

Efficacy of connective tissue massage and Mc Mennell joint manipulation in the rehabilitative treatment of the hands in patients with systemic sclerosis

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Registration date 23/12/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/12/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Efficacy of connective tissue massage and Mc Mennell joint manipulation in the rehabilitative treatment of the hands in patients with systemic sclerosis: a randomised controlled trial

Study objectives

Systemic sclerosis is a connective tissue disease characterised by induration of the skin and internal organs, joint modifications and muscle impairment. Deformations of hands lead to a severe loss of range of motion and functionality, affecting quality of life and activities of daily living.

This trial aims to assess the effectiveness of a rehabilitation programme based on the association of connective massage and Mc Mennell joint manipulation specifically conceived for hands of systemic sclerosis patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at the time of registration

Study design

Randomised controlled single centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Systemic sclerosis

Interventions

Intervention group: 20 systemic sclerosis patients treated for a 9-week period (twice a week, 1 hour per session) with a hand rehabilitation programme based on connective tissue massage and Mc Mennell joint manipulation. Mc Mennell joint manipulation is a technique aiming to recover the "joint play", i.e. the involuntary, subtle range of motion that normal joints display on multiple planes, necessary for normal voluntary joint mobility. It improves articular movement, reduces pain and stretches articular capsulae and ligaments.

Control group: 20 participants assigned only to a home exercise programme.

Patients were assessed at baseline, end of treatment (after 9 weeks) and 9 week follow-up.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Fist closure (cm) at baseline, end of treatment (after 9 weeks) and 9 week follow-up.

Secondary outcome measures

The following were assessed at baseline, end of treatment (after 9 weeks) and 9 week follow-up:

1. Hand disability, assessed by the Hand Mobility in Scleroderma (HAMIS) test and the Cochin Hand Functional Disability scale
2. Quality of life, assessed by 36-item Short Form (SF-36) Health Survey and Health Assessment Questionnaire (HAQ)

Overall study start date

15/02/2007

Completion date

10/01/2008

Eligibility

Key inclusion criteria

1. Both males and females, no age limits
2. Caucasian systemic sclerosis patients (diagnosed according the American College of Rheumatology [ACR] criteria) with the typical systemic sclerosis joint involvement (stiffness and loss of joint function due to flexion contractures, caused by progressive sclerotic retraction of skin, subcutaneous tissues and tendon sheaths)

Participant type(s)

Patient

Age group

Other

Sex

Female

Target number of participants

40

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

15/02/2007

Date of final enrolment

10/01/2008

Locations

Countries of recruitment

Italy

Study participating centre

Viale Pieraccini 18

Florence

Italy

50139

Sponsor information

Organisation

University of Florence (Italy)

Sponsor details

Department of Internal Medicine

Viale Morgagni 85

Florence

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50134

Sponsor type

University/education

Website

<http://www.unifi.it/>

ROR

<https://ror.org/04jr1s763>

Funder(s)

Funder type

University/education

Funder Name

University of Florence (Italy)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration