Informed Consent Form

Qigong for Multiple Sclerosis: A Feasibility Study

NUNM IRB#: 102015

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Participant Informed Consent

Title of Study: Qigong for Multiple Sclerosis: A Feasibility Study

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Student Investigator: Lita Buttolph, PhD (503) 552-1886

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What is the study about?

The purpose of this study is to determine whether qigong (pronounced "chee gung") is a feasible and effective exercise for people with multiple sclerosis (MS). Qigong is an ancient Chinese movement art that combines gentle movements, visualization, breath-work and meditation. Studies have shown qigong to improve balance and quality of life for other neurological disorders, such as Parkinson's disease and fibromyalgia. The objectives of this study are to 1) assess whether people with MS are able to participate in a 10-week course of community qigong classes, and 2) determine if qigong improves balance, mobility, and quality of life for people with MS.

We will recruit 20 adults who have a medical diagnosis of MS. Of these, half will be randomly assigned to a group that attends community qigong classes and the other half to a control group that does not do qigong. The control group will be offered qigong classes after a waiting period.

You have been invited to be a part of this research study because you (1) have MS, (2) are able to walk 50 feet without assistive devices, (3) have not had a change in your disease-modifying medications for MS (like AVONEX or TYSABRI) or for balance within the last 3 months, and (4) are willing to complete the written surveys and physical tests at the beginning and end of this study. If you have any of the following conditions or experiences, you will not be eligible for this study:

- Pregnant or nursing
- Physical or mental illnesses that would prevent attendance and participation in qigong classes
- Any regular qigong, tai chi or yoga practice once a month or more within the past 6 months
- MS relapse 30 days prior to the baseline study visit

How long will I be in the study?

Your part in the study will last 3 months (12 weeks). If you are assigned to the control group, after the 12 weeks you will be given the option of joining a second 10-week qigong group, making your total time involved 23 weeks, if you so choose.

What will happen in the study?

This study consists of 2 to 3 study visits and weekly qigong classes for 10 weeks. Study visits will take place at the Helfgott Research Institute located at 2220 SW 1st Avenue, Portland, OR 97201. Qigong classes will be held at four different locations in the Portland area. You will be able to select from these pre-screened community qigong classes to find the time, location, and style of qigong that is right for you. These classes are open to the public and will include people not enrolled in this study.

If you are interested in participating in this study, you will be asked to come to an initial screening/baseline study visit to complete a series of surveys and physical tests. This visit will determine your eligibility for participation. After this initial visit, if you are eligible, you will be randomly assigned to either a qigong group or a control group. Because this is a randomized study, neither you nor the investigators can choose whether you are selected to be in the qigong group or the control group. You should only join the study if you are willing to participate in either study group. A copy of this consent form will be emailed or mailed to you for your review at least 24 hours prior to Visit 1.

<u>If you are assigned to the qigong group:</u>

You will be sent a list (either by mail or email) of qigong classes, styles and instructors that have been approved for this study. Based on this list, you will select a class to attend for the 10-week study. If you would like help choosing a class, you may contact the instructors directly or go to their website to get more information about their classes and qigong style. You will be asked to participate in qigong classes once a week for 10 weeks. Each class will be 60 to 90 minutes long and led by an experienced instructor. You will have the option of performing the movements in a standing or seated position, depending on your level of ability and comfort. If you are unable to physically perform a movement, the instructor will encourage you to visualize doing the movement. You may also choose not to do any movement you do not want to do.

If, after the first class, you find that the instructor or the studio is not a good fit for you, you can switch to a different class. You will only be allowed to change instructors one time at the beginning of the study. A member of our research team will phone you after weeks 1, 2, and 7 to see how the classes are going for you.

If this new class is still not a good fit for you, you may drop out of the study at any time. If you decide to drop out of the study, we will ask you to complete an exit survey to help us improve future studies. At the end of the 10 weeks of qigong, you will be asked to come to a second study visit and retake the surveys and tests done during the baseline visit.

You will also be encouraged to practice what you have learned in class at home, and document the time you spent practicing in a home practice log that we will provide for you.

If you are assigned to the control group:

We will ask that you do not do any qigong, tai chi or yoga for the initial 12-week period of this study. You will be asked to complete the two study visits at Week 1 and Week 12, during which you will complete several surveys and three short physical tests. At the end of the 12 weeks, you will have the option of joining a qigong study group, in which you will participate in 10 weeks of community qigong classes as described above. At the end of the 10 weeks of qigong you will be asked to complete the surveys and tests again. This will be a repeat of weeks 2-11 of the study. A staff member will contact you, as was done for the initial intervention group.

Study Timeline

Study Visit 1: Screening and Baseline (Week 1 of the study)
This visit will last about 90 minutes and consist of the following:

- Review this consent form with the study coordinator, Lita Buttolph, so that any questions you have can be answered. If you agree to be in the study, you will need to sign this consent form. You will be provided with a copy of the signed consent form.

- Complete the Timed 25-Foot Walk Test (walking 25 feet and back). This test is to determine your eligibility for this study. If you are able to complete this test without the use of an assistive device, you will be asked to complete two additional tests: the Four Square Step Test (stepping into adjacent squares); and the Timed-up and Go (standing up from a seated position and walking 10 feet and back to seated). Each of the three tests will be administered by Lita Buttolph or Angela Senders, and each will generally take 1 to 5 minutes to complete.
- Complete a demographic questionnaire.
- Complete a series of on-line surveys about your current health. We will provide a computer for you to complete these surveys. If you need assistance, the study coordinator will be available to help you. It generally takes about 20 minutes to complete all of the surveys. Surveys include questions about physical function (including balance, mobility, range of motion, fatigue) and mental health (including anxiety and depression).

Weeks 2-11 of the study

- If you are assigned to the qigong group you will attend one community class per week for these 10 weeks. These classes will last between 60-90 minutes. You will be strongly encouraged to practice qigong between classes and to record your home practice in a diary we provide for you.
- If you are assigned to the control group, you will continue your usual activities and care while refraining from any qigong, tai chi or yoga.

Study Visit 2 (Week 12 of the study)

This visit will last about 60 to 90 minutes and consist of the following:

- Repeat the surveys completed at Visit 1.
- Repeat the three physical tests completed at Visit 1.
- If you were in the qigong group, you will complete an exit questionnaire at this visit.
- If you were in the control group, you will be invited to join a new qigong group. If you decide to join this group, you will participate in 10 weeks of qigong classes followed by a third study visit. If you decide not to join the qigong group, you will be asked to complete an exit questionnaire at this visit.

Study Visit 3 (Week 23 of the study – only for control group participants that continue with qigong)
This visit will take about 60 to 90 minutes and consist of the following:

- Repeat the surveys completed at Visit 1.
- Repeat three physical tests completed at Visit 1.
- Complete an exit questionnaire.

If you are eligible and wish to join the study, you must sign this consent form. If you do not sign the consent form you cannot join the study.

We will review this consent form with you at your first visit. You will be given enough time to review the consent and have all your questions about the study answered. We will give you a signed copy of the consent for your records at your first visit.

Table 1. Study related activities.

	Visit 1 - everyone	Qigong group only	Visit 2 - everyone	Qigong for control group	Visit 3 – control group only
Week #:	1	2-11	12	13-22	23
Review consent form and sign if agree	x				
Complete written and online surveys	x		x		x
Complete physical tests	x		x		x
Attend qigong classes (once/week)		x		x	
Log home qigong practice		x		x	
Complete exit questionnaire			x		x
Expected visit length (hours)	1 – 1.5		1 – 1.5		1 – 1.5

What if I have questions?

You can contact Lita Buttolph, the study coordinator, at (503) 552-1886 if you have questions about the study. You may also contact Dr. Angela Senders, Principal Investigator, at 503-552-1743 if you have questions about the study.

Do I have to be in the study?

You decide if you want to be in the study. Deciding not to take part will not affect your relationship with your medical provider or NUNM. If your health care provider is an investigator for the study, you may get a second opinion from another doctor not involved in the study.

You can leave the study at any time and you do not have to give a reason. Leaving the study will not affect your relationship with your medical provider or NUNM.

If you are an NUNM student or employee, this study is completely voluntary. Your decision to not participate or to leave the study will not affect your relationship with NUNM.

The study investigators may ask you to leave the study if it is in your best interest. The study investigator may ask you to leave the study if you do not follow the study rules. If you become pregnant during this study, you will no longer be eligible to participate in this study. Please contact the study coordinator in this case.

What if I don't want to be in the study?

You can choose not to be in the study and you do not have to give a reason. You can choose to talk to your doctor about other options, or investigate outside resources on your own.

Are there any costs?

There are no specific costs to you other than your transportation and your time. All study-related qigong classes are provided to you free of charge.

Will I be paid for being in the study?

You will not be paid for being in the study.

Are there any risks?

There is always a small risk of a breach of confidentiality to your personal health information. However, these risks have been addressed and minimized as much as is possible. We have specific protocols for protecting your privacy. See the privacy section below for details.

Some people may experience pain or discomfort when performing the physical tests or the qigong exercises. There is also the potential for falling. The study coordinator will help minimize any discomfort and risk of falling during the physical tests by encouraging you to move at your own pace and comfort level, and by providing physical support if needed. The qigong instructor will encourage participants to move within their own range of motion to prevent discomfort or injury. You can always choose not to do any movements that are uncomfortable or difficult for you.

Some survey questions may seem personal or embarrassing. You do not have to answer any questions that make you uncomfortable.

There could be risks that we are unaware of at the time of the study. You will be told about any new information that may affect your willingness to participate in the study.

If you experience any difficulty or problems while on the study, contact study coordinator Lita Buttolph at 503-552-1886 or principal investigator Dr. Angela Senders (503-552-1743) as soon as possible.

What if I feel I've been hurt by taking part in the study?

If you feel you have been injured or harmed by taking part in this study, please contact Dr. Angela Senders at 503-552-1743. If you feel you were harmed while taking part in this study, you may be treated at NUNM. However, NUNM does not offer to pay the cost of this treatment.

If you feel your rights have been violated or you have been harmed by this study, please contact the NUNM Institutional Review Board at 503-552-1847.

Are there any benefits?

It is possible you may receive some benefit from participating in qigong classes. There is no guarantee, however, that you will receive any benefit at all. Your participation will help us learn more about how qigong affects people with MS.

Your privacy is important

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law to protect your privacy. Protecting your privacy is very important to us.

During this study we will ask you to provide demographic information about yourself, and questions related to your current health status, including quality of life, balance, mobility, fatigue, and mental and emotional health. We will collect this through paper surveys, online surveys and physical exams. This information will be used to determine your eligibility for the study and provide data for the study. Your personal health information will be kept private and only authorized study staff will have access to this information. Your name will not be associated with any information we collect from you. We will use a study number instead of your name on any data that we collect from you, including survey responses, demographic information, and physical tests. All paper forms will be kept in a locked file cabinet in a locked office. All electronic data will be stored on password-protected computers. Your personal health information will not be associated with any information that is collected from surveys administered on-line. Your name will not be used in any publications or presentations about this study.

During the study, you may not be given access to medical information about you that is part of the study. When the study is over, you may request certain medical information collected about you that is part of your study medical record.

None of your personal information will be shared outside of NUNM**.**

By signing this consent form you are stating that we can use your health information in the ways mentioned above for this study. You are not waiving any of your legal rights by signing this form.

You have the right to take away your permission to use your health information as part of the study. In order to do this you must send a written request to:

Dr. Angela Senders
Helfgott Research Institute
National University of Natural Medicine
2220 SW 1st Avenue
Portland, OR 97201

Once your letter is received no additional information about you will be collected from you for this study. Any data that were collected before we receive your letter will continue to be used for the study. Taking away your permission to use your health information will not affect your relationship with NUNM.

We are collecting only the personal health information that we need for the specific purpose of this study. Your personal health information cannot be used for additional research purposes.

NUNM may be required to provide copies of your personal information to Federal or other government agencies as required by law. It may also be required to provide copies to the Institutional Review Board (IRB) or other groups that monitor the safety and welfare of study participants.

If your personal health information is disclosed by this authorization to an individual or agency not covered by laws that prohibit re-disclosure, your personal health information may not remain confidential. However, Oregon law does not allow redisclosure of HIV/AIDS information, mental health information, genetic information, and drug/alcohol diagnosis, treatment, or referral information.

Your permission to use your identifiable health information (your HIPAA authorization) will expire when the study is complete.

Participant's Initials: _____

Consenter's Initials: _____

Signatures:

By signing this consent form it means the following:

- I know my rights have not been waived by signing.
- I have had all of my questions answered and I know whom to ask if I have more questions.
- I have read this form and understand it.
- I want to join the study.
- I know I can leave the study at any time and do not have to give a reason.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Consenter Date

_____

Printed Name of Consenter

Thank you for participating in our research study!