

Title: Tai Chi via DVD instruction as an introduction to physical activity for women with morbidly obese: a feasibility study

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Clinical Trial Registration Number: NCT04106661

Informed Consent Form

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Husson University Physical Therapy Program
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CONSENT FOR RESEARCH AND TREATMENT

PARTICIPANT NAME:

DATE OF BIRTH:

INVITATION TO PARTICIPATE:

You are invited to take part in the research project identified below because you have a body mass index (BMI) greater than 40.

PROTOCOL NAME: The addition of Tai Chi to regular physical activity in participants who are morbidly obese: impact on health, function, and quality of life.

INVESTIGATORS:

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PURPOSE OF STUDY: Physical activity is an important part of losing weight and getting healthier when you are morbidly obese. There are many different types of physical activity that can help people lose weight, improve their balance and make them feel better about themselves. However, the best type of activity for morbidly obese people is not known. Daily physical activity has been recommended by EMMC Medical Weight Management program and other weight management programs. Our group would like to find out whether slow, controlled movements, such as those done in Tai chi, in addition to regular daily activity, would result in improved function and health. We would also like to know if these activities would be something you will be able to continue on your own into the future.

PROCEDURES: If you are interested in being a part of the study, we will ask you to provide us with some basic information about you. You will then be asked to perform a balance test to make sure you can safely perform the exercises at home. This screening test is called the Four Square Step Test (FSST). It involves placing a grid constructed of one inch PVC pipe on the floor in a cross pattern. You will be asked to step over the canes in a specific order. Your performance will be timed while a researcher stands by to make sure you don't fall. If you are able to do this in a designated amount of time without any loss of balance, you are expected to be able to perform the exercises safely, and you may continue to participate in the research.

Additionally, to be included in this study you must:

1. Have a body mass index of >40 .
2. Have a means to get to Husson once a week for 8 weeks for a supervised exercise session
3. Have a DVD player available for home use and a place to exercise while watching the DVD.
4. Not be at high risk for falls, as determined by our pretesting.

You may not participate in this study if you have any neurological conditions such as stroke, Parkinson's disease, multiple sclerosis, or if you have any heart conditions that would prevent you from participating in an exercise program. Also, you may not participate if you have any painful conditions that would prevent you from exercising or from walking, or if you have had weight loss surgery within the last year.

If you are safe to continue with the study, you will be placed into one of the following groups, based on the order in which you contact us:

- Group A: Regular daily physical activity
- Group B: Regular daily physical activity and participation in Tai Chi exercise group

Everyone will have some measurements taken prior to starting the activity program. We will then ask you to perform several tests involving your balance, walking ability, and strength. These tests include the following:

- 30 Second Sit to Stand: This test will start with you sitting in a chair without armrests. You will be asked to rise from the chair and sit back down as many times as you can in 30 seconds. This will be done without the use of your hands if possible.
- 6 Minute Walk Test: This test will see how far you can walk in 6 minutes. You will be able to rest as much as you need to during the 6 minutes. You will also be able to use a walking aid if needed.
- You will be asked to walk down a 20-foot walkway so that we can record what your walking pattern is like. This recording will not be saved; only the numbers that show us your walking pattern will be saved.

- Time you can stand on one foot with eyes open and eyes closed will be measured.

We will also perform a standard health assessment and measurements including taking your blood pressure, heart rate, and weight. You will be asked to complete a survey that asks your opinion concerning your quality of life and one that asks about your activity level.

If you are assigned to Group A, you will be encouraged to perform your regular physical activity, according to the instructions you have been given by your weight management program for 8 weeks. After you have completed this for 8 weeks, and you have completed the second session of measurements with us, you will be given a copy of the Tai Chi DVD and offered participation in a 4-week supervised exercise group. This is not part of the study, but is simply an added bonus we are offering you.

If you are assigned to Group B, you will be taught to perform Tai Chi as a form of exercise. Tai Chi started in China as a form of martial arts. It involves graceful movements performed in a focused manner with deep breathing. The different movements that we will use in the study were designed for people with joint pain. Avoiding pain and protecting your joints will be closely watched. This group will be asked to come to group exercise sessions 1 time per week for 8 weeks. These sessions will be supervised to provide feedback to make sure you are safe with the exercises. You will also be provided with a DVD of the same Tai Chi program to take home. You will be responsible for doing the Tai Chi exercises with the DVD at home for 2 more sessions during each week. In addition, you will be walking daily for exercise.

All participants will be asked to complete an activity log daily so we can keep track of how often and how much activity is done during the 8 weeks. At the end of the 8 weeks, you will be scheduled to return for one additional session to repeat the balance, walking, and strength tests that you did before you started the exercises. We will also take the other health measures that were collected in the beginning. Your daily activity log will also be turned in at this time. The survey concerning your quality of life will also be repeated.

DURATION OF STUDY: Your participation in the study will take place over a 10 week time frame. The first week will involve the screening visit. If you are in group B, that will be followed by 8 weeks in a row of the supervised exercise sessions and exercises at home. The final week will involve the last visit where you will repeat the tests and measures. Each exercise session is expected to last from 45 to 60 minutes. The testing sessions will last up to 60 minutes. All testing sessions and exercise sessions will take place in the research lab at Husson University in Bangor, Maine or at the location where you attend the weight loss program.

You may be asked to participate in follow-up studies in the future to check on your physical activity status and ongoing participation in exercise. These follow-up studies may ask you to return to the Husson University campus to perform the tests and measures again. These follow-up studies could be up to 5 years from the completion of the initial study.

RISKS AND DISCOMFORTS:

Most of the exercises will be done while you are standing up. This places you at a risk for falling. The screening test will help us determine if your balance is good enough for you to perform the standing exercises safely. The exercises are not designed to be so difficult that they would cause you to fall. In addition we will recommend performing the exercises near a sturdy chair or counter when you are at home. There will be several researchers including a licensed physical therapist supervising while you are doing the exercises during the on-site sessions. They are all trained to guard you should you need it. They may also modify some of the positions or exercises to make them safer for you.

You should stop exercising if you are short of breath, dizzy, have leg pain, chest pain, or joint pain. These might indicate that the exercise you are doing is too intense for you. We do not expect this to happen with the type of exercises we are including in this program, and if you limit the intensity of your exercise to what is considered “somewhat hard”.

Due to the physical nature of this study, it is possible that you could experience muscle soreness from the exercises. This is a natural response of the body when new demands are placed on it. This soreness should not last longer than a few days. We will incorporate stretching exercises which will help prevent some of this soreness. There is also a risk of joint pain from some of the exercises as well. The Tai Chi program we selected is designed by a physician and is specifically designed for people with arthritis. Modifications can be made during the supervised sessions if you experience joint pain. Your body positions will also be monitored during the supervised sessions for both groups to make sure you are using good body position and form. A licensed physical therapist will be present during all on-site exercise sessions for consult and supervision.

POTENTIAL PSYCHOLOGICAL RISKS: This study may involve treatments or procedures not routinely given. It is possible that there may be some psychological stress from being in a study. If you are experiencing any psychological stress related to the study please let us know. You should contact the researchers for possible referral should you experience any psychological stress. You would be responsible for any additional cost of care.

PREGNANCY: Due to increased risk of injury during pregnancy, you will not be able to participate if you are pregnant while attending the exercise sessions.

BENEFITS: There are many proven health and psychological benefits to exercising. By participating in this study, you may improve your strength, balance, and mental health. In addition, you may experience weight loss and improvement in heart function. The benefits of this study will go beyond the group involved and may provide guidance and exercise recommendations for others who are overweight.

ALTERNATIVES: The physical activity recommended by the weight management program involves a physical activity program. If you choose not to be a part of this study, that option would be available to you. However, there are many other forms of physical activity that could

be helpful with weight loss and improved health. Supervised exercise classes are available at fitness centers and the YMCA. Aquatic therapy is an option for decreased stress on the joints. Aerobic exercise using stationary bicycles, treadmills, and elliptical machines is available for home or use in fitness centers. No structured or planned physical activity is another option, but this will not help with weight loss or physical fitness goals.

NEW INFORMATION: We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. It may be necessary to contact you at a future date regarding new information about the treatment you received. For this reason, we ask that you notify Husson University Physical Therapy Program of any changes in address.

COSTS: There will be no charge to you for the exercise sessions or collection of medical information performed at Husson University in regard to this study. You will be provided with the Tai Chi DVD at no cost to you. You may need to have internet access or a DVD player during the study. This cost will not be reimbursed to you.

In case of injury resulting from this study, emergency treatment is available but will be provided at the usual charge by the medical provider. No funds have been set aside to compensate you in the event of injury.

FINANCIAL COMPENSATIONS: There will be no financial compensation for participation.

FINANCIAL INTERESTS: This research project is partially paid for by Husson University Research Fund. This fund will cover the cost of supplies only. Husson University and the researchers have no financial interest in this study.

CONFIDENTIALITY: Any information collected for this research which could be identified with you will be kept strictly private. The researchers will know your identity because they are administering the tests and supervising the exercise sessions, however they will keep your identity confidential. Each participant will be given an identification code, and the data will be stored and analyzed by code. Only the primary investigators will have access to the code, which will be kept in hard copy in their locked offices, and will also be stored on their password protected computers for 5 years. Study results may be presented at scientific meeting or in educational settings, but the results will only be discussed as group outcomes (no individual scores will be reported). No one will be able to relate any individual scores on any of the tests to a specific participant.

Any data created and collected on paper by this study will be kept in the locked offices of the primary investigators. The paper data will be transferred to computers of the primary investigators, which are password protected. When the data are transferred to the computers, only the numerical codes will be used, so even if there were a breach of the computer, no one would be able to figure out that the data was associated with you personally.

Representatives of the U.S. Department of Health and Human Services, the EMMC Institutional Review Board, and the Husson University Institutional Review Board may look at your records to review the results of this research.

If you are part of the EMMC Medical Weight Management Program, your records may be made available to your physician(s) in the future for medical care at EMMC.

The information collected in this study may be printed in scientific magazines. This information may be presented at scientific meetings. Your identity will be kept strictly private.

COMPENSATION FOR INJURY: No payment will be provided for injury resulting from the experimental nature of the research. You should contact the investigator(s) to explain to you what treatments are available if you are injured. Any medical treatment will be your responsibility. This does not take away your rights in the event of negligence.

VOLUNTARY PARTICIPATION: Your participation in the study is voluntary.

You may refuse to take part in the study. You are also free to withdraw from the study at any time. Neither choice will influence your physicians against you in any way.

You may stop taking part in the study without penalty or any loss of benefits to which you are entitled. Information on important new findings occurring during the course of the research will be given to you.

You may take back this consent at any time whether there has been a change in circumstances or not.

WITHDRAWAL FROM THE STUDY: If necessary, for your safety or for other good reason, your physician or researcher may remove you from the study at any time. If this happens, your physician or researcher will explain why you may no longer take part.

QUESTIONS:

If you have questions, please ask.

If you think of questions later please contact the investigator. If you think you have a research-related injury, please contact the investigator(s).

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If you have questions about your rights as a research subject, please call the office of the Institutional Review Board at EMMC at 207-973-7906 or at Husson University at 207-992-1976 (Roger Phipps). The Institutional Review Board is a group of people who review the research to protect your rights.

- You are voluntarily making a decision whether or not to take part in the research study described above.
- No guarantees are made to you about the result of the study or your care.
- Your signature indicates that you have agreed to take part in the study having read the information provided above.
- You will be given a copy of this consent form and a statement of your Research Subjects' Rights to keep.

Signature of Participant

Date

Legally Authorized Representative
(i.e. parent, legal guardian, or individual with durable power
of attorney for health care of participant)

Date

Original Date: _____

Revision Date: _____

RESEARCH PARTICIPANTS' RIGHTS

The rights below are the right of every person who is asked to be in a research study. As a research subject you have the following rights:

1. To be told what the study is trying to find out.
2. To be told what will happen to you and whether any of the procedures, drugs or devices are experimental.
3. To be told about the reasonably anticipated risks or discomforts that may happen to you related to the research.
4. To be told if you can reasonably expect any benefit from taking part, and if so, what that benefit might be.
5. To be told what other appropriate treatment might be worthwhile.
6. To be allowed to ask questions concerning the study both before agreeing to take part and during the course of the study.
7. To be told what sort of medical treatment is available if any injury arises.
8. To refuse to take part at all or to change your mind about taking part after the study is started.
9. To receive a copy of the signed and dated consent form.
10. To be free of pressure or undue influence concerning whether you wish to agree to be in the study.