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A soft pressure-sensitive skin sensor to measure lymphoedema treatment efficiency

Submission date	**Recruitment status**	[X] Prospectively registered
20/09/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/09/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/09/2023	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

The lymphatic system, primarily located in the abdomen, plays a crucial role in regulating fluid volume and removing pathogens. Lymphoedema, venous oedema and swelling occur due to inadequate drainage or when the lymph load exceeds the lymphatic transport capacity. This causes pain, motion difficulties, and an increased risk of skin infections. Cyclic compression of the limbs is currently used to decrease lymph build-up and swelling. However, treatment effectiveness is currently difficult to assess, as the required pressure and waveform timing remain unknown. This is largely due to the inability of current systems to measure the effective pressure applied on the skin and to the absence of an in-situ measurement of the treatment efficacy.

To address these issues, in this study the researchers will augment the functionalities of Flowpresso® with a soft sensing skin (IDE sensor) that will make it possible to measure the interfacial pressure applied on the participant's skin locally. The Flowpresso® suit is a commercialised therapeutic tool that combines compression and heat therapy. Compression therapy promotes better lymphatic function and flow within the body. The application of heat provides pain relief, improves circulation, and promotes metabolic activity.

The IDE sensor is placed between the human body and the Flowpresso® suit. This measurement helps determine the amount of compression exerted on the tissue by the inflated suit. By using the IDEs sensor, the researchers can assess how much of the air pressure inside the suit is transferred to the tissue, allowing evaluation of the effectiveness of the treatment over time.

The aim of this study is to test a soft pressure-sensitive skin (IDEs sensor) to measure lymphoedema treatment efficiency.

Who can participate?

Healthy volunteers of Māori or Pacific ethnicity who are 18 years of age or older.

What does the study involve?

The researchers will ask participants to attend an initial consultation where a consent form, sleep and quality of life questionnaires, bioimpedance spectroscopy and skin fibrometer measurements will be completed (information about these measures are described below). The consultation will take 10-20 minutes.

The sleep questionnaire is a form that will ask questions about sleep disturbance. The quality of

life questionnaire will ask about health and well-being using Whare Tapa Whā; taha tinana (physical), taha hinengaro (mental and emotional), taha wairua (spiritual), taha whānau (family) health. The bioimpedance spectroscopy is used to assess lymphoedema in limbs. Electrodes will be placed on the surface of the skin to measure this. The Skin Fibro Meter is used to assess tissue stiffness. This device is pressed against the skin.
The researchers will ask participants to attend three Flowpresso® sessions where the effects of tissue fluid and tissue stiffness will be assessed with the IDEs Sensor placed on both arms. Only one arm of the Flowpresso® suit will be attached. Bioimpedance spectroscopy and Skin FibroMeter measurements will be taken before and after each session.
Each session will be held at The Centre for Health (103 Third Ave, Tauranga) and will take 40-50 minutes. Three sessions once a week for three consecutive weeks are required for each participant.
After the third Flowpresso® session the researchers will ask participants to complete the sleep and quality of life questionnaires for comparison and ask some questions about the acceptability of the Flowpresso®.

What are the possible benefits and risks of participating?
The pressure and heat from the Flowpresso® suit may have an impact on joints, muscles and other body parts where the compression occurs. The heat and compression can also be uncomfortable. Participants may also experience increased urination for 24 hours after the Flowpresso® session.
A study about health and well-being can potentially affect both positively and negatively on psychological and spiritual wellbeing. To support participants the researchers will adhere to the tikanga (cultural principles) and kawa (cultural practices) that participants advise us to use. If anything difficult arises during the sessions the researchers will help participants to access appropriate support services.

Where is the study run from?
The Centre for Health (New Zealand)

When is the study starting and how long is it expected to run for?
May 2023 to April 2024

Who is funding the study?
1. The Consortium for Medical Device Technologies (CMD) - Te Tītoki Mataora, Med Tech Research Translator (New Zealand)
2. Auckland Bioengineering Institute, University of Auckland (New Zealand)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Flowpressure/ 3726141

Study information

Scientific Title
Functionalities of Flowpresso® to determine patient-specific treatment

Study objectives
The purpose of this research is to see if a newly developed skin sensor (IDEs Sensor) can make it possible to deliver patient-specific treatment when used in conjunction with the Flowpresso® suit. Clinical trials will be performed to demonstrate the ability of the sensing skin (IDEs sensor) to measure the localised applied pressure. The IDEs sensor will make it possible to relate the air pressure applied to the suit with the effective pressure applied to the patient's skin. The instrumented pressure suit will make it possible to deliver patient-specific lymphatic treatment and to monitor its effectiveness in real time, two crucial parameters currently lacking in systems.

The use of the IDE sensor with the suit will be culturally acceptable to Māori and Pacific participants.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/08/2023, Southern Health and Disability Ethics Committee (Ministry of Health, 133 Molesworth Street, PO Box 5013, Wellington, 6011, New Zealand; +64 (0)800 400 569; hdecs@health.govt.nz), ref: 2023 FULL 16764

Study design
Single-centre interventional uncontrolled proof-of-concept study

Primary study design
Interventional

Secondary study design
Proof-of-concept trial

Study setting(s)
Other

Study type(s)
Treatment, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Lymphoedema in Māori and Pacific participants

Interventions
The Centre for Health (TCFH) will recruit 10 participants from the Maori or Pacific Community to undertake three FLOWpresso sessions, one per week. Three sessions in previous trials have shown to achieve the most impact and will ensure sufficient engagement with Maori and Pacific candidates, to understand their experience.

Participants will attend TCFH for an initial consultation with the Coordinating Investigator, where a consent form, sleep questionnaire, Kaupapa Māori Quality of Life Questionnaire (QoL), L-Dex and Skin FibroMeter measure, will be completed (see outcome measures section below).

Participants will then undertake a 40-minute FLOWpresso® session. The effects of tissue fluid and tissue stiffness will be assessed with the pressure-sensitive skin sensor placed within one arm piece of the FLOWpresso suit. The other arm of the FLOWpresso will not be attached to the participant so as to be able to assess the difference in pressure and stiffness between arms. A post-session LDex and SkinFibroMeter measurement will be taken.

Participants will return to TCFH for another 40-minute FLOWpresso® session in week 2 and in week 3. A pre and post LDex and SkinFibroMeter measurement will be taken.

After the third FLOWpresso session, the participants will complete the sleep and kaupapa Māori QoL questionnaire again and be asked about the acceptability and cultural appropriateness of the FLOWpresso by a Māori or Pacific researcher who is part of the wider TCFH research team. This ensures that all participants have received the full benefits of the three sessions and that we can understand the cultural acceptability of the FLOWpresso for Māori and Pacific Islanders.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
IDEs Sensor, FLOWpresso suit initial version without distributing sensing

Primary outcome measure
1. The amount of compression exerted on the tissue by the FLOWpresso suit, measured using the IDEs sensor at sessions 1-3
2. Lymphoedema in limbs measured using bioimpedance spectroscopy (BIS) before and after each session (1-3)
3. Tissue stiffness measured using a Skin FibroMeter before and after each session (1-3)

Secondary outcome measures
1. The health and wellbeing of Māori and Pacific participants, measured using a culturally appropriate Kaupapa Māori QOL Questionnaire prior to the first session and after the third session
2. Sleep disturbance measured using DSM-5 Level 2 – Sleep Disturbance Questionnaire prior to session 1 and after session 3

Overall study start date
01/05/2023

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Of Māori or Pacific ethnicity
2. At least 18 years old
3. Volunteered to participate in this study
4. Volunteered to sign the informed consent

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Not of Māori or Pacific ethnicity
2. Under 18 years old
3. Pregnant or breastfeeding
4. Have congested heart failure
5. Have a pacemaker or defibrillator
6 Have a history of blood clots or deep vein thrombosis
7. Lymphoedema

Date of first enrolment
25/09/2023

Date of final enrolment
20/12/2023

Locations

Countries of recruitment
New Zealand

Study participating centre

The Centre for Health
103 Third Avenue
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Sponsor type
Other

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ROR
https://ror.org/00805ky43

Funder(s)

Funder type
University/education

Funder Name
The Consortium for Medical Device Technologies (CMD) - Te Tīkoki Mataora, Med Tech Research Translator

Funder Name
Auckland Bioengineering Institute, University of Auckland

Results and Publications

Publication and dissemination plan
It is planned that study results will be published in a peer-reviewed journal and internal reports. Dissemination will also be guided by participants at both a provider and whānau (family) level.

Intention to publish date
30/04/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication