NCT01198977

Telehealth-Based Exercise Program to Treat Fatigue in MS (MS-FIT)

version 2.0; 6/22/09

SUBJECT NAME		**SSN:**
TITLE OF STUDY	Motivational Interviewing and Exercise Therapy to Improve Fatigue in Multiple Sclerosis	
PRINCIPAL INVESTIGATOR	Aaron Turner, Ph.D.	

LAY TITLE: MS FIT Study

Researchers:

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Toll-free number: 1-800-329-8387 + * + 6 + last 4 digits of the above telephone numbers

24-hour emergency telephone numbers: Call **911** or call the VA's toll-free number at **1-800-329-8387** and follow the instructions above. Please let the on-call psychiatrist or physician know you are in this study. The operator may contact Dr. Jodie Haselkorn for medical emergencies related to your MS or Dr. Aaron Turner if you are feeling severely depressed, anxious, or suicidal.

You are being invited to participate in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or

this form that is not clear. When we have answered all your questions, you can decide whether you want to be in the study. You are free to discuss this with friends or family. This process is called "informed consent." We will give you a signed copy of this form for your records.

1. Purpose of research study and how long it will last: Many people with Multiple Sclerosis (MS) have difficulties with fatigue. Fatigue is a feeling of physical tiredness and lack of energy that many people experience from time to time. It is one of the most common and disabling symptoms of MS. Fatigue can prevent a person with MS from doing typical daily activities. It can impact relationships with loved ones. Employment can be affected.

In this study, we would like to help people with MS-related fatigue by using an intervention involving exercise. Exercise has been a promising way to help decrease fatigue in MS. It helps reduce physical disability, improve general health, increase energy, and improve physical and mental performance. Many people with MS may find it difficult to feel motivated to exercise because of fatigue. We would like to help change this. In this study, we want to see how well a telephone-based intervention improves your motivation to exercise and reduces fatigue. If you agree to participate, you will be one of approximately 60 veterans at the Veterans Affairs Puget Sound Health Care System (VAPSHCS) in Seattle who will participate in this study. Your participation in the study will be for 6 months.

2. Description of the study including procedures to be used: This is a randomized study where you will be assigned to one of two groups: the Control Group or the Intervention Group. This type of study will help us to compare how well the intervention works in helping people create and maintain a home-based exercise plan and reduce fatigue. The intervention is the telephone-based counseling and uses a home telehealth monitor for support. We call this study a controlled trial because we assign one group to be the control and the other group to be the intervention.

We also use different methods to measure how well the intervention works in helping you exercise and reduce fatigue. Procedures we will use in the study involve written questionnaires and testing your physical mobility and cognition (memory and thinking). We will have you fill out a written questionnaire and participate in a cognitive and physical assessment at three different times: baseline (before you are randomized into a group), Month 3, and Month 6 (end of the study.) The cognitive assessment will test your memory and thinking. The physical assessment will test your physical functioning. Ms. Sloan will conduct your baseline assessment before you are randomized to a group. Month 3 and Month 6 assessments will be conducted by another study coordinator, Marisa Benich, who will not know which study group you are in.

Being in this study is not the same as your current health care because normally you would not receive the memory and thinking tests, the questionnaires, physical assessment, the exercise information and video, or the intervention. As a part of this study, we will access your VA medical record to verify your diagnosis of MS, medical history, pharmacy records, and your contact information. At the end of the study, the Control Group will be offered the opportunity to participate in

a modified version of the intervention. We will collect data for the study if you participate in the modified version of the intervention.

Screening. Before determining your eligibility for the study, we already asked you some screening questions about your age, gender, MS history and symptoms, general health, past exercise habits, fatigue, walking ability, alcohol and substance use. Based on your responses to the screening questions, you are eligible for this study if you are reading this consent form. You will be officially enrolled in the study after you sign this consent form. If you decide not to join this study, we will only include the information you have already given us during screening. We will ask why you declined to be in the study for recruitment statistics for the study.

Baseline Assessment. After consenting to be in the study, we will schedule you to do a baseline assessment at the VAPSHCS. We will have you come to the VAPSHCS again at Month 3 and Month 6. The assessment includes filling out a written questionnaire and participating in physical and cognitive testing. It should take 2½ - 3 hours each time. We will also give you a computerized ankle step monitor to wear for 14 days to assess your physical activity in your daily life. We will arrange for you to mail back the step monitor. The baseline assessment will be with Alicia Sloan, the study coordinator and counselor.

Randomization. After the baseline assessment is completed and you have returned the ankle step monitor, you will be randomized. Randomization means that you will be put into a group by chance, like the flip of a coin. You have an equal (50/50) chance of being in either the Intervention Group or the Control Group. Ms. Sloan will call you and tell you which group you are assigned to. She will then mail you the study materials that correspond with your assigned group as described in the next sections of this consent form.

Mailed Educational Packets. You will be mailed a packet of educational materials about exercise to help you plan your own home-based exercise program. Both groups will receive a DVD entitled “Get Fit for Life” and a brochure from the National Multiple Sclerosis Society entitled “Exercise as Part of Everyday Life.” Participants assigned to the Intervention Group will also receive materials for the intervention involving telephone-based counseling and using the home telehealth monitor.

Months 3 & 6 Assessments. All participants (Control and Intervention groups) will complete assessments at Month 3 and Month 6 similar to the baseline assessment (2½ - 3 hours**)** at the VAPSHCS. These assessments will be with a different study coordinator, Marisa Benich. She will be “blinded” to who is in the Intervention Group. We do not want Ms. Benich to know if you are in the Intervention Group or the Control Group, so it is important that you do not share this information. This helps Ms. Benich from being influenced while testing you during your Month 3 and Month 6 assessments. This helps our study results from being “biased” or influenced by a tester who knows which group you are in.

General Study Schedule for the Control and Intervention Groups:
(includes 3 visits to the VAPSHCS which will be 2½ - 3 hours each)

1. Baseline assessment (with Alicia Sloan): Written questionnaire, cognitive/physical functioning assessment, wear step monitor for 14 days. You mail step monitor back to Ms. Sloan.

2. Randomization (with Alicia Sloan): Ms. Sloan calls and tells you which group you are in, the Control Group or the Intervention Group.

3. Mailed study packet: Ms. Sloan mails study packet of educational materials to Control and Intervention groups.

4. Intervention begins with Ms. Sloan if you are in the Intervention Group.

5. Month 3 (with Marisa Benich): Follow-up written questionnaire, cognitive/physical functioning assessment, wear step monitor for 14 days. You mail step monitor back to Marisa Benich.

6. Month 6 (with Marisa Benich): Follow-up written questionnaire, cognitive/physical functioning assessment, wear step monitor for 14 days. You mail step monitor back to Marisa Benich.

7. Study completed: If you are in the Control Group, you can choose to do a modified version of the telephone-based intervention.

Written Questionnaire. The written questionnaire takes about 1 hour to complete and will include questions about your age, gender, and marital status. There will also be specific questions related to multiple sclerosis, fatigue, depression, motivation, pain, self-esteem, mobility, social life, health status, quality of life, and physical activity. A question about MS, for example, asks, "How many MS attacks or exacerbations have you had in the last year?" Another question related to physical activity asks, "Considering a 7-day period (1 week), how many times on the *average* do you do the following kinds of exercise for more than 15 minutes during your free time?" A question related to fatigue will ask you to rate how you feel based on this statement, "Because of my fatigue *during the past 4 weeks,* I have been less motivated to do anything that requires physical effort."

Physical and Cognitive Assessment. The physical functioning assessment will take about 1 hour to complete. We will measure your walking ability at different distances and time periods. You will be observed and timed with a stop watch during these assessments. We will also measure your home activity level by having you wear a computerized ankle step monitor for 14 days during the day. We will download the activity information from the step monitor into our computer. We will be able to see the number of steps indicating the amount of physical activity you do during a typical day.

The cognitive assessment will measure your thinking, memory, and processing information. One test, for example, will ask you to think of certain words while being timed with a stop watch. Another test will ask you to do simple math calculations while being timed.

Control Group

If you are assigned to be in the Control Group, you will not receive the intervention (telephone-based counseling and home telehealth monitor). You will receive the packet of educational materials and video about exercise as described above. You will also participate in the Month 3 and Month 6 assessments (written questionnaire and cognitive/physical assessments). At the end of the study, the Control Group will be offered the choice to participate in a modified version of the intervention. The modified version includes four sessions of telephone-based motivational counseling. There is also a short questionnaire during the fourth session about exercise, fatigue, vitality, and depression. Data from these sessions will be included as part of this study. Home telehealth monitoring will not be included.

Intervention Group

If you are assigned to be in the Intervention Group, you will receive the same packet of educational materials and video about exercise as the Control Group. You will also participate in the same Month 3 and Month 6 assessments (written questionnaire and physical/cognitive assessment). In addition, you will receive the intervention. Your mailed packet of information will include handouts for the telephone counseling with the study therapist, Ms. Sloan. The telephone counseling sessions will help you develop and maintain a home exercise plan. You will also use a home telehealth monitor to answer questions each week. You will work with Lore Martz, RN, coordinator of the Care Coordination Home Telehealth (CCHT) program at the VAPSHCS. She will train you to install and use the telehealth monitor in your home.

Telephone-Based Counseling Sessions. The Intervention Group will receive six weekly telephone-based counseling sessions with Ms. Sloan, the study counselor, and a home telehealth monitor to answer weekly questions about the exercise plan you will develop with the study counselor. Telephone counseling will provide customized feedback and support using principles of a counseling technique called motivational interviewing. During the counseling sessions, Ms. Sloan will help you explore and plan a home exercise program. Exercise goals and activities will be determined on an individual basis. Ms. Sloan will give additional telephone support to you if you need extra help with meeting your exercise goals.

Intervention - Home Telehealth Monitoring. We will have you answer weekly questions about exercise using a home telehealth monitor. The study counselor will be monitoring your answers. She will also send you personalized motivational text messages through the monitor during a 6-month period. The home telehealth monitor is called the Viterion 100 (V100) made by the Viterion/Bayer

Company. The V100 Monitor is a portable and lightweight device about the size of an answering machine. It uses a traditional “landline” telephone line and power outlet to transmit information.

Each week during the 6-month study period, the monitor will light up when it has questions for you to answer. The questions show up like a text message on a cell phone or an ATM machine. The answers will be yes or no, or multiple choice. One question, for example, will ask, "Did you meet your exercise goal for the week?" Other questions will be related to the response of your previous question. If you answered “No” to the question, “Did you meet your exercise goal for the week?” the next question may ask, "Since you weren't able to exercise as much as you planned this week, what got in the way?" Then, you would push a button for your answer choice.

Answers are stored in the monitor like in a hard drive of a computer. When you are ready to send your answers, you push the button that forwards the information through the telephone line like email. The information is sent to a secure website through the VA computer system monitored by Alicia Sloan, the study therapist. When Ms. Sloan checks the website, she can see how you answered your questions that week. After reviewing your answers, she can respond in one of the following ways: 1) she can send you a customized follow-up question that you will see on your monitor; 2) she can send you a message of encouragement; or 3) she can call you on the telephone.

Intervention - Telephone Counseling Schedule (Alicia Sloan)

NOTE: The telehealth monitor will be ordered and mailed to you during the first few weeks of the intervention.

Session 1: Graphic feedback. Set exercise goals.

Session 2: Telephone counseling. Problem solve installation of telehealth monitor. Incorporate answers from monitor, if possible.

Session 3: Telephone counseling. Review exercise goals.

Session 4: Telephone counseling. Review exercise goals.

Session 5: Telephone counseling. Review exercise goals.

Session 6: Telephone counseling. Review exercise goals.

Additional sessions, if needed by participant.

3. Description of any procedures that may result in discomfort or inconvenience: The physical testing may be physically stressful. Physical testing will involve walking for 6 minutes (the 6-Minute Walk) and walking around cones set 25 feet apart for 3 minutes (the 25-Foot Walk). You may experience fatigue and mild discomfort during or after the in-person physical assessments.

You may not like wearing the ankle step monitor for 14 days. You may feel self-conscious wearing the ankle monitor. You may feel uncomfortable because you are being measured for physical activity.

You may feel stress during the cognitive testing since it involves testing memory and thinking. You may feel nervous or put "on the spot." While doing the telephone counseling, you may have difficulty being on the telephone for a long period of time.

You may feel some stress or discomfort while filling out the written questionnaire. The questionnaire includes questions about depression, substance abuse, alcohol use, and suicide. One question, for example, will ask if you have been bothered by thoughts that you would be better off dead or of hurting yourself in some way. You may decide *not* to answer some or all questions.

4. Potential risks of the study: Potential risks of the study may be related to new or increased levels of exercise. If you are in the Intervention Group, you may be at an increased risk of physical discomfort. You may experience sore muscles and/or fatigue at first from an increase of exercise. The study counselor will help you monitor your exercise.

At the first sign of major discomfort or injury, we will want you to contact the study counselor as soon as possible. She may refer you to Dr. Jodie Haselkorn or an MS Clinic provider. Dr. Haselkorn is the director of the MS Clinic and a physician who specializes in physical rehabilitation and multiple sclerosis. She or a MS Clinic provider can evaluate your injuries and refer you to further care if necessary. For emergencies, we will want you to go to your nearest emergency room or call 911. Other risks may involve emotional stress, especially if you participate in the intervention. If you are in the Intervention Group, you may feel stress during the telephone-based counseling sessions while talking about motivation and exercise issues. You may feel that home monitoring with a telehealth monitor is an invasion of privacy. You may not be used to exercising. You may feel more tired after a telephone counseling session or after exercising. When exercise is new or increased, you may feel sore muscles and fatigue until your body is used to the new program.

If we feel it is important for you to talk with someone in addition to the study therapist, we may ask Dr. Aaron Turner, the psychologist working with the study, to talk with you. If you tell us that you are feeling suicidal, Dr. Turner will need to ask you some additional questions to make sure that you will be safe. If you have a medical emergency related to your MS or other medical problems, we will ask Dr. Jodie Haselkorn, the physician working with the study, to address these issues. If necessary, we may need to work with your home caregiver during a medical or mental health emergency. The study coordinator, Alicia Sloan, is also a trained social worker and therapist who will be available if you have any concerns. She can help coordinate medical emergencies and/or contact Dr. Haselkorn.

Any significant new findings developed during this research, which may relate to your willingness to continue, will also be provided to you.

5. Potential benefits of study: This study may provide you with new strategies and increased support for doing a home-based exercise program. It is possible there may be no direct benefit to

you while participating in the study. We hope this study will help us to improve patient care for other people with MS.

6. Other treatment available: No alternatives to participation in this study are currently available in the MS Clinic. You may decide you do not want to participate in this study. The alternative to taking part in this study is to not participate and continue with your usual care. The MS Clinic does not provide any other exercise programs at this time. We can refer you to other VA exercise-based programs if you decide not to participate in this study. Your decision to participate will not affect your health care at the MS Outpatient Clinic or VA Puget Sound Health Care System.

7. Use of research results/Confidentiality: Although the information obtained about you during the research study will be kept confidential, the following people or groups may know that you are in this study and have access to identifiable data about you: the research team members; Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research); federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), and the VA Office of the Inspector General (OIG); and the VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies.

The purpose of this access is to review the study and make sure that it meets all legal, compliance, and administrative requirements. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to appropriate authorities. Once this study is completed, we will not use your data (or the study code linking it to you) for any additional research.

If you are in the Intervention Group, answers you provide to the telehealth monitor will only be viewed by the study staff and by the Care Coordination Home Telehealth (CCHT) staff unless it is something that your doctor should know about to help take care of you. The CCHT staff will also enter general notes in your medical record in the computerized patient record system (CPRS) when you are assigned to a home telehealth monitor. Monthly notes will also be entered in your chart while using the monitor by the study therapist as a requirement for CCHT. Your answers from the home telehealth monitor may be transferred to your VA electronic medical record by the study therapist if it seems necessary for the information to be accessible to your other VA providers. The study therapist will discuss this with you as necessary.

Information extracted from the telehealth monitor, your medical record, and telephone interviews will be stored in locked filing cabinets and on password-protected computers available only to official project staff. The company Viterion/Bayer that makes the monitor also has the ability to see your information on the VisNet website. We will be requesting from Viterion/Bayer to extract the data from

the website to include in our data analysis. They will transfer the data using a protected computer disk or other technology approved by the VA.

If you are in the Intervention Group, each telephone counseling session will be digitally audio taped by Alicia Sloan, the study counselor. A digital audio tape is a computerized tape recorder that saves your voice recording as a computer file. We audio tape in order for the principal investigator, Aaron Turner, to verify the counseling sessions are following the study protocol and to advise the study counselor. Dr. Turner will review the audio files to rate and provide feedback to Ms. Sloan. Only Ms. Sloan and Dr. Turner will have access to the computer audio files. These files will be de-identified by using your assigned study code by Ms. Sloan as the computer file name and will not contain your name, social security number, or other identifying information. The audio files will be stored on a secured computer server protected by a VA firewall in password-protected folders accessible only to Dr. Turner and Ms. Sloan.

Please note that your voice is technically identifiable according to HIPAA patient privacy rules, so we will do everything possible to protect your voice identity. The digital recorder will only be used within the VA Seattle facility in a private clinical room during your telephone counseling sessions. The recorder will be hand-carried by the study therapist from her locked office area in Building 1, Room 424, to a designated clinical room. It will be kept in her locked desk when not in use.

All study materials and equipment, including filing cabinets and computers, are located in private secure offices at the VAPSHCS in Building 1, Room 424. Your name and social security number will be stored in a different place from your de-identified study information with your study code. Your study code is a unique number assigned to your study data, like “101, 102, 103, etc.,” which is not related to your identity in any way. It is a way for the study to keep track of your study data without revealing your identity to protect your privacy.

Your study code will be held in a secure database until VA receives authorization to destroy the data file that links your data to your study code in accordance with federal records regulations. It may be several years before the study code is actually destroyed, but it will not be used for research after this study is completed. After this link is destroyed, no one will be able to link your name or social security number to your study code. We will retain all other study data forever.

We will also keep your signed consent form on file forever. Only study team members will have access to your study data except when required for VA audits as described previously. We may store your study data at an official VA designated confidential locked storage facility offsite when storage becomes limited in our office space at the VAPSHCS. In this case, only designated VA staff will have access to your study data.

Because we are interested in your health over time, we may contact you before 01/01/2019 to ask you for more information. We may ask you to participate in additional studies. We may want to add information about you to what we already have. You don't have to be in another study just because

you were in this study. You will be asked at the end of this consent form if you are willing to be contacted for future studies by the VA Multiple Sclerosis (MS) Center of Excellence. If you agree to participate in a future study, we will ask you to sign another consent form.

The results of this study may be published, but your identity will not be revealed in any publication without your written permission.

Your study information will be used only for research purposes and will not be sold. Information gained from this research may be used commercially for the development of new ways to diagnose or treat diseases. However, neither you nor your family will gain financially from discoveries made using the information that you provide.

8. Special circumstances: You will be paid:

- $30 for the baseline assessment
- $30 for the Month 3 assessment
- $50 for the Month 6 assessment

This is a total of $110 for the entire study for three in-person appointments. The VA will either mail you a check or auto-deposit the amount to your checking account if you have this already set up with the VA. This takes about 4 weeks after each visit.

The VA is required to report to the IRS as taxable income all payments to an individual subject totaling $600 or more in a calendar year. Your name, social security number, address, and amount of payment will be provided to the IRS.

You will not be charged any fees related to using the Viterion 100 TeleHealth Monitor while participating in this study. If you are sent a bill by mistake, we ask you to contact Alicia Sloan, the study coordinator, at the phone number or address listed in this consent form.

If you are a VA patient, you already have a VA medical record. If you are not a VA patient, we will create a VA medical record for you. We will put information about you from this study into your medical record. All authorized users of the national VA medical records system can have access to your medical record. This may include health insurance companies who are being billed for medical costs. This record will be kept forever.

Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to any of your medical care and services provided by VA that are not part of this research study.

9. Withdrawal from the study: You do not have to take part in this study and you are free to withdraw at any time. Your decision to not participate or to withdraw will involve neither penalty nor loss of VA or other benefits to which you might be otherwise entitled.

Your participation may also be terminated without your consent if your doctor feels that it is in your best interest. For example, if you were injured during the study, we would work with you and your providers whether continuing the study is appropriate. Whether you choose to withdraw or the study doctor withdraws you from the study, the consequences of your withdrawal from the research, if any, and procedures for an orderly termination of participation will be discussed with you by the study physician and staff.

10. Questions or concerns related to the study: If you have any questions about the availability of medical care or if you believe you have experienced a research-related injury as a direct result of participation in the study, you should immediately contact:

During business hours (8:00 a.m.-4:30 p.m.)	Call Dr. Jodie Haselkorn at 1-800-329-8387, Ext. 63452 or the study coordinator, Alicia Sloan, at 206-277-3593 or 1-800-329-8387, Ext. 63593
After business hours (nights and weekends)	Call (206) 762-1010 and ask the operator to page the on-call physician. You may tell the on-call physician that you are in this study and to page Dr. Jodie Haselkorn.

You may contact the Institutional Review Board (IRB) – VA Office at (206) 277-1715 if you:

- Wish to contact an impartial third party not associated with this study;
- Have questions, concerns, or complaints about the research;
- Would like to verify the validity of the study; or
- Have questions about your rights as a research subject.

11. Research-related injury: The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

The VA will pay for reasonable non-reimbursed medical expenses you may incur as a direct result of participation in the study. The VA has not set aside any additional funds to pay for things such as lost wages, lost time, or discomfort due to research-related injury. The VA is not obligated to reimburse medical expenses due to your non-compliance with study procedures as described in this consent form or otherwise communicated to you by study personnel.

You do not waive any legal rights by signing this consent form.

12. Research subject's rights: I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts, possible benefits of the study, and other choices of treatment available to me. My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

I agree to participate in this research study as you have explained it in this document.

_____ _____
Subject Signature **Date**

_____
Print Name of Subject

_____ _____
Witness Signature **Date**

_____
Print Name of Witness
(Witness only to subject signing the consent form)

_____ _____
Signature of Person Obtaining Consent **Date**

_____
Print Name of Person Obtaining Consent