages of design, implementation, monitoring and evaluation, and post-implementation. Each line represents a single study, with each stage of the intervention for that study scored from 0 to 4 (0=no information, 1=information giving, 2=consultation, 3=collaboration, 4=empowerment). Points closer to the centre indicate lower scores of community participation, while points further from the centre indicates higher scores of community participation. M&E, monitoring and evaluation.

Chapter 3.
Study protocol

3.1. Summary

This chapter includes Paper 2, "Community-led delivery of HIV self-testing to improve HIV testing, antiretroviral therapy initiation, and broader social outcomes in rural Malawi: study protocol for a cluster-randomised trial". The paper outlines methods used to answer Objectives 2, 3, and 4 in Chapters 4, 5, and 6, respectively. The protocol for a cluster-randomised trial of community-led HIV self-testing is described, including the design of the trial and intervention procedures. The designs for the economic and process evaluations are also briefly summarised.

The paper was published in 2018 in BMC Infectious Diseases.

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SECTION A – Student Details

Student ID Number	1701865	**Title**	Ms
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Surname/Family Name	Indravudh		
Thesis Title	Evaluation of community-led delivery of HIV self-testing		
Primary Supervisor	Prof. Fern Terris-Prestholt		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	BMC Infectious Diseases		
When was the work published?	2019		
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Have you retained the copyright for the work?*	Yes	Was the work subject to academic peer review?	Yes

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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I led the conceptualisation and design of the study. I also wrote the first draft of the manuscript. Co-authors contributed to the study conceptualisation and design as well as read and approved the final manuscript.

SECTION E

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Date	2nd April 2023

Supervisor Signature	[redacted]
Date	2nd April 2023

Community-led delivery of HIV self-testing to improve HIV testing, antiretroviral therapy initiation, and broader social outcomes in Malawi: study protocol for a cluster-randomised trial

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Abstract

Introduction

Prevention of new HIV infections is a critical public health issue. The highest testing gaps are in men, adolescents aged 15 to 19 years, and older adults aged 40 years and above. Community-based testing services can contribute to increased testing coverage and early diagnosis, with HIV self-testing (HIVST) strategies showing promise. Community-based strategies, however, are not widely implemented. A community-led approach involves supporting communities to plan and implement solutions to improve health. This cluster-randomised trial aims to determine if community-led delivery of HIVST can improve testing uptake, antiretroviral therapy (ART) initiation, and broader social outcomes in Malawi.

Methods

The trial uses a parallel arm, cluster-randomised design with group village heads and their defined catchment areas allocated (1:1) to the community-led HIVST intervention in addition to the standard of care (SOC) or continue with the SOC alone. As part of the intervention, informal community health cadres are supported to plan and implement a 7-day HIVST campaign linked to treatment and prevention. The primary outcome includes the proportion of adolescents who have tested for HIV in their lifetime. Secondary outcomes include recent testing in older adults and men; ART initiation; knowledge of the preventive benefits of HIV treatment; and HIV testing stigma. Outcomes will be measured through a post-intervention survey and health facility registers. Economic evaluation will determine the incremental cost per additional person tested HIV positive.

Discussion

To the best of our knowledge, this is the first trial to assess the effectiveness of community-led testing services, which has recently been enabled by the introduction of HIVST. Community-led delivery of HIVST is a promising new strategy for providing periodic testing to support epidemic control.

Introduction

Prevention of new HIV infections is a critical public health issue. In 2018, 1.7 million people were newly infected, with two-thirds in sub-Saharan Africa [1]. Global strategies to reduce incidence aim to maximise early diagnosis, treatment, and viral suppression of people living with HIV [2]. Regional expansion of facility-based testing services (HTS) has contributed to declining incidence, but almost one-fifth of people living with HIV aged 15 to 64 years remain undiagnosed [1]. The highest testing gaps are in adolescents aged 15 to 19 years, older adults aged 40 years and above, and men, contributing to ongoing transmission and poorer outcomes from late diagnosis [3-5]. Barriers to uptake of facility-based HTS include stigmatising norms, discrimination from health care workers, distance to health facilities, and direct and indirect costs of service utilisation [6].

Community-based HIV testing and self-testing

Community-based HTS can contribute to increased testing coverage, early diagnosis, and reduced incidence [7, 8], with HIV self-testing (HIVST) strategies showing promise [9-11]. In 2016, HIVST was recommended by WHO as an additional approach to providing HTS based on evidence of high acceptability, feasibility, accuracy, and uptake [12]. In urban Malawi, distribution of HIVST kits by community volunteers achieved high uptake and accuracy, with increased demand for antiretroviral therapy (ART) following offer of home-based care [9, 13]. Home-based HIVST in rural Malawi increased recent testing, including in men and adolescents, beyond the coverage achieved by facility-based HTS [11]. The addition of HIVST kit distribution to home-based HTS provided by community health workers (CHWs) in urban Zambia further increased knowledge of status, with a difference in intervention effect by sex [10]. Low adverse events were reported across studies [14].

Community-based HTS, however, is resource intensive, costly, and not widely implemented [15]. In population-based surveys, the percentage of the population most recently testing through community-based services is low [15]. Societal costs of community-based HTS and HIVST tend to be lower than facility-based HTS, but providers costs are consistently higher, especially the cost per new diagnosis [8, 16-18].

Community-led approaches to improve health

Community-led approaches for health programmes involve communities identifying problems contributing to poor health, planning and implementing solutions to improve their health, and evaluating implementation of solutions [19, 20]. Most practice uses participatory learning and action methods, which involve supporting communities to identify their needs, understand the root causes of their needs, and translate awareness into action [21]. Community participation in the

design and management of health programmes is posited to enhance their coverage, efficiency, and equity through context-driven decision making and resource mobilisation [22]. The change process is based on a number of assumptions, namely that communities desire to be involved in decisions regarding their own health care and will contribute resources to improve community health; communities will be more likely to change their attitudes and behaviours as a result of their involvement; and communities will be empowered through knowledge, skills, and confidence gained through their participation [23].

Evaluations of community-led programmes across multiple disease areas report evidence of improved health behaviours and outcomes [24-26]. Within HIV, community-led programmes have involved community mobilisation to promote prevention or provision of HTS within multi-disease campaigns [27, 28]. Most studies involve delivery of vertically defined strategies through community-driven systems, with community motivation for participation often contingent on the severity of the perceived risk of disease and value of strategies to the health and wellbeing of the community [29].

Rationale for randomised trial

The types of programmes that can be delivered by communities are expanding with increasing availability of novel self-care technologies. This cluster-randomised trial aims to determine whether community-led delivery of HIVST can increase uptake of testing, ART initiation, and broader social outcomes in a high burden setting in rural Malawi. While prior randomised trials have established the impact of vertically delivered, community-based HIVST models on uptake of testing, it is uncertain whether similar outcomes could be achieved when increasing responsibility for the design and management of HIVST delivery is transferred to communities. Further, HIVST implementation involves consideration around linkage to routine services and social harm that warrant further evaluation under a randomised trial.

Methods

Aim

The primary aim of this cluster-randomised trial is to test whether community-led delivery of HIVST in rural Malawi can increase the proportion of the population who has tested compared with the standard of care (SOC), with a focus on underserved population subgroups including adolescents aged 15 to 19 years, older adults aged 40 years and above, and men (**Supplementary Text 3.A**). Secondary aims are to assess the impact of the community-led HIVST intervention on ART initiation and broader social outcomes.

Design

The trial uses a parallel arm, cluster-randomised design (**Figure 3.1**). Clusters are defined as group village heads and their respective catchment areas, thereafter referred to as group village heads. The trial includes two arms, with 30 group village heads randomised (1:1) to the community-led HIVST intervention in addition to the SOC or continue with the SOC alone. As part of the intervention, community health action groups and community volunteers plan and implement an HIVST campaign linked to treatment and prevention services in their areas.

Setting and participants

The trial takes place in the catchment areas of five government health facilities in Mangochi district, which has among the highest poverty rates and lowest educational attainment in the country. In 2016, Mangochi had an HIV prevalence of 13.2% in women and 5.7% in men [30]. Coverage of lifetime testing and testing in the last 12 months was, respectively, 70.9% and 36.2% in women and 58.2% and 38.1% in men [30].

Most areas in Malawi are organised by traditional chieftaincy systems. Group village heads have customary authority over a group of villages, while community health action groups promote community health at group village head level [31]. CHWs attached to government health facilities

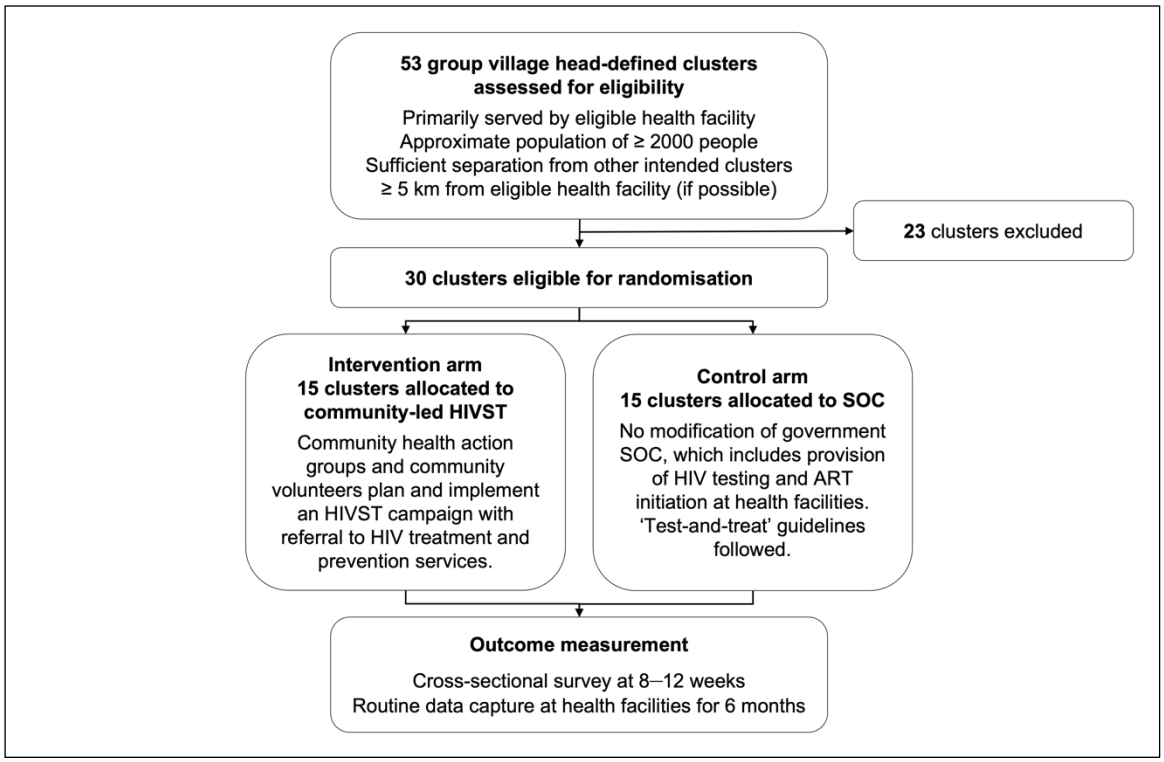


Figure 3.1. Flow diagram of trial design. ART, antiretroviral therapy initiation; HIVST, HIV self-testing; SOC, standard of care.

liaise with community health action groups on delivery of community health services. In practice, the organisational and operational capacity of community health structures vary widely.

Group village heads were included in the study if they were: (i) primarily served by an eligible government primary health centre providing HTS and ART services, (ii) responsible for a catchment population of at least 2000 people, (iii) sufficiently separated from boundaries of other intended clusters, and (iv) at least 5 kilometres away from an eligible health facility, if possible. All adults aged 15 years and older within group village heads were eligible for the evaluation. **Figure 3.2** includes a map of Mangochi district and sites included in the trial.

Randomisation and blinding

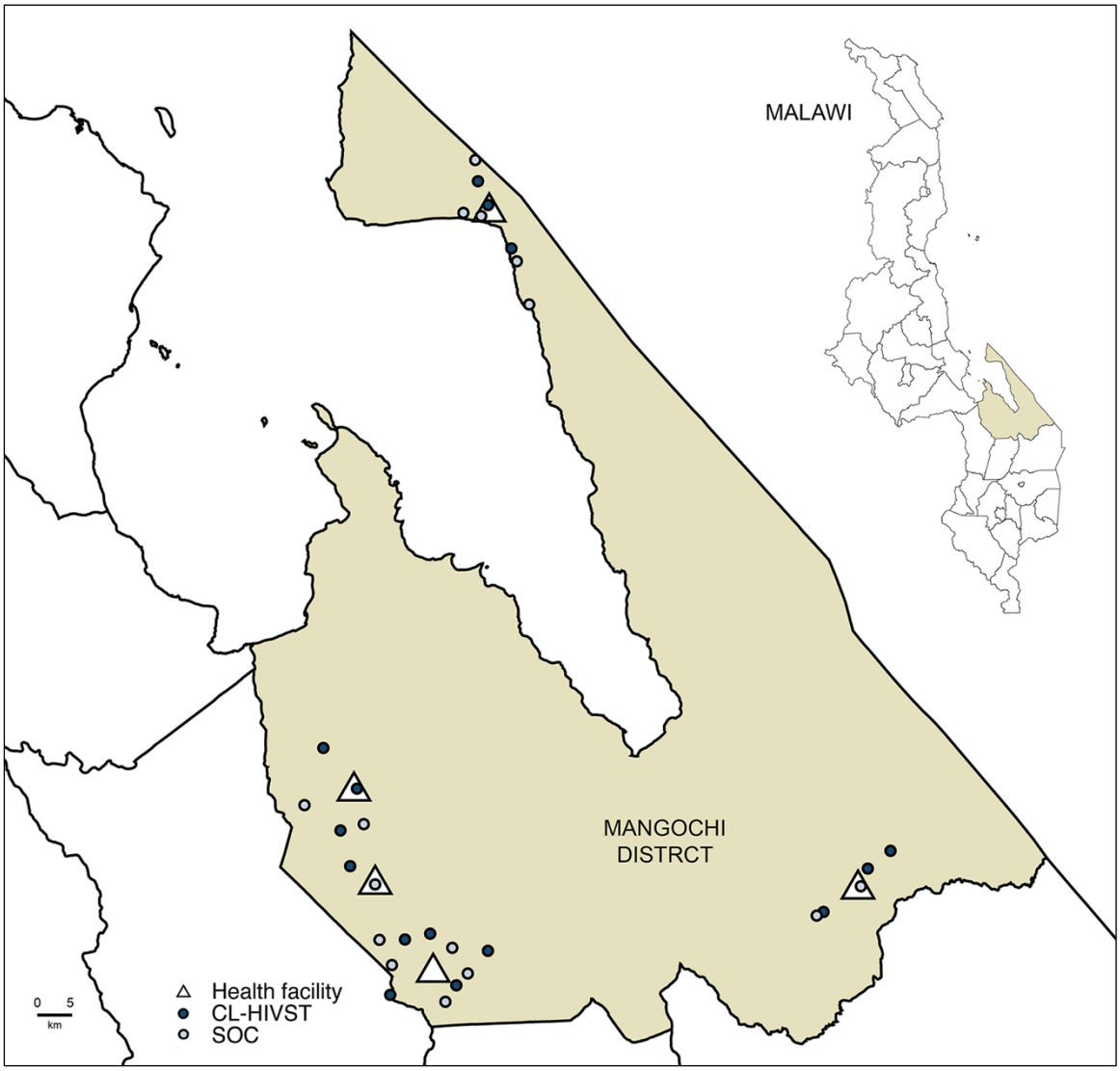


Figure 3.2. Map of clusters in Mangochi district. CL-HIVST, community-led HIV self-testing; SOC, standard of care. Map of Mangochi district with health facilities and group village head-defined clusters. Malawi National Spatial Data Centre, www.masdap.mw.

For the trial, 30 group village heads were randomised 1:1 to the community-led HIVST intervention or SOC. Group village heads were assigned to study arms at a public ceremony. Three balls numbered 0 to 9 were selected from an opaque bag, corresponding to one of 1000 randomisation combinations. Restricted randomisation was used to ensure balance between arms based on the nearest health facility, distance from the health facility, population, and number of villages. Study staff are blinded to the study allocation status as much as possible, with all data managed without reference to arms.

Procedures

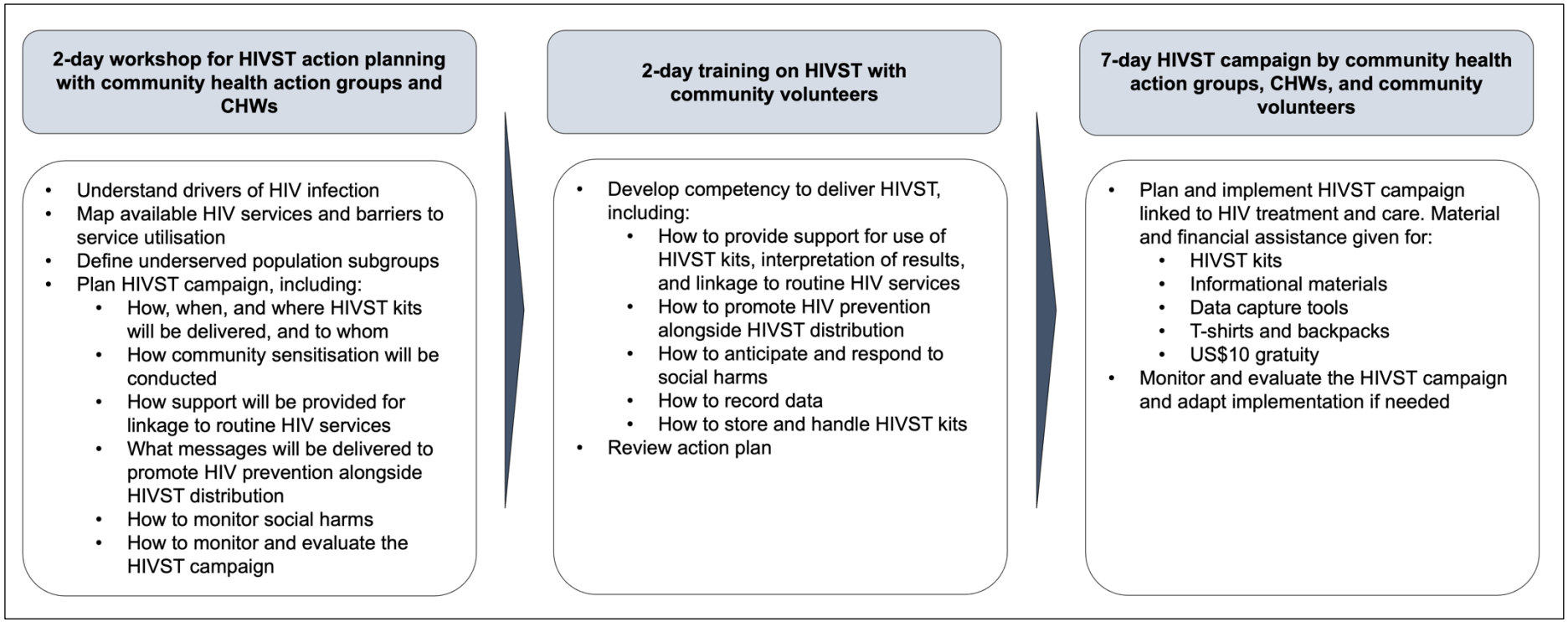
Community-led HIV self-testing

The community-led HIVST intervention consists of (i) participatory workshops for action planning with community health action groups and CHWs, (ii) trainings on HIVST promotion and support with village-level community volunteers, and (iii) HIVST campaigns linked to treatment and prevention (**Figure 3.3**). The framework for the intervention design is modelled after previous community mobilisation interventions, which utilise participatory learning and action methods [21]. The final design was informed by focus group discussions with community residents, stakeholder workshops with representatives from the Department of HIV/AIDS, and piloting prior to the trial (**Supplementary Table 3.A**). The intervention is overseen by the study team, which includes the Malawi-Liverpool-Wellcome Trust Clinical Research Programme, Population Services International (PSI) Malawi, and the Ministry of Health.

Community health action groups and CHWs attend 2-day participatory workshops. The aim of the workshops is to mobilise existing community health structures and support them in planning and delivering HIVST campaigns in their catchment areas. As part of the workshops, community health action groups and CHWs identify drivers of infection, map available services and barriers to service utilisation, define underserved subgroups, and develop a context-driven campaign. Specifically, they are tasked with deciding how, when, and where HIVST kits will be delivered and to whom; how self-testers will be supported to link to routine care and prevention services; what messages will be delivered alongside HIVST to promote prevention; how to monitor social harms related to HIVST; and how to monitor and evaluate the campaign.

Community volunteers also attend 2-day trainings on HIVST promotion and support. Volunteers are trained in how to provide information and support for use of HIVST kits, interpretation of results, and linkage to routine services (confirmatory testing and ART initiation for reactive results, voluntary medical male circumcision [VMMC] for men with non-reactive results, couples testing for serodiscordant partners). Volunteers also receive training in how to provide information on

Figure 3.3. Description of intervention procedures



CHW, community health worker; HIVST, HIV self-testing.

prevention, including effectiveness of ART and VMMC and prevention within serodiscordant partners. Lastly, volunteers are trained in how to anticipate and respond to social harms, record data, and handle and store kits.

Community volunteers then implement 7-day HIVST campaigns linked to treatment and prevention, with supervision by community health action groups and CHWs. The campaign period is based on the typical length of HTS campaigns under the Ministry of Health. The project team provide HIVST kits (OraQuick HIV Self-Test; Orasure Technologies), communications and instructional materials, and data capture tools. Community health action groups and volunteers receive US$10 gratuity per campaign as nationally standardised for informal community health cadres. Adults aged 15 years and older are eligible for HIVST and can take multiple kits if desired.

Standard of care

The SOC is defined based on HIV services currently provided by the Ministry of Health. In Malawi, HTS and ART services are provided at most health facilities and through periodic community-based outreach. Testing is administered using finger-prick rapid diagnostic tests based on the national testing algorithm. Universal "test-and-treat" guidelines are followed.

Outcomes

The primary outcome includes:

- Proportion of adolescents aged 15 to 19 years who have tested for HIV in their lifetime.

Secondary outcomes include:

- Proportion of older adults aged 40 years and above who have tested for HIV in the last 3 months.
- Proportion of men who have tested for HIV in the last 3 months.
- Cumulative incidence of ART initiation across 6 months.
- Measure of knowledge of the preventive benefits of HIV treatment.
- Measure of perceived HIV testing stigma.

Outcomes will be measured through a post-intervention survey administered 8 to 12 weeks after the start of the community-led HIVST intervention, with matched dates in both study arms. ART initiation will be captured by clinic assistants stationed at the nearest health facility for 6 months following the intervention start date.

Sample size

To calculate the sample size, we assumed that the proportion of lifetime HIV testing for adolescents aged 15 to 19 years in the SOC arm was 35% to 50% based on the Malawi Demographic and Health Survey [30]. With 15 clusters per arm and 50 adolescents per cluster, we will have at least 90% power at a 5% significance level to detect a 20% absolute increase in lifetime testing using a coefficient of variation of outcomes (k) of 0.25. With adolescents making up 20% of the adult population, this will require 250 participants per cluster.

Data collection

Outcome evaluation

A post-intervention survey will be administered approximately 8 to 12 weeks after the start of the community-led HIVST intervention (**Figure 3.4**). For each group village head, evaluation villages for the survey will be randomly selected from villages with at least a population of 500 residents and located centrally within the catchment area. All households in the evaluation villages will be eligible to participate in the survey and enumerated, except for villages with more than 500 residents, where 150 households will be enumerated starting with the village head household and proceeding in a clockwise spiral. Inclusion criteria for the survey include residents in eligible households aged 15 years and older.

Written consent will be obtained for all participants, except participants aged 15 to 17 years, who will be asked to assent and their parent or guardian asked to consent. All participants will complete a brief individual questionnaire with modules on sociodemographic characteristics; prior

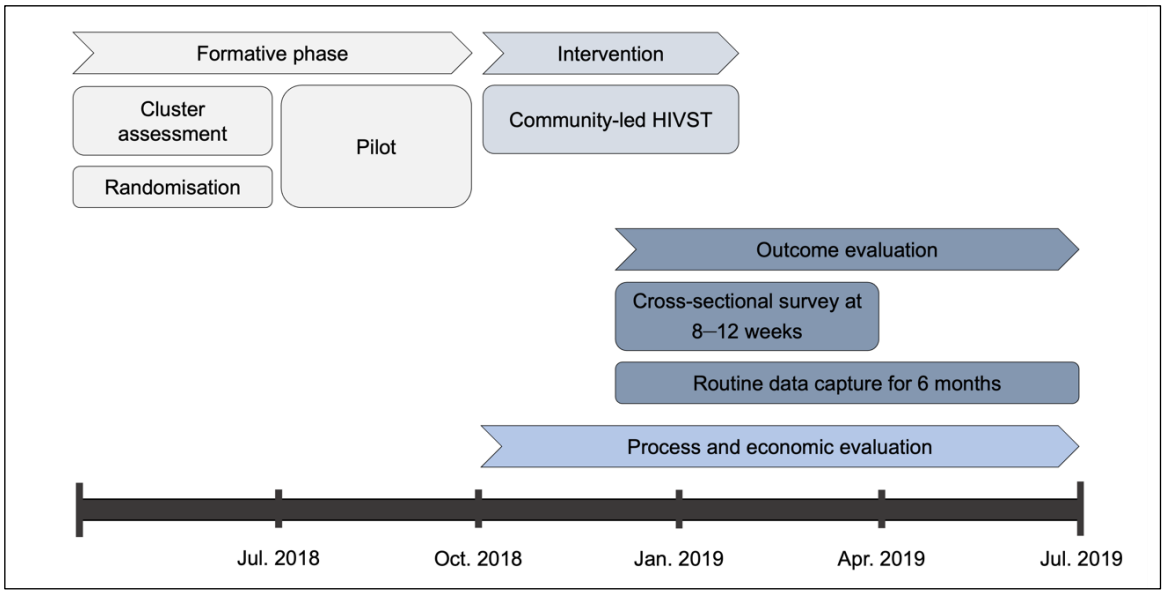


Figure 3.4. Study timeline. HIVST, HIV self-testing.

HIV testing, self-testing, treatment, and prevention; and sexual behaviour. The head of household or representative will also complete a module on household characteristics. A random sample of participants (approximately 20%) will receive an extended questionnaire on community mobilisation and HIV knowledge and attitudes.

ART initiation will be captured for the 6-month period following the start of the trial. Clinic assistants at the five study health facilities will establish eligibility of all incoming ART patients. Eligibility criteria include aged 15 years and older, resident in study clusters, and starting or restarting on ART. Sociodemographic characteristics, prior HIVST, and ART status of eligible patients will be recorded on study forms.

Economic evaluation

Financial and economic data will be collected for the community-led HIVST intervention and SOC. Methods are drawn from global guidelines on costing of health interventions [32]. A provider perspective will be used to capture costs. A combination of gross and micro costing approaches will be used, with financial costs from analysis of expenditures supplemented with full costs obtained through direct observations, individual interviews, and review of databases and records. Number of HIV tests and HIV-positive tests will be obtained through extraction of HTS and HIVST registers. The incremental cost per additional person tested positive will be estimated using post-intervention survey data on individual-level costs and effects [33].

Process evaluation

Quantitative and qualitative data will be collected to understand processes underlying the impact of the community-led HIVST intervention (**Supplementary Figure 3.A**) [34]. To investigate what is implemented and how, data will be collected on the sociodemographic characteristics of community health action groups and community volunteers; attendance by community health action groups and volunteers in workshops, trainings, and HIVST campaigns; and activities planned and implemented during the campaign. Exposure and uptake to the HIVST campaign will be assessed using the post-intervention survey and HIVST registers, which track the sociodemographic background of residents collecting HIVST kits. Mechanisms of impact will be evaluated using mediation analysis of survey data [35].

Data management

Quantitative data will be captured using electronic tablets and optical character recognition forms routinely entered into a dedicated database. Data will be queried regularly for errors or

inconsistencies and followed up according to quality assurance standard operating procedures. Missing data will also be examined by variable and observation to ascertain the quantity of missing data and patterns of missingness. Qualitative data will be recorded using observational notes. Study participants providing written consent will be assigned an identification number, with names linked through paper-based recruitment logs stored in locked filing cabinets.

Statistical analysis

Data analysis for primary and secondary outcomes will be based on intention-to-treat using methods appropriate for cluster-randomised designs [36]. Covariates, including but not restricted to sex and age group, will be summarised by study arm to assess for any imbalance. A systematic assessment of missingness will be conducted.

Trial outcomes will be analysed at cluster level, giving each cluster equal weight. For the primary outcome, the overall outcome risk for each cluster will be calculated, and a log transformation will be applied to the summary value for each cluster if necessary. The mean of these risks and log risks will be used to obtain the geometric mean for each study arm. The risk difference, 95% confidence interval, and *p*-value obtained from *t* tests will be estimated. The risk ratio will also be calculated. Adjusted analysis will use a two-stage approach. Logistic regression will be used to adjust for confounding bias at individual level and calculate expected events. The difference or ratio of observed to expected events will then be calculated for each cluster, and log-transformed if appropriate. The adjusted risk difference or ratio, 95% confidence interval, and *p*-value obtained from *t* tests will be computed. A full statistical analysis plan will be developed prior to unblinding of data.

Social harms

Social harms will be captured by community health action groups and community volunteers using programme registers. Reported social harms will be monitored, categorised based on an established grading system, followed up by the project team, and reported to the trial governance and ethics review committees if appropriate [14]. Social harms will also be assessed through the survey.

Public dissemination

The results of this trial will be distributed to global and national policy makers. Ministry of Health representatives are collaborators on this trial and have advised on the scope of research to ensure its relevance to national policy development. Feedback sessions will also be held with community representatives from participating trial sites.

Trial governance, ethical approvals, and funding

The trial is part of the Unitaid/PSI HIV Self-Testing Africa Initiative (STAR) [http://hivstar.lshtm.ac.uk/]. The trial protocol has been approved by research ethics committees at the University of Malawi College of Medicine (ref: P.01/18/2332), London School of Hygiene and Tropical Medicine (LSHTM) (ref: 14761), and the WHO (ref: STAR-comm led CRT-Malawi), with the latter submission process involving peer review. The trial is registered with ClinicalTrials.gov (ref: NCT03541382).

Oversight of the trial is conducted by an independent technical advisory group (TAG), which consists of six public health experts, scientists, and policy makers guiding research under STAR. The TAG meets semi-annually to review progress, data, and adverse events from ongoing studies. A separate data and safety monitoring board was not established given that HIVST is well established and low risk [12]. The trial is subject to audits from the LSHTM under their remit as sponsor.

Funding is primarily supported by Unitaid, who is independent of the design, management, analysis, and reporting of the trial.

Discussion

This cluster-randomised trial aims to determine if community-led delivery of HIVST can improve HIV testing uptake, ART initiation, and broader social outcomes in rural Malawi. The community-led HIVST intervention also aims to address current implementation gaps related to coverage of testing in adolescents aged 15 to 19 years, older adults aged 40 years and above, and men; resources required for delivering community-based services; and community participation in prevention. To the best of our knowledge, this is the first trial to assess the effectiveness of community-led HTS, which has only recently been enabled by the introduction of HIVST. The trial builds on earlier studies evaluating 'top-down' community-based HTS and HIVST [7-11], which have shown increased uptake of testing and early detection of people living with HIV, and 'bottom-up' community mobilisation for prevention [27].

The intervention evaluated in this trial consists of three components implemented across a 2-week period: (i) participatory workshops for action planning, (ii) trainings on HIVST promotion and support, and (iii) HIVST campaigns linked to treatment and prevention. Previous evaluations of community-led programmes have described the importance of the participatory process [37, 38], which aims to facilitate dialogue among communities and enable them to take action to address factors contributing to poor health [39]. We hypothesise that the introduction of HIVST within a

community-led framework could improve knowledge and access of testing, treatment, and prevention. Potential gains from repeat campaigns are not evaluated in this trial. Periodicity is an important consideration, with more frequent implementation potentially reducing costs but delivering diminishing returns. Further, long-term community involvement could contribute to improved community capacity to address health problems as well as influence broader social norms, including around prevention.

Our intervention aims to facilitate community action around treatment and prevention. As part of the intervention, communities are supported to develop strategies to promote messaging around prevention and linkage to ART initiation for reactive results, VMMC for men with non-reactive results, and couples testing for serodiscordant partners. To assess impact on treatment and prevention, this trial will evaluate changes in ART initiation at population level and knowledge of the preventive benefits of treatment as secondary outcomes. Linking HIVST with treatment strategies is critical for maximising the health impact of testing. Further, HIVST could be used to generate demand for prevention and maintain HIV-negative status [40].

This trial will provide evidence on an alternative model of community-based HTS that could be adopted in settings with established community health structures. Underlying this trial is the question of whether informal community health cadres can effectively lead the design and management of HIVST implementation. Provision of HIVST involves multiple components, including distribution of kits, education on correct use of kits, support for linkage to routine treatment and prevention, safety monitoring, and data capture and assessment. At best, shifting responsibility for HIVST implementation to communities could improve health and social benefits. At worst, poor-quality implementation could result in misdiagnosis, loss to follow-up, and social harm, compromising gains in health. The burden of implementation could place further economic costs on resource-constrained communities [41]. Elite capture, whereby socially and economically privileged subgroups are favoured in resource allocation, could also perpetuate existing health disparities [42].

This trial has a number of anticipated limitations. First, the SOC arm is defined by the standard HTS package provided by the Ministry of Health, which includes facility-based HTS and recurring community-based outreach, rather than community-based HTS or HIVST campaigns. As a result, the separate effects of the intervention components, including use of participatory methods and distribution of HIVST kits, may be difficult to isolate. Second, the trial includes a small number of clusters [36]. Third, trial outcomes cannot be adjusted for cluster-level differences between arms at baseline since data were not collected prior to implementation. Fourth, the trial uses self-reported

outcomes. Fifth, we anticipate wide cluster-level adaptation of implementation, with our process evaluation critical to understanding any outcome variation.

In summary, this trial aims to test whether community-led delivery of HIVST in rural Malawi can increase the proportion of the population that has tested for HIV compared with the SOC, with a focus on underserved population subgroups. The trial also aims to assess the impact of community-led HIVST on ART initiation and broader social outcomes. Community-led HIVST is a promising new strategy for providing periodic testing to support prevention in rural communities. Further, introduction of HIVST through a community-led framework seems particularly apt, with control over health care concurrently devolved to individuals and communities.

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Supplementary materials

Contents

Supplementary Text 3.A. SPIRIT checklist of recommended items to address in a clinical trial protocol

Section/Item	Item #	Description	Page #
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Methods: Trial governance, ethical approvals, and funding
	2b	All items from the World Health Organization Trial Registration Data Set	Not available
Protocol version	3	Date and version identifier	Not available
Funding	4	Sources and types of financial, material, and other support	Methods: Trial governance, ethical approvals, and funding
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Not available
	5b	Name and contact information for the trial sponsor	Not available
	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	Methods: Trial governance, ethical approvals, and funding
	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)	Methods: Trial governance, ethical approvals, and funding
Introduction			
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	Introduction
	6b	Explanation for choice of comparators	Introduction: Rationale for randomised trial
Objectives	7	Specific objectives or hypotheses	Methods: Aim
Trial design	8	Description of trial design including type of trial (e.g., parallel group, crossover, factorial, single group), allocation ratio, and framework (e.g., superiority, equivalence, noninferiority, exploratory)	Methods: Design
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Methods: Setting and population
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (e.g., surgeons, psychotherapists)	Methods: Setting and population Methods: Procedures Methods: Data collection
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Methods: Procedures

Section/Item	Item #	Description	Page #
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving/worsening disease)	Not applicable
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests)	Not applicable
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Not applicable
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Methods: Outcomes
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 4
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	Methods: Sample size
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Methods: Data collection
Methods: Assignment of interventions (for controlled trials)			
Allocation			
Sequence generation	16a	Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Methods: Randomisation and blinding
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Methods: Randomisation and blinding
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Methods: Randomisation and blinding
Blinding (masking)	17a	Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how	Methods: Randomisation and blinding
	17b	If blinded, circumstances under which unblinding is permissible, and	Not applicable

Section/Item	Item #	Description	Page #
		procedure for revealing a participant's allocated intervention during the trial	
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 (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., 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	Methods: Data collection
	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	Not applicable
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Methods: Data management
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Methods: Statistical analysis
	20b	Methods for any additional analyses (e.g., subgroup and adjusted analyses)	Methods: Statistical analysis
	20c	Definition of analysis population relating to protocol non-adherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation)	Methods: Statistical analysis
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Methods: Trial governance, ethical approvals, and funding
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Not applicable
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Methods: Social harms
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Methods: Trial governance, ethical approvals, and funding
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Methods: Trial governance, ethical approvals, and funding

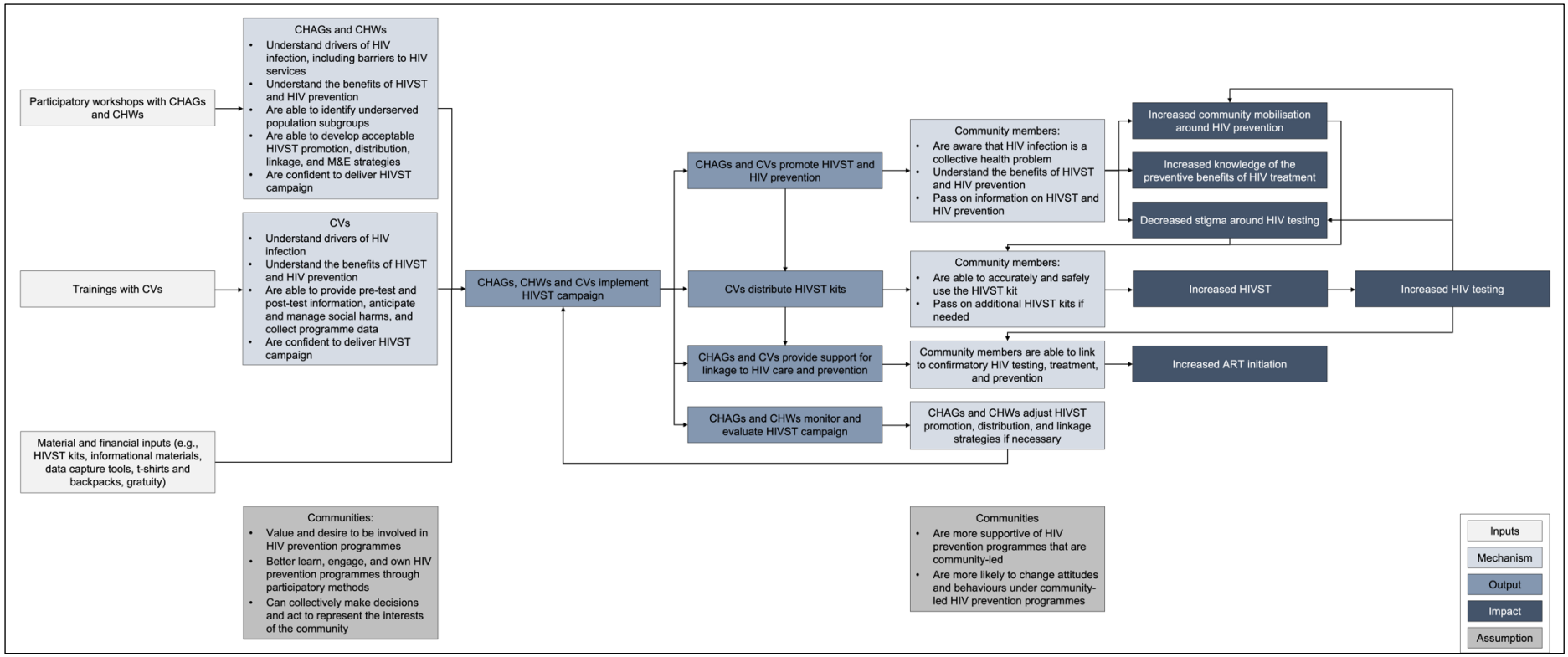
Section/Item	Item #	Description	Page #
Protocol amendments	25	Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Not applicable
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Methods: Data collection
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not applicable
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	Methods: Data management
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Not available
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	Not available
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Not applicable
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, health care professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Methods: Public dissemination
	31b	Authorship eligibility guidelines and any intended use of professional writers	Methods: Public dissemination
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Methods: Public dissemination

Supplementary Table 3.A. Summary of formative qualitative research and pilot

	Design	Results
Focus group discussion	• 16 FGDs among 182 participants, including: ▪ 4 FGDs among 36 adolescents ▪ 4 FGDs among 48 men ▪ 4 FGDs among 50 women ▪ 4 FGDs among 48 village health committee members	• Interest demonstrated in leading HIVST campaign • Close relationship between community members suggested as advantage. Geographical spread and large population size suggested as disadvantage. • Factors seen as critical to implementation included: ▪ Early sensitisation of community members ▪ Committee to oversee implementation, either by involving community health action groups or formed by group village heads or community members ▪ Engagement of CHWs ▪ Financial compensation
Pilot 1	• Community forum to select committee • 2-day participatory workshops with committee to plan HIVST campaign and select community volunteers • 2-day training with community volunteers • 7-day HIVST campaign • No stipend	• 1244 kits distributed (52.3%; *N* = 2,372); 36.9% to men and 21.0% to adolescents • Members outside of community health action groups selected for HIVST committees, resulting in creation of a parallel committee. Members also had poor health literacy. • Concepts and activities introduced in workshops and trainings were too complex • Poor supervision of HIVST campaign by committees • Negative reaction from committees and community volunteers for lack of financial compensation • Low engagement by CHWs
Pilot 2	• Inclusion of CHWs in entrance meetings and participatory workshops • 2-day participatory workshop with community health action groups to plan HIVST campaign, with simplified curriculum • Community forum to select community volunteers • 2-day training with community volunteers, with simplified curriculum • 7-day HIVST campaign • Stipend for community health action groups and community volunteers	• 3487 kits distributed (50.1%; *N* = 6,855); 46.5% to men and 27.7% to adolescents • Community health action groups more literate on HIV-related issues. Resulted in improved planning and implementation of HIVST campaign. • Financial compensation aligned with expectations from prior MoH campaigns. • Community forums were a missed opportunity for distribution of HIVST kits.

CHW, community health workers; FGD, focus group discussion; HIVST, HIV self-testing.

Supplementary Figure 3.A. Theory of change for community-led delivery of HIV self-testing.



ART, antiretroviral therapy; CV, community volunteer; CHAG, community health action group; CHW, community health worker; HIVST, HIV self-testing; M&E, monitoring and evaluation.

Chapter 4.
Cluster-randomised trial

3.2. Summary

This chapter includes Paper 3, "Effect of community-led delivery of HIV self-testing on HIV testing and antiretroviral therapy initiation in Malawi: a cluster-randomised trial". The paper addresses Objective 2 using the methods outlined in Chapter 3. The paper briefly describes the design of the cluster-randomised trial, which involves allocation of group village head clusters to the community-led HIV self-testing (HIVST) intervention or the standard of care. The paper then reports the impact of the intervention on HIV testing, antiretroviral therapy initiation, and HIV-related attitudes and norms using a population-based survey and data from health facilities. Adverse events are also reported. Findings from the cost analysis are reported here and detailed further in Chapter 5. Process outcomes are also presented here and additionally reported in Chapter 6.

The paper was published in 2021 in PLOS Medicine.

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Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	1701865	**Title**	Ms
First Name(s)	Pitchaya Peach		
Surname/Family Name	Indravudh		
Thesis Title	Evaluation of community-led delivery of HIV self-testing		
Primary Supervisor	Prof. Fern Terris-Prestholt		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	BMC Infectious Diseases		
When was the work published?	2019		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	Not applicable		
Have you retained the copyright for the work?*	Yes	Was the work subject to academic peer review?	Yes

*If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.

SECTION C – Prepared for publication, but not yet published

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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I led the conceptualisation and design of the study. I also wrote the first draft of the manuscript. Co-authors contributed to the study conceptualisation and design as well as read and approved the final manuscript.

SECTION E

Student Signature	[redacted]
Date	2nd April 2023

Supervisor Signature	[redacted]
Date	2nd April 2023

Effect of community-led delivery of HIV self-testing on HIV testing and antiretroviral therapy initiation in Malawi: a cluster-randomised trial

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Abstract

Introduction

Undiagnosed HIV infection remains substantial in key population subgroups including adolescents, older adults, and men, driving ongoing transmission in sub-Saharan Africa. We evaluated the impact, safety, and costs of community-led delivery of HIV self-testing (HIVST), aiming to increase testing in underserved subgroups and stimulate demand for antiretroviral therapy (ART).

Methods

This cluster-randomised trial, conducted between October 2018 and July 2019, used restricted randomisation (1:1) to allocate 30 group village head clusters in Mangochi district, Malawi to the community-led HIVST intervention in addition to the standard of care (SOC) or the SOC alone. The intervention involved mobilising community health groups to lead the design and implementation of 7-day HIVST campaigns, with cluster residents (≥15 years) eligible. The primary outcome compared lifetime HIV testing among adolescents (15 to 19 years) between arms. Secondary outcomes compared: recent HIV testing (in the last 3 months) among older adults (≥40 years) and men; cumulative 6-month incidence of ART initiation per 100,000 population; knowledge of the preventive benefits of HIV treatment; and HIV testing stigma. Outcomes were measured through a post-intervention survey and at neighbouring health facilities. Analysis used intention-to-treat for cluster-level outcomes.

Results

Community health groups delivered 24,316 oral fluid-based HIVST kits. The survey included 90.2% (3,960/4,388) of listed participants in the 15 community-led HIVST clusters and 89.2% (3,920/4,394) of listed participants in the 15 SOC clusters. Overall, the proportion of men was 39.0% (3,072/7,880). Most participants obtained primary-level education or below, were married, and reported a sexual partner. Lifetime HIV testing among adolescents was higher in the community-led HIVST arm (84.6%, 770/910) than the SOC arm (67.1%, 582/867; adjusted risk difference [RD] 15.2%, 95% CI 7.5% to 22.9%; $p < 0.001$), especially among 15 to 17 year olds and boys. Recent testing among older adults was also higher in the community-led HIVST arm (74.5%, 869/1,166) than the SOC arm (31.5%, 350/1,111; adjusted RD 42.1%, 95% CI 34.9% to 49.4%; $p < 0.001$). Similarly, the proportions of recently tested men were 74.6% (1,177/1,577) and 33.9% (507/1,495) in the community-led HIVST and SOC arms, respectively (adjusted RD 40.2%, 95% CI 32.9% to 47.4%; $p<0.001$). Knowledge of HIV treatment benefits and HIV testing stigma showed no differences between arms. Cumulative incidence of ART initiation was respectively 305.3 and 226.1 per 100,000 population in the community-led HIVST and SOC arms (RD 72.3, 95% CI −36.2 to 180.8; $p = 0.18$). In post hoc analysis, ART initiations in the 3-month post-

intervention period were higher in the community-led HIVST arm than the SOC arm (RD 97.7, 95% CI 33.4 to 162.1; $p = 0.004$). HIVST uptake was 74.7% (2,956/3,960), with few adverse events (0.6%, 18/2,955) and at 2018 US$5.70 per kit distributed.

Conclusions

In this study, we found that the community-led HIVST intervention was effective, safe, and cost-efficient, with population impact and coverage rapidly realised at relatively low cost. This approach could enable community testing in high HIV prevalence settings and demonstrates potential for economies of scale and scope.

Introduction

In 2018, approximately 1.7 million people were newly infected with HIV, with most cases in sub-Saharan Africa [1]. Regionally, almost one-fifth of people living with HIV were unaware of their status [1]. Gaps remain more substantial among adolescents aged 15 to 19 years, older adults aged 40 years and above, and men [2]. While incidence has been declining, undiagnosed infection in these key population subgroups are drivers of ongoing transmission, impeding achievement of elimination goals [1]. Routine testing is a critical component of providing early diagnosis and treatment to reduce HIV-related morbidity and mortality and maximise prevention benefits [3].

HIV testing services (HTS) are being provided within the context of declining prevalence of undiagnosed HIV [4]. Most HTS are facility-based, though barriers including HIV-related stigma and discrimination, lack of convenience, and economic costs for clients have hindered uptake among underserved subgroups [5, 6]. Community-based HTS can diagnose individuals at earlier stages of disease [7] and improve treatment and viral suppression when combined with convenient antiretroviral therapy (ART) services [8]. Despite their contributions, costs are higher for community-based HTS, with global funding for community health programmes in decline [7, 9]. More efficient and scalable community strategies are needed to reach and maintain universal testing in populations with high prevalence.

Among the most promising approaches are community-led strategies for disease prevention and management, which involve underserved communities leading decision making and resource mobilisation [10-13]. Prior studies have shown increased coverage and efficiency and improved health behaviours and outcomes when communities lead the design, implementation, and evaluation of health services [14-16]. Within HIV, communities have led mobilisation for prevention [17]. Recent innovations in self-care technologies are now expanding the breadth of services that could be directly delivered by communities [18].

HIV self-testing (HIVST) is a recommended approach that can facilitate novel testing strategies [19]. Previous studies have demonstrated the effectiveness of home-based distribution of HIVST kits on increased testing in Malawi and Zambia [20, 21]. Given the impact of vertical community-based HIVST, we evaluated community-led delivery of HIVST. Specifically, we investigated the impact, safety, and costs of mobilising community health groups to lead the design and implementation of 7-day HIVST campaigns, aiming to increase testing in underserved subgroups and stimulate demand for ART in a rural, high prevalence area of Malawi.

Methods

Design

We conducted a cluster-randomised trial and allocated 30 group village head clusters to the community-led HIVST intervention in addition to the standard of care (SOC) or the SOC alone (**Supplementary Text 4.A**). A cluster-randomised design was used since the intervention was delivered at group village head level. The study aimed to determine whether the intervention increased the proportion of the population who tested for HIV at cluster level, focusing on adolescents, older adults, and men. The trial also assessed impacts on population-level ART initiation, knowledge of the preventive benefits of HIV treatment, and HIV testing stigma; adverse events; and costs. A detailed protocol was published separately [22].

Setting and participants

Mangochi is a rural district bordering Lake Malawi and Mozambique with adult HIV prevalence of 10.1% (**Figure 4.1**) [23]. Group village heads hold customary authority over a group of villages. Government community health workers (CHWs) oversee provision of basic health services with community health action groups at group village head level. Community volunteers, including village health committees, provide services at village level.

Group village head clusters serviced by five government primary health centres were assessed by the study team for eligibility. Clusters were defined according to the boundaries of the group village head catchment area. Inclusion criteria for clusters prioritised a minimum population of 2,000 residents, distance of at least 5 kilometres to the health facility, and geographical separation between clusters. The study team obtained verbal consent from group village heads for cluster enrolment.

Randomisation

The 30 group village head clusters were randomised (1:1) to the community-led HIVST or SOC arm. Restricted randomisation was used to ensure balance between arms for key factors that could influence the intervention effect [24]. Restriction criteria included health facility, population, distance from facility, and number of villages (**Supplementary Text 4.B**). From 12,540 unique combinations falling within the restriction parameters, we drew a computer-generated random sample of 1,000 combinations, which were sequentially numbered.

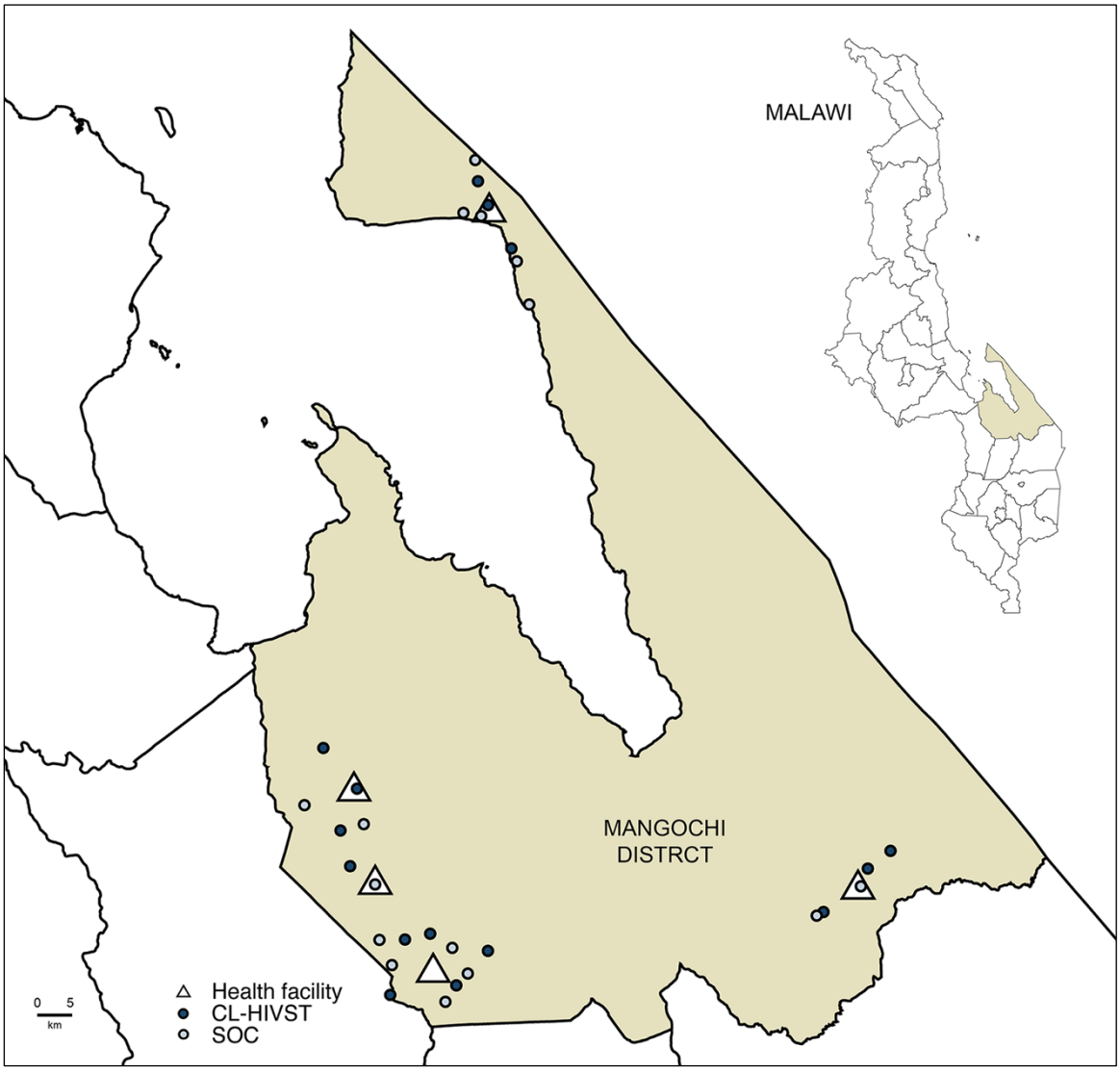


Figure 4.1. Map of clusters in Mangochi district. CL-HIVST, community-led HIV self-testing; SOC, standard of care. Map of Mangochi district with health facilities and group village head-defined clusters. Malawi National Spatial Data Centre, www.masdap.mw.

On July 16, 2018, group village head clusters were randomised at a public ceremony with community and government representatives. Volunteers selected numbered balls corresponding to one combination and one arm allocation from an opaque bag. Masking of community implementers and residents was not feasible since the intervention was delivered at cluster level, but data were managed and analysed without reference to arm allocation where possible.

Procedures

Community-led HIV self-testing

The community-led HIVST intervention involved engaging established community health groups from 15 group village head clusters to lead the design and implementation of HIVST campaigns in their areas. Implementation was staggered, with two to three clusters receiving the intervention

every 14 days. Implementation was administered by the study team, including Population Services International (PSI) Malawi, the Malawi-Liverpool-Wellcome Trust Clinical Research Programme, and the Ministry of Health. Formative research and piloting informed the design [22].

Following entrance meetings, the intervention proceeded in three stages, adapting participatory learning and action methods [25]. First, community health action groups and CHWs attended 2-day participatory workshops. Participants identified drivers of HIV infection, mapped services and barriers to access, defined priority subgroups, and designed a 7-day HIVST campaign to be delivered in their areas. Specifically, participants planned strategies for distribution of HIVST kits, support for linkage to routine care, demand creation for HIVST, social harms reporting, and monitoring and evaluation.

Second, community volunteers attended 2-day trainings on supporting use and interpretation of kits and providing information on linkage to routine services, specifically confirmatory testing and ART initiation for reactive results, voluntary medical male circumcision (VMMC) for nonreactive results among men, and couples testing for serodiscordant results among partners. Volunteers were also trained in communication of prevention messages, including effectiveness of ART, management of social harms, handling and storage of kits, and data collection.

Lastly, community volunteers delivered the campaign in their areas, supervised by community health action groups and CHWs. Implementation was based on strategies defined during participatory workshops for each cluster. In addition to support provided by communities, the study team supplied the OraQuick HIV Self-Test (Orasure Technologies), communications and instructional materials, data collection tools, and nationally standardised gratuity of MWK 7,000 (US$10) per volunteer. Kits could be taken by cluster residents aged 15 years and older. Residents could take an additional kit for secondary distribution and self-test with volunteer support or in private, with or without disclosing results.

Standard of care

The SOC, which was also available in the community-led HIVST clusters, included HTS available through the Ministry of Health. HTS are provided by lay counsellors at health facilities and through periodic community-based outreach. Testing follows standard serial testing algorithms using finger-prick rapid diagnostic tests, with ART universally available immediately following a positive diagnosis.

Outcomes and measurement

Outcomes were selected to understand the effect of the community-led HIVST intervention on uptake of HIV testing, especially among low-coverage subgroups. The primary outcome compared the proportion of adolescents (15 to 19 years) who self-reported lifetime testing for HIV between arms. Lifetime testing was a more relevant measure for adolescents since we anticipated that a high proportion of adolescents would have never tested [23], with the need for testing among this age group highly variable and dependent on the onset of sexual debut and risk. We therefore hypothesised that the intervention would increase coverage of lifetime testing in a subgroup with limited testing experience, with a similar effect achieved on recent testing.

Secondary outcomes compared: self-reported recent HIV testing (in the last 3 months) among older adults (≥40 years) and men; cumulative 6-month incidence of ART initiation per 100,000 population; knowledge of the preventive benefits of HIV treatment; and HIV testing stigma. Exploratory outcomes compared: mutual knowledge of HIV status between sexual partners; recent testing for adolescents; lifetime testing for older adults and men; and testing in the last 12 months for adolescents, older adults, and men.

Outcomes were measured at cluster level through a post-intervention survey, except for ART initiations, which were captured at the five health facilities. The survey was administered 8 to 12 weeks after the intervention start in the community-led HIVST clusters or matched dates in the SOC clusters. Cluster residents were sampled to form the evaluation population for the survey. Within each cluster, villages with at least 500 residents and that included or were located near the group head village were randomly selected per cluster. In villages with approximately 500 residents, all households were eligible for the survey. In larger villages, 150 households were recruited in a clockwise spiral starting with the village head household, with multiple visits made to schedule interviews. Written informed consent or assent was obtained for residents aged 15 years and older in recruited households. Participants were interviewed on household and sociodemographic characteristics, prior use of HIV services, and sexual behavior. A random sample (approximately 20%) received an HIV knowledge and attitudes module (**Supplementary Text 4.C**).

Clinic assistants at the five health facilities interviewed ART patients aged 15 years and older to establish cluster eligibility for 6 months following the intervention. Population estimates for cluster residents aged 15 years and older were obtained from village and facility registers and used as the denominator for cumulative incidence of ART initiations. Process indicators measuring HIVST exposure and uptake were assessed through the survey and HIVST registers, which recorded sociodemographic information for residents collecting HIVST kits. Adverse events related to HIVST were captured through the survey and classified by severity [26]. Economic data on the total and unit costs of the intervention were collected from the provider perspective, with financial costs

from expenditure records supplemented with full costs from direct observations and interviews (**Supplementary Text 4.D**). Costs are reported in 2018 US Dollars.

Sample size

The study was powered to detect a 20% absolute difference between study arms in the primary outcome of lifetime HIV testing for adolescents [20]. We assumed 35% to 50% prevalence of testing among adolescents in the SOC arm based on national estimates [23]. Fifteen group village head clusters per arm with 50 adolescents of 250 residents per cluster provided 90% power at a 5% significance level. We assumed a coefficient of variation (k) of 0.25 based on guidelines for cluster-randomised trials [24]. The study was also powered to measure a difference in recent testing in older adults and men and cumulative ART initiations (**Supplementary Text 4.B**).

Statistical analysis

Analysis used intention-to-treat, that is participants within clusters were analysed based on cluster assignment to study arms rather than individual-level exposure to the community-led HIVST intervention. Outcomes were analysed at cluster level using established methods for cluster-randomised trials with a small number of clusters [24]. Specifically, risk differences, mean differences, and risk ratios for the intervention effect were calculated from cluster-level risks, means, and log risks, respectively (**Supplementary Text 4.B**). Cluster-level summaries were compared between arms with a t test.

Using a two-stage approach [24], effect estimates were adjusted for sex and age group a priori and any imbalance between arms in adolescent covariates. To estimate the risk difference and risk ratio, the first stage used logistic regression to adjust for confounding bias at individual level. Predicted risks were then summed at cluster level and used to calculate the difference and ratio of observed and predicted values. A log transformation was applied to summaries as appropriate. The second stage used a t test to compare covariate-adjusted summary values between arms. To calculate the mean difference, similar procedures were applied using linear regression in the first stage.

A priori subgroup analysis compared the primary outcome by sex and age group (15 to 17 years, 18 to 19 years). Post hoc analysis compared cumulative incidence of ART initiation by first and last 3-month period. Statistical analysis used Stata version 14.0.

Ethical considerations

The study is registered with ClinicalTrials.gov, NCT03541382. Ethical approvals were granted by the University of Malawi College of Medicine (P.01/18/2332), London School of Hygiene & Tropical Medicine (14761), and WHO (STAR-comm led CRT-Malawi). The study is part of the Unitaid/PSI HIV Self-Testing Africa Initiative (STAR) [http://hivstar.lshtm.ac.uk/].

Results

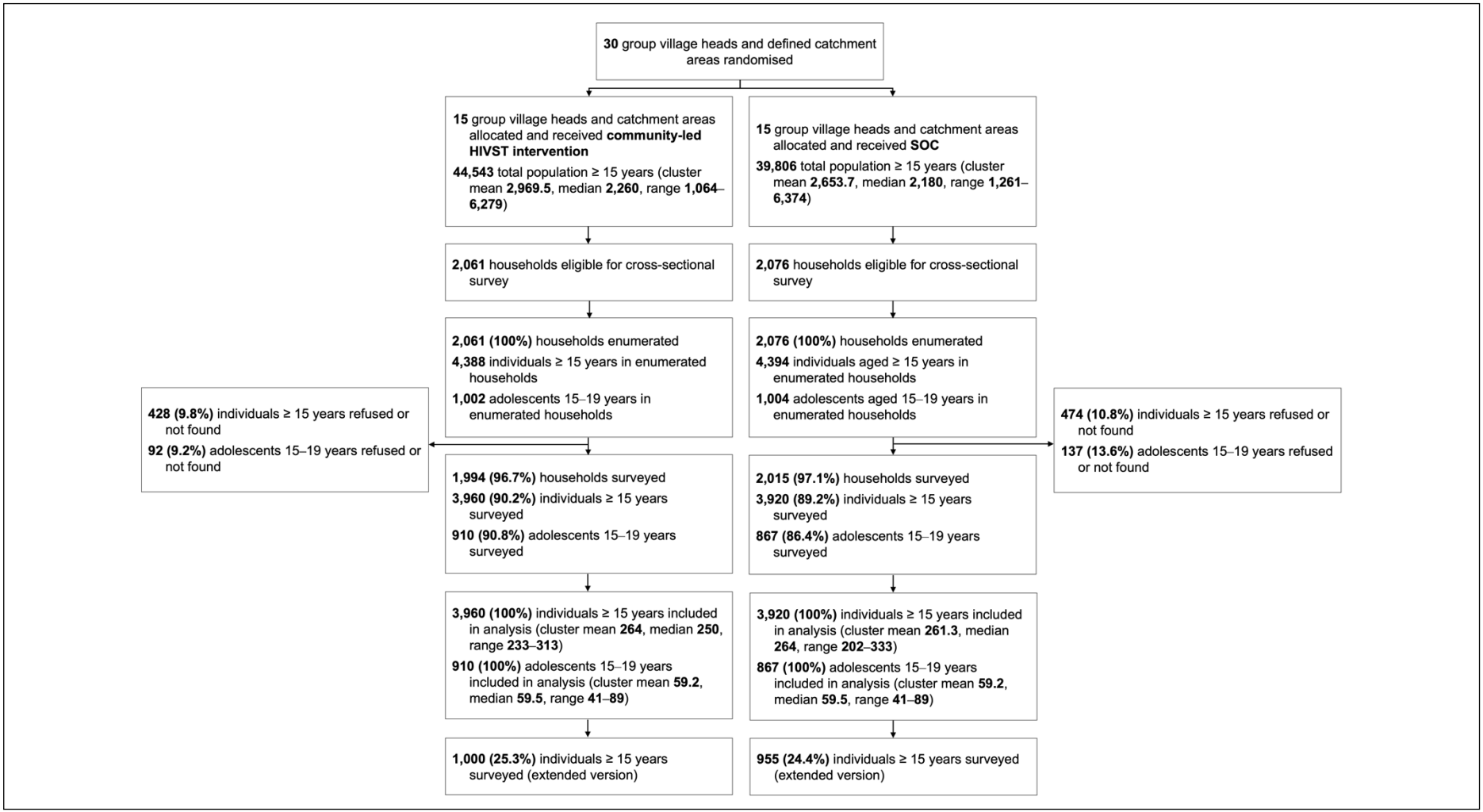
The study population included 44,543 residents in 15 community-led HIVST clusters and 39,806 residents in 15 SOC clusters. The community-led HIVST intervention was delivered from 5 October, 2018 to 17 January, 2019 by 157 community health action group members (cluster mean 10.5) and 190 community volunteers (cluster mean 12.7). Overall, 24,316 HIVST kits (cluster mean 1,621) were distributed, with 47.2% (n = 11,472) of kits distributed to men. Outcomes were measured from 5 December, 2018 to 30 March, 2019 for the post-intervention survey and to 31 July, 2019 for data collection at health facilities. **Figure 4.2** shows the trial flow diagram. The survey included 90.2% (3,960/4,388) and 89.2% (3,920/4,394) of listed participants, respectively, in the community-led HIVST and SOC arms. Adolescent participation was similar at 90.2% (910/1,002) in the community-led HIVST arm and 86.4% (867/1,004) in the SOC arm.

Participant characteristics are summarised in **Table 4.1**. Overall, the proportion of men was 39.0% (3,072/7,880), which was below expected [23] with 84.6% (1,577/1,863) and 82.4% (1,495/1,814) responding in the community-led HIVST and SOC arms, respectively. Most participants obtained primary-level education or below. The majority were married and reported a sexual partner. Characteristics were well balanced by arm, though some differences in literacy, religion, ethnicity, and self-reported health status were observed for adolescents (**Table 4.2**).

Primary and secondary outcomes

Lifetime HIV testing among adolescents was higher in the community-led HIVST arm (84.6%, 770/910) than the SOC arm (67.1%, 582/867), with adjusted risk difference (RD) of 15.2% (95% CI 7.5% to 22.9%; $p < 0.001$; **Table 4.3** and **Supplementary Figure 4.A**). There was strong evidence that the effect of the community-led HIVST intervention differed by age group (p-value for interaction = 0.02), with a more pronounced difference among 15- to 17-year-olds (adjusted RD 21.5%, 95% CI 10.4% to 32.6%; $p < 0.001$) than 18- to 19-year-olds (adjusted RD 10.8%, 95% CI 4.3% to 17.3%; $p = 0.002$). Lifetime testing was also higher for boys (adjusted RD 20.5%, 95% CI 10.7% to 30.3%; $p < 0.001$) than girls (adjusted RD 11.1%, 95% CI 2.8% to 19.4%; $p = 0.01$; p-value for interaction = 0.06).

Figure 4.2. Flow diagram of the cluster-randomised trial



HIVST, HIV self-testing; SOC, standard of care.

Table 4.1. Comparison of population characteristics by study arm

	Community-led HIVST *n* (%)	SOC *n* (%)
Household characteristics	(*N* = 1,994)	(*N* = 2,015)
Adults (median [range])*	2 (0–8)	2 (0–10)
Children (median [range])*	1 (0–1)	1 (0–1)
Household wealth index†		
Lowest	368 (20.3%)	341 (18.6%)
Second	353 (19.4%)	395 (21.6%)
Third	361 (19.9%)	362 (19.8%)
Fourth	358 (19.7%)	373 (20.4%)
Highest	375 (20.7%)	358 (19.6%)
Individual characteristics	(*N* = 3,960)	(*N* = 3,920)
Male	1,577 (39.8%)	1,495 (38.1%)
Age (median [range])	29 (15–96)	29 (15–98)
Age group		
15–19 years	910 (23.0%)	867 (22.1%)
20–24 years	631 (15.9%)	675 (17.2%)
25–39 years	1,253 (31.6%)	1,267 (32.3%)
≥40 years	1,166 (29.4%)	1,111 (28.3%)
Marital status‡		
Married or living together	2,428 (61.3%)	2,467 (62.9%)
Separated, divorced, or widowed	612 (15.5%)	542 (13.8%)
Never married	918 (23.2%)	910 (23.2%)
Educational attainment§		
None	1,730 (43.7%)	1,764 (45.0%)
Primary	1,902 (48.0%)	1,838 (46.9%)
Secondary or higher	328 (8.3%)	317 (8.1%)
Literate‖	2,196 (55.5%)	2,066 (52.7%)
Muslim	2,840 (71.7%)	3,008 (76.7%)
Ethnicity		
Yao	2,778 (70.2%)	2,942 (75.1%)
Ngoni	546 (13.8%)	443 (11.3%)
Other	636 (16.1%)	535 (13.6%)
Resident in the last 2 months	3,877 (97.9%)	3,830 (97.7%)
Self-rated health status¶		
Very good	1,546 (39.1%)	1,314 (33.5%)
Good	1,738 (43.9%)	1,810 (46.2%)
Fair	338 (8.5%)	389 (9.9%)
Poor	337 (8.5%)	407 (10.4%)
Reported current sexual partner**	2,875 (72.6%)	2,931 (74.8%)
Circumcised (for men)††	1,335 (84.9%)	1,285 (86.0%)

HIVST, HIV self-testing; SOC, standard of care.
* 32 missing values in the community-led HIVST arm and 8 missing values in the SOC arm.
† 179 missing values in the community-led HIVST arm and 186 missing values in the SOC arm.
‡ 2 missing values in the community-led HIVST arm and 1 missing value in the SOC arm.
§ 1 missing value in the SOC arm.
‖ 1 missing value in the community-led HIVST arm.
¶ 1 missing value in the community-led HIVST arm.
** 1 missing value in the SOC arm.
†† 5 missing values in the community-led HIVST arm.

Recent HIV testing (in the last 3 months) among older adults was higher in the community-led HIVST arm (74.5%, 869/1,166) than the SOC arm (31.5%, 350/1,111), with adjusted RD of 42.1% (95% CI 34.9% to 49.4%; $p < 0.001$). The proportion of recently tested men was 74.6% (1,177/1,577) in the community-led HIVST arm and 33.9% (507/1,495) in the SOC arm (adjusted

Table 4.2. Comparison of adolescent characteristics by study arm

	Community-led HIVST *n* (%)	SOC *n* (%)
Individual characteristics	(*N* = 910)	(*N* = 867)
Male	387 (42.5%)	381 (43.9%)
Age (median [range])	18 (15–19)	18 (15–19)
Age group		
15–17 years	400 (44.0%)	384 (44.3%)
18–19 years	510 (56.0%)	483 (55.7%)
Marital status*		
Married or living together	138 (15.2%)	147 (17.0%)
Separated, divorced, or widowed	34 (3.7%)	20 (2.3%)
Never married	738 (81.1%)	699 (80.7%)
Educational attainment		
None	239 (26.3%)	262 (30.2%)
Primary	604 (66.4%)	552 (63.7%)
Secondary or higher	67 (7.4%)	53 (6.1%)
Literate	667 (73.3%)	577 (66.6%)
Muslim	672 (73.8%)	686 (79.1%)
Ethnicity		
Yao	665 (73.1%)	684 (78.9%)
Ngoni	126 (13.8%)	88 (10.1%)
Other	119 (13.1%)	95 (11.0%)
Resident in the last 2 months	879 (96.6%)	844 (97.3%)
Self-rated health status†		
Very good	416 (45.8%)	328 (37.8%)
Good	406 (44.7%)	449 (51.8%)
Fair	46 (5.1%)	42 (4.8%)
Poor	41 (4.5%)	48 (5.5%)
Reported current sexual partner	389 (42.7%)	390 (45.0%)
Circumcised (for men)	340 (87.9%)	346 (90.8%)

HIVST, HIV self-testing; SOC, standard of care.
* 1 missing value in the SOC arm.
† 1 missing value in the community-led HIVST arm.

RD 40.2%, 95% CI 32.9% to 47.4%; $p < 0.001$). Knowledge of the preventive benefits of HIV treatment and HIV testing stigma measures showed no differences between arms (**Table 4.3**).

Cumulative 6-month incidence of ART initiation was, respectively, 305.3 and 226.1 per 100,000 population in the community-led HIVST and SOC arms (RD 72.3, 95% CI -36.2 to 180.8; $p = 0.18$). In post hoc analysis, cumulative incidence in the 3-month post-intervention period was, respectively, 186.3 and 93.0 per 100,000 population in the community-led HIVST and SOC arms, with a larger effect in the first 3 months (RD 97.7, 95% CI 33.4 to 162.1; $p = 0.004$) than the last 3 months (RD -10.7, 95% CI -80.5 to 59.2; $p = 0.76$; p-value for interaction = 0.02).

In exploratory analyses, the intervention increased HIV testing in 3-month, 12-month, and lifetime periods, overall and among defined subgroups, and mutual knowledge of HIV status between sexual partners (adjusted RD 14.1%, 95% CI 8.6% to 19.5%; $p < 0.001$; **Supplementary Table 4.A**).

Table 4.3a. Primary outcomes by study arm

	Community-led HIVST		SOC		Risk or mean difference (95% CI)	Adjusted risk or mean difference (95% CI)*	Risk ratio (95% CI)	Adjusted risk ratio (95% CI)*	
	n/*N* (%)	GM	*n*/*N* (%)	GM	*p*-value	*p*-value	*p*-value	*p*-value	*k*
Lifetime HIV testing among adolescents 15–19 years	770/910 (84.6%)	84.6%	582/867 (67.1%)	67.2%	16.4% (7.8%–25.0%) <0.001	15.2% (7.5%–22.9%) <0.001	1.26 (1.11–1.43) <0.001	1.24 (1.11–1.39) <0.001	0.13
Stratified by age group†									
15–17 years	320/400 (80.0%)	79.5%	219/384 (57.0%)	54.3%	22.5% (9.8%–35.3%) 0.001	21.5% (10.4%–32.6%) <0.001	1.47 (1.15–1.87) 0.003	1.44 (1.16–1.79) 0.002	
18–19 years	450/510 (88.2%)	88.0%	363/483 (75.2%)	76.0%	11.5% (4.3%–18.7%) 0.003	10.8% (4.3%–17.3%) 0.002	1.16 (1.06–1.27) 0.003	1.15 (1.06–1.25) 0.002	
Stratified by sex‡									
Male	309/387 (79.8%)	79.6%	218/381 (57.2%)	56.6%	22.3% (11.9%–32.7%) <0.001	20.5% (10.7%–30.3%) <0.001	1.41 (1.19–1.66) <0.001	1.37 (1.17–1.6) <0.001	
Female	461/523 (88.1%)	88.0%	364/486 (74.9%)	74.9%	11.8% (2.6%–21.0%) 0.01	11.1% (2.8%–19.4%) 0.01	1.17 (1.04–1.33) 0.01	1.17 (1.04–1.31) 0.01	

GM, geometric mean (of cluster-level proportions); HIVST, HIV self-testing; *k*, coefficient of variation in group village head-defined clusters; SOC, standard of care

* Analysis adjusted for sex, age group, literacy, religion, ethnicity, and health status. Analysis among adolescents defines levels of age group as 16–17 years and 18–19 years. Analysis among adults ≥40 years defines levels of age group as 40–49 years and ≥50 years. Analysis among men adjusts for the same covariates except for sex.

† *p*-Value for interaction, $p = 0.02$.

‡ *p*-Value for interaction, $p = 0.06$.

Table 4.3b. Secondary outcomes by study arm

	Community-led HIVST		SOC		Risk or mean difference (95% CI)	Adjusted risk or mean difference (95% CI)*	Risk ratio (95% CI)	Adjusted risk ratio (95% CI)*	
	n/*N* (%)	GM	*n*/*N* (%)	GM	*p*-value	*p*-value	*p*-value	*p*-value	*k*
HIV testing in last 3 months among adults ≥40 years†	869/1,166 (74.5%)	73.1%	350/1,111 (31.5%)	30.9%	42.3% (34.7%–50.0%) <0.001	42.1% (34.9%–49.4%) <0.001	2.37 (2.00–2.79) <0.001	2.36 (2.01–2.77) <0.001	0.16
HIV testing in last 3 months among men	1,177/1,577 (74.6%)	73.8%	507/1,495 (33.9%)	33.3%	40.8% (32.9%–48.6%) <0.001	40.2% (32.9%–47.4%) <0.001	2.22 (1.91–2.57) <0.001	2.19 (1.91–2.51) <0.001	0.17
ART initiation per 100,000 population in 6 months‡	136/44,543 (305.3)	270.5	90/39,806 (226.1)	207.3	72.3 (–36.2–180.8) 0.18		1.31 (0.84–2.03) 0.23		0.34
Stratified by post-intervention period§									
First 3 months	83/44,543 (186.3)	184.2	37/39,806 (93.0)	97.5	97.7 (33.4–162.1) 0.004		1.89 (1.21–2.95) 0.007		
Last 3 months	53/44,543 (119.0)	108.0	53/39,806 (133.2)	122.8	-10.7 (-80.5–59.2) 0.76		0.88 (0.51–1.51) 0.63		
Knowledge of the preventive benefits of HIV treatment‖		15.0		14.7	0.3 (-0.6–1.3) 0.51	0.4 (-0.4–1.3) 0.29			
HIV testing stigma¶		7.4		7.6	-0.2 (-0.6–0.2) 0.36	-0.2 (-0.5–0.2) 0.37			

ART, antiretroviral therapy; GM, geometric mean (of cluster-level proportions); HIVST, HIV self-testing; *k*, coefficient of variation in group village head-defined clusters; SOC, standard of care

* Analysis adjusted for sex, age group, literacy, religion, ethnicity, and health status. Analysis among adolescents defines levels of age group as 16–17 years and 18–19 years. Analysis among adults ≥40 years defines levels of age group as 40–49 years and ≥50 years. Analysis among men adjusts for the same covariates except for sex.

† Testing in the last 3 months was ascertained based on the most recent test date. If the month of the test date was not reported, we counted the test as being in the last 3 months if the test date was in 2018 for interview dates in 2018 or if the test date was in 2018 or 2019 for interview dates in 2019. 113 and 156 participants in the community-led HIVST and SOC arms, respectively, did not report month data. We conducted a sensitivity analysis where test dates with missing months were not counted as being in the last 3 months. Among adults ≥40 years, community-led HIVST: 72.0% (839/1,166), SOC: 27.0% (300/1,111); adjusted RD 43.7%, 95% CI 36.0%–51.5%; $p < 0.001$. Among men, community-led HIVST: 72.0% (1,135/1,577), SOC: 30.7% (459/1,495); adjusted RD 40.4%, 95% CI 32.7%–48.0%; p<0.001.

‡ Denominator for ART initiations is the estimated cluster population of adults ≥15 years, which was estimated using village and health facility registers and the proportion of adults reported in household enumeration.

§ Post hoc analysis. *P*-Value for interaction, $p = 0.02$.

‖ $N = 1925$, with 30 missing values. Score is the sum of five questions using a 5-point Likert scale, with range of 5–25 (low to high knowledge).

¶ $N = 1929$, with 26 missing values. Score is the sum of six questions using a 3-point Likert scale, with range of 3–18 (low to high stigma).

Process outcomes

Self-reported HIVST uptake was 74.7% (2,956/3,960) in the community-led HIVST arm, ranging from 68.5% in older men to 84.7% in young women (20 to 24 years), and 3.7% (145/3,920) in the SOC arm (**Table 4.4** and **Supplementary Table 4.A**). The proportion of participants aware of HIVST was 95.3% (3,771/3,960) and 32.4% (1,268/3,920) in the community-led HIVST and SOC arms, respectively. Of 2,956 self-testers in the community-led HIVST arm, most obtained HIVST kits through primary distribution from community health volunteers (93.9%, *n* = 2,775). Only 4.4% (*n* = 130) received kits through secondary distribution from family members.

The majority of HIVST kits were obtained at the home of the participant (80.9%, n = 2,392) followed by the home of community health volunteers (7.4%, n = 220). Further, 10.4% (n = 306) reported no previous HIV testing and 2.4% (*n* = 70) reported a positive result, of whom 40.0% (*n* = 28) were newly identified and 11.4% (*n* = 8) were previously diagnosed and not on treatment. Self-reported ART initiation was 58.3% (21/36). Adverse events related to HIVST were reported

Table 4.4. Fidelity to community-led HIV self-testing intervention

	Community-led HIVST ***n* (%)**	**SOC** ***n* (%)**
	(*N* = 3,960)	(*N* = 3,920)
Heard of self-testing*	3,771 (95.3%)	1,268 (32.4%)
Ever self-tested†	2,956 (74.7%)	145 (3.7%)
Self-tested in the last 3 months‡	2,919 (73.7%)	128 (3.3%)
For most recent self-test:	(*N* = 2,956)	
Self-test distributor§	2,775 (93.9%)	
Community health volunteer	2,775 (93.9%)	
Family member	130 (4.4%)	
Other	49 (1.7%)	
Self-test collection location‖		
Home	2,392 (80.9%)	
Home of community health volunteer	220 (7.4%)	
Other	343 (11.6%)	
First test ever¶	306 (10.4%)	
Self-test result**		
Positive††	70 (2.4%)	
Negative	2,873 (97.4%)	
Invalid	8 (0.3%)	
Harmed before or after self-testing‡‡	18 (0.6%)	

HIVST, HIV self-testing; SOC, standard of care.
* 1 missing value in the community-led HIVST arm and 1 missing value in the SOC arm.
† 1 missing value in the community-led HIVST arm.
‡ 1 missing value in the community-led HIVST arm.
§ 2 missing values in the community-led HIVST arm.
‖ 1 missing value in the community-led HIVST arm.
¶ 1 missing value in the community-led HIVST arm.
** 5 missing values in the community-led HIVST arm.
†† 40% (*n* = 28) were newly HIV positive, 11.4% (*n* = 8) were previously diagnosed and not on treatment, 48.6% (*n* = 34) were previously diagnosed and on treatment. Of 36 HIV positive and not on treatment, 58.3% (*n* = 21) initiated on antiretroviral therapy.
‡‡ 1 missing value in the community-led HIVST arm.

by 0.6% of participants (18/2,955) and classified by severity. Reports included forced self-testing or results disclosure (moderate grade) and one case of physical harm (moderate to severe grade).

Costs

Total provider cost of the community-led HIVST intervention was US$138,624, with a mean cost of US $5.70 per HIVST kit distributed (**Supplementary Table 4.B**). Average costs were US$241 per HIV positive identified, US$602 per new HIV positive identified, and US$468 per HIV positive identified not on treatment.

Discussion

Community-led delivery of 7-day HIVST campaigns linked to treatment and prevention increased HIV testing in underserved subgroups. Lifetime testing increased by 15.2% for adolescents, with more pronounced differences among younger adolescents and boys. Recent testing increased by 42.1% for older adults and by 40.2% for men. Mutual knowledge of HIV status between sexual partners also improved. Cumulative incidence of ART initiation per 100,000 population apparently increased 3 months post-intervention, with 186.3 residents treated in the community-led HIVST arm compared with 93.0 residents treated in the SOC arm. Difference in ART initiations between arms was not found for the predefined 6-month period. The community-led HIVST intervention also achieved 74.7% HIVST uptake with limited adverse events and at US$5.70 per HIVST kit distributed. Our study provides evidence of an effective, safe, and cost-efficient community strategy that rapidly achieved high impact and coverage at low cost and could be scaled in priority settings to meet and maintain elimination goals.

To our knowledge, this is the first randomised trial to assess the impact of community-led delivery of HTS, which was recently enabled by the introduction of HIVST. This is also one of the few studies to report high coverage of testing among subgroups with substantial undiagnosed infection. Community participation has long been advocated as fundamental to primary health care and an approach that could increase coverage and efficiency of health programmes and improve outcomes, enhance the capacity of communities to address ill health, and contribute to the sustainability of community health programmes [27, 28]. We used participatory methods to engage established community health groups in designing and implementing HIVST campaigns adapted to their respective contexts. Our study builds on ‘top-down’ community-based testing and self-testing [6, 7, 20, 21, 29], and ‘bottom-up’ community mobilisation for prevention [17] by using a community-led HIVST model. Future iterations of this intervention could engage groups over time to provide repeat or multidisease services, including strategies to address priority disease areas [30]. With the COVID-19 epidemic, community-led disease control programmes have potential to contribute to

surveillance and early detection, reporting, and management. HIVST may also enable ongoing provision of testing as routine services are disrupted, reducing demand on health care workers to provide in-person testing [31].

We found that community-led HIVST can lead to high coverage and effective targeting, with our study reporting substantially higher uptake from a community-led approach than a previous study of door-to-door HIVST [20]. Uptake was consistent across adolescents, older adults, and men. In contrast, vertical distribution of HIVST kits by community-based distribution agents achieved 42.5% uptake across a 12-month period in Malawi [20]. Uptake may be driven by successful context-informed planning, trust between community health groups and community members, and the value and novelty of HIVST. The intervention also had minimal adverse events, alleviating safety concerns around decentralising management of HIVST implementation [18]. Further, our results may be applicable to high prevalence settings in sub-Saharan Africa with similar community health cadres.

We showed increased lifetime and recent HIV testing in adolescents, especially younger adolescents and boys, older adults, and men, with prevalence of undiagnosed HIV disproportionately concentrated in these subgroups. Mutual knowledge of HIV status between sexual partners also increased. The intervention effect, while slightly lower than assumed for sample size calculations, was achieved against a SOC that included a high saturation of HIV services, with Mangochi a priority district for the Ministry of Health. Diagnosis of recent infection is critical for prevention, with our study reinforcing the importance of community strategies in reaching underserved subgroups [7]. Further, the impact attained within a short period of time makes community-led HIVST a promising candidate for national HIV programmes to consider for periodic implementation to reach underserved subgroups.

Community-led HIVST had an immediate impact on ART initiation 3 months post-intervention, though the effect diminished at 6 months. Population-level impact was measured even as the post-intervention survey reported that 1.2% of self-testers were newly HIV-positive or previously diagnosed but not on treatment, underscoring the potential for HIVST to influence ART demand. The intervention involved engaging government CHWs and health facilities to facilitate linkage to routine services, likely contributing to successful referrals. However, self-reported ART initiation was 58.3% at follow-up. Optimising timely linkage to treatment and prevention services is essential to maximise the health benefits from testing and self-testing [32]. Neither VMMC nor preexposure prophylaxis was available at primary care level during the study, so we were unable to evaluate linkage to these services. Further, despite providing training and materials to community volunteers on prevention messages, the intervention did not improve knowledge of the preventive benefits of

HIV treatment. The absence of effect may reflect insufficient discussion on the topic or difficulties conveying risk reduction concepts.

Our analysis reported average cost of US$5.70 per HIVST kit distributed, which was lower than the cost of door-to-door HIVST models in nearby rural districts (2017 US$8.15) and urban Blantyre (2014 US$8.78) [33, 34]. Average costs of community-based HTS in sub-Saharan Africa were similar [7]. Community health programmes are important for epidemic preparedness and management but can be costly to implement [9]. A community-led approach to HIVST is likely to realise significant economies of scale, with potential cost savings when community health groups are mobilised nationally and recurrently by Ministries of Health in non-research settings. Economies of scope can also lead to greater efficiency by implementing HIVST within a package of interventions addressing a broader set of conditions, including through the use of self-care products. Further, we found that the cost per HIV-positive identified through HIVST was US$241 to US$602. Additional cost reductions and uptake among undiagnosed, untreated HIV-positive persons or high risk persons linking to prevention would ensure greater probability of community-led HIVST as a cost-effective strategy [4].

Our study had multiple limitations. Due to the pragmatic nature of the intervention, there was some contamination of HIVST in the SOC arm, although reported events were nominal. The study design did not allow us to isolate the effects of specific intervention components, including the use of participatory methods and introduction of HIVST. Primary and secondary outcomes on testing were self-reported and subject to misreporting due to recall or social desirability bias, including overreporting in the community-led HIVST arm following exposure to the intervention. We had a small number of clusters per arm and aimed to mimimise bias through randomisation of clusters, using restriction of factors likely to be associated with the outcome, and adjustment for imbalances between arms in individual characteristics. However, we did not measure primary and secondary outcomes in a baseline sample and adjust for baseline testing. Our sampling frame may have included households that had better access to the community-led HIVST intervention due to their location, with potential overestimation of the intervention effect. However, the effect size was relatively large, and our conclusions would have likely remained unchanged. The survey included fewer men than expected with almost one-fifth of eligible men not found. Implementation occurred within a controlled research setting as part of a mature HIVST programme that had been operating since 2015, potentially affecting the generalisability of our costs. Adverse events were reported in the survey, with follow-up to obtain case details not feasible. We also did not evaluate accuracy of HIVST, which previously was shown to be high when given optimised instructional materials and brief demonstrations [29].

Community-led delivery of 7-day HIVST campaigns linked to treatment and prevention was effective in increasing HIV testing in adolescents, older adults, and men and mutual knowledge of HIV status between sexual partners. Population-level ART initiation apparently increased within a 3-month period but showed no difference at 6 months. Community-led delivery of HIVST was safe and associated with higher uptake and relatively lower costs compared with previous evaluations of vertical community-based HIVST. Given evidence of high population impact and coverage rapidly realised at low cost, community-led HIVST shows much promise as an effective, safe, and cost-efficient strategy, while empowering communities with leading solutions for disease control. This approach could enable community testing in high prevalence settings and demonstrates potential for economies of scale and scope.

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Supplementary materials

Contents

Supplementary Text 4.A. CONSORT checklist of information to include when reporting a cluster randomised trial

Section/Item	Item #	Standard checklist item	Extension for cluster designs	Page #
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	See table 2	Abstract
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	Introduction Methods: Design
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	Introduction Methods: Design
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	Methods: Design Methods: Setting and participants Methods: Randomisation
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		Methods: Outcomes and measurement
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	Methods: Setting and population Methods: Procedures Methods: Outcomes and measurement
	4b	Settings and locations where the data were collected		Methods: Setting and participants Figure 1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	Methods: Procedures
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	Methods: Outcomes and measurement
	6b	Any changes to trial outcomes after the trial commenced, with reasons		Methods: Outcomes and measurement
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of	Methods: Sample size

Section/Item	Item #	Standard checklist item	Extension for cluster designs	Page #
			intracluster correlation (ICC or *k*), and an indication of its uncertainty	
	7b	When applicable, explanation of any interim analyses and stopping guidelines		Not applicable
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		Methods: Randomisation
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	Methods: Randomisation
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	Methods: Randomisation
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	Not applicable
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	Methods: Setting and population Methods: Randomisation
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	Methods: Outcomes and measurement
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	Methods: Setting and population Methods – Outcomes and measurement
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		Methods: Randomisation

Section/Item	Item #	Standard checklist item	Extension for cluster designs	Page #
	11b	If relevant, description of the similarity of interventions		Not applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	Methods: Statistical analysis
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		Methods: Statistical analysis
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Results Figure 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Results Figure 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up		Results
	14b	Why the trial ended or was stopped		N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Results Table 1-2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Results Table 1-4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	Results: Primary and secondary outcomes Table 3 Supplementary Table A
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		Results: Primary and secondary outcomes Table 3 Supplementary Table A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		Results: Primary and secondary outcomes; Table 3 Supplementary Table A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		Results: Process outcomes Table 4

Section/Item	Item #	Standard checklist item	Extension for cluster designs	Page #
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		Discussion
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	Discussion
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		Discussion
Other information				
Registration	23	Registration number and name of trial registry		Methods: Ethical considerations
Protocol	24	Where the full trial protocol can be accessed, if available		Methods: Design

Supplementary Text 4.B. Statistical analysis plan

This document outlines the statistical analysis plan for a cluster-randomised trial of community-led delivery of HIV self-testing (HIVST).

Study design

Study arms

Thirty group village heads clusters were allocated using restricted 1:1 randomisation to either:

- **Community-led HIVST arm**: Community representatives are supported to plan and administer an HIVST campaign linked to care and prevention in their communities. Specifically, community health action groups and government community health workers attend participatory workshops to plan the campaign. Community volunteers also receive an HIVST training. Community representatives implement the 7-day campaign, with HIVST kits (OraQuick HIV Self-Test), instructional materials, data collection tools, t-shirts and backpacks, and gratuity provided.
- **Standard of care (SOC) arm**: No HIVST kits are available. Across arms, HIV testing is provided at health facilities based on the national testing algorithm. "Treat all" guidelines for antiretroviral therapy (ART) initiation are followed. Testing is also offered through periodic community-based outreach.

Outcomes

The primary outcome compares between arms the proportion of self-reported lifetime HIV testing in adolescents (15 to 19 years).

Secondary outcomes compare between arms:

- Self-reported recent HIV testing (in the last 3 months) in men
- Self-reported recent HIV testing (in the last 3 months) in older adults (≥40 years)
- Cumulative incidence of population-level ART initiation across 6 months[1]
- Knowledge of the preventive benefits of HIV treatment
- HIV testing stigma

Exploratory analyses compare between arms:

- Mutual knowledge of HIV status between sexual partners
- Self-reported recent HIV testing (in the last 3 months) in adolescents
- Self-reported lifetime HIV testing in (i) men, (ii) older adults, and (iii) overall

[1] In the protocol, the outcome was defined as 'cumulative incidence of population-level ART initiation and voluntary medical male circumcision (VMMC) uptake across 6 months'. However, VMMC services in Mangochi were discontinued prior to the start of the trial, meaning assessment of VMMC uptake was not possible.

- Self-reported recent HIV testing (in the last 12 months) in (i) adolescents, (ii) men, (iii) older adults, and (iv) overall

Outcomes are measured through a post-intervention survey and data collection at health facilities.

Methods

Study population

Cluster residents aged 15 years and older are eligible for the study. Group village head clusters in the catchment areas of five government primary health centres were assessed for eligibility. Out of 53 clusters, 30 were included in the study, prioritising clusters with:

- Catchment population of at least 2000 people
- Distance of at least 5 kilometres away from the health facility
- Sufficient distance and separation from boundaries of other intended clusters

Randomisation and blinding

Thirty group village head clusters were randomised, with restriction factors including nearest health facility, distance from health facility, catchment population, and number of villages. From 12,540 unique combinations falling within the restriction parameters, 1,000 were drawn by computer-generated random sampling. The final allocation was selected in a public ceremony on 16th July 2018.

Because of the nature of the intervention, the study team are not blinded to the allocation status of arms. Data are managed without reference to arm allocation where possible.

Table. Restriction criteria for randomisation

Restriction		Number of clusters	Criteria
Health facility	Chilipa	8	3-5/arm
	Chilonga	5	2-3/arm
	Makanjira	8	3-5/arm
	Mkumba	5	2-3/arm
	Phirilongwe	4	2/arm
Number of villages	1-5	15	6-9/arm
	6-11	15	6-9/arm
Population size			Keep if average population size/arm is with ±2SD of mean
Distance			Keep if average population size/arm is with ±2SD of mean

Sample size

Sample size calculations were based on the primary outcome as well as selected secondary outcomes.

Table. Sample size calculations

SOC	% increase, absolute	Community-led HIVST	Cluster size	*k*	No. of clusters per arm 80% power	90% power
Lifetime HIV testing in adolescents						
35.0%	20%	55.0%	50	0.25	8.08	10.47
40.0%	20%	60.0%	50	0.25	9.26	12.06
45.0%	20%	65.0%	50	0.25	10.53	13.76
50.0%	20%	70.0%	50	0.25	11.88	15.57
Recent HIV testing in older adults						
25.0%	20%	45.0%	50	0.25	5.96	7.64
30.0%	20%	50.0%	50	0.25	6.97	9.00
35.0%	20%	55.0%	50	0.25	8.08	10.47
40.0%	20%	60.0%	50	0.25	9.26	12.06
Cumulative incidence of ART initiation						
0.5%	1.40	0.7%	4000	0.25	15.93	20.98
1.0%	1.40	1.4%	4000	0.25	12.98	17.04
1.5%	1.40	2.1%	4000	0.25	12.00	15.73
2.0%	1.40	2.8%	4000	0.25	11.51	15.07

ART, antiretroviral therapy; HIVST, HIV self-testing; *k*, coefficient of variation in group village head-defined clusters; SOC, standard of care.

Outcome measurement

Primary outcome – lifetime HIV testing among adolescents

The primary outcome is defined as the proportion of adolescents who self-report testing for HIV in their lifetime. The numerator is the count of adolescents aged 15 to 19 years who report ever testing in the survey. The denominator is the count of adolescents with non-missing data (including do not know and decline to answer responses).

Secondary outcomes – recent HIV testing among men

The outcome is defined as the proportion of men who self-report testing for HIV in the last 3 months. The numerator is the count of men aged 15 years and older who report a recent test date less than 4 months from the interview date in the survey. Test dates are given as month-year. If the month is unknown and the interview date is in 2019, test dates in 2018 and 2019 are counted. If the month is unknown and the interview date is 2018, test dates in 2018 are counted. If the year is unknown, test dates are not counted. The denominator is the count of men with non-missing data (including do not know and decline to answer responses).

Secondary outcomes – recent HIV testing among older adults

The outcome is defined as the proportion of older adults who self-report testing for HIV in the last 3 months. The numerator is the count of older adults aged 40 years and older who report a recent test date less than 4 months from the interview date in the post-intervention survey. Test dates are given as month-year. If the month is unknown and the interview date is in 2019, test dates in 2018 and 2019 are counted. If the month is unknown and the interview date is 2018, test dates in 2018

are counted. If the year is unknown, test dates are not counted. The denominator is the count of older adults with non-missing data (including do not know and decline to answer responses).

Secondary outcomes – cumulative incidence of ART initiation

The outcome is defined as the cumulative incidence of adults per 100,000 population initiating on ART across 6 months. The numerator is the count of adults aged 15 years and older who are resident in the study clusters and initiated on ART within 168 days of the start of the HIVST campaign in their respective groups. The denominator is the adult population of study clusters, which is estimated using village and health facility data and the proportion of adults enumerated for the survey.

Secondary outcomes – knowledge of preventive benefits of HIV treatment

The outcome is defined as the mean score for knowledge of the preventive benefits of HIV treatment. The score is derived from five questions in the extended version of the survey. Responses are given based on a 5-point Likert scale and summed, with scores ranging from 5 to 25 (low to high knowledge). Questions were adapted from Obermeyer et al[2].

Secondary outcomes – HIV testing stigma

The outcome is defined as the mean score for HIV testing stigma. The score is derived from six questions in the extended version of the survey. Responses are given based on a 3-point Likert scale and summed, with scores ranging from 3 to 18 (low to high stigma). Questions were adapted from Boshamer et al[3].

Data collection

Implementation of the intervention and outcome evaluation is staggered by group, with groups pragmatically organised based on location. Surveys are timed 8 to 12 weeks after the start of the intervention in their respective groups. Data collection at health facilities will continue for 6 months following the start of the HIVST campaign in their respective groups.

Survey

In each cluster, one or two evaluation villages for the survey were randomly selected from villages that met the following criteria:

- Located within close proximity of the main village
- Population of at least 500 people

[2] Obermeyer CM, Bott S, Carrieri P, Parsons M, Pulerwitz J, Rutenberg N, et al. HIV testing, treatment, and prevention: generic tools for operational research. Geneva: World Health Organisation, 2009.
[3] Boshamer CB, Bruce KE. A scale to measure attitudes about HIV-antibody testing: development and psychometric validation. *AIDS Educ Prev*. 1999;11(5):400-13.

If evaluation villages have approximately 500 people, surveyors will interview all households. If evaluation villages have more than 500 people, surveyors will interview 150 households, starting with the house of the village head and proceeding in a clockwise spiral outward.

Inclusion criteria are:

- Aged 15 years and older
- Resident in an eligible household
- Able and willing to provide written consent, or assent for participants aged 15 to17 years

A random subset of participants (approximately 20%) will receive the extended version of the survey.

Table. Intervention and evaluation groups

Cluster	Health facility	Arm	Intervention group	Evaluation group
Makanjira	Makanjira	Community-led HIVST	1	1
Mikochi	Makanjira	Community-led HIVST	1	1
Mpangama	Makanjira	Community-led HIVST	1	2
Malamia	Makanjira	SOC		2
Lukoloma	Makanjira	Community-led HIVST	2	3
Mtwana	Makanjira	SOC		3
Mtiule	Makanjira	Community-led HIVST	2	4
Njerenje	Makanjira	SOC		4
Mkumba	Mkumba	Community-led HIVST	3	5
Limbalire	Mkumba	SOC		5
Mgao	Mkumba	SOC		5
Jilamu	Mkumba	Community-led HIVST	3	6
Mkambiri	Mkumba	SOC		6
Songa 1	Phirilongwe	Community-led HIVST	4	7
Malopa 2	Phirilongwe	SOC		7
Malopa 1	Phirilongwe	Community-led HIVST	4	8
Mlongoti	Phirilongwe	SOC		8
Chilonga	Chilonga	Community-led HIVST	5	9
Makunula	Chilonga	Community-led HIVST	5	9
Kella	Chilonga	SOC		9
Maloya	Chilonga	Community-led HIVST	5	10
Binali	Chilonga	SOC		10
Chalenga	Chilipa	Community-led HIVST	6	11
Jekete	Chilipa	Community-led HIVST	6	11
Malenga	Chilipa	SOC		11
Naunje	Chilipa	Community-led HIVST	6	12
Leveni	Chilipa	SOC		12
Masapi	Chilipa	SOC		12
Nikisi	Chilipa	SOC		13
Bamusi	Chilipa	SOC		13

HIVST, HIV self-testing; SOC, standard of care.

Facility data capture

Clinic assistants will interview new ART clients presenting at health facilities serving the study population.

Inclusion criteria are:

- Aged 15 years or older
- Residence in group village head clusters included in the trial
- Initiating on ART

Statistical analysis

Statistical analysis will be done on an intention-to-treat basis and use methods appropriate for cluster-randomised trials with a small number of clusters[4]. Analysis will be done in Stata version 14.0.

Trial flow diagram

A trial flow diagram will be produced that conforms to the 2010 CONSORT statement as applicable to cluster-randomised trials[15]. Response rates for households, individuals, and adolescents from the survey will be summarised.

Sample characteristics

Sample characteristics will also be compared by arm, overall and among adolescents. Household-level characteristics will include household composition and socioeconomic status. Individual-level characteristics will at minimum include sex, age, marital status, educational attainment, literacy, religion, ethnicity, residence status, and health status.

Unadjusted analysis

The overall risk/mean for each cluster will be calculated, with each cluster given equal weight and a log transformation applied to the summary value for each cluster as appropriate. The risk/mean difference, 95% CI, and *p*-value will be estimated using cluster risks/means and a *t* test by arm. The risk ratio, 95% CI, and *p*-value will be calculated using cluster log risks and a *t* test by arm.

Adjusted analysis

The adjusted analysis is the primary analysis. Effect estimates will be adjusted for age and sex*, a priori*. Covariates for adolescents will also be assessed for imbalances between arms. The adjusted analysis will adopt a two-stage approach[4]. A regression model will be used to adjust for confounding bias at the individual level and include terms for the adjustment factors. Covariate-adjusted residuals will be obtained from the fitted model and used to calculate the adjusted risk/mean difference and risk ratio as appropriate.

Subgroup analysis

[4] Hayes RJ, Moulton LH. Cluster Randomised Trials, 2nd edn. New York: Chapman and Hall/CRC; 2017.
[5] Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. *BMJ*. 2012;345:e5661.

A subgroup analysis will assess differences in lifetime HIV testing among adolescents by sex and age group (15 to 17 years, 18 to 19 years).

Sensitivity analysis

A sensitivity analysis will not include test dates with unknown months in the outcome definition for recent HIV testing among men and recent HIV testing among older adults.

Missing data

Missing data will be examined for each variable and for each cluster or individual participant. A systematic assessment of missingness will be conducted to ascertain the reason and possible mechanism for missing data by identifying the quantity of missing data and patterns within the data. Missingness will be examined by cluster and between randomised arms to assess for systematic biases.

Process evaluation

The following process measures will be summarised alongside the outcome evaluation:

- Number of HIVST kits distributed
- Proportion of participants who have heard of self-testing
- Proportion of participants who have ever self-tested
- Proportion of participants who have self-tested in the last 3 months
- Proportion of self-testers with a positive result
- Proportion of self-testers harmed before or after self-testing

Supplementary Text 4.C. Question items for knowledge of HIV prevention and HIV testing stigma measures

Knowledge of HIV prevention

Questions were adapted and piloted from Obermeyer et al[1]. The score was derived from five questions using a 5-point Likert scale (strongly agree, agree, unsure, disagree, strongly disagree), with a range of 5 to 25 (low to high knowledge).

1. I believe that HIV treatment makes people with HIV less infectious.
2. I would feel safe having intercourse with someone who is HIV positive as long as they are receiving HIV treatment.
3. I am less worried about HIV infection than I used to be.
4. HIV treatment makes me less anxious about having unprotected sex.
5. HIV treatment can help prevent a person with HIV from infecting a partner.

HIV testing stigma

Questions were adapted and piloted from Boshamer et al[2]. The score was derived from six questions using a 3-point Likert scale (strongly agree, somewhat agree, disagree), with a range of 3 to 18 (low to high stigma).

1. I would not want anyone I know to see me queuing for an HIV test.
2. My friends or family would not approve if I went for HIV testing.
3. It would be embarrassing if someone found out I tested for HIV.
4. You know there are problems in a marriage when the couple tests for HIV.
5. Everyone who tests for HIV is HIV positive.
6. Testing for HIV means that you are immoral.

[1] Obermeyer CM, Bott S, Carrieri P, Parsons M, Pulerwitz J, Rutenberg N, et al. HIV testing, treatment, and prevention: generic tools for operational research. Geneva: World Health Organisation, 2009.
[2] Boshamer CB, Bruce KE. A scale to measure attitudes about HIV-antibody testing: development and psychometric validation. *AIDS Educ Prev.* 1999;11(5):400-13.

Supplementary Text 4.D. Methods for cost analysis

The community-led HIV self-testing (HIVST) intervention was delivered by Population Services International Malawi and the Malawi-Liverpool-Wellcome Trust Clinical Research Programme as part of a broader package of HIVST distribution models.

Partial cost analysis of the intervention was undertaken from the provider perspective to estimate economic costs. Financial data from expenditure records were supplemented with economic data from microcosting. Gross costing involved allocating each expenditure item to a cost category and activity. Microcosting involved direct observations and interviews with the study team and community volunteers.

Shared costs were allocated by activity using a factor for each cost category. Costs are reported in 2018 US Dollars, with local costs converted using the median exchange rate during the period of analysis[1]. The costing period was September 2018 to January 2019.

Community costs were excluded from the analysis due to incomplete data collection. Research costs, including piloting to inform the intervention design, were also excluded.

Start-up costs

Start-up costs included costs of training and sensitisation activities and costs incurred in the month prior to the intervention start, with the majority of development costs spent during this period.

Training activities included a 2-day participatory workshop with 157 community health action group members and an HIVST training with 190 community volunteers. A total of six pairs of workshops and trainings were administered in groups of two-to-three clusters. Costs associated with trainings included costs of venue hire, projector, staff per diem, participant sit-in allowances, office stationery, and food and drink. Common costs for training were allocated using the weighted average of allocation factors for other shared costs.

Sensitisation activities included entry meetings with the district health office, five primary health centres, and 15 group village heads, with costs incurred for participant sit-in allowances and staff per diem. Shared costs for sensitisation, including production of information, education, and communication materials, were allocated using the weighted average of allocation factors for other common costs. Other start-up costs included costs of personnel and transportation.

[1] Bank of Malawi. Exchange Rates. [https://www.rbm.mw/Statistics/MajorRates/#].

Start-up costs were annualised over a 2-year period[2] and assumed a 3% discount rate[3].

Capital costs

Capital costs included building and storage, equipment, and vehicle-related costs.

Building and storage costs included common costs for rent and were allocated using the weighted average of allocation factors for shared costs. Shared equipment costs were similarly apportioned. Costs of backpacks were imputed for each volunteer (MWK 30,000; US$40). Vehicle costs included common costs for vehicle hire and were allocated using the proportion of miles from the central office to sites.

Capital costs, excluding costs of building or vehicle-related hire, were annualised over their useful life and assumed a 3% discount rate[3].

Recurrent costs

Recurrent costs included costs of personnel; supplies; HIVST kits; vehicle operation, maintenance, and transportation; building operation and maintenance; and other recurrent inputs.

Personnel costs included staff and consultant salaries, fringe, and per diem. Direct personnel included a program manager, program coordinator, training coordinators, monitoring and evaluation officers, field officers, and data clerks. Shared costs for direct and indirect personnel were allocated using the proportion of reported staff time stratified by salary grade, which was ascertained through a time use questionnaire. Gratuity for community health action group members and community volunteers was provided at MWK 7,000 (US$10) per person.

Supplies costs included costs of t-shirts, data collection forms, and office stationery. Costs of t-shirts were imputed for each volunteer (MWK 4,000; US$5.50). Common costs for supplies were allocated using the proportion of HIVST kits distributed.

Costs of HIVST kits were estimated based on the unit price for the OraQuick HIV Self-Test (US$2.50), including purchase, freight, and estimated wastage, and the number of kits distributed. Wastage of 5% was based on the approximate number of kits provided to community health groups and the number of kits distributed.

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[2] Mangenah C, Mwenge L, Sande L, Ahmed N, d'Elbee M, Chiwawa P *et al*. Economic cost analysis of door-to-door community-based distribution of HIV self-test kits in Malawi, Zambia and Zimbabwe. *J Int AIDS Soc.* 2019; 22(Suppl 1):e25255.

[3] Vassall A, Sweeney S, Kahn J, Gomez GB, Bollinger L, Marseille E *et al*. Reference Case for Estimating the Costs of Global Health Services and Interventions. [https://ghcosting.org/pages/standards/reference_case].

Recurrent vehicle costs included costs of vehicle fuel, operation, and maintenance, with common costs allocated using the proportion of miles from the central office to sites. Recurrent building costs included utilities and maintenance for office and warehouse buildings. Common costs for office-related buildings were allocated using the weighted average of allocation factors for shared costs, while common costs for warehouse-related buildings were allocated using the proportion of kits distributed.

Other recurrent inputs included communications, equipment repairs and maintenance, printing, postage and delivery, and miscellaneous fees. Shared costs for other recurrent inputs were allocated using the proportion of kits distributed.

Supplementary Table 4.A. Exploratory HIV testing outcomes by study arm

	Community-led HIVST		SOC		Risk or mean difference (95% CI)	Adjusted risk or mean difference (95% CI)*	Risk ratio (95% CI)	Adjusted risk ratio (95% CI)*
	n/*N* (%)	GM	*n*/*N* (%)	GM	*p*-value	*p*-value	*p*-value	*p*-value
Mutual knowledge of HIV status between sexual partners†	2,051/2,875 (71.3%)	70.6%	1,665/2,931 (56.8%)	56.2%	14.6% (8.5%–20.7%) <0.001	14.1% (8.6%–19.5%) <0.001	1.26 (1.14–1.39) <0.001	1.25 (1.14–1.37) <0.001
Lifetime HIV testing								
Adults ≥15 years	3,635/3,960 (91.8%)	91.8%	3,318/3,920 (84.6%)	84.5%	7.3% (3.8%–10.7%) <0.001	7.2% (4.0%–10.5%) <0.001	1.09 (1.04–1.13) <0.001	1.09 (1.05–1.13) <0.001
Adults ≥40 years	1,064/1,166 (91.3%)	91.0%	907/1,111 (81.6%)	80.4%	10.1% (4.2%–15.9%) 0.001	10.2% (4.5%–16.0%) 0.001	1.13 (1.05–1.22) 0.002	1.13 (1.05–1.22) 0.002
Men	1,391/1,577 (88.2%)	88.2%	1,165/1,495 (77.9%)	77.2%	11.0% (6.1%–15.8%) <0.001	10.2% (5.8%–14.7%) <0.001	1.14 (1.08–1.21) <0.001	1.13 (1.07–1.20) <0.001
HIV testing in the last 3 months								
Adults ≥15 years	3,145/3,960 (79.4%)	78.9%	1,556/3,920 (39.7%)	39.5%	39.5% (33.3%–45.8%) <0.001	39.5% (33.8%–45.2%) <0.001	2.00 (1.80–2.22) <0.001	2.00 (1.81–2.20) <0.001
Adolescents 15–19 years	700/910 (76.9%)	76.8%	309/867 (35.6%)	34.3%	41.4% (32.8%–49.9%) <0.001	39.9% (32.1%–47.8%) <0.001	2.24 (1.85–2.71) <0.001	2.18 (1.83–2.60) <0.001
HIV testing in the last 12 months								
Adults ≥15 years	3,363/3,960 (84.9%)	84.7%	2,574/3,920 (65.7%)	65.4%	19.3% (14.6%–24.0%) <0.001	19.5% (15.0%–24.0%) <0.001	1.30 (1.22–1.38) <0.001	1.30 (1.22–1.38) <0.001
Adolescents 15–19 years	737/910 (81.0%)	80.9%	497/867 (57.3%)	57.1%	22.5% (13.5%–31.6%) <0.001	21.3% (13.2%–29.5%) <0.001	1.42 (1.22–1.64) <0.001	1.39 (1.22–1.60) <0.001
Adults ≥40 years	940/1,166 (80.6%)	79.8%	587/1,111 (52.8%)	51.5%	27.7% (20.3%–35.1%) <0.001	27.8% (20.6%–35.0%) <0.001	1.55 (1.36–1.76) <0.001	1.55 (1.37–1.76) <0.001
Men	1,277/1,577 (81.0%)	80.8%	864/1,495 (57.8%)	57.1%	23.7% (18.0%–29.5%) <0.001	23.1% (17.8%–28.4%) <0.001	1.42 (1.30–1.54) <0.001	1.40 (1.3–1.51) <0.001

GM, geometric mean (of cluster-level proportions); HIVST, HIV self-testing; SOC, standard of care.

* Analysis adjusted for sex, age group, literacy, religion, ethnicity, and health status. Analysis among adolescents defines levels of age group as 16–17 years and 18–19 years. Analysis among adults ≥40 years defines levels of age group as 40–49 years and ≥50 years. Analysis among men adjusts for the same covariates except for sex.

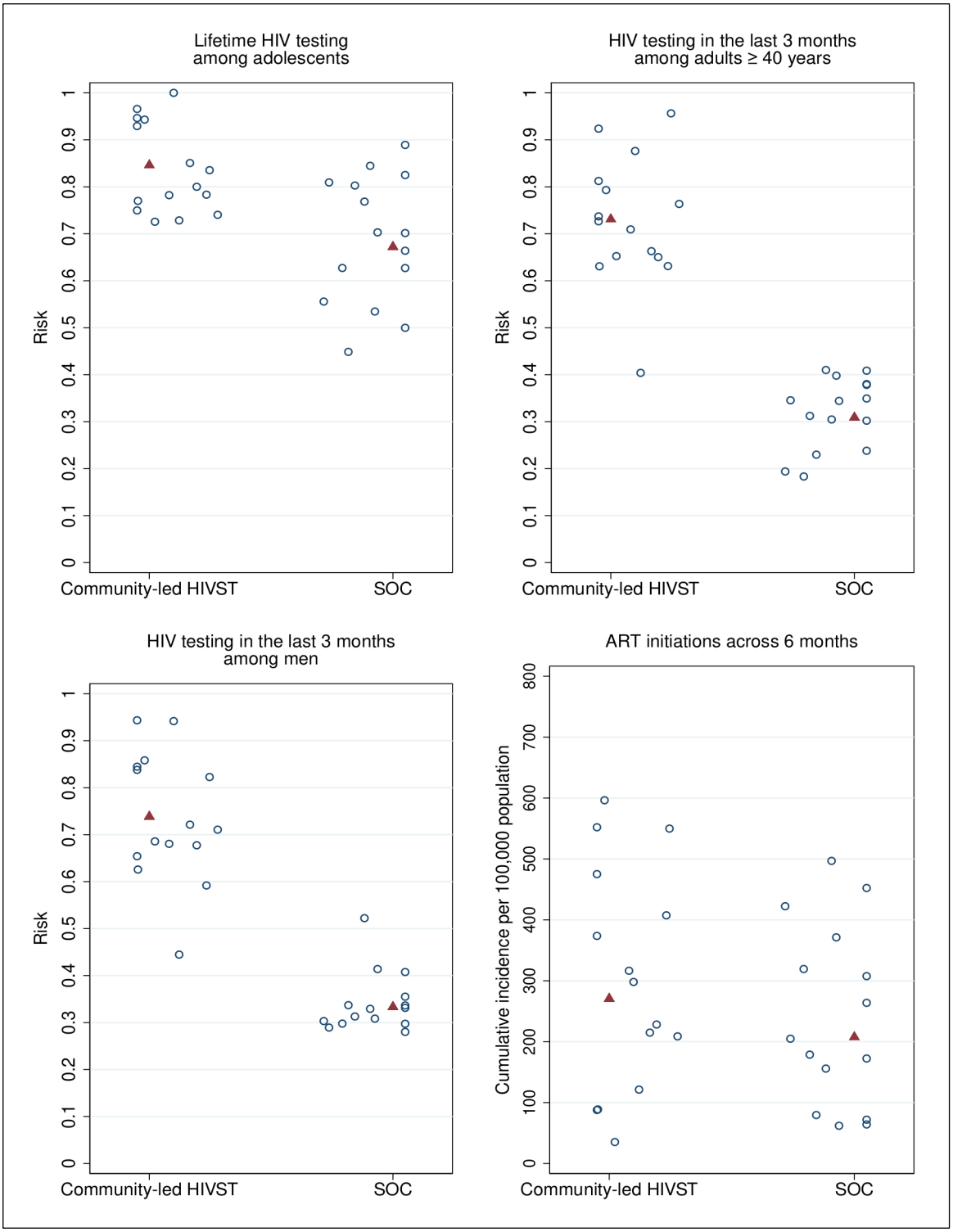
† *N* = 5806, with 5 missing values. Defined as individuals who have mutually disclosed with a current sexual partner their results from a negative test in the last 12 months or a positive test ever.

Supplementary Table 4.B. Costs of the community-led HIV self-testing intervention

	Community-led HIVST
Total costs (2018 US$)	138624
Outcomes *	
Number of HIVST kits distributed	24316
Number of HIV positives identified	576
Number of new HIV positives identified	230
Number of HIV positives identified not on treatment	296
Unit costs	
Cost per HIVST kit distributed (2018 US$)	5.70
Cost per HIV positive identified (2018 US$)	241
Cost per new HIV positive identified (2018 US$)	602
Cost per HIV positive identified not on treatment (2018 US$)	468

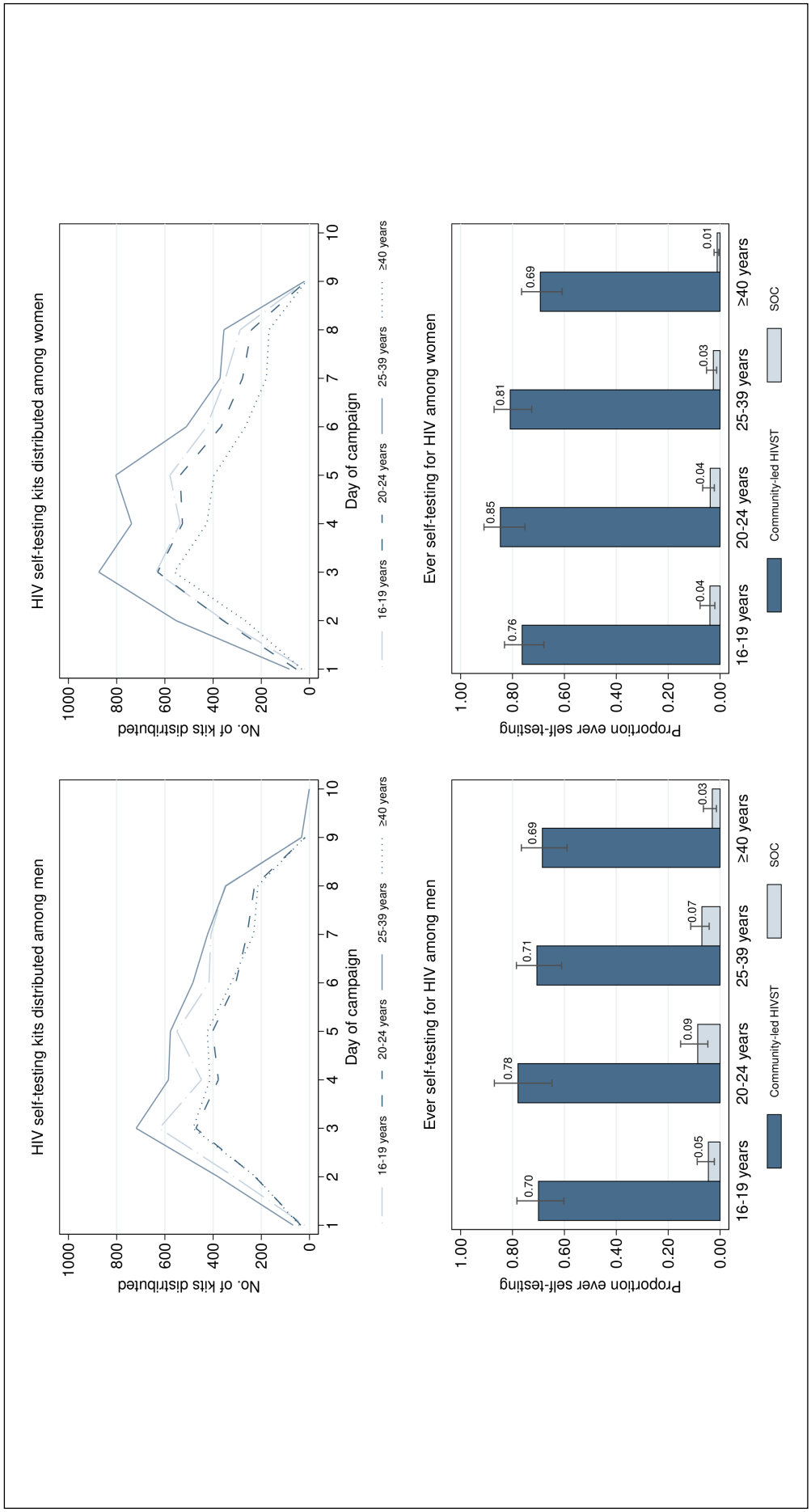
HIVST, HIV self-testing.
* Of 2,956 self-testers in the community-led HIVST arm, 2.4% (*n* = 70) were HIV positive, 0.9% (*n* = 28) were newly HIV positive, and 1.2% (*n* = 36) were previously diagnosed and not on treatment.

Supplementary Figure 4.A. Cluster risks for primary and secondary outcomes



ART, antiretroviral therapy; HIVST, HIV self-testing; SOC, standard of care. Comparison of cluster risks for primary and secondary outcomes by study arm, with blue circles indicating cluster risks and red triangles indicating geometric means of cluster risks.

Supplementary Figure 4.B. Exposure and uptake of the community-led HIV self-testing intervention by sex and age group



HIVST, HIV self-testing; SOC, standard of care. Top graphs indicate the number of HIVST kits distributed across the campaign period of the community-led HIVST intervention. Bottom graphs indicate the proportion ever self-testing and 95% CI adjusted for clustering following the community-led HIVST intervention. Data are stratified by study arm, sex, and age group.

Chapter 5.
Economic evaluation

3.3. Summary

This chapter includes Paper 4, “Pragmatic economic evaluation of community-led delivery of HIV self-testing in Malawi”. The paper addresses Objective 3 by using the cluster-randomised trial of community-led HIV self-testing (Chapters 3 and 4) as a vehicle for economic evaluation. The paper describes the design of the economic evaluation, which uses a trial-based approach for individual-level data. The paper then reports the incremental costs and effects between study arms and the incremental cost per additional person tested HIV positive. Uncertainty was also investigated.

The paper was published in 2021 in BMJ Global Health.

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SECTION A – Student Details

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Thesis Title	Evaluation of community-led delivery of HIV self-testing		
Primary Supervisor	Prof. Fern Terris-Prestholt		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	BMJ Global Health		
When was the work published?	2021		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	Not applicable		
Have you retained the copyright for the work?*	Yes	Was the work subject to academic peer review?	Yes

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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I led the conceptualisation and design of the study. I supervised implementation of the study, including procedures for the intervention and evaluation, and conducted the statistical and cost analysis. I also wrote the first draft of the manuscript. Co-authors contributed to the study conceptualisation and design and study implementation as well as read and approved the final manuscript.

SECTION E

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Date	2nd April 2023

Pragmatic economic evaluation of community-led delivery of HIV self-testing in Malawi

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Abstract

Introduction

Community-based strategies can extend coverage of HIV testing services (HTS) and diagnose HIV at earlier stages of infection but can be costly to implement. We evaluated the costs and effects of community-led delivery of HIV self-testing (HIVST) in Mangochi District, Malawi.

Methods

This economic evaluation was based within a pragmatic cluster-randomised trial of 30 group village heads and their catchment areas comparing the community-led HIVST intervention in addition to the standard of care (SOC) versus the SOC alone. The intervention involved mobilising community health groups to lead 7-day HIVST campaigns including distribution of HIVST kits. The SOC included facility-based HTS. Primary costings estimated economic costs of the intervention and SOC from the provider perspective, with costs annualised and measured in 2018 US Dollars. A post-intervention survey captured individual-level costs, which were valued by combining data on testing and self-testing events with unit costs from primary costings, and outcomes. The incremental cost per additional person tested HIV positive and associated uncertainty were estimated.

Results

Overall, the community-led HIVST intervention costed $138,624 or $5.70 per HIVST kit, with test kits and personnel the main contributing costs. The SOC costed $263,400 or $4.57 per test. Individual-level costs were higher in the community-led HIVST arm than the SOC arm (adjusted mean difference $3.77, 95% CI $2.44 to $5.10; $p < 0.001$) due to repeat testing, specifically HIVST uptake among individuals who recently tested at health facilities. Individual-level outcomes for HIV testing positivity varied based on adjustment for previous diagnosis. The incremental cost per person tested HIV positive was $324 but increased to $1,312 and $985 when accounting for previously diagnosed self-testers or self-testers on treatment, respectively. The intervention demonstrated low probability of cost-effectiveness against a plausible willingness-to-pay value of $315, with testing positivity a key determinant.

Conclusions

Community-led HIVST can provide testing at a low additional unit cost. However, introduction of community-led HIVST was not likely to be cost-effective, especially in contexts with low prevalence of undiagnosed HIV.

Introduction

Expanding access to HIV testing services (HTS) is important for early diagnosis to reduce HIV-related morbidity and mortality and prevent transmission [1]. In 2018, approximately 1.7 million people were newly infected, with 800 000 new cases in southern and eastern Africa [2]. Almost one-fifth of people living with HIV were unaware of their status [2]. Demand and supply-side barriers to conventional facility-based HTS have resulted in poorer knowledge of status among certain population subgroups, hindering achievement of elimination goals [3-5].

Aimed at addressing barriers to access, community-based strategies can extend coverage of HTS and diagnose HIV at earlier stages of infection but can be costly to implement [6]. Meeting and maintaining high awareness of status is dependent on identifying sustainable approaches for providing HTS beyond health facilities, especially with declining global funding for community health programmes [7]. Moreover, as countries successfully scale-up testing and treatment services, the cost per new diagnosis is increasing [8]. To remain cost-effective, community-based HTS must further minimise costs and maximise the proportion diagnosed, treated, or linked to prevention [8].

Community-led approaches involve engaging underserved communities in leading disease prevention and management [9-12]. Community participation in health programmes has been shown to improve health behaviours and outcomes and achieve gains in coverage and efficiency [13-15]. HIV self-testing (HIVST), which is recommended as an additional strategy to reach underserved populations [16], could be introduced within a community-led framework to enable direct provision of HTS by communities and improve the coverage, efficiency, and sustainability of community programmes [17, 18]. In this study, we evaluated the costs and effects of community-led delivery of HIVST within a pragmatic cluster-randomised trial comparing the community-led HIVST intervention in addition to the standard of care (SOC) versus the SOC alone.

Methods

Trial design, setting, and participants

We conducted an economic evaluation of community-led delivery of HIVST using individual-level data on costs and effects generated from a cluster-randomised trial in Mangochi District, Malawi (**Supplementary Text 5.A**). Clusters, defined as group village heads and their catchment areas, were identified from communities served by five government primary health centres in a high HIV-prevalence district [19]. Thirty clusters were randomised 1:1 to the community-led HIVST intervention in addition to the SOC or the SOC alone, which includes facility-based HTS. The aim of the trial was to determine whether the intervention increased the proportion of the population who tested for HIV, especially among subgroups with high prevalence of undiagnosed HIV,

including adolescents, older adults, and men. The trial protocol and analysis are reported separately [20, 21].

The trial was conducted through the Unitaid/Population Services International (PSI) HIV Self-Testing Africa Initiative (STAR) (http://hivstar.lshtm.ac.uk/). The study team included PSI Malawi, the Malawi-Liverpool-Wellcome Trust Clinical Research Programme, and the Ministry of Health.

Procedures

The community-led HIVST intervention involved mobilising established community health groups to lead the design and implementation of HIVST campaigns. Established groups included community health action groups, who deliver basic health services with government community health workers (CHWs) at group village head level, and community volunteers, including village health committees, who oversee service provision at village level.

The intervention was delivered in groups of two-to-three clusters every 14 days and consisted of three main components: participatory workshops, trainings, and HIVST campaigns. Community health action groups and CHWs were invited to a 2-day participatory workshop facilitated by the study team. To inform the design of an HIVST campaign in their respective areas, participants identified drivers of HIV, available services and barriers to access, and underserved subgroups. Participants then determined how the campaign would be implemented, including plans for distribution of HIVST kits, support for linkage to routine services, and demand creation for HIVST. Afterwards, community volunteers attended 2-day trainings on how to support HIVST use, interpretation, and linkage to routine services. Volunteers were also trained in communicating prevention messages, managing social harms, handling and storing kits, and collecting data.

Community volunteers then delivered 7-day HIVST campaigns under the supervision of community health action groups and CHWs. Implementation was based on strategies outlined by each cluster during participatory workshops. Inputs provided by the study team included the OraQuick HIV Self-Test (Orasure Technologies), communications and instructional materials, data collection tools, and a nationally standardised gratuity of MWK 7000 (US$10) per volunteer. Cluster residents aged 15 years and older were eligible to take an HIVST kit for themselves and an additional kit for secondary distribution.

The SOC, which was available in both study arms, included HTS provided by the Ministry of Health. HTS is primarily available at facility level through provider-initiated testing in outpatient services or client-initiated testing, or at community level through periodic outreach by health facilities. Lay health care workers perform testing using finger-prick rapid diagnostic tests based

on serial testing algorithms using Determine HIV-1/2 (Abbott) and Unigold HIV-1/2 (Trinity Biotech).

Cost measurement

Economic costs of the community-led HIVST intervention and the SOC were estimated from the provider perspective using global costing guidelines [22]. Costing methods are described in detail in **Supplementary Text 5.B**. Intervention costs were collected for the 5-month intervention period. Gross costing involved extracting financial data from expenditure records, with each expenditure item assigned to a cost ingredient and activity. Microcosting involved direct observations and interviews with the study team and community volunteers. Start-up costs included the costs of training and sensitisation and other costs incurred during the start-up period in the month prior to the intervention. Implementation costs included costs of capital and recurrent inputs, including building and storage, equipment, vehicles, personnel, supplies, and HIVST kits (unit price of $2.50). Shared costs were allocated using the volume of HIVST kits distributed, reported time use by staff, mileage from the central office to sites, and a weighted average of allocation factors. The value of resources donated by communities were captured but excluded from analysis due to incomplete data collection.

Costs for the SOC were retrospectively collected for a 12-month period. Using a microcosting approach, resources required to deliver HTS were identified for each cost category and valued through observations and interviews with facility personnel in the five health facilities. Unit prices were US$0.98 for Determine and US$1.97 for Unigold. Shared costs were allocated using the number of patients accessing HTS and reported time use by staff.

Start-up and capital costs were annualised using a 3% discount rate [22]. A useful life of 2 years was assumed for start-up costs, while the useful life for capital costs differed by input. Wastage assumptions also varied . Local costs were converted to 2018 US Dollars using the median exchange rate over the analysis period [23]. Overall and site-level unit costs for the intervention and the SOC were estimated, with programme and facility registers respectively providing the number of HIVST kits distributed and the number of persons tested for the costing periods. The number of persons self-tested was obtained by adjusting the number of kits distributed with the proportion of kit usage reported from the post-intervention survey for the outcome measurement.

Activity and site-specific unit costs were then combined with frequency of HIV testing and self-testing events in the last 12 months as reported in the survey, with individual-level provider costs estimated for each survey participant.

Outcome measurement

For the economic evaluation, we measured the effect of the community-led HIVST intervention on the proportion tested HIV positive, defined as individuals who self-reported a positive test in the last 12 months through the post-intervention survey. To measure new diagnoses, we alternatively defined the proportion tested positive as: (1) testing positive through the SOC or newly self-testing positive and (ii) testing positive through the SOC or self-testing positive and not on antiretroviral therapy (ART). We did not account for confirmatory testing following HIVST. Further, data on previous diagnosis were only collected for individuals who self-tested and not for individuals who tested through standard HTS. HIV testing in the last 12 months was also included as an outcome of interest. Outcomes were captured for a 12-month period since community-led HIVST was designed to be delivered as an annual intervention to a high HIV-prevalence population who might benefit from recurrent testing.

Outcomes were measured through a post-intervention survey administered 8 to 12 weeks after the start of the intervention in the community-led HIVST arm or corresponding dates in the SOC arm. Cluster residents were sampled to form the evaluation population. In each cluster, villages with at least 500 residents and located near the group head village were randomly selected for the survey. Households were then recruited in a clockwise spiral starting from a common location across selected villages, aiming to include at least 250 participants per cluster based on sample size calculations for the trial [20]. Residents aged 15 years and older were eligible to participate in the survey, with written informed consent or assent obtained. Participants provided information on sociodemographic background and prior experience with HIV services.

Statistical analysis

Incremental costs and effects were estimated using individual-level data from the post-intervention survey. Analysis used intention-to-treat and cluster-level methods appropriate for cluster-randomised trials with a small number of clusters [24]. To estimate the mean difference (MD) in costs, we used linear regression and included variables for sex, age group, and covariates showing imbalance between arms at individual level. Covariate-adjusted residuals comparing fitted and observed values were then summed for each cluster and compared by arm using a *t* test. Risk differences (RDs) for the proportion tested for HIV and tested HIV positive were also estimated using a cluster-level analysis, with logistic regression used at individual level to obtain covariate-adjusted summary values.

The incremental cost per additional person tested HIV positive was calculated as the ratio of adjusted incremental costs and adjusted incremental effects. Uncertainty was estimated using two-stage non-parametric bootstrap, whereby clusters were sampled in the first stage and individuals within clusters were sampled in the second stage, both with replacement [25-27]. A shrinkage correction was applied [25-27]. Incremental costs and incremental effects were calculated across 1000 bootstrap replicates and plotted on cost-effectiveness planes [28]. CIs were estimated using bias-corrected percentiles [28]. Cost-effectiveness acceptability curves were also generated from bootstrap replicates to illustrate probabilities for a range of willingness-to-pay values. Subgroup analyses were conducted to understand differences in individual-level costs and effects by sex. Statistical analysis used Stata version 14.0.

We estimated probabilities across alternative outcome definitions that the incremental cost per person tested HIV positive was below a willingness-to-pay threshold of $315. The threshold is based on a simulation study in Southern Africa, which showed that additional testing beyond the SOC was considered cost-effective if the cost per new diagnosis was below a threshold of 2018 US$315 and therefore strongly associated with cost per disability-adjusted life year (DALY) averted below a threshold of 2018 US$500 [8]. We aimed to improve comparability of our outcome to the threshold by adjusting for previous diagnosis among self-testers. Further, the threshold represents opportunity costs of reallocating resources within an HIV programme from other HIV-related activities to testing and relevant to national programmes dependent on international funding [8].

Deterministic sensitivity and scenario analysis

One-way deterministic sensitivity and scenario analysis assessed the impact of varying parameters on the mean cost per HIVST kit distributed and the incremental cost per person tested HIV positive. In sensitivity analysis, we varied cost assumptions, including the discount rate (none, 16%) and exchange rate (minimum, maximum) [23]. In scenario analysis, we varied inputs that were considered to be important cost determinants, including the price of HIVST kits from $0.98 (price of HIV rapid diagnostic tests) to $3.40 (unsubsidised price of HIVST kits) [29]. Further, we modelled real-world scenarios for routine implementation under the Ministry of Health by varying personnel costs (±10%), start-up costs (±10%), lifespan of start-up costs (1 year, 5 years) and number of kits distributed (±10%). Parameters were selected based on scenarios evaluated in earlier STAR studies in anticipation of scale-up [29]. We also assessed the impact of uncertainty using 95% CIs for the effect estimate. Lastly, we estimated best and worst-case scenarios for routine implementation by adjusting parameters that produced the lowest and highest values.

Results

The community-led HIVST intervention was delivered in 15 clusters between 5 October, 2018 to 17 January, 2019. HIVST campaigns were implemented in each cluster, with 157 community health action group members and 190 community volunteers distributing 24,316 HIVST kits. The post-intervention survey included 90.2% (3,960/4,388) and 89.2% (3,920/4,394) of listed residents in the community-led HIVST and SOC arms, respectively (**Supplementary Figure 5.A**). Across arms, response rates were lower among men (83.5%, 3,072/3,677) compared with women (94.2%, 4,808/5,105). Participant characteristics are summarised in **Supplementary Table A**, with differences between arms observed for literacy, religion, ethnicity, and self-reported health status.

Mean costs

The total provider cost of the community-led HIVST intervention was $138,624, which includes costs of the 5-month start-up and implementation period (**Table 5.1**). The proportion of start-up and capital costs were respectively 10.3% ($14,308) and 9.4% ($13,023). Recurrent costs accounted for 80.3% ($111,293) of the total cost, with the main contributing inputs including test kits (46.0%) followed by personnel (25.3%) and vehicle operation and maintenance (4.2%). The mean cost per HIVST kit was $5.70. Mean costs varied by cluster from $4.45 to $8.49, with lower costs achieved in clusters with higher volumes of kits distributed (**Supplementary Figure 5.B**). The mean cost per person self-tested was $5.73, which was estimated based on self-reported kit usage among survey participants who collected kits (99.6%, 3,128/3,142).

From January to December 2018, the total provider cost of the SOC was $263,400 (**Table 5.1**). Of total costs, capital costs were 3.0% ($7,887), while recurrent costs were 97.0% ($255,513). In contrast with the intervention, personnel (48.1%) contributed the largest proportion to costs followed by test kits (24.6%) and supplies (23.5%). The mean cost per test was $4.57, ranging from $2.90 to $6.41 by health facility.

Incremental costs

Based on the frequency of HIV testing and self-testing events reported in the survey, participants in the community-led HIVST arm had a mean number of 1.66 tests in the last 12 months (**Supplementary Figure 5.C**), providing a mean annual cost per person of $9.06 (**Table 5.2**). In the SOC arm, the mean number of recent tests was 1.17, with a mean annual cost per person of $5.52. The adjusted MD was $3.77 (95% CI $2.44 to $5.10; $p < 0.001$). Among men, the mean annual cost per person was $8.04 and $4.68 in the community-led HIVST and SOC arms, respectively. Mean annual costs were higher for women than men in both the community-led HIVST ($9.74) and SOC ($6.04) arms, reflecting higher frequency of testing among women. The

Table 5.1. Total and average unit costs of the community-led HIV self-testing intervention and standard of care

	Community-led HIVST intervention		SOC	
	Costs (2018 US$)	Col. %	Costs (2018 US$)	Col. %
Start-up costs	**$14,308**	**10.3%**		
Training	$3,843	2.8%	-	-
Sensitisation	$891	0.6%	-	-
Start-up other	$9,573	6.9%	-	-
Capital costs	**$13,023**	**9.4%**	**$7,887**	**3.0%**
Building and storage	$4,907	3.5%	$2,154	0.8%
Equipment	$778	0.6%	$1,722	0.7%
Vehicles	$7,338	5.3%	$4,012	1.5%
Recurrent costs	**$111,293**	**80.3%**	**$255,513**	**97.0%**
Personnel and per diems	$35,111	25.3%	$126,805	48.1%
Supplies	$1,931	1.4%	$61,803	23.5%
Test kits	$63,830	46.0%	$64,802	24.6%
Vehicle operation, maintenance, and transportation	$5,807	4.2%	$43	0.0%
Building operation and maintenance	$502	0.4%	$689	0.3%
Recurrent training	-	-	$1,081	0.4%
Waste management	-	-	$290	0.1%
Other recurrent	$4,113	3.0%	-	-
Total costs	**$138,624**		**$263,400**	
Number of HIVST kits	24,316		NA	
Number of tests*	24,219		57,695	
Mean cost per HIVST kit	$5.70		NA	
Mean cost per test	$5.73		$4.57	

HIVST, HIV self-testing; NA, not applicable; SOC, standard of care. Costs were collected from September 2018 to January 2019 for the community-led HIVST intervention and from January 2018 to December 2018 for the SOC.
* Number of persons tested for community-led HIVST was estimated based on the number of HIVST kits distributed and self-reported usage of HIVST kits from the post-intervention survey (99.6%, 3,128/3,142).

MD in costs was similar among men (adjusted MD 3.57, 95% CI 2.33 to 4.81; $p < 0.001$) and women (adjusted MD 3.91, 95% CI 2.49 to 5.32; $p < 0.001$; p-value for interaction; $p = 0.25$).

Incremental effects

HIV testing in the last 12 months was higher in the community-led HIVST arm (84.9%, 3,363/3,960) compared with the SOC arm (65.7%, 2,574/3,920), with adjusted RD of 19.5% (95% CI 15.0% to 24.0%; **Table 5.2**). The intervention effect was greater among men (adjusted RD 23.1%, 95% CI 17.8% to 28.4%; p < 0.001) than women (adjusted RD 17.2%, 95% CI 12.7% to 21.8%; $p < 0.001$; p-value for interaction = 0.002).

HIV testing positivity was also higher in the community-led HIVST arm (2.6%, 104/3,960) than the SOC arm (1.7%, 67/3,920; adjusted RD 1.2%, 95% CI 0.3% to 2.0%; $p = 0.008$), with a more pronounced difference among women (adjusted RD 1.6%, 95% CI 0.5% to 2.6%; $p = 0.005$) than men (adjusted RD 0.5%, 95% CI -0.5% to 1.5%; $p = 0.29$; p-value for interaction = 0.06; **Table 5.2**). However, differences between arms were not observed when the outcome definition excluded

Table 5.2. Incremental costs and effects of community-led HIV self-testing

	Community-led HIVST arm Mean or % (*n*/*N*)	SOC arm Mean or % (*n*/*N*)	Unadjusted mean or risk difference (95% CI) *p*-value	Adjusted mean or risk difference (95% CI)* *p*-value
Overall				
Annual provider costs (2018 US$)	9.06	5.52	3.66 (2.31–5.01) <0.001	3.77 (2.44–5.10) <0.001
Tested HIV positive	2.6% (104/3,960)	1.7% (67/3,920)	1.0% (0.1–1.8%) 0.03	1.2% (0.3–2.0%) 0.008
Excluding previously diagnosed self-testers†	1.7% (69/3,960)	1.6% (64/3,920)	0.1% (-0.6–0.9%) 0.68	0.3% (-0.4–1.0%) 0.42
Excluding self-testers on treatment‡	1.8% (73/3,960)	1.6% (64/3,920)	0.2% (-0.4–0.9%) 0.48	0.4% (-0.3–1.1%) 0.27
Men§				
Annual provider costs (2018 US$)	8.04	4.68	3.61 (2.36–4.86) <0.001	3.57 (2.33–4.81) <0.001
Tested HIV positive	1.5% (23/1,577)	1.1% (17/1,495)	0.4% (-0.5–1.4%) 0.34	0.5% (-0.5–1.5%) 0.29
Women§				
Annual provider costs (2018 US$)	9.74	6.04	3.74 (2.25–5.23) <0.001	3.91 (2.49–5.32) <0.001
Tested HIV positive	3.4% (81/2,383)	2.1% (50/2,425)	1.4% (0.3–2.5%) 0.02	1.6% (0.5–2.6%) 0.005

HIVST, HIV self-testing; SOC, standard of care.
* Analysis adjusted for sex, age group, literacy, religion, ethnicity, and health status. Subgroup analysis adjusts for the same covariates except for sex.
† Defined as testing positive through the SOC or newly self-testing positive,
‡ Defined as testing positive through the SOC or self-testing positive and not on treatment.
§ *p*-Value for interaction by sex. Provider costs: $p = 0.25$. Tested HIV positive: $p = 0.06$.

previously diagnosed self-testers (adjusted RD 0.3%, 95% CI -0.4% to 1.0%; p = 0.42) or self-testers on treatment (adjusted RD 0.4%, 95% CI -0.3% to 1.1%; p = 0.27).

Incremental cost per person tested HIV positive

The incremental cost per person tested was $19.35 and lower for men ($15.44) than women ($22.67). The incremental cost per person tested HIV positive was $324, and higher for men ($716) compared with women ($246) due to lower testing positivity (**Supplementary Figure 5.D**). The incremental cost per person tested positive was $1,312 and $985 when previously diagnosed self-testers or self-testers on treatment were respectively excluded.

Bias-corrected confidence intervals are presented with cost-effectiveness planes in **Figure 5.1**. The joint distribution of the difference in costs and difference in the proportion tested positive fell in the upper left and right quadrants of the cost-effectiveness plane, meaning incurred costs could potentially result in zero or negative benefits. Cost-effectiveness acceptability curves are illustrated in **Figure 5.2**. With respect to a threshold of $315 per positive test, cost-effectiveness probabilities varied depending on the outcome definition: 45.0% for testing positive, 3.6% when excluding previously diagnosed self-testers, and 3.5% when excluding self-testers on treatment.

Deterministic sensitivity and scenario analysis

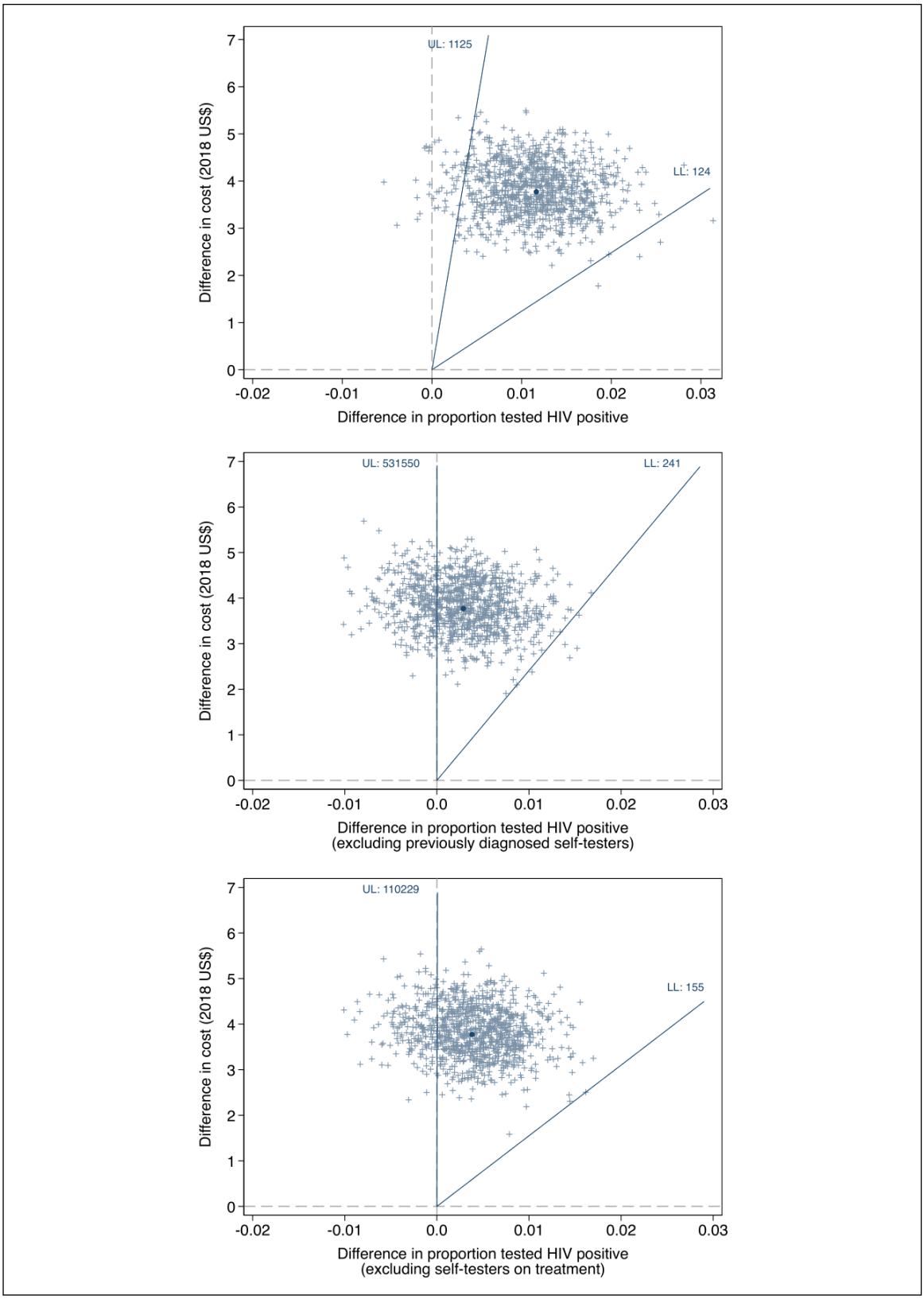
One-way sensitivity and scenario analysis for the mean cost per HIVST kit and the incremental cost per person tested HIV positive are presented in **Figure 5.3**. Varying the price of the kit from $0.98 to $3.40 led to the largest changes in average costs, from $4.09 to $6.70. Best and worst-case scenarios for routine practice, which varied personnel costs, start-up costs, lifespan of start-up costs, and the volume of kits, yielded average costs ranging from $3.57 to $7.56. Results remained relatively robust to variations in sensitivity analysis.

Uncertainty associated with testing positivity led to the largest changes in the incremental cost per person tested positive, ranging from $184 to $1,141 based on 95% CIs for the effect estimate. In best and worst-case scenarios modelling routine implementation and uncertainty in the effect estimate, the incremental cost per person tested positive varied from $105 to $1,614.

Discussion

We conducted an economic evaluation within a cluster- randomised trial of community-led delivery of 7-day HIVST campaigns in Malawi. The community-led HIVST intervention showed relatively

Figure 5.1. Cost-effectiveness plane for community-led HIV self-testing



LL, lower limit; UL upper limit. Cost-effectiveness plane of adding community-led HIVST to the standard of care. The incremental cost per person tested HIV positive for alternative outcome definitions are illustrated. Each point represents the adjusted mean difference in cost (incremental cost) and adjusted risk difference in the proportion tested HIV positive (incremental effect) for one bootstrap replicate. The dark blue circle indicates the incremental cost per person tested positive and the dark blue line indicates the bootstrap confidence intervals using the bias-corrected percentile method.

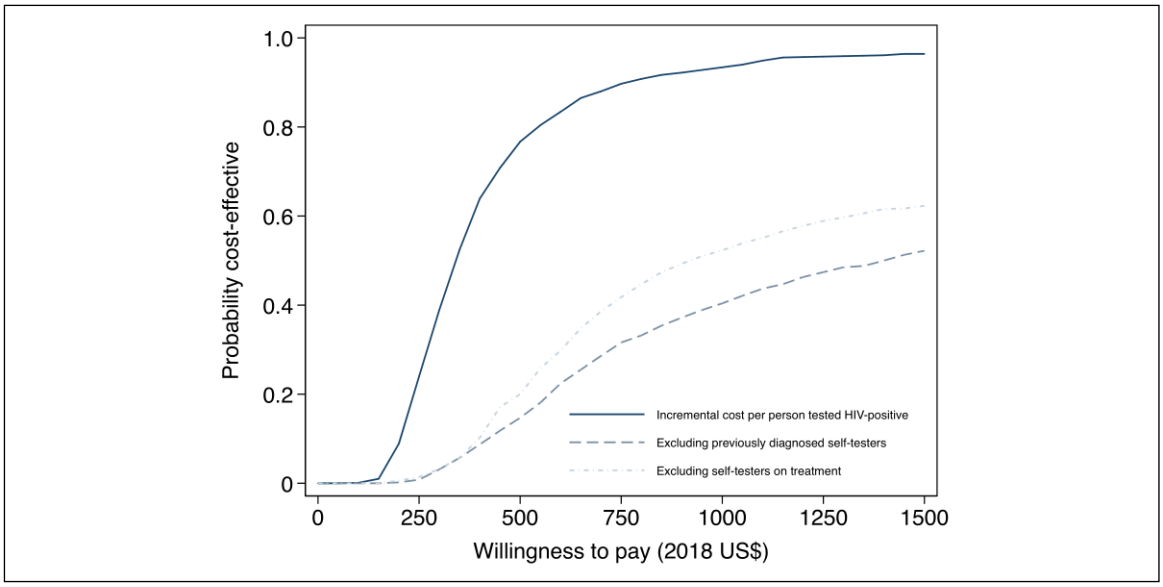
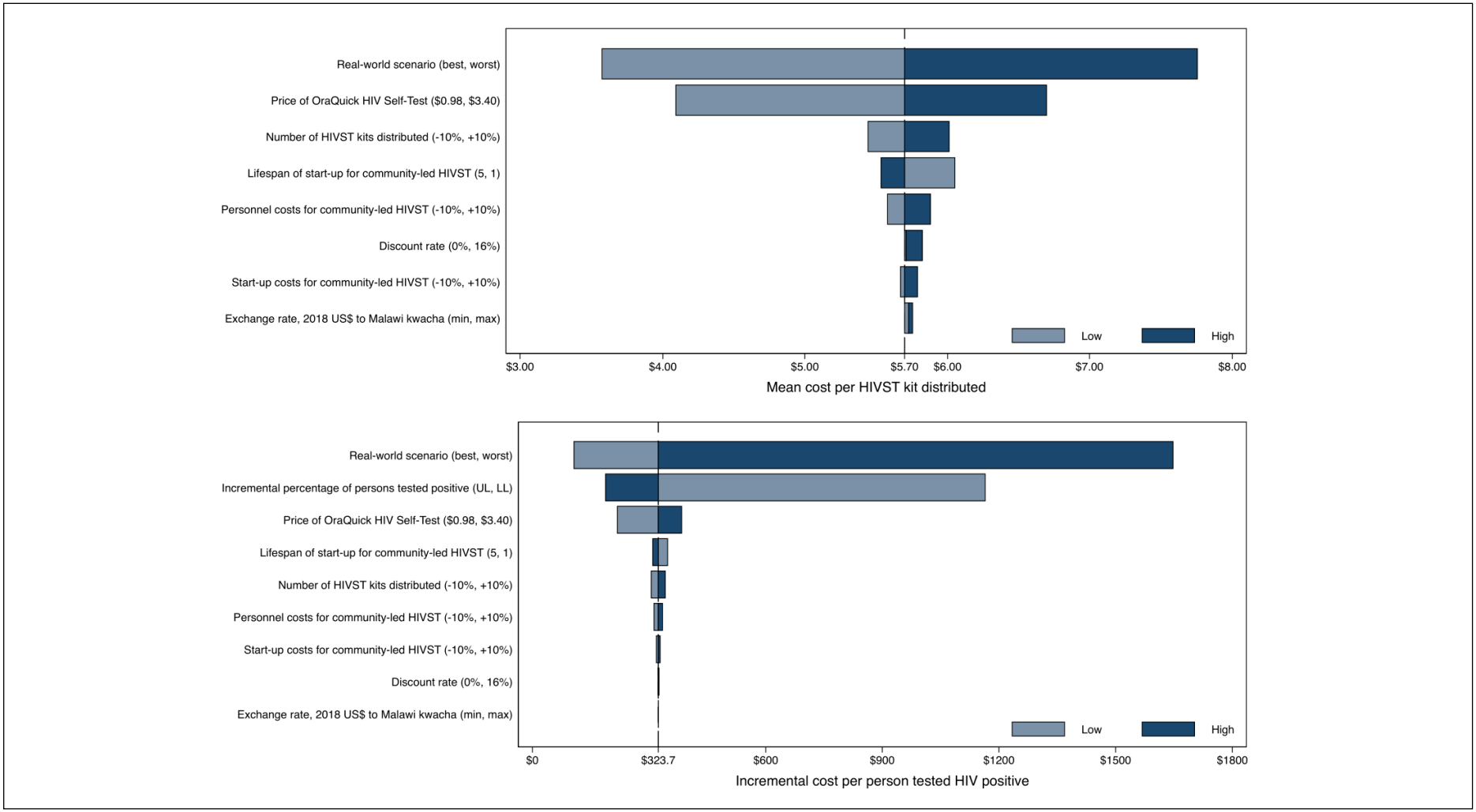


Figure 5.2. Cost-effectiveness acceptability curves for community-led HIVST by outcome.
Cost-effectiveness acceptability curves of adding community-led HIV self-testing to the standard of care. Cost-effectiveness probabilities for the incremental cost per person tested HIV positive are plotted for alternative outcome definitions across a range of willingness-to-pay values.

low average cost of $5.70 per HIVST kit distributed, with test kits and personnel the main contributing costs. Individual-level annual provider costs were higher in the community-led HIVST arm than the SOC arm due to repeat testing, specifically HIVST uptake among individuals who recently tested at health facilities. The intervention effect on HIV testing positivity varied based on previous diagnosis. The incremental cost per person tested HIV positive was $324 but increased to $1,312 and $985 when adjusting for previously diagnosed self-testers or self-testers on treatment, respectively. The addition of the intervention to the SOC demonstrated low probability of being cost-effective, with testing positivity a key determinant. Despite providing testing at a low additional unit cost, community-led HIVST was not likely to be a cost-effective strategy, especially in contexts with low prevalence of undiagnosed HIV.

Universal testing and treatment can be used to support reductions in incidence in the general population [1], but financial sustainability remains a limiting factor [7]. Our cost analysis showed a mean cost of $5.70 per kit through the intervention and $4.57 per test through the SOC. The largest contributors to intervention costs were test kits and personnel. SOC costs were driven by personnel followed by test kits and supplies. Differences in resource use reflect the higher price of HIVST kits but lower proportion of personnel costs from campaign-style implementation by community volunteers. Costs of supplies was also higher in the SOC due to recurrent use of medical supplies alongside HIV RDTs. The average cost of HIVST implementation reported in this study is lower than average costs previously reported for door-to-door distribution of kits in Malawi, both in rural and urban settings [29, 30]. Lower costs are likely influenced by the high volume of

Figure 5.3. Tornado diagram of one-way deterministic sensitivity and scenario analysis.



LL, lower limit; UL upper limit. Tornado diagram illustrating changes in the mean cost per HIV self-testing kit and incremental cost per person tested HIV positive based on variations to inputs. Light blue bars represent changes at minimum input values, while dark blue bars represent changes at maximum input values.

kits delivered within a short period of time in addition to pragmatic implementation through established community health groups, who are routinely activated to support basic health service provision.

Our findings highlight potential areas for cost reductions. Personnel salaries and per diems contributed substantially to costs and could potentially be reduced under routine implementation. Packaging HIVST with other health interventions could also reduce the ratio of fixed costs to variable costs through economies of scope. Community-led HIVST is also likely to realise economies of scale as unit costs decrease with increasing number of sites and kits distributed. Further, recurrent implementation could produce efficiency gains as community health groups become more familiar with HIVST and start-up costs are spread over a longer period of time. Lastly, minimising retesting among recently tested individuals or reducing the price of HIVST kits could additionally lower costs, with kits accounting for the majority of costs.

A community-led approach has often been promoted as a mechanism for integrating context-specific knowledge and resources in the delivery of health programmes [17, 18]. Implementation through community-driven systems could expand the pool of available resources for service provision and improve efficiency [17, 31]. However, there is a risk of shifting economic costs down to resource-constrained communities. In a multi-country study, community-led multi-disease campaigns were less costly than the SOC, but higher median opportunity costs were reported by community volunteers [31]. In our analysis, costs incurred by communities were not captured due to incomplete data collection, though community contributions observed by the study were relatively nominal and included donated building space, equipment, and transportation. Opportunity costs were also captured through gratuity received by community volunteers.

Accounting for retesting among previously diagnosed self-testers or self-testers on treatment yielded an incremental cost per person tested HIV positive of $1,312 and $985, respectively. Community volunteers were trained to advise against self-testing on ART to avoid false negative results. However, volunteers did not discourage self-testing among recently tested individuals or individuals known to be positive but not on treatment. High prevalence of retesting among known HIV-positive individuals has previously been reported, with retesting motivated by lost to treatment follow-up [32]. We also reported low substitution, with instances of HIVST uptake among recently tested individuals. Reasons reported for retesting among HIV-negative individuals include to monitor status, respond to risk exposure, and facilitate partner testing [33-35]. Pressure to self-test could also lead to unnecessary retesting but was reported to be limited in the main trial [21]. Targeting of subgroups currently underserved by facility-based HTS could improve rational use and reduce costs, with variable costs associated with HIVST kits higher than fixed costs. Equally,

targeted distribution could heighten stigma around testing and reduce uptake among priority subgroups. Under such conditions, wider implementation might be required despite losses in efficiency.

Introduction of community-led HIVST had 4% to 45% probability of being cost-effective at a threshold of $315 per positive test. We used testing positivity as an outcome but did not distinguish between newly and previously identified people living with HIV. We aimed to improve comparability with the threshold, which is based on the cost per new diagnosis, by adjusting for previously diagnosed self-testers or self-testers on treatment. However, we did not collect data on previous diagnosis among individuals who tested through standard HTS and may have underestimated known HIV-positive status in the SOC arm [33]. We also did not account for confirmatory testing following HIVST and may have overestimated diagnosis in the community-led HIVST arm. Further, we used a willingness-to-pay threshold recommended for decision making within testing programmes, with thresholds as low as $150 per new diagnosis suggested when considering resource allocation across the health care sector [8].

Cost-effectiveness of community-based testing is dependent on minimising implementation costs and maximising uptake among populations with high prevalence of undiagnosed HIV [36, 37]. Using a community-led approach, we aimed to increase efficiency through pragmatic and short-term implementation and outcomes through community participation. Mobilising community health groups beyond an annual period may improve probability of cost-effectiveness, given the low impact on testing positivity reported in this study. Districts with more substantial prevalence of undiagnosed HIV should also be targeted, though diminishing returns to testing will continue to influence cost-effectiveness as countries near global elimination targets. Additional health benefits could also potentially be gained by delivering HIVST within a broader package of multi-disease programmes at community level.

The main strength of our study is the use of a cluster-randomised trial as an instrument for economic evaluation, with our analysis based on individual-level data for costs and effects. Individual-level costs were estimated using the frequency of testing and self-testing events, providing insights into retesting behaviours and potential opportunities for efficiency gains. In our analysis, we also accounted for the clustered design, correlation between costs and effects, and covariate adjustment. Further, we included findings from a pragmatic intervention implemented through established community health groups. The intervention was aimed at replicating real-world implementation, underpinning the generalisability of our costs to settings in sub-Saharan Africa with similar community health systems. However, our findings on cost-effectiveness were highly sensitive to variations in testing positivity.

The study, however, has limitations. First, costs of the intervention were collected from the perspective of a non-governmental organisation rather than the health system. However, we aimed to replicate scenarios for routine implementation by varying start-up and personnel costs and the volume of kits distributed. We also did not account for costs incurred by patients and communities, though this was expected to be very low [30]. Second, individual-level costs and effects were based on self-report and subject to recall or social desirability bias, with potential for overreporting of testing in the community-led HIVST arm following exposure to the intervention and underreporting of testing positivity across study arms. Third, trial-based economic evaluations have limitations, with costs and effects measured within a controlled setting and limited to the trial period. Fourth, our outcome was restricted to testing positivity. We aimed to adjust our outcome for known HIV-positive individuals to improve comparability with the willingness-to-pay threshold based on the cost per new diagnosis. However, we were unable to account for previous diagnosis under standard HTS or confirmatory testing following HIVST. We also did not evaluate treatment or prevention outcomes or generic health endpoints. Finally, we did not consider non-health benefits associated with community-led programmes.

Community-led delivery of 7-day HIVST campaigns provided testing at a low additional unit cost. However, HIVST uptake among recently tested individuals was prevalent, with repeat testing contributing to substantially higher individual-level annual costs in the community-led HIVST arm compared with the SOC arm. The intervention effect on testing positivity varied. As a result, adding community-led HIVST to the SOC was not likely to be cost-effective, especially in contexts with low prevalence of undiagnosed HIV. To maximise the value of community-led HIVST, we recommend targeted delivery to settings and populations with more substantial prevalence of undiagnosed HIV.

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Supplementary materials

Contents

Supplementary Text 5.A. CHEERS checklist of items to include when reporting economic evaluations of health interventions

Section/Item	Item #	Recommendation	Page #
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared.	Title
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	Abstract
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study.	Introduction
		Present the study question and its relevance for health policy or practice decisions.	Introduction
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	Methods: Trial design, setting, and participants
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	Methods: Trial design, setting, and participants
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	Methods: Cost measurement
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	Methods: Procedures
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	Methods: Cost measurement Methods: Outcome measurement
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	Methods: Cost measurement
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	Methods: Outcome measurement
Measurement of effectiveness	11a	*Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	Methods: Trial design, setting, and participants Procedures
	11b	*Synthesis-based estimates*: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	Not applicable
Measurement and valuation of preference based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	Not applicable
Estimating resources and costs	13a	*Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate opportunity costs.	Methods: Cost measurement Supplementary Text B
	13b	*Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	Not applicable
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	Methods: Cost measurement Results Supplementary Text B

Section/Item	Item #	Recommendation	Page #
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	Not applicable
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	Not applicable
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	Methods: Statistical analysis Methods: Deterministic sensitivity and scenario analysis
Results			
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	Not applicable
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	Results Table 1 Table 2
Characterising uncertainty	20a	*Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).	Results Figure 1 Figure 2 Figure 3
	20b	*Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	Not applicable
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	Results Supplementary Figure B Supplementary Figure D
Discussion			
Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	Discussion

Supplementary Text 5.B. Methods for cost analysis

Community-led HIVST intervention

The community-led HIV self-testing (HIVST) intervention was delivered by Population Services International Malawi and the Malawi-Liverpool-Wellcome Trust Clinical Research Programme as part of a broader package of HIVST distribution models.

Economic costs of the intervention were estimated from the provider perspective. Financial data from expenditure records were supplemented with economic data from microcosting. Gross costing involved allocating each expenditure item to a cost category and activity. Microcosting involved direct observations and interviews with the study team and community volunteers.

Shared costs were allocated by activity using a factor for each cost category. Costs are reported in 2018 US Dollars, with local costs converted using the median exchange rate during the period of analysis[1]. The costing period was September 2018 to January 2019.

Community costs were excluded from the analysis due to incomplete data collection. Research costs, including piloting to inform the intervention design, were also excluded.

Start-up costs

Start-up costs included costs of training and sensitisation activities and costs incurred in the month prior to the intervention start, with the majority of development costs spent during this period.

Training activities included a 2-day participatory workshop with 157 community health action group members and an HIVST training with 190 community volunteers. A total of six pairs of workshops and trainings were administered in groups of two-to-three clusters. Costs associated with trainings included costs of venue hire, projector, staff per diem, participant sit-in allowances, office stationery, and food and drink. Common costs for training were allocated using the weighted average of allocation factors for other shared costs.

Sensitisation activities included entry meetings with the district health office, five primary health centres, and 15 group village heads, with costs incurred for participant sit-in allowances and staff per diem. Shared costs for sensitisation, including production of information, education, and communication materials, were allocated using the weighted average of allocation factors for other common costs. Other start-up costs included costs of personnel and transportation, which were also allocated using the weighted average of allocation factors.

[1] Bank of Malawi. Exchange Rates. [https://www.rbm.mw/Statistics/MajorRates/#].

Start-up costs were annualised over a 2-year period[2] and assumed a 3% discount rate[3].

Capital costs

Capital costs included building and storage, equipment, and vehicle-related costs.

Building and storage costs included common costs for rent and were allocated using the weighted average of allocation factors for shared costs. Shared equipment costs were similarly apportioned. Costs of backpacks were imputed for each volunteer (MWK 30,000; US$40). Vehicle costs included common costs for vehicle hire and were allocated using the proportion of miles from the central office to sites.

Capital costs, excluding costs of building or vehicle-related hire, were annualised over their useful life and assumed a 3% discount rate[3].

Recurrent costs

Recurrent costs included costs of personnel; supplies; HIVST kits; vehicle operation, maintenance, and transportation; building operation and maintenance; and other recurrent inputs.

Personnel costs included staff and consultant salaries, fringe, and per diem. Direct personnel included a program manager, program coordinator, training coordinators, monitoring and evaluation officers, field officers, and data clerks. Shared costs for direct and indirect personnel were allocated using the proportion of reported staff time stratified by salary grade, which was ascertained through a time use questionnaire. Gratuity for community health action group members and community volunteers was provided at MWK 7,000 (US$10) per volunteer.

Supplies costs included costs of t-shirts, data collection forms, and office stationery. Costs of t-shirts were imputed for each volunteer (MWK 4,000; US$5.50). Common costs for supplies were allocated using the proportion of HIVST kits distributed.

Costs of HIVST kits were estimated based on the unit price for the OraQuick HIV Self-Test (US$2.50), including purchase, freight, and estimated wastage, and the number of kits distributed. Wastage of 5% was based on the approximate number of kits provided to community health groups and the number of kits distributed.

Recurrent vehicle costs included costs of vehicle fuel, operation, and maintenance, with common costs allocated using the proportion of miles from the central office to sites. Recurrent building costs

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[2] Mangenah C, Mwenge L, Sande L, Ahmed N, d'Elbee M, Chiwawa P *et al*. Economic cost analysis of door-to-door community-based distribution of HIV self-test kits in Malawi, Zambia and Zimbabwe. *J Int AIDS Soc.* 2019; 22(Suppl 1):e25255.

[3] Vassall A, Sweeney S, Kahn J, Gomez GB, Bollinger L, Marseille E *et al*. Reference Case for Estimating the Costs of Global Health Services and Interventions. [https://ghcosting.org/pages/standards/reference_case].

included utilities and maintenance for office and warehouse buildings. Common costs for office-related buildings were allocated using the weighted average of allocation factors for shared costs, while common costs for warehouse-related buildings were allocated using the proportion of kits distributed.

Other recurrent inputs included communications, equipment repairs and maintenance, printing, postage and delivery, and miscellaneous fees. Shared costs for other recurrent inputs were allocated using the proportion of kits distributed.

Standard of care

The standard of care for HIV testing services was delivered by government primary health centres, with cost analysis undertaken from the provider perspective. Economic costs were obtained using an ingredients-based approach, whereby resources required to deliver HIV testing services were identified by cost category and valued based on their quantity and unit price. Direct observations and interviews were conducted with facility personnel in five health facilities.

Shared costs were allocated by activity using a factor for each cost category. Costs are reported in 2018 US Dollars. Local costs were converted using the median exchange rate during the period of analysis[4]. Data were retrospectively collected through direct observations and interviews with facility personnel for the period of January to December 2018.

Capital costs

Capital costs included building and storage, equipment, and vehicle-related costs. Building and storage costs were estimated based on the size of the space and quoted price per square metre. Equipment costs included costs of medical and office equipment used for core and HIV testing services, including tables, chairs, bins, and timers. Prices were obtained from account records or from Central Medical Stores databases[5]. Vehicle costs include costs of core vehicles based on the purchase price.

Shared costs for central inputs were allocated using the proportion of outpatients tested. Capital costs were annualised over their useful life. Capital costs assumed a 3% discount rate[6].

Recurrent costs

Recurrent costs included costs of personnel; supplies; HIV rapid diagnostic tests (RDT); vehicle operation, maintenance, and transportation; building operation and maintenance; recurrent training; and waste management.

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[4] Bank of Malawi. Exchange Rates. [https://www.rbm.mw/Statistics/MajorRates/#].
[5] The Central Medical Stores Trust. Catalogue. [http://www.cmst.mw/catalogue/].
[6] Vassall A, Sweeney S, Kahn J, Gomez GB, Bollinger L, Marseille E *et al*. Reference Case for Estimating the Costs of Global Health Services and Interventions. [https://ghcosting.org/pages/standards/reference_case].

Personnel included staff salaries, including HIV diagnostic assistants and health surveillance assistants.

Supplies costs included costs of medical and office supplies, including alcohol spirit, bin liners, cotton wool, disposable aprons, disposable gloves, hand soap or sanitiser, data collection forms, and office stationery. Prices not available in account records were obtained from Central Medical Stores[7]. Costs of HIV RDTs were estimated based on the unit price for Determine HIV-1/2 (US$0.98) and Unigold HIV-1/2 (US$1.97) and the number of persons tested[8]. Supplies and HIV RDTs were assumed to have supply chain costs and wastage of 10%[9].

Recurrent vehicle costs included costs of vehicle fuel for community-based services, which was estimated based on the number of miles to site. Recurrent building costs included electricity credit. Recurrent training included training of core and testing staff, including HIV diagnostic and health surveillance assistants.

Waste management included incinerators, paraffin, and matches, with incinerators annualised over their useful life and assuming a 3% discount rate[10].

Shared costs were allocated using the proportion of outpatients tested, except for the costs of core personnel, which were allocated using the reported proportion of time spent on HIV testing services per outpatient stratified by salary grade.

[7] The Central Medical Stores Trust. Catalogue, 2020. Available from: http://www.cmst.mw/catalogue/.
[8] The Global Fund. Sourcing and Management of Health Products, 2020. Available from: https://www.theglobalfund.org/en/sourcing-management/.
[9] Mwenge L, Sande L, Mangenah C, Ahmed N, Kanema S, d'Elbee M, et al. Costs of facility-based HIV testing in Malawi, Zambia and Zimbabwe. *PLOS ONE*. 2017;12(10):e0185740.
[10] Vassall A, Sweeney S, Kahn J. Reference case for estimating the costs of global health services and interventions. Global Health Cost Consortium, 2017.

Supplementary Table 5.A. Comparison of population characteristics by study arm

	Community-led HIVST arm *n* (%)	SOC arm *n* (%)
Household characteristics	(*N* = 1,994)	(*N* = 2,015)
Adults (median [range])*	2 (0–8)	2 (0–10)
Children (median [range])*	1 (0–1)	1 (0–1)
Household wealth index†		
Lowest	368 (20.3%)	341 (18.6%)
Second	353 (19.4%)	395 (21.6%)
Third	361 (19.9%)	362 (19.8%)
Fourth	358 (19.7%)	373 (20.4%)
Highest	375 (20.7%)	358 (19.6%)
Individual characteristics	(*N* = 3,960)	(*N* = 3,920)
Male	1,577 (39.8%)	1,495 (38.1%)
Age (median [range])	29 (15–96)	29 (15–98)
Age group		
15–19 years	910 (23%)	867 (22.1%)
20–24 years	631 (15.9%)	675 (17.2%)
25–39 years	1,253 (31.6%)	1,267 (32.3%)
≥40 years	1,166 (29.4%)	1,111 (28.3%)
Marital status‡		
Married or living together	2,428 (61.3%)	2,467 (62.9%)
Separated, divorced, or widowed	612 (15.5%)	542 (13.8%)
Never married	918 (23.2%)	910 (23.2%)
Educational attainment§		
None	1,730 (43.7%)	1,764 (45%)
Primary	1,902 (48%)	1,838 (46.9%)
Secondary or higher	328 (8.3%)	317 (8.1%)
Literate‖	2,196 (55.5%)	2,066 (52.7%)
Muslim	2,840 (71.7%)	3,008 (76.7%)
Ethnicity		
Yao	2,778 (70.2%)	2,942 (75.1%)
Ngoni	546 (13.8%)	443 (11.3%)
Other	636 (16.1%)	535 (13.6%)
Self-rated health status¶		
Very good	1,546 (39.1%)	1,314 (33.5%)
Good	1,738 (43.9%)	1,810 (46.2%)
Fair	338 (8.5%)	389 (9.9%)
Poor	337 (8.5%)	407 (10.4%)

HIVST, HIV self-testing; SOC, standard of care.
* 32 missing values in the community-led HIVST arm and 8 missing values in the SOC arm.
† 179 missing values in the community-led HIVST arm and 186 missing values in the SOC arm.
‡ 2 missing values in the community-led HIVST arm and 1 missing value in the SOC arm.
§ 1 missing value in the SOC arm.
‖ 1 missing value in the community-led HIVST arm.
¶ 1 missing value in the community-led HIVST arm.

Supplementary Table 5.B. Incremental costs and effects of community-led HIV self-testing

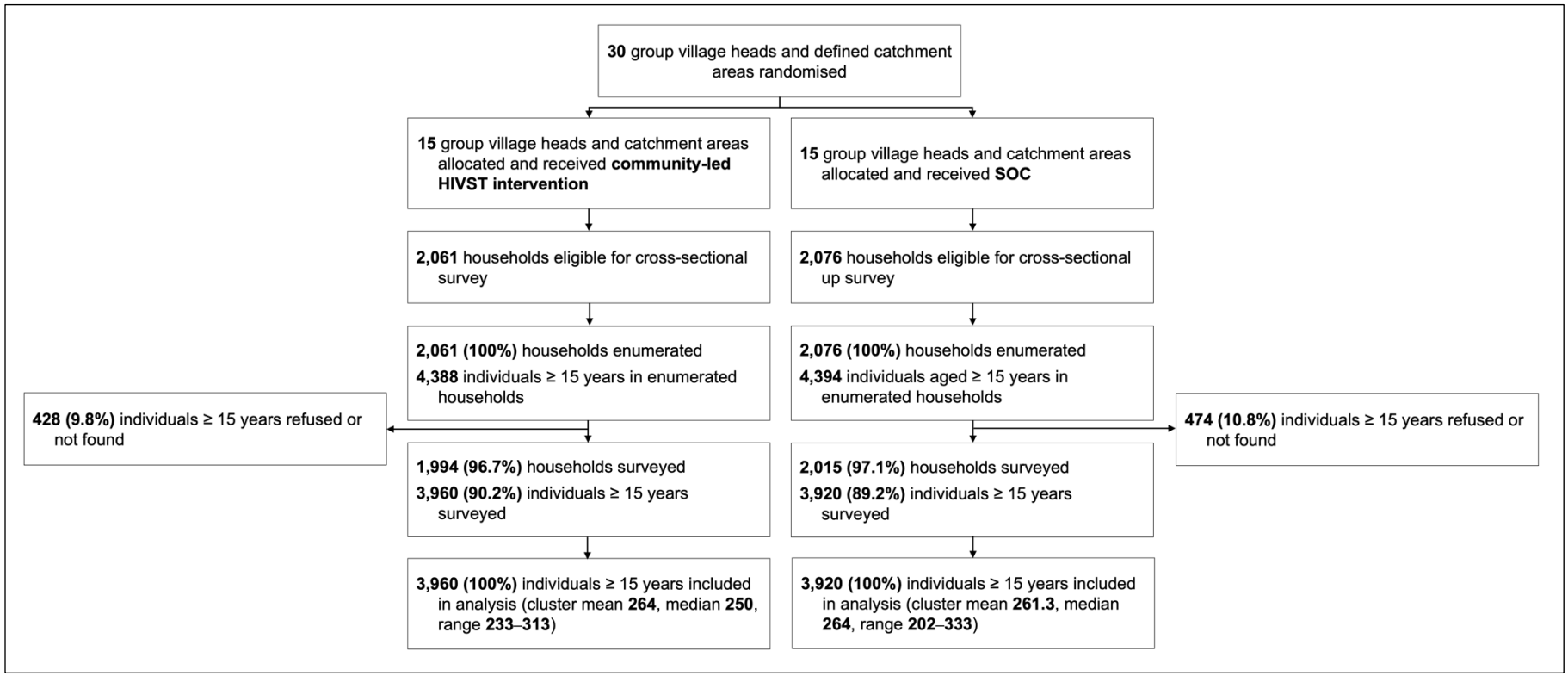
	Community-led HIVST arm Mean or % (*n*/*N*)	SOC arm Mean or % (*n*/*N*)	Unadjusted mean or risk difference (95% CI) *p*-value	Adjusted mean or risk difference (95% CI)* *p*-value
Overall				
Provider costs (2018 US$)	9.06	5.52	3.66 (2.31–5.01) <0.001	3.77 (2.44–5.10) <0.001
Tested for HIV	84.9% (3,363/3,960)	65.7% (2,574/3,920)	19.3% (14.6–24.0%) <0.001	19.5% (15.0–24.0%) <0.001
Men†				
Provider costs (2018 US$)	8.04	4.68	3.61 (2.36–4.86) <0.001	3.57 (2.33–4.81) <0.001
Tested for HIV	81.0% (1,277/1,577)	57.8% (864/1,495)	23.7% (18.0–29.5%) <0.001	23.1% (17.8–28.4%) <0.001
Women†				
Provider costs (2018 US$)	9.74	6.04	3.74 (2.25–5.23) <0.001	3.91 (2.49–5.32) <0.001
Tested for HIV	87.5% (2,086/2,383)	70.5% (1,710/2,425)	16.8% (12.2–21.5%) <0.001	17.2% (12.7–21.8%) <0.001

HIVST, HIV self-testing; SOC, standard of care.

* Analysis adjusted for sex, age group, literacy, religion, ethnicity, and health status. Subgroup analysis adjusts for the same covariates except for sex.

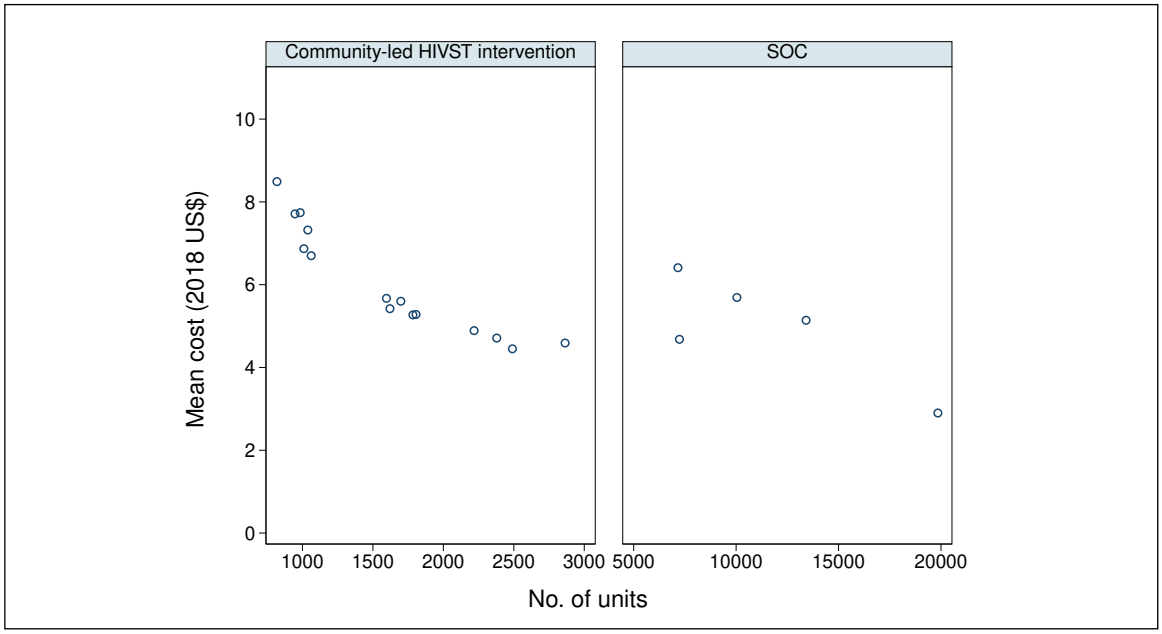
† *p*-Value for interaction by sex. Provider costs: $p = 0.25$. Tested for HIV: $p = 0.002$.

Supplementary Figure 5.A. Flow diagram of the cluster-randomised trial



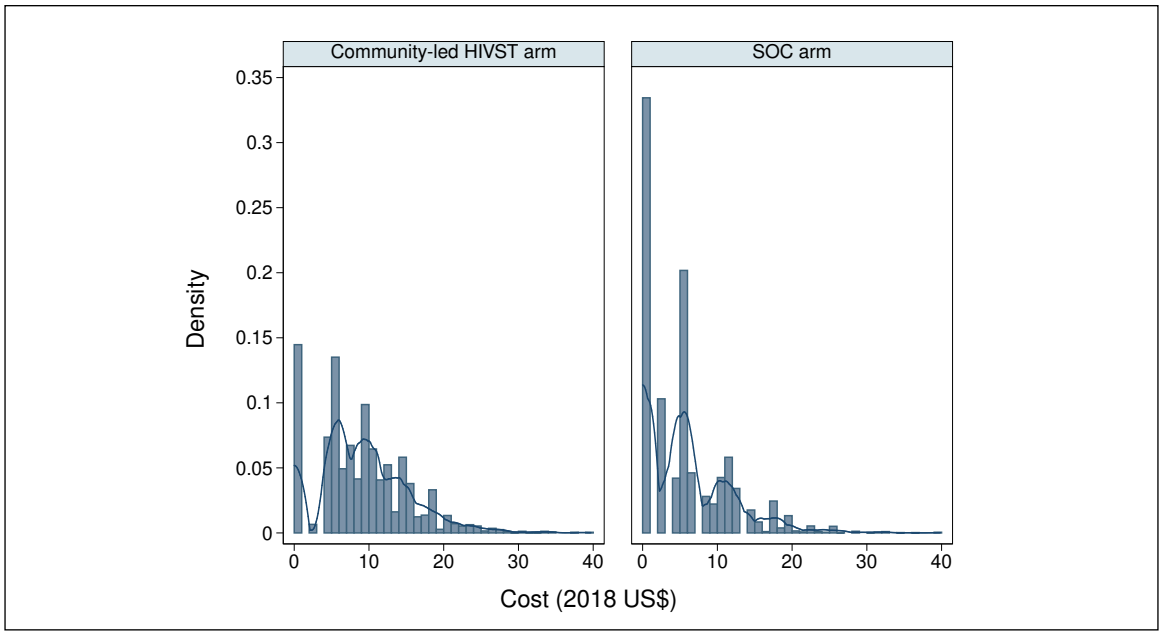
HIVST, HIV self-testing; SOC, standard of care.

Supplementary Figure 5.B. Site-level average costs and quantity by HIV testing strategy



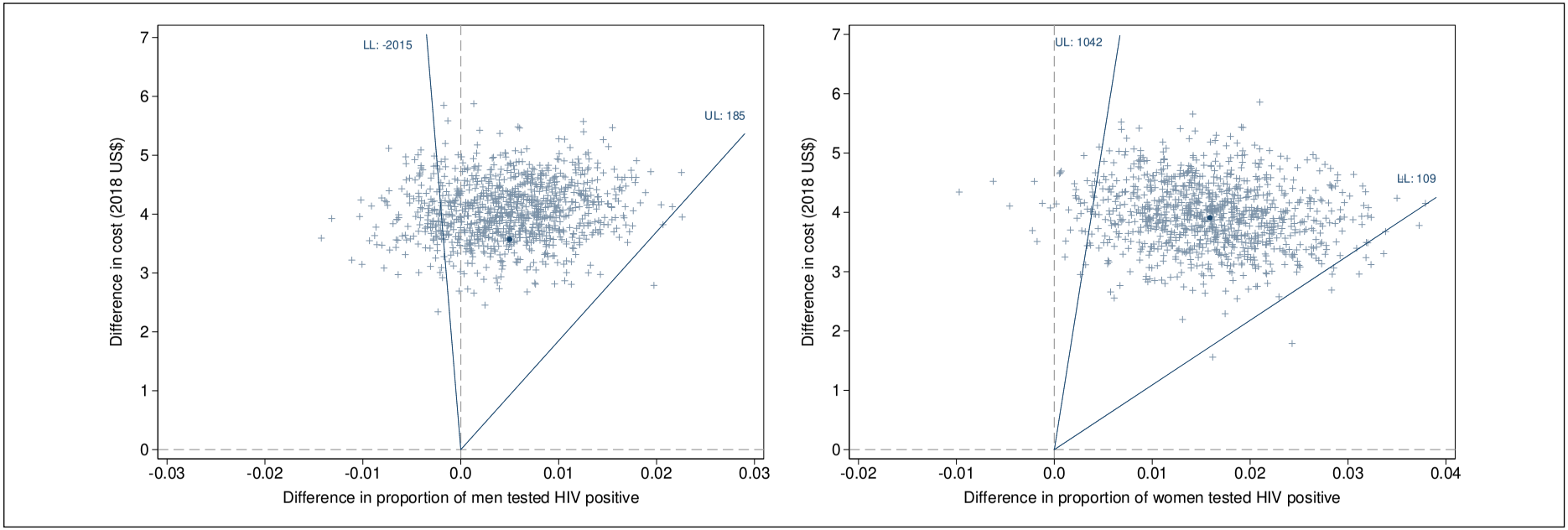
HIVST, HIV self-testing; SOC, standard of care. Site-level mean costs and the number of units by HIV testing strategy. Units are HIVST kits for the community-led HIVST intervention and HIV tests for the SOC.

Supplementary Figure 5.C. Distribution of individual-level costs of HIV testing and self-testing by study arm



HIVST, HIV self-testing; SOC, standard of care. Density of individual-level provider costs of HIV testing and self-testing by study arm.

Supplementary Figure 5.D. Cost-effectiveness plane for community-led HIV self-testing by subgroup



HIVST, HIV self-testing; LL, lower limit; UL upper limit. Cost-effectiveness plane of adding community-led HIVST to the standard of care. The incremental cost per person tested HIV positive for men and women are illustrated. Each point represents the adjusted mean difference in cost (incremental cost) and adjusted risk difference in the proportion tested HIV positive (incremental effect) for one bootstrap replicate. The dark blue circle indicates the incremental cost per person tested positive and the dark blue line indicates the bootstrap confidence intervals using the bias-corrected percentile method.

Chapter 6.
Mediation analysis

6.1. Summary

This chapter includes Paper 5, "Understanding mechanisms of impact from community-led delivery of HIV self-testing: mediation analysis of a cluster-randomised trial in Malawi". Addressing Objective 4, the paper evaluates mechanisms underlying the impact of community-led HIV self-testing using mediation analysis of the cluster-randomised trial presented in Chapters 3 and 4. The paper describes the methods used to conduct the mediation analysis, with hypothesised mediators including dimensions of community mobilisation (social cohesion, shared concern for HIV, critical consciousness raising), and community HIV stigma. The paper then reports the direct and indirect effects of community-led HIV self-testing on the outcome of HIV testing in the last 3 months. Process indicators on implementation are also reported.

The paper was published in 2022 in PLOS Global Public Health.

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	1701865	**Title**	Ms
First Name(s)	Pitchaya Peach		
Surname/Family Name	Indravudh		
Thesis Title	Evaluation of community-led delivery of HIV self-testing		
Primary Supervisor	Prof. Fern Terris-Prestholt		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	PLOS Global Public Health		
When was the work published?	2022		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	Not applicable		
Have you retained the copyright for the work?*	Yes	Was the work subject to academic peer review?	Yes

*If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	
Please list the paper's authors in the intended authorship order:	
Stage of publication	

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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I led the conceptualisation and design of the study. I supervised implementation of the study, including procedures for the intervention and evaluation, and conducted the statistical and cost analysis. I also wrote the first draft of the manuscript. Co-authors contributed to the study conceptualisation and design and study implementation as well as read and approved the final manuscript.

SECTION E

Student Signature	[redacted]
Date	2nd April 2023

Supervisor Signature	[redacted]
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Understanding mechanisms of impact from community-led delivery of HIV self-testing: mediation analysis of a cluster-randomised trial in Malawi

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Abstract

Introduction

Community HIV strategies are important for early diagnosis and treatment, with new self-care technologies expanding the types of services that can be led by communities. We evaluated mechanisms underlying the impact of community-led delivery of HIV self-testing (HIVST) using mediation analysis.

Methods

We conducted a cluster-randomised trial allocating 30 group village heads and their catchment areas to the community-led HIVST intervention in addition to the standard of care (SOC) or the SOC alone. The intervention used participatory approaches to engage established community health groups to lead the design and implementation of HIVST campaigns. Potential mediators (individual perceptions of social cohesion, shared HIV concern, critical consciousness, community HIV stigma) and the outcome (HIV testing in the last 3 months) were measured through a post-intervention survey. Analysis used regression-based models to test (i) intervention-mediator effects, (ii) mediator-outcome effects, and (iii) direct and indirect effects.

Results

The survey included 972 and 924 participants in the community-led HIVST and SOC clusters, respectively. The community-led HIVST intervention increased uptake of recent HIV testing, with no evidence of indirect effects from changes in hypothesised mediators. However, standardised scores for community cohesion (adjusted mean difference [MD] 0.15, 95% CI -0.03 to 0.32, p = 0.10) and shared concern for HIV (adjusted MD 0.13, 95% CI -0.02 to 0.29, p = 0.09) were slightly higher in the community-led HIVST arm than the SOC arm. Social cohesion, community concern, and critical consciousness also apparently had a quadratic association with recent testing in the community-led HIVST arm, with a positive relationship indicated at lower ranges of each score. We did not find strong evidence of intervention effects on community HIV stigma and its association with recent testing.

Conclusions

We conclude that the effect of the community-led HIVST intervention mostly operated directly through community-driven service delivery of a novel technology rather than through intermediate effects on perceived community mobilisation and HIV stigma.

Introduction

Knowledge of HIV status is critical for controlling transmission, with 1.7 million people newly infected in 2018 [1]. Effective HIV testing services (HTS) can enable early diagnosis and linkage to treatment among HIV-positive individuals and linkage to prevention among individuals at substantial risk. Expanded HTS provision through health facilities has improved awareness of status in sub-Saharan Africa, which contributes the majority of new cases [1]. Community strategies can facilitate early diagnosis and treatment to reduce HIV-related morbidity and mortality and limit transmission through treatment and prevention [2-4]. Self-care technologies, including HIV self-testing (HIVST), are also generating opportunities beyond health facilities to reach underserved population subgroups [5, 6].

Community-led strategies for prevention and management involve communities leading the design and implementation of programmes [7-10], with novel self-care products expanding the types of programmes that can be led by communities. Previous studies have reported improved identification of HIV-positive cases and reduced incidence when communities were involved in the provision of mobile HTS [11, 12]. Community mobilisation approaches that address social and structural drivers can also impact protective behaviours, including improved condom use and reduced concurrency of sexual partners [13]. Across disease areas, studies have demonstrated the health impact of strategies involving community participation [14-16]. Understanding how community-led approaches affect outcomes is important for maximising the effect of community health programmes, though evidence on pathways to impact is limited [17].

Mediation analysis involves evaluating how an intervention changes an outcome by testing hypotheses about the potential causal mechanisms [18]. A mediator is an intermediate variable that is affected by an exposure and subsequently affects an outcome, with statistical techniques used to quantify the intervention effect through hypothesised mediators [19]. Mediation analysis has been applied within randomised trials to test hypothesised pathways underlying the effect of an intervention on an outcome [18]. Findings from mediation analysis can therefore support explanation of cause-effect relationships and inform optimisation of future interventions to influence key mechanisms.

We assessed mediation within a cluster-randomised trial of community-led delivery of HIVST in Malawi. Primary analysis from the trial previously reported an increase in the proportion of the population who tested for HIV, including among adolescents aged 15 to 19 years, older adults aged 40 years and above, and men [20]. We examined whether changes in the hypothesised mediators, community mobilisation domains and community HIV stigma, mediated the impact of the intervention on HIV testing, aiming to consider broader lessons for community-led programmes.

Specifically, we tested (i) the effect of the intervention on the potential mediators, (ii) the effect of the potential mediators on recent testing, and (iii) the direct intervention effect on recent testing and the indirect effect from changing the potential mediators.

Methods

Trial design, procedures, and data collection

We evaluated the role of community mobilisation domains and community HIV stigma as mediators between community-led delivery of HIVST and recent HIV testing within a cluster-randomised trial (**Supplementary Text 6.A**) [21]. The trial was conducted in Mangochi district and randomised 30 group village heads and their catchment areas 1:1 to the community-led HIVST intervention in addition to the standard of care (SOC) or the SOC alone. The intervention used participatory approaches to engage established community health groups to lead the design and implementation of HIVST campaigns [22]. Community actors included community health action groups and community volunteers, who respectively provide community health services at group village head and village level, and government community health workers (CHWs). The SOC involved testing by lay counsellors through government health facilities and periodic community-based outreach. The study team included Population Services International (PSI) Malawi, the Malawi-Liverpool-Wellcome Trust Clinical Research Programme, and the Ministry of Health.

The intervention adapted participatory learning and action methods, with each cluster developing HIVST campaign strategies unique to their respective areas [22]. Implementation was staggered in groups of two-to-three clusters. The study team held 2-day participatory workshops attended by community health action groups and CHWs. In their respective clusters, participants defined determinants of HIV infection, mapped services and barriers to access, and identified priority subgroups with low uptake of services. Participants designed cluster-specific HIVST campaigns and decided on how to distribute HIVST kits, provide support for linkage to routine care, and generate demand for HIVST. The study team then conducted 2-day trainings with community volunteers on supporting use and interpretation of HIVST kits and linkage to prevention and treatment, communicating prevention messages, managing social harms, handling and storing kits, and collecting data. Afterwards, community health actions groups, community volunteers, and CHWs led a fixed 7-day campaign based on strategies developed for each cluster. Cluster residents aged 15 years and older were eligible to take an HIVST kit for themselves and for secondary distribution. The study team provided the OraQuick HIV Self-Test (Orasure Technologies), communications and instructional materials, data collection tools, and nationally standardised gratuity of MWK 7,000 (US$10) per volunteer.

Outcomes were measured through a post-intervention survey administered 8 to 12 weeks after the start of the intervention in community-led HIVST clusters or matched dates in SOC clusters. In each cluster, villages with at least 500 residents and located near the group head village were randomly selected, with households recruited using a clockwise spiral from a designated location. The survey aimed to recruit at least 250 participants based on sample size calculations for the trial, with cluster residents aged 15 years and older eligible. Cluster residents provided written informed consent or assent for adolescents aged 15 to 17 years with parent or guardian consent. Participants were interviewed on their sociodemographic background and prior use of HIV services. Process data were collected through the survey and HIVST registers.

Mediation framework

The causal directed acyclic graph illustrating the mediation framework for the current study is presented in **Figure 6.1**. Potential mediators were identified based on a conceptual framework drawn from the literature on community participation in health programmes. Community participation can be conceptualised along a continuum of increasing empowerment [22], defined as "a social action process by which individuals, communities, and organisations gain mastery over their lives in the context of changing their social and political environment to improve equity and quality of life" [23]. Most practice of community empowerment for health is operationalised through participatory learning and action methods that engage communities in the design, implementation, and evaluation of health programmes [22]. Localising decision making and resource allocation is posited to enhance the coverage and efficiency of programmes, while devolvement of power and control to marginalised populations is proposed to enable more equitable health care distribution [24, 25].

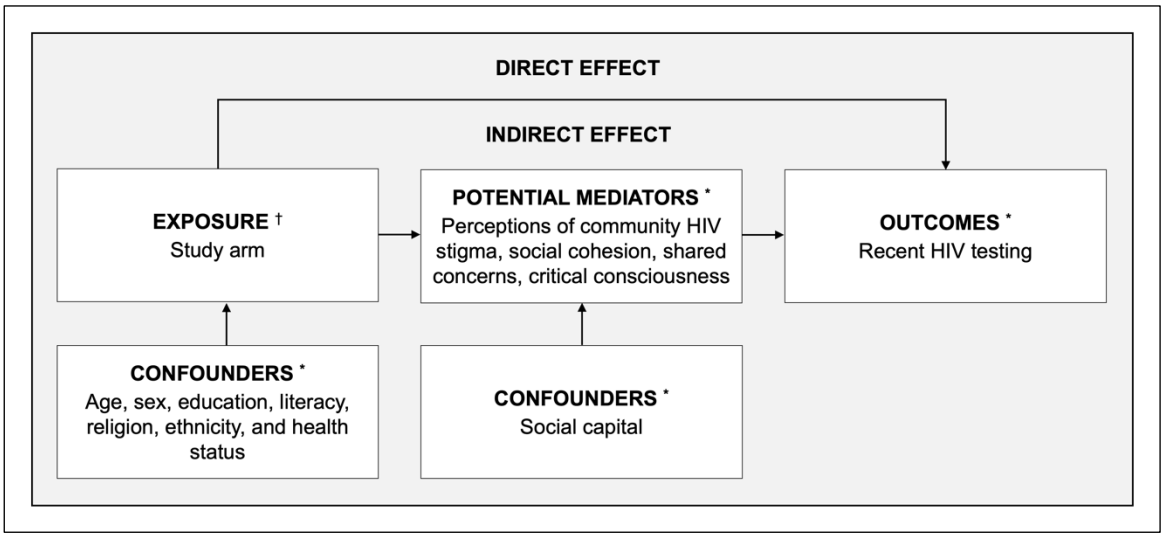


Figure 6.1. Diagram of mediation framework. HIVST, HIV self-testing. Causal directed acrylic graph of the mediation framework. * Measured at the individual level. † Measured at the cluster level.

In the context of HIV prevention, Lippman (2013) proposed multiple domains of community mobilisation that would need to be affected to improve HIV-related outcomes [26]. Building social cohesion, specifically through a common sense of identity and trust, was regarded as a necessary antecedent for successful social mobilisation [26, 27]. Raising critical consciousness through collective dialogue and action was also considered an important component of community mobilisation [26-28]. Additional domains included shared concern for HIV as a priority health issue, participation in collective action, and organisational structures and networks and leadership to facilitate action [26, 28].

Another hypothesised mechanism of action is by influencing HIV stigma, which has been consistently noted as a barrier to engagement with services [29, 30]. HIV stigma stems from drivers such as fear of infection and social judgement and can subsequently impede service access and utilisation [31]. Community-led strategies could change norms around care seeking by activating community support for prevention and treatment. A separate hypothesis suggests the role of HIVST in reducing HIV stigma by empowering individuals and normalising testing [32].

For the current study, we hypothesised that individual-level community mobilisation domains and community HIV stigma acted as mediators between the community-led HIVST intervention and the outcome of tested for HIV in the last 3 months. We collected data on hypothesised mediators in the post-intervention survey among a random sample (approximately 20%) of participants receiving an extended questionnaire. Community constructs are commonly captured at individual level to represent individual perceptions within the community or aggregated at community level to denote shared perceptions. Given the brief implementation period, we hypothesised that the intervention would likely impact individual perceptions of community measures rather than broader norms.

To measure dimensions of community mobilisation, we used a subset of domains from previously validated scores [33]. Data were captured on perceived social cohesion, a six-item scale for sense of community; perceived shared HIV concern, a 10-item scale for community concern and prioritisation of HIV; and perceived critical consciousness, an 11-item scale for collective problem assessment and resolution [33]. Community HIV stigma included five items measuring perceptions of HIV stigma within the community [34]. Responses were based on a 3-point Likert scale (**Supplementary Text 6.B**).

Statistical analysis

Analysis was restricted to participants providing complete data for the outcome and potential mediators. We assessed implementation, including HIVST campaign strategies and awareness and

uptake of HIVST, and evaluated intervention and mediation effects. Our mediation model estimated the effect of the cluster-level intervention (community-led HIVST) on the individual-level mediators (social cohesion, shared HIV concern, critical consciousness, community HIV stigma) and outcome (tested for HIV in the last 3 months). Individual-level scores for each potential mediator were generated by summing the question items and standardising the raw scores, with higher scores representing higher levels of each domain. To assess scale reliability, we calculated Raykov's rho from confirmatory factor analysis using a weighted least squares approach [35]. Coefficients for social cohesion (0.86), shared concern (0.95), critical consciousness (0.96), and community HIV stigma (0.77) showed acceptable reliability.

Mediation analysis was based on a counterfactual framework that extends the product-of-coefficients approach to accommodate a common binary outcome and interaction between the intervention and mediator [19, 36-38]. Effect estimates include natural direct and indirect effects. The direct effect is the intervention effect on the outcome excluding the effect through the mediator. The indirect effect measures the effect on the outcome caused by the intervention effect on the mediator and the subsequent effect of the mediator on the outcome. Effects can be causally interpreted assuming control is made for intervention-mediator, intervention-outcome, and mediator-outcome confounding and mediator-outcome confounders are not affected by the intervention [19]. Randomisation of the intervention can minimise confounding bias, though further control may be needed to account for cluster randomisation [39]. Adjustment for mediator-outcome confounding is also important given the strong assumptions required for causal interpretation of direct and indirect effects.

We fitted a set of regression models for each potential mediator. To estimate intervention-mediator effects, model 1 included linear regression of the potential mediator on the study arm. The model also included a set of covariates that showed imbalance between study arms (sex, age group, literacy, religion, ethnicity, health status), or was a potential mediator-outcome confounder (social capital) as identified through **Figure 6.1**. Social capital, defined as membership in community groups, was selected since the measure represented a time-invariant measure of social relationships and networks (**Supplementary Text 6.B**). A random effect for the cluster was used to account for the cluster-randomised design [39, 40]. To estimate mediator-outcome effects, model 2, which was stratified by arm, used Poisson regression, and included the outcome on the mediator, covariates, and the mediator-outcome confounder. A Poisson model with robust standard errors was used to approximate risk ratios (RRs) since the outcome was common [41]. We investigated the relationship between the standardised score of the mediator and the outcome by including linear and quadratic terms of the mediator. The model also adjusted for clustering with a random effect.

To calculate direct and indirect effects, we used estimates from Model 1 and a third model [19]. Model 3 included Poisson regression of the outcome on the study arm, the potential mediator, an intervention-mediator interaction term, covariates, and the mediator-outcome confounder, with a robust standard error and random effect for cluster. Mediators showing a nonlinear relationship with the outcome were log-transformed in both models [19]. To calculate confidence intervals for direct and indirect effects, we used a bias-corrected cluster bootstrap approach with 1,000 replicates [42]. To explore heterogeneity in intervention and mediation effects, we additionally stratified our analysis by sex and age group, with a focus on adolescents aged 15 to 19 years and older adults aged 40 years and above due to more substantial gaps in undiagnosed HIV among these subgroups. Stata version 14.0 was used for statistical analysis.

Ethics statement

The trial, which is registered with ClinicalTrials.gov (NCT03541382), was conducted as part of the Unitaid/PSI HIV Self-Testing Africa Initiative (STAR) [http://hivstar.lshtm.ac.uk/]. Ethical approvals were received from the University of Malawi College of Medicine (P.01/18/2332), London School of Hygiene & Tropical Medicine (14761), and WHO (STAR-comm led CRT-Malawi).

Results

Response rates for the post-intervention survey were 90.2% (3,960/4,388) and 89.2% (3,920/ 4,394) in the community-led HIVST and SOC arms, respectively (**Supplementary Figure 6.A**). Of eligible participants, 24.8% (1,955/7,880) were selected for the extended module. Most participants were included in the primary analysis, with 97.0% (970/1,000) in the community-led HIVST arm and 96.6% (923/955) in the SOC arm providing complete data. The majority of participants obtained primary-level education or below and were married (**Table 6.1**). Individual characteristics were mainly balanced between arms.

Implementation

The community-led HIVST intervention was delivered in 15 eligible clusters from 5 October, 2018 to 17 January, 2019. HIVST campaigns were implemented by 157 community health action group members (cluster mean 10.5) and 190 community volunteers (cluster mean 12.7; **Supplementary Table 6.A**). Implementation strategies involved sensitisation and distribution of HIVST kits at village head-led community meetings, homes, and fixed locations and social hotspots, including schools, churches and mosques, boreholes, fishing docks, sports fields, and video shows. Strategies to support linkage to routine services included active post-test follow-up, phone referrals to

Table 6.1. Comparison of population characteristics by study arm

	Community-led HIVST *n* (%)	SOC *n* (%)
Household characteristics	(*N* = 834)	(*N* = 822)
Adults (median [range])*	2 (1–8)	2 (0–10)
Children (median [range])*	1 (0–1)	1 (0–1)
Household wealth index †		
Lowest	177 (22.8%)	174 (22.7%)
Second	157 (20.2%)	174 (22.7%)
Third	157 (20.2%)	150 (19.6%)
Fourth	131 (16.9%)	137 (17.9%)
Highest	154 (19.8%)	130 (17.0%)
Individual characteristics	(*N* = 970)	(*N* = 923)
Male	394 (40.6%)	363 (39.3%)
Age (median [range])	29 (15–96)	29 (15–90)
Age group		
15–19 years	214 (22.1%)	193 (20.9%)
20–39 years	478 (49.3%)	476 (51.6%)
≥40 years	278 (28.7%)	254 (27.5%)
Marital status		
Married or living together	609 (62.8%)	581 (62.9%)
Separated, divorced, or widowed	150 (15.5%)	125 (13.5%)
Never married	211 (21.8%)	217 (23.5%)
Educational attainment		
None	414 (42.7%)	396 (42.9%)
Primary	457 (47.1%)	442 (47.9%)
Secondary or higher	99 (10.2%)	85 (9.2%)
Literate	562 (57.9%)	515 (55.8%)
Muslim	699 (72.1%)	695 (75.3%)
Ethnicity		
Yao	688 (70.9%)	681 (73.8%)
Ngoni	122 (12.6%)	103 (11.2%)
Other	160 (16.5%)	139 (15.1%)
Self-rated health status		
Very good	394 (40.6%)	318 (34.5%)
Good	403 (41.5%)	425 (46.0%)
Fair	80 (8.2%)	83 (9.0%)
Poor	93 (9.6%)	97 (10.5%)

HIVST, HIV self-testing; SOC, standard of care.
* 13 missing values in the HIVST arm and 6 missing values in the SOC arm.
† 58 missing values in the HIVST arm and 57 missing values in the SOC arm.

health facilities, and material assistance such as transportation funds. Overall, 24,316 kits (cluster mean 1,621) were distributed.

Self-testing for HIV in the last 3 months was 72.6% (704/970) in the community-led HIVST arm, ranging by cluster from 40.3% to 92.7%, and 5.4% (50/923) in the SOC arm (**Supplementary Table 6.A**). In the community-led HIVST arm, HIVST uptake was lowest among women aged 40 years and older (65.2%, 101/155) and highest among women aged 20 to 39 years (82.5%, 241/292; **Supplementary Figure 6.B**). The proportion of participants who had heard of HIVST was 96.1% (932/970) in the community-led HIVST arm, varying by cluster from 83.5% to 100.0%, and 36.5% (337/923) in the SOC arm.

Effect of the intervention on potential mediators

Table 6.2 includes estimates of the intervention effect on standardised scores for the potential mediators. Compared with the SOC arm, social cohesion (adjusted mean difference [MD] 0.15, 95% CI -0.03 to 0.32; $p = 0.10$) and shared concern for HIV (adjusted MD 0.13, 95% CI -0.02 to 0.29; $p = 0.09$) were slightly higher in the community-led HIVST arm, though evidence of an intervention effect was weak. Evidence of differences between study arms was not observed for community HIV stigma (adjusted MD -0.01, 95% CI -0.18 to 0.16; $p = 0.91$) and critical consciousness (adjusted MD 0.11, 95% CI -0.08 to 0.31; $p = 0.26$).

In subgroup analysis, there was some evidence of an intervention effect among women for social cohesion (adjusted MD 0.17, 95% CI -0.01 to 0.35; $p = 0.06$), shared HIV concern (adjusted MD 0.16, 95% CI 0.00 to 0.31; $p = 0.05$), and critical consciousness (adjusted MD 0.18, 95% CI -0.02 to 0.37; p = 0.07). There was no evidence of an intervention effect among men (**Supplementary Table 6.B**). In older adults, weak evidence of an intervention effect was observed for social cohesion (adjusted MD 0.15, 95% CI -0.01 to 0.31; p = 0.06; **Supplementary Table 6.D**). Differences between study arms were not detected in adolescents.

Effect of the potential mediators on outcome

Estimates of causal associations between the standardised scores for the potential mediators and the outcome by study arm are presented in **Table 6.2**, with the RR denoting the change in recent HIV testing (in the last 3 months) associated with a standard deviation increase in the score for the potential mediator. As illustrated in **Figure 6.2**, social cohesion and shared concern for HIV demonstrated a strong quadratic association with recent testing in the community-led HIVST arm, with a positive relationship measured at lower levels of scores followed by a waning effect at higher levels. Similarly, critical consciousness showed a positive association with recent testing at lower ranges of scores and a negative association at higher ranges. There was some evidence of an association between community HIV stigma and recent testing (adjusted RR 0.97, 95% CI 0.93 to 1.01; p=0.12). In the SOC arm, there was no evidence of a strong association between each potential mediator and recent testing nor an interaction effect by study arm.

In sub-group analysis, social cohesion showed a strong quadratic relationship with recent testing among women in the community-led HIVST arm (**Supplementary Figure 6.C**). Community HIV stigma was also strongly associated with recent testing (adjusted RR 0.95, 95% CI 0.90 to 1.00; $p = 0.05$). Among men, shared HIV concern and critical consciousness were found to have a strong quadratic association with recent testing in the community-led HIVST arm. There was also

Table 6.2. Effect of community-led HIV self-testing intervention and potential mediators

		(1) Effect of intervention on potential mediator *	(2) Effect of potential mediator on HIV testing in the last 3 months by study arm †		
		Adjusted mean difference (95% CI) *p*-value	Community-led HIVST Adjusted risk ratio (95% CI) *p*-value	SOC Adjusted risk ratio (95% CI) *p*-value	*p*-value for interaction for study arm ‡
(A)	Community HIV stigma	-0.01 (-0.18–0.16) 0.91	0.97 (0.93–1.01) 0.12	0.91 (0.82–1.02) 0.10	0.42
(B)	Social cohesion	0.15 (-0.03–0.32) 0.10	0.92 (0.87–0.98) 0.006	1.02 (0.96–1.08) 0.59	0.12
	Social cohesion^2		0.95 (0.91–0.99) 0.01	1.00 (0.94–1.06) 0.94	
(C)	Shared concern for HIV	0.13 (-0.02–0.29) 0.09	0.91 (0.87–0.97) 0.001	0.98 (0.92–1.04) 0.47	0.18
	Shared concern for HIV^2		0.94 (0.91–0.98) 0.006	0.98 (0.94–1.02) 0.42	
(D)	Critical consciousness	0.11 (-0.08–0.31) 0.26	0.92 (0.86–0.99) 0.02	1.02 (0.92–1.13) 0.69	0.09
	Critical consciousness^2		0.96 (0.92–1.01) 0.10	1.01 (0.92–1.10) 0.88	

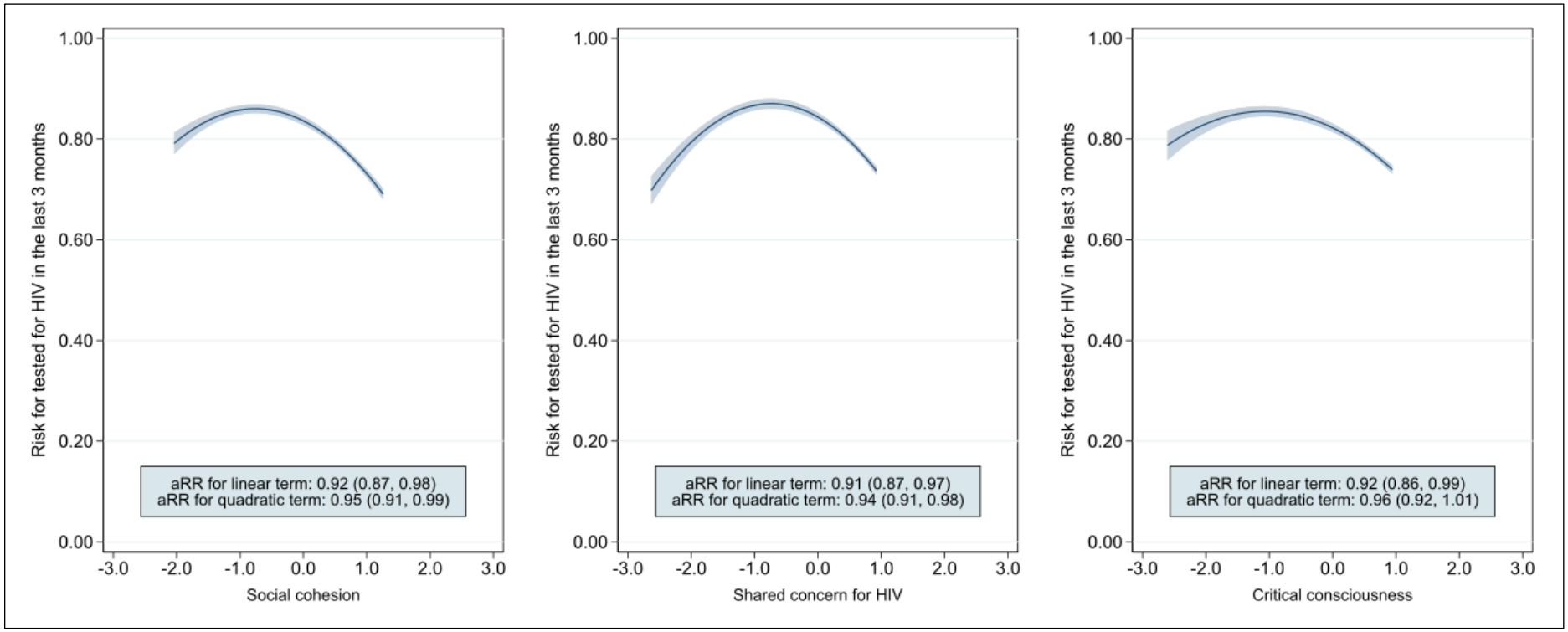
HIVST, HIV self-testing; SOC, standard of care. *N* = 1893.

* Adjusted mean difference for the study arm (intervention-control). Model 1 is a linear regression model of the potential mediators on the study arm, with each mediator evaluated separately as the outcome in Models A to D. Analysis adjusts for sex, age group, literacy, religion, ethnicity, health status, and social capital, with a random effect for cluster.

† Adjusted risk ratio for the linear term for the potential mediator. Model 2 is a Poisson regression model of recent HIV testing on the mediators, with each mediator evaluated separately as the exposure in Models A to D. Models 2B to D include both a linear and quadratic term for the mediators. Analysis is stratified by study arm and adjusts for sex, age group, literacy, religion, ethnicity, health status, and social capital, with a robust standard error and random effect for cluster.

‡ Interaction *p*-value in Model 2A is for the study arm and the linear term for the potential mediator. Interaction *p*-values in Models 2B to D are for the study arm and the linear and quadratic terms for the mediator.

Figure 6.2. Prediction plots of recent HIV testing and potential mediators.



aRR, adjusted risk ratio. Prediction plots with fitted values and 95% CIs. Prediction values obtained from Poisson regression of recent HIV testing on the linear and quadratic terms for the potential mediators, as standardised scores, in the community-led HIV self-testing arm.

evidence of a quadratic relationship between shared HIV concern and recent testing among older adults in the community-led HIVST arm. No evidence of an association was observed between potential mediators and recent testing in adolescent counterparts (**Supplementary Figure 6.D**). Further, subgroup analysis did not detect a strong association between nearly all potential mediators and recent testing in the SOC arm as well as an interaction effect by study arm (**Supplementary Table 6.B**, **Supplementary Table 6.D**).

Direct and indirect effects of intervention on outcome

Analyses reported strong evidence of a direct effect of the community-led HIVST intervention on recent testing (**Table 6.3**). Indirect effects appeared to be limited across potential mediators, overall and for most subgroups (**Supplementary Table 6.C**, **Supplementary Table 6.E**).

Discussion

This study used causal mediation approaches to assess whether measures of community mobilisation and community HIV stigma mediated the effect of community-led delivery of HIVST on recent HIV testing. We found that the community-led HIVST intervention increased uptake of recent testing, with the effect appearing to be almost entirely direct. There was no evidence of indirect effects from changes in perceived social cohesion, shared HIV concern, critical consciousness, and community HIV stigma at individual level. However, the intervention did slightly increase levels of perceived social cohesion and shared concern for HIV. In the community-led HIVST arm, higher perceived social cohesion, community concern for HIV, and critical consciousness also apparently had a positive relationship with recent testing at lower levels of scores followed by a diminishing effect. We did not find strong evidence of intervention effects on perceptions of critical consciousness and community HIV stigma as well as an association between

Table 6.3. Direct and indirect effect of community-led HIV self-testing intervention

		Effect of intervention on HIV testing in the last 3 months		
		Direct effect Adjusted risk ratio (bootstrap CI)	Indirect effect Adjusted risk ratio (bootstrap CI)	Total effect Adjusted risk ratio (bootstrap CI)
(A)	Community HIV stigma	1.85 (1.72–2.01)	1.00 (1.00–1.01)	1.85 (1.72–2.02)
(B)	Social cohesion *	1.75 (1.58–1.99)	1.00 (0.99–1.00)	1.74 (1.57–1.98)
(C)	Shared concern for HIV *	1.79 (1.62–2.02)	1.00 (0.99–1.00)	1.78 (1.61–2.01)
(D)	Critical consciousness *	1.75 (1.57–1.97)	1.00 (0.99–1.01)	1.75 (1.57–1.97)

N = 1893. Estimates for direct and indirect effects are based on Models 1 and 3. Model 3 is a Poisson regression model of recent HIV testing on the study arm, with each potential mediator evaluated separately as a covariate in Models A to D. An interaction term for the study arm and the mediator is included. Analysis adjusts for sex, age group, literacy, religion, ethnicity, health status, and social capital, with a robust standard error and random effect for cluster. Confidence intervals are calculated using a bias-corrected bootstrap approach.

* Model includes log transformation of the potential mediator.

community stigma and recent testing. Few studies have quantitatively assessed mechanisms underlying the effect of community participation in health programmes. We conclude that the intervention effect mostly operated directly through community-driven service delivery of a novel technology rather than through intermediate effects on individual perceptions of community mobilisation and HIV stigma.

We reported that the effect of the intervention on recent testing mostly occurred through direct pathways. Therefore, we mainly attribute the impact of the intervention to community ownership in the design and implementation of the HIVST campaign, which showed good coverage, rather than to changes in individual perceptions of social cohesion, shared HIV concern, and critical consciousness [25]. The absence of indirect effects potentially stems from the intervention design. The intervention was developed for communities to periodically lead provision of programmes, with frequency dependent on contextual factors including prevalence of undiagnosed HIV. The short implementation period had certain advantages, with the intervention yielding low unit costs for a community testing programme [43]. However, such a strategy is perhaps more conducive to community participation in biomedical interventions in contrast with interventions aimed at impacting social and structural determinants. Previous studies of community participation involved multi-year implementation to build community empowerment [13, 44]. Longer implementation periods and more explicit intervention on dimensions of community empowerment may therefore be needed to influence upstream determinants but would likely require additional economic investment.

Despite the lack of evidence for indirect effects, we found that the community-led HIVST intervention may have led to changes in individual perceptions of shared HIV concern and social cohesion, overall and among subgroups including women. Of the potential mediators, we posited that the intervention would most likely impact community HIV concern, which captures the importance of HIV as a collective priority, since the measure was specific to HIV. More generic scores included social cohesion, which captured community connectedness, and critical consciousness, which measured collective problem awareness and resolution. In the community-led HIVST arm, individual perceptions of social cohesion, community concern for HIV, and critical consciousness had positive associations with recent testing at lower ranges of each score followed by negative associations at higher levels. The quadratic relationship may indicate the limited effect of community mobilisation domains on the outcome, which reached a maximum point at low scores. Few studies have quantitatively evaluated the contribution of community participation towards improving HIV-related outcomes. A multi-country study in southern Africa and Thailand reported that community mobilisation delivered with mobile HTS increased positive social norms for testing [11]. Success was attributed to community engagement and relationship building and

context-specific, iterative implementation [45]. A South African study reported associations between community mobilisation domains and testing following the implementation of a community mobilisation intervention [44], with interpersonal and community-level respect, communication, and empathy concluded to be integral components of change [46]. Our study adds to the literature by evaluating the role of community participation and continues to highlight the potential of investing in community health systems as a prevention strategy.

We hypothesised that the intervention could reduce perceived community HIV stigma at individual level by mobilising community support for prevention or normalising testing through HIVST. This study did not find strong evidence of an intervention effect on community HIV stigma nor an effect of stigma levels on recent testing. To reduce stigma, interventions might also require longer periods of implementation that specifically target drivers of stigma [47]. Disentangling the effects of stigma can be challenging and is perhaps limited by our mediation framework. Community HIV stigma was posited to be on the causal pathway between the intervention and outcome, but it is possible, for example, that changes in community concern for HIV might first be necessary to reduce stigma. Further, community HIV stigma may have a bidirectional relationship with the outcome, with reduced stigma increasing uptake of HIVST and further normalising testing and reducing stigma. In the context of a multiple component intervention with simultaneous multilevel impacts, the challenge of establishing causal effects could be addressed by prospectively measuring variables at sequential timepoints [19].

A strength of our study is the use of recent mediation methods to evaluate mechanisms of action underlying the effect of a complex intervention and their relative contribution to changes in the outcome. We used statistical techniques that extend traditional mediation approaches to allow for multilevel mediation, nonlinearities, and intervention-mediator interaction. We also assessed mediation effects within a cluster-randomised design. By randomising the intervention, the study design minimises confounding and accounts for temporality assumptions between the intervention and mediator and the intervention and outcome, satisfying certain conditions important for causal interpretation [19]. Further, lessons from our study can potentially be applied to interventions that involve self-care technologies and engage community groups in similar settings.

A limitation of our study is the use of a cross-sectional survey to measure the outcome, potential mediators, and mediator-outcome confounders, meaning the assumption that the mediator precedes the outcome was not automatically satisfied by the study design. For example, it is possible that engaging in testing might affect an individual's perception of shared HIV concern or community HIV stigma. To account for the direction of causality, we ideally would have measured the potential mediators and outcome in temporal order. The assumption that the intervention does not impact

mediator-outcome confounders may also not be completely satisfied, though we aimed to select variables that conceptually were less likely be affected by the intervention. We also did not measure the potential mediators prior to the intervention and adjust for their levels at baseline, which may be a source of unmeasured mediator-outcome confounding. Sensitivity analysis can account for the respective associations between unmeasured confounders and the mediator and outcome and their impact on effect estimates [48]. We reported a lack of association between the potential mediators and outcome in the SOC arm, which could function as a proxy for baseline estimates and indicates that our conclusions would be unlikely to change.

Our mediation framework assessed a single mediator variable at a time but did not evaluate direct and indirect effects based on a combined set of mediators [48]. Given that we did not find evidence of an indirect effect for each mediator, we would be unlikely to observe a combined effect. We also did not account for whether the potential mediators affected other mediators of interest on the causal pathway [48], including the possibility that changes in community mobilisation domains might be requisite for changes in community HIV stigma, and bidirectional relationships between the potential mediators and outcome. Final limitations concern the measurement of outcomes and potential mediators. Measures for community mobilisation and community HIV stigma were based on perceived rather than experienced constructs and represent individual perceptions within the community [33]. We also only used a subset of domains of community mobilisation from a previously validated score [33]. Finally, our data were self-reported, which may have resulted in overestimation of outcomes and mediators in the community-led HIVST arm due to recall or social desirability bias.

Community-led delivery of HIVST increased uptake of recent testing, with the intervention effect predominantly occurring through direct pathways rather than indirectly by modifying individual perceptions of community mobilisation and community HIV stigma. The community-led HIVST intervention apparently increased perceived shared concern for HIV and social cohesion, which alongside perceived critical consciousness, had a protective effect on recent testing in the intervention arm but only at lower ranges of scores. By investigating mediation effects, we were able to evaluate factors important for optimising community-led strategies. Our findings suggest that the impact of the intervention mainly stemmed from community-driven service delivery rather than by modifying social and structural determinants. More frequent or active community participation might be required to achieve changes in community mobilisation and other social enablers as mechanisms for improving HIV-related outcomes. Trade-offs between immediate economic costs and building more sustainable community responses for prevention, however, would need to be considered.

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Supplementary materials

Contents

Supplementary Text 6.A. AGReMA checklist of items to include when reporting secondary mediation analyses within primary reports of randomised controlled trials

Section/Item	Item #	Recommendation	Page #
Introduction			
Objectives	1	State the objectives of the study specific to the mechanisms of interest. The objectives should specify whether the study aims to test or estimate the mechanistic effects	Introduction
Methods			
Effects of interest	2	Specify the effects of interest	Methods: Statistical analysis
Causal assumptions	3	Specify assumptions about the causal model	Methods: Statistical analysis
Measurement	4	Clearly describe the interventions or exposures, mediators, outcomes, confounders, and moderators that were used in the analyses. Specify how and when they were measured, the measurement properties, and whether blinded assessment was used	Methods: Mediation framework Methods: Statistical analysis
Statistical methods	5	Describe the statistical methods used to estimate the causal relationships of interest. This description should specify analytical strategies used to reduce confounding, model building procedures, justification for the inclusion or exclusion of possible interaction terms, modelling assumptions, and methods used to handle missing data. Provide a reference to the statistical software and package used	Methods: Statistical analysis
Results			
Participants	6	Describe baseline characteristics of participants included in mediation analyses. Report the total sample size and number of participants lost during follow-up or with missing data	Results
Outcomes and estimates	7	Report point estimates and uncertainty estimates for the exposure-mediator and mediator-outcome relationships. If inference concerning the causal relationship of interest is considered feasible given the causal assumptions, report the point estimate and uncertainty estimate	Results
Discussion			
Limitations	8	Discuss the limitations of the study including potential sources of bias	Discussion
Interpretation	9	Interpret the estimated effects considering the study's magnitude and uncertainty, plausibility of the causal assumptions, limitations, generalizability of the findings, and results from relevant studies	Discussion

Supplementary Text 6.B. Question items for community HIV stigma, community mobilisation, and social capital measures

Item
Social cohesion *
For each of the following statements, please indicate whether you strongly agree, somewhat agree, or disagree. 1. People in this village are willing to help their neighbors. 2. This is a close-knit community. 3. People in this village can be trusted. 4. People in this village generally get along well with each other. 5. People in this village share the same values. 6. People in this village look out for each other.
Shared concern for HIV *
For each of the following statements, please indicate whether you strongly agree, somewhat agree, or disagree. 1. People in your village are concerned about HIV. 2. People in your village consider HIV/AIDS an important issue. 3. People in your village talk openly about HIV. 4. People in your village believe that HIV impacts the community. 5. People in your village talk about HIV/AIDS at community meetings. 6. People in your village work together to prevent HIV from spreading. 7. People in your village work together to reduce the effects of HIV. 8. People in your village believe they can change the course of the HIV/AIDS epidemic. 9. People in your village exchange information about HIV/AIDS. 10. People in your village take HIV/AIDS seriously.
Critical consciousness *
For each of the following statements, please indicate whether you strongly agree, somewhat agree, or disagree. 1. People work together to solve problems in the village. 2. People in your village talk to each other about how to solve village problems. 3. People in your village enjoy discussing different ways to solve village problems. 4. People in your village are open to hearing different views about community problems and solutions. 5. People in your village volunteer to help solve village problems. 6. People in your village think about why there are problems so they can address the cause of problems. 7. There is a lot of cooperation between groups in the village. 8. People in this village not only talk about problems but they also try to solve them. 9. If your community fails to resolve a community problem, they will try another different approach to solve the problem. 10. If your community fails to resolve a community problem, they will learn from that experience and do a better job when they try to solve the problem in the future. 11. If leaders in the village fail to resolve a village problem, the villagers will work together to find a solution.
Community HIV stigma †
For each of the following statements, please indicate whether you strongly agree, somewhat agree, or disagree. 1. People living with or thought to be living with HIV are sometimes physically assaulted. 2. People sometimes talk badly about people living with or thought to be living with HIV. 3. People living with or thought to be living with HIV lose respect or standing. 4. People living with or thought to be living with HIV are verbally insulted, harassed, and/or threatened.
Social capital ‡
Are you a member of any of the following committees or groups? 1. Chiefs council 2. Development committee 3. Health committee 4. School committee 5. Women's group 6. Peer/youth group 7. Celebration/burial group 8. Commerce/finance group 9. Church or mosque 10. Sports group

* Questions were adapted from Lippman et al.[1] Responses used a three-point Likert scale (0–2).
† Questions were adapted from Stangl et al.[2] Responses used a three-point Likert scale (0–2).
‡ Questions were adapted from the Malawi Longitudinal Study of Families and Health.[3] Responses were binary (0–1).

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Supplementary Table 6.A. Implementation and process outcomes of community-led HIV self-testing intervention

Cluster	Description of strategies	Description of community health volunteers	Kits distributed *N*	Post-intervention survey *N*	Heard of self-testing for HIV *n* (%)	Self-tested for HIV in the last 3 months *n* (%)
1	Sensitisation and distribution: bawo match, boreholes, community meeting, door-to-door, religious centres. Linkage: active follow-up, accompany to facility.	9 CHAG members: women (*n* = 5), men (*n* = 4); 20–39 years (*n* = 8), ≥40 years (*n* = 1). 12 CVs*: women (*n* = 3), men (*n* = 9); 20–39 years (*n* = 10), ≥40 years (*n* = 1).	1,062	68	66 (97.1%)	63 (92.6%)
2	Sensitisation and distribution: community hall, community meeting, door-to-door, religious centres, sports fields. Linkage: active follow-up, material assistance, phone referral.	10 CHAG members: women (*n* = 4), men (*n* = 6); 15–19 years (*n* = 1), 20–39 years (*n* = 5), ≥40 years (*n* = 4). 15 CVs*: women (*n* = 8), men (*n* = 7); 20–39 years (*n* = 14).	2,218	77	77 (100.0%)	62 (80.5%)
3	Sensitisation and distribution: bawo match, community meeting, door-to-door, health post, markets, religious centres. Linkage: accompany to facility, active follow-up, material assistance.	10 CHAG members: women (*n* = 5), men (*n* = 5); 20–39 years (*n* = 9), ≥40 years (*n* = 1). 16 CVs: women (*n* = 8), men (*n* = 8); 15–19 years (*n* = 2), 20–39 years (*n* = 12), ≥40 years (*n* = 2).	1,621	49	48 (98.0%)	36 (73.5%)
4	Sensitisation and distribution: agricultural fields, community meeting, door-to-door, markets, religious centres, schools, sports fields, video shows. Linkage: active follow-up, material assistance, phone referral.	11 CHAG members: women (*n* = 9), men (*n* = 2); 20–39 years (*n* = 7), ≥40 years (*n* = 4). 14 CVs*: women (*n* = 11), men (*n* = 2); 20–39 years (*n* = 11), ≥40 years (*n* = 2).	1,806	43	41 (95.3%)	25 (58.1%)
5	Sensitisation and distribution: bawo match, bicycle repair shops, boreholes, community meeting, door-to-door, fishing docks, markets, restaurants and bars, schools, sports fields, video shows. Linkage: accompany to facility, material assistance.	10 CHAG members: women (*n* = 6), men (*n* = 4); 15–19 years (*n* = 1), 20–39 years (*n* = 8), ≥40 years (*n* = 1). 10 CVs: women (*n* = 3), men (*n* = 7); 15–19 years (*n* = 2), 20–39 years (*n* = 7), ≥40 years (*n* = 1).	1,698	55	54 (98.2%)	44 (80.0%)
6	Sensitisation and distribution: businesses and shops, community meeting, door-to-door, markets, religious centres, schools, sports fields.	11 CHAG members*: women (*n* = 5), men (*n* = 6); 20–39 years (*n* = 9), ≥40 years (*n* = 1). 20 CVs: women (*n* = 12), men (*n* = 8); 20–39 years (*n* = 17), ≥40 years (*n* = 3).	2,864	67	64 (95.5%)	27 (40.3%)

Cluster	Description of strategies	Description of community health volunteers	Kits distributed *N*	*N*	Post-intervention survey: Heard of self-testing for HIV *n* (%)	Post-intervention survey: Self-tested for HIV in the last 3 months *n* (%)
	Linkage: active follow-up, accompany to facility.					
7	Sensitisation and distribution: community meeting and gule wamkulu, door-to-door, markets, religious centres. Linkage: active follow-up, material assistance, phone referral.	11 CHAG members: women (*n* = 6), men (*n* = 5); 20–39 years (*n* = 11). 11 CVs: women (*n* = 5), men (*n* = 6); 20–39 years (*n* = 11).	2,379	95	92 (96.8%)	74 (77.9%)
8	Sensitisation and distribution: barbershops, bawo match, boreholes, community meeting, door-to-door, maize mills, under-5 clinic. Linkage: accompany to facility, active follow-up, material assistance.	11 CHAG members: women (*n* = 8), men (*n* = 3); 15–19 years (*n* = 1), 20–39 years (*n* = 9), ≥40 years (*n* = 1). 16 CVs: women (*n* = 8), men (*n* = 8); 15–19 years (*n* = 1), 20–39 years (*n* = 15).	984	52	52 (100.0%)	44 (84.6%)
9	Sensitisation and distribution: bawo match, boreholes, businesses and shops, community meeting, door-to-door, maize mills, religious centres, schools, sports fields, video shows, youth clubs. Linkage: active follow-up, material assistance, phone referral.	11 CHAG members: women (*n* = 5), men (*n* = 6); 20–39 years (*n* = 5), ≥40 years (*n* = 6). 13 CVs: women (*n* = 8), men (*n* = 5); 15–19 years (*n* = 1), 20–39 years (*n* = 10), ≥40 years (*n* = 2).	1,596	55	55 (100.0%)	45 (81.8%)
10	Sensitisation and distribution: bawo match, boreholes, businesses and shops, community hall, community meeting, door-to-door, markets, schools, sports fields.	7 CHAG members*: women (*n* = 4), men (*n* = 3); 20–39 years (*n* = 2), ≥40 years (*n* = 3). 10 CVs: women (*n* = 4), men (*n* = 6), 20–39 years (*n* = 5), ≥40 years (*n* = 5).	819	60	57 (95.0%)	49 (81.7%)
11	Sensitisation and distribution: agricultural fields, community hall, community meeting, door-to-door, markets, religious centres, schools, sports fields, youth hall. Linkage: active follow-up, phone referral.	12 CHAG members: women (*n* = 11), men (*n* = 1); 20–39 years (*n* = 10), ≥40 years (*n* = 2). 16 CVs: women (*n* = 13), men (*n* = 3); 20–39 years (*n* = 14), ≥40 years (*n* = 2).	2,490	79	66 (83.5%)	36 (45.6%)
12	Sensitisation and distribution: chief home, community hall, community meeting, door-to-door, sports fields, video shows. Linkage: active follow-up, accompany to facility.	11 CHAG members*: women (*n* = 7), men (*n* = 4); 20–39 years (*n* = 7), ≥40 years (*n* = 3). 8 CVs: women (*n* = 6), men (*n* = 2); 20–39 years (*n* = 7), ≥40 years (*n* = 1).	1,038	97	90 (92.8%)	64 (66.0%)

Cluster	Description of strategies	Description of community health volunteers	Kits distributed *N*	Post-intervention survey *N*	Heard of self-testing for HIV *n* (%)	Self-tested for HIV in the last 3 months *n* (%)
13	Sensitisation and distribution: bawo match, community meeting, door-to-door, fishing docks. Linkage: material assistance, phone referral.	11 CHAG members: women (*n* = 4), men (*n* = 7); 20–39 years (*n* = 9), ≥40 years (*n* = 2). 8 CVs*: women (*n* = 2), men (*n* = 5); 20–39 years (*n* = 4), ≥40 years (*n* = 3).	947	53	53 (100.0%)	41 (77.4%)
14	Sensitisation and distribution: boreholes, community meeting, door-to-door, health post, markets, religious centres, sports fields. Linkage: active follow-up, accompany to facility, material assistance.	10 CHAG members: women (*n* = 9), men (*n* = 1); 20–39 years (*n* = 10). 13 CVs: women (*n* = 7), men (*n* = 6); 15–19 years (*n* = 2), 20–39 years (*n* = 10), ≥40 years (*n* = 1).	1,010	54	54 (100.0%)	45 (83.3%)
15	Sensitisation and distribution: community hall, community meeting, door-to-door, markets, religious centres, sports fields. Linkage: active follow-up, accompany to facility, material assistance.	12 CHAG members: women (*n* = 9), men (*n* = 3); 20–39 years (*n* = 9), ≥40 years (*n* = 3). 16 CVs*: women (*n* = 9), men (*n* = 6); 20–39 years (*n* = 11), ≥40 years (*n* = 4).	1,784	66	63 (95.5%)	49 (74.2%)
Total			24,316	970	932 (96.1%)	704 (72.6%)

CHAG, community health action group; CV, community volunteer.
* Missing data on sex or age.

Supplementary Table 6.B1. Effect of community-led HIV self-testing intervention and potential mediators among men

		(1) Effect of intervention on potential mediator *	(2) Effect of potential mediator on HIV testing in the last 3 months by study arm †		
		Adjusted mean difference (95% CI) *p*-value	Community-led HIVST Adjusted risk ratio (95% CI) *p*-value	SOC Adjusted risk ratio (95% CI) *p*-value	*p*-value for interaction for study arm ‡
(A)	Community HIV stigma	0.00 (-0.17–0.17) 1.00	0.99 (0.93–1.05) 0.68	0.92 (0.78–1.08) 0.31	0.33
(B)	Social cohesion	0.10 (-0.09–0.29) 0.30	0.89 (0.83–0.96) 0.003	1.06 (0.93–1.20) 0.39	0.10
	Social cohesion^2		0.94 (0.87–1.03) 0.18	1.01 (0.88–1.15) 0.92	
(C)	Shared concern for HIV	0.11 (-0.08–0.30) 0.24	0.89 (0.82–0.97) 0.01	1.04 (0.81–1.32) 0.78	0.18
	Shared concern for HIV^2		0.89 (0.82–0.97) 0.006	1.04 (0.90–1.21) 0.61	
(D)	Critical consciousness	0.01 (-0.19–0.21) 0.89	0.88 (0.82–0.95) 0.001	1.06 (0.86–1.29) 0.59	0.12
	Critical consciousness^2		0.92 (0.86–0 .99) 0.04	1.00 (0.84–1.19) 0.98	

HIVST, HIV self-testing; SOC, standard of care. *N* = 757.

* Adjusted mean difference for the study arm (intervention-control). Model 1 is a linear regression model of the potential mediators on the study arm, with each mediator evaluated separately as the outcome in Models A to D. Analysis adjusts for age group, literacy, religion, ethnicity, health status, and social capital, with a random effect for cluster.

† Adjusted risk ratio for the linear term for the potential mediator. Model 2 is a Poisson regression model of recent HIV testing on the mediators with each mediator evaluated separately as the exposure in Models A to D. Models 2B to D include both a linear and quadratic term for the mediators. Analysis is stratified by study arm and adjusts for age group, literacy, religion, ethnicity, health status, and social capital, with a robust standard error and random effect for cluster.

‡ Interaction *p*-value in Model 2A is for the study arm and the linear term for the potential mediator. Interaction *p*-values in Models 2B to D are for the study arm and the linear and quadratic terms for the mediators.

Supplementary Table 6.B2. Effect of community-led HIV self-testing intervention and potential mediators among women

		(1) Effect of intervention on potential mediator *	(2) Effect of potential mediator on HIV testing in the last 3 months by study arm †		
		Adjusted mean difference (95% CI) *p*-value	Community-led HIVST Adjusted risk ratio (95% CI) *p*-value	SOC Adjusted risk ratio (95% CI) *p*-value	*p*-value for interaction for study arm ‡
(A)	Community HIV stigma	-0.01 (-0.21–0.19) 0.91	0.95 (0.90–1.00) 0.05	0.92 (0.81–1.04) 0.18	0.80
(B)	Social cohesion	0.17 (-0.01–0.35) 0.06	0.95 (0.89–1.01) 0.09	1.00 (0.93–1.07) 0.99	0.27
	Social cohesion^2		0.96 (0.94–0.99) 0.01	1.00 (0.95–1.05) 1.00	
(C)	Shared concern for HIV	0.16 (0.00–0.31) 0.05	0.93 (0.88–0.99) 0.02	0.94 (0.84–1.06) 0.32	0.67
	Shared concern for HIV^2		0.98 (0.93–1.02) 0.26	0.95 (0.88–1.02) 0.17	
(D)	Critical consciousness	0.18 (-0.02–0.37) 0.07	0.95 (0.88–1.03) 0.22	1.00 (0.89–1.13) 0.98	0.66
	Critical consciousness^2		0.99 (0.95–1.02) 0.45	1.01 (0.91–1.11) 0.91	

HIVST, HIV self-testing; SOC, standard of care. Female, *N* = 1136.

* Adjusted mean difference for the study arm (intervention-control). Model 1 is a linear regression model of the potential mediators on the study arm, with each mediator evaluated separately as the outcome in Models A to D. Analysis adjusts for age group, literacy, religion, ethnicity, health status, and social capital, with a random effect for cluster.

† Adjusted risk ratio for the linear term for the potential mediator. Model 2 is a Poisson regression model of recent HIV testing on the mediators with each mediator evaluated separately as the exposure in Models A to D. Models 2B to D include both a linear and quadratic term for the mediators. Analysis is stratified by study arm and adjusts for age group, literacy, religion, ethnicity, health status, and social capital, with a robust standard error and random effect for cluster.

‡ Interaction *p*-value in Model 2A is for the study arm and the linear term for the potential mediator. Interaction *p*-values in Models 2B to D are for the study arm and the linear and quadratic terms for the mediators.

Supplementary Table 6.C. Direct and indirect effect of community-led HIV self-testing intervention by sex

		Effect of intervention on HIV testing in the last 3 months		
		Direct effect Adjusted risk ratio (bootstrap CI)	Indirect effect Adjusted risk ratio (bootstrap CI)	Total effect Adjusted risk ratio (bootstrap CI)
Men				
(A)	Community HIV stigma	1.92 (1.67–2.25)	1.00 (0.99–1.01)	1.92 (1.67–2.24)
(B)	Social cohesion *	1.72 (1.45–2.17)	0.99 (0.97–1.01)	1.71 (1.45–2.15)
(C)	Shared concern for HIV *	1.82 (1.49–2.22)	1.00 (0.99–1.03)	1.83 (1.51–2.24)
(D)	Critical consciousness *	1.79 (1.49–2.18)	1.02 (0.99–1.05)	1.82 (1.53–2.23)
Women				
(A)	Community HIV stigma	1.80 (1.66–2.00)	1.00 (0.99–1.01)	1.81 (1.66–2.00)
(B)	Social cohesion *	1.75 (1.51–2.02)	1.00 (0.99–1.01)	1.75 (1.52–2.02)
(C)	Shared concern for HIV *	1.75 (1.54–2.01)	0.99 (0.98–1.00)	1.74 (1.53–1.99)
(D)	Critical consciousness *	1.72 (1.52–1.99)	1.00 (0.98–1.00)	1.71 (1.52–1.99)

Men: *N* = 757; Women: *N* = 1136. Estimates for direct and indirect effects are based on Models 1 and 3. Model 3 is a Poisson regression model of recent HIV testing on the study arm, with each potential mediator evaluated separately as a covariate in Models A to D. An interaction term for the study arm and the mediator is included. Analysis adjusts for age group, literacy, religion, ethnicity, health status, and social capital, with a robust standard error and random effect for cluster. Confidence intervals are calculated using a bias-corrected bootstrap approach.

* Model includes log transformation of the potential mediator.

Supplementary Table 6.D1. Effect of community-led HIV self-testing intervention and potential mediators among adolescents

		(1) Effect of intervention on potential mediator *	(2) Effect of potential mediator on HIV testing in the last 3 months by study arm †		
		Adjusted mean difference (95% CI) *p*-value	Community-led HIVST Adjusted risk ratio (95% CI) *p*-value	SOC Adjusted risk ratio (95% CI) *p*-value	*p*-value for interaction for study arm ‡
(A)	Community HIV stigma	0.05 (-0.14–0.24) 0.58	0.95 (0.87–1.03) 0.24	0.86 (0.72–1.02) 0.08	0.18
(B)	Social cohesion	-0.06 (-0.26–0.13) 0.54	0.98 (0.90–1.06) 0.57	1.01 (0.83–1.23) 0.92	0.85
	Social cohesion^2		0.95 (0.88–1.02) 0.15	0.99 (0.83–1.17) 0.88	
(C)	Shared concern for HIV	-0.02 (-0.23–0.19) 0.84	0.92 (0.83–1.01) 0.07	0.99 (0.83–1.16) 0.87	0.47
	Shared concern for HIV^2		0.95 (0.89–1.02) 0.16	1.02 (0.90–1.14) 0.79	
(D)	Critical consciousness	-0.08 (-0.27–0.10) 0.36	0.94 (0.86–1.02) 0.13	0.95 (0.82–1.10) 0.52	0.74
	Critical consciousness^2		0.94 (0.87–1.01) 0.11	0.95 (0.79–1.15) 0.63	

HIVST, HIV self-testing; SOC, standard of care. *N* = 407.
* Adjusted mean difference for the study arm (intervention-control). Model 1 is a linear regression model of the potential mediators on the study arm, with each mediator evaluated separately as the outcome in Models A to D. Analysis adjusts for sex, literacy, religion, ethnicity, health status, and social capital, with a random effect for cluster.
† Adjusted risk ratio for the linear term for the potential mediator. Model 2 is a Poisson regression model of recent HIV testing on the mediators, with each mediator evaluated separately as the exposure in Models A to D. Models 2B to D include both a linear and quadratic term for the mediators. Analysis is stratified by study arm and adjusts for sex, literacy, religion, ethnicity, health status, and social capital, with a robust standard error and random effect for cluster.
‡ Interaction *p*-value in Model 2A is for the study arm and the linear term for the potential mediator. Interaction *p*-values in Models 2B to D are for the study arm and the linear and quadratic terms for the mediators.

Supplementary Table 6.D2. Effect of community-led HIV self-testing intervention and potential mediators among adults aged 40 years and older

		(1) Effect of intervention on potential mediator *	(2) Effect of potential mediator on HIV testing in the last 3 months by study arm †		
		Adjusted mean difference (95% CI) *p*-value	Community-led HIVST Adjusted risk ratio (95% CI) *p*-value	SOC Adjusted risk ratio (95% CI) *p*-value	*p*-value for interaction for study arm ‡
(A)	Community HIV stigma	-0.06 (-0.30–0.18) 0.64	0.93 (0.85–1.02) 0.12	0.83 (0.70–0.98) 0.03	0.25
(B)	Social cohesion	0.15 (-0.01–0.31) 0.06	0.92 (0.86–0.99) 0.02	1.10 (0.96–1.26) 0.17	0.28
	Social cohesion^2		0.98 (0.93–1.03) 0.36	0.93 (0.79–1.08) 0.34	
(C)	Shared concern for HIV	0.10 (-0.10–0.29) 0.33	0.91 (0.82–1.00) 0.06	0.98 (0.81–1.20) 0.88	0.69
	Shared concern for HIV^2		0.85 (0.77–0.95) 0.004	0.82 (0.63–1.07) 0.14	
(D)	Critical consciousness	0.13 (-0.13–0.38) 0.33	0.91 (0.79–1.04) 0.17	1.01 (0.81–1.26) 0.93	0.76
	Critical consciousness^2		0.94 (0.87–1.03) 0.18	1.02 (0.88–1.19) 0.78	

HIVST, HIV self-testing; SOC, standard of care. *N* = 532.

* Adjusted mean difference for the study arm (intervention-control). Model 1 is a linear regression model of the potential mediators on the study arm, with each mediator evaluated separately as the outcome in Models A to D. Analysis adjusts for sex, literacy, religion, ethnicity, health status, and social capital, with a random effect for cluster.

† Adjusted risk ratio for the linear term for the potential mediator. Model 2 is a Poisson regression model of recent HIV testing on the mediators, with each mediator evaluated separately as the exposure in Models A to D. Models 2B to D include both a linear and quadratic term for the mediators. Analysis is stratified by study arm and adjusts for sex, literacy, religion, ethnicity, health status, and social capital, with a robust standard error and random effect for cluster.

‡ Interaction *p*-value in Model 2A is for the study arm and the linear term for the potential mediator. Interaction *p*-values in Models 2B to D are for the study arm and the linear and quadratic terms for the mediators.

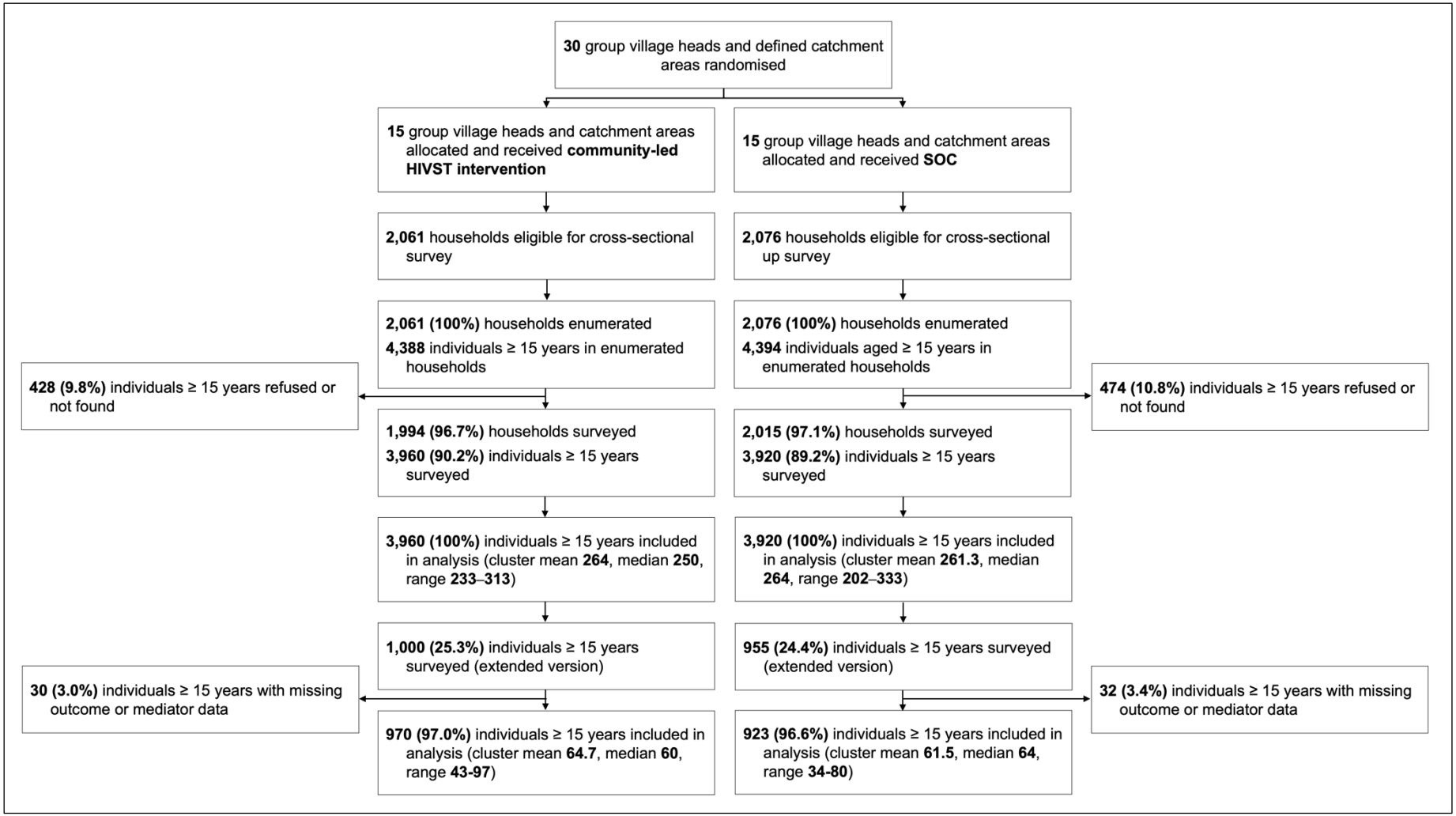
Supplementary Table 6.E. Direct and indirect effect of community-led HIV self-testing intervention by sex

		Effect of intervention on HIV testing in the last 3 months		
		Direct effect Adjusted risk ratio (bootstrap CI)	Indirect effect Adjusted risk ratio (bootstrap CI)	Total effect Adjusted risk ratio (bootstrap CI)
15–19 years				
(A)	Community HIV stigma	1.77 (1.49–2.12)	1.00 (0.98–1.01)	1.76 (1.48–2.11)
(B)	Social cohesion *	1.66 (1.31–2.13)	1.00 (0.97–1.02)	1.66 (1.32–2.13)
(C)	Shared concern for HIV *	1.66 (1.22–2.25)	1.01 (0.99–1.06)	1.67 (1.24–2.27)
(D)	Critical consciousness *	1.61 (0.89–2.50)	1.05 (1.01–1.12)	1.69 (0.95–2.59)
≥40 years				
(A)	Community HIV stigma	1.78 (1.56–2.02)	1.00 (1.00–1.01)	1.78 (1.56–2.03)
(B)	Social cohesion *	1.71 (1.43–2.13)	1.00 (0.98–1.03)	1.71 (1.44–2.14)
(C)	Shared concern for HIV *	1.71 (1.46–2.12)	1.00 (0.99–1.02)	1.71 (1.46–2.12)
(D)	Critical consciousness *	1.59 (1.34–1.91)	1.00 (1.00–1.02)	1.59 (1.34–1.91)

15–19 years, *N* = 407; ≥40 years, *N* = 532. Estimates for direct and indirect effects are based on Models 1 and 3. Model 3 is a Poisson regression model of recent HIV testing on the study arm, with each potential mediator evaluated separately as a covariate in Models A to D. An interaction term for the study arm and the mediator is included. Analysis adjusts for sex, literacy, religion, ethnicity, health status, and social capital, with a robust standard error and random effect for cluster. Confidence intervals are calculated using a bias-corrected bootstrap approach.

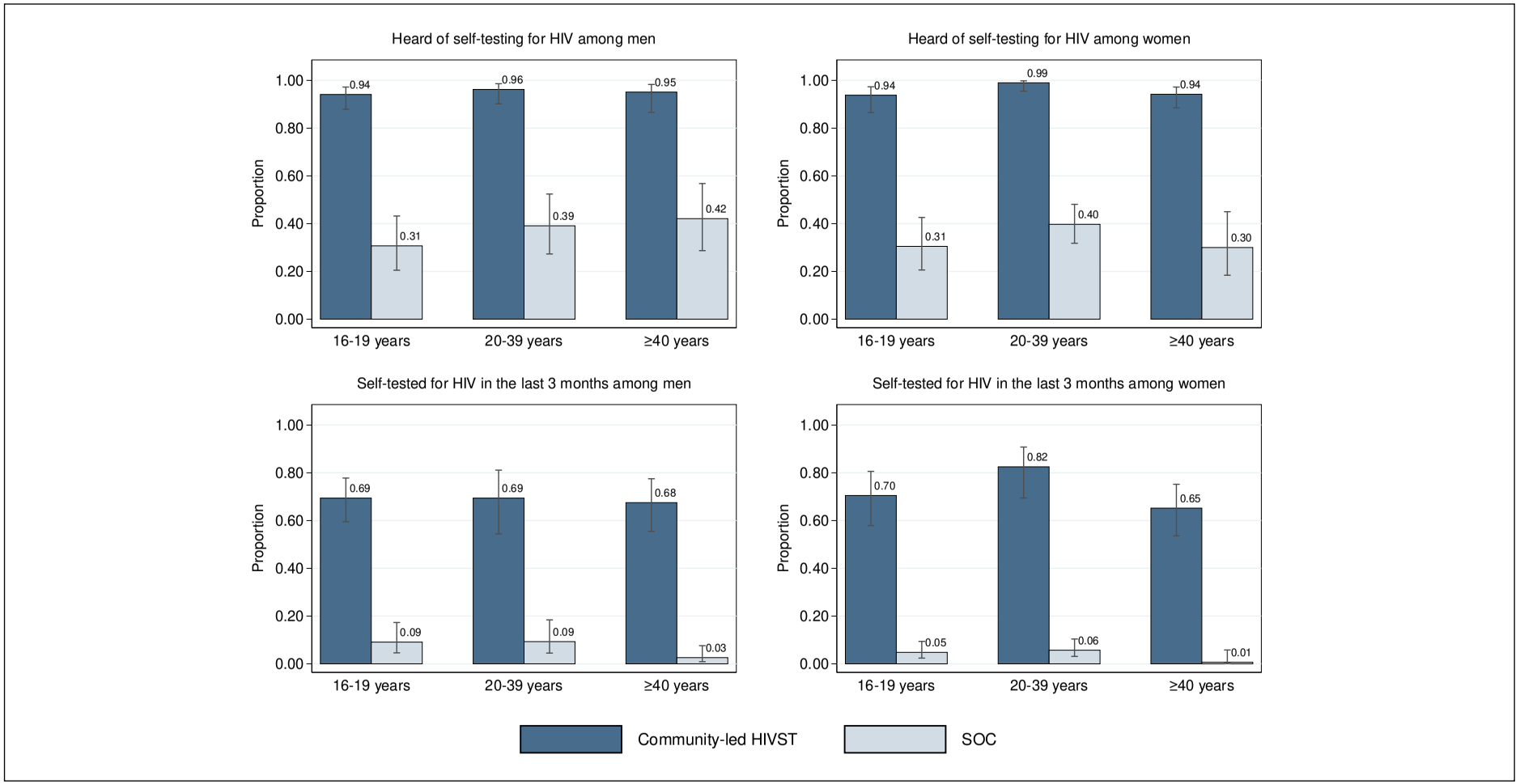
* Model includes log transformation of the potential mediator.

Supplementary Figure 6.A. Flow diagram of the cluster-randomised trial



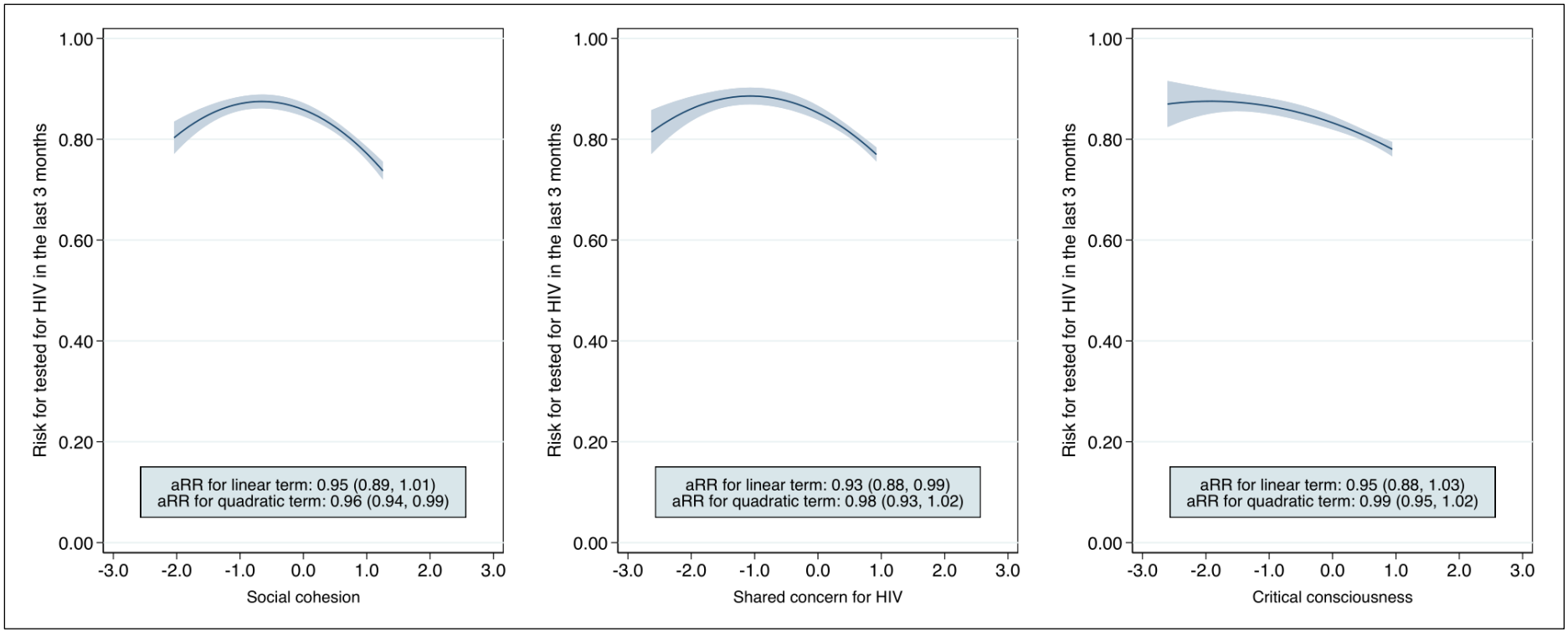
HIVST, HIV self-testing; SOC, standard of care

Supplementary Figure 6.B. Process outcomes of community-led HIV self-testing intervention by sex and age group



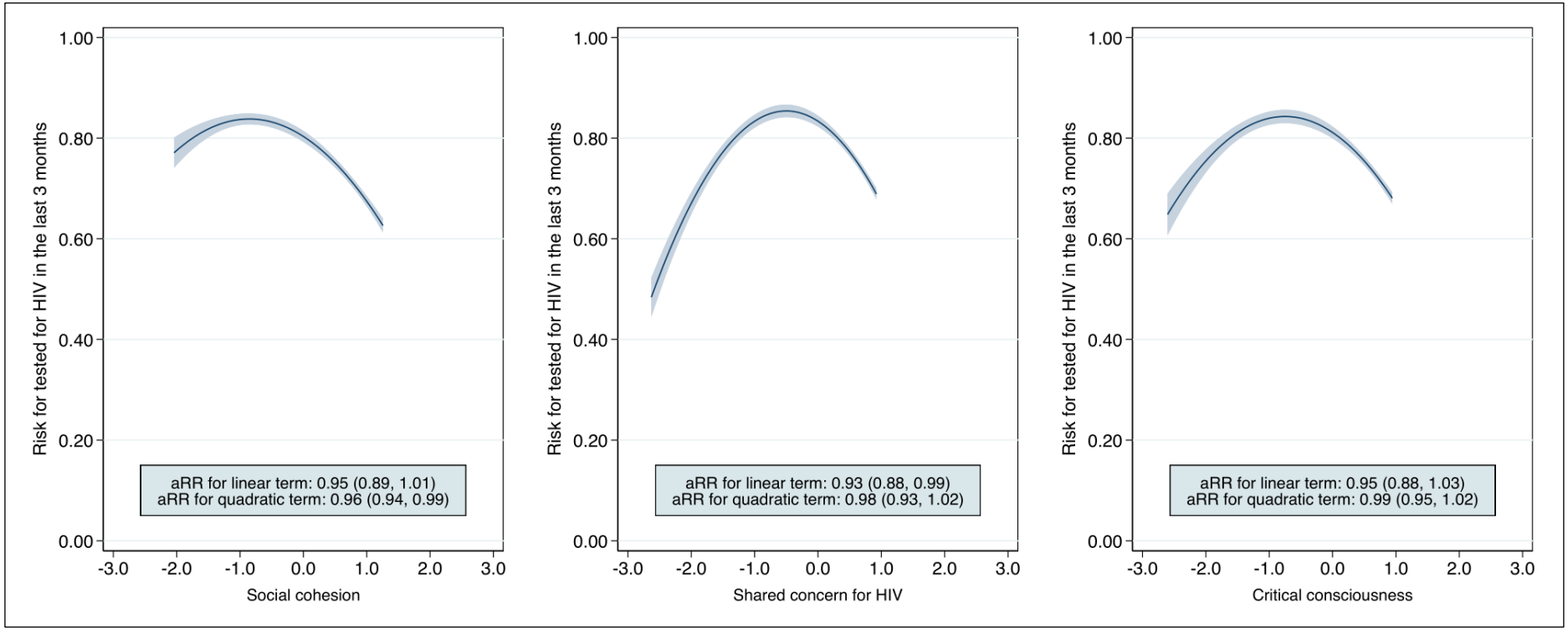
HIVST, HIV self-testing; SOC, standard of care. Graphs indicate the proportions and 95% CIs adjusted for clustering following the community-led HIVST intervention. Data are stratified by study arm, sex, and age group.

Supplementary Figure 6.C1. Prediction plots of recent HIV testing and potential mediators among women



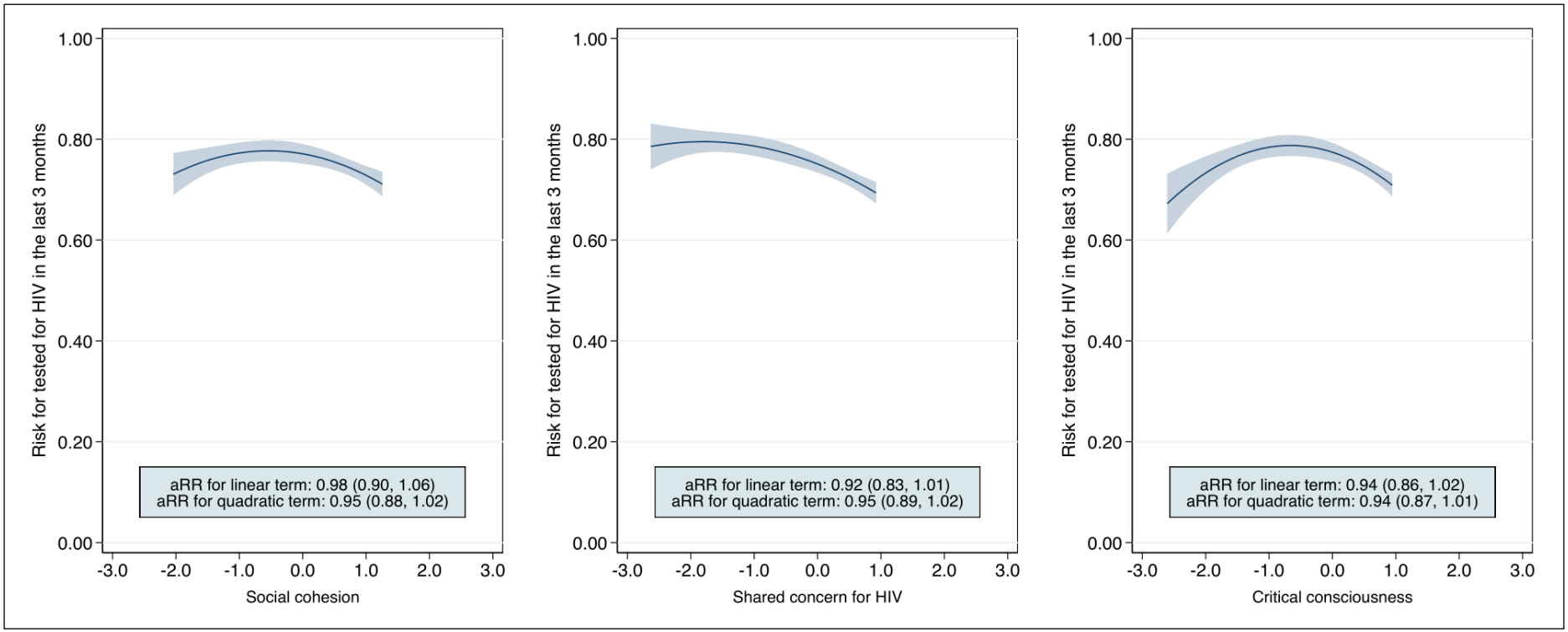
aRR, adjusted risk ratio. Prediction plots with fitted values and 95% CIs. Prediction values obtained from Poisson regression of recent HIV testing on the linear and quadratic terms for the potential mediators among women in the community-led HIV self-testing arm. Scores for mediators are standardised.

Supplementary Figure 6.C2. Prediction plots of recent HIV testing and potential mediators among men



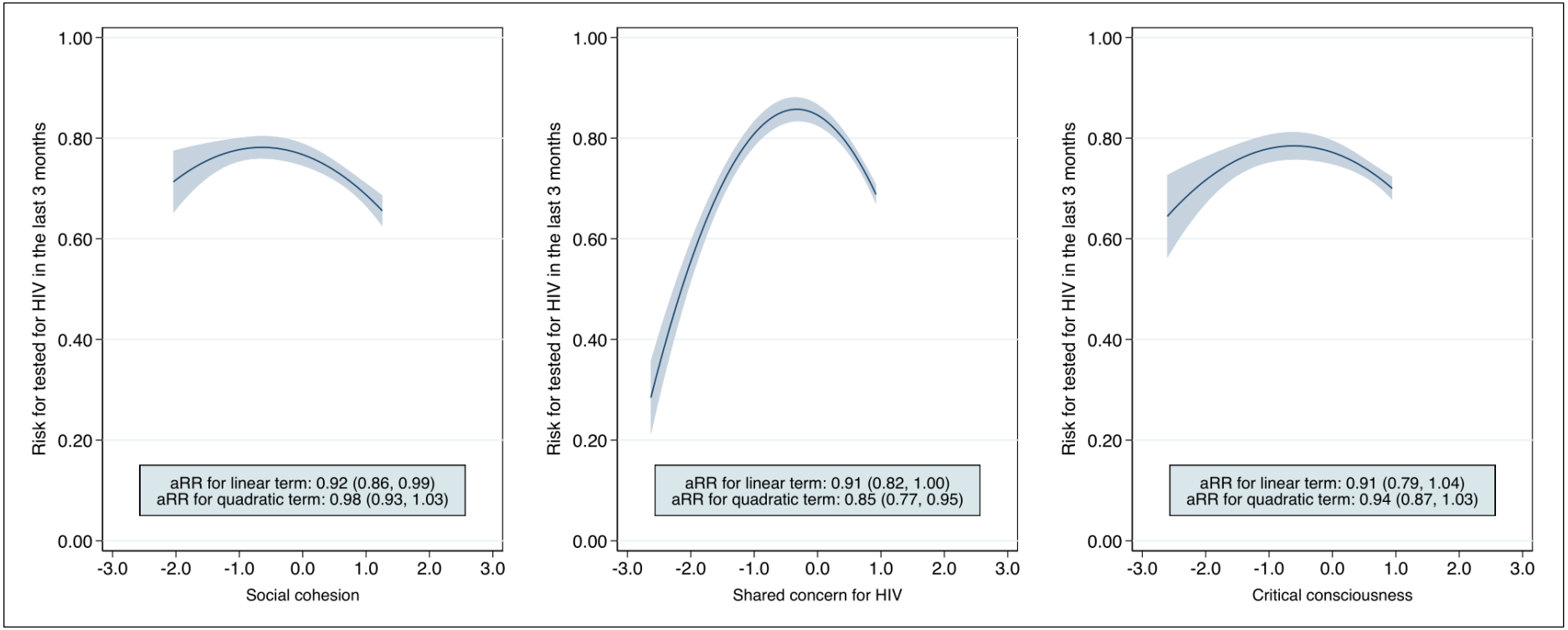
aRR, adjusted risk ratio. Prediction plots with fitted values and 95% CIs. Prediction values obtained from Poisson regression of recent HIV testing on the linear and quadratic terms for the potential mediators among men in the community-led HIV self-testing arm. Scores for mediators are standardised.

Supplementary Figure 6.D1. Prediction plots of recent HIV testing and potential mediators among adolescents



aRR, adjusted risk ratio. Prediction plots with fitted values and 95% CIs. Prediction values obtained from Poisson regression of recent HIV testing on the linear and quadratic terms for the potential mediators among adolescents aged 15-19 years in the community-led HIV self-testing arm. Scores for mediators are standardised.

Supplementary Figure 6.D2. Prediction plots of recent HIV testing and potential mediators among adults aged 40 years and older



aRR, adjusted risk ratio. Prediction plots with fitted values and 95% CIs. Prediction values obtained from Poisson regression of recent HIV testing on the linear and quadratic terms for the potential mediators among adults aged 40 years and older in the community-led HIV self-testing arm. Scores for mediators are standardised.

Chapter 7.
Conclusion

7.1 Main findings

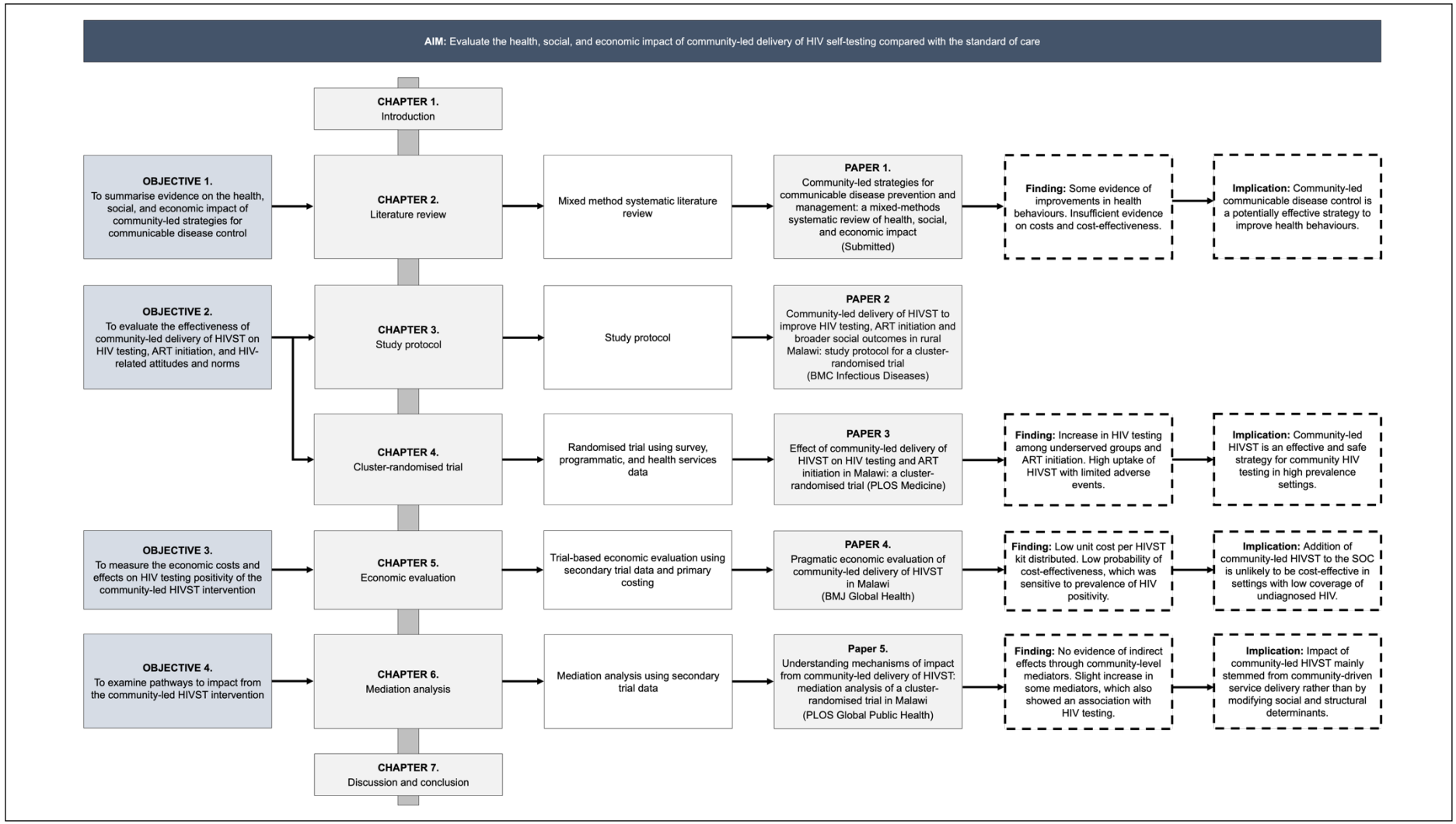
Alternative models for HIV testing services (HTS) are needed to meet and maintain global elimination goals, especially among population subgroups with barriers to accessing services at facility level. Community-based HTS can improve coverage of testing and diagnose people at earlier stages of disease, but national HIV programmes in high-burden settings remain limited by financial and resource constraints. Community-led HIV self-testing (HIVST) could address both supply and demand-side barriers to HTS by concurrently devolving control to communities, who lead decision making and resource mobilisation for service provision, and individuals, who perform their own tests.

The aim of this thesis was to evaluate the health, social, and economic impact of community-led delivery of HIVST compared with the standard of care (SOC) among rural populations in Malawi. The thesis included four objectives, with key findings associated with each objective outlined in this section (**Figure 7.1**).

Objective 1: To summarise evidence on the health, social, and economic impact of community-led strategies for communicable disease control.

Chapter 2 includes a mixed-methods systematic literature review that aimed to understand the impact of community-led strategies for improving communicable disease prevention and management: to what extent, at what costs, through which mechanisms, and in what contexts. The review included cluster-randomised trials and related economic and process evaluations that evaluated community-led strategies for communicable disease control in low-and-middle-income countries.

Figure 7.1. Structure of thesis.



ART, antiretroviral therapy; HIVST, HIV self-testing. Mapping of thesis aims, objectives, chapters, and methods with findings and implications.

I found that community-led approaches can improve health behaviours including for diarrhoeal diseases, HIV, malaria, and neglected tropical diseases, based on evidence with moderate risk of bias. Evidence for impact on mortality and morbidity, health care access and utilisation, and community and social outcomes was less conclusive, with fewer trials measuring these outcomes and results inconsistent among these studies. Impact was dependent on achieving sufficient intensity of implementation by community actors, and that factors facilitating implementation included motivation to engage and implement communicable disease strategies, trust between community actors and the wider community, and engagement with stakeholders including health care providers. Contextual influences included demographic and social factors, such as attitudes and norms around communicable diseases. Economic studies were few and many omitted societal costs and consequences. The chapter concluded that community-led communicable disease control is a potentially effective strategy for improving health behaviours and contributing to sustainable development goals.

Objective 2: To evaluate the effectiveness of community-led delivery of HIVST on HIV testing, antiretroviral therapy initiation, and HIV-related attitudes and norms.

In Chapter 3, I developed an intervention, which engaged established community health groups and volunteers in participatory workshops and trainings to design and deliver HIVST campaigns linked to treatment and prevention. To evaluate the intervention, I conducted a cluster-randomised trial allocating group village-head catchment areas to either the community-led HIVST intervention or the SOC arm, as presented in Chapter 4.

I found that community-led delivery of 7-day HIVST campaigns increased HIV testing in underserved subgroups. Lifetime testing among adolescents increased by 15.2%, with more substantial differences in the intervention effect among younger adolescents aged 15 to 17 years and boys. Compared with the SOC arm, testing in the last 3 months was substantially higher in the community-led HIVST arm for older adults aged 40 years and above (adjusted risk difference [RD], 42.1%, 95% CI 34.9% to 49.4%; $p < 0.001$) and men (adjusted RD 40.2%, 95% CI 32.9% to 47.4%; $p < 0.001$). Mutual knowledge of HIV status between sexual partners also increased in post-hoc analysis. Strong evidence of an increase in cumulative incidence of antiretroviral therapy (ART) initiation per 100,000 population was measured 3 months post-intervention (risk ratio, 1.89, 95% CI 1.21 to 2.95; $p = 0.007$), but not for the predefined 6-month period. Knowledge of the preventive benefits of HIV treatment and HIV testing stigma measures showed no differences between arms. HIVST uptake was high (74.7%), with limited adverse events. The chapter concluded that community-led HIVST was an effective and safe strategy that could rapidly achieve high impact and coverage in high prevalence settings.

Objective 3: To measure the economic costs and effects on HIV testing positivity of the community-led HIVST intervention.

Chapter 5 presented the results of the economic evaluation of the community-led HIVST intervention. I used a trial-based approach for individual-level data to estimate incremental costs and effects between study arms and the incremental cost per additional person tested HIV positive. Uncertainty was also examined.

From a provider perspective, the community-led HIVST showed an average cost of $5.70 per HIVST kit distributed, with test kits and personnel the main contributors of costs. The SOC costed $4.57 per person tested. Individual-level costs for HIV testing across an annual period were higher in the community-led HIVST arm than the SOC arm due to repeat testing, specifically HIVST uptake among individuals who recently tested at health facilities. Recent HIV testing positivity was higher in the community-led HIVST arm than the SOC arm (adjusted RD 1.2%, 95% CI 0.3% to 2.0%; p = 0.008). The incremental cost per additional person tested HIV positive was $324 but increased to $1,312 and $985 when adjusting for previously diagnosed self-testers or self-testers on treatment, respectively. Addition of community-led HIVST to the SOC had 4% to 45% probability of cost-effectiveness against a recommended threshold of $315 [1], with testing positivity a leading determinant of cost-effectiveness. The chapter concluded that community-led HIVST can be provided at a low additional unit cost but is unlikely to be cost-effective in settings with low coverage of undiagnosed HIV.

Objective 4: To examine pathways to impact from the community-led HIVST intervention.

In Chapter 6, I used mediation analysis to evaluate potential mediators of the effect of the community-led HIVST intervention on the outcome of HIV testing in the last 3 months. Hypothesised mediators included dimensions of community mobilisation, including social cohesion, shared concern for HIV, and raising critical consciousness, and community HIV stigma.

I reported that the effect of the intervention on recent HIV testing was almost entirely direct, with no evidence of indirect effects from changes in perceived social cohesion, shared HIV concern, critical consciousness, and community HIV stigma. Community-led HIVST apparently increased social cohesion (adjusted MD 0.15, 95% CI -0.03 to 0.32; p = 0.10) and shared HIV concern (adjusted MD 0.13, 95% CI -0.02 to 0.29; p = 0.09). Higher perceived social cohesion, community HIV concern, and critical consciousness also apparently had a positive relationship with recent testing but only at lower levels of scores. There was no evidence of intervention effects on critical

consciousness and community HIV stigma or an association between community stigma and recent testing. The chapter concluded that the effect of community-led HIVST mostly operated directly through community-driven service delivery rather than indirectly by modifying social and structural determinants.

7.2 Contributions of thesis

Defining innovative strategies to achieve global elimination goals for HIV

The Fast Track targets aim to achieve universal diagnosis, ART initiation, and viral suppression among people living with HIV, with substantial undiagnosed infection in underserved population subgroups [2]. This thesis delivered the first randomised trial on community-led HTS, which was described in Chapter 3. The trial builds on earlier studies of community-based HIVST that also demonstrated evidence of impact [3-6]. Findings from Chapter 4 established that community-led HIVST can notably increase testing among adolescents, older adults, and men and demand for ART initiation [7]. Uptake was considerably higher than a previous study of community-based HIVST in Malawi [5] as well as a sister trial of community-led HIVST in Zimbabwe [8]. Whereas the current trial used participatory workshops to facilitate action planning with established community health groups, the Zimbabwean trial involved less guidance of lay community members, demonstrating the importance of building community capacity for decision making and resource mobilisation. Further, the trial in this thesis reported minimal adverse events, moderating safety concerns around decentralising HIVST implementation [9].

Therefore, this thesis provides evidence to support community-led HIVST as an additional approach for HTS among subgroups with barriers to accessing facility-based services. Evidence is potentially generalisable to rural sub-Saharan African settings with high prevalence and similar community health cadres. Lessons may also be transferrable to other self-care technologies. There are increased calls for global investment in community-led service delivery in recognition of the importance of engaging communities living with and affected by HIV for epidemic control [10]. As national HIV programmes near global elimination goals, community-led HIVST could be considered for periodic implementation to rapidly increase testing coverage among underserved subgroups [11].

Identifying sustainable approaches for community HIV programmes

Evidence from this thesis supports community-led HIVST as a cost-efficient option for HTS at community level. Chapter 5 reported lower costs for community-led HIVST compared with community-based HIVST programmes in neighbouring rural districts and urban Blantyre as well

as community-based HTS in sub-Saharan Africa [12-14]. Lower costs were likely driven by the high volume of HIVST kits delivered within a short period of time as well as implementation through established community health systems. However, the economic analysis excluded community costs, potentially leading to underestimation of cost measures. Further, the community-led HIVST intervention showed low probability of cost-effectiveness, which was highly sensitive to prevalence of undiagnosed HIV. The findings from this thesis are important given that the share of global funding for community health programmes has been in decline [15]. The cost per new diagnosis is also increasing with decreasing coverage of undiagnosed HIV [1]. This thesis delivered a community-led approach that could potentially be adapted by national HIV programmes as a more sustainable model for periodic implementation of testing at community level, with potential for economies of scale and scope. Maximising likelihood of cost-effectiveness would require delivery to populations with more substantial prevalence of undiagnosed HIV. Programmes would also need to appropriately account for community costs, since there is a risk that decentralisation of resource use will be exploited as a substitute for more costly community-based strategies [16].

Understanding the value of community participation

Community participation in health care has long been advocated as a strategy that could increase the coverage and efficiency of health programmes and address upstream determinants of health [17]. Chapter 2 summarised the literature on the health, social, and economic impact of community-led approaches for communicable disease control and identified attributes of community participation and communicable disease strategies that influenced outcomes. Chapter 6 assessed causal mediation effects of the community-led HIVST intervention and found that the impact of the intervention most likely stemmed from community involvement in the design and implementation of HIVST delivery rather than from changes in social and structural determinants, with no evidence of indirect intervention effects. However, it is important to note that community and social outcomes are often difficult to measure and most studies are not powered to measure these outcomes [18]. Additionally, the model of community-led HIVST evaluated in this thesis was developed for communities to periodically lead provision of HTS. To impact more distal determinants of HIV, previous studies of community mobilisation for HIV prevention have involved multi-year implementation to build community empowerment and target social enablers [19, 20]. Nevertheless, findings generated from this thesis contribute evidence on the value of community participation in health programmes and the potential of investing in community health systems as a strategy for epidemic control.

Using novel methods in trial, economic and mediation analysis

Chapter 4 generated high-quality evidence on effectiveness through the cluster-randomised design. This thesis also employed novel methods in trial-based economic evaluation and mediation analysis. Chapter 5 used the cluster-randomised trial as an instrument for estimating individual-level costs and effects. Individual-level costs were estimated using the frequency of testing and self-testing events, providing insights into retesting behaviours and potential opportunities for efficiency gains. Estimation of incremental cost-effectiveness ratios used cluster-level methods and two-stage non-parametric bootstrap to account for the clustered design, correlation between costs and effects, and covariate adjustment [21-25]. For mediation analysis, Chapter 6 used recent statistical methods that extend traditional mediation approaches to allow for multi-level mediation, nonlinearities, and interactions [26-29]. By randomising the intervention, the study design minimises confounding and accounts for temporality assumptions between the intervention and mediator and the intervention and outcome, satisfying certain conditions important for causal interpretation [26].

7.3 Limitations

The first limitation of this thesis concerns the design of the cluster-randomised trial. The control arm of the SOC included facility-based HTS, conflating the impact of the community-led HIVST intervention by capturing both the effects of community participation and availability of HIVST. In contrast, a sister trial in Zimbabwe compared community-led HIVST against HIVST delivery by externally supported community distributors and found comparable HIVST uptake between arms [8]. The trial conducted in this thesis also had a small number of clusters. To minimise bias, randomisation was restricted using factors likely to be associated with the outcome [25]. Cluster-level analysis also adjusted for imbalances between arms in individual characteristics [25]. However, the analysis did not adjust for baseline differences since these outcomes were not measured. There was also a risk of contamination in cluster-randomised trials, with a handful of survey participants reporting use of HIVST kits in the SOC arm Additionally, allocation of arms could not be concealed during implementation due to the pragmatic study design.

Second, there were limitations related to outcome measurement. Most primary and secondary outcomes were self-reported, which could introduce recall or social desirability bias, including overreporting of testing in the community-led HIVST arm. For the mediation analysis, hypothesised mediators were not measured at baseline and accounted for in the analysis, potentially introducing a source of unmeasured mediator-outcome confounding. Mediator and outcome measures were also captured at the same time point, meaning the assumption that the mediator precedes the outcome was not immediately satisfied by the study design [26]. Further, measures for community and social variables were captured at individual level to represent perceptions rather than experiences within the community. While these measures have been validated in previous studies [30, 31] and showed

acceptable reliability in Chapter 6, constructs are nevertheless difficult to measure and studies may be underpowered to detect their effects [18]. Lastly, the sampling frame for the survey involved recruiting more geographically accessible households, potentially overestimating the intervention effect.

Third, the economic evaluation had limitations. Costs of pragmatic implementation were collected but within a controlled setting and therefore were likely higher than costs of routine implementation. At the same time, estimation of economic costs incurred by communities included time contributions but excluded other in-kind donations due to inconsistent measurement, though clusters with more complete data collection reported nominal costs. User costs were also not measured. To account for these limitations, sensitivity analysis aimed to evaluate uncertainty in costs. The outcome used was HIV testing positivity, with some adjustments made to improve comparison with the willingness-to-pay threshold based on the cost per new diagnosis [1]. However, outcomes did not use generic health metrics or consider non-health benefits. Impact can also occur at individual and community levels, immediate and extended time horizons, and through direct and indirect exposure, meaning benefits generated from the community-led HIVST intervention were likely to be underestimated [32-37]. For example, the unit of intervention is the community, with the value of collective benefits possibly different from the sum of individual benefits [37]. The time horizon was limited to the study period, with potential for benefits to manifest beyond the study period [34, 38, 39]. Benefits could have also been experienced indirectly; for example, by deriving value from potential to benefit from a programme in the future, knowledge gained from direct beneficiaries, or feelings of altruism from improvements experienced by direct beneficiaries [35].

7.4 Recommendations

Applying community-led approaches for HIV and beyond

This thesis proposes a potential model for providing community-led HTS to underserved population subgroups, including adolescents, older adults, and men. This model should be considered by national HIV programmes to mobilise community groups, organisations, and networks for testing, with costs likely to be reduced under routine implementation and through economies of scale. Subnational areas with substantial prevalence of undiagnosed HIV should be targeted, though diminishing returns to testing will continue to influence cost-effectiveness as programmes near global elimination targets [1]. Therefore, timely linkage to prevention and care is important to maximise health benefits from testing [40]. Future adaptations should facilitate linkage to preexposure prophylaxis and voluntary medical male circumcision or involve provision of care.

Community-led health promotion that underscores the preventive benefits of preexposure prophylaxis, voluntary medical male circumcision, and ART could also help to generate demand for services.

Future iterations should also consider implementation beyond an annual period, with recurrent community engagement more likely to impact upstream determinants. While implementation would require further initial investment, costs are likely to reduce as communities become more familiar with programming and start-up costs are spread over time. There is also opportunity to involve different forms of communities, including implementation led by and to priority subgroups; for example, service delivery by female sex workers to their peers [41]. Further, the remit of services delivered by communities should be expanded to include an integrated package of multi-disease services, with potential for efficiency gains from economies of scope [42]. Service integration is an increasing priority for policy makers [43] and there is a growing range of self-care technologies available that could enable direct provision of prevention, screening, and management by communities [44]. However, evidence from multi-disease strategies that include HIV are limited [45] and would benefit from additional evaluation.

Improving evaluation of health interventions involving community participation

Community participation in health programmes is both a social process and an outcome, which can introduce complexities in evaluation [46]. Heterogeneity in implementation due to local adaptation can also pose challenges in measurement. Future research should aim to adopt process evaluation frameworks that measure the nature and extent of community participation and their influence on intermediate and final outcomes [47]. Process indicators should capture levels of decision making, time spent on activities, degree of community ownership, representativeness of decision makers, and community satisfaction with the process of participation and achievement of goals [47]. Outcomes should include intermediate community and social-level outcomes in addition to benefits to health. To measure pathways to impact, hypothesised mediators and outcomes should ideally be measured in temporal order to improve assumptions underlying causal analysis [26].

Conventional methods of economic evaluation often underestimate benefits associated with community participation in health programmes. Extensions to standard approaches propose qualitatively documenting change processes resulting from community participation and narratively describing non-health sources of value [48]. Benefits excluded from the economic evaluation are thus clearly articulated and presented as limitations. Costs of community participation are also frequently underestimated. While some methodological guidance is available to inform measurement of opportunity costs and donated goods and services, application can be

difficult due to the adaptive and evolving nature of implementation, meaning frameworks are difficult to standardise. Full measurement of costs is important to ensure that the benefits of community participation are not offset by their costs and resource-constrained communities are not exploited as an alternative to the substantial investment required for community-based strategies [16]. Our synthesis also highlights the need for consensus on and use of an operational framework for community-led approaches to define key concepts and practices, support more complete and consistent reporting, including on costs and processes, and enable lessons to be learned across health and development. Sufficient investment in training of community groups, organisations, and networks on reporting of time and resource contributions as part of routine data collection could improve availability of community costs.

7.5 Conclusion

This thesis had four main findings. First, community-led responses for communicable disease control can improve health behaviours, including for disease prevention, screening, and management. Second, community-led delivery of HIVST campaigns linked to treatment and prevention was effective in increasing HIV testing in adolescents, older, and men as well as population-level ART initiation immediately following implementation. Additionally, the community-led HIVST intervention was safe and associated with high uptake. Third, community-led HIVST provided testing at a low additional cost but was unlikely to be cost-effective in contexts with low prevalence of undiagnosed HIV. Lastly, community-led HIVST increased uptake of HIV testing directly through community contributions to service delivery rather than indirectly by modifying social and structural determinants.

Collectively, this thesis shows that community-led delivery of HIVST is an effective and cost-efficient strategy that enables communities to lead solutions for disease control, with potential for economies of scale and scope. This thesis also provides insights on the value of community participation in public health and approaches to support their application in the delivery of novel self-care technologies. Further, provision of HIVST through a community-led framework seems particularly apt, with control over health care concurrently devolved to individuals and communities.

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Appendix 1.

Ethical approvals and sponsorship

CERTIFICATE OF ETHICS APPROVAL

This is to certify that the College of Medicine Research and Ethics Committee (COMREC) has reviewed and approved a study entitled:

P.01/18/2332 - Community-led delivery of HIV self-testing: a cluster randomised trial investigating feasibility, uptake of HIV testing and linkage to treatment and prevention, and safety in rural Malawi version 2.0 by Dr Nicola Desmond

On 15-Jul-18

As you proceed with the implementation of your study, we would like you to adhere to international ethical guidelines, national guidelines and all requirements by COMREC as indicated on the next page

[redacted]

15-Jul-18

Dr. YB. Mlombe - Chairperson (COMREC)

Approved by College of Medicine
Date 15 JUL 2018
(COMREC)
Research and Ethics Committee

London School of Hygiene & Tropical Medicine
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Observational / Interventions Research Ethics Committee

Prof Liz Corbett
Professor of Clinical Epidemiology
Department of Clinical Research (CRD)
LSHTM

6 April 2018

Dear Prof Liz Corbett ,

Study Title: Community-led distribution of HIV self-tests: a cluster randomised trial investigating uptake of HIV testing and linkage to treatment and prevention, costs and safety in rural Malawi

LSHTM ethics ref: 14761

Thank you for your application for the above research, which has now been considered by the Interventions Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Investigator CV	CV Augustine Choko	15/01/2018	1.0
Investigator CV	CV Chiwawa Nkhoma	15/01/2018	1.0
Investigator CV	CV Elizabeth Corbett	15/01/2018	1.0
Investigator CV	CV Linda Sande	15/01/2018	1.0
Investigator CV	CV Moses Kumwenda	15/01/2018	1.0
Investigator CV	CV Nicola Desmond	15/01/2018	1.0
Investigator CV	CV Pitchaya Indravudh	15/01/2018	1.0
Investigator CV	CV Richard Chilongosi	15/01/2018	1.0
Other	GCP Certificate_Liz Corbett	15/01/2018	1.0
Other	GCP Certificate_Nic Desmond	15/01/2018	1.0
Protocol / Proposal	PS.CL.301, 302, 303 - Household Survey V1.0	15/01/2018	1.0
Protocol / Proposal	PS.CL.401 - Topic Guide, Semi-Structured Interviews, Community Members V1.0	15/01/2018	1.0
Protocol / Proposal	PS.CL.402 - Topic Guide, Semi-Structured Interviews, Community Distributors V1.0	15/01/2018	1.0
Sponsor Letter	LSHTM sponsorship letter	22/01/2018	1.0
Protocol / Proposal	Community-led CRT protocol V2.0	31/01/2018	2.0
Information Sheet	PS.CL.03A - Participant Information Sheet, Household Survey V2.0	31/01/2018	2.0
Information Sheet	PS.CL.03B - Consent Form, Household Survey V2.0	31/01/2018	2.0
Information Sheet	PS.CL.03C - Assent Form, Household Survey V2.0	31/01/2018	2.0
Information Sheet	PS.CL.04A - Participant Information Sheet, Semi-Structured Interviews V2.0	31/01/2018	2.0
Information Sheet	PS.CL.04B - Consent Form, Semi-Structured Interviews V2.0	31/01/2018	2.0

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Improving health worldwide

World Health Organization

Research Ethics Review Committee (WHO ERC)

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – HTTP://WWW.WHO.INT/ETHICS/REVIEW-COMMITTEE/EN/ – HTTPS://EXTRANET.WHO.INT/ERCWEB/LOGIN.PHP

Protocol ID: STAR - comm led CRT - Malawi

Based on the above comments, the Committee has the following recommendation(s) for this proposal:

[ ] The proposal is ***Approved as submitted.*** No modifications are required.

[X] The proposal is ***Conditionally Approved; requires amendments and/or clarifications.*** Final approval is contingent upon an adequate response by the Principal Investigator, to the satisfaction of the reviewers or the Chair on behalf of the ERC.

[ ] The proposal is ***Not approved; requires additional information and/or rewriting.*** A revised version of the proposal should be re-submitted by the WHO responsible staff member as a new submission to the ERC for re-review by Committee.

[ ] The proposal is ***Rejected***. The proposal is ethically unacceptable, for the reasons stated above. The Principal Investigator may submit a new proposal that takes into consideration the ethical issues raised by the Committee. If you do not agree with the Committee's assessment, please feel free to submit an appeal to the Chair of the ERC, through the Secretariat.

NOTE: Final Approval of the Proposal is contingent upon submission of the following:
[ ] Local ethics approval(s) [ ] Other relevant documents
The ERC would like to receive a copy of the recommendations of the local ethics committee when available.

IMPORTANT
1. *Any changes to the proposal or to the attachments (informed consent/study instruments etc.) should be approved by ERC before being implemented.*
2. *The approval for this proposal is valid for a period of* ***one year only.***
3. *Please resubmit this proposal for a Continuing Review at least 2 months before the next re-approval period.*

Chairperson [redacted] **Date**..27/3/2018

Name: Katya Fernandez

FINAL APPROVAL

Amendments and Clarifications to the proposal have been reviewed. The protocol (Version:2.1 Date:29.05.16) and informed consent Forms (Dated: –) submitted on 30.05.2018 are approved by the ERC

Chairperson [redacted]
KF/PO/AL
Name .....
Date 24 July 2018

FOR THE SECRETARIAT

Amendments and Clarifications to be reviewed:
[ ] Electronically by ERC
[ ] by Primary reviewers
[ ] by Secretariat

Amendments approved / Clarifications accepted on
Local ERC approval(s) obtained on
Malawi 15.07.18, London School 06.04.18
Relevant Documents submitted on
20.07.2018
Comments: N/A

Signature Date 24.07.18

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Our ref: 2018-KEP-006

Prof Liz Corbett
LSHTM

22nd January 2018

Dear Prof Corbett,

Re: Community-led distribution of HIV self-tests: a cluster randomised trial investigating uptake of HIV testing and linkage to treatment and prevention, costs and safety in Malawi

As the authorised representative for the London School of Hygiene & Tropical Medicine (LSHTM), I can confirm that LSHTM will act as the identified Research Sponsor, the organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial, for the above titled project. I can confirm that the research proposal has been reviewed, assessed and registered by the Research Governance and Integrity Office.

It is the Chief Investigator's responsibility to ensure that members of the research team comply with all local regulations applicable to the performance of the project, including, but not limited to: the Declaration of Helsinki (2008), ICH Good Clinical Practice Guidelines (1996), and for projects conducted in the UK: the Medicines for Human Use (Clinical Trials) Regulations (2004), the Research Governance Framework for Health and Social Care (2005), the Data Protection Act (1998) and the Human Tissue Act (2004).

LSHTM carries Clinical Trial/Non Negligent Harm Insurance and Medical Malpractice Insurance applicable to this study. I can confirm that this study does not fall under any exclusion criteria in the policy:

Insurer	Newline
Certification No.	FI0816117 (renewable annually in June)
Finance Cover	£10 million pounds sterling
No. of Participants	35,000

The Non-Negligent harm policy is worldwide, with the exception of the United States and Canada. The policy is subject to terms, conditions and exceptions.

LSHTM Sponsorship is conditional on the project receiving applicable ethical and regulatory approval, complying with LSHTM policies and procedures, as well as successful contract and agreement negotiations from the Research Operations Office, where relevant, before the study commences.

A copy of the ethics and regulatory approval letters **must** be sent to the Quality & Governance Manager prior to the study commencing. Sponsorship is dependent on obtaining local approval for all sites where the research is being conducted. It is recommended that all members of the study team attend Good Clinical Practice (GCP) training every two years.

Yours sincerely,

[redacted]

Patricia Henley
Quality & Governance Manager
T: 020 7927 2626
E: patricia.henley@lshtm.ac.uk

Appendix 2.

Informed consent forms

PS.CL.03A: PARTICIPANT INFORMATION SHEET FOR HOUSEHOLD SURVEY

Exploring access and use of HIV testing, treatment and prevention

1. Why are we doing this study?

Regular HIV testing is very important in Malawi and worldwide because it helps people with HIV get treatment and it may also help to cut down the spread of HIV. We are interested in making it easy for people to get tested for HIV, and then get treatment if they are HIV-positive or better protection if they are HIV-negative. HIV self-testing is a way for people to test themselves for HIV, and could allow for more people to test.

This study is designed to find out about the experiences of communities with HIV services, and whether communities could benefit from being provided with HIV self-tests.

2. Why are we asking you to take part in this study?

HIV self-testing has been offered in certain communities, which was determined by chance. We are interested in learning about your experiences with HIV testing, treatment and prevention. We want to understand what changes there have been in communities provided with HIV self-testing compared to communities without these services. This is important in order to learn whether HIV self-testing should be available in Malawi, and if so, how HIV self-testing should be provided.

3. What will happen if you decide to take part in this study?

You will be asked questions about your use of HIV services, including testing, treatment and actions that you may have taken to protect yourself from HIV. You will also be asked about your risk and perceptions of HIV, and the views of your community on HIV.

The interview will take place in your home. This will take approximately 1 hour of your time.

4. Who are we asking to participate?

Households in this community were selected by chance to participate in the study. We are asking all members of this household who are 15 years or older to participate, but you have been selected by chance to answer a longer set of questions.

5. Where do we come from?

We work at the Malawi-Liverpool-Wellcome Trust Clinical Research Programme (MLW) and Population Services International (PSI). MLW and PSI conduct research and implement projects on diseases of local importance to Malawi and the region.

6. What are the risks and benefits of the study?

You should feel comfortable discussing issues related to HIV and sexual health. HIV is still stigmatised in many places, and you may experience negative consequences from your family, friends or community members for participating in a study on HIV.

Your contribution will help us to understand how best to provide HIV self-testing in Malawi.

7. Do I have to participate in this study?

Your participation is voluntary. You may withdraw from the study at any time and without giving any reason. You can also decide to answer some questions, and not to answer other questions. If you do not agree to take part in the interview, you will not be penalised in any way.

8. Confidentiality

All information obtained from the study will be stored securely on paper or computer files and only researchers in this study will have access to them. We will use a number to identify you, and will only record your name on one enrollment book. The data you provide will be stored and shared, with confidentiality maintained through all data handling and storage processes.

The data you provide may be published in journals and reports so others can learn from your experience. The data may also be made available through a public data repository or to other researchers so it can be used to improve how HIV services are provided. Your personal information will not be included.

9. Costs

Taking part in the study will not cost you anything. If selected for the extended questionnaire, we will give you MWK 7000 to cover the cost of your time or transport.

10. The Ethics Committees that have approved the study are:

College of Medicine Research and Ethics Committee and London School of Hygiene and Tropical Medicine Research Ethics Committee.

11. What if I have any questions?

If you have any questions about HIV or about this study please feel free to ask them. If you think of any questions after we have gone please feel free to contact us by calling the following number and asking for Moses Kumwenda or Pitchaya Indravudh.

Tel: 01874628 / 01876444

Please contact the COMREC Secretariat should you wish further information about your rights, safety, and wellbeing in research:

COMREC Secretariat
College of Medicine Research and Ethics Committee
P/Bag 360, Chichiri, Blantyre 3, Malawi
Telephone: 01877 245 / 01 877 291 – ext. 334

PS.CL.03B: CONSENT FORM FOR HOUSEHOLD SURVEY

Participant ID

Consent Form

Statement	Please initial or thumbprint* each box
I confirm that I have read the information sheet for the study and understand the procedures involved. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily. **OR** I have had the information explained to me by study personnel in a language that I understand and understand the procedures involved. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	
I understand that data collected during the study may be looked at by authorised individuals, where it is relevant to my participation in this research. I give permission for these individuals to have access to my records.	
I understand that the data I provide may be shared via a public data repository or by sharing directly with other researchers, and that I will not be identifiable from this information.	
I agree to take part in the study.	

.....	...../...../.....	.....
Name of participant	Date	Signature or thumb print

I attest that I have explained the study information accurately, and was understood to the best of my knowledge by, the participant and that he/she has freely given their consent to participate* in the presence of the below named impartial witness (where applicable).

.....	...../...../.....	.....
Name of witness	Date	Signature

[*Only required if the participant is unable to read or write]

.....	...../...../.....	.....
Name of interviewer	Date	Signature

PS.CL.03C: ASSENT FORM FOR HOUSEHOLD SURVEY

Participant ID

Assent Form

For parent or guardian:

Statement	**Please initial or thumbprint* each box**
I confirm that I have read the information sheet for the study and understand the procedures involved for the young adult. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily. **OR** I have had the information explained to me by study personnel in a language that I understand and understand the procedures involved for the young adult. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
I understand that the participation of the young adult is voluntary and that he or she is free to withdraw at any time without giving any reason.	
I understand that data collected during the study may be looked at by authorised individuals, where it is relevant to the young adult's participation in this research. I give permission for these individuals to have access to records of the young adult.	
I understand that the data the young adult provides may be shared via a public data repository or by sharing directly with other researchers, and that the young adult will not be identifiable from this information.	
I agree for the young adult to take part in the study.	

…… ……

Name of young adult Age

…… ……./……./……. ……

Name of parent/guardian Date Signature or thumbprint

I attest that I have explained the study information accurately, and was understood to the best of my knowledge by, the participant and that he/she has freely given their consent to participate* in the presence of the below named impartial witness (where applicable).

…… ……./……./……. ……

Name of witness Date Signature

[*Only required if the participant is unable to read or write]

Appendix 3.

Data collection tools

POST-INTERVENTION SURVEY

HH enumeration

To be completed by interviewer

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
HE01	Clinic ID	1 Chilipa 2 Chilonga 3 Makanjira 4 Mkumba 5 Phirilongwe				
HE02	Group Village Head ID	1 Bamusi 2 Binali 3 Chalenga 4 Chilonga 5 Jekete 6 Jilamu 7 Kela 8 Leveni 9 Limbalire 10 Lukloma 11 Makanjira 12 Makunula 13 Malamia 14 Malenga 15 Malopa 1 16 Malopa 2 17 Maloya 18 Masapi 19 Mgao 20 Mikochi 21 Mkambiri 22 Mkumba 23 Mlongoti 24 Mpangama 25 Mtiule				
HE03	Household ID	Unique ID				
HE04	Interviewer ID	Choose from list				
HE05		Automatic				
HE06	Interview date	Automatic with option to change if incorrect				
HE07	Start time	Automatic				
HE08	Visit outcome	1 Household interview started 2 Household interview refused 3 Housing unit vacant		If 2 or 3, skip to end		
HE09	Description of household location	Text	If visitlog=1			
HE10	GPS coordinates	Automatic	If visitlog=1			

POST-INTERVENTION SURVEY

HE11	Is there a phone number we can use to reach you?	Y-N	If visitlog=1	If no, skip to hhct		
HE12	Phone number 1	Number	If phoneyn=yes		10 digits	
HE13	Phone number 2	Number	If phoneyn=yes		Blank or 10 digits	
HE14	Phone number 3	Number	If phoneyn=yes		Blank or 10 digits	

To be completed by head of household or representative

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
HE15	How many people live in your household? [Count all the people who normally live with you and eat meals together. Include yourself when counting.]	Number			>0 & <30	
HE16	**I would like to ask about the [HEAD OF HOUSEHOLD/[NTH] PERSON IN THIS HOUSEHOLD].** What is the first name of [head of household/[NTH] household member]? **[Write only the initial]**	Short text	Asked for each in hhct		One character in length	
HE17	What is the surname of [head of household/[NTH] household member]? **[Write only the initial]**	Short text	Asked for each in hhct		One character in length	
HE18	What is the sex of [head of household/[NTH] household member]?	1 Male 2 Female	Asked for each in hhct			
HE19	What is the date of birth of [head of household/[NTH] household member]?	Select for Day Month Year	Asked for each in hhct	If respdob_year!=8888, skip to end	[TODAY'S DATE]-[TOMORROW'S DATE-99 YEARS]	
HE20	What is the age of [head of household/[NTH] household member]?	Number	Asked for each in hhct		0-99	Approximate if not sure.

POST-INTERVENTION SURVEY

Individual questionnaire - eligibility

To be completed by interviewer

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
HH01	Clinic ID	1 Chilipa 2 Chilonga 3 Makanjira 4 Mkumba 5 Phirilongwe				
HH02	Group Village Head ID	1 Bamusi 2 Binali 3 Chalenga 4 Chilonga 5 Jekete 6 Jilamu 7 Kela 8 Leveni 9 Limbalire 10 Lukloma 11 Makanjira 12 Makunula 13 Malamia 14 Malenga 15 Malopa 1 16 Malopa 2 17 Maloya 18 Masapi 19 Mgao 20 Mikochi 21 Mkambiri 22 Mkumba 23 Mlongoti 24 Mpangama 25 Mtiule 26 Mtwana 27 Naunje				
HH03	Household ID	Unique ID				
HH04	Interviewer ID	Choose from list				
HH05	Device ID	Automatic				
HH06	Interview date	Automatic with option to change if incorrect				
HH07	Start time	Automatic				

Prompt: I am speaking to each member of this household. I would like to ask you questions about yourself and your experience with HIV services. You may be selected for a longer questionnaire.

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
IE01	Have you consented (or do you consent) to participate?	YN		If no, skip to end		
IE02	Individual ID	Unique ID or barcode	If consent=yes			
IE03	Selected for individiaul questionnaire	Randomly select 1/5 individuals for extended household/individual questionnaire.	If consent=yes			

POST-INTERVENTION SURVEY

Individual questionnaire - head of household

To be completed by head of household or representative

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
HS01	Who is the respondent?	1 Respondent is head of household 2 Respondent is reporting on behalf of head of household, who is not available to answer the questionnaire 3 Respondent is not head of household or reporting on behalf	If eligcons=yes	If hhrespond=3, skip to next section		Check that only one person identifies as the head of household or is reporting on behalf of the head of household.
HS02	**Please think about the person who is the head of your household. It may be you, or it may be someone else.** What is the first name of the head of household? [WRITE ONLY THE INITIAL]	Short text	If hhrespond=1 or 2		One character in length	
HS03	What is the surname of the head of household? [WRITE ONLY THE INITIAL]	Short text	If hhrespond=1 or 2	If hhrespond=1, now go to pmt_hohenglit	One character in length	
HS04	What is the sex of the head of household?	1 Male 2 Female	If hhrespond=2			
HS05	What is the date of birth of the head of household?	Select for Day Month Year	If hhrespond=2	If hohdob_year!=8888, skip to pmt_hohedu	[TODAY'S DATE-15] - [TOMORROW'S DATE-99]	
HS06	How old is the head of household?	Number	If hhrespond=2 & hohdob_year=8888		15-99	Approximate if not sure.
HS07	What is the highest level of education completed by the head of household?	1 None 2 PSLC 3 JCE 4 MSCE 5 Non-university diploma 6 University diploma/degree 7 Postgraduate degree 9 Decline to answer	If hhrespond=2			

HS08	Is the head of household able to read and write in English?	Y-N-DTA	If hh respond=1 or 2			
HS09	How many people live in your household? [Count all the people who normally live with you and eat meals together. Include yourself when counting.]	Number	If hh respond=1 or 2		1-30, 88, 99	Enter 88 for don't know or 99 for decline to answer
HS10	In the past 7 days, did you worry that your household would not have enough food?	Y-N-DTA	If hh respond=1 or 2			
HS11	Concerning your housing, which of the following is true?	1 It was less than adequate for household needs 2 It was just adequate for household needs 3 It was more than adequate for household needs 9 Decline to answer	If hh respond=1 or 2			
HS12	Concerning your household clothing, which of the following is true?	1 It was less than adequate for household needs 2 It was just adequate for household needs 3 It was more than adequate for household needs 9 Decline to answer	If hh respond=1 or 2			
HS13	Imagine six steps, where on the bottom, the first step, stand the poorest people, and on the highest step, the sixth, stand the rich. On which step are you today? [Show the picture of the steps]	Number	If hh respond=1 or 2		1-6, 88, 99	Enter 88 for don't know or 99 for decline to answer
HS14	What does the head of household sleep on?	1 Bed and mattress 2 Bed and mat (grass) 3 Bed alone 4 Mattress on the floor 5 Mat (grass) on the floor 6 Cloth/sack on the floor 7 Floor (nothing else) 8 Other 9 Decline to answer	If hh respond=1 or 2			
HS15	Does your household own a bed?	Y-N-DTA	If hh respond=1 or 2			
HS16	Does you household own a table?	Y-N-DTA	If hh respond=1 or 2			

POST-INTERVENTION SURVEY

HS17	In the last month, that is since [TODAY'S DATE-1 MONTH], how much money did you or any of your household members receive?	Number	If hh respond=1 or 2		1-1000000, 8888888, 9999999	Approximate if not sure. Enter 8888888 for don't know or 9999999 for decline to answer

POST-INTERVENTION SURVEY

Individual questionnaire - sociodemographics

To be completed by all individuals

Prompt: I would now like to ask you questions about yourself.

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
A01	What is your relationship to the head of household?	1 I am the head of houshold 2 I am the wife or husband of the head of household 3 I am a son or daughter of the head of household 4 I am a son-in-law or daughter-in-law of the head of household 5 I am a grandchild of the head of household 7 I am a parent of the head of household 8 I am a parent-in-law of the head of household 9 I am a brother or sister of the head of household 10 I am a niece or nephew of the head of household 10 I am co-wife of the head of household 11 I am an adopted/foster/stepchild of the head of household 12 I am an other relative of the head of household 13 I am a domestic servant in household 14 I am a lodger in household 15 I am not related to head of household, other categories not applicable 99 Decline to answer	If eligcons=yes			
A02	(Interviewer to indicate sex)	1 Male 2 Female	If eligcons=yes			
A03	What is your date of birth?	Select for Day Month Year	If eligcons=yes	If respdob_year!=8888, skip to edu	[TODAY'S DATE-15 YEARS]-[TOMORROW'S DATE-99 YEARS]	
A04	How old are you?	Number	If respdob_year=8888		15-99	

POST-INTERVENTION SURVEY

A05	What is the highest level of education that you have completed?	1 None 2 PSLC 3 JCE 4 MSCE 5 Non-university diploma 6 University diploma/degree 7 Postgraduate degree 9 Decline to answer	If eligcons=yes			
A06	Can you read a newspaper or letter?	Y-N-DTA	If eligcons=yes			
A07	Are you employed for a wage salary, commission or any formal payment in kind excluding casual labour, for anyone who is not a member of your household?	Y-N-DTA	If eligcons=yes			
A08	What is your religion?	1 Catholic 2 CCAP 3 Anglican 4 Seventh Day Adventist / Baptist 5 Other Christian 6 Muslim 7 No religion 9 Decline to answer	If eligcons=yes			
A09	What is your ethnicity?	1 Chewa 2 Yao 3 Tambuka 4 Lomwe 5 Tonga 6 Sena 7 Nkhonde 8 Ngoni 9 Other 99 Decline to answer	If eligcons=yes			
A10	Have you resided in this community for the past two months?	Y-N-DTA	If eligcons=yes	If no or DTA, skip to marital		
A11	Did you live here 12 months ago? That is, did you live here in [MONTH] 2017?	Y-N-DTA	If residmos=yes	If yes or DTA, skip to marital		
A12	In what month did you move to this dwelling?	Select for Month Year	If residlastyr=no		[THIS MONTH-2 MONTH]-[THIS MONTH-11 MONTHS]	
A13	What is your current marital status?	1 Married or living together 2 Separated/divorced 3 Widowed 4 Never married or never lived together 9 Decline to answer	If eligcons=yes	If marital!=1, skip to srhealth		

POST-INTERVENTION SURVEY

A14	How long have you been together with your spouse or partner [or first spouse/partner for persons with multiple spouses]?	1 <1 year 2 1-5 years 3 More than 5 years 9 Decline to answer	If marital=1			
A15	Are you currently living with your spouse/partner?	Y-N-DTA	If marital=1			
A16	How do you rate your general health?	1 Very good 2 Good 3 Fair 4 Poor 9 Decline to answer	If eligcons=yes			

POST-INTERVENTION SURVEY

Individual questionnaire - extended sociodemographics

To be completed by SELECTED individuals

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
AE01	Over the past 2 weeks how often have you been having little interest or pleasure in doing things?	1 Not at all 2 Several days 3 More than half the days 4 Nearly every day 9 Decline to answer	If select=yes			
AE02	Over the past 2 weeks how often have you been feeling down, depressed or hopeless?	1 Not at all 2 Several days 3 More than half the days 4 Nearly every day 9 Decline to answer	If select=yes			

POST-INTERVENTION SURVEY

Individual questionnaire - extended community mobilization

To be completed by SELECTED individuals

Prompt: I would now like to as you questions about you and your community.

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
CM01	How many times in the last month have you been to:	A A ceremony? - Number B A beer place? - Number C A place where people dance? - Number D A market? - Number E A community meeting? - Number	If select=yes		0-30, 88, 99	Enter 88 for don't know or 99 for decline to answer.
CM02	How many times in the last year have you spoken to:	A The village headman ? - Number B The development committee? - Number C The health committee? - Number	If select=yes		0-30, 88, 99	Enter 88 for don't know or 99 for decline to answer.
CM03	Are you a member of any of the following committees or groups?	A Chiefs council - Y-N-DTA B Development committee - Y-N-DTA C Health committee - Y-N-DTA D School committee - Y-N-DTA E Women's group - Y-N-DTA F Peer/youth group - Y-N-DTA G Celebration/burial group - Y-N-DTA H Commerce/finance group - Y-N-DTA I Church or mosque - Y-N-DTA J Sports group - Y-N-DTA	If select=yes		If decline to answer for one choice, must have decline to answer for all choices	

Prompt: For each of the following statements, please indicate whether you strongly agree, somewhat agree, or disagree.
Funsani : Pa ziganizo zotsatirazi, chonde owetsani ngati mukuvomereza kwambiri, mukuvomereza pang'ono, simukuvomereza.

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
CM04	People in this village are willing to help their neighbors	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM05	This is a close knit community	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM06	People in this village can be trusted	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			

POST-INTERVENTION SURVEY

CM07	People in this village generally get along well with each other	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM08	People in this village share the same values	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM09	People in this village look out for each other	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM10	People in your village are concerned about HIV	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM11	People in your village consider HIV/AIDS an important issue	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM12	People in your village talk openly about HIV	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM13	People in your village believe that HIV impacts the community	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM14	People in your village talk about HIV/AIDS at community meetings	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM15	People in your village work together to prevent HIV from spreading	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM16	People in your village work together to reduce the effects of HIV	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM17	People in your village believe they can change the course of the HIV/AIDS epidemic	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			

CM18	People in your village exchange information about HIV/AIDS	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM19	People in your village take HIV/AIDS seriously	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM20	People work together to solve problems in the village	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM21	People in your village talk to each other about how to solve village problems	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM22	People in your village enjoy discussing different ways to solve village problems	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM23	People in your village are open to hearing different views about community problems and solutions	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM24	People in your village volunteer to help solve village problems	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM25	People in your village think about why there are problems so they can address the cause of problems	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM26	There is a lot of cooperation between groups in the village	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM27	People in this village not only talk about problems but they also try to solve them	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM28	If your community fails to resolve a community problem, they will try another-different approach to solve the problem	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			

POST-INTERVENTION SURVEY

CM29	If your community fails to resolve a community problem, they will learn from that experience and do a better job when they try to solve the problem in the future	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
CM30	If leaders in the village fail to resolve a village problem, the villagers will work together to find a solution	1 Strongly agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			

POST-INTERVENTION SURVEY

Individual questionnaire - past testing

To be completed by all individuals

Prompt: Now I would like to ask you some questions about your experiences testing for HIV.

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
B01	Have you ever tested for HIV [including self-tested for HIV]?	Y-N-DTA	If eligcons=yes	If no or DTA, skip to heardst		
B02	In total, how many HIV tests have you had in your lifetime [including HIV self-tests]? **Tests to follow-up and confirm earlier results from a self-test should be counted separately.**	Number	If evertest=yes		1-50, 88, 99	Enter 88 for don't know or 99 for decline to answer.
B03	In the last 12 months, that is before [TODAY'S DATE-12 MONTHS], have you tested for HIV [including self-testing for HIV]?	Y-N-DTA	If evertest=yes	If no or DTA, skip to heardst		
B04	In the last 12 months, how many times have you tested for HIV [including self-testing for HIV]? **Tests to confirm earlier results from a self-test should be counted separately.**	Number	If yrtest=yes		1-15, 88, 99	Enter 88 for don't know or 99 for decline to answer
B05	Before this interview, had you heard about HIV self-testing as a method for testing for HIV? **HIV self-testing is a process whereby a person who wants to know his or her HIV status collects a specimen, performs a test, and interprets the test result in private.**	Y-N-DTA	If eligcons=yes	If no or DTA & evertest=yes, skip to testdate If no or DTA & (evertest=no or DTA), skip to testoffered		

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
B06	Who did you first hear about HIV self-testing from?	Check all that apply: A Community distributor - Y-N-DTA B Health committee - Y-N-DTA C Healthcare worker / HSA - Y-N-DTA D Partner - Y-N-DTA E Parent - Y-N-DTA F Child - Y-N-DTA G Other family member - Y-N-DTA H Friend - Y-N-DTA I Neighbor - Y-N-DTA J Chief - Y-N-DTA K Religious group member - Y-N-DTA L Employer / worker - Y-N-DTA M Teacher / student - Y-N-DTA N Community group member - Y-N-DTA O Shop keeper - Y-N-DTA P Other - Y-N-DTA	If heardst=yes	If evertest=yes, now go to everst	Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	
B07	Have you ever been offered an HIV test [including an HIV self-test]?	Y-N-DTA	If evertest=no or DTA	If (evertest=no or DTA) & heardst=yes, now go to next section If evertest=DTA & (heardst=no or DTA) & respsex=male, now go to vmmc section If evertest=DTA & (heardst=no or DTA) & respsex=female, now go to part test section		

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
B08	What are the reasons why you have not tested for HIV?	Check all that apply: A I am not at risk of HIV - Y-N-DTA B I am not yet sexually active - Y-N-DTA C I don't feel sick enough to test for HIV - Y-N-DTA D I don't want to know my HIV status - Y-N-DTA E HIV testing is not a dignified thing to do at my age- Y-N-DTA F I am afraid of testing positive - Y-N-DTA G I do not want to be seen queuing for HIV testing services - Y-N-DTA H My partner won't let me test- Y-N-DTA I Another family member won't let me test - Y-N-DTA J It is against my religious beliefs to test for HIV - Y-N-DTA K I don't know where to get an HIV test- Y-N-DTA L It is too expensive for me to visit the health facility - Y-N-DTA M I cannot take time off work to go test - Y-N-DTA N The waiting time at the health facility is too long - Y-N-DTA O I don't think the results will stay confidential - Y-N-DTA P I don't like the attitude of health care workers - Y-N-DTA Q HIV tests at the health facility were out of stock- Y-N-DTA R Other reason - Y-N-DTA	If evertest=no & (heardst=no or DTA)	If respsex=male, now go to vmmc section If respsex=femle, now to go part test section	Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	
B09	Have you ever used a self-test to test for HIV?	Y-N-DTA	If evertest=yes & heardst=yes	If evertest=no & (heardst=no or DTA)		
B10	In the last 12 months, that is before [TODAY'S DATE-12 MONTHS], have you self-tested for HIV?	Y-N-DTA	If everst=yes & yrtest=yes	If no or DTA, skip to selftest		
B11	In the last 12 months, how many times have you self-tested for HIV?	Number	If yrst=yes		1-[YRTESTCOUNT], 88, 99	Enter 88 for don't know or 99 for decline to answer

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
B12	Was your most recent HIV test a self-test?	Y-N	If everst=yes	If yes, go to next section		
B13	Was your most recent HIV test to confirm an earlier result from a self-test?	Y-N	If selftest=no	If yes, go to next section		

Prompt: Now I would like to ask you some questions about <u>your most recent HIV test</u>.

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
B14	What was the date of your test?	MY	If (evertest=yes & ((heardst=no or DTA) or (everst=no or DTA)) or (conftest=no)		[TODAY'S DATE]-[DATE OF BIRTH]	For dates prior to 2017, indicate only the year.
B15	Where was the location of your test?	1 Hospital or health centre 2 Health post / outreach 3 Mobile clinic 4 Door-to-door / home 5 Other 9 Decline to answer	If (evertest=yes & ((heardst=no or DTA) or (everst=no or DTA)) or (conftest=no)			
B16	You don't have to tell me if you don't want to, but what were the results of your test?	1 Positive 2 Negative 3 Indeterminate 9 Decline to answer	If (evertest=yes & ((heardst=no or DTA) or (everst=no or DTA)) or (conftest=no)			

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
B17	Did anything bad happen to you because of the test or the results of the test?	0 No 1 Yes because of the test 2 Yes because of the test results 9 Decline to answer	If (evertest=yes & ((heardst=no or DTA) or (everst=no or DTA))) or (conftest=no)	If no or DTA & testres=1, skip to testart If no or DTA & (testres=2, 3 or DTA) & respsex=male, now go to testvmmc If no or DTA & (testres=2, 3 or DTA) & respsex=female & heardst=yes, now go to next section If no or DTA & (testres=2, 3 or DTA) & respsex=female & (heardst=no or DTA), now go to art section		
B18	What happened to you because of the test or the results of the test?	Check all that apply: A Excluded from social events - Y-N-DTA B Got into an argument with my spouse or partner C Abandoned by my spouse or partner - Y-N-DTA D Got into an argument with another family member E Abandoned by another family member - Y-N-DTA F Ridiculed in public - Y-N-DTA G Expelled from your home - Y-N-DTA H Had property or resources taken away - Y-N-DTA I Threatened with violence - Y-N-DTA J Physically hurt - Y-N-DTA K Forced to have sex against your will - Y-N-DTA L Other - Y-N-DTA	If testharmyn=1 or 2		Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint

B19	Had you ever experienced anything like this before?	1 Never
		2 Rarely
		3 Frequently
		4 Decline to answer
			If testharmyn=1 or 2	If (testres=2, 3 or DTA) & respsex=male, now go to testvmmc
				
				If (testres=2, 3 or DTA) & respsex=female & heardst=yes, now go to next section
				
				If (testres=2, 3 or DTA) & respsex=female & (heardst=no or DTA), now go to art section		

B20	Did you start on ART after the test?	0 No 1 Yes, I started on ART for the first time 2 Yes, I restarted on ART 9 Decline to answer	If testres=1	If 1 or 2, skip to testartdate If DTA & heardst=yes, skip to next section If DTA & (heardst=no or DTA) & respsex=male, skip to vmmc section If DTA & (heardst=no or DTA) & respsex=female, skip to art section		

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
B21	What were the reasons why you did you not start on ART drugs?	Check all that apply: A I don't feel sick enough to start on ART - Y-N-DTA B I do not trust my HIV-positive results - Y-N-DTA C I do not want to be seen queuing for ART services - Y-N-DTA D My partner won't let me start on ART - Y-N-DTA E Another family member won't let me start on ART - Y-N-DTA F It is against my religious beliefs to start on ART - Y-N-DTA G It is too expensive for me to visit the health facility - Y-N-DTA H I cannot take time off work to go to the health facility - Y-N-DTA I The waiting time at the health facility was too long - Y-N-DTA J I don't think my visit will stay confidential - Y-N-DTA K I don't like the attitude of health care workers - Y-N-DTA L ART at the health facility were out of stock - Y-N-DTA M I am afraid of experiencing side effects from the drugs - Y-N-DTA N I could not start on ART immediately after testing - Y-N-DTA O Other reason - Y-N-DTA	If testart=0	If heardst=yes, now go to next section If heardst=no or DTA & respsex=male, now go to vmmc section If heardst=no or DTA & respsex=female, now go to art section	Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	
B22	What date did you start on ART?	MY	If testart=1 or 2		[TODAY'S DATE]-[TESTDATE]	
B23	What was the name of the clinic where you started on ART?	1 Chilipa 2 Chilonga 3 Makanjira 4 Mkumba 5 Phirilongwe 6 Other 7 Decline to answer	If testart=1 or 2	If testartloc!=other & heardst=yes, skip to next section If testartloc!=other & (heardst=no or DTA) & respsex=male, skip to vmmc section If testartloc!=other & (heardst=no or DTA) & respsex=female, skip to art section		

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
B24	Specify health facility if other	Short text	If testartloc=other	If heardst=yes, now go to next section If heardst=no or DTA & respsex=male, now go to vmmc section If heardst=no or DTA & respsex=female, now go to art section		
B25	[Asked of men only:] Did you go for medical male circumcision after the test?	0 No 1 No, I am already circumcised 2 Yes 9 Decline to answer	If (testres=2, 3 or DTA) & respsex=male	If 0, 1 or DTA & heardst=yes, skip to next section If 0, 1 or DTA & (heardst=no or DTA), skip to vmmc section		
B26	What date did you go for circumcision?	MY	If testvmmc=2		[TODAY'S DATE]-[TESTDATE]	
B27	What was the name of the clinic where you went for circumcision?	Short text	If testvmmc=2	If heardst=yes, now go to next section If heardst=no or DTA, now go to vmmc section		

POST-INTERVENTION SURVEY

Individual questionnaire - past self-testing

To be completed by all individuals who have heard of self-testing

Relevant if everst=yes
Prompt: Now I would like to ask you some questions about your most recent HIV self-test.

Relevant if heardselftest=yes & ([evertest=no or DTA] or [everst=no or DTA])
Prompt: Now I would like to ask you some questions about your most recent experience with HIV self-testing.

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C01	Have you ever collected a self-test kit?	Y-N-DTA	If heardst=yes	If yes, skip to stdist		
C02	Have you ever approached someone to obtain a self-test kit or been offered a self-test kit?	0 No 1 Yes, I approached someone to obtain a self-test kit 2 Yes, I was offered a self-test kit 9 DTA	If stcollect=no or DTA	If stcollect=DTA & respsex=male, now go to next section If stcollect=DTA & respsex=female & evertest=yes, now go to art section If stcollect=DTA & respsex=female & (evertest=no or DTA), now go to part test section		

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C03	What were the reasons why you did not collect a self-test kit?	Check all that apply: A Self-test kits were not being distributed in my community - Y-N-DTA B I recently tested and do not feel the need to self-test - Y-N-DTA C I prefer to be tested by a health care worker - Y-N-DTA D I do not trust the self-test kit or oral-fluid tests - Y-N-DTA E I do not know where to get a self-test kit - Y-N-DTA F It was not easy to access self-test kits - Y-N-DTA G I don't want to get a self-test kit from someone I know - Y-N-DTA H I don't think the results will stay confidential - Y-N-DTA I I don't like the attitude of community distributors - Y-N-DTA J HIV self-test kits were out of stock - Y-N-DTA K I heard about HIV self-testing too late - Y-N-DTA L I am not at risk of HIV - Y-N-DTA M I am not yet sexually active - Y-N-DTA N I don't feel sick enough to test for HIV - Y-N-DTA O I don't want to know my HIV status - Y-N-DTA P HIV testing is not dignified at my age - Y-N-DTA Q I am afraid of testing positive - Y-N-DTA R I do not want to be seen queuing for an HIVST kit - Y-N-DTA	If stcollect=no	If respsex=male, now go to next section If respsex=female & evertest=yes, now go to art section If respsex=female & (evertest=no or DTA), now go to part test section	Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	
C04	**Prompt: I would like to ask you some questions about the person you collected the self-test kit from.** Who did you collect the self-test kit from?	1 Community distributor 2 Health committee 3 Healthcare worker / HSA 4 Partner 5 Parent 6 Child 7 Other family member 8 Friend 9 Neighbor 10 Chief 11 Religious group member 12 Employer / worker 13 Teacher / student 14 Community group member 15 Shopkeeper 16 Other 17 Decline to answer	If stcollect=yes			

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C05	Where did you collect the self-test kit from [STDIST]?	1 My home 2 Hospital or health centre 3 Home of community distributor 4 Home of chief 5 Other home 6 Church or mosque 7 Work 8 School 9 Public event 10 Community hall 11 Community group meeting 12 NGO / CBO 13 Market / shop 14 Bar / restaurant 15 Fishing dock 16 Transport hub 17 Agricultural field 18 Sports field 19 Borehole / well 20 Other 21 Decline to answer	If stcollect=yes			
C06	Is the [STDIST] male or female?	1 Male 2 Female 3 Decline to answer	If stcollect=yes			
C07	How old is the [STDIST]? **Use your best guess.**	1 15-19 2 20-24 3 25-29 4 30-39 5 40-49 6 50-59 7 60+ 88 Don't know 99 Decline to answer	If stcollect=yes			
C08	Do you live in the same village as the [STDIST]?	Y-N-DTA	If stcollect=yes			

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C09	How does the wealth of the [STDIST] compare to yours?	1 Wealthier 2 Less wealthy 3 About the same 4 Don't know 5 Decline to answer	If stcollect=yes			
C10	In the last year, did you give or receive help from the [STDIST] for the following?	A Money - Y-N-DTA B Collecting firewood or water - Y-N-DTA C Cooking - Y-N-DTA D Farming - Y-N-DTA E Taking care of each other or other people - Y-N-DTA F Building or maintenance - Y-N-DTA	If stcollect=yes		If decline to answer for one choice, must have decline to answer for all choices	
C11	Besides [STDIST], was anyone else with you when you collected the self-test kit?	Y-N-DTA	If stcollect=yes	If no or DTA, skip to stpressyn		
C12	Who else was with you when you collected the self-test kit?	Check all that apply: A Community distributor - Y-N-DTA B Health committee - Y-N-DTA C Healthcare worker / HSA - Y-N-DTA D Partner - Y-N-DTA E Parent - Y-N-DTA F Child - Y-N-DTA G Other family member - Y-N-DTA H Friend - Y-N-DTA I Neighbor - Y-N-DTA J Chief - Y-N-DTA K Religious group member - Y-N-DTA L Employer / worker - Y-N-DTA M Teacher / student - Y-N-DTA N Community group member - Y-N-DTA O Shop keeper - Y-N-DTA P Public crowd - Y-N-DTA Q Other - Y-N-DTA	If stotheryn=yes		Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	
C13	Did you feel pressured or forced to take a self-test kit that you did not want?	Y-N-DTA	If stcollect=yes	If no or DTA, skip to stcount		

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C14	Who did you feel pressure or force from?	Check all that apply: A Community distributor - Y-N-DTA B Health committee - Y-N-DTA C Healthcare worker / HSA - Y-N-DTA D Partner - Y-N-DTA E Parent - Y-N-DTA F Child - Y-N-DTA G Other family member - Y-N-DTA H Friend - Y-N-DTA I Neighbor - Y-N-DTA J Chief - Y-N-DTA K Religious group member - Y-N-DTA L Employer / worker - Y-N-DTA M Teacher / student - Y-N-DTA N Community group member - Y-N-DTA O Shop keeper - Y-N-DTA P Public crowd - Y-N-DTA Q Other - Y-N-DTA	If stpressyn=yes		Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	
C15	How many self-test kits did you collect?	Number	If stcollect=yes		1-5, 88, 99	Enter 88 for don't know or 99 for decline to answer

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint

C16	Did you take a self-test kit for yourself?	Y-N-DTA	If stcollect=yes	If ([yes & stcount=1] or DTA or [stcount=88 or 99]) & everst=yes, skip to stdate
				
				If ([yes & stcount=1] or DTA or [stcount=88 or 99]) & (evertest=no or everst=no), skip to whynotst_X
				
				If ([yes & stcount=1] or DTA or [stcount=88 or 99]) & (evertest=DTA or everst=DTA) & respsex=male, skip to next section
				
				If ([yes & stcount=1] or DTA or [stcount=88 or 99]) & (everst=DTA) & respsex=female, skip to art section
				
				If ([yes & stcount=1] or DTA or [stcount=88 or 99]) & (evertest=DTA) &		

C17	**Prompt: I would like to ask you some questions about each person you gave the self-test kit to.** Who is the [COUNT] person who gave youthe self-test kit to?	1 Community distributor 2 Health committee 3 Healthcare worker / HSA 4 Partner 5 Parent 6 Child 7 Other family member 8 Friend 9 Neighbor 10 Chief 11 Religious group member 12 Employer / worker 13 Teacher / student 14 Community group member 15 Shopkeeper 16 Other 99 Decline to answer	If (stselfuse=yes & stcount>1 & stcount!=88 & stcount!=99) or (stselfuse=no & stcount!=88 & stcount!=99) If stselfuse=yes, asked for each in stcount-1 If stselfuse=no, asked for each in stcount		Should not be strec_X=1	

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C18	Where did you give the self-test kit to the [STREC_X]?	1 My home 2 Hospital or health centre 3 Home of community distributor 4 Home of chief 5 Other home 6 Church or mosque 7 Work 8 School 9 Public event 10 Community hall 11 Community group meeting 12 NGO / CBO 13 Market / shop 14 Bar / restaurant 15 Fishing dock 16 Transport hub 17 Agricultural field 18 Sports field 19 Borehole / well 20 Other 21 Decline to answer	If (stselfuse=yes & stcount>1 & stcount!=88 & stcount!=99) or (stselfuse=no & stcount!=88 & stcount!=99) If stselfuse=yes, asked for each in stcount-1 If stselfuse=no, asked for each in stcount			
C19	Is the [STREC_X] male or female?	1 Male 2 Female 3 Decline to answer	If (stselfuse=yes & stcount>1 & stcount!=88 & stcount!=99) or (stselfuse=no & stcount!=88 & stcount!=99) If stselfuse=yes, asked for each in stcount-1 If stselfuse=no, asked for each in stcount			
C20	How old is the [STREC_X]? **Use your best guess.**	1 0-15 2 15-19 3 20-24 4 25-29 5 30-39 6 40-49 7 50-59 8 60+ 88 Don't know 99 Decline to answer	If (stselfuse=yes & stcount>1 & stcount!=88 & stcount!=99) or (stselfuse=no & stcount!=88 & stcount!=99) If stselfuse=yes, asked for each in stcount-1		1-99	Enter 88 for don't know or 99 for decline to answer

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C21	Do you live in the same village as [STREC_X]?	Y-N-DTA	If (stselfuse=yes & stcount>1 & stcount!=88 & stcount!=99) or (stselfuse=no & stcount!=88 & stcount!=99) If stselfuse=yes, asked for each in stcount-1 If stselfuse=no, asked for each in stcount			
C22	How does the wealth of the [STREC_X] compare to yours?	1 Wealthier 2 Less wealthy 3 About the same 4 Don't know 5 Decline to answer	If (stselfuse=yes & stcount>1 & stcount!=88 & stcount!=99) or (stselfuse=no & stcount!=88 & stcount!=99) If stselfuse=yes, asked for each in stcount-1 If stselfuse=no, asked for each in stcount			
C23	In the last year, did you give or receive help from the [STDIST] for the following?	A Money - Y-N-DTA B Collecting firewood or water - Y-N-DTA C Cooking - Y-N-DTA D Farming - Y-N-DTA E Taking care of each other or other people - Y-N-DTA F Building or maintenance - Y-N-DTA	If (stselfuse=yes & stcount>1 & stcount!=88 & stcount!=99) or (stselfuse=no & stcount!=88 & stcount!=99) If stselfuse=yes, asked for each in stcount-1 If stselfuse=no, asked for each in stcount			

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C24	How worried are you that the [STREC_X] might get HIV?	1 Not worried at all 2 Worried a little 3 Worried a lot 4 Decline to answer	If (stselfuse=yes & stcount>1 & stcount!=88 & stcount!=99) or (stselfuse=no & stcount!=88 & stcount!=99) If stselfuse=yes, asked for each in stcount-1 If stselfuse=no, asked for each in stcount			
C25	Which of the following best describes why you did not use the self-test kit?	1 I did not want the self-test kit but felt I had to take it 2 I did not feel confident enough to use the self-test kit 3 Someone else wanted the self-test kit so I gave it away 4 Someone else took the self-test kit from me 5 My partner won't let me use the self-test kit 6 Another family member won't let me use the self-test kit 7 I haven't found the right time or place to use the self-test kit 8 I am HIV positive but did not want anyone to know 9 Decline to answer	If stcollect=yes & (evertest=no or everst=no)	If respsex=male, now go to next section If respsex=female & evertest=yes, now go to art section If respsex=female & (evertest=no or DTA), now go to part test section		
C26	**Prompt: I would now like to ask you some questions about your experience using the self-test kit.** What was the date when you used the self-test?	MY	If everst=yes		[TODAY'S DATE]-[DATE OF BIRTH]	

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C27	Was this self-test the first HIV test you had ever done?	Y-N-DTA	If everst=yes			
C28	How much longer after collecting the self-test kit did you self-test?	1 Same day 2 2-3 days later 3 Same week 4 2 weeks later 5 1 month later 6 Other	If everst=yes			
C29	Was anyone else with you when you self-tested?	Y-N-DTA	If everst=yes	If no or DTA, skip to stpartner		
C30	Who was with you when you self-tested?	Check all that apply: A Community distributor - Y-N-DTA B Health committee - Y-N-DTA C Healthcare worker / HSA - Y-N-DTA D Partner - Y-N-DTA E Parent - Y-N-DTA F Child - Y-N-DTA G Other family member - Y-N-DTA H Friend - Y-N-DTA I Neighbor - Y-N-DTA J Chief - Y-N-DTA K Religious group member - Y-N-DTA L Employer / worker - Y-N-DTA M Teacher / student - Y-N-DTA N Community group member - Y-N-DTA O Shop keeper - Y-N-DTA P Other - Y-N-DTA	If stpresentyn=yes		Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C31	Did you feel pressured or forced to use a self-test kit that you did not want?	Y-N-DTA	If everst=yes	If stforceyn=no, skip to stres		
C32	Who did you feel pressure or force from?	Check all that apply: A Community distributor - Y-N-DTA B Health committee - Y-N-DTA C Healthcare worker / HSA - Y-N-DTA D Partner - Y-N-DTA E Parent - Y-N-DTA F Child - Y-N-DTA G Other family member - Y-N-DTA H Friend - Y-N-DTA I Neighbor - Y-N-DTA J Chief - Y-N-DTA K Religious group member - Y-N-DTA L Employer / worker - Y-N-DTA M Teacher / student - Y-N-DTA N Community group member - Y-N-DTA O Shop keeper - Y-N-DTA P Other - Y-N-DTA	If stforceyn=yes		Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	
C33	You don't have to tell me if you don't want to, but what were the results of the self-test?	1 Positive 2 Negative 3 Invalid 9 Decline to answer	If everst=yes	If 2, 3 or DTA, skip to discyn		
C34	Was this self-test the first time you had received a positive result?	Y-N-DTA	If stres=1			
C35	Did you disclose the result of the self-test to anyone?	Y-N-DTA	If everst=yes	If stdiscyn=no or DTA, skip to stharmyn		
C36	Who did you disclose the results of the self-test to?	Check all that apply: A Community distributor - Y-N-DTA B Health committee - Y-N-DTA C Healthcare worker / HSA - Y-N-DTA D Partner - Y-N-DTA E Parent - Y-N-DTA F Child - Y-N-DTA G Other family member - Y-N-DTA H Friend - Y-N-DTA I Neighbor - Y-N-DTA J Chief - Y-N-DTA K Religious group member - Y-N-DTA L Employer / worker - Y-N-DTA M Teacher / student - Y-N-DTA N Community group member - Y-N-DTA O Shop keeper - Y-N-DTA P Other - Y-N-DTA	If stdiscyn=yes		Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C37	Were you forced to disclose your results, or someone disclosed your status to another person without your permission?	Y-N-DTA	If stdiscyn=yes	If stforcediscyn=no, skip to stharm		
C38	Who forced you to disclose the results of the self-test?	Check all that apply: A Community distributor - Y-N-DTA B Health committee - Y-N-DTA C Healthcare worker / HSA - Y-N-DTA D Partner - Y-N-DTA E Parent - Y-N-DTA F Child - Y-N-DTA G Other family member - Y-N-DTA H Friend - Y-N-DTA I Neighbor - Y-N-DTA J Chief - Y-N-DTA K Religious group member - Y-N-DTA L Employer / worker - Y-N-DTA M Teacher / student - Y-N-DTA N Community group member - Y-N-DTA O Shop keeper - Y-N-DTA	If stforcediscyn=yes		Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	
C39	Did anything bad happen to you because of the self-test or the results of the self-test?	0 No 1 Yes because of the test 2 Yes because of the test results 9 Decline to answer	If everst=yes	If no or DTA, skip to stconf		
C40	What happened to you because of the self-test or the results of the self-test?	Check all that apply: A Excluded from social events - Y-N-DTA B Got into an argument with my spouse or partner C Abandoned by my spouse or partner - Y-N-DTA D Got into an argument with another family member E Abandoned by another family member - Y-N-DTA F Ridiculed in public - Y-N-DTA G Expelled from your home - Y-N-DTA H Had property or resources taken away - Y-N-DTA I Threatened with violence - Y-N-DTA J Physically hurt - Y-N-DTA K Forced to have sex against your will - Y-N-DTA L Other - Y-N-DTA	If stharmyn=1 or 2		Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C41	Had you ever experienced anything like this before?	1 Never 2 Rarely 3 Frequently 4 Decline to answer	If stharmyn=1 or 2			

C42	Did you receive a test to confirm the result from the self-test?	Y-N-DTA	If everst=yes	If stconf=yes, skip to stconfdate
				
				If ([stconf=no & stres=2, 3 or 9] or stconf=DTA) & respsex=male, skip to stvmmc
				
				If ([stconf=no & stres=2, 3 or 9] or stconf=DTA) & respex=female, skip to art section		

C43	Why did not yet receive a confirmatory test?	Check all that apply: A I am not at risk of HIV - Y-N-DTA B I am not yet sexually active - Y-N-DTA C I don't feel sick enough to test for HIV - Y-N-DTA D I don't want to know my HIV status - Y-N-DTA E HIV testing is not a dignified thing to do at my age - Y-N-DTA F I am afraid of testing positive - Y-N-DTA G I do not want to be seen queuing for HIV testing services - Y-N-DTA H My partner won't let me test - Y-N-DTA I Another family member won't let me test - Y-N-DTA J It is against my religious beliefs to test for HIV - Y-N-DTA K I don't know where to get an HIV test Y-N-DTA L It is too expensive for me to visit the health facility - Y-N-DTA M I cannot take time off work to go test - Y-N-DTA N The waiting time at the health facility is too long - Y-N-DTA O I don't think the results will stay confidential - Y-N-DTA P I don't like the attitude of health care workers - Y-N-DTA Q HIV tests at the health facility were out of stock - Y-N-DTA R Other reason - Y-N-DTA	If stconf=no & stres=1		Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C44	How likely are you to confirm the positive self-test result in the future?	1 Very likely 2 Somewhat likely 3 Somewhat unlikely 4 Very unlikely 9 Decline to answer	If stconf=no & stres=1	If respsex=male, now go to next section If respsex=female, now go to art section		
C45	What date did you have your confirmatory test?	MY	If stconf=yes		[TODAY'S DATE]-[STDATE]	
C46	What was the name of the clinic where you went for confirmatory testing?	1 Chilipa 2 Chilonga 3 Makanjira 4 Mkumba 5 Phirilongwe 6 Other 9 Decline to answer	If stconf=yes	If stconfloc!=other, skip to stconfres		
C47	Specify clinic if other	Short text	If stfconfloc=other			
C48	You don't have to tell me if you don't want to, but what were the results of the confirmatory test?	1 Positive 2 Negative 3 Indeterminate 9 Decline to answer	If stconf=yes	If 2, 3 or DTA & respsex=male, skip to stvmmc If 2, 3 or DTA & respsex=female, skip to art section		
C49	Did you start on ART drugs after the confirmatory test?	0 No 1 Yes, I started on ART for the first time 2 Yes, I restarted on ART 9 Decline to answer	If stconfres=1	If 1 or 2, skip to startdate If DTA & respsex=male, skip to next section If DTA & respsex=female, skip to art section		

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C50	What were the reasons why you did not start on ART drugs?	Check all that apply: A I don't feel sick enough to start on ART - Y-N-DTA B I do not trust my HIV-positive results - Y-N-DTA C I do not want to be seen queuing for ART services - Y-N-DTA D My partner won't let me start on ART - Y-N-DTA E Another family member won't let me start on ART - Y-N-DTA F It is against my religious beliefs to start on ART - Y-N-DTA G It is too expensive for me to visit the health facility - Y-N-DTA H I cannot take time off work to go to the health facility - Y-N-DTA I The waiting time at the health facility was too long - Y-N-DTA J I don't think my visit will stay confidential - Y-N-DTA K I don't like the attitude of health care workers - Y-N-DTA L ART at the health facility were out of stock - Y-N-DTA M I am afraid of experiencing side effects from the drugs - Y-N-DTA N I could not start on ART immediately after testing - Y-N-DTA O Other reason - Y-N-DTA	If start=0	If respsex=male, now go to next section If respsex=female, now go to art section	Need to select yes for at least one option or if decline to answer for one choice, must have decline to answer for all choices	
C51	What date did you start on ART drugs?	MY	If start=1 or 2		[TODAY'S DATE]-[STCONFDATE]	
C52	What was the name of the clinic where you started on ART drugs?	1 Chilipa 2 Chilonga 3 Makanjira 4 Mkumba 5 Phirilongwe 6 Other 9 Decline to answer	If start=1 or 2	If startloc!=other & respsex=male, skip to next section 'If startloc!=other & respsex=female, skip to art section		
C53	Specify health facility if other	Short text	If startloc=other	If respsex=male, now go to next section If respsex=female, now go to art section		

POST-INTERVENTION SURVEY

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
C54	Did you go for medical male circumcision after this test?	0 No 1 No, I am already circumcised 2 Yes 9 Decline to answer	If respsex=male &[(stres=2, 3 or DTA) or (stconfres=2, 3 or DTA)]	If 0, 1 or DTA, skip to next section		
C55	What date did you go for circumcision?	MY	If stvmmc=2		'[TODAY'S DATE]-[STDATE]	
C56	What was the name of the clinic where you went for circumcision?	Short text	If stvmmc=2			

POST-INTERVENTION SURVEY

Individual questionnaire - VMMC

To be completed by all men

Now I will ask you questions regading circumcision. Some men are circumcised; that is, the foreskin is completely removed from the penis.

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
D01	Please can you look at these pictures which show a penis that has had a foreskin completely removed. Does your penis look like this?	Y-N-DTA	If respsex=male	If no or DTA, skip to circaccess		
D02	Who did the circumcision?	1 Traditional or religious practitioner 2 Family or friend 3 Health care worker or professional 8 Don't know 9 Decline to answer	If circstatus=yes	Now go to next section		
D03	Do you know any facilities offering VMMC (voluntary medical male circumcision) to people who live around here?	Y-N-DTA	If circstatus=no or DTA	If circstatus=DTA, now to next section		
D04	How likely would you go for circumcision if it were offered within your neighborhood?	1 Very likely 2 Somewhat likely 3 Somewhat unlikely 4 Very unlikely 9 Decline to answer	If circstatus=no			

POST-INTERVENTION SURVEY

Individual questionnaire - HIV care

To be completed by all individuals who have ever tested

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
E01	Have you ever had a positive HIV test result?	Y-N-DTA	If evertest=yes	If no or DTA, skip to next section		
E02	Have you ever taken ART drugs?	Y-N-DTA	If posttest=yes	If no or DTA, skip to next section		
E03	Are you currently using ART drugs?	Y-N-DTA	If artlifeuse=yes	If (heardst=no or DTA) or (everst=no or DTA) now go to next section		
E04	Were you using ART drugs when you most recently self-tested?	Y-N-DTA	If artlifeuse=yes & everst=yes			

POST-INTERVENTION SURVEY

Individual questionnaire - past testing continued

To be completed by all individuals

Prompt: Now I would like to ask you some questions about your experiences testing for HIV with a partner.

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
F01	Do you have a steady partner? [Steady partner is defined as a spouse, a partner you live with, or a partner with whom you have been in a relationship with for at least 3 months]	Y-N-DTA	If eligcons=yes	If no or DTA, skip to otheryn		
F02	How many steady partners do you have?	Number	If steadyyn=yes		1-25, 88, 99	Enter 88 for don't know or 99 for decline to answer
F03	[Apart from your steady partner(s)], have you had any casual partners in the last three months? [Casual partner is defined as a partner with whom you have been in a sexual relationship with but is not your steady partner]	Y-N-DTA	If eligcons=yes	If no or DTA & steadyyn=yes, skip to parttest If no or DTA & (steadyyn=no or DTA) & everst=yes, skip to recst If no or DTA & (steadyyn=no or DTA) & ([evertest=no or DTA] or [heardst=no or DTA] or [everst=no or DTA]) skip to prefmod		
F04	How many casual partners do you have?	Number	If otheryn=yes		1-25, 88, 99	Enter 88 for don't know or 99 for decline to answer
F05	Has your partner recently tested for HIV? By this we mean any test in the last 12 months or a positive test at any time. **If you have multiple partners, think about the partner with whom you have had the longest relationship with**	Y-N-DK-DTA	If steadyyn=yes or otheryn=yes	If no, DK or DTA & (yrtest=yes or posttest=yes), skip to ownstatknw If no or DK or DTA & ([evertest=no or DTA] or [[yrtest=no or DTA] & [posttest=no or DTA]]), skip to partdisc		

POST-INTERVENTION SURVEY

F06	Has your partner shared his or her recent HIV test result with you? This includes any test in the last 12 months or a positive test at any time.	Y-N-DTA	If parttest=yes	If no or DTA & (yrtest=yes or posttest=yes), skip to ownstatknw If no or DTA & ([evertest=no or DTA] or [[yrtest=no or DTA] & [posttest=no or DTA]),skip to partdisc		
F07	Which of the following best describes how you learnt your partner's recent HIV status?	1 My partner told me after testing with a health care worker 2 I was present while my partner tested with a health care worker 3 My partner and I tested together with a health care worker 4 I was notified by a health care worker through a written slip or phone call 5 My partner told me after he or she self-tested 6 I was present while my partner self-tested 7 My partner and I self-tested together 9 Decline to answer	If partstatknw=yes	If ([evertest=no or DTA] or [[yrtest=no or DTA] & [posttest=no or DTA]), go to partdisc		
F08	Have you shared your recent HIV test result with your current partner?	Y-N-DTA	If (yrtest=yes or posttest=yes) & (steadyyn=yes or otheryn=yes)	If no or DTA, skip to partdisc		
F09	Which of the following best describes how your current partner learnt your recent HIV status?	1 I told my partner after I tested with a health care worker 2 My partner was there while I tested with a health care worker 3 My partner and I tested together with a health care worker 4 My partner was notified by a health care worker through a written slip or phone call 5 I told my partner after I self-tested 6 My partner was there while I self-tested 7 My partner and I self-tested together 9 Decline to answer	If ownstatknw=yes			
F10	Do you and your current partner know each other's recent HIV status? This includes any test in the last 12 months or a positive test at any time.	Y-N-DTA	If steadyyn=yes or otheryn=yes	If (evertest=no or DTA) or (heardst=no or DTA)or (everst=no or DTA), now go to prefmode		
F11	Would you recommend HIV self-testing to a friend or family member?	Y-N-DTA	If everst=yes			

F12	If you were to test for HIV, where would you prefer to have your next test?	1 Hospital or health centre 2 Health post / outreach 3 Mobile clinic 4 Door-to-door / home 5 Self-testing 8 Don't know 9 Decline to answer	If eligcons=yes			

POST-INTERVENTION SURVEY

Individual questionnaire - willingness to pay

To be completed by SELECTED individuals

Relevant if everst=yes
Prompt: You may be familiar with HIV testing. The most common approach for HIV testing involves having blood taken from your finger by a health care worker at a clinic. HIV testing is free, but you might have to pay for other cost

HIV self-testing is being introduced in Malawi. Some HIV self-test kits can come with a fee. We want to know how you might be affected by these fees. There is no right or wrong answer, so please be honest and tell us what would b true for you

Relevant if (evertest=no or DTA) or (heardst=no or DTA) or everst=(no or DTA)
Prompt: You may be familiar with HIV testing. The most common approach for HIV testing involves having blood taken from your finger by a health care worker at a clinic. HIV testing is free, but you might have to pay for other cost

New tests are being introduced in Malawi called HIV self-testing. This involves collecting your own saliva or blood, performing the test and interpreting your own results without a health care worker. [Show self-test kit]. This is an HIV self-test kit. The kit consists of three parts: testing pad, bottle with liquid solution, and stand. The testing pad is used to collect the saliva by rubbing the gums. After collecting the saliva, the testing pad is placed in the bottle. The stand holds the bottle and testing pad. After 20 minutes, the results can be read on the testing pad.

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
W01	Would you be interested in an HIV self-test kit if it were made available to you?	Y-N-DTA	If select=yes & ((evertest=no or DTA) or (heardst=no or DTA) or (everst=no or DTA))	If no or DTA, skip to wtp_com If yes & ([evertest=yes & [heardst=no or DTA]) or (everst=no or DTA), skip to wtp_yn_B		
W02	Where is the nearest place where you could go to get an HIV test?	1 Hospital or health centre 2 Health post / outreach 3 Mobile clinic 4 Door-to-door / home 5 Other 9 Decline to answer	If select=yes & ((wtp_interest=yes & (evertest=no or DTA)) or (selftest=yes & lifetestcount=1))	If wtp_interest=yes & (evertest=no or DTA), now to go wtp_yn_A If selftest=yes & lifetestcount=1, now go to wtp_yn_C		
W03	Where was your most recent test before the self-test?	1 Hospital or health centre 2 Health post / outreach 3 Mobile clinic 4 Door-to-door / home 5 Other 9 Decline to answer	If select=yes & (selftest=yes & lifetestcount>1)	Now go to wtp_yn_C		

W04	**Now imagine that you are being offered the opportunity to buy an HIV self-testing kit. You would be using your available household income to pay for the kit.** **Think about the time and costs you will have spent to get tested for HIV at the [WTP_NEARLOC]? HIV testing is free, but you might have to pay for other costs, such as transport, food or work lost. Also consider the time you will have spent travelling and waiting to get tested.** Would you be willing to pay for an HIV self-testing kit if it were made available to you, instead of being tested at the [WTP_NEARLOC]? **If [WTP_NEARLOC]= 5 or DTA, [WTP_NEARLOC]="Health facility"*	Y-N-DTA	If wtp_interest=yes & (evertest=no or DTA)	If yes, skip to wtp_amount_X If no, skip to wtp_whynot If DTA, skip to wtp_com		
W04	**Now imagine that you are being offered the opportunity to buy an HIV self-testing kit. You would be using your available household income to pay for the kit.** **Think about the last time you tested for HIV at the [TESTLOC], and the time and costs you spent on these services. HIV testing is free, but you might have paid for other costs, such as transport, food or work lost. Also consider the time you spent travelling and waiting to get tested.** Would you be willing to pay for an HIV self-testing kit if it were made available to you instead of being tested at the [TESTLOC]? **If [TESTLOC]= 5 or DTA, [TESTLOC]="Health facility"*	Y-N-DTA	If wtp_interest=yes & ([evertest=yes & [heardst=no or DTA]) or (everst=no or DTA)	If yes, skip to wtp_amount_X If no, skip to wtp_whynot If DTA, skip to wtp_com		

POST-INTERVENTION SURVEY

W04	**Think about the last time you tested for HIV at the [TESTLOC/STCONFLOC/WTP_NEARLOC/ WTP_BEFORESTLOC], and the time and costs you spent on these services. HIV testing is free, but you might have paid for other costs, such as transport, food or work lost. Also consider the time you spent travelling and waiting to get tested.** Would you have been willing to pay for the HIV self-testing kit you used instead of being tested at [TESTLOC/STCONFLOC/WTP_NEARLOC/WTP_BEFORESTLOC]? **If selftest=no & conftest=no, use [TESTLOC]* **If selftest=no & conftest=yes, use "Health facility"* **If selftest=yes & lifetestcount=1, use [WTP_NEARLOC]* **If selftest=yes & lifetestcount>1, use [WTP_BEFORESTLOC]* **If [TESTLOC/WTP_NEARLOC/ WTP_BEFORESTLOC]=5 or DTA, use "Health facility"*	Y-N-DTA	If select=yes & everst=yes	If yes, skip to wtp_amount_X If DTA, skip to wtp_com		
W05	Which of the following best describes why you would not be willing to pay for an HIV self-test kit?	1 I am unable to pay for a kit 2 I object to paying for a kit. 3 I object to pay for any HIV services. 9 Decline to answer	If wtp_yn_A=no or wtp_yn_B=no or wtp_yn_C=no			
W06	If you were interested in an HIV self-test kit but were not willing to pay, what would you do instead?	1 Not test for HIV 2 Get tested at a health facility 3 Get tested at a health post or outreach 4 Get tested at a mobile clinic 9 Decline to answer	If wtp_yn_A=no or wtp_yn_B=no or wtp_yn_C=no	Now to go wtp_com		

POST-INTERVENTION SURVEY

W07	Would you be willing to pay MK [N] for an HIV self-test kit? **[N] for wtp_mk_1 randomly allocated to low, middle or high starting value* **[N] for low value – 300 350 400 450 500* 550 **600** 650 **700*** **[N] for medium value – **600a 700a** 800 **900** 1000* 1100 **1200** 1300 1400* **[N] for high value – **900a** 1050 **1200a** 1350 1500* 1650 1800 1950 2050* **Starting value*	Y-N	If wtp_yn_A=yes or wtp_yn_B=yes or wtp_yn_C=yes	If wtp_yn_1=yes, wtp_yn_2>wtp_yn_1; if wtp_yn_2=no, go to wtp_certain; if wtp_yn_2=yes, wtp_yn_3>wtp_yn_2; if wtp_yn_3=no, go to wtp_certain; if wtp_yn_3=yes, wtp_yn_4>wtp_yn_3; if wtp_yn_4=no, go to wtp_certain; if wtp_yn_4=yes, wtp_yn_5>wtp_yn_4; if wtp_yn_5=no, go to wtp_certain; if wtp_yn_4=yes, go to wtp_max If wtp_yn_1=no		
W08	**You said you would (not) be willing to pay MK [N] for an HIV self-test kit.** What is the highest price you would be willing to pay for an HIV self-test kit? **[N]=[N] for wtp_mk_5*	Number	If wtp_mk_5=yes if upward bidding or wtp_mk_5=no if downward bidding		1-20,000	
W09	**Imagine that you wanted to test for HIV right now.** How sure are you that you would be willing to pay MK [N] for an HIV self-test kit? **If wtp_mk_1=yes & wtp_mk_2=no, [N]=[N] for wtp_mk_1; if wtp_mk_2=yes & wtp_mk_3=no, [N]=[N] for wtp_mk_2; if wtp_mk_3=yes & wtp_mk_4=no, [N]=[N] for wtp_mk_3; if wtp_mk_4=yes & wtp_mk_5=no, [N]=[N] for wtp_mk_4; if wtp_mk_5=yes, [N]=wtp_max* **If wtp_mk_1=no & wtp_mk_2=yes, [N]=[N] for wtp_mk_2; if wtp_mk_2=no & wtp_mk_3=yes [N]=[N] for wtp_mk_3; if wtp_mk_3=no & wtp_mk_4=yes, [N]=[N] for wtp_mk_4; if wtp_mk_4=no & wtp_mk_5=yes, [N]=[N] for wtp_mk_5; if wtp_mk_5=no, [N]=wtp_max*	1 Very sure 2 Probably sure	If wtp_yn_A=yes or wtp_yn_B=yes or wtp_yn_C=yes			

POST-INTERVENTION SURVEY

W10	**The chief would need contributions from residents to support distribution of HIV self-test kits in your village next year. The village health committee and community volunteers would be responsible for distribution. HIV self-test kits would be free.** Would you be willing to contribute to have HIV self-test kits distributed in your village next year?	Y-N-DTA	If select=yes	If no or DTA, skip to next section		
W11	What is the maximum you would be willing to contribute in order to have HIV self-test kits disributed in your village next year?	Number	If wtp_contribute=yes		1-20000	Enter 888888 for don't know or 99999 for decline to answer

POST-INTERVENTION SURVEY

Individual questionnaire - HIV prevention knowledge

To be completed by SELECTED individuals

Prompt: For each of the following statements, please indicate whether you strongly agree, agree, unsure, disagree or strongly disagree.

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
P01	It is necessary for me to test for HIV even though my partner has already tested	1 Strongly Agree 2 Agree 3 Unsure 4 Disagree 5 Strongly disagree 9 Decline to answer	If select=yes			
P02	I believe that HIV treatment makes people with HIV less infectious	1 Strongly Agree 2 Agree 3 Unsure 4 Disagree 5 Strongly disagree 9 Decline to answer	If select=yes			
P03	I would feel safe having intercourse with someone who is HIV-positive as long as they are receiving HIV treatment	1 Strongly Agree 2 Agree 3 Unsure 4 Disagree 5 Strongly disagree 9 Decline to answer	If select=yes			
P04	I am less worried about HIV infection than I used to be	1 Strongly Agree 2 Agree 3 Unsure 4 Disagree 5 Strongly disagree 9 Decline to answer	If select=yes			
P05	HIV treatment makes me less anxious about having unprotected sex	1 Strongly Agree 2 Agree 3 Unsure 4 Disagree 5 Strongly disagree 9 Decline to answer	If select=yes			
P06	I would feel more protected from HIV if I were circumcised	1 Strongly Agree 2 Agree 3 Unsure 4 Disagree 5 Strongly disagree 9 Decline to answer	If select=yes & respsex=male			

POST-INTERVENTION SURVEY

P07	It is possible for an HIV-negative man to have an HIV-positive wife	1 Strongly Agree 2 Agree 3 Unsure 4 Disagree 5 Strongly disagree 9 Decline to answer	If select=yes			
P08	It is possible for an HIV-negative woman to have an HIV-positive husband	1 Strongly Agree 2 Agree 3 Unsure 4 Disagree 5 Strongly disagree 9 Decline to answer	If select=yes			
P09	HIV treatment can help prevent a person with HIV from infecting a partner	1 Strongly Agree 2 Agree 3 Unsure 4 Disagree 5 Strongly disagree 9 Decline to answer	If select=yes			
P10	If a man is circumcised, it will be more difficult for him to get HIV from his partner	1 Strongly Agree 2 Agree 3 Unsure 4 Disagree 5 Strongly disagree 9 Decline to answer	If select=yes & respsex=male			

POST-INTERVENTION SURVEY

Individual questionnaire - stigma

To be completed by SELECTED individuals

Prompt: For each of the following statements, please indicate whether you strongly agree, agree, disagree or strongly disagree.

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
S01	People are hesitant to take an HIV test due to fear of other people's reaction if the test result is positive for HIV	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S02	People sometimes talk badly about people living with or thought to be living with HIV	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S03	Health workers sometimes talk badly about people living with or thought to be living with HIV	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S04	People living with or thought to be living with HIV lose respect or standing	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S05	People living with or thought to be living with HIV are verbally insulted, harassed, and/or threatened	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S06	People living with or thought to be living with HIV are sometimes phyiscally assaulted	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S07	I would be ashamed if someone in my family had HIV	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			

POST-INTERVENTION SURVEY

S08	I would not like to sit close to someone living with HIV,for example on public transport, at church, or in a waiting room	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S09	I fear that I could contract HIV if I come into contact with the saliva of a person with HIV	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S10	People sometimes disclose that other people are HIV positive without their permission	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S11	Health workers sometimes disclose that other people are HIV positive without their permission	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S12	People living with HIV who are taking ART are treated better by others than people living with HIV who are not taking ART	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S13	I would not want anyone I know to see me queuing for an HIV test	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
S14	My friends or family would not approve if I went for HIV testing	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
S15	It would be embarrassing if someone found out I tested for HIV	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
S16	You know there are problems in a marriage when the couple tests for HIV	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
S17	Everyone who tests for HIV is HIV-positive	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			

S18	Testing for HIV means that you are immoral	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes			
S19	It is acceptable for the chief to demand that everyone in a community test for HIV	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S20	It is acceptable for a health care worker to nag a person to test for HIV despite making it clear that he or she does not want to test	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S21	It is acceptable for a group of friends to pressure a peer into testing for HIV	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S22	It is acceptable for a woman to refuse to have sex with her husband until he tests for HIV	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S23	It is acceptable for a man to threaten to hit a woman, but not actually hit her, so that she tests for HIV	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			
S24	It is acceptable for parents to force a young child to test for HIV	1 Strongly Agree 2 Agree 3 Disagree 4 Strongly disagree 9 Decline to answer	If select=yes			

POST-INTERVENTION SURVEY

Individual questionnaire - sexual behaviour

To be completed by all individuals who have a partner

If steadyyn=yes or otheryn=yes
Prompt: Now I would like to ask you questions about your sexual activity in order to gain a better understanding of some important life issues. Let me asure you that your answers are completely confidential and will not be told to

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
F01	In the last three months, have you had **sex without using a condom with a steady partner**, even if it was only on one occasion? [Steady partner is defined as a spouse, a partner you live with, or a partner with whom you have been in a relationship with for at least 3 months]	Y-N-DTA	If steadyyn=yes	If no or DTA & otheryn=yes, skip to othernoconyn If no or DTA & (otheryn=no or DTA) & ([evertest=no or DTA] or [yrtest=no or DTA]), skip to next section If no or DTA & (otheryn=no or DTA) & yrtest=yes, skip to parttestyn		

F02	In the last three months, how many steady partners have you had **sex with and did not use a condom?**	Number	If steadynoconyn=yes	If (otheryn=no or DTA) & ([evertest=no or DTA] or [yrtest=no or DTA]), now go to next section
				
				If (otheryn=no or DTA) & yrtest=yes, now go to parttestyn
					1-[STEADYCT], 88, 99	Enter 88 for don't know or 99 for decline to answer

F03	In the last three months, have you had **sex without using a condom with a casual partner**, even if it was only on one occasion? [Casual partner is defined as a partner with whom you have been in a sexual relationship with but is not your steady partner]	Y-N-DTA	If otheryn=yes	If no or DTA & ([evertest=no or DTA] or [yrtest=no or DTA]), skip to next section If no or DTA & yrtest=yes, skip to parttestyn		
F04	In the last three months, how many casual partners have you had **sex with and did not use a condom**?	Number	If othernoconyn=yes	If ([evertest=no or DTA] or [yrtest=no or DTA]), now go to next section	1-[OTHERYNCT], 88, 99	Enter 88 for don't know or 99 for decline to answer

F05	Thinking to the last time you tested for HIV, have you had **sex without using a condom** since you tested, even if it was only on one occasion?	Y-N-DTA	If (steadyyn=yes or otheryn=yes) & yrtest=yes	If no or DTA, skip to next section		
F06	How many people have you had**sex with and did not use a condom** since the last time you tested for HIV?	Number	If parttestyn=yes		1-50, 88, 99	Enter 88 for don't know or 99 for decline to answer

POST-INTERVENTION SURVEY

Individual questionnaire - stigma

To be completed by SELECTED MEN

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
GM01	A woman's most important role is to take care of her home and cook for her family	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM02	Men need sex more than women do	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM03	Men don't talk about sex, they just do it	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM04	There are times when a woman deserves to be beaten	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM05	Changing diapers, giving kids a bath and feeding kids are a mother's responsibility	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM06	It is a woman's responsibility to avoid getting pregnant if pregnancy is not wanted	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM07	A man should have the final word about decisions in his home	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM08	Men are always ready to have sex	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM09	A woman should tolerate violence in order to keep her family together	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			

GM10	I would be outraged if my wife asked me to use a condom	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM11	A man and a woman should decide together what type of contraceptive to use	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM12	If someone insults me, I will defend my reputation, with force if I have to	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM13	To be a man, you need to be tough	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM14	If a man gets a woman pregnant, the child is the responsibility of both	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM15	The participation of the father is important in raising children	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM16	It's important for a man to have friends to talk about his problems	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			
GM17	A couple should decide together if they want to have children	1 Strongly Agree 2 Somewhat agree 3 Disagree 9 Decline to answer	If select=yes & respsex=men			

POST-INTERVENTION SURVEY

Individual questionnaire - end

To be completed by interviewer

Question No.	Question	Data type	Relevance	Skips	Ranges for continuous variables	Hint
X01	Time interview ended	Automatic				
X02	Interview status:	1 Complete 2 Incomplete - provide additional comments below				
X03	Interviewer comments on specific questions, respondent, interview. Include here whether interview was truncated for some reason	Long text				

SITE

Site	
Health facility	
Sources of funding	

Period of data collection	
Start date	
End date	

Annual period (last 12 months before data collection start date)	
Start month	
End month	

COSTING TOOL

BUILDING

Building	
Item	**Value**
Name	
Location/address 1	
Location/address 2	
Ownership (select)	
Value if sold today or annual rent	
Annual maintenance expenditure	
Size of building (m^2)	
Size of land (m^2)	
Operating hours, days per week	
Operating hours, hours per day	

Buidling rooms				
Room name	**Size of room** (m2)	**Activity 1**	**Activity 2**	**Activity 3**

COSTING TOOL

EQUIPMENT

Item	Room	Ownership	Manufacturer	Model	Unit price	Useful life	Activity 1	Activity 2	Activity 3
Medical equipment									
Laboratory equipment									
IT and office equipment									
Furniture									

COSTING TOOL

VEHICLES

Vehicles						
Item	Ownership	Value if sold today or annual	Useful life	Annual maintenance	Annual fuel expenditure	Annual driver expenditure

PERSONNEL

Item	Salary grade	Gross annual salary	Gross annual benefits	Average working hours
Direct service personnel				
Support personnel				
Volunteers				

COSTING TOOL

RECURRENT

Item	Annual expenditure
Utilities	
Administrative	
Cleaning and security	
Communications	
Food	
Other costs	

TRAINING AND SENSITISATION

Training

Name	Type of training activity	Location	Start date	Number of days	Number of participants	Expenditure per participant	Transportation cost per participant	Per diem per participant	Other costs per participant

Sensitisation

Name	Type of sensitisation activity	Location	Start date	Number of days	Number of persons reached	Expenditure per participant	Transportation cost per person	Per diem per person	Other costs per person

COSTING TOOL

SUPPLIES

Item	Annual expenditure	Activity 1	Activity 2	Activity 3
Medical and laboratory supplies				
Non-medical supplies				
Office supplies				

CONSUMABLES

Item	Brand	Unit of measure	Price per unit	Quantity per unit	Activity 1	Activity 2	Activity 3
Diagnostics							
Drugs							
Other medical consumables							
Non-medical consumables							

COSTING TOOL

SERVICE OUTPUT

	Quantity (in the last 12 months), visits		
Month - Year	Total	Positive	Negative
Outpatient services			
HIV testing services			

COSTING TOOL

OBSERVATIONS AND INTERVIEWS

Activity	

Tasks	Personnel	Time			Room	Supplies and consumables		Equipment	
		Start	End	Total (in min)		Item	Quantity	Item	Quantity (in min)

Activity	

Tasks	Personnel	Time			Room	Supplies and consumables		Equipment	
		Start	End	Total (in min)		Item	Quantity	Item	Quantity (in min)

Activity	

Tasks	Personnel	Time			Room	Supplies and consumables		Equipment	
		Start	End	Total (in min)		Item	Quantity	Item	Quantity (in min)

COSTING TOOL

TIME SHEET

Name	
Job title	

	Monday			Tuesday			Wednesday			Thursday			Friday		
	HIV testing	HIV care	Other services	HIV testing	HIV care	Other services	HIV testing	HIV care	Other services	HIV testing	HIV care	Other services	HIV testing	HIV care	Other services
Clients per day															
Clients per day															
8:00 - 9:00															
9:00 - 10:00															
10:00 - 11:00															
11:00 - 12:00															
12:00 - 13:00															
13:00 - 14:00															
14:00 - 15:00															
15:00 - 16:00															
16:00 - 17:00															
17:00 - 18:00															
18:00 - 19:00															
19:00 - 20:00															

Appendix 4.

Files for statistical analysis

```
*************************************************************************

*About: This do-file includes a demonstration of the primary analysis for Chapter 4

*************************************************************************

*************************************************************************
*CLUSTER-LEVEL ANALYSIS
*************************************************************************

*Import data
use "`input_iq'", clear

*Set variable locals
glob outc evertest
glob cluster gvhid
glob arm arm
glob grp="respage>=15 & respage<=19"
glob subgrp agegroup_ado respsex
glob adj respsex agegroup_ado literate muslim ethnic srhealth
glob subadj1 respsex literate muslim ethnic srhealth
glob subadj2 agegroup_ado literate muslim ethnic srhealth

*Keep sample
keep if $grp

* * *

preserve

*Collapse to cluster level
gen total=1
collapse (sum) $outc total, by($arm $cluster)

*Compute risk
gen risk=$outc/total
gen logrisk=log(risk)

*Compute reciprocal
gen total_inv=1/total

*Compute-k
forval i=1/2 {
        sum risk if $arm==`i'
        loc Var=r(Var)
        sum total_inv if $arm==`i'
        loc mean=r(mean)
        loc k`i'=sqrt(`Var'-(`n'/`N')*(1-(`n'/`N'))*`mean')/(`n'/`N')
}

*Compute unadjusted effect estimates

*Compute risk difference
ttest risk, by($arm)
loc crudeRD=round(100*(r(mu_1)-r(mu_2)), 0.1)
loc crudeRDlower=round(100*(r(mu_1)-r(mu_2)-invttail(r(df_t),0.025)*(r(mu_1)-
r(mu_2))/r(t)), 0.1)
loc crudeRDupper=round(100*(r(mu_1)-r(mu_2)+invttail(r(df_t),0.025)*(r(mu_1)-
r(mu_2))/r(t)), 0.1)
loc crudeRDpval=round(r(p), 0.001)
loc pval=r(p)

*Compute risk ratio
ttest logrisk, by($arm)
loc crudeRR=round(exp(r(mu_1)-r(mu_2)), 0.01)
loc crudeRRlower=round(exp(r(mu_1)-r(mu_2)-invttail(r(df_t),0.025)*(r(mu_1)-
r(mu_2))/r(t)), 0.01)
loc crudeRRupper=round(exp(r(mu_1)-r(mu_2)+invttail(r(df_t),0.025)*(r(mu_1)-
r(mu_2))/r(t)), 0.01)
loc crudeRRpval=round(r(p), 0.001)
loc pval=r(p)

restore

*Compute adjusted effect estimates

preserve
```

```
*Generate list of covariates for regression
loc adj_list=""
foreach var of varlist $adj {
	loc adj_list="`adj_list' i.`var'"
}

*Generate list of covariates for N
loc j=1
loc adj_total=""
foreach var of varlist $adj {
	if `j'==1 {
		loc adj_total="`adj_total' `var'"
	}
	else {
		loc adj_total="`adj_total', `var'"
	}
	loc j=`j'+1
}

*Compute adjusted residual
logistic $outc `adj_list'
predict prob_outc

*Collapse to cluster level
gen total=1 if !missing(`adj_n') // if no missing data
collapse (sum) $outc prob_outc total, by($arm $cluster)

*Compute ratio-residual and difference-residual
gen residd=($outc-prob_outc)/total
gen residr=$outc/prob_outc
gen logresidr=log(residr)

*Compute adjusted risk difference
ttest residd, by($arm)
loc adjRD=round(100*(r(mu_1)-r(mu_2)), 0.1)
loc adjRDlower=round(100*(r(mu_1)-r(mu_2)-invttail(r(df_t),0.025)*(r(mu_1)-r(mu_2))/r(t)),
0.1)
loc adjRDupper=round(100*(r(mu_1)-r(mu_2)+invttail(r(df_t),0.025)*(r(mu_1)-r(mu_2))/r(t)),
0.1)
loc adjRDpval=round(r(p), 0.001)
loc pval=r(p)

*Compute adjusted risk ratio
ttest logresidr, by($arm)
loc adjRR=round(exp(r(mu_1)-r(mu_2)), 0.01)
loc adjRRlower=round(exp(r(mu_1)-r(mu_2)-invttail(r(df_t),0.025)*(r(mu_1)-r(mu_2))/r(t)),
0.01)
loc adjRRupper=round(exp(r(mu_1)-r(mu_2)+invttail(r(df_t),0.025)*(r(mu_1)-r(mu_2))/r(t)),
0.01)
loc adjRRpval=round(r(p), 0.001)
loc pval=r(p)

restore

* * *

*Set loop for each subgroup
foreach var of varlist $subgrp {

	* * Generate headings * *

	*Set loop for each level
	foreach l in `level' {

		* * Generate estimates * *

		preserve

		*Keep subgroup
		keep if `var'==`l'

		*Collapse to cluster level
		gen total=1
		collapse (sum) $outc total, by($arm $cluster)

		*Compute risk
```

```
gen risk=$outc/total
gen logrisk=log(risk)

*Compute unadjusted effect estimates

*Compute risk difference
ttest risk, by($arm)
loc crudeRD=round(100*(r(mu_1)-r(mu_2)), 0.1)
loc crudeRDlower=round(100*(r(mu_1)-r(mu_2)-invttail(r(df_t),0.025)*
(r(mu_1)-r(mu_2))/r(t)), 0.1)
loc crudeRDupper=round(100*(r(mu_1)- r(mu_2)+invttail(r(df_t),0.025)*
(r(mu_1)-r(mu_2))/r(t)), 0.1)
loc crudeRDpval=round(r(p), 0.001)
loc pval=r(p)

*Compute risk ratio
ttest logrisk, by($arm)
loc crudeRR=round(exp(r(mu_1)-r(mu_2)), 0.01)
loc crudeRRlower=round(exp(r(mu_1)-r(mu_2)-invttail(r(df_t),0.025)*
(r(mu_1)-r(mu_2))/r(t)), 0.01)
loc crudeRRupper=round(exp(r(mu_1)- r(mu_2)+invttail(r(df_t),0.025)*
(r(mu_1)-r(mu_2))/r(t)), 0.01)
loc crudeRRpval=round(r(p), 0.001)
loc pval=r(p)

restore

*Compute adjusted effect estimates

preserve

*Generate list of covariates for regression
loc adj_list=""
foreach var of varlist ${subadj`s'} {
        loc adj_list="`adj_list' i.`var'"
}

*Generate list of covariates for N
loc j=1
loc adj_total=""
foreach var of varlist ${subadj`s'} {
        if `j'==1 {
                loc adj_total="`adj_total' `var'"
        }
        else {
                loc adj_total="`adj_total', `var'"
        }
        loc j=`j'+1
}

*Keep subgroup
keep if `var'==`l'

*Compute adjusted residual
logistic $outc `adj_list'
predict prob_outc

*Collapse to cluster level
gen total=1 if !missing(`adj_n') // if no missing data
collapse (sum) $outc prob_outc total, by($arm $cluster)

*Compute ratio-residual and difference-residual
gen residd=($outc-prob_outc)/total
gen residr=$outc/prob_outc
gen logresidr=log(residr)

*Compute adjusted risk difference
ttest residd, by($arm)
loc adjRD=round(100*(r(mu_1)-r(mu_2)), 0.1)
loc adjRDlower=round(100*(r(mu_1)-r(mu_2)-invttail(r(df_t),0.025)*(r(mu_1)-
r(mu_2))/r(t)), 0.1)
loc adjRDupper=round(100*(r(mu_1)-r(mu_2)+invttail(r(df_t),0.025)*(r(mu_1)-
r(mu_2))/r(t)), 0.1)
loc adjRDpval=round(r(p), 0.001)
loc pval=r(p)

*Compute adjusted risk ratio
```

```
                ttest logresidr, by($arm)
                loc adjRR=round(exp(r(mu_1)-r(mu_2)), 0.01)
                loc adjRRlower=round(exp(r(mu_1)-r(mu_2)-invttail(r(df_t),0.025)*(r(mu_1)-
                r(mu_2))/r(t)), 0.01)
                loc adjRRupper=round(exp(r(mu_1)-r(mu_2)+invttail(r(df_t),0.025)*(r(mu_1)-
                r(mu_2))/r(t)), 0.01)
                loc adjRRpval=round(r(p), 0.001)
                loc pval=r(p)

                *Save file for interaction effect
                keep $cluster $arm residd
                rename residd residd`l'

                tempfile temp_subgrp`l'
                save `temp_subgrp`l'', replace

                restore
        }

        *Compute interaction effect estimate

        preserve

        *Merge data
        loc x : word 1 of `level'
        loc y=`x'+1
        use `temp_subgrp`x'', clear
        merge 1:1 $cluster using `temp_subgrp`y''

        *Export-interaction p-value
        gen diff=residd`y'-residd`x'
        ttest diff, by($arm)
        loc     intpval_`var'=round(r(p), 0.001)

        restore

        *Reset local
        loc s=`s'+1
}
*******************************************************************************
```

```
*******************************************************************************

*About: This do-file includes a demonstration of the primary analysis for Chapter 5

*******************************************************************************

*******************************************************************************
*INCREMENTAL COSTS
*******************************************************************************

*Import data
use "`input'", clear

*Set macros
glob outc cost
glob arm arm
glob cluster gvhid
glob adj respsex agegroup literate muslim ethnic srhealth

* * *

preserve

*Collapse to cluster level
collapse (mean) $outc, by($arm $cluster)

*Compute unadjusted effect estimates

*Compute mean difference
ttest $outc, by($arm)
loc crudeMD=round(r(mu_1)-r(mu_2), 0.01)
loc crudeMDlower=round(r(mu_1)-r(mu_2)-invttail(r(df_t),0.025)*(r(mu_1)-r(mu_2))/r(t),
0.01)
loc crudeMDupper=round(r(mu_1)-r(mu_2)+invttail(r(df_t),0.025)*(r(mu_1)-r(mu_2))/r(t),
0.01)
loc crudeMDpval=round(r(p), 0.001)
loc pval=r(p)

restore

*Compute adjusted effect estimates

preserve

*Generate list of covariates for regression
loc adj_list=""
foreach var of varlist $adj {
        loc adj_list="`adj_list' i.`var'"
}

*Compute adjusted residual
reg $outc `adj_list'
predict prob_outc

*Collapse to cluster level
collapse (mean) $outc prob_outc, by($arm $cluster)

*Compute difference-residual
gen residd=$outc-prob_outc

*Compute adjusted mean difference
ttest residd, by($arm)
loc adjMD=round(r(mu_1)-r(mu_2), 0.01)
loc adjMDlower=round(r(mu_1)-r(mu_2)-invttail(r(df_t),0.025)*(r(mu_1)-r(mu_2))/r(t), 0.01)
loc adjMDupper=round(r(mu_1)-r(mu_2)+invttail(r(df_t),0.025)*(r(mu_1)-r(mu_2))/r(t), 0.01)
loc adjMDpval=round(r(p), 0.001)
loc pval=r(p)

*Set global for adjusted mean difference
glob IC=r(mu_1)-r(mu_2)

restore

*******************************************************************************
*INCREMENTAL EFFECTS
*******************************************************************************
```

```
*Import data
use "`input'", clear

*Set variable locals
glob outc testpos12mths
glob arm arm
glob cluster gvhid
glob adj respsex agegroup literate muslim ethnic srhealth

* * *

preserve

*Generate N
gen total=1

*Collapse to cluster level
collapse (sum) $outc total, by($arm $cluster)

*Compute risk
gen risk=$outc/total

*Compute unadjusted effect estimates

*Compute risk difference
ttest risk, by($arm)
loc crudeRD=round(100*(r(mu_1)-r(mu_2)), 0.1)
loc crudeRDlower=round(100*(r(mu_1)-r(mu_2)-invttail(r(df_t),0.025)*(r(mu_1)-
r(mu_2))/r(t)), 0.1)
loc crudeRDupper=round(100*(r(mu_1)-r(mu_2)+invttail(r(df_t),0.025)*(r(mu_1)-
r(mu_2))/r(t)), 0.1)
loc crudeRDpval=round(r(p), 0.001)
loc pval=r(p)

restore

*Compute adjusted effect estimates

preserve

*Generate list of covariates for regression
loc adj_list=""
foreach var of varlist $adj {
        loc adj_list="`adj_list' i.`var'"
}

*Generate list of covariates for N
loc j=1
loc adj_total=""
foreach var of varlist $adj {
        if `j'==1 {
                loc adj_total="`adj_total' `var'"
        }
        else {
                loc adj_total="`adj_total', `var'"
        }
        loc j=`j'+1
}

*Compute adjusted residual
logistic $outc `adj_list'
predict prob_outc

*Collapse to cluster level
gen total=1 if !missing(`adj_total') // if no missing data
collapse (sum) $outc prob_outc total, by($arm $cluster)

*Compute difference-residual
gen residd=($outc-prob_outc)/total

*Compute adjusted risk difference
ttest residd, by($arm)

loc adjRD=round(100*(r(mu_1)-r(mu_2)), 0.1)
loc adjRDlower=round(100*(r(mu_1)-r(mu_2)-invttail(r(df_t),0.025)*(r(mu_1)-r(mu_2))/r(t)),
0.1)
```

```
loc adjRDupper=round(100*(r(mu_1)-r(mu_2)+invttail(r(df_t),0.025)*(r(mu_1)-r(mu_2))/r(t)),
0.1)
loc adjRDpval=round(r(p), 0.001)
loc pval=r(p)

*Set global for adjusted risk difference
glob IE_testpos=r(mu_1)-r(mu_2)

restore

*Compute ICER
glob ICER_testpos=round($IC/$IE_testpos, 0.01)

*******************************************************************************
*TWO-STAGE BOOTSTRAP
*******************************************************************************

glob outc_c cost
glob outc_e testpos12mths
glob outc $outc_c $outc_e
glob arm arm
glob cluster gvhid
glob adj respsex agegroup literate muslim ethnic srhealth

* * *

*Calculate shrunken cluster means and individual residuals

*Set loop for each arm
forval i=1/2 {

        *Import data
        use "`input'", clear

        *Keep data in arm
        keep if $arm==`i'

        *No of observations (N')
        count
        loc N=r(N)

        *No of clusters (a')
        levelsof gvhid
        loc a=wordcount(r(levels))

        *No of observations by cluster (n)
        preserve
        gen n=1
        collapse (sum) n, by($arm $cluster)

        *Average no of observations
        loc b=(`N'-(sum(n^2)/`N'))/(`a'-1) // Based on Gomes et al.

        *Save data-cluster-level
        tempfile temp_cluster`i'
        save "`temp_cluster`i''", replace
        restore

        *Set loop for each outcome
        foreach var in $outc {

                *Mean by cluster (var_x)
                preserve
                rename `var' `var'_x
                collapse (mean) `var'_x, by($arm $cluster)

                *Mean of cluster means (xbar2')
                sum `var'_x
                loc xbar2=r(mean)

                *Between sum of squares (ssb')
                loc ssb=sum((`var'_x-`xbar2')^2) // Based on Gomes et al.

                *Save data-cluster-level for each outcome
                tempfile temp_`var'`i'
                save "`temp_`var'`i''", replace
                restore
```

```
                *Deviation of observation from cluster mean (var_dfm)
                merge m:1 $cluster using "`temp_`var'`i'", nogen
                gen `var'_dfm=`var'-`var'_x

                *Standardised individual residuals (var_z)
                gen `var'_z=`var'_dfm/sqrt(1-1/`b')

                *Within sum of squares (ssw')
                loc ssw=sum(`var'_dfm^2)

                *Right hand side of constant c for shrinkage correction (rhs')
                loc rhs=`a'/(`a'-1)-`ssw'/(`b'*(`b'-1)*`ssb')

                *Constant c for shrinkage correction (c')
                if `rhs'<0 {
                        loc c=1
                }
                else {
                        loc c=1-sqrt(`rhs')
                }

                *Overall mean (xbar')
                sum `var'
                loc xbar=r(mean)

                *Drop variable
                drop `var'_x
        }

        *Save data-individual-level
        tempfile temp_indiv`i'
        save "`temp_indiv`i'", replace

        *Import data-cluster-level
        use "`temp_cluster`i'", clear

        *Shrunken cluster mean (var_x) for each outcome
        foreach var in $outc {
                merge m:1 $cluster using "`temp_`var'`i'", nogen
                replace `var'_x=`c'*`xbar'+(1-`c')*`var'_x
        }

        *Save data-cluster-level
        save "`temp_cluster`i'", replace
}

*Append and save data-cluster-level
use "`temp_cluster1'", clear
append using "`temp_cluster2'"
save "file_ce_cluster", replace

*Append and save data-individual-level
use "`temp_indiv1'", clear
append using "`temp_indiv2'"
save "file_ce_indiv", replace

* * *

*Generate program

*Program two-stage bootstrap
cap program drop tsb2
program define tsb2, rclass
version 14.2

*Generate bootstrap sample

*Set loop for each arm
forval i=1/2 {

        *Import data
        use "file_ce_cluster", clear

        *Keep data in arm
        keep if $arm==`i'
```

```
	*Number of clusters (a)
	levelsof gvhid
	loc a=wordcount(r(levels))

	*Resample clusters and generate ID
	bsample

	*Set loop for each cluster (j)
	gen id=_n
	forval j=1/`a' {

		*Merge individual-level data
		preserve
		keep if id==`j'
		merge 1:m $cluster using "file_ce_indiv", nogen keep(3)

		*Generate individual-level bootstrap sample
		bsample

		*Save data-bootstrap sample
		tempfile temp_bs`j'
		save "`temp_bs`j''", replace

		*Append data-bootstrap sample
		if `j'=1 {
			tempfile temp_bs
			save "`temp_bs'", replace
		}
		else `j'>1 {
			use "`temp_bs'", clear
			append using "`temp_bs`j''"
			save "`temp_bs'", replace
		}
		restore
	}

	*Combine shrunken cluster mean with individual residuals for each outcome
	foreach var in $outc {
		replace `var'=`var'_x+`var'_z
	}

	*Drop variables
	drop *_x *_z *_dfm n

	*Save data-bootstrap sample
	tempfile temp_bs_arm`i'
	save "`temp_bs_arm`i''", replace
}

*Append data-bootstrap sample
use "`temp_bs_arm1'", clear
append using "`temp_bs_arm2'"

*Compute adjusted effect estimates

*Generate list of covariates for regression
loc adj_list=""
foreach var of varlist $adj {
	loc adj_list="`adj_list' i.`var'"
}

*Compute adjusted incremental costs and effects
loc i=1
foreach v in c e {

	*Compute adjusted residual
	reg ${outc_`v'} `adj_list'
	predict prob_outc_`v' if !missing(${outc_`v'})

	*Collapse to cluster level
	preserve
	collapse (mean) ${outc_`v'} prob_outc_`v', by($arm $cluster)

	*Compute difference-residual
	gen residd_`v'=${outc_`v'}-prob_outc_`v'

	*Compute adjusted mean difference
```

```
        ttest residd_`v', by($arm)

        *Set macro for point estimate
        return scalar diff_`v'=r(mu_1)-r(mu_2)
        restore

        loc i=`i'+1
}
end

* * *

*Generate bootstrap replicates

*Compute incremental costs and effects
simulate ic=r(diff_c) ie=r(diff_e), seed(10101) reps(1000): tsb2

*Save simulation file
save "`file_ce_sim'", replace

*******************************************************************************
*CONFIDENCE INTERVALS
*******************************************************************************

*Import data
use "`file_ce_sim'", clear

*Compute bc CIs

*ICER
gen icer=ic/ie

*N
count
loc N=r(N)

*q
count if icer<$ICER_testpos
loc q=r(N)/`N'

*z-hat
loc zhat=invnormal(`q')

*z
loc alpha=0.05
loc z1=invnormal(`alpha'/2)
loc z2=invnormal(1-(`alpha'/2))

*alpha
loc a1=normal(`z1'+(2*`zhat'))
loc a2=normal(`z2'+(2*`zhat'))

*Compute bc CIs
sort icer
loc icer_ll=round(icer[(`N'*`a1')])
if `icer_ll'<0 {
        count if icer<0
        loc icer_ll=round(icer[r(N)+1])
}
loc icer_ul=round(icer[(`N'*`a2')])

*******************************************************************************
*CE PROBABILITIES
*******************************************************************************

*Import data
use "`file_ce_sim'", clear

*ICER
gen icer=ic/ie

*N
count
loc N=r(N)

*CE probabilities
forval lambda=0(50)1500 {
```

```
        gen ceprob_`lambda'=icer<=`lambda' if icer>0
}

collapse (sum) ceprob*
gen id=_n
reshape long ceprob_, i(id) j(lambda_)
replace ceprob_=ceprob_/`N'

*******************************************************************************
```

```
*******************************************************************************

*About: This do-file includes a demonstration of the primary analysis for Chapter 6

*******************************************************************************

*******************************************************************************
*INTERVENTION-MEDIATOR AND MEDIATOR-OUTCOME MODELS
*******************************************************************************

*Import data
use "`input_iq'", clear

*Set variable locals
glob outc test3mths
glob med1 stigma_com_sd // Linear mediator-outcome relationship
glob med2 cm_cohesion_sd cm_sharcon_sd cm_critcon_sd // Non-linear mediator-outcome
relationship
glob cluster gvhid
glob arm arm
glob adj_ql male agegroup literate muslim ethnic srhealth
glob adj_qt capital_score

* * *

*Generate list of covariates for regression
loc adj_list=""
foreach var of varlist $adj_ql {
	loc adj_list="`adj_list' i.`var'"
}
loc adj_list="`adj_list' $adj_qt"

*Set loop for each set of mediators
forval i=1/2 {

	*Set loop for each mediator
	foreach mvar of varlist ${med`i'} {

		*Intervention-mediator

		*Compute adjusted mean difference
		xtreg `mvar' ib2.$arm `adj_list', mle i($cluster)
		mat est=r(table)
		loc b=round(est[1,1], .01)
		loc ll=round(est[5,1], .01)
		loc ul=round(est[6,1], .01)
		loc p=round(est[4,1], .001)

		*If linear mediator-outcome relationship
		if `i'==1 {

			*Set loop for each arm
			forval j=1/2 {

				*Compute adjusted risk ratio
				xtpoisson $outc `mvar' `adj_list' if $arm==`j', irr
				vce(robust) re i($cluster)
				mat est=r(table)
				loc b=round(est[1,1], .01)
				loc ll=round(est[5,1], .01)
				loc ul=round(est[6,1], .01)
				loc p=round(est[4,1], .001)
			}

			*Compute p-value for interaction
			xtpoisson $outc ib2.$arm `mvar' ib2.$arm#c.`mvar' `adj_list',
			vce(robust) re i($cluster)
			mat est=r(table)
			loc p=round(est[4,4], .001)
		}

		*If non-linear mediator-outcome relationship
		if `i'==2 {

			*Set loop for each arm
			forval j=1/2 {
```

```
                                *Compute adjusted risk ratio
                                xtpoisson $outc `mvar' `mvar'2 `adj_list' if $arm==`j', irr
                                vce(robust) re i($cluster)
                                mat est=r(table)
                                loc b=round(est[1,1], .01)
                                loc ll=round(est[5,1], .01)
                                loc ul=round(est[6,1], .01)
                                loc p=round(est[4,1], .001)

                                *Compute adjusted risk ratio-quadratic term
                                loc b=round(est[1,2], .01)
                                loc ll=round(est[5,2], .01)
                                loc ul=round(est[6,2], .01)
                                loc p=round(est[4,2], .001)

                        }

                        *Compute p-value for interaction
                        xtpoisson $outc ib2.$arm `mvar' ib2.$arm#c.`mvar' `mvar'2
                        ib2.$arm#c.`mvar'2 `adj_list', vce(robust) re i($cluster)
                        testparm 1.$arm#c.`mvar' 1.$arm#c.`mvar'2
                        loc p=round(r(p), .001)
                }
        }
}

*******************************************************************************
*DIRECT AND INDIRECT EFFECTS
*******************************************************************************

*Import data
use "`input_iq'", clear

*Set variable locals
glob outc test3mths
glob med1 stigma_com_sd // Linear mediator-outcome relationship
glob med2 cm_cohesion_sd_log cm_sharcon_sd_log cm_critcon_sd_log // Non-linear mediator-
outcome relationship
glob cluster gvhid
glob arm arm_bin
glob adj_ql male agegroup literate muslim ethnic srhealth
glob adj_qt capital_score

* * *

*Generate program

*Program mediation
cap program drop med
program define med, rclass

        *Generate list of covariates for regression
        loc adj_list=""
        foreach var of varlist $adj_ql {
                loc adj_list="`adj_list' i.`var'"
        }
        loc adj_list="`adj_list' $adj_qt"

        loc a0=0 // natural exposure level
        loc a1=1 // alternative exposure level
        loc m=0 // mediator level at which CDE is to be estimated

        *Generate values to calculate direct and indirect effects
        xtpoisson $outc i.$arm $mvar i.$arm#c.$mvar `adj_list', vce(robust) re i($cluster)
        loc theta1=_b[1.$arm] // theta 1
        loc theta2=_b[$mvar] // theta 2
        loc theta3=_b[1.$arm#c.$mvar] // theta 3

        xtreg $mvar i.$arm `adj_list', mle i($cluster)
        loc beta0=_b[_cons] // beta 0
        loc beta1=_b[1.$arm] // beta 1

        loc j=1
        loc beta2_C="" // beta 2
        foreach cvar of varlist $adj_ql {
                loc k=1
                loc beta2C_`cvar'=""
```

```
                levelsof `cvar', loc(level)
                foreach l in `level' {
                        tempvar `cvar'`l'
                        gen ``cvar'`l''=`cvar'==`l'
                        sum ``cvar'`l''
                        loc C_`cvar'`l'=r(mean)
                        if `k'==2 {
                                loc beta2_C_`cvar'=(_b[`l'.`cvar']*`C_`cvar'`l'')
                        }
                        if `k'>2 {
                                loc beta2_C_`cvar'=`beta2_C_`cvar''+(_b[`l'.`cvar']*
                                `C_`cvar'`l'')
                        }
                        loc k=`k'+1
                }
                if `j'==1 {
                        loc beta2_C=`beta2_C_`cvar''
                }
                if `j'>1 {
                        loc beta2_C=`beta2_C'+`beta2_C_`cvar''
                }
                loc j=`j'+1
        }
        foreach cvar of varlist $adj_qt {
                sum `cvar'
                loc C_`cvar'=r(mean)
                loc beta2_C=`beta2_C'+(_b[`cvar']*`C_`cvar'')
        }

        xtreg $mvar i.$arm `adj_list', mle i($cluster)
        tempvar yhat resid
        predict `yhat'
        gen `resid'=$mvar-`yhat'
        sum `resid'
        loc sigma2=r(Var) // sigma^2

        *Compute CDE
        return scalar cde=(`theta1'+`theta3'*`m')*(`a1'-`a0') // cde=exp{(θ1+θ3*m)(a1-a0)}

        *Compute NDE
        return scalar nde=(`theta1'+`theta3'*`beta0'+`theta3'*`beta1'*`a0'+`theta3'*
        (`beta2_C')+`theta3'*`theta2'*`sigma2')*(`a1'-`a0')+(.5*`theta3'^2*`sigma2')*
        (`a1'^2-`a0'^2) //
        nde=exp{(θ1+θ3*B0+θ3*B1*a0+θ3*B2*C+θ3*θ2*σ^2)(a1-a0)+(0.5*θ3^2*σ^2)(a1^2-a0^2)}

        *Compute NIE
        return scalar nie=(`theta2'*`beta1'+`theta3'*`beta1')*(`a1'-`a0') //
        nie=exp(θ2*B1+θ3*B1)(a1-a0)

        *Compute TE
        return scalar te=((`theta1'+`theta3'*`beta0'+`theta3'*`beta1'*`a0'+`theta3'*
        (`beta2_C')+`theta3'*`theta2'*`sigma2')*(`a1'-`a0')+(.5*`theta3'^2*`sigma2')*
        (`a1'^2-`a0'^2))+((`theta2'*`beta1'+`theta3'*`beta1')*(`a1'-`a0')) //
        te=nde*nie
end

*Set loop for each set of mediators
forval i=1/2 {

        *Set loop for each variable
        foreach mvar of varlist ${med`i'} {

                *Set variable locals
                glob mvar `mvar'
                glob i=`i'

                *Generate bootstrap replicates

                *Compute direct and indirect effects and confidence intervals
                set seed 10101
                bootstrap r(cde) r(nde) r(nie) r(te), cluster($cluster) reps(1000): med
                mat table=r(table)
                mat table_bs=e(ci_bc)

                loc j=1
                foreach name in cde nde nie te {
                        loc `name'_b=round(exp(table[1,`j']),.01)
```

```
                        loc `name'_ll=round(exp(table_bs[1,`j']),.01)
                        loc `name'_ul=round(exp(table_bs[2,`j']),.01)
                        loc j=`j'+1
                }
        }
}
```