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Sensory trick imagery as an additional treatment for involuntary neck muscle contractions (cervical dystonia)

Submission date
04/02/2021

Recruitment status
No longer recruiting

Registration date
25/02/2021

Overall study status
Completed

Last Edited
26/02/2021

Condition category
Nervous System 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
Cervical dystonia is a movement disorder characterized by involuntary contractions of muscles around the neck that cause abnormal postures and/or movements. It can be painful, limit the range of motion, and is associated with mental health problems such as anxiety and depression. The main treatment for cervical dystonia is with an injection of botulinum toxin into affective muscle. There are limited other options that are available.
Many people who experience cervical dystonia can experience alleviation of their involuntary muscle contractions by lightly touching a certain part of their face or neck. This phenomenon is called a "sensory trick."
In this study, we wish to determine whether people who have these sensory tricks can obtain relief from their cervical dystonia by simply imagining their sensory trick, rather than physically performing it. Further, we wish to determine whether practising this imaginary sensory trick (a technique called visual imagery), can strengthen its effect over time. In this way, the act of simply imagining one's sensory trick may be a treatment strategy for individuals with cervical dystonia.

Who can participate?
Patients at the Toronto Western Hospital movement disorder clinic who are receiving botulinum injections for cervical dystonia, with a working fluency of the English language

What does the study involve?
The study involves answering some questions about your medical history and dystonia. If a sensory trick is identified, you will be asked to demonstrate this sensory trick and be given instructions on how you can perform this sensory trick in your head (ie... visual imagery). This will be recorded on camera. You will be asked to practice visual imagery as much as possible before you next visit, at which point, you will be asked to demonstrate your sensory trick, and imagined sensory again. This will be recorded a second time.

What are the possible benefits and risks of participating?
The possible benefits include having another way of utilizing a sensory trick where hands-on practice is not possible (eg while driving) or in socially precarious situations.

Where is the study run from?
The study run from the University Health Network (Toronto Western Hospital) (Canada)

When is the study starting and how long is it expected to run for?
March 2016 to August 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ken Little, ken.little@alumni.ubc.ca

Contact information

Type(s)
Scientific

Contact name
Dr Ken Little

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
15-5059

Study information

Scientific Title
Sensory trick imagery as an adjunctive treatment modality in cervical dystonia – an open pilot study

Study objectives
1. In patients with cervical dystonia and a sensory trick, sensory trick imagery can alleviate symptoms of dystonia.
2. Practice of sensory trick imagery between appointments can strengthen its alleviating effect on cervical dystonia.
3. Practice of sensory trick imagery reduces Pain and Disability related to cervical dystonia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/04/2016, University Health Network Research Ethics Board (10th Floor, Room 1056, 700 University Ave. Toronto, Ontario, M5G1Z5, Canada; +1 (416) 581-7849; reb@uhnresearch.ca), ref: 15-5059-AE

Study design
Prospective single arm longitudinal cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

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
Alleviation of cervical dystonia

Interventions
Cervical dystonia patients are provided a questionnaire to obtain information about their dystonia and to identify whether they had a sensory trick.

Those with a sensory trick are asked to demonstrate it. This will be recorded.

This will provide the baseline measurement of the effect of the sensory trick in reducing dystonia severity.

A standard script will be adapted to each patient, in which they are asked to perform their sensory trick.

Immediately after, they will then be asked to imagine this process without any physical movements.

They will be asked to repeat this imagery process a second time, at which point the process will be recorded through video.

After this initial appointment, study participants will be asked to repeat this visual imagery process as often as possible, until the next study appointment.

At a follow-up visit 3 to 6 months later, subjects will be asked how often they practiced this visual imagery technique, whether they found that practice improved efficacy for alleviating dystonia, and to elaborate on this in an open ended fashion. The actual sensory trick and the imagined sensory trick will be video recorded again at this follow-up visit for later rating.

Intervention Type
Behavioural

Primary outcome measure
For patients who have completed both follow-up visit (baseline and second visit at 3 - 9 months), two movement disorders neurologists will independently rate the videos for the severity of dystonia using the Tsui scale at 6 time points: (a) baseline at first visit, (b) manual sensory trick at first visit, (c) imagined sensory trick at first visit, (d) baseline at second visit, (e) manual sensory trick at second visit and (f) imagined sensory trick at second visit. The videos will be presented in random order and the raters will be blind to the order in which the recordings are made.

Secondary outcome measures
At both visits (baseline and visit 3 - 9 months afterwards), pain and disability are measured using the Pain Subscale and Disability Subscale of the Toronto Western Spasmotic Torticollis Rating Scale (TWSTRS) will be completed.

Overall study start date
03/03/2016

Completion date
11/08/2017

Eligibility

Key inclusion criteria
1. Diagnosis of cervical dystonia
2. Working fluency in the english language

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
80

Total final enrolment
23

Key exclusion criteria
1. Unable to consent
2. Enrolment in other interventional dystonia research study

Date of first enrolment
03/06/2016

Date of final enrolment
09/12/2016

Locations

Countries of recruitment
Canada

Study participating centre
Toronto Western Hospital
399 Bathurst St.
Toronto
Canada
M5T2S8

Sponsor information

Organisation
Toronto Western Hospital

Sponsor details
399 Bathurst Street
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Sponsor type
Hospital/treatment centre

Website

http://www.uhn.ca/

ROR
https://ror.org/03qv8yq19

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a low-impact peer-reviewed journal.

Intention to publish date
01/03/2021

Individual participant data (IPD) sharing plan
The anonymized datasets generated during and/or analysed during the current study will be available upon request from Ken Little (ken.little@alumni.ubc.ca) upon publication of the study and for 5 years subsequently.
Datasets will be available to academic institutions for meta-analysis or systematic review, within the ethical and legal policies dictated by the University Health Network, Toronto.

IPD sharing plan summary
Available on request