Research protocol for Australian & NZ trials

Title:	The effect of noisy galvanic vestibular stimulation on somatosensory responses in older adults.
Rationale:	It is well known that the vestibular system imparts the foundational control signals for position, motion, and postural control, relative to the extrinsic environment. All these complex functions need to incorporate vestibular inputs with signals from the various sensory systems. Somato-sensation is one such sensory modality. Some evidence in healthy people (Ferre et al., 2013) suggests that supra-threshold galvanic vestibular stimulation (GVS) when delivered through different polarities has specific facilitatory effects on somatosensory detection. (Ferre et al., 2013). As supra-threshold GVS is uncomfortable and can cause adverse effects such as dizziness and vomiting, it is more feasible to deliver nGVS which delivers GVS with a sub-threshold weak current. A meta-analysis of nGVS studies and the effect on balance showed no impact of nGVS on balance in adults ≥ 40 years as compared to ≤ 40 years. In the literature to quantify balance or the ability to maintain an upright posture, many variables are used for older population. The Centre of pressure (COP) sway length is one of them i.e., length of path travelled by COP. The increased COP sway length is considered as predictor of falls in standing (Howcroft et al., 2017), however, the normative quite standing cannot test older person's prediction to falls and is not considered as the appropriate measure for balance. It is important to embrace the person for spontaneous sway which could be either done by eyes closed or through narrow base of support (BOS) (Mancini & Horak, 2010). A study conducted by Johnson & Charlotte (2020) showed the touch thresholds could be a significant predictors of balance performance. Previously, a study was conducted to investigate the effect of nGVS on somatosensory perception in on young healthy adults (18-45 years); this showed a significant effect on the somatosensory perception of tactile stimuli to the foot from pre to post intervention. On the other hand, for maintaining balance, cognition has emerged as an important factor in older population. To evaluate the interaction between cognition and mobility, the dual-task paradigm is an accepted way in clinical practice where a person is observed during the balance task while they perform another task (Muir-Hunter et al., 2016). Therefore, through all these findings, we want to conduct a new study investigating the effect of nGVS on the somatosensory perception of tactile stimuli in older adults aged ≥ 65 years. The study will involve participants with ≥ 65 years of age as 65 years is defined the age for older adults.

	The study is conducted to determine whether the nGVS alters somatosensory perception (i.e., if receiving galvanic stimulation impacts on the individual's ability to perceive sensory stimuli on the foot), the effects of nGVS on the true positive rate (TPR) for sensory perception will be compared with sham stimulation. In addition to measuring sensory perception, this study will assess if the change in somatosensory perception could have impact on balance outcomes i.e., COP sway length on force plates through dual task paradigm approach where participant is attending to somatosensory task while maintaining balance on the force plates. The findings from this study will be used to better understand any somatosensory enhancement induced by nGVS in older adults. It is assumed that this proposed study will help to give a detailed view of whether the vestibular system can influence processing within the somatosensory pathway which is important for human balance and if the change in somatosensory perception could enhance COP sway length through dual task paradigm. This research will help to expand our understanding of the links between the vestibular system and the somatosensory system. It is hoped that future research will develop a nGVS intervention capable of improving balance and preventing falls in older adults.
Aims and Objectives:	**Primary Aim:** To determine whether a single session of nGVS, compared with sham stimulation, alters sensory perception of a tactile stimulus measured FOLLOWING the intervention in healthy older adults.
	Secondary objectives: **1)** To determine whether nGVS, compared with sham stimulation, alters sensory perception of a tactile stimulus measured DURING the intervention in healthy older adults. **2)** To determine whether change in sensory perception alters COP sway length during dual task paradigm.
Study Design:	Repeated-measures crossover design
Number of Sessions:	Two
Study Population:	27 healthy older adults, ≥ 65 years to be recruited from the community on first come first served based.
Recruitment	• AUT gym through Never too old group • Participants from other related studies who have given consent to contact them for the future studies

	• Personal networks of students and staff members • The researcher will provide the flyers to different community groups and to the professional networks. The researcher will put the flyers on the reception areas. • The flyer is advertised online through FB community pages (as many older adults look FB); the researcher or the research assistant will send the e-copy of the flyer to the admin of Facebook pages such as AUT students, AUT gym, local Facebook area community group pages etc. • Briefing about the study and providing flyers to different community health providers. The potential participant will be given study flyer and invitation for the study; however, no personal information will be given by health provider about the participant. • Flyers will be placed on the AUT AH clinic notice board and placed on the reception. • Retirement villages. The researcher will drop flyers for the residents to read. The researcher will also provide a brief talk at the village (depending on the consent and time availability from the manager) regarding her study for the people who will be interested in balance-related research.
Method	Each participant will be met at the car park and will be greeted Kia ora/Good morning and will be offered a seat and then water. They will be thanked for coming in. Then the participant will be given information about the methodology "In the participant information sheet, it explains that this research is about noisy galvanic vestibular stimulation where you will receive very mild current behind your ears. During the stimulation we will test the feeling in your right foot by applying some mild electrical stimulation (called sensory tests). I will ask you to tell me if you feel the current or not. We will also test this before and after we stimulated behind your ears. There will be in-between breaks which will allow you to sit down on chair. If at any stage you feel tired or uncomfortable, please say without any hesitation. If in case you do not feel like participating or want to withdraw, you will be able to do so without any hesitation, and it will not affect the research. If you have any questions, please ask. Also,

	while doing sensory testing during the intervention, we will ask you to stand on force plates; this will only take about 2 minutes without any burden to you. Next, I will be completing a health screening form to check that you do not have any medical condition that would prevent you in participating in this research study". Just to make sure your handedness, I am also going to give you a simple questionnaire named Edinburgh Handedness Inventory (EDI) in which you tick the column that from which hand you do the activities written in questionnaire. "Now, I am going to give you a consent form to get your written consent that you are ready to participate in this study. Then the consent form will be given to the participant for his/her consent followed by health screening form and Edinburgh Handedness Inventory questionnaire and will be requested to fill the forms. The participant will be again asked about any doubt that he/she may have before starting the method. If you wish to withdraw you will be free to withdraw from the study at any point. Then the participant will be asked or Karakia. Participants (n = 27 older healthy adults) will attend two intervention sessions with two different conditions. Each participant will receive the two conditions in a randomised order. During the first intervention session (day 1), introductions, the consent process, and familiarisation will be undertaken. Following this, the process involves three steps for each of the two respective sessions: Step 1: Setup, Step 2: Outcome measures, and Step 3: Intervention. There will be at least 48 hours or 2-7 days gap between the two sessions i.e., the first session will be performed at day 1 and session 2 will be performed on the day 3. ***<u>Setup:</u>*** For setup, the staircase procedure will be used to setup the thresholds for somatosensory detection task (SSDT) measurements. This involves determining the sensory threshold. The sensory threshold will be termed "100%". A simple example for determining sensory threshold is 5mA=100% sensory threshold, 4.5 mA= 90% sensory threshold, 5.5mA=110% sensory threshold) ***<u>Outcome Measures:</u>***

	This measurement process involves carrying out an SSDT. The SSDT will be administered using a repeated-measure design before, during and after delivering each intervention (real nGVS or sham). During the SSDT, electrical stimuli will be delivered to the lateral border of the right foot through electrical stimulation (Digitimer, DS7A). The different stimulus type trials which will be delivered to the right foot during the SSDT are A (above: 10% threshold, i.e., 110%); B (below: -10% threshold, i.e., 90%) and C (Catch, in which no stimulus will be present, i.e., 0%). The trials will be delivered randomly to avoid any learning effect by the participant. Participants will report whether they can detect each trial. Through these measurements, the following outcome measures will be determined: • True positive rate (TPR): The number of tactile stimuli a person can feel when stimulation is set at 90% of sensory threshold. • True negative rate: When a person received a catch (i.e., no stimulation), and said "NO". • False positive rate: When a person received a catch and said, "YES". • False negative rate: When a person received a 110% stimulus and said, "NO" ***Intervention:*** Following the baseline (pre-stimulation) measurement, the participants will receive one of the two intervention conditions for 20 minutes in a randomised order within a 2 to 7 days period. The two conditions for interventions are as follows: **i. nGVS** The participant will receive 20 minutes of real nGVS. **ii. Control protocol (sham)** The participant will receive 20 minutes sham (electrodes applied, but no stimulation is given). During the first 5-20 minutes of stimulation, the A (110% threshold), B (90% threshold) and C (0% threshold) will be measured through SSDT. Further, after the cessation of stimulation, for 5-20 minutes post-stimulation, the A (110% threshold), B (90% threshold) and C (0% threshold) will be measured through SSDT. Whilst performing sensory testing, during the first 5 minutes, the participant will be asked to stand on the force plates where COP sway length will be measures for balance. COP sway length will be measured twice for 30 seconds each on participants before intervention (Pre-stimulation), during first 5 minutes of intervention and post intervention. During the experiment, the fade-in and fade-out times will be set at 5 seconds and COP sway length will be measured for 30 seconds after the fade in time.

Debriefing	At the end of the second session participant will be thanked for coming in and for their valuable time. Koha will be given to them. The researcher will further say: "Thank you for coming in today and giving your valuable time for this research. This is a small token of appreciation for you. Just because of you this research is possible. Regarding the stimulation on your foot, we were expecting that you would not be able to feel all the stimulation, and that was because 30 trials were given at a high level, 30 at a low level, and 10 trials had no stimulation at all. We did not tell you earlier that there would be some trials without stimulation because we did not want that information to affect your response. Given this new information are you happy that all your data is still included in the study? You are also welcomed to withdraw your data if you do not agree. If you agree, we will use your findings for the analyses and if you need the summary of the results or your own data individually (which you have ticked in the consent form), we will either post or email you at the completion of the study. If you have given consent to contact you for future research, then one of our team members will be in touch base with you regarding that. Once again thank you for coming in today and for your time." Karakia singing. Then the researcher will accompany participant to the car park for see off.

1. General information

2.1 PROTOCOL TITLE

THE EFFECT OF NOISY GALVANIC VESTIBULAR STIMULATION ON SOMATOSENSORY RESPONSES IN OLDER ADULTS.

2.2 DATE PROTOCOL WRITTEN

24th November 2022

2.3 SPONSOR

AUT University and Eisdell Moore Centre (University of Auckland)

2.4 RESEARCH SITE

AUT University, 90 Akoranga Drive, Northcote, Auckland.

2.5 RESEARCH TEAM

Preet Kamal Kaur, PhD candidate, AUT (responsible for managing research)

Research Assistant (Yet to be named)

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Sharon Olsen, PhD, Lecturer, AUT (secondary supervisor)

Dr. Nicola Saywell, PhD, Head of Department (Physiotherapy), AUT (advisor)

Dr. Imran Niazi, Research Officer, AUT (programmer)

2. Rationale & background information

It is well known that the vestibular system imparts the foundational control signals for position, motion, and postural control relative to the extrinsic environment. All these complex functions need to incorporate vestibular inputs with signals from the various sensory systems. The somatosensory system is one such system. In electrophysiological studies, a complex vestibular network called the parieto-insular vestibular network was identified and this is a neuroanatomical possibility for the vestibular and somatosensory confluence (Grüsser et al., 1990a, 1990b). These studies elicit an interesting suggestion that the vestibular system has a widespread interaction with multisensory cortical networks which include somatosensory areas. A study conducted by Fasold and colleagues (2002) on healthy adults suggested that there is an anatomical projection of the vestibular and somatosensory system. These projections go into the higher centres, activating the parieto-insular cortex, around the central sulcus, and in parietal, temporal, occipital, and frontal areas (Fasold et al., 2002). Several studies have used caloric vestibular stimulation to find the direct effects of vestibular

stimulation on somato-sensation (Bottini et al., 2013; Ferre et al., 2012; Ferrè et al., 2011; Ferre et al., 2013). However, caloric vestibular stimulation has some methodological limitations. There is no complete control of some stimulation parameters with this technique, such as the control of volume of cold air or the timing of the stimulation (Lopez et al., 2010).

In 2013, Ferrè and colleagues used the non-invasive technique of GVS on somatosensory perception by administering different GVS polarities. The process involved using a small weak direct current through electrodes placed on the mastoid process. It is known that GVS can regulate the firing rate of vestibular afferents by changing the stimulation polarity, and can increased the firing rate through cathodal currents and decreased through anodal currents (Ferrè et al., 2013; Fitzpatrick & Day, 2004). According to a study by Ferre and colleagues (2013), GVS activates the vestibular cortical projections by inducing excitatory postsynaptic potentials (EPSPs) in both tactile and vestibular neurons. GVS through the bipolar binaural way causes firing of both vestibular organs, thus imitating head motion in space. A recent development of GVS is nGVS, which uses subsensory stimulation levels of GVS delivered along with a gaussian noise signal to enhance weak sensory input and facilitate information processing in sensory systems. nGVS also has the potential to influence postural responses.

It is well known that the vestibular system imparts the foundational control signals for position, motion, and postural control, relative to the extrinsic environment. All these complex functions need to incorporate vestibular inputs with signals from the various sensory systems. Somato-sensation is one such sensory modality. Some evidence in healthy people (Ferre et al., 2013) suggests that supra-threshold galvanic vestibular stimulation (GVS) when delivered through different polarities has specific facilitatory effects on somatosensory detection. (Ferre et al., 2013). As supra-threshold GVS is uncomfortable and can cause adverse effects such as dizziness and vomiting, it is more feasible to deliver nGVS which delivers GVS with a sub-threshold weak current.

A meta-analysis of nGVS studies and the effect on balance showed no impact of nGVS on balance in adults ≥ 40 years as compared to ≤ 40 years. In the literature to quantify balance or the ability to maintain an upright posture, many variables are used for older population. The Centre of pressure (COP) sway length is one of them i.e., length of path travelled by COP. The increased COP sway length is considered as predictor of falls in standing (Howcroft et al., 2017), however, the normative quite standing cannot test older person's prediction to falls and is not considered as the appropriate measure for balance. It is important to embrace the person for spontaneous sway which could be either done by eyes closed or through narrow base of support (BOS) (Mancini & Horak, 2010).

Previously, a study was conducted to investigate the effect of nGVS on somatosensory perception in on young healthy adults (18-45 years); this showed a significant effect on the somatosensory perception of tactile stimuli to the foot from pre to post intervention. A study conducted by Johnson & Charlotte (2020) showed the touch thresholds could be a significant predictors of balance performance.

On the other hand, for maintaining balance, cognition has emerged as an important factor in older population. To evaluate the interaction between cognition and mobility, the dual-task paradigm is an accepted way in clinical practice where a person is observed during the balance task while they perform another task (Muir-Hunter et al., 2016).

Therefore, through all these findings, we want to conduct a new study investigating the effect of nGVS on the somatosensory perception of tactile stimuli in older adults aged ≥ 65 years. The study will involve participants with ≥ 65 years of age as 65 years is defined the age for older adults.

The study is conducted to determine whether the nGVS alters somatosensory perception (i.e., if receiving galvanic stimulation impacts on the individual's ability to perceive sensory stimuli on the foot), the effects of nGVS on the true positive rate (TPR) for sensory perception will be compared with sham stimulation. In addition to measuring sensory perception, this study will assess if the change in somatosensory perception could have impact on balance outcomes i.e., COP sway length on force plates through dual task paradigm approach where participant is attending to somatosensory task while maintaining balance on the force plates.

Therefore, the primary aim of the study is to determine whether a single session of nGVS, compared with sham stimulation, alters sensory perception of a tactile stimulus measured FOLLOWING the intervention in healthy older adults. The secondary objectives are: 1) To determine whether nGVS, compared with sham stimulation, alters sensory perception of a tactile stimulus measured DURING the intervention in healthy older adults.; 2) To determine whether change in sensory perception alters COP sway length during dual task paradigm.

The findings from this study will be used to better understand any somatosensory enhancement induced by nGVS in older adults. It is assumed that this proposed study will help to give a detailed view of whether the vestibular system can influence processing within the somatosensory pathway which is important for human balance and change in somatosensory perception could enhance COP sway length through dual task paradigm. This research will help to expand our understanding of the links between the vestibular system and the somatosensory system. It is hoped that future research will develop a nGVS intervention capable of improving balance and preventing falls in older adults

3. Research Question

Research question 1: What are the effects of a single session of nGVS compared to sham stimulation on sensory perception of tactile stimuli in older adults post intervention?

Research question 2: What are the effects of nGVS on sensory perception of tactile stimulus in older adults during stimulation?

Research question 3: Does the change in sensory perception alters the COP sway length (total excursion) in healthy older adults during dual task paradigm?

4. Study Design

5.1 DESIGN

Repeated measures crossover design. Each participant will receive each of the interventions, at least 48 hours apart within 2-7 days gap between the sessions, in a randomised order. The study is double blinded.

5.2 INCLUSION CRITERIA

- Adults aged 65 years and over
- Right-handed
- Can stand for 1 hour without any difficulty or assistance (which is divided into 3 sessions of 20 minutes standing, with 2 minutes of break in between each 20-minute period)

- Willing to take part in research for two sessions
- Willing to give consent to touch head and neck
- Can come to AUT (Akoranga campus)

5.3 EXCLUSION CRITERIA

- Diagnosed vestibular disorder or active BPPV
- Fallen more than twice in the past 6 months (Gaebler et al, 1993)
- Any diagnosed neurological impairment
- Medical conditions that are contraindicated with nGVS such as implants in head, neck, ankle or right foot, epilepsy, cardiac arrhythmias, unexplained recurring headaches, diabetic neuropathy (Thakral et al., 2013).
- Medical conditions that are cautioned with electrical pheripheral stimulation of the foot such as metal implants in the area, skin lesions (Kuzyk & Schemitsch, 2009)
- Medical conditions that might affect the testing such as such as speech dysfunction, cognitive impairment
- Any allergic skin reaction to sticking plasters as a similar substance is used in the foot electrodes and to fix the nGVS electrodes

5.4 PRIMARY OUTCOME MEASURE:

- True positive rate (TPR): The electrical stimulation will be applied at 10% below threshold, i.e., at 90% sensory threshold for 30 times. The number of times the participant correctly identifies the stimuli will be scored out of total 30 number of trials (Bottini et al., 2013; Ferre et al., 2012; Ferrè et al., 2011; Ferre et al., 2013).

5.5 SECONDARY OUTCOME MEASURES:

- True negative rate (specificity): This will be the number of trials in which the participants received a catch (i.e., no stimulation), and said “NO”. (Ferre et al., 2011).
- False positive rates: This will be the number of trials in which the participants received a catch and said, “YES”.
- False negative rate: This will be the number of trials in which 110% stimulus is given and participants say ‘no’.
- Perceptual sensitivity (d’)
- Response bias (C)

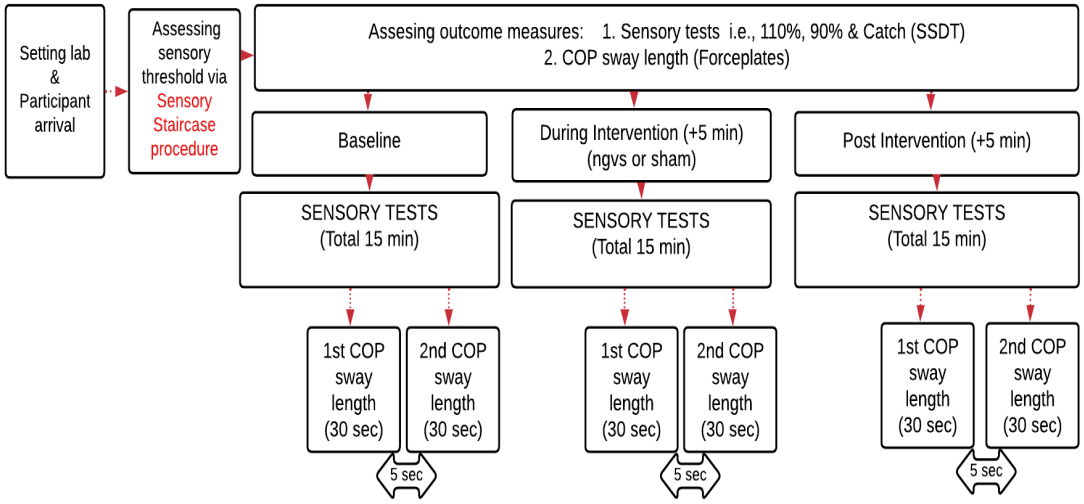
Signal detection analysis (Macmillan et al, 1991) will be used to interpret the data for the SSDT task. That is a reason for the plan to measure three categories (as described above) according to the participant’s responses.

- COP sway length will be obtained from VALD Performance Force decks dual force plate system.

5. Methodology

6.1 SCHEDULE

Written consent will be obtained from the participants who were screened and met the study criteria during the first session (day 1), followed by intervention with either the nGVS or sham intervention. The participants will attend the second session 2-7 days later. The order of sessions one and two will be randomised according to a schedule determined by the researcher using www.randomization.com.



The same above mentioned procedure is done on :
Session 1 (day 1, with intervention ngvs or sham) and repeated atleast 48 hours after on Session 2 (between day 2-7, with intervention sham or ngvs)

6.2 PROCEDURE

6.2.1 SET UP

The set-up is predetermined prior the start of data collection.

The nGVS machine, electrical stimulator, and associated leads/electrodes will be set up as below:

nGVS through 1X1 Galvanic vestibular stimulator

- Parameters set for the noisy galvanic stimulation (subthreshold)@ Waveform: Random Noise; Intensity: 1 mA, Polarity: Bipolar; Durations: 20 minutes.

Electrical stimulation through Digitimer DS7A

- Parameters set for the electrical stimulation; Voltage: 400(Vmax); Pulse width: 2000 us(microseconds) (I have chosen 2000 microseconds because it is 2 milliseconds, and 2 milliseconds is indeed 0.002 second which is bigger in turning the trigger and is not faint than the 500 microsecond). Also 500us is really brief pinprick and fires of the nerve; Intensity: as per staircase procedure.

Force plates

COP sway length was measured for 30 s twice at three timepoints: baseline, during intervention (+5 min) and post intervention (+ 5 min), at 100 Hz, in standing by VALD Performance Force decks dual force plate system. The average COP sway length value will be calculated.

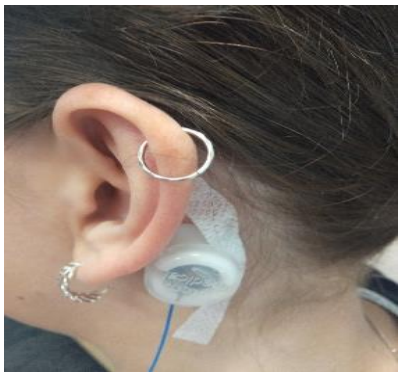
6.2.2 PARTICIPANT ARRIVAL

The participant will be asked to sit comfortably. Consent will be documented, and all procedures will be explained the participant, as follows:

The researcher will prepare the skin behind the ear by rubbing it with alcohol swab to take any extra body oil and allowing to dry. The nGVS electrodes will be applied behind both ears on the mastoid process and the Ambu blue sensor ECG electrodes on the lateral border of the right foot, respectively.

Instructions to participant:

- *This is an electrode. I am going to place behind your both ears. I will prepare the skin by cleaning it with alcohol swab to get rid of body oil. I will be placing two of these electrodes, one each on your left and right ear.*



- *This is an electrode. I am going to place on outer border of your right foot. I will prepare the skin by cleaning it with alcohol swab to get rid of any body oil. I will be placing 4 of these electrodes on the outer border of your right foot.*

- *Is it ok for me to apply both types of electrodes now?*

Then the “sensory threshold” will be determined using a staircase procedure (Ellaway et al., 2012; Schmidt et al., 2013) through the Digitimer. This is followed by measurement of the detection rate using a stimulus below the -10% threshold.

6.2.3 SETTING SENSORY – THRESHOLD THROUGH STAIRCASE PROCEDURE

To setup the threshold for somatosensory detection task (SSDT) measurements, a staircase procedure will be used. This involves determining the sensory threshold. The sensory threshold is termed the 100% threshold. To initially calibrate the stimulus intensity for each potential participant, the current intensity will be delivered through the Digitimer at 1mA and increasing in steps of 0.1 mA until the participant responds YES, indicating a tingling sensation (first threshold) to the researcher. The stimulus intensity will be decreased until the participant reports NO, indicating the disappearance of sensation (second threshold). This procedure will be repeated a second time and the median of these values will be defined as the sensory threshold of the participant (K Oppenlander et al., 2015).

To record the sensory threshold, the participant is required to stand with their feet together.

The following instructions given to participant:

- *Please stand still.*
- Now we are *going to measure how strong you feel the current on your feet.*
- *I will do this two times.*
- *Ready to start?*
- *Are you ready?*
- *Just let me know when you feel the sensation by saying Yes/No*

6.2.4 OUTCOME MEASUREMENT PROCESS THROUGH SOMATOSENSORY SIGNAL DETECTION TASK (SSDT)

This outcome measurement process involves carrying out a SSDT. The SSDT will be administered using a repeated-measure design before, during and after delivering each intervention (real nGVS or sham). During the SSDT, electrical stimuli will be delivered to the lateral border of the right foot through electrical stimulation (Digitimer, DS7A) to identify the threshold and -10% (Ferre et al., 2011). The different stimulus type trials which will be delivered to the right foot during the SSDT are A (above: 10% threshold, i.e., 110%), B (below: -10% threshold, i.e., 90%) and C (sham in which no stimulus will be present i.e., 0%). The trials will be delivered randomly to avoid any learning effect by the participant. Participants will report whether they can detect each trial. Through these measurements, we will determine the following outcome measures:

- True positive rate (TPR): The number of tactile stimuli a person can feel when stimulation is set at 90% sensory threshold.
- True negative rate: When a person receives a catch (no stimulation), they say “no”
- False positive rate: When a person receives a catch (no stimulation), they say “yes”
- False negative rate: When a person receives a 110% stimulus, they say “no”
- COP sway length in millimetres

6.2.5.1 BEFORE, DURING, AND FOLLOWING INTERVENTION

As mentioned above in the SSDT section, overall, 70 trials (explained below) will be administered to the lateral border of the right foot. A, B and C will be randomised. The participants will be blinded throughout the task.

- 30 trials of A (above, at +10% threshold, i.e., 110%) on the right foot
- 30 trials of B (below, at -10% threshold, i.e., 90%) on the right foot
- 10 trials of C (catch in which no signal will be present i.e., 0%) on the right foot

The trials will be delivered via programmed computer. The participant will indicate whether they have felt the stimulus, and this will be recorded. Each trial will last for 13 seconds (Kuzyk & Schemitsch). The following will be explained:

- *Please stand still.*
- *Now we are going to deliver small pulses to your foot and record when you can feel them.*
- *We will test you for about 15 minutes, and you will hear regular warning signals to let you know to pay attention. You may or may not feel something after the signal and we want you to indicate if you feel something by saying Yes or No after the warning signal.*
- *Ready to start.*
- *Are you ready?*
- *Please indicate if you feel something.*

Whilst participant completing sensory testing, and responding Yes/No, during the last 2 minutes of sensory testing, the COP sway length will be measured twice in standing at each timepoint for 30 seconds with 5 seconds in between the two consecutive measurements on the force plates (VALD Performance Force decks dual force plate system).. During the experiment, the fade-in and fade-out times will be set at 5 seconds and COP sway will be measured for 30 seconds after the fade in time. The following will be explained.

- *Please could you come on these force plates and stand still.*
- *Could you please place your feet on the stickers below.*
- *Now we are going to measure your balance.*
- *You don't need to do anything as the force plates will automatically measure your data.*
- *We are also delivering small pulses to your foot as we did before.*
- *Say yes/No after the warning signal.*

6.2.5.1 FOLLOWING INTERVENTION

As mentioned above in the SSDT section, overall, 70 trials (explained below) will be administered to the lateral border of the right foot. A, B and C will be randomised. The participants will be blinded throughout the task.

- 30 trials of A (above, at +10% threshold, i.e., 110%) on the right foot
- 30 trials of B (below, at -10% threshold, i.e., 90%) on the right foot
- 10 trials of C (catch in which no signal will be present i.e., 0%) on the right foot

The trials will be delivered via programmed computer. The participant will indicate whether they have felt the stimulus, and this will be recorded. Each trial will last for 13 seconds {warning (2 seconds) followed by trigger (1 second) followed by break (10 seconds)}. The following will be explained:

- *Please stand still.*
- *Now we are going to deliver small pulses to your foot and record when you can feel them.*
- *We will test you for about 15 minutes, and you will hear regular warning signals to let you know to pay attention. You may or may not feel something after the signal and we want you to indicate if you feel something by saying Yes or No after the warning signal.*
- *Ready to start.*
- *Are you ready?*

- *Please indicate if you feel something.*

6.2.6 INTERVENTION DELIVERY FOR CONDITION 1 OR 2

The participant will be standing comfortably. The stimulator and computer screen will never be visible for the participants.

Prior to the intervention, the following is explained to the participant:

- *The intervention involves applying some electrical stimulation to the electrodes behind your ears.*
- *I will turn up the stimulation until you can feel something behind your ears. Please let me know when you feel something. It should not hurt as it is very weak current, but please let me know if it does.*
- *Is it ok if I start now?*

The researcher will start the stimulation slowly by turning the current value up through adjustor switch called "RELAX" on the machine until the participant will perceive a tingling behind the ears. This intensity and location will be used in the subsequent intervention for the total of 20 minutes duration.

For the nGVS

The participant will receive 20 minutes of nGVS.

For the control protocol (Sham)

The participant will receive 20 minutes of sham for the sham stimulation, the stimulation will be started and then stopped without any notice to participant.

NOTE: When the researcher is not collecting data during the stimulation is on, the participant will be allowed to move the foot to avoid fatigue or discomfort from standing too still.

6.3 DATA COLLECTION:

All data will be collected using a combination of written data collection forms and computer software (MATLAB, Signal).

6.4 DATA ANALYSIS:

The data processing and analysis will be done by blinded assessor.

7. Safety Considerations

7.1 ELECTRODES

Electrodes may cause temporary skin irritation and redness. Participants will be offered aloe vera lotion following electrode removal.

7.2 ADVERSE EVENTS

Any adverse events will be recorded in an adverse event form and reported to Prof. Denise Taylor (primary supervisor) for appropriate follow up.

8. Follow-Up

When the study results have been interpreted, a summary of the study findings will be sent to the participants.

9. Data Management

Screening and consent forms will be kept in a locked filling office. After consent, participants will be given a unique participant code, and all subsequent data will be recorded against this code. Computer files will be saved in a folder on AUT's hard drive that is only accessible to Prof. Denise Taylor, Dr. Sharon Olsen and Preet Kamal, and on a USB hard drive that will be stored in a locked cabinet in Denise's office. Data collection sheets will be kept in a locked cabinet in Preet's office.

10. Sample size calculation

Based on data collected in previous study conducted by the team on healthy young adults "Investigating the effects on nGVS on somatosensory perception in healthy adults, a sample size of 27 participants is required after seeing the normality and order effect.

11. Statistical analysis

The SSDT results will be analysed using Signal detection analysis (Macmillam et al., 1991). The number of HITS (number of stimulus-present trials in which participant will say 'YES'), FALSE ALARMS (number of stimulus-absent catch trials in which participants will say 'YES'), MISSES (number of stimulus-present trials in which participant will say 'NO') and CORRECT REJECTIONS (number of stimulus-absent catch trials in which participant said 'NO') will be considered.
Further, a mixed between within subjects' analysis of variance (ANOVA) will be conducted to assess the impact of two different interventions (nGVS and sham) on the participant's scores of perceptual sensitivity d' and response bias (C) across three timepoints (Pre intervention, during intervention and post intervention). The normative check will be conducted using distribution before proceeding for ANOVA. A longitudinal analysis of covariance will be conducted to evaluate the primary null hypothesis that the true positive rate is equal across the two conditions. For this purpose, a linear mixed regression model will be constructed. The model will be estimated post-intervention outcomes while adjusting for the pre-intervention outcomes. To account for repeat measures from the same participants, the model estimation will be done as a participant-wise random intercept. The null hypothesis will be tested by statistically comparing the model-estimated post-intervention means using t-tests. The statistical significance level will be set at 0.05. These means and their differences will be reported along with their 95% confidence intervals

A statistical analysis will be carried out using SPSS software. Data from each outcome measure will be analysed using two-way repeated measures ANOVA and post hoc t-tests to explore main effects and interactions.

The mean difference of Sway path length parameter will be analysed.

12.Quality Assurance

The research assistant will be trained in the protocol (if required) by Preet Kamal Kaur.

13.Recruitment

If all participants have not been recruited by six months, recruitment will be ceased, and data collection/analysis will continue with those already recruited.

14.Project Management

Preet Kamal Kaur	Responsible for overall management of the research including organising appointment and supervision of RAs, recruitment, scheduling sessions, data collection, data processing, and data analysis.
Research Assistant	Responsible for assisting with data collection in lab sessions and doing randomisation and delivering the interventions or control as required.
Prof. Denise Taylor	Supervising project (primary supervisor).
Dr Sharon Olsen	Supervising project (secondary supervisor). Overseeing data collection processes.
Dr Nicola Saywell	Supervising project (Advisor).

15.Screening

The Researcher will screen all potential participants using a screening form.

Forms attached separately.

16.Informed Consent

All participants will be given an information sheet and will be asked to sign a consent form. Forms attached separately.

17.Budget

The following costs will be funded through previously sourced EMC funding and from FHES PhD student funds (AUT).

Resources Required	**Quantity**	**Estimated Costs**	**Funding Agency**
Consumables:			
Electrodes (ECG Mini Electrodes)	2 Packets	$60	
Gel Whiteleys	1	$25	
Fixomull stretch (5cm X 10m) Whiteleys	2	$27	**HRRI Funds**
Paper envelope for randomisation	1 Packet	$2	

Medi-Alcoholic Swabs (200/pack) Whiteleys Plastic container to store electrodes	1	$5 $10	
Countdown vouchers	27 participants x 2 visits=54	$1080	**EMC funds**
Research Assistant	50 hours (includes 3 hours training) X $23.30 60min X 2 sessions x 27 participants=3240 min =54 hours X $24.50	$ 1323	**EMC funds**
Printing and Photocopying Information sheets Consent sheets Data collection sheets	 30 sheets 30 sheets 30 sheets	$30	**FHES Doctoral Funds**
TOTAL		**$ 2562**	

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