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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

Registration date
23/12/2008

Overall study status
Completed

Last Edited
23/12/2008

Condition category
Musculoskeletal Diseases

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

Protocol serial number
N/A

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.

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

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