

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

<b>Submission date</b> 12/12/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/12/2008	<b>Condition category</b> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## 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 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 measure**

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)

**Secondary outcome measures**

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 (MHIS) scale
2. Quality of life, assessed by the 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. 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

**Age group**

Other

**Sex**

Both

**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**

**Villa Monna Tessa**

Florence

Italy

50139

## **Sponsor information**

**Organisation**

University of Florence (Italy)

**Sponsor details**

Department of Medicine

Viale Morgagni, 85

Florence

Italy

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) - Department of Medicine

## **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