Training for Health Professionals

Randomized Control Trial
Study Protocol
Grant number: R01HD092655

NCT03923582

Approved, July 1, 2021

Table of Contents

A. Timeline for Randomized Control Trial (RCT)

Timelines	Activity/Task
Jun 15	All recruitment materials finalized and signed off
Jun 15	Final copies of all advertising materials, surveys and study instruments to be submitted to IRB
Jul 1-Aug 1	Recruitment
Jun 28	Refresher training of SPs; Staff training for the assessment
Jul 7-Sep 26	Completion of baseline assessment (baseline survey and SP) for intervention and control conditions
Sept 27-Oct 1 and Oct 3- 6	Dates of the training (Intervention only)
Oct 4	Day to make up training in case of emergency (intervention only)
Nov	Revision and finalization of protocol for the final assessment.
Dec	3-month follow-up surveys for both intervention and control Follow-up SP evaluations. (Project Coordinator will add date in once MUHAS Almanac is published in September).
Sept 2022	Intervention is run for the control group participants

C. Study Participants

1. Inclusion criteria: A set of standards will be used to determine which students are eligible to participate in the September 2021 randomized controlled trial (RCT):

A health student studying at MUHAS (as verified by being registered in one of the following classes):

a. Year 2 and 3 nursing students (the final year but one or two where students have significant community and Clinical experience).
b. Year 2 and 3 midwifery students (the final year but one or two where students have significant community and clinical experience).
c. Year 3 and 4 medical students (the final year but one or two where students have significant community and clinical experience).
d. Able to speak English and Swahili. Because the education seminars are in English, but history talks are in Swahili. Therefore all students must be able to understand and converse in English and Swahili.

2. Exclusion criteria. Students who meet the eligibility requirements above will be excluded from enrolling and participating in the RCT if::

a. Students who will not be able to attend MUHAS on all days of the seminar
b. If they are not available during the follow-up assessment dates.
c. Students who express any reservations about attending (e.g., due to religious objections)
d. Students who show fear of violence due to attending (e.g., from a spouse or relative).
e. Students who are physically unwell during the RCT.
f. Students who have a body temperature greater than 37.5 C.

***Procedure**:* All enrollees are logged at enrollment with their name, student ID and contact details. If a student meets any of the exclusion criteria, their student ID and the reason why they were excluded will be logged.

3. Number of participants to be enrolled for the RCT. There will be 422 students enrolled for the September 2021 full trial: 412 of whom will be participants in the trial, plus 10 extra medical students to be waitlisted in case of absences.

a. 284 medical students (which includes 274 confirmed participants and 10 waitlisted enrollees). Of these, 137 will be randomized to the control arm and 137 to the intervention.
b. 103 nursing students. Of these, 52 will be randomized to the control arm and 51 to the intervention.
c. 35 midwifery students. Of these, 18 will be randomized to the control arm and 17 to the intervention.

Back-up plan: If there are insufficient students using these inclusion criteria, **Project Coordinator** may extend the invitation to be in the study to Year 3 midwifery, then Year 3 nursing, and then Year 4 medical students as well (on an "as space available" basis).

4. Process for recruiting student participants and how to increase student participation for the full trial.

The Project Coordinator in Dar es Salaam, TZ, will enroll 422 students (412 participants and 10 extra waitlisted enrollees) participants. WhatsApp, flyers, and advertising on notice boards methods, will be

used to recruit students **(see appendix F).** Recruitment will begin on **July 1** and continue until all participants and waitlisted enrollees are recruited.

Research Assistant is in charge of designing advertisements and posters. Deadline for signoff on all advertising is **June 25, 2021**. Advertisements and posters, once approved, need to be printed by **June 30, 2021.**

Researcher 1 will notify student leaders and ask them to post the adverts in the student WhatsApp chats.

Principal Investigator is responsible for liaising with the medical school to inform them about the study and to ensure institutional buy-in and support.

The leadership team will receive weekly email updates from **Project Coordinator** starting on July 10 and be available to problem solve any difficulties in recruitment.

5. Enrollment: To enroll in the study, interested students will be informed on the posters, recruitment materials and in class announcements to call the study phone number or to visit the study office. **Study staff** will have each interested student complete a form detailing the name, phone number, MUHAS student ID, whether the phone number can receive texts, email address, type of student (midwifery, nursing, medicine), year of study, and date of enrollment. The staff will confirm eligibility and exclusion criteria as detailed above. Each student's information will be entered into a database with prefered contact information. Either when the student enrolls, or when the study staff contact her to confirm enrollment, the study staff will give them a day (and approximate time) to come to MUHAS to complete the baseline study activities. They will also inform them to bring their phone or other device to complete an online survey when they come to their baseline appointment.

6. Recruitment timeline: Recruitment should be completed at least one week before the start of the trial (i.e. by Friday, September 17). **Project Coordinator** will confirm with all participants three days prior to the first day of baseline measures. Waitlisted persons will be asked to complete the baseline measures and SP, be paid for doing so, and to provide a cell phone number to be contacted in case of no shows on Day 1.

7. Confidential list of participants. This list will be kept in a locked file cabinet. Only **Project Coordinator and Principal Investigator** will have a key to the cabinet. **Project Coordinator** will also download a copy onto the external hard drive and store it in a different location.

All electronic information containing names and/or student ID numbers shall only be saved behind electronically protected password firewalls.

8. Attendance at the Seminar by Non-participants. For ethical reasons, in the grant we have said that students who do not want to participate in the research but do want to attend the training can do so on a space available basis. Given the COVID requirements for spacing, all such students will be informed they may attend the training in **September 2022**, but that only research participants and study faculty can attend in 2021. Similarly, this training is closed to other faculty. Only study staff, the trainers and the participants should be allowed inside the lecture theater.

9. Randomization of Participants to Study Arms

Objective: The purpose of the randomization is to assign students to the intervention or control group arms of the trial in a way that is fair and is seen by the participants to be fair. It is also done to prevent students from trying to change their assignment from one group to the other.

We will use a block randomization for each group (midwifery, nursing and medical students), batch (in groups of ten) randomization process. Once students have completed the baseline SP and survey, they will receive their assignment in an envelope.

For logistical reasons, the students are randomized after undertaking the baseline assessment. To prevent several threats to study validity, the students and staff should not be told a student's assignment to the intervention arm or the control arm until after they have completed the baseline assessment.

a. **Researcher 2 and Researcher 3** are in charge of the randomization.
b. **Researcher 3** will keep three envelopes titled "midwifery", "nursing", and "medical student" envelopes. Inside these envelopes at the start of each cycle are 10 pieces of paper, all the same size. Five pieces of paper will have the word "2021" on them and five will have "2022."
e**. Researcher 3** draws a piece of paper with 2021 on it, they will record the student who will be attending the training in 2021 (i.e., next week). If s/he draws a piece of paper with 2022 on it, they will be recording the student as eligible to attend the training in 2022.
f. Batch **Randomization:** Once a piece of paper is drawn, it is NOT returned to the envelope but instead put in the "used envelope" for reuse later. So, when the first medical student is to be randomized, **Researcher 3** draws from the medical students' envelope with 10 pieces of paper in it; for the second, they draw from the envelope which now has 9 pieces of paper in it, and so forth. When the envelope has no more pieces of paper left in it, the envelope is refilled so it has 5 2021 and 5 2022 pieces of paper.
g. **Researcher 3** hen records the randomization on a master list of students.
h. **Note:** Staff involved in the randomization should avoid using the terms "intervention" and "control" groups. Instead, we use the term, the training happening next week or the training for next year.
i. Students cannot trade their place in the training with another student. This is to avoid bias such as more committed students ending up in the intervention arm.
j. Note: Students who enroll as a "waitlist" student (i.e., the 7 students who enroll after the category is filled) complete the baseline assessment but are not required to be randomized. (This is because they will be assigned to the intervention if another student cannot make it).

D. Assigning study IDs for Students and SPs:

a. ***How do we make sure we are not mixing up the numbers/giving the wrong number to a different person during the trial?***
   i. Project staff will create a database for all participants.
   ii. Each participant will use their student ID (their ID provided by MUHAS) number for ALL documents in the study. They will write or type in on their consent form, the baseline survey, each SP form, the post-test, and the follow-up survey, and is verbally reported on at the start of each SP videotape.
   iii. For the electronic surveys, the programming will be set up so that the person cannot start the survey until the student ID is entered.

b. ***How do we make sure numbers are consistent for both baseline and follow-up during an intervention trial?***

   i. Project staff are responsible, when they collect forms, to check that the student ID is on each document and that it is readable.

ii. During data cleaning at each phase of the study, the data cleaning staff will check that the student ID number is consistent.

c. ***At the intervention****:* Project staff will verify students' ID and names at the door against a master list of those randomized to the intervention before the student can enter the seminar.

d. ***At post-intervention survey****.* Should pen and paper surveys be used, staff will check that there is a student ID when collecting the completed survey.

e. ***The study ID code***

i. Methodologist has asked for all student ID numbers to be numbers only not letters.
ii. The ID code for each participant is as follows:
   a. Student ID (provided by MUHAS) followed by a hyphen, then
   b. Profession, followed by a hyphen (with the following code), then
      i. Medical student – 01
      ii. Midwifery student – 02
      iii. Nurse – 03 (Numbers correspond to the alphabetical order)
   c. Study component number. These three digits indicate what component of the study this is:
      i. Baseline survey – 100
      ii. Immediate post-seminar evaluation – 200
      iii. Follow-up survey – 300

   Each SP is assigned a number from 01-12, and each study has a unique identification study number as follows:

      iv. SP Case study A – 401-412 (one for each SP) [Erectile Dysfunction ED]
      v. SP Case study B – 501-512 [Sexual violence-SV]
      vi. SP Case study C – 601-612 [Penile Drip –PD]
      vii. SP Case study D – 701-712 [Adolescent Pregnancy]

   So, Blessed is say, 09. When Blessed is acting for Case Study B. the number is 509. But if Blessed also works on Case study D, that would be 709.

   d. Treatment arm: [THIS INFORMATION IS DELIBERATELY NOT IN THE SOP SO THAT THE TEAM MEMBERS AT MUHAS EVALUATING THE SP VIDEOS REMAIN BLIND TO THE CODE. THE CODE IS TWO NUMBERS BETWEEN 20 AND 79 GENERATED BY METHODOLOGIST. SHE WILL SEND THESE NUMBERS TO PROJECT COORDINATOR WITH THE INSTRUCTION TO USE THEM WITH THE PARTICIPANTS AT BASELINE. AT FOLLOW-UP METHODOLOGIST WILL SEND ANOTHER SET OF NUMBERS, ALSO BETWEEN 20 AND 79 FOR USE ONLY AT FOLLOW-UP. METHODOLOGIST WILL RETAIN THE KEY TO INTERPRETING THESE DIFFERENT NUMBERS].
   e. Expert raters are assigned a number that mirrors the SPs, starting at 51-60
      i. Expert Rater Case study A – 451-460 (one for each rater)
      ii. Expert Rater Case study B – 551-560
      iii. Expert Rater Case study C – 651-660
      iv. Expert Rater Case study D – 751-760

So, **Researcher 2** is assigned a unique number, say, 55. When **Researcher 2** is evaluating Case Study B, she assigned each case 555. But if **Researcher 2** also evaluated Case Study C. she would use the number 655.

Examples:

So, the study number appearing on a survey may look like this:

671423 – 02 – 300 – 54
Student ID# – Midwifery student – follow-up survey – Intervention arm

451207 – 03 – 100 – 27
Student ID# – Nursing student – baseline survey – Control arm

671523 – 01 – 200 – 54
Student ID# – Med student – post-test survey – Intervention arm

So, the study number appearing on an SP rater form may look like this:

671523 – 01 – 401 – 54
Student ID# – Med student – Case Study A (John SP) – Intervention arm

671423 – 02 – 603 – 54
Student ID# – Midwifery student – Case Study C (Sara SP) – Intervention arm

451207 – 03 – 502 – 27
Student ID# – Nursing student – Case Study B (Mary SP) – Control arm

The number on the expert rating form will look like this

451207 – 03 – 502 – 27 – 553
Student ID# – Nurse – Case Study B (Mary SP) – Control arm – **Dr. X** rater

671423 – 02 – 402 – 54 – 455
Student ID# – Nurse – Case Study A (John SP) – Intervention arm – **Researcher 2** rater

671523 – 01 – 702 – 54 – 753
Student ID# – Nurse – Case Study D (John SP) – Intervention arm – **Dr. X** rater

E. Trial Preparations

Project Coordinator will oversee preparations for the full trial. Key tasks include:

a. Booking of rooms to run the baseline assessment, and the training.
b. Food arrangements for the participants. Because this is during the vacation, Project Coordinator should check and confirm the arrangements to provide tea breaks and lunch to at least 204 participants plus staff on the specific days of the training.
c. Recruitment materials
d. Preparation of all baseline assessment materials including consent forms, backup pen, and paper baseline surveys, SP evaluation forms
e. Study materials (including computers, pens, paper, handouts)
f. Assignment of staff to ensure the baseline assessment is fully staffed.
g. Assignment of staff to ensure the training is fully staffed.
h. Payment (each participant will be paid in cash)
i. Protection of all study materials that have been completed including consent forms, backup pen, and paper baseline surveys, and SP evaluation forms.
j. Training for all staff prior to the assessment to ensure all staff is familiar with all protocols including:
    i.

ii. **Baseline assessment roles and responsibilities**

- Training roles and responsibilities
- Working with SPs and the simulations
- COVID precautions

F. Standardized Patient Training

1. Recruitment of Standardized Patients (SPs)

a. SPs were recruited from acting students at Local Arts College. Advertising for SP positions was placed on school notice boards. The advertisements briefly described the purpose of the project, what SPs will do, and the criteria actors need to meet to be eligible for the four cases. Participants applied and mentioned exactly what case they want to work on. Study investigators met with applicants in person and notified them of the training date. Nursing and midwifery alumni were also recruited and they were contacted directly by study investigators because their contact information was available since they participated in Aim 1 interviews.
b. Hire and sign a contract and a talent release form which includes permission for use of images/videos for teaching and research.
c. For the trial, a total of 12 SPs who participated in the pilot will participate in the trial.

2. Scheduling SP refresher training

a. Project Coordinator will schedule an in-person refresher training for the end of June 2021.
b. Email zoom link & all case materials to participants including room assignments and Zoom Roles **[Project Coordinator]**
c. Schedule 3 to 4 hours for each training
d. Include an agenda for the training. **Project Coordinator** will develop this agenda.

3. Important topics to introduce during refresher training:

a. Introducing Medical Simulation to new SPs
b. Role-playing/acting within parameters
c. SPs are in a supportive role
d. SPs role play and observe simultaneously
e. How SPs respond during the interview
f. Written Feedback Tool.

4. Delving into the cases:

a. Read through each case via share screen
b. Address any questions & make edits
c. Discuss SP's portrayal for each case – standardize
d. Discuss the SPs affect & make sure they're all standardized (have them physically portray it in unison – they can all see each other and make the necessary adjustments)
e. Read through Interpersonal Skills Checklist
f. Role Play (1 SP and "SP educator (s)" – have the SPs watching fill out the checklist (if applicable) during the role play and the SP role-playing fill it out afterward then give verbal feedback using the interpersonal skills checklist as a guide – if applicable) Repeat this with other SPs as necessary
g. Give Feedback and make amendments

5. Simulated Patient Exercise during the trial

Responsibilities for the various tasks required to successfully implement the simulated patient exercise for the THP full trial will be divided amongst staff who are on the ground at MUHAS. Responsibilities include scheduling SPs, making sure SPs are on time, set up rooms (simulation laboratory), maintaining the "control center", maintenance of technology, set up Zoom rooms, which are detailed below.

***a. Scheduling SPs*:** Finalized SP schedules will be sent to SPs via email and WhatsApp one week prior to the RCT by **Project Coordinator.**

Phone calls: Researcher 2/Project Coordinator will call SPs on the evening prior to the date when they need to be at MUHAS to ensure that the SPs will attend the trial.

b. Coordinating SPs: SPs must arrive at MUHAS one hour early.

i. **Researcher 2** is in charge of making sure all SPs are present in the room one hour early.
ii. **Researcher 2** will call any SPs who are late.
iii. **Researcher 2** is in charge of making sure all SPs have dressed appropriately for their role and have all the materials ready to successfully play their role.

c. Set up of rooms (simulation laboratory). This is the room where the simulated patients are located, and where students will be conducting the SP exercise for the full trial.

i. **Project Coordinator** is the primary investigator in charge of the physical setup of the simulation laboratory.
ii. All study staff will ensure that the dividers are set up, and tables and chairs are set up one day prior to the exercise. There should be no need to do any setup on the day of the trial.
iii. This will include setting up the screens/stations (6 stations), computers chairs, tables, extensions, cables, testing zoom link, and recording options.

e. ***Lab setting*:** There will be eight rooms to be used as labs. Per day we will conduct four groups for eight hours which should take about 4.5 days to assess 420 students. This will take place during their long-term vacation from Monday, September 27 through Friday, October 1. (Monday, October 4 is reserved as a catch-up day in case of power outages or if a student could not attend).

f. ***Calculation of number of SPs.***

We will need 3 SPs assigned for each case and four cases, so 12 SPs in total. Assuming each SP processes 2.5 students per hour, in a 4 hour day, an SP sees 10 students. With 12 stations and each student having two cases (at baseline), that is 20 x 6 = 120 students processed per day. 120 students x 4 days = 480 students which are greater than 420 students needed for the study.

Note: To avoid SP fatigue, no SP should see more than 15 students in a day.

G. Baseline Assessment

Critical tasks:

There are **6** critical tasks that need to be completed at the baseline assessment. These include:

a. Ensure only healthy students, staff and SPs enter the study area.
b. Consent the participants
c. Completion of the baseline SP evaluation
d. Completion of the baseline survey
e. Informing the student whether they are randomized to receive the intervention in 2021 or 2022.
f. Payment of the participants for completing the baseline assessment.

(For ease of staffing, tasks ***(e)*** and ***(f)*** are completed at one station.
A total of 422 participants (which is 412 participants plus 10 on the waitlist) will first complete an online Qualtrics survey and then will move through a 90-minute session that involves reading and signing a consent form, two SP simulations involving a simulated patient (SP) presenting with a sexual health problem (15 min. each), then completing an online Qualtrics survey post-test assessing demographics, sexual health knowledge, attitudes, and counseling skills (30 minutes). After this, the participant is randomized to the intervention or control condition, and then receives payment for completing the baseline assessment.

Staffing: Project Coordinator will appoint and supervise at least two staff members (see the study team staff overview) to**:**

a. oversee the consent process
b. supervise the SP
c. help participants complete the baseline survey
d. randomize the participant and assign the person to the intervention or control condition, and
e. provide the participant payment.

1. Ensure health

Only healthy students, staff, and SPs enter the study area.

As per the COVID protocol (see below), all students, staff, and SPs will have the temperature taken before they enter the study rooms and are required to wear masks while completing the baseline assessment.

Procedure*:* The staff member will welcome the student and tell them that before they can participate, they need to take their temperature. The staff member will log the following information: (1) The name of the student and student ID number, enter "OK" if the temperature is within normal range, or enter the temperature if it is elevated. If the temperature is elevated, the staff member will activate the COVID response protocol which is undertaken by a licensed health professional. Key elements include informing the person that they have a temperature, asking how they are feeling, and assessing whether the person needs immediate help. The person should remain separated from the other staff and students and is informed that they cannot participate that day. They will be recommended to either return home to rest or to go to a clinic/hospital for further assessment. Should the temperature be mild, the student is welcome to reschedule and have their temperature tested at the rescheduled meeting (e.g., the following day). Similarly, all staff members and SPs have their temperature taken before they start and are excused from working if they have a temperature.

2. Consent the Participants

The consent form will describe:

a. Study purpose; (e.g., to evaluate a new sexual health training curriculum for MUHAS students)
b. Tasks: The main tasks both have to be explicitly mentioned:
    i. Taking 2-3 online surveys, one at baseline, one possibly immediately at the end of the training, and one at 3-month follow-up.
    ii. Videoed simulated patient sexual history taking (to be assessed using Zoom recording of simulated intervention with standardized patients (SPs), at baseline and again in 3-months and to attend the seminar. This should include consent for video recording and the use of images for research and educational purposes.

c. Risks (the primary one being emotional discomfort), limits on confidentiality, and benefits (none). Note: compensation should not be listed as a benefit)
d. Practical details (e.g., detailed compensation) and what to do, and who to inform if they become ill during the study.
e. Consent to be contacted at some future time for possible follow-up (if possible with a way to contact them for such follow-ups such as a cell phone number and non-MUHAS email address).

3. Consent form development and procedures for administering form:

The study will use an updated consent form that has been approved by the University of Minnesota IRB, and if necessary MUHAS IRB for the purpose of this trial.

Procedure in administering consent form:

a. **Research Assistant** is in charge of updating the consent form and submitting it to the IRB by June 30.
b. **Researcher 1** is in charge of distributing, monitoring students, and collecting the consent forms. She will:
c. Initially print 500 consent forms. This should be completed at least one day before the baseline assessment commences (i.e., by **Friday, September 24**). Each student should be offered a copy that they can take for their records and one copy that will remain for the study. (If more consent forms are needed they can be printed overnight).
d. Each consent form should have two labels: one with the student's full name and one with the student's ID number.
e. Place the forms in a folder clearly labeled "consent forms"
f. Once the student enters the room, she welcomes them, hands out the consent forms to the correct individual, and tells them if they have any questions to ask her.
g. She instructs the students to read the whole form, and sign and date the form. When the student returns the form, **Researcher 1** again asks if they have any questions, answers them, and then once the student has signed, she signs the form on behalf of the study team.
h. She offers the student if they would like a copy of the consent form.
i. She places the completed consent forms in a folder clearly labeled "complete consent forms. She instructs the student to go to the **Control Center.**

Once the student has signed the consent form, they are sent to the "control center" table.

4. SP Simulation Lab i.e., arrangement and setting

This is a table from which investigators will run the simulations. The table is located in the lab.

i. **Dr. X** is in charge of running the simulation lab.
ii. The "control center" will be a table and several chairs located in an easily accessible location in the simulation laboratory.
iii. All supplies and equipment will be stored/or placed in this area. All paperwork will be kept in the control center for easy access.
iv. At least 1 staff member will always be at the control center to answer questions that students or SPs may have and to troubleshoot any problems.
v. The control center will be maintained throughout the day and kept clean and organized.
vi. At the end of the day during the interventions and training, all materials used for the study will be stored for the full trial use.
vii. We have planned to have 12 simulations running concurrently in 4 rooms. Each room will have the 3 SPs with the same case. The student waits outside the room until called,

then enters the room and completes the case. When the student has completed the case they are directed to the next room to complete their second case. So, the first student completes Case A (in-room A) and then goes to Room B to complete case B. The second student goes to Room C to complete Case C and then Room D to complete Case D. The third student goes to Room A (to complete A&B), while the 4th student is sent to Room C (to complete Case C and then to Room D to complete Case D). In this way, half of the students end up completing Case A&B at baseline and half these cases at follow-up.

viii. Dr. Lucy Mgopa (or the person at the table) will log whether the student was assigned to cases AB or cases CD before sending them to the room. She supervises each student putting their ID number on each form.

SP and learner's arrangement: Each participant will complete two SP cases of about 15 minutes each, i.e., 30-40 minutes in total.

Case A: Woman who has been sexually assaulted (see **Rehema scenario**)(20 minutes)

Case B: Man with erectile dysfunction and homosexual history (20 minutes)

Case C: 16-year-old girl is worried about getting pregnant by her sugar daddy (case has been developed, see **Aliyah Scenario)** (20 minutes)

Case D: Young man with a drip (urethral discharge) and groin pain (case has been developed, see **Emmanuel scenario**) (20 minutes)

Participants (learners and SP) will spend 20 minutes at each station.

Breakdown of 20 minutes:

i. Five minutes will be spent in the introduction of the case at each station.
ii. 10 minutes will be used during the discussion/history taking
iii. Each participant (learner and SP) will be required to fill in a survey/checklist before moving to the next station which will take about 5 minutes.

Dr. X will be responsible for assigning learners to different stations. SP will not move/leave their station, they will remain in the original station. Between sessions, participants will be given snacks and bathroom breaks. **Dr. X** will keep time and address any concerns or questions as they may arise.

Setting up a simulation scenario: The following are the steps that SPs will take when setting up for a scenario: Sit on the appropriate chair

Turn on the computer

i. Open Zoom
ii. Wait for the student to arrive and sit down
iii. Press the "record" button ← **Very important**
iv. The student says aloud their student ID number and the case study (as A, B, C, or D).
v. Play role as SP
vi. Watch for the "1 minute left" warning sign
vii. Once 10 minutes are over, end the conversation with a student
viii. Press the "stop recording" button
ix. Fill in the SP evaluation for the student (including the student id and date of the evaluation)
x. Wait for the next student to arrive --
xi. Repeat process

At the end of the simulation, the student is informed to return to **Dr. X** and to provide her with their completed simulation forms. Each student should hand two forms to her. **Dr. X** checks the form and sends the student to the baseline survey station.

5. Baseline survey administration and its procedures

Objective: The purpose of the baseline survey is to collect information on the student's knowledge level and comfort level on the topic of sexual health. The surveys will be completed during the student's appointment for their baseline assessment.

Procedures for administering the survey

a. **Researcher 3** is in charge of overseeing the baseline survey completion.
b. Each participant is instructed to complete the online using their phone, laptop, or other online devices.
c. The survey will be completed online using a Qualtrics survey.
d. As a backup plan, 100 surveys will be printed on paper, to be distributed to any student who does not have access online and/or if the Internet goes down.
e. **Researcher 3** will ensure she has enough surveys, along with **pens and pencils.**
f. If more surveys are needed they can be printed while the first 100 are being used.
g. **Researcher 3** will inform each participant as she hands them the survey, to ask her if they have any questions.
h. For online surveys, once the student completes the survey the responses will be saved automatically in the Qualtrics database. **Project Coordinator** will monitor the database and make sure that all survey data has been recorded.
i. For paper surveys, **Researcher 3** is responsible for collecting them and handing them to Project Coordinator at the end of each day.
j. Stella Mushy will address any participant concerns. Should a student be in a hurry and asks if they can complete the online survey on their phone later, Stella Mushy may allow them to do so. But she will tell the participant they will not receive any payment or be randomized to the intervention or control until they complete the online survey.
k. Each student is informed to return to **Researcher 3** when they have completed the baseline survey. **Researcher 3** will check if they have completed the survey online, that they have reached the last page. For any participant who completes the pen and paper survey, **Researcher 3** will collect the form, while the student is in front of her, she will quickly check that no pages have been skipped and if the form is completed, thank the student.
l. She instructs the participant that they have completed the baseline survey and should go next to the randomization table.

6. Informing the students about their randomization to the seminar in 2021 or 2022.

a. Once the student has completed the baseline assessment, they return to the final table.
b. **Project Coordinator** will ask each participant whether s/he has signed their consent form, completed two SP scenarios and rated themselves on two SP forms, and completed the baseline survey.
c. For students who say yes to all questions, **Project Coordinator** then consults the master list to see if the student is assigned to attend the seminar in 2021 or 2022.
d. For students assigned to 2021, **Project Coordinator** hands the student the one-page flyer providing the student with all the information about the seminar including the dates, times, and location of the seminar, that the student is expected to attend all days, the need to wear a mask and other COVID precautions in place, that the student will be expected to attend all four days of the seminar, the amount per day and the total amount of compensation and that the student will only be compensated for each day they attend the seminar, that the student cannot trade their place in the seminar with another student, the cell phone to call in case of problems, and any

other information. This flyer will also ask students not to share information on the baseline assessment with other students, and not to share information or content from the training with students who are not at the training. For ethical reasons, this flyer will have a sentence noting that participation in the research study is voluntary and that the student can withdraw from the study at any time. However, students will be compensated only for the tasks they complete such as filling in the surveys and attending the seminar. **Project Coordinator** will then ask if s/he has any questions and answer them. And then he will ask the student to confirm their intention to attend the seminar.

e. For students assigned to 2022, he hands the student a different one-page flyer. This flyer thanks the student for completing the baseline assessment and informs them they will be asked to complete another assessment in 3-6 months' time. They are also informed we intend to run training in September 2022 for those who are interested. They are informed that they are not allowed to trade places with a student who is assigned to the training in 2021. This flyer will outline the nature of the randomized controlled trial which is evaluating the training and ask students not to share information on the baseline assessment with other students, or to ask students who attend the 2021 training, questions about the content covered in the training. For ethical reasons, this flyer will have a sentence noting that participation in the research study is voluntary and that the student can withdraw from the study at any time. However, students will be compensated only for the tasks they complete such as filling in the surveys.

f. **Note:** Staff involved in the randomization should avoid using the terms "intervention" and "control" groups. Instead, we use the term, the 2021 training happening next week or the 2022 training planned for next year.

7. Payment Procedures & Handling

All the THP funds are deposited into the MUHAS account and controlled by the MUHAS procurement officer. THP has a unique code that they will use to request funds from the MUHAS procurement officer.

a. During the trial, **Project Coordinator** reviews the students' schedule of payments and the amount they will receive for participating in the study and send a request to the procurement officer.
b. The procurement officer will procure the fund that is required for the task for the said period of time, e.g., a week.
c. **Project Accountant**, a person in charge of payments, under **Project Coordinator's** guidance, will request a daily amount based on the number of participants for each day.
d. Each morning, **Project Accountant** will collect student registration forms from Project Coordinator to the MUHAS procurement officer.
e. **Project Accountant** will procure the funds from the MUHAS procurement officer each day and maintain them in a locked cabinet/lockbox. On the day of the study, he will hand students or standardize patients (SPs) the payment for completing the baseline assessment or seminar. The student/SPs sign that they have received payment. Every other day the original signatures from students will be handed over to the MUHAS procurement officer for records. **Project Accountant** will maintain a copy of the payments on file in the THP study office. The procurement officer will not release the fund for the next day without receiving the signatures from the previous day.
f. **Seminar day:** We expect each student to be present in the seminars for 7 hours to be compensated. If a student attended less than 5 hours under any circumstances, he/she would not

be paid for that day. Project Coordinator and the team will evaluate each situation and make a decision about the students' absences.

H. Seminar Preparation and Procedure

1. Prior to the Seminar

a. ***3-month Seminar Planning Meeting*.** In June, **Project Coordinator** will hold a planning implementation meeting with all the trainers at the seminar. Using the proposed timetable (or schedule) from the Aim 2 subcommittee, the team will: (a) confirm the faculty member in charge of leading each section, including the faculty member in charge of each small group. (b) In case of illness, the meeting will also identify a backup faculty member to teach each segment. It is the responsibility of the backup member to be familiar with the material and ready to teach it if necessary. (c) The team will identify any difficulties they anticipate in running the training for 204 students, and brainstorm ways of solving these. Specifically, they will look at the time needed to feed people, answer questions, have breaks where 200 participants may need to use the restroom, and other logistical questions.
(d) The team will also address the additional monitoring tasks involved in the training. These include (i) someone to take the temperature of each staff and participant when they arrive each day, (ii) someone monitoring the door of lecture Theater 4 to ensure only participants attend, and during the seminar to monitor and document any participant who arrives late, needs to leave early, and/or has questions about the evaluation being conducted, (iii) someone to help any students who is uncomfortable or upset by the material or who become ill during the training; (iv) a process monitor to conduct the fidelity check each day, and (v) someone to answer questions about payments. (vi) To keep on time, the team may want to appoint a time-keeper who can monitor time and cue the presenter when they are close to time.

b. ***Documents and handouts.*** **Project Coordinator** is responsible to ensure that all the participant handouts are prepared well ahead of time. Given we are planning on 206 participants and 6 faculty, we will likely need 210-215 copies of any materials. **Project Coordinator** will create a list of all seminar materials needed. These may include:
   i. 215 Short handbook and 250 pens, sufficient for each student to write notes
   ii. 6 copies of the schedule (one for each leader and/or staff).
   iii. copies of any written quizzes
   iv. a question and answer box for any question's students may want to ask anonymously;
   v. cards so that students can place questions in the question box
   vi. 215 electronic reprints of the paper: Rosser et al. (2020) legal and Ethical Considerations in the Delivery of Sexual Health Care in Tanzania, African Journal of Health, Nursing and Midwifery, 3(7): 84-102. (This should be sent out to students the day before they are expected to discuss the cases in the ethics session).
   vii. Other materials as identified by the faculty.
   viii. Signs which seats are allocated to students to sit on and which to avoid
   ix. Room signs for the "boot camp" day where students divide into three groups.

x. Sign in and sign-out sheets for participants.
xi. Two copies of the fidelity check form.
xii. Signs for the timekeeper to hold out (e.g., 5min; 1min).
xiii. 215 flyers thanking the students for attending the seminar and providing them with a cell phone and email on how to contact the study in case of sickness or other problems.

c. ***Pre-meeting to Pilot Procedures for the Training and to Prepare the Room.*** 1-2 days before the training, the faculty should meet to finalize all tasks and to ensure all procedures are feasible. **Project Coordinator** should confirm when each person needs to be there, identify if any faculty may need to be absent for some reason and to assign who will monitor temperature, the door, be a referral for students, be the process monitor, and payments. At the meeting, the team should confirm when they will meet at the end of each day to debrief and to make any later minute changes to the following day. At this meeting **Project Coordinator** will determine who is responsible for preparing the room each day so it is ready when the first participant arrives.

d. ***Feedback***

i. **Project Coordinator** asks each participant if they have any other questions or any feedback about their experience in the baseline assessment.
ii. For students who provide feedback, **Project Coordinator** logs this information for discussion at the team meeting.
iii. Whenever problems are identified and are immediate and easily fixed, **Project Coordinator** is authorized to modify study procedures to improve the student experience.

2. During the Seminar

Objective: The primary objectives during the seminar are to ensure:

a. Participant and staff health and safety
b. The training is professional and complete
c. That participants have a good experience
d. That at the end of the seminar, two things happen:
i. the post-seminar evaluation of the seminar is conducted
ii. Those participants are compensated

a. ***Participant and staff health and safety***. This is covered in the COVID protocol (see below).

b. The training is professional and complete. **Project Coordinator** is responsible for monitoring the overall tone of the seminar, for making decisions when the seminar starts and ends each day, and whether the seminar should extend into Friday (in case power failure or other event affecting the students prevents them from receiving the full training.

c. ***That participants have a good experience***. All the team is responsible for ensuring that participants have a good experience. Based on other seminars, strategies each team member can do include:

i. During the seminar show interest in the presentation. Avoid talking with other leaders in the back of the class or otherwise distracting participants from the presentation.

ii. During breaks, ask participants how they are enjoying the seminar and express interest. Be available to answer questions that students may want to ask one-on-one.

iii. During the debrief, bring any observations or student feedback to the attention of the team.

iv. When presenting, keep to time, be prepared and know what is happening after your presentation so that transitions from one presenter to the next are seamless.

d. ***Two things happen at the end of the seminar.***

i. post-seminar survey: Immediately after the training, students remain in the room to complete online post-test surveys that measure the change in knowledge and attitudes, as well as a process evaluation of the training (30 minutes).

Back-up plan: Should there be internet connection issues on the last day of training, then three study staff will be responsible persons for distributing and collecting paper copies of the surveys, and ensuring that all questions are filled out correctly. This will not be the case for online Qualtrics surveys since the survey will be programmed in a way that will minimize incomplete responses and data entry errors.

ii. **That participants are compensated**
Students in the training will be notified when they will receive a token of appreciation for their participation in the study after they have finished participating in the trial. The study coordinator **and Project Accountant** will be responsible for compensating students and making sure all participants sign the attendance and payment sheet. Each student will be responsible for signing a log showing the total compensation for study financial records and accounting (auditing) purposes. **Project Accountant** will be preparing a payment protocol and is responsible for handling and documenting participant payments.

Compensation will be prorated according to the number of days the student participated in the trial - Students will not receive financial compensation for days where they have unexcused absences. Each participant is responsible for attending each day of the trial. **Project Coordinator** is responsible for determining whether an absence is excused.

Students will be compensated for travel expenses, accommodation, and food each day during the trial.
Compensating SP: Each SP will be paid a daily stipend of 52 USD per day, for completing the post-seminar evaluation.

3. Anticipated challenges and how to address them

1. ***If a student arrives late or leaves early, what happens?*** If a situation like this happens then the supervisor (**Project Coordinator**) will discuss with the students if she wishes to continue or not. The supervisor will weigh the reasons provided and the time frame then he will make decisions.
    a. **Project Coordinator** is the person responsible for deciding who can enter the study or not. We anticipate two types of non-attendance:
    b. **Group non-attendance.** If because of weather or some other event a significant portion of the participants cannot attend, then **Project Coordinator** shall decide whether to delay the start of the seminar and/or change the timetable to facilitate everyone's attendance.
    c. **Individual non-attendance**:

i. If an individual notifies the study that s/he cannot attend, then if it is on or before Day 1 of the seminar, Project Coordinator shall replace this participant with one of the waitlist participants.
ii. If an individual arrives within an hour of the seminar starting, study staff will record the time of arrival, the student's ID number, and any reason given for lateness, before admitting them. Similarly, if a participant needs to leave up to an hour early, study staff will record the time of departure, student's ID, and any reason given for the early departure.
iii. If an individual is more than an hour late or needs to leave more than an hour early, or requests being absent from the training for more than an hour, this shall be referred to **Project Coordinator.** They will decide whether to let the participant continue and whether the participant receives compensation for that day. (Note: We prefer students to continue receiving the training and, in the study, wherever possible).

d. **Individual withdrawal from the Study.** This study is voluntary, therefore if anyone chooses to withdraw from the study, study staff will allow them to do so. Anyone notifying the study that intends to not attend the rest of the training shall be referred to **Project Coordinator. Project Coordinator** will review the intent of the participant and any reason why they will not be continuing in the training. Depending on the reason (e.g., sickness, family emergency, the decision to withdraw), he will thank them for informing the study of this decision, inform them that they will be compensated for the days attended but not days not attended, and will record the reason given why the participant dropped out of the study. Finally, **Project Coordinator** will ask if the participant is dropping out of the training only, or is wishing to drop out of the study. (NOTE: If a participant drops out of the training, they are still considered a participant and we prefer them to complete the post-seminar evaluation and the follow-up even if they missed part of the training).

2. If a student misses a survey, what happens? If a student is missing the baseline survey and/or the SP evaluation, he/she will not be allowed to participate in the training. Instead, his/her place will be given to one of the students on the waitlist.

4. After the seminar

Two faculty (**Dr. X, Project Coordinator**) are identified resources for students following the seminar. At the end of the seminar, all participants are informed that if any student has follow-up questions, concerns or issues, they should contact either **Dr. X** or **Project Coordinator**. The role of **Project Coordinator** and **Dr. X** in this situation is to determine if this is a clinical issue or simply feedback on the seminar.

If it is a clinical concern, Project Coordinator* or *Dr. X shall:

a. Assess and advise any student who reports difficulty following the seminar. For example, a student might wish to discuss some personal experience (e.g., history of assault, sexual difficulty). In this case, the faculty shall provide brief supportive counseling, and where appropriate, help the student to develop a plan to get more help if needed.
b. For a student in difficulty, the faculty shall be a resource and will check in with the student.
c. While protecting the student's confidentiality, **Dr. X** and **Project Coordinator** should log the details of the presenting concern and any action recommended or taken. Without compromising the student's confidentiality, any such concerns should be reported to Simon within 10 days of the event.

d. As mandated reporters, should a student report themselves to be an immediate threat to themselves or others, the faculty member shall take whatever appropriate response, including if necessary breaking confidentiality, to preserve life.
e. **The Principal Investigator (UMN)** is responsible for reporting all such incidents to the IRBs of each institution if it is deemed an adverse event or an unanticipated or new finding. He is also responsible for informing the Principal Investigator at MUHAS, the senior leadership team, and if appropriate, the NIH.

If it is a not clinical concern, Project Coordinator, Dr. X, or any other team member shall:

a. Address the feedback from the student and provide any information as appropriate.
b. Email **Project Coordinator** that a student has followed up with them about the training. The email should provide a brief note, "e.g., a student stopped me to say they found the training really helpful," or "a student said they used the training in addressing a patient."
c. **Project Coordinator** is responsible for keeping a log of this feedback and for bringing them to the attention of the Principal Investigators and/or the senior leadership team, or the whole team, as appropriate.

5. Additional Resources

Prof. Z will create a list of educational materials/resources such as a website**,** scientific manuscripts, peer to peer learning as part of the seminar to get additional information. Provide references for all the information that they can look for online. This needs to be done by **mid-July**.

6. Study Quality control/intervention fidelity

Intervention fidelity will be monitored by two investigators (i.e., **Principal Investigator and Dr. X**) observing each seminar. In the time where **Dr. X** is delivering a lecture, **Researcher 2** will assist **Dr. X** to conduct a fidelity check. Monitors will note the start and end times of each session, monitor curriculum fidelity, note any unusual events, provide ongoing feedback to the two seminar leaders, and write up notes for a train-the-trainer manual.

I. Data Management and Storage

1. **Data entry for hard copies for participants who complete paper surveys.**
   The project Coordinator (**Project Coordinator**), will be responsible to identify vendors who will conduct data entry after data collection. Data entry will be done at MUHAS, and later unidentified electronic data will be shared with the rest of the team. All data will be stored in the cloud on BOX.
2. **Data storage (Baseline survey, SP and learners Checklists, and consent forms)**
   Researcher 2 and **3** will submit completed surveys each day to the project coordinator (**Project Coordinator**). **Project Coordinator** will be responsible for making sure that these surveys are locked and confidentiality is maintained. All pen and paper survey responses will be stored at the MUHAS (Dr. Mkoka's office) in the locked cabinet. All databases will be stored on MUHAS (Dr. Mkoka's office) servers behind password-protected files, and made available to researchers as a de-identified data set. A copy of all the data will also be stored on BOX per University of Minnesota policy. Personal comments to open-ended questions will be checked and, if necessary, redacted to preserve confidentiality. After data entry for both pilot and trial, the original survey will be returned to the locked cabinet at MUHAS and then stored until 3 years after the study ends.
3. **Storage of SP and Learner Zoom Records**

Project Coordinator will be responsible for storing data for all the recorded zoom videos for SP data. All electronic data will be stored in the secured drive protected by passwords in multiple places (in the external drive and in the computer) to avoid data loss.
At the end of each session, the IT person will make sure each session's recorded videos/clips are saved before inviting another learner into the station. **Project Coordinator** will identify the vendor who will do data entry and share the anonymous data to U of M staff for analysis.

4. **Video Data for RCT**
   A 3,296 video clips (412 participants x 4 videos x 2 admins) will each be assigned a unique code number matched to a master database. All videos are uploaded into the database and stored at two sites in Tanzania. Video data will also be saved to the BOX cloud at the end of each day.
   a. Project Coordinator is the data manager for the videos which will be saved in password-protected files. Since the videos contain identifying information (faces), he will allow access to the videos on an as necessary basis.
   b. **Rating: Drs. Y and X** will oversee the rating of videos.
   c. Videos are randomized so raters are blind to participant condition assignment (intervention or control) and blind to whether the assessment is pretest or posttest.
   d. No videos are reviewed by the expert raters until all the videos have been completed.
   e. On the rating form, the rater begins the review by writing out the Student ID, the three-digit Case-SP number (as reported on the video), and their assigned rater ID.
   f. Once the raters have rated all the videos their ratings are sent to **analyst. Study analyst** has the key to the blind and so can identify for each student, which are the two baseline videos and which are the two follow-up videos.
5. **Primary Dependent Variables.**
   The following are the primary dependent variables:
   a. Knowledge is assessed using the 12-item knowledge quiz that is tailored to assess knowledge items taught in the curriculum.
   b. Attitude change: is from the SHEPS attitude/comfort scale
   c. Clinical skills are assessed using the clinical/expert raters review of the SP videos. See https://link.springer.com/content/pdf/10.1023/A:1009878124073.pdf.

J. Ethical Considerations

Research Approval
The study has the IRBs approval for both the MUHAS and U of M. Final documents need to be submitted to the UMN IRB two months prior to the trial (July 27) (**See a copy of IRB in Appendix A)**.

1. Potential Risks to Participants.
To ensure participants have a good experience, as documented in the original grant application we identify the following potential risks in this section.

a. **It is possible some students may assume they should participate or feel obligated to participate**. **Project Coordinator,** and the consent form, will make it clear to students that their participation is voluntary and that there will be no penalty for the decision not to participate. Because the training has been scheduled during the students' vacation, we view this risk as unlikely.
b. Some students may feel embarrassed completing study tasks, participating in the curriculum, and/or admitting to sexual behavior. We view this risk as likely to be common, but mild.
c. By participating in sex education, some students may be negatively viewed by others. Given the diverse backgrounds of the student population, it is possible that some students may have

their morality questioned for receiving sexual health education. About half of our pilot group were women, including women from conservative religious, familial, and tribal backgrounds. This risk is highly dependent on the student sharing information on what s/he is studying with others. We assess this risk as hypothetical (we simply do not know if anyone would do this) but potentially serious.

d. **Students with sensitive personal histories may share that information in the seminar, and by doing so, may feel exposed**. It is possible that some students may feel the group to be a safe place to disclose personal information (such as experience of assault, HIV/STI status, or sexual minority identity) which may leave them feeling overexposed. We assess this risk as hypothetical, but potentially serious.

e. Loss of confidentiality. Personal data are collected which, if confidentiality was breached, could result in negative outcomes. With protections in place (see below), we believe the risk of breach of confidentiality is low.

f. Risk of physical harm to the research and teaching staff, students, and ultimately patients. In this highly conservative country, with some politicians using sexual issues to promote political agendas, there is a risk to staff students and ultimately patients. Since the risks differ by group, there are considered separately:

- **i. Staff:** There is a risk to staff if a person(s) opposed to sexual education of medical and nursing students learns of the curriculum and takes steps to prevent it. Examples of risk include threats of violence or arrest for anyone seen to be advocating for a particular sexual health issue. We assess this risk as hypothetical and given the preeminence of MUHAS as a teaching university and strong cultural respect for health professionals, extremely unlikely.
- **ii. Students:** There is a risk to students who learn sexual health counseling and interviewing if a patient or other person complains that they are acting illegally or threatening the status quo. We assess this risk as hypothetical and given the context of a medical interview, unlikely.
- **iii. Patients:** There is a risk to patients if they are asked sexual questions which leads them to experience negative consequences. Examples include the health professional reporting them to authorities (for illegal behaviors such as being homosexual, taking drugs, sex work, or seeking an abortion), or if a record of illegal behavior is kept and later used against them by another health professional. A second risk is if some third party learns of illegal behavior and tries to use this knowledge against the patient. This risk is also hypothetical but potentially common if best health practices are not followed.

g. Risk of psychological or emotional distress. It is possible that a student, by taking this class, or in practicing interviewing skills with patients, may become psychologically distressed. Examples include students who have unresolved sexual health concerns being reminded of them as content focuses on sexual health, or distressed by how common their patients experience serious negative sexual events (e.g., rape, sexual trauma, HIV/STIs, mutilation).

2. Strategies and procedures for protection against risks

Recruitment and Informed Consent.

This study will be undertaken under the oversight of the Muhimbili University of Health and Allied Sciences (MUHAS) and the University of Minnesota Institutional Review Boards (IRB), human subjects protection programs. Recruitment of health students will be through announcements in class, flyers on student notice boards, and email. Students will be enrolled during a regular class in their respective disciplines. Students will be fully informed that this is a new sexual health training program

for Africa health professionals and that they have the opportunity to both attend the training and participate in its evaluation. Given strong motivation by MUHAS students to receive as much training as possible, it will be stressed that participation is voluntary.
All potential participants will be informed where the study office is and office hours (so they can visit) and given the email address or phone number for the study so they can ask any questions of the researchers prior to entering the study (or indeed at any time). Further, given several faculty are both co-investigators or presenters of the curriculum, and teachers at MUHAS, **Principal Investigator** email address will also be listed explicitly for students who wish to report any reservations about participating or other concerns to someone who is not faculty at MUHAS.

Procedures for Protecting Against Risk:
Human Subjects' Advocate: To be proactive in ensuring the highest standards of ethics, the PIs have overall responsibility for all human subjects' concerns. In addition, we have asked **Dr. X** (at MUHAS) to serve as our human participants' advocate. In this role, Principal Investigator has a special responsibility to think through all study decisions in terms of how they affect the participants, to "stand in the place of participants", and to raise any such issues or concerns as they arise.
Each of the protections against the risks listed above will be addressed in the order listed.

a. **Protection against students assuming they should participate.** Both in the recruitment flyers, posters, oral announcements, and in the consent form, the voluntary nature of the research will be stressed. On the last page where students sign the consent, it will state, "I know this study is voluntary and I can withdraw at any time." Given the low level of risk of harm, by explicitly emphasizing the voluntary nature of the research, this risk is reduced to negligible.
b. Protection against some students feeling embarrassed. Principal Investigator at UMN has overseen sex surveys involving over 25,000 participants. While some mild discomfort may be common, given we have had less than a handful of persons report significant embarrassment, and none to the point where they could not continue, we are confident this risk is rare and mild. We plan to note on the consent form that participants can refuse to answer any item. With these protections, the risk is reduced to negligible.
c. **Protection against some students being negatively viewed by others for receiving sex education.** In the consent form, we will emphasize that this is a standard part of many health training programs. However, if any student is concerned that participation may cause them embarrassment or harm, they should talk to one of the investigators prior to consenting. The investigator shall assess the degree of risk. If there is a reasonable chance of harm, the student will be excused from the study. Alternatively, if the student wishes to participate despite the possible risk of harm, the investigator will work with them to develop an individual risk prevention plan (e.g., not taking any curriculum materials or text home with them; what to say if someone finds out they have received education).
d. **Protection against students with sensitive personal histories feeling overexposed**. All participants in this study are adults over 18 years who have studied with their fellow students for years. We feel the students are well placed to make informed decisions about any disclosure. To prevent over-disclosure, at the start of the seminar, as part of discussing boundaries, students will be encouraged to practice good boundaries, and explicitly informed that they do not have to disclose any information that they do not want to. Further, students will be explicitly told to hold any information that is disclosed as confidential (to the limits of medical ethics). The module addressing professional ethics also reinforces this. In addition, **Dr. X** is a certified mental health provider who has made herself available to discuss with any students, any concerns they may have. With these protections, since the level of risk is similar to students having conversations

over lunch, the risk appears minimized and not beyond everyday life.

e. **Protection against breach of confidentiality.** This study will maintain state-of-practice procedures for reducing the risk of breach of confidentiality. These include all surveys being stored in locked filing cabinets, no use of names on surveys, all electronic data being encrypted during transfer and stored behind password-protected firewalls, and no identifiable data being reported.
   - **i.** **Protection against risk of physical harm to the research and teaching staff, students, and ultimately patients.** Tanzania is a conservative country but given the preeminence of MUHAS and the revered status health workers have in Tanzania, it is considered highly unlikely that a person or politician would use the course against the University, staff, or students. Medical courses are typically not advertised beyond the student body, and the study will keep a low profile, publically. To protect against the risk of physical harm, **Principal Investigator** will brief the MUHAS administration. During the study**, Principal Investigator** will observe all classes. Should any threat be observed, he is the designated investigator who will intervene. All participants' names and identifying information are protected behind password-protected files.
   - **ii.** **Staff:** The risk to staff is low since the curriculum is standardized and reviewed to ensure a culturally appropriate and medical framing of controversial topics. Only **the Principal Investigators** are authorized to speak to the press.
   - **iii.** **Students:** Students who learn medical or other health techniques, including sexual counseling, may place themselves at risk if someone objects to their interventions. (In Tanzania, this has historically been limited to objections by traditional and alternative healers). We protect against this risk by training all participants to assess potential harm before addressing any issue, by asking permission to take a history to ask questions, by giving the patient the right to pass on answering, by highlighting cultural sensitivities (e.g., matching gender of health worker and patient where possible) and by practicing professional skills. In addition, all MUHAS students are taught professional boundaries and how to work in a culturally appropriate and sensitive way in the Tanzanian context, including how to address traditional approaches and alternative healers in the work.
   - **iv.** **Patients:** The legal rights (e.g., confidentiality) and limits of rights (e.g., in situations of mandated reporting) are a critical part of this training. **The Principal Investigator** will advise on Tanzania law regarding mandated reporting (e.g., of child abuse), and non-reporting of illegal behaviors or stigmatized identities (e.g., HIV positive, LGBT, sex workers). All participants will receive our recent paper detailing health professionals' ethical and legal responsibilities and summarizing case studies in this area. The ethical principle to "First do no harm" will be emphasized and applied explicitly through case studies to specific situations. Students will be encouraged to always seek peer or faculty consultation before any action which may jeopardize a patient. Finally, students are taught to assess for confidentiality prior to conducting any sexual health interviewing.
   - v. **With these protections** in place, we assess these risks have been reduced to levels similar to those in Tanzanian society and not beyond those inherent to teaching, being a student, or patient.

f. **Protection against risk of psychological or emotional distress.** First, we highlight that the Sexual Health Model, the theoretical model underlying this curriculum, is an assets-based resiliency model focused on health, not pathology. Similarly, the content covered focuses on normalizing most issues as common (as accurate and appropriate). At the opening of the course, and at appropriate times during multiple units, students are encouraged to treat sexual health like

any other health topic, to take care of themselves, and to talk with faculty if they have questions or concerns. In addition, students will be explicitly told verbally, and in writing, that if concerns or emotional distress arise to contact **Dr. X**, a licensed psychiatrist in the MUHAS Department of Psychiatry. She will assess the level of distress and with the participant either engage in brief counseling or make an appropriate referral.

3. Potential Benefits of the Proposed Research to the Participants and Others

While a reasonable person might infer that three days of structured education and training in sexual history taking is a substantial benefit to students, the curriculum has not to be evaluated; and thus, these benefits are hypothetical, not proven. As part of the consent process, we will state there are no known benefits to the participants by participating in this research or the seminar. Consistent with the definition of compensation as repayments to participants for time and other costs to them in attending the seminar, compensation will NOT be described as a benefit.

K. Mitigating the Risk of COVID Transmission

Steps to Prevent COVID Transmission

1. Where will the full trial take place?

a. All research will take place at the Muhimbili University of Health and Allied Sciences (MUHAS), a public university specializing in training health professionals in Dar es Salaam, Tanzania. MUHAS is described as Tanzania's premier institution in training health students and in conducting health-related research. The vice-chancellor of the university is a medical doctor who we met with and apprised of this study. The site's principal investigator, is a licensed health professional as well.
b. We have deliberately chosen to run the trial during the MUHAS break when there are fewer faculty and students on campus (and so the largest lecture theaters are available). The study will be conducted in full compliance with all requirements both at MUHAS and U of MN.

2. Mitigating participating risk

We do not anticipate any situation where the researchers will not be able to maintain at least 6 feet between themselves and participants. The only situations where a person may be within 6 feet distance are:

a. At the start of the video counseling session, a MUHAS IT person may have to assist a student if they have a computer difficulty. We anticipate any problems to involve less than 2-3 minutes of within 6 feet contact with both students and staff wearing face masks.
b. When students arrive or leave the lecture theater, **Researcher 2 and Researcher 3** will be at the door to open it for them so that only one person touches the door.
c. We anticipate within 6-foot contact to last less than 15 seconds.

3. Steps for research staff to self-assess health risk

a. All research staff (including faculty, IT support, and simulated patients) will be required to take both body temperature and be symptom-free to work on the study each day.
b. When the staff member arrives, they will meet the project coordinator, or his designee, at a pre-assigned desk outside the lecture theater.
c. The project coordinator will ask the staff member if they have any COVID-19 symptoms and then will take their temperature using a digital thermometer.

d. If they report symptoms or have a temperature, they will not be allowed to enter any room where others are present. Instead, the person taking the temperature will log the temperature on the study form and take appropriate action (see next section).

4. Procedure for study participants to self-assess health risk

a. Upon arrival at the MUHAS campus, all persons entering are required to wear facemasks.
b. Each day when the participant arrives at class, outside the classroom will be a desk. The staff member welcoming them will ask if they have any symptoms and take their temperature.
c. Only those who state they have no symptoms and who do not have a temperature will be allowed to enter the lecture theater.
d. If someone has symptoms or a temperature, they will be instructed that they cannot attend the session. Depending on the severity of symptoms, the staff member will help the participant or staff member to identify the appropriate immediate next steps both to help the individual and to protect against COVID spread to others.
e. In addition, throughout this curriculum, all participants (and staff) will be informed multiple times that if they feel ill or like they have a temperature, they should immediately report this to **Dr. X.**
f. This staff member will escort the person outside (or away from any other person), then ask what is wrong. They will inquire about specific COVID symptoms and also take their temperature. Depending on what is found, they will help the participant or staff member to identify the appropriate immediate next steps both to help the individual and protect against COVID spread to others.

5. Procedures for minimizing face to face contact

a. The day before their participation, participants will receive an email reminder confirming their participation and details of where to meet and COVID-19 measures to follow.
b. On the day of the study, participants will be staggered to minimize the number of persons arriving at any one time.
    i. The participants arrive at the welcome desk where their temperature is taken and handwashing is observed.
    ii. Then, they first read a welcome overview of the study and review the consent form, and if comfortable, sign it.
    iii. Each person will be given a pen and pencil for them to keep so there is no sharing of writing instruments.
    iv. After this, they are sent to the "lab" where they are videoed taking three sexual histories.
    v. Only 6 students will be allowed in the lab at any one time (with 2 staff members and 1 IT person present). Each station has a laptop and headphones and will be at least 6 feet from another station.
    vi. In addition, we have purchased dividing screens both to promote privacy and to prevent COVID-19 transmission, so each person will have their own "cube".

c. During the 44 days of the curriculum, the student participants are given a contact email and phone (of a faculty licensed health professional) so that if they feel ill or develop a temperature outside of when the intervention is occurring, they can inform the study. Anyone reporting symptoms will be encouraged not to continue participation but instead, to prioritize their health.

Use of PPE

a. We have purchased masks and hand sanitizers from a medical vendor in Dar es Salaam. **Project Coordinator** will check and, if necessary, purchase more to have sufficient for the trial.
b. Each staff member and participant will be required to wear a mask at all times when participating in the study (except when eating lunch which will be outside the lecture theater) and to follow all MUHAS rules about wearing masks on campus coming to and from study participation.

Procedure to disinfect surfaces

a. MUHAS University has disinfectant procedures in place using hospital-grade disinfectant for each room we will use. In addition, the study has purchased disinfectants. The project coordinator will appoint one of the faculty (a nurse or midwife) to make sure all surfaces will be sanitized whenever the students leave the room (e.g., at lunch and end of the day).
b. In addition, we will have a staff member at the door of the lecture theater. After each student has washed or sanitized their hands, this staff member will open the door for each student so that only one person touches the door.

L. COVID Protocol for the Seminar

a. The training will be conducted in a lecture theater big enough to accommodate 600 students. The full trial will involve a maximum of 412 students while the trial will be limited to 206 students per session.
b. We will ensure that during training sessions, students are seated two meters apart from each other by labeling alternate seats with stickers indicating “sit here”, allowing enough space in between individuals. Faculty will also be required to sit two meters apart.
c. Before everyone gets into the hall there will be an isolation area with touch-free running water with soap for washing hands and disposable tissues for drying their hands.
d. Surgical masks will be distributed to every participant after they have washed and dried their hands, and they must be worn properly before entering the theater.
e. One supporting staff will be sitting near the door, for the purpose of opening and closing the door for everyone, to avoid participants touching the door handle.
f. When each enrollee arrives, they will pick up a pack of study materials that include a welcome letter, consent form, pre-test survey, and a unique study pen for them to keep. Only the participant will touch this pen.
g. Breakfast and lunch will be served at the University cafeteria which is well equipped with COVID 19 safety measures and it is a place where participants normally take lunch or dinner on a daily basis.
h. Each time participants or facilitators get out of the theatre, they will not get back in until all disinfection measures have taken place.
i. When participants get in the room we will make sure that they sit exactly where they sat before they went out of the room.
j. Groups for discussion will be kept as small as possible, only 4-6 participants instead of 6 to 8 and they will be one meter apart from each other, and weather permitting, held on the lawn outside the theatre. In addition, we will minimize time spent in a group by providing short and clear instructions.

k. All tables that will be used for participants and standardized patients (SP) will be disinfected after every session to make sure that it is safe for the next group, regardless of them having masks on or disinfecting their hands.
l. The students who will be videotaped taking histories will be instructed not to touch computers on the tables, as there will be an IT person in place who will be setting computers for everyone. The IT person will also observe the safety measures as everyone else (from a safe distance).

M. Technology: Zoom Information

1. Computers and other equipment

a. Study staff are in charge of transporting computers, tablets, headsets, extension cords from storage to the lab
b. All equipment needs to be tested prior to the beginning of the SP session
c. Videos need to be stored on the external hard drive after the SP session has ended.
d. All equipment needs to be locked up immediately after the end of the SP session

2. Recording of videos:

The SP encounters will be recorded via Zoom using 6 computers and headsets.
30 minutes before students start the SP exercise, computers will be placed on the table and connected to the internet for zoom meetings by the IT person.

a. The IT person will make sure headsets are plugged into the computers and that all computers are plugged into power outlets and are charging.
b. The IT person will make sure that Zoom is working properly on all the computers by turning Zoom on and recording a short test video.
c. IT person is in charge of making sure all SPs are recording their Zoom session
d. The project coordinator is in charge of making sure that all recorded Zoom sessions are saved on Box.com

3. Zoom procedures during the pilot:

a. Use speaker view during the interview
b. Be aware of the position of the camera
c. Be aware of lighting
d. Make sure you are not muted
e. Make sure the recording light is on - this is very important

N. Administration of the Follow-up

This follow-up protocol is to be revised in November 2021, based on the experience of conducting the baseline assessment.
There are four main tasks to think about during the period between baseline and follow-up. They are:

1. Avoidance of bias
2. Minimization of dropout
3. Administration of the follow-up survey
4. Administration of the follow-up SP assessment
5. Giving the Control participants the opportunity to attend the seminar (**September 2022).**

1. Avoidance of Bias

It is critical for the follow-up that participants in both arms of the trial be treated in the same way. Given that some participants may complete the SP assessment and others in May, it will be important to

randomize treatment and control arm participants so that both groups, on average, complete the follow-up assessment at the same time and under the same conditions.
As there is no reason for the SPs and the staff to know what arm of the study the participant was in, all study staff and SPs should be kept blind to this knowledge.

2. Minimization of Drop Out

a. Participants in both arms of the trial are easily followed up since they are enrolled students at MUHAS. At enrollment, students will be asked to supply a mobile number to contact them in case they need to. Should a participating student not keep their pre-test or 3-month follow-up appointment, every effort will be made to facilitate another session for them to complete study tasks. Participant attendance at the seminar is monitored.
b. If a participant leaves MUHAS and is no longer considered a student, they can remain a participant in the study and so can participate in the follow-up portion of the study. **Project Coordinator** is the staff person who shall discuss with the participant the reason why they are no longer a student and may include or exclude the student from further participation (as appropriate).
c. **Project Coordinator** will keep a log of any students who inform the study that they wish to no longer participate. This study is voluntary so a participant may choose to leave the study at any time. **Project Coordinator** shall ask them for any reasons for withdrawal.
d. Also, he will follow up with any participant who completed the baseline assessment but failed to complete the follow-up. Every effort will be made to facilitate the student completing the follow-up. Should he encounter participants who "disappear" from the study (i.e., they enrolled in the study and completed the baseline but then were not contactable for follow-up, he will check with MUHAS administration and the relevant school whether the participant is still a current student, and if not, the reason why. Given the COVID epidemic, he will log the reason given why the participant is no longer a student (e.g., illness or death at the time of follow-up).

3. Administration of the Follow-up Survey

Objective: The purpose of the final survey is to collect information on student's knowledge, attitudes, and self-evaluation of skills related to sexual health at least 3 months after the baseline assessment. To ensure all participants are treated equally, to reduce participant burden, and for ease of administration, the follow-up survey will be completed online by all participants at the same time.

Procedure

a. Prior to the survey being sent to participants, **Project Coordinator** is responsible for pre-piloting the survey with internal staff to ensure that all questions are being asked and that the survey is free of bugs.
b. **Researcher 3** is in charge of overseeing the final survey completion. Before sending out the link to the survey, they will check that the Internet is working well. If it is problematic, **Researcher 3** may delay sending out the email until the Internet is working.
c. In December (i.e., 24 hours before the first follow-up SP assessment) **Researcher 3** will send out an email and/or text to all participants (i.e., both those in the intervention and the control conditions) with a link to the survey. The participants are asked to complete this follow-up survey within 7 days. All instructions on the survey should mirror those on the baseline survey with the following differences. It will be noted that completing both the survey and the SP follow-up assessment is needed to receive compensation. The link will provide a phone number and email in case a participant has questions or difficulties. And participants will be asked to complete this by themselves without asking anyone else answers to any question.

d. Each participant is instructed to complete the online using their phone, laptop, computer, or other online devices at a time and place convenient to them.
e. **Project Coordinator** will monitor the completion rate of surveys on a daily basis. Monitoring involves checking the surveys that have been completed (to ensure they are complete then sending a thank you email to those who have completed that they did so.
f. **Minimization of Attrition Protocol:** All participants who have not completed the follow-up survey within 7 days will be sent an email and/or text reminder at 7-days asking them to complete it within 48 hours. Two days later, anyone who has not completed the survey receives a second email and/or text asking them to complete it within 48 hours. Those who have not completed it after the second reminder then receive a personalized phone call asking them to complete it within the next 48 hours.
g. The goal is to have everyone complete the follow-up surveys. During the two weeks devoted to the administration of the follow-up survey, **Project Coordinator** will give regular updates on the number and percent of participants who have completed the follow-up survey.
h. **Project Accountant** is in charge of the payments which will be approximately $25 for completion of both the SP assessment and the online follow-up survey. There is no partial payment for completing only one or these two activities.

4. Administration of the Follow-up SP Assessment (five critical steps to follow)

***Objective**:* The administration of the follow-up should be conducted in a way that reflects a high standard and replicates as much as possible the methods used for the baseline assessment.

There are 5 critical tasks that need to be completed at the follow-up assessment. They are:

i. Ensure the SP evaluation is completed with no bias
ii. Ensure only healthy students, staff and SPs enter the study area.
iii. Completion of the follow-up SP evaluation
iv. Payment of the participants for completing the baseline assessment.
v. Wait-listing the control participants for the 2022 seminar.

Ideally, a total of 412 participants are expected to move through a 90-minute session that involves two SP simulations involving a simulated patient (SP) presenting with a sexual health problem (15 min. each).

Staffing: In addition to **Project Coordinator**, we need staff members to (a) supervise the SP; (b) provide the participant payment, and (c) wait-list those from the waitlist control condition who wish to participate in the 2022 training.

a. Ensure the SP evaluation is completed with no bias

The goal is to have every participant complete the follow-up SP assessment with the SPs (and ideally staff) blind to whether the participant was in the intervention or control arms. Care should be taken so that both intervention and control arms are treated equally. This means that intervention and control arm participants should complete the follow-up assessment at the same time.

If the SP assessment has to be spread over two months (e.g., January and May) it is critical that equal numbers of intervention and control arm participants complete it in January, with the rest completing it in May.

b. Ensure only healthy students, staff and SPs enter the study area.

As per the COVID protocol (see below), all students, staff, and SPs will have the temperature taken and are required to wear masks while completing the final assessment. A student, staff, or SP with a temperature will activate the COVID protocol.

c. SP Simulation Lab

Control center: This is a table from which investigators will run the simulations. The table is located in the lab.

i. **Researcher 1** is in charge of running the simulation lab.
ii. The "control center" will be a table and several chairs located in an easily accessible location in the simulation laboratory.
iii. All supplies and equipment will be stored/or placed in this area. All paperwork will be kept in the control center for easy access.
iv. At least 1 staff member will always be at the control center to answer questions that students or SPs may have and to troubleshoot any problems.
v. The control center will be maintained throughout the day and kept clean and organized.
vi. At the end of the day during the interventions and training, all materials used for the study will be stored for the full trial use.
vii. We have planned to have 12 simulations running concurrently in 4 rooms. Each room will have the 3 SPs with the same case. The student waits outside the room until called, then enters the room and completes the case. When the student has completed the case they are directed to the next room to complete their second case. So, the first student completes Case A (in-room A) and then goes to Room B to complete case B. The second student goes to Room C to complete Case C and then Room D to complete Case D. The third student goes to Room A (to complete A&B), while the 4th student is sent to Room C (to complete Case C and then to Room D to complete Case D).
viii. SP and learners arrangement: Each participant will complete two SP cases of about 15 minutes each; i.e., 30-40 minutes in total.

Participants (learners and SP) will spend 20 minutes at each station.

Breakdown of 20 minutes:

- Five minutes will be spent in the introduction of the case at each station.
- 10 minutes will be used during the discussion/history taking
- Each participant (learner and SP) will be required to fill in a survey/checklist before moving to the next station which will take about 5 minutes.

Dr. X will be responsible for assigning learners to different stations. SP will not move/leave their station, they will remain in the original station. Between sessions, participants will be given snacks and bathroom breaks. **Dr. X** will keep time and address any concerns or questions as they may arise.

d. Setting up a simulation scenario:

The following are the steps that SPs will take when setting up for a scenario:
Sit on the appropriate chair
Turn on the computer

i. Open Zoom
ii. Wait for the student to arrive and sit down
iii. Press the "record" button ← Very important
iv. Play role as SP
v. Watch for the "1 minute left" warning sign
vi. Once 10 minutes are over, end the conversation with a student
vii. Press the "stop recording" button
viii. Wait for the next student to arrive
ix. Repeat process

At the end of the simulation, the student is informed to return **to Dr. X** and to provide her with their completed simulation forms. Each student should hand two forms to her. **Dr. X** checks the form and sends the student to the baseline survey station.

e. Payment and Feedback

a. **Project Accountant** is the person in charge of payments.
b. **Project Coordinator** reviews with the student that they have completed the two SP assessments and checks that the survey responses have been captured in qualities.
c. **Project Accountant** then hands them the payment for completing the assessment.
d. Finally, **Project Coordinator** asks each participant if they have any other questions or any feedback about their experience in the trial.
e. For students who provide feedback, **Project Coordinator** logs this information for discussion at the team meeting.
f. Whenever problems are identified and are immediate and easily fixed, **Project Coordinator** is authorized to modify study procedures to improve the student experience.

f. ***Waitlist: Being waitlisted for the September 2022 seminar***

a. **Project Coordinator** will ask all control arm participants once they have been paid if they wish to be waitlisted for the September 2022 training. He shall also extend this invitation to any participant assigned to the intervention arm who was not able to attend the training (e.g., because of illness). Because of limited resources, students who completed the training in 2021 will not be allowed to repeat it in 2022.
b. Project Coordinator will explain to each participant that the training in 2022 will occur if sufficient students register and confirm in July 2022. Project Coordinator will hand each person who wishes to be on the waitlist a one-page flyer detailing the likely dates of the seminar, and ways to contact the study.
c. **Project Coordinator** will review and update contact information for any student who is waitlisted for the seminar.