Flinders UNIVERSITY
College of Nursing & Health Sciences

INSPIRING ACHIEVEMENT

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Flinders University

Title	The impact of light therapy and/or aerobic exercise compared to usual care on clinical signs and symptoms of Parkinson's Disease: A pilot crossover study
Short Title	Impact of photobiomodulation and/or aerobic exercise on Parkinson's disease
Protocol Number	5709
Project Sponsor	The Hospital Research Foundation; and Flinders University
Coordinating Principal Investigator **Principal Investigator**	Dr Joyce Ramos
Associate Investigator(s)	Dr Ranjay Chakraborty; Olivia Nassaris; Prof Raj Shekhawat; A/Prof Maarten Immink; Joanne Dalton
Location	Flinders University Exercise Science/Clinical Exercise Physiology Laboratories, Sturt Gym and Sturt Building, Flinders University, Bedford park, SA, 5042 Health2Go clinic, Flinders University

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. The research project is testing the impact of nondrug light and/or aerobic exercise therapies, versus usual care on multiple signs and symptoms of Parkinson's disease, quality of life, and overall cardiovascular health.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, or a friend. With your permission, research staff also wish to contact your local doctor or general practitioner (GP) to acquire consent for you to participate in this research study.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the participant information and consent form and COVID-19 self-declaration and consent form. By signing it you are telling us that you:
- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.
- that you agree to have read the 'Information for research staff and participants on the resumption of research activities during COVID-19' sheet

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Parkinson's disease (PD) affects 100,000 people in Australia for which there is no cure. It is also the most common movement disorder, with about 38 Australians diagnosed each day.

The primary motor signs of PD are slowness of movement (bradykinesia), resting tremor, rigidity, and poor balance. In addition to these motor signs, there are also many key non-motor symptoms such as impaired cognition, smell, and sleep. Collectively, these motor sings and non-motor symptoms negatively affects activities of daily living and health-related quality of life (HRQoL).

Drugs used to manage clinical signs and symptoms of PD are not often sufficient and may cause intolerable side effects. There is therefore increased interest in non-drug therapies in the management of PD. Numerous studies have revealed benefits of aerobic exercise (AE) in this population. However, long-term exercise adherence in this population is low. Alternative or adjunct management strategies to improve clinical signs and symptoms of PD are therefore warranted.

Light therapy or photobiomodulation (PBM) is an experimental method that appears to increase our capacity to generate energy for optimal bodily functions via the application of light to the head and belly on a repeated basis. As with exercise, there is evidence to suggest that PBM may offer brain protection related to PD. It is

therefore tempting to speculate that the combined use of these two non-drug treatment options would induce even more improvements in clinical signs and symptoms of PD.

BFR exercise on metabolic syndrome and overall heart and vessel health.

Purpose of the study:

To investigate the impact of a non-drug PBM and/or AE therapy compared to usual care on clinical signs and symptoms suffered by those diagnosed with idiopathic PD.

This research has been initiated by Dr. Joyce Ramos, Dr Ranjay Chakraborty, Olivia Nassaris, Prof Raj Shekhawat, A/Prof Maarten Immink, and Joanne Dalton .

This research is being conducted by Flinders University

3 What does participation in this research involve?

You will be participating in a randomised crossover experimental research project. You will be randomly assigned into groups, with each group completing a different sequence of interventions or fake treatment across four 8-week study periods. For example, you may be randomised into Group 2 with the following sequence of treatment/fake intervention: A-B-C-D where A, B, C, and D represents PBM, AE, combined PBM and AE (PBM + AE), and fake treatments, respectively. Whereas if you were to be randomised into Group 3, a different sequence of intervention/fake intervention may apply such as B-C-D-A, where you will then receive the PBM intervention in the final 8-week period of the study.

This research project has been designed to ensure the researchers interpret the results in a fair and appropriate way, warranting avoidance of biased analysis.

1 Participation in this study will require:

- Completion of online questionnaires to assess at each assessment time points (8 times, at baseline (4) and post-8 weeks (4) of each 8-week study periods: non-motor symptoms of PD, quality of life, functional capacity, falls risk, sleep quality, and cognitive function
- Eight (8) visits to the Exercise Science/Clinical Exercise Physiology/Health2go clinic/laboratories at Flinders University, Sturt campus, for testing across all the four 8-week study periods.
- Assessment of your sleep quality using a device that will be installed in your bed by a qualified technician
- A 4-week period without intervention between the 4 x 8-week study periods
- Attendance to four supervised fake treatment (control) or the study treatments (AE, PBM, or PBM + AE) across four 8-week study periods; Weeks 1-4 will require participants to attend the research clinic/laboratories twice per week for one hour, whilst week 5-8 thrice weekly.

A phone will be available in close proximity to all testing visits and PBM and AE sessions for emergencies.

Dr Joyce Ramos will conduct the screening for the study eligibility criteria in collaboration with a clinical nurse consultant (Joanne Dalton) with significant clinical experience in neurological disorders.

<u>Testing Visits:</u>

These will occur eight (8) times: at baseline (4) and post-8 weeks (4) of each 8-week study periods.

You will be asked to attend the Exercise Science/Clinical Exercise Physiology laboratories at Flinders University for 2 hours per testing session. Please refrain from strenuous exercise for 48 hours and caffeine and alcohol for 24 hours before arriving at the laboratory.

During your testing visits at Flinders University you will undertake the following tests and measures:

- A maximal treadmill test while the electrical activity of your heart is monitored with a specialised device.
- Measures of the stiffness and function of your blood vessels by putting a small pen like device on the pulse in your neck, and blood pressure cuffs around your right arm and upper thigh. Please fast for 12 hours and refrain from caffeine and alcohol 2 hours prior to this measurement.
- Blood pressure will also be measured using a pressure cuff. Please fast for 12 hours prior to this measurement.
- A small finger prick blood sample will be collected to measure your fasted glucose level, cholesterol level, and other markers of health. Please fast for 12 hours and refrain from caffeine and alcohol 2 hours prior to this measurement.
- Body composition measures such as waist circumference, hip circumference, weight, and height will also be measured.

After the initial testing, you will be randomly assigned into one of four (4) groups of which you will be exposed to all treatments/fake treatment in a different order depending on the group you have been assigned. The sequence of treatment/fake treatment for each group, with each group consisting of the following:

A. PBM: performed for 24 minutes per session, 2-3 sessions per week (Weeks 1-4 = 2 days per week; Weeks 5-8 = 3 days per week)
B. AE: performed for 60 minutes per session, 2-3 times per week (Weeks 1-4 = 2 days per week; Weeks 5-8 = 3 days per week)
C. PBM + AE: two sessions (1 x PBM and 1 x AE) per week in weeks 1-4 and three sessions (2 x PBM and 1 x AE) per week in weeks 5-8
D. Fake treatment/control – will follow the same PBM protocol

We ask that you not divulge which group you have been randomly allocated

All exercise training sessions will be under the supervision of an experienced and qualified health care professional.

There are no additional costs associated with participating in this research project, nor will you be paid. All tests required as part of the research project will be provided to you free of charge. You will be provided with a ‘head’ a hand-held’ light therapy devices at the conclusion of your study participation to thank you for your time.

Prior to your inclusion in the study, the research team will contact your local doctor or GP to acquire consent for you to participate in this research project.

4 Other relevant information about the research project

Twenty participants (age, 60-80 years) clinically diagnosed with idiopathic PD within five years of diagnosis by a neurologist will be included and randomized to either of the following groups assigned to a different sequence of interventions or fake treatment across four 8-week study periods. Each of the intervention or fake periods will be supervised in a centre-based environment

and will be separated by a 4-week period without intervention. The participants will be tested before and after each of the four 8-week study period (Figure 1). Written informed consent will be obtained from all participants before inclusion in the study. All participants will receive verbal and written information about each of the intervention/fake intervention.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with Flinders University and THRF Parkinsons.

6 What are the alternatives to participation?

You do not have to take part in this research project to receive benefits from AE and PBM. These treatments are accessible outside the research study. The current aerobic exercise guideline to improve health people with PD is 150 minutes per week of moderate-vigorous intensity training (i.e. brisk walking at 60-70% peak heart rate for 30 min, 3 days per week). The PBM devices used in this study are also readily available for purchase online.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, you will be given a written result sheet at the end of the study and this will be explained to you face-to-face at the time. You will gain increased knowledge and awareness of your health and fitness through information that is not routinely assessed by your GP. Additionally, possible benefits may include provision of evidence to support the importance of PBM and/or AE as an alternative/adjunct management tool in the improvement of clinical signs and symptoms of PD.

8 What are the possible risks and disadvantages of taking part?

Risks involved with the study:

- Exercise intervention/tests used in the study may increase risk of musculoskeletal injury, or fatigue, and unfavourable events such as heart attack. It is recognised that for many people, particularly those who are not very active, the risk of adverse effects during vigorous activity increases. While short-term increases in adverse effects have been shown, the longer-term benefits of regular physical activity outweigh these risks. All research staff will be required to have a first-aid certificate to enable immediate attendance/care to a potential incident.
- Medications prescribed to people with Parkinson's disease may contain ingredients that may cause increased sensitivity to light. This may in turn increase development of . a rash, sunburn, or other adverse effect from exposure to light of an intensity or duration that would normally not affect that individual. Individuals taking these medications (imipramine, hypericum, phenothiazine, lithium, chloroquine, hydrocholorothizide, tetracycline) will be excluded from this study
- The battery-operated PDCare Laser device has a risk of overheating which may cause

skin burns. All research staff will be required to have a first-aid certificate to enable immediate attendance/care to such potential incident (skin burn). The PDCare Laser is also safe for home use, not requiring protective eyewear or specific training. There are no known side effects that could impose a risk or harm. The PDCare Laser has met all compliance testing standards . It is listed on Australia Register of Therapeutic Goods (ARTG, 335443) as an approved medical device and is cleared for use in the treatment of pain and other clinical conditions.

- Collection of blood samples involve a very small puncture on the participants' finger which may induce risk of bruising, fainting, excessive bleeding, and infection. Blood collection risks will be minimised as all collection will be conducted by a trained health professional. No lancets used to puncture the finger will be reused. All disposable items will be destroyed after each use. As an additional safeguard in preventing contamination, new disposable gloves will be worn for all blood collection. All contaminated items will be disposed of promptly in sharps containers. All research staff will be required to have a first-aid certificate to enable immediate attendance/care to a potential incident.

All suspected adverse results/incidental findings will be reported to you without diagnosis. You will be encouraged to seek medical follow-up from your general practitioner or specialist for further investigation. With your permission, research staff will also contact your GP/specialist about the suspected adverse result/incidental finding and overall participation in the study.

9 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the intervention that is being studied. If this happens, a member of the research team will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, a member of the research team will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, the research team might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

10 Can I have other treatments during this research project?

It is important to tell the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell a research staff member about any changes to these during your participation in the research project.

11 What if I withdraw from this research project?

Participants have the right to withdraw from the study at any point if they feel the treatments are too uncomfortable. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with the law. You should be aware that data collected by the sponsor up to the time

you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

12 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:
• Unacceptable side effects
• The treatments being shown not to be effective
• The treatments being shown to work and not need further testing

13 What happens when the research project ends?

When the study has finished you will be provided with all of your results within approximately 3 months. You will also be given the opportunity to ask any questions regarding the results and anything else to do with the study in a de-briefing session.
The study data will be retained for 5 years.

Part 2 How is the research project being conducted?

14 What will happen to information about me?

By signing the consent form, you consent to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Personal information gained from the study such as fitness and cardiovascular measures will be recorded but not easily identified to any individual. To ensure longevity of the data, results will also be kept in a password locked computer with access granted only to the primary investigators. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities the institution relevant to this Participant Information Sheet, Flinders University, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Hardcopy data (e.g. signed consent forms and case report forms [CRFs]) will be stored within locked filing cabinets located in the Exercise Science/Clinical Exercise Physiology Unit, College of Nursing and Health Sciences, Flinders University. Only the research team will have access to these filing cabinets. The CRFs and other source data will be kept in a separate folder to the consent forms to ensure the study data is not identifiable. On completion of the project, identifying data will be removed from the record.

In accordance with relevant Australian and South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

Your de-identified data may be used in future projects. Human Research Ethics Committee (HREC) approval will be required for any future projects.

15 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. Participation in this study does not impact on your basic legal right to seek compensation; however, if you do suffer harm, you may receive compensation without litigation.

16 Who is organising and funding the research?

This research project is being conducted by Dr Joyce Ramos, Dr Ranjay Chakraborty, Olivia Nassaris, A/Prof Raj Shekhawat, A/Prof Maarten Immink

This research project is being conducted by Flinders University.

You will not benefit financially from your involvement in this research project. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

17 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Flinders University.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal investigator on +61882013272 or any of the following people:

Clinical contact person

Name	Dr Joyce Ramos
Position	Chief Investigator
Telephone	+61882013272
Email	joyce.ramos@flinders.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Position	The Flinders University's Research Ethics & Compliance Office team
Telephone	08 8201 3116

Email	human.researchethics@flinders.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	The Flinders University's Research Ethics & Compliance Office team
HREC Executive Officer	Executive Officer
Telephone	08 8201 3116
Email	human.researchethics@flinders.edu.au

Consent Form - *Adult providing own consent*

Title	The impact of light therapy and/or aerobic exercise compared to usual care on clinical signs and symptoms of Parkinson's Disease: A pilot crossover study
Short Title	Impact of photobiomodulation and/or aerobic exercise on Parkinson's disease
Protocol Number	5709
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Coordinating Principal Investigator **Principal Investigator**	Dr Joyce S. Ramos
Associate Investigator(s)	Dr Ranjay Chakraborty; Olivia Nassaris; Prof Raj Shekhawat; A/Prof Maarten Immink; Joanne Dalton
Location	Flinders University Exercise Science/Clinical Exercise Physiology Laboratory, Sturt Gym, Flinders University, Bedford park, SA, 5042 Health2Go clinic, Flinders University

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future relationship with Flinders University.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status.

I understand that my de-identified data collected during this research project may be used in future projects.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.