A counseling intervention to address HIV stigma at entry into antenatal care in Tanzania (Maisha): Study protocol for a pilot randomized controlled trial

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Abstract

Background: HIV-related stigma significantly impacts HIV care engagement, including in prevention of mother-to-child transmission of HIV (PMTCT) programs. Maisha is a stigma-based counseling intervention delivered during the first antenatal care (ANC) visit, complementing routine HIV counselling and testing. The goal of Maisha is to promote readiness to initiate and sustain treatment among those who are HIV-positive, and to reduce HIV stigmatizing attitudes among those who test negative.

Methods : A pilot randomized control trial (RCT) will assess the feasibility and acceptability of delivering Maisha in a clinical setting, and the potential efficacy of the intervention on HIV care engagement outcomes (for HIV-positive participants) and HIV stigma constructs (for all participants). 1000 women and approximately 700 male partners will be recruited from two study clinics in the Moshi municipality of Tanzania. Participants will be enrolled at their first ANC visit, prior to HIV testing. It is estimated that 50 women (5%) will be identified as HIV-positive. Following consent and a baseline survey, participants will be randomly assigned to either the control (standard of care) or the Maisha intervention. The Maisha intervention includes a video and counseling session prior to HIV testing, and two additional counseling sessions if the participant tests positive for HIV or has an established HIV diagnosis. A sub-set of approximately 500 enrolled participants (all HIV-positive participants, and a random selection of HIV-negative participants who have elevated stigma attitude scores) will complete a follow-up assessment at 3 months. Measures will include health outcomes (care engagement, antiretroviral adherence, depression) and HIV stigma outcomes. Quality assurance data will be collected and the feasibility and acceptability of the intervention will be described. Statistical analysis will examine potential differences between conditions in health outcomes and stigma measures, stratified by HIV status.

Discussion : Antenatal care (ANC) provides a unique and important entry point to address HIV stigma. Interventions are needed to improve retention in PMTCT care and to improve community attitudes toward people living with HIV. Results of the Maisha pilot will be used to generate parameter estimates and potential ranges of values to estimate power for a full cluster-randomized trial in PMTCT settings, with extended follow-up and enhanced adherence measurement using a biomarker.

Background

Prevention of mother-to-child transmission (PMTCT) programming serves as an essential entry point for HIV testing and linkage to care, and has the potential to eliminate the incidence of vertical mother-to-child transmission. Under the Option B+ guidelines for PMTCT recommended by the World Health Organization, universal HIV testing in antenatal care is followed by initiation of lifelong antiretroviral therapy (ART) for pregnant and breastfeeding women living with HIV (1). Despite the global roll-out of Option B+ programs, retention in HIV care during the pregnancy and post-partum periods has been sub-optimal (2,3).

HIV-related stigma—whether anticipated, internalized or enacted—has a profound impact on decisions related to HIV (4,5) and is a primary factor influencing linkage and retention in PMTCT programs (6–8). In addition, stigma undermines the quality of life of people living with HIV (PLWH), contributing to emotional distress and social alienation (5). Among HIV-negative individuals, misinformation and prejudicial attitudes about HIV can fuel stigma and contribute to discrimination against PLWH, and can lead individuals to avoid or delay HIV testing (9). Social environments where enacted stigma occurs, or where stigma is strongly anticipated, contribute to internalized feelings of shame among PLWH and undermine the success of PMTCT programs (10,11).

Entry into antenatal care (ANC) provides a unique opportunity to reach pregnant women and their male partners to reduce community-level HIV stigma and to improve linkage to and retention in HIV care for individuals living with HIV. Addressing HIV stigma at the first ANC visit can help women who test positive to overcome stigma-related barriers to the initiation and maintenance of HIV care, and can help women who know their status to cope with HIV-related stigma during pregnancy and the transition to PMTCT services. Additionally, partner HIV testing during ANC provides a unique opportunity to reach men, in order to address HIV stigmatizing attitudes and improve men's linkage to HIV care. Long-term HIV care engagement for both women and men has important implications for health outcomes, quality of life, and the risk of future transmission to their child or others.

The goal of this study is to conduct a pilot evaluation of a brief, scalable counseling intervention called *Maisha,* which addresses HIV stigma at entry into ANC. The study will be conducted in Moshi, Tanzania. The intervention includes up to 3 sessions (one session prior to HIV testing, and two additional sessions for those who test positive for HIV). Male partners will be invited to attend *Maisha* 1 and *Maisha* 2; *Maisha* 3 is for women only. The intervention content is based on principles of cognitive-behavioral therapy (addressing automatic negative thoughts about the self, future, and the world/others) to address and mitigate multiple forms of HIV stigma (internalized, anticipated, and enacted). The intervention approach is novel because it addresses HIV stigma at a key, early juncture of care time point, and, among those who are HIV-negative, it promotes acceptance and empathy towards PLWH during the heightened emotional period of HIV testing.

Methods

Study design

The studyis a pilot randomized control trial aimed at determining the feasibility, acceptability, and potential efficacy of an HIV stigma counseling intervention for individuals entering antenatal care. The study has two parallel groups: control and intervention. The control group will receive standard of care from the clinical sites; the intervention group will receive standard of care paired with up to three *Maisha* counseling sessions. The allocation ratio for these parallel groups is 1:1. Table 1 summarizes key elements of the study, and Figure 1 illustrates participant flow through the study.

Ethical approval and registration

The study has been approved by the ethical review committees at Duke University, Kilimanjaro Christian Medical Center, and the National Institute for Medical Research in Tanzania. It is registered at ClinicalTrials.gov (NCT03600142).

Study setting

The study will be conducted in two government health facilities in Moshi municipality, Tanzania. The Majengo and Pasua Health Centers together see approximately 2,500 pregnant women per year; an estimated 4.8% of pregnant women seen at the clinics are living with HIV. All patients are required to have an HIV test at entry to ANC, unless they present a clinic card confirming that they have previously tested positive for HIV. Pregnant patients are strongly encouraged to bring their male partner to the first ANC visit for pregnancy education as well as partner HIV testing.

Participants

The study will enroll 1000 women into the study. Women will be enrolled at entry into ANC, prior to receiving a routine HIV text; of the 1000 female participants, we expect that approximately 50 will be established or newly diagnosed as HIV-positive. Based on record review at the study clinics, we estimate that 70% of female participants will attend the ANC visit with their male partner, allowing for an enrollment of up to 700 men. The sample size was selected in order to have adequate power to detect differences in our outcome of HIV stigma attitudes for our HIV-negative clients, and to have pilot feasibility data related to outcomes for HIV-positive clients (12,13).

Participants will be enrolled prior to attending their ANC appointment, which is where routine HIV testing occurs. Following written consent to participate in the study, participants will complete the baseline survey and be randomized to a condition. Following the survey and *Maisha 1 (*if randomized to intervention arm), they will return to the clinic for standard of care services, including HIV testing.

Participants will be eligible for the study if they meet the following criteria:

- Minimum 18 years of age
- Women: Pregnant and attending first ANC appointment for current pregnancy
- Men: Accompanying a partner to her first ANC appointment (Note: the partner must be enrolled for the man to be eligible to participate)
- Able to understand and speak Kiswahili
- Able to provide consent

Procedures

Screening and recruitment

First ANC attendees and their partners will be identified in the clinic waiting room by the clinic nurses. The nurses, in cooperation with research staff, will provide a brief description of the research activities, including the time commitment. Individuals who are interested in learning more will meet with the research team in a private research office, either alone or with their partner. The research staff will confirm the individual(s) meet the eligibility requirements, will clearly explain the study, and will obtain written informed consent. Contact information will be gathered from participants in order to facilitate the scheduling of follow-up assessments; this information will be securely stored in a locked file cabinet, separate from other participant information and data, and accessed by authorized study staff only.

Baseline data collection

After providing consent, all participants will complete a structured survey using audio computer-assisted self-interview (ACASI) technology on tablets running Questionnaire Development System (QDS) software. ACASI modality can ensure participant privacy and improve data validity by minimizing social desirability bias (14). Participants will complete the assessment on individual tablets where they can read (on the screen) and listen (through recorded audio) to the questions and response options in Kiswahili. As response options are read aloud, the corresponding text will light up on the screen. Participants can select their response using the tablet touch screen. The computerized assessments are programmed to skip questions that are not applicable based on previous question responses. Validity check items (e.g., “For this question, choose *strongly agree”)*) are included throughout to assess for data quality and participant attentiveness. A research staff member will be present in the room to answer any questions and provide assistance as needed. The data files will be securely transferred each day to the local data manager, who will store the files in a centralized location on a secured drive and review the files on a weekly basis for any quality issues. Stored data will be identified by a unique ID only, with access limited to authorized investigators and staff.

Allocation

Upon completion of the baseline assessment, the participant will be randomized to receive either the standard of care HIV testing and counseling, or the standard of care plus the *Maisha* intervention. Female participants will be randomized at a 1:1 ratio using a block randomization method (10 per block) to ensure equal sample sizes by condition and to manage the flow of participants to the intervention condition. The allocation sequences will be prepared ahead of time by a statistician using an online randomization program (www.sealedenvelope.com). Sequences will be generated separately for each of the two study clinics. Study staff who are not involved in participant enrollment, assignment, assessment, or delivery of the intervention will prepare sealed, opaque envelopes for each study ID containing the randomized condition assignment. After a female participant completes the baseline assessment, she

will open the envelope marked with her corresponding study ID and will learn her assignment; male participants will be assigned to the same condition as their partners. Participants will not be blinded to their allocation, as all participants will be aware of the additional time and activity commitments required as part of participation in the intervention condition. The research staff who give the participants their assignment envelopes will not know the randomization sequence until the conditions are assigned. Health care personnel at the study clinics will not be informed of participants' study conditions, in order to prevent interference in standard of care delivery.

Experimental conditions

Control: Standard of care HIV testing and counseling

Participants randomized to the control condition will receive the standard HIV testing and counseling protocol in the clinic, which is administered by clinic nurses. The standard of care was chosen as the comparator in order to evaluate whether the *Maisha* intervention has an impact above-and-beyond the standard clinic procedures for HIV counseling and testing. According to the Tanzania PMTCT guidelines, HIV pre-test counseling should provide education about HIV and prepare a woman (and her partner, if present) for HIV testing (15). For anyone who tests positive for HIV, counseling should help the woman/couple to accept an HIV test result and discuss implications for treatment. HIV-infected women should be registered for PMTCT and immediately initiated on ARVs. HIV-infected men should be referred to the HIV care and treatment clinic (CTC) for same-day initiation of ARVs.

Intervention: Standard of care + Maisha

Participants randomized to the intervention condition will attend the standard of care HIV testing and counseling and will also receive the *Maisha* intervention. *Maisha* is a brief, scalable, theory-based counseling intervention that addresses HIV stigma at entry into antenatal care and includes up to three counseling sessions. The intervention model combines a stigma framework with principles of cognitive-behavioral therapy to address and mitigate the impact of stigma on health outcomes.In Earnshaw and Chaudoir's HIV Stigma Framework, internalized, anticipated, and enacted stigma all intersect to undermine health-seeking behaviors (4,16). In developing the intervention framework, we observed that these components of stigma track onto the CBT 'cognitive triad' of negative beliefs about oneself, the future, and others/the world (17). Thus, the *Maisha* intervention addresses these three forms of stigma using principles of cognitive-behavioral therapy and formative work by Tshabalala and Visser (16,18).

Upon entry to ANC (for most, prior to learning their HIV status), we will deliver information, present the lived experiences of PLWH using a video, and promote self-reflection about community attitudes related to HIV. Participants will examine how community perceptions influence their beliefs about PLWH, including prejudicial beliefs that contribute to self-stigma in the event of a positive test. In sessions two and three, with participants who are HIV-positive (either presenting to ANC knowing their status or getting

a new diagnosis of HIV), we will review the video content and provide additional structured counseling to address the difficult emotions and cognitions often associated with a positive status. Through linkage to the video, we will use Beck's interventions for cognitive bias (19,20) as well as Third Wave behavioral concepts (21,22) to address one's automatic negative thoughts about the self (internalized HIV stigma), the future (anticipated HIV stigma) and the world (enacted stigma). Intervention techniques include recognizing and reframing cognitive distortions, helping individuals to develop a positive self-schema, and promoting personal acceptance and value-driven behavior to reduce stigma and encourage positive HIV care engagement (Figure 2). Table 2 provides an overview of the *Maisha* intervention.

The development of the *Maisha* intervention was informed by our team's previous research (2,3,23), qualitative interviews with patients and healthcare providers, and input from a study advisory board. In order to develop the video content, we engaged the local community advisory group, comprised of individuals who were living with or affected by HIV. These "expert patients" helped us to develop the video, which tells a story of a pregnant woman and her husband who both test positive for HIV and take steps to cope with the diagnosis. The actors for the video were selected from the community advisory group, and participated in the iterative refinement of the script during filming. Following the production of the video and the development of the intervention scripts, we conducted a trial run of the intervention with eight participants recruited from the ANC. Their input was elicited, which contributed to further modifications in the final intervention.

The *Maisha* intervention will be delivered by Bachelor's-level counselors who have social work or counseling backgrounds. Counselors will receive a minimum of two weeks of training on counseling techniques and the intervention content, and thereafter will receive at least one hour per week of clinical supervision, with opportunity for additional supervision as needed. The counseling sessions will take place in a private research office at the clinic site.

Intervention fidelity

The intervention counselor will complete a quality assurance (QA) and process rating form after each session. This form records issues raised in the session, coverage of session content, and feasibility of delivery. All intervention sessions will be recorded (with participant consent), and each week one session from each counselor will be reviewed during a group supervision session. Using a structured form (24), the counselors and supervising staff will assess the recorded sessions for intervention fidelity and presence of core components of counseling. During the group supervision session, the team will review the recording to discuss challenges and provide additional feedback and training.

Scheduling

For participants who are assigned to receive *Maisha* 2 and 3, the counselor will aim to deliver the *Maisha* 2 session on the same day as enrollment and *Maisha* 1 (i.e., the day of the first ANC appointment). If this

is not possible (e.g., if the participant does not return after testing, or the participant does not have time to complete the session that day), the counselor will attempt to schedule the session for another day, ideally within 72 hours. The *Maisha* 3 session will be scheduled approximately two weeks after completing *Maisha* 2. In order to reduce the burden on participants and improve attendance, the counselor will try to schedule the *Maisha* 3 session on the same day as the participant's next clinic appointment. The counselor will call participants to remind them of upcoming sessions. If a participant misses a scheduled session, the counselor will call to follow up and reschedule if possible. Participants may choose to stop attending *Maisha* sessions or withdraw from the study at any time.

Follow-up assessment

A subset of participants (approximately 300 women and 200 men) will be selected to complete a follow-up assessment 3 months after completing the baseline assessment. All HIV-positive participants and their partners (if enrolled) will be contacted for follow-up. A subset of HIV-negative participants will also be eligible for follow-up. In order to observe changes in stigmatizing attitude scores among HIV-uninfected participants, individuals with stigmatizing attitude scores in the top two quartiles will be eligible for follow-up assessment; of those who meet criteria, a random 60% will be invited for follow-up.

Participants selected for follow-up will complete a structured post assessment, following the same procedures for ACASI-based data collection used for the baseline assessment. At the end of the assessment, all *Maisha* intervention participants will also respond to a short series of open-ended feedback questions about the intervention; this section of the assessment will be orally administered and audio recorded to fully capture participant responses. Responses to the open-ended questions will be directly translated into English from the audio, and entered into a REDCap database. For all HIV-positive study participants, data on HIV care engagement will be abstracted from their medical records and entered into REDCap using double data entry, allowing for data quality checks and secure data storage and transfer.

Participant tracking and retention

Research staff will conduct a daily review of the clinic ANC logs to record the number of potentially eligible participants who were not enrolled in the study. For enrolled participants, the HIV test results and estimated date of delivery will be recorded on the day of enrollment. The research staff will maintain tracking logs to record the dates when assessments and *Maisha* sessions are scheduled and completed. In preparation for the scheduled sessions, research staff will contact participants to remind them of upcoming appointments in order to ensure retention. If participants are unreachable or did not provide a contact number, research staff will consult the participant's medical record for upcoming appointments and try to speak to them in person to schedule a follow-up visit. All participants will receive a transport allowance (5,000 TSh = approx. 2 USD) to facilitate their return to the clinic. For participants who fail to

return for a scheduled follow-up appointment, the reasons will be documented and collated across participants.

Outcomes

Measures were selected based on previous research in East Africa, including measure validation when available, and evaluation of face validity by the Tanzanian researchers on our team. All measures were translated from English into Swahili and then back-translated and discussed to reach consensus on best translation. Table 3 summarizes the outcome measures that were assessed at baseline and 3-month follow-up, specific to the participant's known HIV status.

Primary outcomes for HIV-positive participants

HIV care retention. Among female HIV-positive participants, retention in care at 3-month follow-up will be assessed via medical record review, with retention defined as having no more than a 60 day gap between PMTCT visits at the study clinic, or having record of an official transfer to another clinic (25).

Internalized HIV stigma. Among HIV-infected participants, internalized stigma will be self-reported, measured by Scale A of the HIV and Abuse Related Shame Inventory (HARSI) (26), plus one added item.

Primary outcomes for HIV-negative participants

Attitudes toward people living with HIV (PLWH). Among HIV-negative individuals, the primary outcome will be attitudes toward PLWH. Attitudes will be measured at both the baseline and post assessments by self-report, using a modified version of Personal and Attributed Stigma Scale (PASS), which includes two sub-scales: blame/judgement and interpersonal distancing (27,28). The scale was adapted to the local context based on formative qualitative data collection and revised after a pilot of the measure with 88 individuals.

Secondary outcomes for HIV-positive participants

ART adherence. Adherence to antiretroviral therapy at the 3 month follow-up will be measured by self-reported medication adherence; missing two or more pills in the past 30 days (<94% adherence) will be considered poor adherence.

Depression. Depression will be measured by the Edinburgh Postnatal Depression Scale (EPDS) (29) for women and the Patient Health Questionnaire (PHQ–9) for male partners (30).

HIV disclosure. HIV disclosure will be measured by self-report of whether or not participants have ever disclosed their HIV status to a person outside of the heath care workers directly involved in their antenatal

and PMTCT care.

Anticipated HIV stigma. For HIV-positive participants, anticipated HIV stigma will be measured using an adapted scale (31), which includes 16 items assessing the degree to which PLWH expect that they would experience prejudice and discrimination from others if their status were known.

Linkage to care. Among HIV-positive male partners, linkage to care at a Care and Treatment Clinic (CTC) will be self-reported at the 3 month follow-up, with linkage to care defined as having attended any CTC appointment.

Secondary outcomes for HIV-negative participants

Willingness to test for HIV in the future. Willingness to test for HIV in the future will be measured by self-report of whether or not participants intend to test for HIV in the next 12 months.

Anticipated HIV stigma. For HIV-negative participants, anticipated HIV stigma will be measured using an adapted scale (31), which includes 16 items assessing the degree to which participants would expect to experience prejudice and discrimination if they were to become HIV-positive.

Quality assurance (QA) data

Participant satisfaction with the intervention will be assessed at 3 month follow-up via structured and open-ended questions about satisfaction with the intervention and facilitator, satisfaction with the timing and length of the sessions, ability of the intervention to address issues specific to participant's experience and context, and suggested changes to the intervention. Intervention sessions will be recorded and a subset of recordings will be reviewed to assess whether core components of the sessions were completed, and to evaluate the effectiveness of the counselor in achieving session objectives.

Statistical analysis

Feasibility, acceptability, and potential efficacy of the intervention

Data analysis will follow guidelines of the CONSORT 2010 statement, as extended to pilot feasibility trials (32). Feasibility and acceptability of the intervention and the associated trial will be described by: recruitment and retention patterns, participant satisfaction and fidelity of intervention delivery. Retention will be monitored to calculate the percentage of eligible intervention participants who attend the *Maisha* 2 and 3 sessions and participants who complete the 3-month assessment. The team will document barriers to attendance for participants and will examine differences between participants who attend and those

who do not. Participant satisfaction data at the 3-month follow-up will be described, with >80% satisfaction used as a metric of acceptability. Open-ended questions will be thematically coded to summarize participants' perceptions of the intervention, suggestions for changes, and feasibility moving forward. The fidelity to the intervention will be assessed by examining the percentage of components from the *Maisha* session guides that are covered in each session.

Potential efficacy will be examined by analyzing separate outcomes for HIV-positive and HIV-negative individuals. For HIV-positive individuals, we are interested in differences between conditions in health outcomes (retention in PMTCT and medication adherence for women, linkage to CTC for men, depression) and stigma constructs (anticipated stigma, internalized stigma, and HIV disclosure). For HIV-negative individuals, we are interested in differences between conditions in stigma constructs (attitudes to PLWH and anticipated stigma), as well as willingness to test for HIV in the future. Additional analyses will examine changes in stigma attitudes by sub-scales (i.e., moral judgment and social distancing) and will examine stratified analysis by gender.

For outcomes where there is a baseline measure, mixed-effects regressions will be used to model pre-post differences within and between arms, using a time by condition model specification (time, condition, and time*condition). Individual-level random intercepts will be used to account for correlation due to repeated measurement. Using a mixed-effects regression approach leaves flexibility to control for baseline outcome values that may not be balanced between groups due to small sample size, and may improve precision of treatment effect estimation. For outcomes where there is no baseline measure, we will examine differences in means or proportions with 95% confidence intervals. If we suspect, a priori, that baseline imbalance in prognostic covariates may be an issue, we will move into a regression framework. Given ACASI data collection methods, we expect low amounts of missing data. In cases of missing data, multiple imputation methods will be used.

Monitoring

Given the low-risk nature of the counseling intervention, we do not anticipate any adverse events as a result of intervention exposure. If adverse events are spontaneously reported, we will discuss as a team and report to the ethical review committee, as appropriate.

The depression measure that is included in the survey includes a question that assesses for suicidal ideation (29,30). If the suicidal ideation question is endorsed, a coded message will be displayed to the research staff at the end of the assessment. The counselor will also make note if a participant says something during a *Maisha* session that indicates they are experiencing suicidal ideation. In either of these cases where ideation is indicated, the staff will follow a protocol to assess the risk, identify sources of support, make a plan for the participant's safety, and make referrals to clinic personnel as needed. Research staff have been trained on procedures related to emotional distress and the assessment of personal safety and risk and will report any adverse events to the study coordinator and the local Principal Investigator for further follow-up.

Dissemination

A study advisory board has been established to provide ongoing stakeholder input on the study and share emerging data and findings. The board will be convened for three half-day workshops during the study: initially, for input on intervention content; mid-way, for feedback on the curriculum and preliminary findings; and at the conclusion, for interpretation/dissemination of results. Advisory board members will be sent a quarterly newsletter with updates on the study progress.

At the conclusion of the study, we will conduct a feedback forum with a larger audience of stakeholders from a variety of institutions, including clinic staff and patients, regional representatives of the Ministry of Health, HIV advocacy and service organizations, and women's health organizations. During the forum, the team will share the findings of the study and facilitate a discussion about the implications of the data for future research and practice. Results will also be published in peer-reviewed journals and presented at appropriate scientific meetings, including regional, national, and international meetings. Authorship eligibility guidelines will follow the authorship guidelines of the International Committee for Medical Journal Editors (www.icmje.org).

All study investigators, along with the data management team, will have access to the final trial dataset. Researchers from outside the team can request access; data can be shared with a data transfer agreement from the respective Institutional Review Boards and within the constraints required for the protection of confidentiality for study subjects.

Study organization

As the principal investigators of the Maisha intervention, Drs. Melissa Watt and Blandina Mmbaga are charged with co-leading the study. They will ensure the completion and integrity of the study by managing and monitoring study activities and the reporting of study findings. They will facilitate collaboration between Duke University and KCMC by initiating and maintaining communication between these two institutions and the study staff at both locations. Drs. Watt and Mmbaga will monitor the ethical overall conduct of research activities, and be responsible for overseeing compliance of financial expenditures in accordance with sponsoring agency regulations.

The faculty investigators in the study, Drs. James Ngocho and Jenny Renju, will bring expertise on PMTCT care delivery and mental health to the Maisha intervention. They will support the scientific oversight of the study, meeting weekly with study staff and providing on-going supervision and support.

A minimum of one data collection staff member will be based at each of the clinical sites, and be responsible for recruiting participants and obtaining study data through surveys (using ACASI technology) and qualitative interviews. One counselor will be based at each clinical site, and will be responsible for delivering the Maisha sessions. The data management team, led by statistician Linda Minja at KCMC, will be responsible for storing, analyzing, and interpreting quantitative data. The team will

clean data and code measures at each time point in order to ensure that the data is valid and easily interpreted.

To elicit stakeholder input, we have established a study advisory board (see *Dissemination* section) that includes representatives from the Tanzanian Ministry of Health, leadership in the study clinics, community-based organizations, and members from the KCMC HIV Community Advisory Board.

Discussion

Despite the significant impact of stigma on HIV care engagement, few evidence-based interventions to address HIV stigma exist (33–35). The *Maisha* intervention is novel because it addresses HIV stigma during the first ANC appointment, which is a key, early juncture of HIV care for women who test positive. Additionally, it takes advantage of universal HIV testing of women and their partners during the first ANC visit, and promotes acceptance and empathy towards PLWH during the heightened emotional period of HIV testing.

Although this study includes a large number of participants (n = 1700), it remains a pilot feasibility trial, because the estimated number of HIV-positive participants (n = 50 women) remains under-powered to evaluate the primary outcome of retention in PMTCT care. If the preliminary data demonstrates that the intervention is feasible and acceptable, with potential to impact our study outcomes, we will move forward with a full cluster-randomized trial of the intervention in an increased geographical area within the PMTCT setting. A future study will have a larger sample size to capture more HIV-positive women, include longer follow-up through the postpartum period, and we will use biomarker outcomes to assess medication adherence and HIV progression.

The *Maisha* trial was designed withconsideration for future scale-up and implementation in the Tanzanian setting. This includes efforts to use existing clinic resources, minimize additional costs, and avoid placing burden on thinly stretched clinic providers. In this pilot feasibility trial, we will examine the potential for integrating *Maisha* into routine clinical care as a way to address community-level HIV stigma and promote HIV care engagement. We will assess the feasibility of delivery by Bachelor-level counselors, and examine whether the video format of Session 1 will allow for efficient and standardized delivery of the session content. Future iterations of the intervention may seek to train existing clinic staff to deliver *Maisha* as an enhancement to the standard of care, and to deliver the video content in a group format within the clinic space. Should the *Maisha* prove feasible and acceptable in our feasibility trial, we will engage a broader group of stakeholders and policymakers to explore future scale-up.

Trial Status

This trial was registered at ClinicalTrials.gov on 25 July 2018 (NCT03600142). The first participant was enrolled on 8 April 2019. Participant recruitment and enrollment is ongoing and expected to be completed by March 2020, with final follow-up expected by June 2020.

Abbreviations

ACASI: audio computer-assisted self-interview

ANC: antenatal care

ART/ARV: antiretroviral [therapy]

CTC: care and treatment clinic

HIV: human immunodeficiency virus

PLWH: people living with HIV/AIDS

PMTCT: prevention of mother-to-child transmission

QA: quality assurance

QDS: Questionnaire Development System

Declarations

Ethics approval and consent to participate

All procedures performed in studies involving human participants are in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. (Duke University D0371, Kilimanjaro Christian Medical Centre 915, National Institute for Medical Research, Tanzania 2183). Informed consent is obtained from all individual participants included in the study. Model consent forms are available at clinicaltrials.gov (NCT 03600142).

Protocol version

The original protocol (Version 1) was approved by the ethical review committees in July 2018. The protocol was substantively amended (Version 2) in October 2018, in order to include male participants. The published protocol is current as of August 20, 2019. Protocol modifications will be submitted to the relevant ethical review committees and modified on clinicaltrials.gov.

Consent for publication

Not applicable.

Availability of data and material

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Trial sponsor

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Authors’ contributions

MHW and BTM conceptualized the study and secured funding from the NIH as Principal Investigators. ETK, GK, BAK, JSN and JR contributed to the design of the study and writing of the original protocol. LM contributed to the statistical analysis plan. HO, JJR and RM were involved in the early implementation of the study and adaptation of the protocol to the local context. All authors provided input on the manuscript and approved the final submission.

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Tables

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Figures

Figure 1. Study flow chart

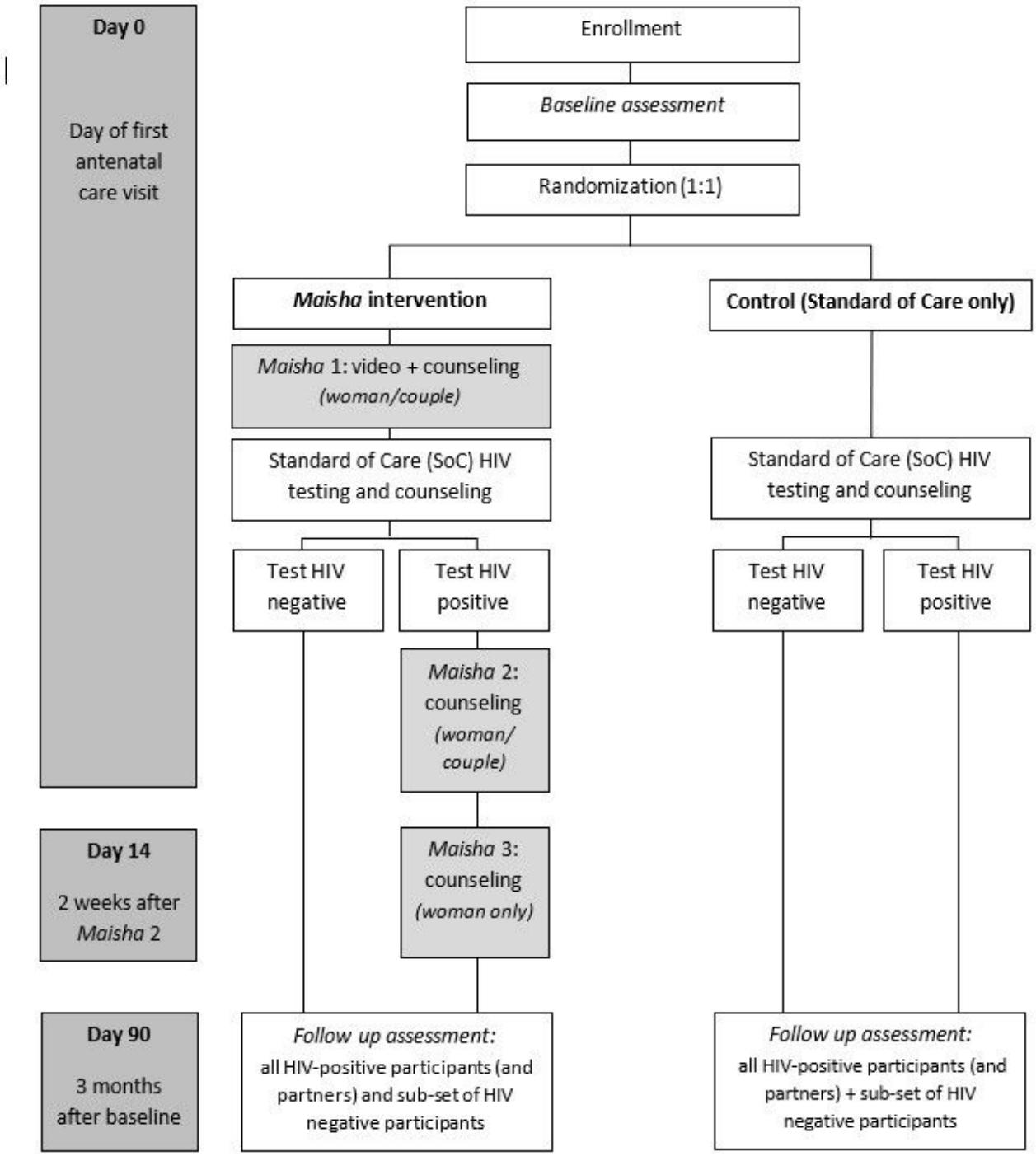

Figure 1

Flow Chart

Figure 2. Intervention Theoretical Framework

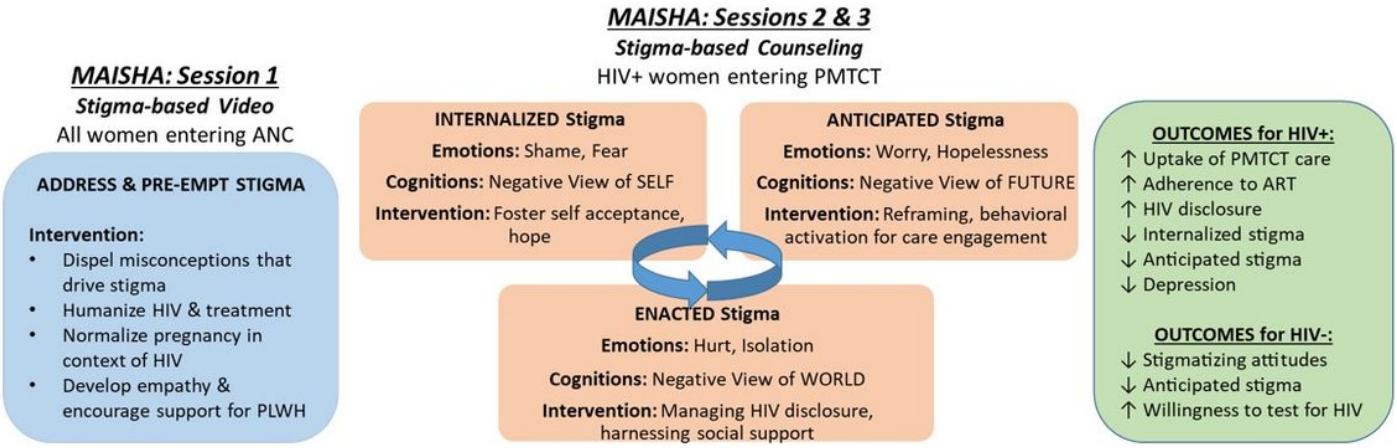

Figure 2

Intervention Theoretical Framework

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