ISRCTN94599670 https://doi.org/10.1186/ISRCTN94599670

Wearable textile with integrated electrotherapy for joint pain management

Submission date
12/09/2024

Recruitment status
Recruiting

Registration date
17/09/2024

Overall study status
Ongoing

Last Edited
08/07/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the most common musculoskeletal condition and affects about a fifth of adults over the age of 45 years. Currently, there is no single treatment, with most patients being advised to control their weight, take regular exercise and use painkillers as necessary. Transcutaneous electrical nerve stimulation (TENS) is a non-invasive stimulation technique that applies a mild current through electrodes that are in contact with your skin. The research team have developed a wearable garment with built-in TENS electrodes. TENS can be used to help to manage knee pain. Therefore, this research study funded by the Medical Research Council will assess how effective this treatment is at controlling knee pain.

Who can participate?
Adult people aged between 45 to 70 years old who have been diagnosed with knee osteoarthritis

What does the study involve?
If the participant decides to take part in the study, a member of the research team will answer any questions they may have. They will be asked some initial screening questions, and if eligible, they will be asked to sign a consent form, receiving a copy for their records. The research team will take their body measurements, and the participant will try on a prototype garment that best matches their size. After a week, they will collect the wearable garment, a control device, and a diary to track usage. The participant will wear the garment for 12 weeks, 5 days per week, using TENS therapy daily. After 12 weeks, they will return the garment and complete a final questionnaire during an in-person session at the University of Southampton. The research team will also contact the participants for brief interviews and reminders to complete questionnaires throughout the study.

What are the possible benefits and risks of participating?
Participants will have the opportunity to use a TENS garment for 12 weeks. The information gathered from this study will help the research team evaluate the effectiveness of TENS in managing knee pain, and the findings may contribute to scientific evidence for future recommendations. Participants will receive £20 for each in-person session, plus reimbursement for travel expenses.

As for risks, the knee sleeve is made of fabric commonly used in everyday clothing, and the electrode materials have passed biocompatibility tests. The TENS device's electronics follow standard safety guidelines, and participants can adjust the current to a comfortable level, with a safe maximum limit in place. However, participants may experience muscle soreness, similar to that felt after intense exercise, and there is a possibility of mild skin irritation developing over time.

Where is the study run from?
University of Southhampton

When is the study starting and how long is it expected to run for?
July 2022 to March 2026

Who is funding the study?
Medical Research Council (MRC)

Who is the main contact?
Prof Kai Yang, ky2e09@soton.ac.uk

Study website
None

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Kai Yang

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Additional identifiers

EudraCT/CTIS number

IRAS number
335669

ClinicalTrials.gov number

Secondary identifying numbers
University Hospitals Southampton sponsorship: RHM RHE0001, IRAS 335669

Study information

Scientific Title
Efficacy of electronic textile based transcutaneous nerve stimulation (TENS) in patients with knee pain due to osteoarthritis: a pilot randomised controlled trial

Acronym
OA-Tex

Study objectives
Osteoarthritis (OA) is the most common musculoskeletal condition, with painful knee OA being highly prevalent. While people with knee OA who exercise regularly experience less pain and improved physical function, pain typically reduces physical activity, which is linked to a range of adverse health events. Knee pain is traditionally managed using medication (NSAIDs/opioids), which costs the UK £195.3 million p.a., however these medications can cause side effects. TENS is a non-pharmacological treatment that may be beneficial for pain relief, reduction of stiffness, and improvement of knee joint function. Previous research studies have highlighted a possible role for TENS in the management of painful knee OA. However, methodological concerns remain about how to use this technology optimally.

The research team has developed a wearable garment with two pairs of integrated TENS electrodes around the knee together with a TENS electronic control unit. Following laboratory and home usability studies, a pilot RCT will be used to inform the design of a future trial by estimating the variability of pain reduction and functional outcomes of TENS use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/12/2024, South Central – Hampshire A Research Ethics Committee (HRA, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; Telephone number not provided; hampshirea.rec@hra.nhs.uk), ref: 24/SC/0358

Study design
Single-centre double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Wearable Textile with Integrated Electrotherapy for Joint Pain Management. Participants will be randomly allocated to treatment or control (sham treatment) in a 1:1 ratio according to a randomisation schedule held by the statistician. The schedule will be based on block randomisation with varying block sizes to avoid imbalance in treatment allocation concerning known and unknown confounders and to avoid any potential for anticipation of future participants' treatment allocation.

Intervention group and sham (2 x 40 participants) - double-blinded randomised. Home use of garment with wired TENS unit for 12 weeks.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
OA-Tex wearable textile with integrated electrotherapy for joint pain management

Primary outcome measure
Pain measured using a Visual Analogue Scale (VAS) at baseline, 1 week, 4 weeks, 8 weeks, 12 weeks

Secondary outcome measures
The following secondary outcome measures will be assessed at baseline, 1 week, 4 weeks, 8 weeks, 12 weeks
1. Patient-reported pain, joint stiffness and physical function measured using the VAS, the Western Ontario and McMaster Universities Arthritis Index (WOMAC) and the Oxford Knee Score (OKS)
2. Health-related quality of life measured using the EuroQol-5 Dimensions-5 Levels (EQ-5D-5L)

Overall study start date
01/07/2022

Completion date
31/03/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/01/2025:

1. Adults between 45 and 75 years of age
2. Diagnosed with knee OA according to American College of Rheumatology criteria
3. Pain score ranging from 3 to 7 on the Visual Analog Scale (VAS)
4. Participants will not have prior experience with TENS or other electrotherapy (e.g. interferential therapy)
5. Able to stand up unaided
6. Willing and able to give informed consent

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Previous inclusion criteria:

1. Adults between 45 and 70 years of age
2. Diagnosed with knee OA according to American College of Rheumatology criteria
3. Pain score ranging from 3 to 7 on the Visual Analog Scale (VAS)
4. Participants will not have prior experience with TENS or other electrotherapy (e.g. interferential therapy)
5. Able to stand up unaided
6. Willing and able to give informed consent

Participant type(s)
Patient

Age group
Mixed

Lower age limit
45 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
100

Total final enrolment
80

Key exclusion criteria
1. Prior major knee surgery (i.e. partial or total knee arthroplasty)
2. Anticipated surgery during the study (no anticipated surgery during the 12 weeks of the study)
3. Skin sensitivities and sensation problems
4. Uncontrolled epilepsy
5. Those who are pregnant; planning to become pregnant or are breastfeeding
6. An active device implant (e.g. pacemaker user)
7. A stent in the lower limb

Date of first enrolment

01/02/2025

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Southampton
Southampton University Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

Sponsor details
Tremona Road
Southampton
England
United Kingdom
SO16 6YD
+44 (0)2380 777222
sponsor@uhs.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.uhs.nhs.uk/

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trial will be reported in a manuscript that will be submitted to a peer-reviewed medical journal as open access. The trial will be reported in accordance with relevant Consort Guidelines. All publications arising from this trial will acknowledge the Funder. The trial protocol will also be submitted for open-access publication in a peer-reviewed journal. A lay summary of the trial results will be produced and provided to sites to pass on to trial participants.

Intention to publish date
30/09/2026

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from the Chief Investigator Prof Kai Yang, ky2e09@soton.ac.uk, and Sponsor (University Hospital Southampton NHS Foundation Trust). The data arising from the trial will be owned by the Sponsor and the Project Team. On completion of the trial, the data will be analysed and tabulated and a Final Trial Report prepared. This report will be submitted to the Trial Sponsor and will be publicly available. Participating investigators will not have the right to publish any of the trial data without the permission of the CI and Sponsor.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	version 1.5				

Participant information sheet			16/09/2024	No	Yes
Protocol file	version 1.4		16/09/2024	No	No
Participant information sheet	version 1.9	23/12/2024	20/01/2025	No	Yes
Protocol file	version 1.8	01/12/2024	20/01/2025	No	No
Participant information sheet	version 2.0		08/07/2025	No	Yes