PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT

Effects of transcranial direct current stimulation on gait in people with Parkinson's Disease (PD)

QUT Ethics Approval Number 1500001094

RESEARCH TEAM

Principal Researcher:	Vida Alizad	PhD candidate
Associate Researchers:	Professor Graham Kerr	Principal Supervisor
	Associate Professor Simon Smith	Associate Supervisor
	Associate Professor Marcus Meinzer	External Supervisor
	Adjunct Prof Laurent Frossard	Associate Supervisor

School of Exercise and Nutrition Sciences, Faculty of Health
Institute of Health and Biomedical Innovation (IHBI)
Queensland University of Technology (QUT)

DESCRIPTION

This research project is being undertaken by Mrs Vida Alizad for her PhD which examines whether gait and balance can be improved in people with and without Parkinson's disease (PD) using transcranial Direct Current Stimulation (tDCS). tDCS is widely used in neuroscientific and clinical research and is known to improve some movement abilities in people with and without Parkinson's disease.

PARTICIPATION

The study requires people with PD, 40-80 years old who are able to walk without assistance.

You should not be pregnant, have uncontrolled blood pressure (hypotension or hypertension), any musculoskeletal disorders, functional limitations associated with osteoporosis, or have had orthopaedic surgery within the last 12 months. You should also not have had brain surgery, have no metal implants in your head, have no history of epilepsy, migraines or neural trauma and should not be taking any psychoactive medications.

The research will be conducted at IHBI, 60 Musk Avenue, Kelvin Grove. Participation will involve four visits; one visit will be for clinical assessment and three visits will be for the intervention and gait assessment. Photos and videos will be recorded during assessment and intervention sessions. Videos will be used for further movement evaluation. Both photos and videos may be used for presentations but in these instances, faces will be blurred to preserve anonymity.

Visit 1 (60 minutes): Clinical Assessment

After signing the consent form, two assessments will be undertaken to determine your eligibility for participation in the study.

- Cognitive function assessment will be used for screening cognitive functions and dementia.
- Visual function tests will assess your visual functioning.

If you are eligible to participate in the study, at the end of this session you will be provided with questionnaires to be completed at home.

You will then undertake three further assessments:

- Disease severity assessment will be used to determine the severity and progression of the symptoms of Parkinson's disease.
- Lower Limb peripheral sensation involves a touch sensitivity task which will be performed with your eyes closed.
- Clinical balance and mobility tests will be used to assess your balance and mobility.

Visit 2-4 (60 minutes, each visit): gait and muscle activity recording and intervention

You will be asked to walk over ground along a straight-line walkway to establish your preferred and comfortable walking speed. Your walking gait will be recorded while you are walking on a treadmill at your self-selected and comfortable speed and over ground by a motion capture system that uses reflective markers placed on your limbs to record your movement.

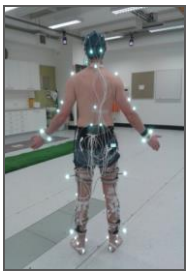
Figure 1

Figure 1 shows reflective markers placed on the body for recording walking.

At the same time, muscle activity will be examined using surface Electromyography which requires electrodes to be placed over your leg muscles. This may require some hair to be shaved from the skin over your leg muscles (a circle with 2 cm diameter) using single-use disposal safety razor and to be cleaned with alcohol-based wipes.

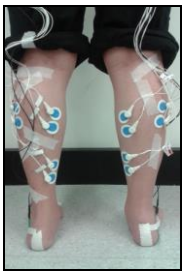
Figure 2

Figure 2 shows EMG electrodes placed on both legs. After recording gait and muscle activity, you will be allocated into one of the three intervention sessions randomly. In two sessions you will receive continuous stimulation over 20 minutes.

For the other session, stimulation will be stopped after 10 seconds. You will have electrodes placed on your head and you may experience a brief tingling sensation in all three sessions, which arrives from the battery driven stimulator. During the stimulation you will be required to walk on a treadmill at a comfortable walking speed. You will be asked to wear a safety harness attached to the overhead support rail. After each tDCS session you will be asked to complete an adverse effect of tDCS questionnaire.


Figure 3

Figure 3 shows tDCS devices and electrodes attached to the head.

In each session, immediately after applying tDCS, gait and muscle activity recordings will be repeated.

EXPECTED BENEFITS

It is expected that this project will benefit you directly through clinical assessment of balance, gait, your risk of falls and disease severity. These assessments can be made available to your GP/neurologist if requested.

If this research finds that tDCS during treadmill walking is beneficial, if you participated in the group with no stimulation, you will be given the opportunity to benefit from the real stimulation.

Visitor parking or reimbursement of regular public transport between home and IHBI will be provided.

RISKS

There are minimal risks associated with your participation in this project. These include:

- **Feeling a mild tingling or itchy sensation under the tDCS electrodes.**
  This may occur when the machine is first turned on, but is unlikely persist to the low level of stimulation that is being used. The sensation of itching and tingling will be monitored by the investigator during the intervention sessions and tDCS will be terminated immediately if you become uncomfortable.

- **Loss of balance or falling during walking assessments on the treadmill or over ground.**
  At all times, at least one researcher will be positioned in close proximity to you to protect you during walking on a treadmill or over ground. In addition you will wear a harness attached to the ceiling during the intervention while walking on treadmill with this.
- **Fatigue during assessments.**
  To minimize fatigue regular rest sessions are scheduled during the assessments. To avoid extra sessions, all questionnaires will be posted to you and assessment for eligibility criteria will be done via telephone by the principal investigator. If you become fatigued during the assessment, you will be offered additional rest breaks and/or the opportunity to discontinue the session and/or resume the testing at a later date.

It should be noted that if you do agree to participate, you can withdraw from participation at any time during the project without comment or penalty.

QUT provides for limited free or counselling services (face-to-face only) for research participants of QUT projects who may experience discomfort or distress as a result of their participation in the research. Should you wish to access this service please call the Clinic Receptionist on **07 3138 0999** (Monday–Friday only 9am–5pm), QUT Psychology and Counselling Clinic, 44 Musk Avenue, Kelvin Grove, and indicate that you are a research participant.

PRIVACY AND CONFIDENTIALITY

All comments and responses will be treated confidentially unless required by law. The names of individual persons are not required in any of the responses. Any data collected as part of this project will be stored securely as per QUT's Management of research data policy.

The project is funded by faculty of Health, QUT and they will not have access to the data obtained during the project.

Please note that non-identifiable data collected in this project may be used as comparative data in future projects or stored on an open access database for secondary analysis.

CONSENT TO PARTICIPATE

We would like to ask you to sign a written consent form (enclosed) to confirm your agreement to participate.

QUESTIONS / FURTHER INFORMATION ABOUT THE PROJECT

If you have any questions or require further information please contact one of the researchers listed below.

Vida Alizad	07 3138 6304	vida.alizad@hdr.qut.edu.au
Graham Kerr	07 3138 6303	g.kerr@qut.edu.au

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE PROJECT

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the project you may contact the QUT Research Ethics Advisory Team on 07 3138 5123 or email humanethics@qut.edu.au. The QUT Research Ethics Advisory Team is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

THANK YOU FOR HELPING WITH THIS RESEARCH PROJECT.
PLEASE KEEP THIS SHEET FOR YOUR INFORMATION.

FULL EXPLANATION OF ASSESSMENTS AND INTERVENTION

Assessments

1. Demographic and Health Questionnaires:

The demographic and health questionnaire consists of questions relating to your background details, physical activity, mood, mobility, balance, gait and falls, vision, health and medications.

2. Clinical Assessments:

***i) Cognitive function assessment*:** Addenbroock's cognitive examination-ACE-R is a questionnaire that will be used for assessing cognitive functions and screening dementia.

ii) Visual function tests: These tests will assess your visual functioning using standard vision charts whilst you are wearing your normal prescription lenses.

iii) Disease severity assessment: Movement Disorder Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS) will be used to determine the severity of your disease.

iv) Lower Limb Sensation: These tests involve a touch sensitivity task which will be performed with your eyes closed. For the touch sensitivity test, plastic fibres of different thicknesses will be pressed against your ball of foot, ankle, toe and heel. Loss of sensation from the legs and feet is not only a common finding with increasing age, but has an association with falls risk because of the central role that sensory feedback from our skin plays in balance control. This test is non-invasive and you will be seated throughout these tests.

v) Clinical Balance and Mobility Tests: The Tinetti test will also be used to assess your balance and mobility.

3. Gait Assessment

You will be asked to walk at a self-selected and comfortable pace on a treadmill and over ground along a straight-line walkway. During this test you will wear reflective markers that will enable a video-based analysis system to record your movements. As such, it is necessary for you to be wearing shorts and a sleeveless shirt so we can easily place these markers on your neck shoulders, hips and lower back.

4. Muscle Activity Assessment (electromyography or EMG):

The EMG measures the activity of the active muscle. Muscle activity of a number of leg muscles will be monitored via electrodes placed on skin's surface. This may require some hair to be shaved from these sites and cleaned with an alcohol wipe. You will be asked to walk at a self-selected and comfortable pace on a treadmill and over ground while EMG activity is recorded.

Intervention

Transcranial direct current stimulation (tDCS):

You will participate in a tDCS intervention that aims to improve your gait and balance. tDCS sessions will last for 20 minutes and will be supervised by the principal researcher of the study at all times. During the tDCS session, stimulation will be delivered using a battery driven stimulator with two electrodes placed on your head. During the stimulation you will be walking on a treadmill while wearing a safety harness to protect you from accidental falls. This stimulation will occur over three consecutive days with two-week intervals.

CONSENT FORM FOR QUT RESEARCH PROJECT

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RESEARCH TEAM CONTACTS

Vida Alizad 07 3138 6304 vida.alizad@hdr.qut.edu.au
Graham Kerr 07 3138 6303 g.kerr@qut.edu.au

STATEMENT OF CONSENT

I agree to be a participant in the research project entitled "Effects of transcranial direct current stimulation on gait in people with Parkinson's disease" as described in the participant information form.

I acknowledge that:

1. The testing procedures and their possible effects have been explained to me and I have been given the opportunity to ask questions regarding this project and the tests involved.
2. I understand that questions related to this project are welcome at any time and can be directed to **the QUT Movement Neuroscience** Program on **07 3138 6304** or **07 3138 6303**.
3. I have been informed that I am free to withdraw from the study at any time, without comment or penalty.
4. I understand the project is for the purpose of research and not for treatment.
5. I have been informed that the confidentiality of the information I will provide will be safeguarded.
6. Understand that if I have concerns about the ethical conduct of the project I can contact the Research Ethics Advisory Team on 07 3138 5123 or email humanethics@qut.edu.au.

After considering all these points, I consent to my participation in this project, which will involve the following:

Demographic and Health Questionnaires
Clinical assessments (cognition, balance, vision and touch sensitivity)
Gait Assessment (3D Motion Analysis)
Muscle Activity Assessment (electromyography)
transcranial Direct Current Stimulation
Walking on a treadmill
Photo video recording

☐ Please indicate by ticking the box whether you would be happy to have the information collected from this study included in a larger data set which examines changes over a longer period of time.

☐ Please indicate by ticking the box whether you would be happy to be contacted to participate in any future assessments related to this research (e.g. for a follow-up examination).

☐ Please indicate by ticking the box whether you would be happy your collected data to be used in other relevant research in future.

A full explanation of the identified procedures is provided.

Participant's Name: ..... Date: .....

Participant's Signature: .....

Researcher's Name: ..... Date: .....

Researcher's Signature: .....

PLEASE RETURN THE SIGNED CONSENT FORM TO THE RESEARCHER.