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What is the best way to treat hand swelling?

Submission date
14/08/2017

Recruitment status
No longer recruiting

Registration date
16/08/2017

Overall study status
Completed

Last Edited
17/05/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Following an injury or surgery to the hand it may become swollen. This is a normal part of the healing process, but swelling which persists can have a negative impact on hand function and can delay recovery. This can require more frequent appointments, delays in return to work and difficulties with activities of daily living. Therapists use different methods to reduce the swelling in the hand to prevent it from causing long-term problems and to restore movement and function. However, therapists are not sure what the best methods are. The aim of this study is to compare two treatments that help reduce hand swelling, compression and elasticated tape, to establish which treatment works best.

Who can participate?
Patients aged over 18 who have had a hand injury or surgery and have hand swelling that needs treatment by a hand therapist at the Norfolk and Norwich Hospital

What does the study involve?
Participants are randomly allocated into two groups to receive either treatment as usual (compression) or the study treatment (elasticated tape) with full instruction from a hand therapist. Treatment as usual is some form of compression (called a compression glove, compression finger sleeve, or elasticated finger wrap) plus elevation and massage. The study treatment is elasticated tape plus elevation and massage. Participation in this study involves having one assessment of the swelling in the hand (inserting the hand into a container of water called a Volumeter) and completing three brief questionnaires, taking no more than 30 minutes. The same four assessments are repeated 4 and 12 weeks later by a research therapist who is not involved in treatment. Where possible, this is combined with usual hand therapy appointments. If this is not possible participants' travel and parking costs are reimbursed. Other aspects of hand therapy treatment continue as normal and are monitored by the treating hand therapist as needed.

What are the possible benefits and risks of participating?
This study will help to finding out which treatments work for hand swelling after an injury or surgery. This could help future patients with hand swelling and future studies into treatments for hand swelling. There are very few risks associated with taking part in this study. Treatment is stopped or changed at the discretion of the treating hand therapist in the following cases: worsening swelling or other relevant symptoms (pain, stiffness), or if a participant no longer

finds the treatment acceptable and wishes to discontinue. Details of barriers to using treatments (such as appearance, cleanliness etc) are recorded in a diary and questionnaire. A possible disadvantage is that therapy sessions take a little longer. If additional parking charges are incurred due to the study these can be reimbursed.

Where is the study run from?
Norfolk and Norwich University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2017 to June 2018

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

Who is the main contact?
Leanne Miller
leanne.miller@uea.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Leanne Miller

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Additional identifiers

Protocol serial number
35261

Study information

Scientific Title
The treatment of sub-acute hand oedema post trauma: a pilot randomized controlled trial

Acronym
STRETCH

Study objectives

The purpose of this project is to compare two treatments that help reduce hand swelling, compression and elasticated tape, and establish which treatment works best.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Service, 02/08/2017, ref: 17/ES/0098

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Rehabilitation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Musculoskeletal disorders, Primary sub-specialty: Other; UKCRC code/ Disease: Other/ General symptoms and signs

Interventions
Participants will be randomised using sealed envelopes to receive either:
1. Treatment as usual: compression (glove, wrap or digital sleeve) with elevation and massage
2. Trial treatment: elasticated Kinesiology tape with elevation and massage

Participation in this study involves having one assessment of the swelling in the hand (inserting the hand into a container of water called a Volumeter) and completing three brief questionnaires, taking no more than 30 minutes. The same four assessments will be repeated 4 and 12 weeks later by a research therapist who is not involved in treatment. Where possible, this will be combined with usual hand therapy appointments. If this is not possible patients' travel and parking costs will be reimbursed. Other aspects of hand therapy treatment will continue as normal and will be monitored by the treating hand therapist as needed.

Intervention Type
Other

Primary outcome(s)
1. Hand volume in millilitres, assessed using the Volumeter at baseline, 4 and 12 weeks
2. Severity of hand oedema, assessed using Oedema Rating Scale at baseline, 4 and 12 weeks

Key secondary outcome(s))
1. Function, assessed using the Patient Evaluation Measure (patient rated outcome measure) at baseline, 4 and 12 weeks
2. Quality of life, assessed using EQ-5D-5L at baseline, 4 and 12 weeks
3. Patient adherence, assessed using patient diary at 12 weeks
4. Patient acceptability, assessed using purpose designed questionnaire with a 0-10 scale at 12 weeks

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. Over 18 years old
2. Male or female
3. Referred to hand therapy post trauma or surgery
4. Hand oedema confirmed by a hand therapist as requiring hand therapy intervention
5. Reads and understands English language
6. Willing to take part and has full understanding of the randomization and allocation to treatment process
7. Able to give full informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
26

Key exclusion criteria
1. Patients more than 6-weeks after their injury and/or surgery whose oedema is not classified as sub-acute
2. Patients who are within the specified sub-acute timeframe but have already commenced oedema management treatments
3. Patients with diagnosed lymphedema, acute infections, deep vein thrombosis, blood clot or haematoma, active cancer, chronic heart failure, cardiac problems or renal dysfunction/failure /kidney disease, pulmonary problems or any other factor (physical or mental health) that may affect the patient's ability to adequately and safely monitor the use of tapes or gloves
4. Patients in the first 4 weeks of tendon repairs where removal of their splints in order to apply a glove would be contraindicated
5. Patients who do not have someone available to assist in the reapplication of kinesiology tape every 5-5 days, and who do not feel confident to reapply the tape themselves
6. Fragile skin (elderly and long-term steroid use) and open wounds
7. Patients with excessive amount of hair on their hand/forearms who would find the tape too

uncomfortable to be removed every 3-5 days and who may find the pull on the hairs from the tape an unacceptable side effect of using this method (Often patients will shave the section where the tape is being applied if this is deemed necessary and acceptable to the patient)

Date of first enrolment
01/09/2017

Date of final enrolment
30/03/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norfolk and Norwich University Hospitals NHS Trust
Colney Lane
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
University of East Anglia

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Trainees Co-ordinating Centre (TCC); Grant Codes: CDRF-2014-05-064

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Leanne Miller (leanne.miller@uea.ac.uk). This would be in the form of Excel spreadsheets with anonymised outcome measure results for the three data collection points for the analyses as stated in the protocol.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		17/05/2021	17/05/2021	No	No
HRA research summary			26/07/2023	No	No
Protocol file	version v1	30/05/2017	02/04/2019	No	No