ISRCTN64093359 https://doi.org/10.1186/ISRCTN64093359

Investigating the effectiveness of visual illusions in treating pain

Submission date
09/07/2018

Recruitment status
No longer recruiting

Registration date
17/07/2018

Overall study status
Completed

Last Edited
17/07/2018

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Complex Regional Pain Syndrome (CRPS) is excruciating pain of unknown origin in a limb. Symptom onset is typically triggered by trauma (soft tissue or a fracture) yet the pain continues well after the injury has healed and extends up the limb far beyond the original injured site. Persistent pain is disproportionate in severity to the resolved trauma and there is no known cure. Pain is accompanied by limb colour and temperature changes in addition to abnormalities in sweating, swelling, skin, hair and nail growth. Altered perceptions of the affected bodily region are described by patients as being distorted in shape and size and different from objective assessment. UK incidence is about 16,000 per year, with one in 60 of the UK population developing CRPS during their lifetime. Up to 26% of cases experience ongoing and unremitting symptoms causing long-term disability and impacting on their ability to work and their general wellbeing. These complex cases do not respond to conventional treatments. A recent small study found that viewing visual illusions that alter the size and shape of the painful hand can provide pain relief for CRPS patients. The aim of this study is to investigate the effects of this intervention on pain and other symptoms, in particular movement performance, in a larger sample of patients.

Who can participate?
Patients aged 18 and over with CRPS in one upper limb

What does the study involve?
The study uses the MIRAGE system developed for the upper limb by Dr Newport at Nottingham University. This system digitally manipulates real-time video of the hands and displays them so that they appear in the same physical and spatial location as the real hands allowing the presentation of a variety of visual illusions. The image of one hand is manipulated in various ways such as enlarging or shrinking the whole hand or specific digits and altering the colour of the hand. These manipulations are performed in real-time so that the participant is able to view their hands moving and can view handling objects within the illusion as though watching their own real hands. Whilst seated, the participant places each arm into one of the two apertures of the MIRAGE system so that their hands rest palm down on a flat surface within the system. Participants view their hands in a ‘window like’ surface above and perpendicular to these apertures. The MIRAGE system operator sits on the opposite side of the system facing the

participant. Illusions can be stopped immediately and returned to the real view without moving or withdrawing the hands from the box. The illusions do not require the operator to touch the participant's hands. Participants are randomly allocated to either the control group or the experimental group. Those allocated to the experimental group view their affected hand within the MIRAGE system and are asked to describe how they would like the appearance of their hand to be changed to represent how they wish their hand to look. The MIRAGE operator changes the appearance of the hand according to the participants' descriptions. Digital changes in size, colour, and shape are made to suit the specific requests of the participant. Participants are asked to confirm with the operator when the hand image looks correct to them and view the resultant image for a maximum of two minutes. Those allocated to the control group are asked to describe how they would like the appearance of their hand to be changed so that it represents how they wish their hand to look. The MIRAGE operator undertakes a sham procedure as if making these changes but no visual change is made to the hand image. The image is then viewed for a maximum of two minutes. Hand pain is measured before and after the intervention.

What are the possible benefits and risks of participating?
Results from the recent small study showed that the MIRAGE system did help relieve pain in some people with CRPS but not everyone. It is not known whether the MIRAGE device will be helpful or not to symptoms of CRPS. Improving knowledge in this area may help to inform treatments for patients with CRPS and other chronic pain conditions.

Where is the study run from?
1. Royal United Hospitals NHS Trust (UK)
2. The Walton Centre NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2013 to February 2016

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Jenny Lewis
jenny.lewis8@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Jenny Lewis

ORCID ID
http://orcid.org/0000-0002-6503-3749

Contact details
The Royal National Hospital for Rheumatic Diseases
Royal United Hospitals NHS Trust
Upper Borough Walls

Bath
United Kingdom
BA1 1RL
+44 (0)1225 473403
jenny.lewis8@nhs.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14768

Study information

Scientific Title
An intervention trial to investigate the effectiveness of visual illusions in manipulating body perception disturbances to reduce chronic pain and improve movement performance

Study objectives
This protocol describes an intervention trial to investigate the effectiveness of viewing visual illusions that alter the size and shape of the painful hand to provide pain relief for those with Complex Regional Pain Syndrome (CRPS). Recent pilot findings revealed that visual manipulation of the painful hands in CRPS patients provided pain relief. The proposed controlled study investigates the intervention effectiveness in a larger sample (n=88) on pain and other symptoms, in particular, movement performance. The optimum duration of the intervention to sustain these clinical effects will be determined.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Berkshire B, 04/06/2013, REC ref: 13/SC/0232

Study design
Randomised; Interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Musculoskeletal Disorders, Primary sub-specialty: Musculoskeletal Pain Disorders

Interventions
Study intervention
The study intervention utilises the MIRAGE system developed for the upper limb by Dr Newport at Nottingham University. This system digitally manipulates real-time video of the hands and displays them so that they appear in the same physical and spatial location as the real hands allowing the presentation of a variety of visual illusions. The image of one hand will be manipulated in various ways such as enlarging or shrinking the whole hand or specific digits and altering the colour of the hand. These manipulations are performed in real-time so that the participant is able to view their hands moving and can view handling objects within the illusion as though watching their own real hands.

Whilst seated, the participant places each arm into one of the two apertures of the MIRAGE system so that their hands rest palm down on a flat surface within the system. Participants view their hands in a 'window like' surface above and perpendicular to these apertures. The MIRAGE system operator sits the opposite side of the system facing the participant. Illusions can be stopped immediately and returned to the real view without moving or withdrawing the hands from the box. The illusions do not require the operator to touch the participant's hands.

Trial arm allocation
Following written consent participants will be randomly allocated to either the control or intervention arm by the MIRAGE operator in a 1:1 ratio. The clinical assessor will be blinded to this procedure.

Experimental arm
Those allocated to the experimental arm will undertake the experimental intervention. Whilst viewing their affected hand within the MIRAGE system the participant will be asked to describe how they would like the appearance of their hand to be changed to represent how they wish their hand to look i.e. desired appearance. The operator will change the appearance of the hand according to the participants' descriptions. Digital changes in size, colour, and shape will be made to suit the specific requests of the individual. Participants will be asked to confirm with the operator when the hand image looks correct to them and view the resultant image for a maximum of two minutes.

Control arm
Those allocated to the control arm will undertake the control condition. Participants will be asked to describe how they would like the appearance of their hand to be changed so that it represents how they wish their hand to look i.e. desired appearance. The MIRAGE operator will undertake a sham procedure as if making these changes yet no visual change will be made to the hand image. The image will be subsequently viewed for a maximum of two minutes.

Session 1
Consent, baseline outcome measures, allocation to trial arm, control or experimental

intervention, dependent on trial arm, post intervention measures. Approximate total session duration is two hours.

Sessions 2 to 4
Control or experimental intervention
The approximate total duration for each session is one and a half hours which involves a maximum intervention time of 30 minutes. Data will be collected within these intervention sessions.

Intervention Type
Other

Primary outcome measure
Measured at baseline, post intervention where stated and follow up in session 5:
1. Pain specific to the hand will be verbally captured using a 0-10 numerical rating scale (NRS) where 0 is no pain and 10 is worst pain imaginable, undertaken pre-post intervention
2. Pain assessed using the Neuropathic Pain Symptom Inventory at baseline
3. Body perception disturbance measured using the Bath CRPS body perception disturbance scale

Secondary outcome measures
Tactile acuity, measured using a two-point discrimination test pre and post intervention

Overall study start date
16/06/2013

Completion date
16/02/2016

Eligibility

Key inclusion criteria
1. Participants meet the Budapest criteria for CRPS (Harden 2010) in one upper limb and may have lower limb involvement (unilateral or bilateral)
2. >/= 18 years
3. Male or female
4. Describe an altered perception of their painful body
5. Able to understand verbal and written English
6. Willing to participate and provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Planned Sample Size: 88; UK Sample Size: 88

Key exclusion criteria
1. Serious ill health
2. Bilateral upper limb involvement
3. Dystonia
4. Co-morbidity that may influence CRPS symptoms i.e. stroke, diabetic peripheral neuropathy, progressive neurological disease such as multiple sclerosis, Parkinson's disease
5. Currently participating in an intervention trial

Date of first enrolment
16/06/2013

Date of final enrolment
16/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal National Hospital for Rheumatic Diseases, Royal United Hospitals NHS Trust
Upper Borough Walls
Bath
United Kingdom
BA1 1RL

Study participating centre
The Walton Centre NHS Foundation Trust
Lower Lane
Fazakerley
Liverpool
United Kingdom
L9 7LJ

Sponsor information

Organisation
Royal United Hospitals Bath NHS Foundation Trust

Sponsor details
c/o Jane Carter, R&D Manager
Royal National Hospital of Rheumatic Diseases
Bath
England
United Kingdom
BA1 1RL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/058x7dy48

Funder(s)

Funder type
Government

Funder Name
NIHR Trainees Co-ordinating Centre (TCC); Grant Codes: CAT-CL-03-2012-019

Results and Publications

Publication and dissemination plan
Preliminary findings from this study have been presented at the European Pain Congress (EFIC) Vienna 2015 and IASP CRPS Special interest group conference, Zurich 2015. Future presentations are confirmed for British Pain Society annual congress, Harrogate April 2016, and Allied Health Professional conferences in Belfast and Liverpool in the summer. An abstract was submitted to IASP biannual congress, Japan in September 2016. A manuscript has been written for submission to an international peer-reviewed journal - Pain. Furthermore, this data has formed the basis of a larger grant application to Arthritis Research UK which has been successful that includes brain imaging to better understand the therapeutic mechanisms of action of visual illusions in chronic pain to help improve central targets for future treatment.

Intention to publish date
17/10/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v4	21/05/2014	17/07/2018	No	Yes
HRA research summary			28/06/2023	No	No