

The rehabilitation of facial involvement in systemic sclerosis: efficacy of the combination of Kabat's technique, connective tissue massage and kinesitherapy

Submission date 12/12/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
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

Contact name

Dr Susanna Maddali Bongi

Contact details

Villa Monna Tessa
Viale Pieraccini 18
Florence
Italy
50139

Additional identifiers

Study information

Scientific Title

The rehabilitation of facial involvement in systemic sclerosis: efficacy of the combination of Kabat's technique, connective tissue massage and kinesitherapy - a randomised controlled trial

Study objectives

Systemic sclerosis is a connective tissue disease characterised by induration of the skin and internal organs, by joint modifications and muscle impairment. Skin fibrosis leads to tissue retraction and atrophy, and consequently to disability and reduction of patients' quality of life.

This trial aims to assess the efficacy of a rehabilitation programme based on the combination of Kabat's technique, connective massage and kinesitherapy specifically conceived for the face of systemic sclerosis patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Primary study design

Interventional

Study design

Single-centre randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Systemic sclerosis

Interventions

Intervention group: 20 patients treated for 9 weeks (twice a week, 1 hour per session) with a combined face rehabilitation programme (Kabat's technique, connective tissue massage, kinesitherapy and home exercise programme)

Control group: 20 patients were assigned only to home exercise programme.

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

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

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

1. Improvement of facial skin score (modified Rodnan Skin Score)
2. Mouth opening (distance in centimetres between the tips of upper and lower right incisive teeth)

Key secondary outcome(s)

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

1. Facial systemic sclerosis disability, assessed by the Mouth Handicap In Systemic Sclerosis (MHISS) scale
2. Quality of life, assessed by the 36-item Short Form (SF-36) Health Survey and Health Assessment Questionnaire (HAQ)

Completion date

10/01/2008

Eligibility

Key inclusion criteria

1. Both males and females, no age limits
2. Systemic sclerosis patients fulfilling the American College of Rheumatology (ACR) criteria with facial involvement assessed by a Rodnan skin score greater than or equal to 1

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

Villa Monna Tessa

Florence

Italy

50139

Sponsor information

Organisation

University of Florence (Italy)

ROR

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

Funder(s)

Funder type

University/education

Funder Name

University of Florence (Italy) - Department of Medicine

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration