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The use of heated wax bath treatments for the hands in people with scleroderma: do they make hand exercises more effective?

Submission date
11/11/2013

Recruitment status
No longer recruiting

Registration date
17/12/2013

Overall study status
Completed

Last Edited
16/10/2018

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Systemic Sclerosis (SSc) is a multi-system connective tissue disease, the musculoskeletal symptoms of SSc are a major cause of disability, causing limitations to movement and function. The purpose of this study is to compare the effects of daily hand exercises with or without daily home wax bath hand treatment in people with SSc.

Who can participate?
Male or female participants with scleroderma and who have not received hand wax treatment before.

What does the study involve?
Participants will be randomly allocated to one of two groups: wax bath (treatment group) versus no wax bath (control group). In addition both groups perform regular hand exercises as part of standard care. Participants in the intervention group will be asked to use their wax bath daily as a 10 minute heating treatment to their hands prior to their home exercises. In the control group, participants will perform the exercises without any pre-exercise heat treatment.

What are the possible benefits and risks of participating?
We do not, at this stage, anticipate any more pronounced benefits when comparing intervention to control groups. There should be immediate benefits for all participants regarding hand and wrist function, range of movement and strength and associated health assessment questionnaire scores. Longer term benefits should include better self-management skills, knowledge of an appropriate hand and wrist stretch programme and the wax machine for home use. In addition to the expected risk of aches to the muscles, joints or skin associated with starting a new regular home hand exercise programme, the study will require some participants to use wax baths. The risks associated with the home use of wax baths are overheating of the hands, and infection or ulcer risk if using the machine with any compromise to skin integrity. These risks will be minimised by an information on how to set up and use the machine, a hand-out for participants and regular participant monitoring of skin integrity. Participation in the study will require participants to attend additional appointments and to receive a follow up

phone call. Where possible these will be arranged around the participants normal clinical schedule. Travel expenses will be reimbursed.

Where is the study run from?
This is a single site study. Recruitment will take place in the Rheumatology Out-Patient Department at Salford Royal Hospital (UK). Measurements, hand exercise and wax treatment demonstration and instruction will happen in the Physiotherapy Department at Salford Royal Hospital. The wax and hand exercise treatments themselves will be performed by the appropriately trained participant in their own home.

When is the study starting and how long is it expected to run for?
The study will start in November 2013 and end in June 2015. Recruitment is expected to start from December 2013 (ethics dependent) and last until 36 participants have completed measures (as late as January 2015).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Wax SSc PROTOCOL v3

Study information

Scientific Title
Wax therapy for Systemic Sclerosis: An assessor blinded, randomised controlled clinical trial

Study objectives

Primary research question:
Does the use of home wax baths in addition to a standard hand exercise programme in people with scleroderma improve their hand function?

Secondary research question:
If any changes are seen at the completion of a 9 week programme, are these changes sustained 9 weeks later after the intensive exercise and wax treatment period has ceased?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester East, 18/12/2013, REC reference: 13/NW /0773

Primary study design
Interventional

Study design
Single-centre randomised controlled trial of parallel group design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Systemic Sclerosis / Scleroderma

Interventions
The study will involve 36 people with scleroderma and some associated hand function limitation being recruited from the Rheumatology Department at Salford Royal Hospital. Participation will be over an 18 week period with treatment protocols being followed for the first 9 weeks and the 18 week assessment acting as a longer-term effect review.

Intervention group will use their wax bath daily, for the 9 weeks, to heat and soften the hands prior to standardised hand exercises.

The control group will perform the exercises with no prior hand warming / softening techniques.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The primary outcome measure in this study is the Hand Mobility in Scleroderma (HAMIS) (Sanqvist & Eklund 2000). It consists of 9 items that measure mobility of the fingers and the wrist; its primary purpose is to estimate the mobility of the hand precisely enough to detect limitations in range of movement, and at the same time, provide an indication of the patient's ability to use the hand in daily activities (Sanqvist et al. 2004, p.981). It requires some specific equipment which is used to score these nine items between 0 and 3. It takes about 3 minutes to

complete.
Measured at baseline (week 0), and week 9 (+/-14days) and at week 18 (+/-14days).

Key secondary outcome(s)
The secondary outcome measures are:
1. SHAQ, Scleroderma Health Assessment Questionnaire (Johnson & Lee 2004) is used to measure disability. It assesses difficulty with daily activities (20 items) and interference of scleroderma symptoms with activities (visual analogue scale [VAS] 0-10 cm for Raynaud phenomenon, finger ulcers, lung problems, pain, gastrointestinal problems and general disease related problems).
2. Pinch / Grip strength: Assessed using a Jamar grip meter and a Jamar pinch meter along standard three repetition maximum score protocols (Roberts et al. 2011).
3. Durouz / Cochin hand scale: A participant completed questionnaire (Brower & Poole 2004). It contains 18 items regarding hand ability in the kitchen, during dressing, while performing personal hygiene, while performing office tasks, and other general items. Persons rate their ability from 0 (no difficulty) to 5 (impossible to do). The questionnaire yields a score from 0 to 90 and takes about 3 minutes to complete
4. Modified Rodnan skin score (mRss): A physician completed assessment of skin thickness and elasticity (Furst et al 1998).
5. Visual Analogue Scale for pain in the hands: To give a score out of ten for the participants perceived pain levels experiences in their hands over the past week
6. Pain relief medications use (journal / diary): To be reviewed in relation to the participant's VAS pain score
7. Patient completed exercise journal / diary: To assess for compliance and indicate tolerability

Measured at baseline (week 0), and week 9 (+/-14days) and at week 18 (+/-14days).

Completion date
01/06/2015

Eligibility

Key inclusion criteria
1. Patients with scleroderma (systemic sclerosis) all diagnosed by a consultant rheumatologist with an interest in scleroderma, and attending Salford Royal NHS Foundation Trust
2. No previous treatment with hand wax treatment
3. Able to perform wax treatment
4. No known or suspected allergy to the wax used in the treatment
5. Some degree of hand involvement from their scleroderma (modified Rodnan skin score of the fingers >1)
6. No contra-indication to the use of the intervention, primarily digital ulcers, but also including neurological or sensory deficits
7. Willing and able to give informed consent
8. Male and female, aged 18 or over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Unlikely or unable to complete outcome assessments
2. Does not meet the inclusion criteria

Date of first enrolment
09/12/2013

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Salford Royal Hospital
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Salford Royal NHS Foundation Trust (UK)

ROR
https://ror.org/019j78370

Funder(s)

Funder type

Charity

Funder Name
The Scleroderma Society (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2019		Yes	No
HRA research summary			28/06/2023	No	No