

UMCIRB #:

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UNIVERSITY AND MEDICAL CENTER INSTITUTIONAL REVIEW BOARD
REVISION FORM

UMCIRB #: 11-0366

Date this form was completed: 6/12/2011

Title of research: Comparative Study on the Effects of Tai Chi and Matter of Balance on Measures of Balance and Fall-Efficacy in Older Adults

Principal Investigator: Lacey A. Burgess

Sponsor: none

Fund number for IRB fee collection (applies to all for-profit, private industry or pharmaceutical company sponsored project revisions requiring review by the convened UMCIRB committee). If you are a non-ECU entity payment is required at the time of submission:

Fund	Organization	Account	Program	Activity (optional)
		73059		

Version of the most currently approved protocol:
Version of the most currently approved consent document:

CHECK ALL INSTITUTIONS OR SITES WHERE THIS RESEARCH STUDY WILL BE CONDUCTED:

- East Carolina University
- Pitt County Memorial Hospital, Inc
- Heritage Hospital
- Other Cypress Glen
- Beaufort County Hospital
- Carteret General Hospital
- Boice-Willis Clinic

The following items are being submitted for review and approval:

- Protocol: version or date 06/12/2011 (UPF) - Rec 6.14.11 - KK
- Consent: version or date 06/12/2011 6.14.11 - KK
- Additional material: version or date 06/12/2011 - 8-foot up and go (UG) Test (Rec-6.14.11) - KK
- MDRT - (Rec. 6.14.11) - KK
- ABC Scale - Rec. 6.14.11 - KK

Complete the following:

1. Level of IRB review required by sponsor: full expedited
2. Revision effects on risk analysis: increased no change decreased
3. Provide an explanation if there has been a greater than 60 day delay in the submission of this revision to the UMCIRB.
4. Does this revision add any procedures, tests or medications? yes no If yes, describe the additional information: Modified Timed Up and Go (TUG) test. We will now use the Up and Go (UP) test. The UG is a modified version of the TUG which ask participants to rise from a seated position walk eight feet (rather than ten feet in the TUG protocol) and return to a seated position. They are allowed three trails and the average of those timed trials is used.
5. Have participants been locally enrolled in this research study? yes no
6. Will the revision require previously enrolled participants to sign a new consent document? yes no

Briefly describe and provide a rationale for this revision Title was incorrect but is now being sent back with the correct title, as well a modification to the Timed Up and Go test being administered.

Lacey A. Burgess

Lacey A. Burgess

June 12, 2011

Principal Investigator Signature

Print

Date

Box for Office Use Only

The above revision has been reviewed by:

- Full committee review on _____
- Expedited review on 6/15/11

The following action has been taken:

- Approval for period of 6/15/11 to 6/5/12
- Approval by expedited review according to category 45 CFR 46.110
- See separate correspondence for further required action.

Susan McCammon *Susan McCammon* 6/15/11
Signature Print Date



East Carolina University



Informed Consent to Participate in Research

Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: Comparitative Study on the Effects of Tai Chi and Matter of Balance on Measures of Balance and Fall-Efficacy in Older Adults.

Principal Investigator: Lacey A. Burgess

Institution/Department or Division: Recreation and Leisure Studies; Masters in Recreational Therapy Administration; College of Health and Human Performance

Address: 2833 A. Holly Glen Dr, Greenville, NC 27834

Telephone #: 704-467-4418

Researchers at East Carolina University (ECU) study problems in society, health problems, environmental problems, behavior problems and the human condition. Our goal is to try to find ways to improve the lives of you and others. To do this, we need the help of volunteers who are willing to take part in research.

Why is this research being done?

The purpose of this research is to compare the effects of a Tai Chi intervention program (e.g. a Chinese martial art involving flowing movements used to enhance balance and fall-efficacy) and a Matter of Balance intervention program (e.g., a falls prevention program aimed at increasing falls-efficacy in older adults), and a control group on balance and fall-efficacy in older adults) on balance and fall-efficacy in older adults. The decision to take part in this research is yours to make. By doing this research, we hope to determine if one strategy is better than another on balance and fall-efficacy among older adults to better formulate a falls prevention program.

Why am I being invited to take part in this research?

You are being invited to take part in this research because you are an older adult who has volunteered to participate in the balance and fall-efficacy data collection process. If you volunteer to take part in this research, you will be one of about 45 people to do so.

Are there reasons I should not take part in this research?

I understand I should not volunteer for this research if I am under the age of 65. It is recommended that you have approval from your doctor to participate in either intervention.

What other choices do I have if I do not take part in this research?

You can choose not to participate.

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FROM 6.15.11
TO 6.5.12

Participant's Initials

Title of Study:

Where is the research going to take place and how long will it last?

The balance screening and research procedures will be conducted at your housing complex. You will be asked to come to the site at a designated time for your initial balance screening and again approximately 8 – 10 weeks following the initial assessment for a retest. The testing will take approximately 10 minutes to administer.

What will I be asked to do?

You will be asked to participate in a balance screening two times approximately 8 – 10 weeks apart. Testing will last for approximately 10 minutes for each test date. Testing will consist of two balance screenings (i.e., 8-Foot Up and Go (UG) (e.g. you must rise from a seated position, walk eight feet, turn around and sit back down while being timed) and Multi-Directional Reach Test (MDRT) (e.g., must reach along a yard stick from a standing position in all four directions, (i.e., front, back, left and right)) and a fall-efficacy screening (i.e., Activities-specific Balance Confidence Scale (ABC Scale) (e.g., a 16 item questionnaire on falls confidence)), as well as being asked to provide demographic information.

What possible harms or discomforts might I experience if I take part in the research?

Tests performed have minimal risk associated with them and are frequently used to assess balance and fall-efficacy.

What are the possible benefits I may experience from taking part in this research?

Participation in the study will offer you an indication of your current functioning related to balance. This research may help us learn more about fall-efficacy and balance in older adults. You may personally benefit from the knowledge gained as a result of the testing.

Will I be paid for taking part in this research?

We will not be able to pay you for the time you volunteer while being in this study.

What will it cost me to take part in this research?

It will not cost you any money to be part of the research.

Who will know that I took part in this research and learn personal information about me?

To do this research, ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- Any agency of the federal, state, or local government that regulates human research. This includes the Department of Health and Human Services (DHHS), the North Carolina Department of Health, the Office for Human Research Protections.
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff, who have responsibility for overseeing your welfare during this research, and other ECU staff who oversee this research.
- Additionally, the following people and/or organizations may be given access to your personal health information and they are: the researcher (Lacey A. Burgess) and research supervisor (Dr. Thomas K. Skalko).

How will you keep the information you collect about me secure? How long will you keep it?

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Participant's Initials

Title of Study:

Proceeding consent, all participants will choose a unique and confidential four digit number that will correspond to individual results. Names and numbers will be stored separately for 5-7 years in a locked file cabinet and only the researcher and faculty supervisor will have access to individual data. If data from this study is deemed beneficial for further research, third party researchers and/or organizations may have access to data, but not to individual data.

What if I decide I do not want to continue in this research?

If you decide you no longer want to be in this research after it has already started, you may stop at any time. You will not be penalized or criticized for stopping. You will not lose any benefits that you should normally receive.

Who should I contact if I have questions?

The people conducting this study will be available to answer any questions concerning this research, now or in the future. You may contact the Principal Investigator (Ms. Lacey Burgess) at: 704-467-4418 (M-F between 10am-6pm), or the Research Supervisor (Dr. Thomas Skalko) at: 252-328-0018 (M-F between 10-4 pm).

If you have questions about your rights as someone taking part in research, you may call the Office for Human Research Integrity (OHRI) at phone number 252-744-2914 (days, 8:00 am-5:00 pm). If you would like to report a complaint or concern about this research study, you may call the Director of the OHRI, at 252-744-1971

Is there anything else I should know?

Questions concerning this study should be directed to Lacey A. Burgess at 704-467-4418 M-F between 10am-6pm.

I have decided I want to take part in this research. What should I do now?

The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

Participant's Name (PRINT)	Signature	Date
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Witness's Name (PRINT)	Signature	Date
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Title of Study:

Person Obtaining Informed Consent: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person's questions about the research.

Person Obtaining Consent (PRINT)	Signature	Date
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[Optional]

Principal Investigator (PRINT)	Signature	Date
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