Consent Form for Main Study

Dalhousie University Health Sciences Research Ethics Board (REB) #: 2019-4954
Effective Date: January 09, 2020

CONSENT FORM

Project title: Evaluating the Individual Managing Fatigue Program in People Living with Parkinson`s Disease: A randomised Pilot Feasibility Study

Lead researcher: Neda Alizadeh, Candidate, PhD in Health, Dalhousie University
Neda.alizadeh@dal.ca, Tell: (902) 494-5082

Research Supervisor
Dr. Tanya Packer, Professor, School of Occupational Therapy, Dalhousie University,
Tanya.packer@dal.ca, Tell: (902) 494-3788

Introduction

Thank you for your interest in participating in this study. This research is being conducted by me, Neda Alizadeh, as part of my PhD degree at Dalhousie University. Participating in this research study is entirely voluntary and there will be no consequences if you decide not to participate at any time during the study. Please read the information below carefully. It will outline what you will be asked to do and any benefit, risk, inconvenience or discomfort that you might experience. You may discuss any questions/concerns with the research team, before making your decision about participating. If you have any questions or comments at any time, please contact us. We are happy to answer all of your questions.

Purpose and Outline of the Research Study

You have been asked to participate in this study because you have shown an interest and met the initial needs of the study. In this study, we will evaluate the individual form of the Managing Fatigue Program, from the perspective of individuals with Parkinson's disease (PD) and prepare the program for larger future studies. This research will use questionnaires and group discussions to evaluate the program' s feasibility.

Who Can Take Part in the Research Study

To match the criteria for this study, you need to be over the age of 18, live in the Halifax Regional Municipality (HRM), have a diagnosis of PD, and experience fatigue severe enough to interfere with your daily life. To participate, you also need to read and speak English. If you have previously completed this fatigue program, have another condition that causes fatigue (e.g. heart failure, cancer), or have difficulty with concentration, memory or recall skills, you won't match the needs of the study and we will not ask you to participate.

What You Will Be Asked to Do

This consent form has been mailed to you because you expressed interest in and met the needs of our study based on your initial screening phone call. Please read this information carefully and contact us if you are interested in participating. If we do not hear from you after a

week, a research assistant will contact you using the contact information you provided. They will ask if you are interested in participating. If you are interested, the research assistant will schedule a screening and data collection visit at a time convenient to you. When you come to the visit, we will ask you to sign this consent form. You will also be given your own copy of the consent form.

During the first part of this visit, there will be time for you to ask questions before signing the consent form. After providing your consent, we will ask you some questions and conduct some simple tests to be sure you match all the criteria for this study. We will ask you to complete tests that assess your cognitive skills (things like attention, memory and orientation) and level of fatigue. If you do not meet the study criteria, we still want to thank you for your time, and you will receive a $20 gift card. The reasons for not being included will be recorded and explained to you. This meeting will take approximately an hour to complete and will be held at Carleton Campus at Dalhousie University.

Once we confirm you match the criteria for the study, you will begin the first round of testing. You will be asked more detailed questions about yourself (gender, age, disease duration, etc), the impact of your fatigue on your life, for example, your sleep, your ability to complete everyday activities, your self-confidence in looking after yourself, and how happy you are with your life.

Following this visit you will be randomly assigned to one of the two groups in the study. You will not get to choose which group you are in. One group will receive the Managing Fatigue Program, and the other group will not. We will mail you a letter to tell you to which group you have been assigned to. The group that does not receive the program will receive a manual and be invited to participate in a workshop about the program once the main study has been completed. No matter which group you are in, you should continue receiving your current healthcare services. For research purposes, we will ask you to not share your group allocation with the researcher who does your testings at any stage of the research. This assessor should not know which group you are in.

The research team will contact you to schedule two other meetings when you will again answer the same questions about yourself, your fatigue etc. These meetings will take place six weeks after the first visit, and again three months after that. If you are in the group receiving the program, the schedule for your therapeutic sessions (weeks 1-6) will be determined by you and your therapist, at a time that is convenient for both of you.

Below is a brief overview of what people in each group will be asked to do:

If you are in the group who will receive the fatigue program, we will ask you to:

- participate in six one-to-one sessions with an occupational therapist,
- complete a short questionnaire after each session (10 questions) and another one after completing all six-sessions (12 questions),
- complete the same questionnaires done at the screening and data collection visit two more times, once after you finish all the sessions and again three months later (approximately 60 minutes each time).

You may also be asked to participate in a group discussion, but not everyone will have to do this. We will ask you about this possibility after you finish the 6 sessions. In these group

meetings, you will be asked to further discuss your opinions about the program. Each group discussion will take approximately 90 minutes. These meetings will be led by an experienced research assistant. If you are asked to participate in the group discussion, you will be given a separate consent form that includes more information about this part of the study.

*Details of the Managing Fatigue Program**.*** The program we use in this study is the Individual Managing Fatigue Program. The Individual Managing Fatigue Program consists of six weekly sessions. The sessions cover topics such as the importance of rest and sleep, communication and body mechanics, activity stations, priorities and standards, and balancing your schedule. Each session includes three parts: 1) a pre-session activity 2) in-session activities/information and 3) homework. Prior to coming to each session, you will be asked to complete some activities that will help you prepare for the in-session discussions. During each session, you will discuss and practice the topics that are most important to you with your therapist. Based on your discussions, you and your therapist will decide on things you will practice between each session as your homework. Your therapist will help you begin your homework at the end of each session, and you will finish it outside of the session at your home. At the beginning of the following session, you and your therapist will review your homework.

In-session activities will take approximately 60 to 90 minutes based on your needs. Participants should plan additional time each week for pre-session activities (30 minutes) and homework (1-2 hours). The occupational therapist (OT) that delivers the program will be registered with the College of Occupational Therapists of Nova Scotia. Prior to delivering the program, OTs will complete an online training session developed by the research team, which includes experts in Parkinson's disease and fatigue management. You and your therapist will schedule your therapy sessions each week based on your most convenient times.

The questionnaires that you will complete after each session and following completion of the program will evaluate the relevance, usability, and acceptability of each session and the entire program. Each of these questionnaires will take approximately 10 minutes to complete. Your therapist will hand out the questionnaires in envelopes following each session. You will then complete the questionnaires and return them to your therapist in the sealed envelope.

If you are in the group that does not receive the program, we will ask you to:

- complete the same questionnaires done at the screening and data collection visit two more times, once after six-week and again three months later (approximately 60 minutes each time).

After completing the third visit (3 months after the beginning of the study), you will have the opportunity to attend a three-hour workshop that includes the content of the Managing Fatigue Program, including the pre-session activities, in-session activities, and homework. This workshop will be conducted by licensed occupational therapists. In this workshop, you also will receive the manual used in the program.

All the meetings, visits, therapy sessions will take place on the Carleton Campus at Dalhousie University.

Possible Benefits, Risks and Discomforts

There is a small chance that you may find some of the questions difficult or uncomfortable to answer. You can skip any questions you wish, or you can ask to take a break and return to those questions later. Some people may experience an increase in fatigue during the completion of the program or questionnaires. To minimize any tiredness that may occur, you will be offered rest breaks when you are completing the questionnaires and during the session activities. Additionally, visits will be scheduled based on what is most convenient for you.

There is also a small chance that during the screening and data collection visit your test result may show some potential difficulties with attention, memory or orientation. If that happens, we will provide you with a list of available resources to seek support. If you would like, we advise you to contact your primary health care provider for further testing.

We cannot promise that participating in the 6-week program or the workshop will help you. However, this program is commonly delivered in clinical practice in many countries and other studies have shown positive effects such as reduced fatigue impact, depression, and sleep problems, and improved quality of life, participation and self-efficacy in people living with multiple sclerosis. This will be the first time that it will be evaluated in people with PD. Your participation will help to decide if this program should be further researched for people with PD.

Compensation / Reimbursement

To thank you for your participation in this study, you will receive a gift card of $20.

How your information will be protected

The data we collect from you will be kept confidential. Only the research team at Dalhousie University will have access to your data. In any published report we will not include any information that makes it possible to identify you or anyone else participating in the study. This means that it will not be possible to connect your data to your identity in any way in our reports.

All research data will be kept in locked cabinets in a locked office at Dalhousie University in Halifax, Nova Scotia, or on secure, password-protected computers. None of this data will have your name attached to it. Instead, you will be assigned an ID code. The key to the ID code will be kept in a locked cabinet, away from all other information, and only the study supervisor and trained research staff will have access to this. We will keep the information for five years. After that, all data will be destroyed in keeping with the Dalhousie Ethics policies.

If You Decide to Stop Participating

Your participation is voluntary. You may leave the study at any time for any reason without consequences. You do not need to tell us why. If you wish to remove your data from the study, you simply need to notify our research team. You can ask for your information to be removed from the study up until two months after your first visit. After this time, your data will have been analysed and it will no longer be possible for us to remove your data from the study.

How to Obtain Results

At your last visit with the team, we will ask you if you would like to receive the results of the study. If so, a summary of the study results will be sent to you, using the contact information you have provided, approximately a year after the study start point. Please remember that only the overall results will be provided, and no individual results will be shared.

Results of the study will also be disseminated at provincial, national and/or international conferences. Additionally, results will be shared on the website of the International Chronic and Complex Conditions Research Group, which you can find at https://www.dal.ca/sites/ic3rg/projects.html

Questions

We are happy to answer any questions or concerns you may have about your participation in this research. Please contact the research team at (902) 494-5086, or email: neda.alizadeh@dal.ca at any time with questions, comments, or concerns about the research study. We will also inform you if we learn any new information that could affect your decision to participate.

This research has been reviewed by the Research Ethics Board at Dalhousie University. If you have any ethical concerns about your participation in this research, you may also contact Research Ethics, Dalhousie University at (902) 494-1462, or email: ethics@dal.ca (REB file # 2019-4954).

Signature Page

Project Title: Evaluating the Individual Managing Fatigue Program in People Living with Parkinson`s Disease.

I have read the explanation about this study. I have been given the opportunity to discuss it and my questions have been answered to my satisfaction. By signing this consent form, I understand that:

- ☐ I will be assigned to one of the two groups in the study and I will not get to choose which group I am in.
- ☐ I may be in the group that does not receive the program. Only one group will receive the Managing Fatigue Program, and the other group will not. After the study ends, the group that does not receive it will receive the program manuals and be able to attend a workshop with the same content as the Managing Fatigue Program.
- ☐ I will complete a number of questionnaires, three times over a six-month period. Each time will take about 60 minutes.
- ☐ I know how to find about the result of the study.
- ☐ If I am in the group that receives the Managing Fatigue Program, I will have six sessions with an occupational therapist that will take from 6 to 9 additional hours.
- ☐ I can continue receiving any current healthcare services no matter which group I am in.
- ☐ I will be participating in this research voluntarily and I can withdraw from the study at any time.

Name	Signature	Date

Consent Form for Focus Groups

Dalhousie University Health Sciences Research Ethics Board (REB) #: 2019-4954
Effective Date: January 09, 2020

CONSENT TO PARTICIPATE IN A GROUP DISCUSSION

Project title: Understanding the feasibility of the Individual Managing Fatigue Program (IMFP) from the perspective of People Living with Parkinson`s Disease Using Group Discussion

Lead researcher: Neda Alizadeh, Candidate, PhD in Health, Dalhousie University
Neda.alizadeh@dal.ca, Tell: (902) 494-5082

Research Supervisor
Dr. Tanya Packer, Professor, School of Occupational Therapy, Dalhousie University,
Tanya.packer@dal.ca, Tell: (902) 494-3788

Introduction

Thank you for participating in the first part of this study and for your interest in participating in one of the discussion groups. This research is being conducted by me, Neda Alizadeh, as part of my PhD at Dalhousie University. This research uses group discussions to further understand your views on the Individual Managing Fatigue Program. Participating in this group discussion is entirely voluntary and there will be no consequences if you decide not to participate at any time. Please carefully read the information below. It will outline what you will be asked to do and any benefit, risk, inconvenience or discomfort that you may experience.

We are happy to discuss any questions/concerns with you, before you make your decision about participating. If you have any questions or comments later, please contact us. We are happy to respond at any time.

Purpose of the Group Discussion

You have been asked to join this group discussion because of your participation in the Individual Managing Fatigue Program over the past six weeks. Our research team would like to further understand your opinions about the program. We are interested in hearing your suggestions to improve the program. A research assistant will contact you by phone within the next week to confirm your interest and availability to participate in one of the group discussions.

Who Can Take Part in this Group Discussion?

To match the criteria of this study, you must have participated in the Individual Managing Fatigue Program.

What You Will Be Asked to Do

When the research assistant contacts you, they will provide you with multiple dates and times for group discussions and you can choose which is most appropriate for you. When you come to the group discussion, you will have an opportunity to ask any further questions that you may have. To participate you will also be asked to provide written consent by signing this consent form.

This group discussion will be an open discussion with about five people in the group. In this group discussion, we will ask for your opinion on the feasibility of the program. For example, we want to know if you will use the skills you learnt, if the program manual was understandable and interesting to you, if the times and locations were convenient, and if you have experienced any benefits from participating in the program. There are no right or wrong answers. Any positive or negative comments are appreciated so that we can improve the program for the future. Please note that the group discussions will be audio-taped and transcribed for research purposes.

This meeting will be guided by an experienced research assistant and will take approximately 60 minutes to complete. All the visits will take place on the Carleton campus at Dalhousie University.

Possible Benefits, Risks and Discomforts

There is a small chance that you may experience fatigue by participating in the group discussion, however they will be no more tiering that the one to one session you attended with your therapist. We cannot guarantee that others participating in the discussion group will protect your confidentiality and identity. To minimize this, we will remind all participants not to talk about the discussion outside of the group and not to disclose who participates. During the session, we ask that you only disclose the information you wish to disclose.

Compensation / Reimbursement

To thank you for your participation in this part of the study, you will receive a gift card of $20.

How your information will be protected

The group meetings will be audiotaped and transcribed. When we transcribe the group meetings, identifying information will be removed. No names or identifying information will be in the written transcriptions and once transcribed, the audiotapes will be destroyed based on the regulations of the ethics board at Dalhousie University. The audio files will be encrypted and saved in a password-protected laptop. All written transcribed data will be saved in a locked cabinet at Dalhousie University. We will never reveal your identity or connect it with the comments you made in any way. In any published report we will not include any information that makes it possible to identify you or anyone else participating in the study. While we may report quotes collected during this focus group in our results\publications, these quotes will never be connected with your identity. Only the research team members will have access to audio recorded files and transcripts. The occupational therapists who administered the program will not have access to the tapes or transcripts and will never be aware of who said

what during the group discussions. In keeping with the Dalhousie Research Ethics policies, we will keep the information for five years. After that, all data will be destroyed.

If You Decide to Stop Participating

Your participation is voluntary. You may leave the study at any time for any reason without consequence. If you wish to remove your data from the study, you simply need to notify the research team. You can ask for your information to be removed from the study up to one month after your group discussion. After that time, your data will have been analysed and it will no longer be possible for us to remove your data from the study.

How to Obtain Results

A summary of the results of this study will be shared alongside the results of the main study one year after the study start point. Please remember that only the overall results will be provided, and no individual results will be shared. The results of this study may also be shared at provincial, national or international conferences. Additionally, results will be shared on the website of the International Chronic and Complex Conditions Research Group at https://www.dal.ca/sites/ic3rg/projects.html

Questions

We are happy to answer any questions or concerns you may have about your participation in this research. Please contact our research team at 902-494-5086, or email: neda.alizadeh@dal.ca at any time with questions, comments, or concerns about the research study. We will also inform you if any new information comes up that could affect your decision to participate.

This research has been reviewed by the Research Ethics Board at Dalhousie University. If you have any ethical concerns about your participation in this research, you may also contact Research Ethics, Dalhousie University at (902) 494-1462, or email: ethics@dal.ca (REB file # 2019-4954).

Signature Page

Project Title: Understanding the feasibility of the Individual Managing Fatigue Program (IMFP) from the perspective of People Living with Parkinson`s Disease

I have read the explanation about this study. I have been given the opportunity to discuss it and my questions have been answered to my satisfaction. By signing this consent form, I understand that:

- ☐ The research team cannot completely guarantee that other participants in the discussion groups will respect my anonymity and confidentiality. However, the research team will do everything possible to protect my anonymity and confidentiality during group discussions.
- ☐ I can remove my data from the group discussion up until one months after the group discussion ends. After three months, it will not be possible for the research team to remove my data.
- ☐ I know how to find out about the study results.

- ☐ I am agreeing to allow quotes to be used as part of the reports and presentations about the study. I understand that there will be no way to link the quote to me.
- ☐ I am participating in this study voluntarily, and I understand that I am free to withdraw from the study at any time.
- ☐ I agree to take part in this study.

Name Signature Date