NCT04868123

Title of Study: Impact of Distal Sensory Polyneuropathy on Function in Persons Living with HIV and a Pilot Study of Mindfulness Meditation and Transcutaneous Nerve Stimulation (TENS) in Persons Living with HIV-related Peripheral Neuropathy (Brief Title: Effects of TENS and Mindfulness Meditation in Persons With HIV-related Neuropathy)

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RUTGERS
School of Health Professions
DEPARTMENT OF REHABILITATION AND MOVEMENT SCIENCES

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# CONSENT FORM
# FOR PARTICIPANTS WITH PERIPHERAL NEUROPATHY
## [participating in both observational and interventional phases of study]

**Title of Study:** Impact of Distal Sensory Polyneuropathy on Function in Persons Living with HIV and a Pilot Study of Mindfulness Meditation and Transcutaneous Nerve Stimulation (TENS) in Persons Living with HIV-related Peripheral Neuropathy
**Principal Investigator: David Kietrys, PT, PhD, FCPP**

**STUDY SUMMARY:** This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to compare walking, physical performance, physical activity, and pain pressure threshold in HIV+ people with neuropathy in the feet to those without neuropathy in the feet, and to explore if home-based treatment over 6 weeks can help improved symptoms and physical function in persons with HIV and painful neuropathy in their feet. If you take part in the research, you will be asked to complete a number of tests of that include tests of walking, strength, balance and pain pressure threshold, and questionnaires about your pain, ability to do things, and your mood. After that, you will be asked to wear an activity monitoring device around your wrist for 5 days and then return the device. You will be randomly placed in one of three groups for the next 6 weeks. The three groups are: Standard Care, Mindfulness Meditation, and Transcutaneous Electrical Nerve Stimulation (TENS). Those in Mindfulness Meditation or the TENS group will be asked to do meditation or TENS for 30 minutes every day, at home, for 6 weeks. After 6 weeks, you will be asked to return to the test center to repeat all of the test that were done at the beginning, as well as a satisfaction questionnaire. After that, you will be asked to wear an activity monitoring device around your wrist for 5 days and then return the device. Each of the 2 testing sessions will be completed in about an hour and a half. Your time in the study will take about 8 weeks overall if you are randomized to the Usual Care group. If you are randomized to the TENS or Mindfulness Meditation groups, you will receive a short follow-up questionnaire about 8 weeks later, bringing your total time in the study to about 15 weeks.

**Possible harms or burdens** of taking part in the study may be temporary fatigue during or after the testing session and muscle soreness for a day or two after the testing session.
You may experience some emotional discomfort from some of the questions on the questionnaire.
Those in the TEN group may experience mild skin irritation after a TENS treatment.
Those in the mindfulness meditation group may experience some emotional discomfort after doing a meditation session. You may have travel costs, such as gas or bus fare, in order to get to and from the testing center.
The benefits of taking part in this study may be less pain and better physical functioning. However, it is possible that you may not receive any direct benefit from taking part in this study.

Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the

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research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

**Who is conducting this study?**
Dr. David Kietrys, PT, PhD, FCPP is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.
Dr. Kietrys may be reached at (845) 566-7186 or kietrydm@shp.rutgers.edu.
The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

**Sponsor of the Study**: This study is sponsored by the Rutgers Interdisciplinary Center for HIV Research.

**Why is this study being done?**
This study is being done to compare walking, physical performance, physical activity, and pain pressure threshold in HIV+ people with neuropathy in the feet to those without neuropathy in the feet, and to explore if home-based treatment over 6 weeks can help improved symptoms and physical function in persons with HIV and painful neuropathy in their feet.

**Who may take part in this study and who may not?**
People with HIV between the ages of 18 and 89, who own a mobile phone or device on which they can received text messages, and who have pain in their feet due to neuropathy may take part in this study. People who currently have an opportunistic infection or a CD4 count of less than 200, dementia or an uncontrolled psychiatric disorder, or wounds or sores on the feet, or conditions (other than neuropathy) that affect walking may not participate. In addition, pregnant women may not participate.

**Why have I been asked to take part in this study?**
You have been asked to participate in this phase of the study because you are an adult living with HIV and you have painful neuropathy in your feet.

**How long will the study take and how many subjects will take part?**
You are being asked to participate over a period of about 8 weeks. Overall, the study will be ongoing for a year, but you will only be involved for about 8 weeks. If you are in the TENS or Mindfulness meditation groups, you will receive a short follow up questionnaire about 2 months after the 2nd testing session, bring your total time in the study to about 15 weeks.

**What will I be asked to do if I take part in this study?**
If you participate in this study, you will be asked to complete a number of tests of that include tests of walking, strength, balance and pain pressure threshold, and questionnaires about your pain, ability to do things, and your mood. These tests will be completed in about an hour and a half at a testing center. After that, you will be asked to wear an activity monitoring device around your wrist for 5 days and then return the device. The device records your amount of activity over the day and night. It does not track where you are located. You will be randomly placed in one of three groups for the next 6 weeks. The three groups are:

- Standard care. Those in this group will continue with their standard/usual care over a 6-week period. They will continue seeing any health care providers they normally see, and continue using any pain medications or treatments that they normally use.
- Mindfulness meditation. Those in this group will be provided with links to online recordings of guided meditations of about 30 minutes in length, and asked to do one meditation every day, at home, for 6 weeks.

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- TENS. TENS is a commonly used device that provides a mild electrical current through the skin through sticky pads (electrodes) that will be placed on the legs. Those in this group will be asked to do TENS for 30 minutes every day, at home, for 6 weeks.

After 6 weeks, you will be asked to return to the test center to repeat all of the test that were done at the beginning, as well as a satisfaction questionnaire. These tests will be completed in about an hour and a half at a testing center. After that, you will be asked to wear an activity monitoring device around your wrist for 5 days and then return the device. The device records your amount of activity over the day and night. It does not track where you are located. Those who were assigned to the educational group will be offered TENS and mindfulness meditation audios upon conclusion of study. Those who are in the TENS or Mindfulness Meditation groups will receive a short follow-up questionnaire that can be done at home around 8 weeks later.

**What are the risks of harm or discomforts I might experience if I take part in this study?**
You may experience temporary fatigue during or after the testing session. About 10% of participants in the study may experience short term fatigue during the testing or for the remainder of the day after the testing.
You may experience muscle soreness for a day or two after the testing session. About 5% of participants in the study may experience mild to moderate muscle soreness for a day or two after the testing.
You may experience some emotional discomfort from some of the questions on the questionnaire, as these questions will ask you about your pain, how you manage your pain, your emotions, and your feelings. About 1% of the participants in the study may experience mild short-term emotional discomfort lasting for a day after doing the questionnaire.
Those in the TEN group may experience some skin irritation after removing the sticky pads (electrodes) from their legs after a TENS treatment. About 1% of the participants in the study may experience mild short-term skin irritation lasting a few hours after a TENS session.
Those in the mindfulness meditation group may experience some emotional discomfort after doing a meditation session. About 1% of the participants in the study may experience mild short-term emotional discomfort lasting a few hours after a meditation session.
You may have travel costs, such as gas or bus fare, in order to get to and from the testing center.

**Are there any benefits to me if I choose to take part in this study?**
The benefits of taking part in this study may be less pain and better physical functioning. However, it is possible that you may not receive any direct benefit from taking part in this study.

**What are my alternatives if I do not want to take part in this study?**
There are no alternative available. Your alternative is not to take part in this study.

**How will I know if new information is learned that may affect whether I am willing to stay in the study?**
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

**Will there be any cost to me to take Part in this study?**
It your travel to and from the test site is more than $5, you will be responsible for that cost.

**Will I be paid to take part in this study?**
You will receive two $ 5.00 cash payments (to offset travel costs) and a two $25 gift cards for taking part

in this study. The schedule for payment is:

- $ 5.00 cash and $25.00 gift card on the testing day at start of study
- $ 5.00 cash and $25.00 gift card on the testing day at end of study

**How will information about me be kept private or confidential?**
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. All data generated from this study will be stored in password protected folders on Rutgers University servers. Dr. Kietrys is in charge of properly storing and securing all study data. Data will not be linked to you name or any other personal identifiers. De-indentified data will be shared only with the researchers who are members of the team for this study.

The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

A description of this study will be available on ClinicalTrials.gov. 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.

**What will happen to my information—data, recordings and/or images collected for this research after the study is over?**

The information collected from you in this research will not be used by or distributed to investigators for other research.

**What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?**
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. David Kietrys, Rutgers DPT Program, 200 College Drive, Jefferson Hall #308, Blackwood, NJ 08012

**Who can I contact if I have questions?**
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Dr. David Kietrys, PT, PhD, FCPP, at Rutgers School of Health Professions, Department of Rehabilitation and Movement Sciences: (856) 566-7186.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB Director at Newark Health Sciences IRB, 65 Bergen St., SSB 511, Newark, NJ 07107, (973)-972-3608 or the Rutgers Human Subjects Protection Program at (973) 972-3608 or (732)235-9806), email us at human-

subjects@research.rutgers.edu., or write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

## AGREEMENT TO TAKE PART IN RESEARCH

**Subject Consent:**

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

**Signature of Investigator/Individual Obtaining Consent:**

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____