NCT04889521

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

Document Date: 6.2.2022

RUTGERS
School of Health Professions
DEPARTMENT OF REHABILITATION AND MOVEMENT SCIENCES

Department of Rehabilitation and Movement Sciences
DPT Program
200 College Drive - Jefferson Hall #308
Blackwood, NJ 08012

CONSENT FORM
FOR PARTICIPANTS WITHOUT PERIPHERAL NEUROPATHY
[PARTICIPATING IN OBSERVATIONAL PHASE ONLY]

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. If you take part in the research, you will be asked to come to a testing location to complete a number of tests of that include tests of walking, strength, balance and pain pressure threshold. After that, you will be asked to wear an activity monitoring device around your wrist for 5 days and then return the device. Your time in the study will involve a 90-minute testing session followed by 5 days of wearing the activity monitor.

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 have travel costs, such as gas or bus fares, to get to and from the testing center.
You will 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 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.

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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.

Who may take part in this study and who may not?
People with HIV between the ages of 18 and 64 may take part in this study. However, people who currently have an opportunistic infection, a CD4 count of less than 200, dementia, an uncontrolled psychiatric disorder, wounds or sores on the feet, diabetes, or conditions 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, but you do not have painful neuropathy in your feet.

How long will the study take and how many subjects will take part?
The phase of the study that you are being asked to participate with will take about 6 days. Overall, the study will be ongoing for a year, but you will only be involved for 6 consecutive days.

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. These tests will be completed in about 1 hour of testing 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.

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. If you experience fatigue after the testing session, the fatigue might last for the remainder of the day. About 20% of participants in the study may experience short term fatigue during or after the testing.
You may experience muscle soreness for a day or two after the testing session. About 20% of participants in the study may experience muscle soreness for a day or two after the testing.
You may have travel costs, such as gas or bus fares, to get to and from the testing center.

Are there any benefits to me if I choose to take part in this study?
You will 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 $ 5.00 cash and a $25 gift card for taking part in this study on the day of testing.

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.

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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: _____