Queensland University of Technology
Brisbane Australia

PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT

Improving postural stability and reducing falls risk in people with Parkinson's disease using textured insoles: a randomised controlled trial

QUT Ethics Approval Number 1300000584

RESEARCH TEAM CONTACTS

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Institute of Health and Biomedical Innovation (IHBI) – Queensland University of Technology (QUT)

DESCRIPTION

The purpose of this project is to develop an improved understanding of interventions to prevent falls in older people and people with Parkinson's disease, contributing to improvement in quality of life for individuals. This project is supported by the National Health and Medical Research Council and is a collaboration between QUT and the University of Queensland (UQ).

The research team is looking for community dwelling older people and people with Parkinson's disease (expected age 55-85 years) who have not had surgical treatment or recent musculoskeletal injury, who wear covered shoes for most of the day and who are able to walk without assistance. We request your participation in this research study that will investigate whether a new textured insole can improve postural stability and thereby prevent falls. Diminished sensory information of the feet that occurs in older people and people with Parkinson's disease leads to impaired mobility and postural instability, which causes the high risks of admission to hospitals or nursing homes. This insole is developed to stimulate the perception of sensory information from your feet during standing and walking and improve your postural stability.

THE PROJECT

The project will require involvement over eight months. During an initial 4 week period your daily physical activity and balance will be monitored whilst you undergo your normal activities of daily living in your home environment. At the end of this period you will be randomly allocated into different groups. Depending on which you may be provided with customized insoles to wear in your normal shoes. If you have been allocated insoles you will be requested to wear these as much as possible over the next 28 weeks. During this time you will be asked to keep a record of your daily activity, balance and falls.

At the start and end of the insole wearing period you will also undergo assessment of your cognition, strength, peripheral sensation, peripheral nerve function, balance and walking at IHBI at QUT. These assessments, which are described below, will occur over two separate days.

HOME BASED ASSESSMENTS:

Falls and activity calendars will be provided to enable you to record any falls and injuries and what footwear and insoles you are wearing on a daily basis. Once a month we will also ask you to complete a diary over a one week period which records the type, duration and frequency of physical activity. During this time you will also be asked to wear an activity monitor on your wrist so that the overall amount of activity can be measured. You will also be provided with an iPod touch device to enable you to record your own balance stability during this same period.

LABORATORY BASED ASSESSMENTS:

These will be undertaken at the start and end of the intervention and will include the following:

Questionnaires & Clinical Assessments:

You will be asked to complete questionnaires related to your health and medical conditions, physical activity, falls and quality of life. An assessment of your cognitive function will be undertaken.

For people with Parkinson's disease assessment of disease severity will be undertaken using clinical examination and questionnaires.

Falls Risk Assessment:

The Falls Risk Assessment involves simple tests of balance, lower limb strength, reaction time, vision and coordination. These assessments have been designed to provide quick, easy and safe assessments of the different components that contribute towards overall balance.

Balance and Gait Assessment:

You will be asked to undertake a series of balance and walking tests in different surfaces. These assessments will be undertaken while you are (i) barefoot, (ii) wearing shoes with a smooth insole and (iii) wearing shoes with a textured insole.

Peripheral Nerve Function:
These assessments include evaluating your perception of touch, vibration, joint positions sense, hot and cold temperatures and pain. The function of the nerves of your legs will also be assessed by recording how your muscles are activated with small electrical stimuli.

The research will be conducted at IHBI, QUT Kelvin Grove Campus. Free parking is available at the Institute and Kelvin Grove is easily accessible via public transport. The duration of each session is expected to take approximately 2 hours.

PARTICIPATION

Your participation in this project is voluntary. If you do agree to participate, you can withdraw from participation at any time during the project without comment or penalty. Your decision to participate will in no way impact upon your current or future relationship with IHBI, QUT or UQ. Your participation will involve questionnaires and other assessments as follows:

EXPECTED BENEFITS

This project will provide you with an assessment of your falls risk. Your involvement in this study will assist in exploring the mechanism on falls and develop interventions to prevent fall-related injuries in older people and people with Parkinson's disease, which will contribute to improvement in quality of life for individuals. Furthermore, this project will enable changes in postural stability and gait to be correlated with quantified measurements of peripheral nerve function.

RISKS

Through your involvement in this research, there is a chance that you may feel fatigued or loss of balance during some components of the laboratory testing protocols. However, you will be provided with rest breaks between tests and you may request additional breaks if you require them. The investigators will be positioned in close proximity to protect you. Also you can stop the research procedure as soon as you feel that you are likely to lose balance. However, the risks are no greater than that experienced in similar routines incorporated into everyday life.

The assessments of peripheral nerve function, nerve conduction tests involve applying a small electrical current to the limb which may feel like a tingling sensation; this may be uncomfortable for you. No discomfort should be felt once the test has been completed. There is a chance of some discomfort due to the temperature changes of cold and hot. A ticklish sensation may be experienced due to the vibration. These uncomfortable feelings are all slight and tolerable. The risks are no greater than that experienced in similar routine clinical tests.

Additionally, QUT provides for limited free counseling for research participants of QUT projects, who may experience some distress as a result of their participation in the research. Should you wish to access this service please contact the Clinic Receptionist of the QUT Psychology Clinic on 07 3138 0999. Please indicate to the receptionist that you are a research participant.

PRIVACY AND CONFIDENTIALITY

All data will be kept at IHBI in a locked storage cabinet. Data will also be stored in password-protected files on a computer within the Institute and back-up copies will be held on removable media for storage off-site. The researchers will take every care to ensure that individually identifying material will be removed from the data as soon as it is possible, in order to preserve the privacy and confidentiality of the subjects. Your identity will not be disclosed in the reporting of the research.

CONSENT TO PARTICIPATE

Participation in this project is entirely voluntary; however, it is important to recognize that you are free to withdraw consent before during or after the experiment without comment or penalty. Under no circumstances will you be prejudiced as a result of your actions, your participation or withdrawal of consent will not influence your present or future involvement with IHBI, QUT or UQ.

QUESTIONS / FURTHER INFORMATION ABOUT THE PROJECT

Please contact the researcher team members named above to have any questions answered or if you require further information about the project.

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE PROJECT

QUT is committed to researcher 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 Unit** on **07 3138 5123** or email ethicscontact@qut.edu.au. The Research Ethics Unit is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

Full Explanation of Tests

Questionnaires and Clinical Assessments

Demographic and Health Questionnaires:

The demographic and health questionnaire consists of questions relating to your demographics, physical activity, falls, vision, health and medical conditions, medications, disabilities and pain.

Cognitive Functioning and Memory Assessment:

During a brief interview, your attention and memory will be assessed using a short questionnaire-based assessment known as the Addenbrookes Cognitive Examination (ACE).

Disease Severity:

For people with Parkinson's the severity of the disease will be assessed by the motor part of the Unified Parkinson Disease Rating Scale (UPDRS), the Parkinson's Disease Questionnaire-39 (PDQ-39), the PD Gait and Falls Questionnaire (Freezing of Gait) and the Modified Falls Efficacy Scale.

Clinical Mobility Tests:

Clinical mobility tests will also be used to assess your balance and mobility. The Berg Balance Scale, the Tinetti Test, Functional Reach Test and the Get Up and Go Test are all clinical tests of balance.

Falls Risk Assessment:

The falls risk assessment consists of five core components. These include tests of visual function, proprioception, muscle strength, reaction time and postural sway. The details of these five components are outlined below:

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

b) ***Muscle Strength:*** This test will be measured around your knee using a strain gauge attached with a padded strap. This test will last about two minutes and you will be required to perform three near-maximal isometric knee extension (quadriceps) contractions while seated. The knee flexion force will be measured using the same procedure. Your dorsiflexion force will be measured by using a footplate attached to a spring gauge. Your hand grip strength will be measured by a hand-held dynamometer.

b) ***Reaction Time:*** Finger reaction time will be measured whilst seated and using a red light stimulus. When you see the red light illuminate you will be required to press a button in response to this light to turn it off as quickly as you possibly can.

d) ***Postural Sway:*** This test will take place under four sensory conditions (eyes open, eyes closed, standing on a firm surface or standing on a foam block). Postural sway will be measured by a recording device attached to a belt and on a force plate, while you attempt to stand as still as possible for a thirty second period. To ensure safety, an investigator will be standing beside you at all times.

Dynamic Postural Stability and Gait Assessment

Standing Balance:

You will be required to stand with the eyes open and closed on a firm force plate and on a piece of medium density foam rubber. 3D motion measurement devices will be mounted on your head, upper trunk, lower trunk, the pelvis and the heels of the feet, the sway data will be recorded during standing.

Walking:

You will be asked to walk at a self-selected pace under specific conditions that are common to everyday living, including walking on different surfaces (e.g. firm or uneven). During these tests you will wear reflective markers that are used to record the position of your limbs and body. As such, it is necessary for you to be wearing shorts and a t-shirt so we can easily place these pieces of equipment on the surface of the skin.

All measurements will be undertaken in the following conditions:

(1) Barefoot
(2) Shoes with smooth insole.
(3) Shoes with textured insole.

Peripheral Nerve Function

a) ***Electrodiagnosis:*** Electrodiagnosis-Neuropack S1 (Nihon Kohden) will be used to evaluate the nerve conduction functions of feet. Perform tests on the peroneal, tibial and sural nerves of your feet. A small electrical current will be applied to the sensor which may feel like a tingling sensation. Thus the computer can undertake the waveform measurements, calculate the conduction velocity of nerves.

b) ***Vibration Sense and nociception (Pain and temperature):*** Vibration sense of leg is measured using an electronic device that generates a 200-Hz vibration of varying intensity. The vibration is applied to your leg via a 1-cm-diameter rubber stopper and is measured in microns of motion perpendicular to the body surface. Three readings in the ascending mode and 3 readings in the descending mode are made, and an average of these 6 measurements is recorded as the vibration threshold. Medoc Advanced Medical Systems (Medoc Ltd) will also be used to evaluate the vibratory perception of the feet. A vibratory device will be positioned to your feet, the vibratory option measures thresholds for vibratory stimuli at 200-Hz and amplitudes between 0.1 to 130micros. This method provides two types of stimuli: stimuli that increase in intensity until a sensation is felt and stimuli that decrease in intensity until no sensation is felt.

c) ***Nociception (Pain and temperature):*** In this test, a small device, called Thermode will be attached to your skin of feet. The device is capable of heating or cooling the skin as needed. For threshold measurement, a quantified measureable temperature stimulus is induced by the device. A simple push-button response by you, recorded by the computer will terminate the stimulus. As soon as you feel a temperature change you can press the button, making the thermode return to adaptation temperature. This test is NOT a pain tolerance test. The stimulus is gradually increased beyond the initial thermal sensation, and when it starts to become unpleasant, that is about to become painful, the response button is pressed again (do not let it cause you pain). You will be instructed to press the button before the temperature causes you pain. Thus the pain threshold can be obtained.

d) ***Touch Sensitivity:*** This test will measure sensory in different parts of your feet using Semmes-Weinstein-type pressure aesthesiometer, which contains different filaments of equal length, but varying in diameter. We will apply smaller and smaller filaments until you can no longer detect them and then applies larger filaments until a filament is detected. Thus the touch sensitivity threshold will be recorded.

e) ***Lower Limb Proprioception:*** This test requires you to match your leg position with your eyes closed. A graded Perspex partition will be placed between your feet and you will be asked to match the position of your second leg to your first leg's position, by moving your leg at the knee. 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 played by proprioceptive inputs in balance. This test is non-invasive and you will be seated throughout this test.