

What is the best way to treat hand swelling?

Submission date 14/08/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/08/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/05/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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

Study website

N/A

Contact information

Type(s)

Scientific

Contact name

Miss Leanne Miller

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2017

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 100; UK Sample Size: 100

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

England

United Kingdom

Study participating centre

Norfolk and Norwich University Hospitals NHS Trust

Colney Lane

Norwich

United Kingdom

NR4 7UY

Sponsor information

Organisation

University of East Anglia

Sponsor details

Research and Enterprise Service
Norwich Research Park
Norwich
England
United Kingdom
NR4 7TJ

Sponsor type

University/education

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**Publication and dissemination plan**

Primarily the results of this observational study will form part of my doctoral thesis however it will also inform updates in local departmental oedema guidelines, will be presented, at national

and international hand therapy conferences and published in a relevant open-access peer-reviewed journal. Those patients who confirmed they would like to receive a report of the finding will be posted a basic science summary which will undergo patient and public involvement review.

Intention to publish date

30/12/2019

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?
Protocol file	version v1	30/05/2017	02/04/2019	No	No
Basic results		17/05/2021	17/05/2021	No	No
HRA research summary			26/07/2023	No	No