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Testing a device to improve sensation in a painful limb

Submission date
12/05/2021

Recruitment status
No longer recruiting

Registration date
28/05/2021

Overall study status
Completed

Last Edited
30/12/2024

Condition category
Signs and Symptoms

[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
Complex Regional Pain Syndrome (CRPS) is a chronic pain condition of the limbs that is commonly triggered by trauma. About half of patients treated get partial relief from pain and very few, if any, experience complete pain relief. Furthermore, stopping medication is common due to unwanted side effects. GP attendances for chronic pain equate to 4.6 million per year and about £584 million for prescription pain medications. These populations experience poor response to current treatments, are very disabled, and care is primarily focused on self-management of persistent pain.
People with CRPS often perceive non-painful stimuli, such as a light touch, as painful (known as 'allodynia'). Furthermore, when a person with CRPS receives contact to their painful body part, they are usually unable to determine the texture, temperature and location of that contact. A two-point discrimination test can be used to measure an individual's ability to discriminate between two close points on the skin. The assessment involves touching the skin in one or two places and, without looking, the individual is asked how many points of touch they can feel. This indicates how well sensations are felt in this area.
Research studies have demonstrated that sensory discrimination training can improve sensory discrimination and therefore reduce patient-reported pain. Current sensory discrimination training provided in clinical practice involves a therapist or carer manually applying different textiles or stimuli to both the 'affected' and an 'unaffected' body site. Therapy is slow to deliver improvements and attendance is poor.
Researchers have developed a computer-controlled device (Sensory Training System [STS]) that provides this sensory training using electrical stimulation. The device consists of four electrodes on a strip which are held in place using a soft wearable band. The device is connected to a tablet computer which has a choice of two training games and one relaxation activity. The training games ask participants to pay attention to the electrodes and decide which one is delivering a buzzing sensation. One of the training games has various levels. Participants can also be challenged by changing the spacing between the four electrodes. Five electrode strips will be provided, each with different sized spacing between the electrodes. The smaller the spacing, the more difficult participants may find it. In the relaxation activity the electrodes will buzz in time to music. The buzzing sensation will be gentle and should not be painful. A similar device has been shown to be effective in improving pain levels in other chronic pain conditions.
The aim of this study is to see if people with CRPS find the device is usable, acceptable and

interesting enough to use for a minimum of 30 minutes each day for 30 days. This study will also investigate the effect of the device on awareness of sensation in or near the painful limb and the impact on the level of pain experienced by participants.

Who can participate?
Adults (aged over 18 years) with CRPS who are willing to use the STS in their home for 30 minutes a day for 30 days can participate in this study. Participants must be able to place a wearable band with an electrode strip above their painful site, have an average pain level of 5 or lower at rest on a 0-10 scale in the past 7 days, and have access to appropriate technology and a person within their household or appropriate COVID-19 bubble to conduct the two-point discrimination assessment.

What does the study involve?
Eligible and willing participants will be asked to complete an online consent form and the first of two questionnaires. The first online questionnaire will record the result of their sensory discrimination assessment and include questions about pain intensity, pain interference, sensitivity and emotional feeling about their affected limb.
Participants will receive the STS kit which will include instructions for use and a paper diary. The instructions for use will also be available in video format. Participants will be asked to use the STS device every day for a minimum of 30 minutes a day. This can be during a single session or divided over multiple sessions over the day as determined by participant preference. The device will record the frequency and duration of use. The simple paper diary will allow participants to record changes in electrode size and comment on their experience of using the device.
Participants will be contacted once a week by the researcher to provide support and to answer any questions.
At the end of the 30 days, a second questionnaire will be sent to participants. This will include the same questions as the previous questionnaire, plus four additional questions about changes in pain, interference, sensitivity and feelings towards their limb.
Within 1 week of participants completing the 30-day STS device use at home, the researcher will conduct a telephone interview to ask them about their experiences of participating in the study and using the device.

What are the possible benefits and risks of participating?
The information from the study may help improve treatment for people with CRPS. Participants may temporarily exacerbate their pain, but the wearable band may be moved to a position further away from the painful area and participants can stop using the device at any point. Some participants may experience irritation where the electrodes are applied to the skin, but this is unlikely. The risk for pregnant women has not been investigated, so pregnant women will be excluded from this study. A standard operating procedure has been written to ensure compliance with infection control and COVID-19-related guidance.

Where is the study run from?
1. Royal United Hospitals Bath NHS Foundation Trust (RUH) (UK)
2. University of the West of England (UWE) (UK)

When is the study starting and how long is it expected to run for?
April 2019 to May 2023

Who is funding the study?
Versus Arthritis (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
273106

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 48600, IRAS 273106

Study information

Scientific Title
A sensory training system for use at home by people with persistent limb pain

Acronym
STS

Study objectives
1. Individuals with Complex Regional Pain Syndrome will use the Sensory Training System (STS) device, adhering to the treatment plan of 30 minutes a day for 30 days.
2. Participants will experience a change in sensory discrimination and perceived pain after 30 days of use of the STS device.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/04/2021, London – Stanmore Research Ethics Committee (Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)20 7104 8064; stanmore.rec@hra.nhs.uk), REC ref: 21/LO/0200

Study design
Proof of concept study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Treatment

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
Complex Regional Pain Syndrome (CRPS)

Interventions
All participants will be asked to use the STS for a minimum of 30 minutes a day for 30 days at home. The STS encompasses a customised wearable electrode array and a game-based training environment.

Eligible and willing participants will be asked to complete an online consent form and the first of two questionnaires. The first online questionnaire will record the result of their sensory discrimination assessment and include questions about pain intensity, pain interference, sensitivity and emotional feeling about their affected limb.

Participants will receive the STS kit which will include instructions for use and a paper diary. The instructions for use will also be available in video format. Participants will be asked to use the STS device every day for a minimum of 30 minutes a day. This can be during a single session or divided over multiple sessions over the day as determined by participant preference. The device will record the frequency and duration of use. The simple paper diary will allow participants to record changes in electrode size and comment on their experience of using the device. Participants will be contacted once a week by the researcher to provide support and to answer any questions.

At the end of the 30 days, a second questionnaire will be sent to participants. This will include the same questions as the previous questionnaire, plus four additional questions about changes in pain, interference, sensitivity and feelings towards their limb.

Within 1 week of participants completing the 30 day STS device use at home, the researcher will conduct a telephone interview to ask them about their experiences of participating in the study and using the device.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sensory Training System (STS) device

Primary outcome measure
Use of the STS device and adherence to the treatment plan, recorded by the STS device during the 30-day usage

Secondary outcome measures
Measured before and after 30 days of use of the STS device:
1. Average pain intensity over the past 7 days assessed using the Patient-Reported Outcomes Measurement Information System (PROMIS®) Numeric Rating Scale (v.1.0 -Pain Intensity 1a)
2. Pain interference over the past 7 days assessed using an 11-point numerical rating scale (0-10). This comprises four items in the PROMIS Item Bank (v1.1 – Pain Interference – Short Form 4a).
3. Average sensitivity over the past 7 days assessed on an 11-point numerical rating scale (0-10)
4. Participant's emotional feeling about their affected limb assessed on an 11-point numerical rating scale (0-10), informed by the Bath CRPS Body Perception Disturbance Scale

Overall study start date
08/04/2019

Completion date
04/05/2023

Eligibility

Key inclusion criteria
1. Adults (aged 18+ years) meeting the Budapest clinical criteria for upper or lower limb CRPS Type I
2. An area on their limb where a wearable band with electrode array can be attached above their painful site
3. An average pain level in the last 7 days rated as ≥5 at rest on a 0-10 scale
4. Access to appropriate technology and willingness to use this technology, that enables full study participation (a smart phone, tablet computer or computer compatible with using the video call function on Microsoft Teams, internet access, camera and an email address, physical and mental capacity to tolerate use of technology)
5. A person within their household, carer or a friend to carry out the two-point discrimination measurement

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
15

Key exclusion criteria
1. Diagnosis of any other neurological, motor disorder or major nerve damage (including CRPS Type II)
2. Any mental health condition which may detrimentally impede on study participation, in the judgement of the patient or researcher
3. The presence of any other limb pathology or pain on the affected CRPS limb
4. Poor skin condition on the area to be stimulated
5. Poorly controlled epilepsy
6. Receiving intensive CRPS specific multidisciplinary team rehabilitation in an inpatient setting during the time course of the study or within the previous month
7. Unable to understand written or verbal English and give informed consent
8. Active medical implants such as cardiac pacemakers or other devices
9. Exposed orthopaedic metalwork in the area of electrical stimulation
10. Pregnancy
11. Those living alone who have not formed a ‘support bubble’ with another household (applies only if social distancing measures, as recommended by the government, are still in place, as there would be no-one able to take the two-point discrimination measurement)
12. Known allergy to acrylates (added 20/07/2021)

Date of first enrolment
09/08/2021

Date of final enrolment
04/05/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal United Hospital
Royal United Hospital Bath NHS Foundation Trust
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University/education

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ROR
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Funder(s)

Funder type
Charity

Funder Name
Versus Arthritis

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The researchers intend to publish the protocol. On completion of the study a report will be prepared which will be submitted to the Research Ethics Committee and the funders, Versus Arthritis. Dissemination will include peer-reviewed publications, presentations at national /international conferences, social media and reports for relevant patient charities (CRPS UK and Burning Nights). The funder will be acknowledged in the publications and presentations. At the end of the study, the results will be available on the CRPS UK Clinical & Research Network website and a written summary will be available on request.

Intention to publish date

30/09/2025

Individual participant data (IPD) sharing plan

As this study is the first stage in a route to commercialisation, the researchers feel that the data produced would not be appropriate to share widely and may have implications on intellectual property ownership. The data would not be replicable or comparable in any way.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/05/2023	31/05/2023	Yes	No
HRA research summary			28/06/2023	No	No