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Informed Consent

Department/Section of *Department of Recreation Therapy*

EFFICACY OF A RECREATION THERAPY WELLNESS RECOVERY PROGRAM FOR INDIVIDUALS WITH PARKINSON'S DISEASE

Informed Consent Form to Participate in Research

Peggy Cromer, LRT, CTRS, FDRT, Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have been diagnosed with Parkinson's disease. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to see what effects (good and bad) the Recreation Therapy Wellness Recovery program has on you and your condition.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to six people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

You will participate for 14 weeks in the study; the first two weeks will involve a baseline fitness assessment prior to starting the exercise program. You will then begin the 12 weeks of participating in a community-based Recreation Therapy Wellness Recovery Program designed for individuals with Parkinson's disease. This group exercise program is designed and led by a Licensed Recreation Therapist and currently has approximately 6 - 12 participants. The group meets twice a week; study participants may attend one or both weekly sessions and still participate in the study.

Each one-hour session is developed by the LRT/CTRS and involves moderate to high intensity physical exercises geared to improve balance and coordination. The first 10 minutes of the program is a warm up in sitting position. The next 10 minutes involves power walking with various movements (backwards, grapevine, side step, skip, high knee moves), 5 minutes of posture activity against the wall, 25 minutes of varied activities that utilize 4 basic moves (sit, stand, prone supine and on all 4s) that address gross motor movements, balance, and posture (e.g., circuit training, boxing, obstacle course), and a 10 minute cool down.

If you take part in this study, you will have the following tests and assessments that will be

completed five times during the study (2 weeks of baseline tests, and at weeks 4, 8, and 12):

- Parkinson's Disease Questionnaire Short Form
- Four balance tests:
  - Sit to Stand test
  - Timed Floor Transfer Test
  - Timed Up and Go Test
  - The Blue Foam (stand) with Trek Poles
- Psychological Need Satisfaction in Exercise scale
- Perceived Stress Scale
- Weekly activity level journal completed each day attends the 12 week program (0 – 2 times per week)

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for 14 weeks. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the program we are studying include: The Recreation Therapy Wellness Recovery Program will require that you engage in physical exercise which could result in pain, discomfort, or injury. The likelihood of this occurring is a minor increase in risk over what is expected from normal daily routines. Proper stretching and self-report of any discomfort prior to the session will help to determine whether you can safely participate in the program on any given day. The risks of the exercise program are minimal, but may include fainting, dizziness, irregular heartbeat, chest pain, or heart attack, and stresses and strains of muscles, twisted ankles, or falls. All exercise interventionists will instruct participants in proper exercise techniques to minimize this risk.

As part of this study, you will be asked questions about whether you have experienced feelings of depression, difficulty with personal relationships, or problems with concentration or communication. You will also be asked about the amount of stress you have experienced and your ability to handle stressful events. If you become upset in regards to these questions and wish to talk about these feelings, let Peggy Cromer, LRT, CTRS, FDRT know and she will talk with you about your options to deal with these feelings including notifying your primary physician and/or a referral for counseling services. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure

and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be improved balance and/or improved quality of life.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study you have the option of enrolling in the exercise program without taking part in the research study.

WHAT ARE THE COSTS?

The Recreation Therapy Wellness Recovery Program is a community based program where individuals pay $10 per class. During the 12-week research period, if the participant attends all 24 sessions, the overall cost would be $240. Individuals consenting to participate as a research participant will not be charged for the two week baseline testing period.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Department of Recreation Therapy at Wake Forest University Health Sciences to help conduct this study.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated does not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call *Peggy Cromer* at [redacted] 24 hours a day.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** General demographic information (age, years since diagnosis, stage of disease, level of physical activity, reasons for participation), several assessment instruments including the Psychological Need Satisfaction in Exercise scale, Parkinson's Disease Quality of Life Questionnaire, Perceived Stress Scale, and four balance tests (balance test, Timed Floor Transfer Test, Timed Up and Go Test and the Blue Foam (stand) with Trek Poles). Weekly journals will include your level of activity in the past week, level of pain intensity, report any falls, rate physical and emotional health, whether you are on or off medication and rate your current level of balance before and after participating in class.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or

recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Peggy Cromer that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Peggy Cromer, LRT, CTRS, FDRT

[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because your condition has worsened or you had an unexpected reaction.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, you may contact the study investigator, *Peggy Cromer* at [redacted] 24 hours a day.

The Institutional Review Board (IRB) is a group of people who review the research to protect

your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted]

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject:_____

Legal Representative Signature: _____ Date:_____ Time:_____ am pm