Title: Developing a Resiliency Intervention to Support Healthcare Workers Engaged in the Provision of HIV Care

Project Number: R34MH126753

NTC Number: NCT06548035

PIs: Christina Psaros, PhD and Jenni Smit, PhD

Ethics Approvals: All research procedures have been performed in accordance with the Declaration of Helsinki and approved by local and international ethics committees. Ethics approval of the study protocol has been obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand (240106, Johannesburg, SA) and the Massachusetts General Brigham Institutional Review Board (2024P001407, Boston, Massachusetts, USA). Approval was obtained from the KwaZulu-Natal (KZN) Provincial Department of Health, the eThekwini District provided a letter of support, and other organizations providing HIV treatment and care in eThekwini district.

Form Type: Informed Consent Form

Study Phase: Pilot RCT

Version 3.0, 5 March 2025

WITS MRU
MATERNAL, ADOLESCENT AND CHILD HEALTH RESEARCH UNIT
UNIVERSITY OF THE WITWATERSRAND

INFORMED CONSENT FORM – Randomized Pilot

Developing a Resiliency Intervention to Support Nurses Engaged in the Provision of HIV Care (Phase 2): The Qinisa (Strengthen) Study

PI: PROF JENNI SMIT

Good day, my name is …….. I am a …… [insert designation] at Wits MRU (Wits MatCH Research Unit), of the University of the Witwatersrand, based in Durban. Researchers at Wits MRU and at Massachusetts General Hospital / Harvard Medical School in the United States would like to invite you to consider participating in a research study.

Introduction

This form, called an Informed Consent Form, will explain what this study is about. Please read this form or have it read to you. Before you decide if you want to join this study or not, we want to explain the study, its risks, its potential benefits, and what you will be asked to do. You may ask questions as we discuss the study, so that you understand what the study is about. It is important you know the following:

- Your participation in this study is entirely voluntary.
- You can ask questions now or at any time during the study.
- If you join the study, you can change your mind later and quit the study at any time.

Before you decide whether to join this study, a member of the study staff will explain:

- The purpose of this study
- How the study may help you or others
- Any risks you may face while participating in this study
- What is expected of you during the study

Once you understand the study, and if you decide to take part, you will be asked to sign this consent form, and you will be given a signed copy of it to keep. This process is called informed consent.

Purpose of the Study

There will be a randomized pilot comprised of 60 professional nurses working in public clinics or nurses working in partner organizations that are providing HIV care services in eThekwini district, South Africa, who have provided HIV related health services for at least one year**.** The randomized pilot study is being conducted to test the feasibility and acceptability of an adapted version of a stress management and resiliency-enhancing intervention, called the Relaxation Response Resiliency Program (3RP) for nurses that care for persons with HIV in this context.

Randomized Pilot Procedures

We are asking you to take part in this randomized pilot study to assess the implementation of the 3RP intervention, and how it may meet the needs of nurses that care for persons with HIV in the public sector in South Africa. If you agree to participate, you would be randomized to one of two groups, or conditions. "Randomized" means that which group you will be in is decided by chance, like a coin toss. You and the study team cannot choose the study groups. You will have an equal chance of being assigned to each of the two groups.

One group is called the intervention group. If you are placed in the intervention group, you will attend two, 4-hour, in-person group sessions with a coach/facilitator held in-person at the Wits MatCH Research Unit (Wits MRU) study site or other convenient location, along with having the option of accessing a closed (e.g., limited to group members) WhatsApp group moderated by the interventionist. Participants will be encouraged to complete weekly practice notes after each session for collection by the study staff, which will correspond with several intervention modules (e.g., relaxation practice); this is not required for participation. You will learn how to identify stress, how to think about stress differently, and skills to manage your stress. If you are randomized to the other group, the control group, you will attend a one-time, ~90-minute, group stress management session. You will also have the option to participate in the full, two 4-hour sessions intervention later in the study, after the intervention group ends.

Participants must be aged 18 years and older. The intervention sessions will be held in a private room at Wits MRU, clinics if space is available, or some other mutually acceptable location. Wits MRU will provide reimbursement for transport if the intervention is conducted at the Wits MRU site or other convenient location. The intervention sessions will be conducted at a time that is convenient for participants. The intervention will be comprised of two 4-hour sessions. Participants will be provided with refreshments and a token of appreciation (e.g., lunch bag and pens). The intervention sessions will be facilitated by a trained facilitator who is professional research nurse. We will also ask you to complete three sets of questionnaires and a qualitative exit interview over the course of the study.

Transport cost

Transport cost for travelling to the training venue and inconvenience amounting to R500 will be paid to you per training session.

Possible risks

There are minimal risks in taking part in this randomized pilot. There is a chance that you may experience psychological discomfort while participating in the intervention and reflecting on challenging circumstance*s.* You are allowed to step out for any reason. There is a possible risk that other group members will disclose some of the information you discuss, but all members will be instructed to keep information confidential. Our study staff members are trained to create a supportive and safe environment for talking about sensitive issues, and can offer a referral to a registered independent counsellor for psychotherapy and counselling services, if you need or want them.

Possible benefits

There are no direct benefits to you in participating in this research but the information you give us will help us in pilot testing an existing stress management and resiliency-enhancing intervention for nurses that care for persons with HIV. This may help nurses in the future.

Confidentiality

All study staff will treat participant data collected during this study with the strictest confidentiality. All study information or material will be identified only by individual participant code numbers and will be kept confidential in a locked file drawer at Wits MRU. This information or material will be available only to study staff, as part of routine checks to ensure that this study is being conducted in a professional way that protects your rights. Your name will never be used in any publication or presentation about this study.

Your data will be collected, processed and stored according to the South African Protection of Personal Information (POPI) Act of 2013. All study documents will be stored for a duration of 10 years as required by Good Clinical Practice (GCP).

The staff of *Massachusetts General Hospital / Harvard Medical School*, our collaborating partners in this study, will look at the research records of those who take part in the study. Other parties that might have access to inspect your records include *the National Health Research Ethics Council (NHREC), University of the Witwatersrand Human Research Ethics Committee* and *Mass General Brigham Institutional Review Board*. These parties will be granted direct access to your data, to the extent permitted by the applicable laws and regulations. By signing the written Informed Consent Form, you authorize such access to your records.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

We will ask all group participants to keep everything discussed private and not to reveal the opinions of any participants with others, and we will remind them of the importance of confidentiality. However, we cannot guarantee that the other members of the groups will keep your information private. You should remember this when deciding what you talk about.

Digital recording

You will be asked to allow the study team to digitally record the audio of the intervention sessions, so that the study staff can make sure that it is being carried out correctly and to provide feedback to the facilitator. Each digital recording will be transcribed, and all recordings will be erased within two years of publication of study findings, or if there is no publication, no later than six years after the study has ended. The intervention sessions will be confidential; you will be identified only by a unique number assigned to you, and no individual names will appear on the audio file or the transcript of the interview. No one, except the researchers at Wits MRU and Massachusetts General Hospital / Harvard Medical School will have access to the audio file or the transcript of the intervention sessions. You can decide to withdraw from the intervention sessions at any time. If you do not want the intervention sessions to be digitally recorded, you will not be eligible to participate in the research study, since it is important that we have digital recordings to understand exactly what is being said.

Alternative to study participation

The alternative to participating in this study would be simply not to participate. Your nonparticipation in this study will not affect you in any way, including your employment or receiving your own services at KwaZulu-Natal Department of Health clinics.

Research standards and rights of participants

Your participation in this study is entirely voluntary. If you decide not to participate or if you later decide to stop participating, or refuse to answer any question, at any time, you will not lose any benefit to which you are entitled to as a *healthcare provider*. We retain the right to withdraw you from the study if it is considered to be in your best interest.

Contact details

Please feel free to contact us about the project in the future, or to ask for any updates. We appreciate the time you may take to participate in this study.

If you have any questions about this study or study procedures now or in the future, you can call the programme director/study coordinator, Nzwakie Mosery, at 031-001 1915 / 083 962 7003, or Prof Jenni Smit, the Wits MRU Principal Investigator, at 031-001 1904 / 082 926 5762.

The Human Research Ethics Committee of the University of the Witwatersrand, and the Mass General Brigham Institutional Review Board have approved the recruitment of participants for this study. The Institutional Review Boards/ethics committees oversee the protection of people participating in research studies.

The study has been structured in accordance with the Declaration of Helsinki (last updated October 2013), which deals with recommendations guiding doctors in biomedical research involving human participants.

If you want any information regarding your rights as a research participant, or complaints regarding this research study, you may contact the following ethics committee. The University of the Witwatersrand, Human Research Ethics Committee (HREC), is an independent committee established to help protect the rights of research participants.

Prof Paul Ruff
Chairperson of the Human Research Ethics Committee
(HREC) University of the Witwatersrand Tel: 011 717 2301

You now have an opportunity to ask me questions concerning the project.

Declaration of the volunteer

I understand the purpose of this study. I have read the above information. I have had the opportunity to ask questions, and any questions that I asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I have the right to stop my participation at any time.

_____	_____	_____
Participant Print Name and Surname	Participant Signature	DD-MMM-YYYY Time: _____:_____ H H : M M
_____	_____	_____
Witness Print Name and Surname (or thumbprint if applicable)	Participant Signature	DD-MMM-YYYY Time: _____:_____

H H : M M

Print Name and Surname Person obtaining consent	Signature	DD-MMM-YYYY Time: _____:_____ H H : M M

Consent to digital recording

I have been informed that the audio of the *intervention* sessions will be digitally recorded. I know that I can refuse to participate if I do not want to be digitally recorded. I voluntarily give permission for the *intervention sessions* to be digitally recorded.

Participant Print Name and Surname	Participant Signature	DD-MMM-YYYY Time: _____:_____ H H : M M
Witness Print Name and Surname (or thumbprint if applicable)	Participant Signature	DD-MMM-YYYY Time: _____:_____ H H : M M
Print Name and Surname Person obtaining consent	Signature	DD-MMM-YYYY Time: _____:_____ H H : M M