# The effects of tuina on patients with obstructive sleep apnea/hypopnea syndrome

<b>Submission date</b> 09/03/2014	Recruitment status  No longer recruiting	Prospectively registered
		☐ Protocol
Registration date 04/04/2014	Overall study status Completed	Statistical analysis plan
		Results
Last Edited	Condition category	Individual participant data
04/04/2014	Nervous System Diseases	Record updated in last year

#### Plain English summary of protocol

Background and study aims

This study aims to find out about the effects of a traditional Chinese therapeutic massage called tuina on patients with a sleep disorder called obstructive sleep apnea/hypopnea syndrome (OSAHS).

#### Who can participate?

OSAHS patients who did not want to have usual treatment or surgery were recruited.

#### What does the study involve?

Patients were randomly allocated to receive tuina massage or no treatment. Patients received tuina in various sessions spread over 10 weeks. Quality of life, snoring and sleepiness in daytime were recorded before and 3 months after the treatment.

#### What are the possible benefits and risks of participating?

Symptoms/signs of OSAHS may get better after treatment. The patients were also informed about the possible side effects of the massage, such as deep venous thrombosis, burns, skin infections, eczema, open wounds, bone fractures, and advanced osteoporosis. In addition, the patients were told about rare serious side effects, such as bone fractures and liver rupture, and minor adverse effects, such as significant pain or discomfort during or shortly after treatment.

#### Where is the study run from?

We performed this study at the outpatient clinic of acupuncture and sleep center of Chang Gung Memorial Hospital (CGMH) Kaohsiung Medical Center, Taiwan.

When is the study starting and how long is it expected to run for? This study ran between January 2010 and January 2011.

Who is funding the study?

The Chang Gung Memorial Hospital (Taiwan).

Who is the main contact?
Dr Cheng-Nan Lu (lu43364430@gmail.com)
Dr Hsin-Ching Lin

## Contact information

#### Type(s)

Scientific

#### Contact name

Dr cheng-nan lu

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

#### Scientific Title

The effects of tuina on patients with obstructive sleep apnea/hypopnea syndrome: a one-year single-blind randomised trial

## **Study objectives**

To study the effects of tuina (traditional Chinese therapeutic massage) on patients with obstructive sleep apnea/hypopnea syndrome (OSAHS).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Institutional Review Board of Chang Gung Memorial Hospital for Biomedical Research, IRB#98-1059B

#### Study design

One-year single-blind randomised trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### Health condition(s) or problem(s) studied

Obstructive Sleep Apnea/Hypopnea Syndrome

#### **Interventions**

Patients were randomised to receive either tuina treatment or no treatment.

The patients received tuina treatment two times per week for 10 weeks. When we used tuina for treatment, the definite course of action was to first use the rolling, pressing and kneading methods on the median line of the neck on the GV16, GV15 and GV14 and both sides of GB20 down to BL11, with back-and-forth manipulation for 3 minutes. GV15, CV23, external Jinjin, Yuye and TH17 on the posterior neck and chin were pressed for 20 seconds. Rolling/kneading and pushing manipulation with one finger were used on the back part of the bladder meridian and governor vessel for 3 minutes. CV12, CV6 and CV3 were pressed for 20 seconds, then the abdomen vibrating method was used for 5 minutes. Treatment time was approximately 15 minutes per session, two times a week for 10 weeks.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

- 1. Polysomnography (PSG)
- 2. Neck circumference (NC, cm)
- 3. Body mass index (BMI, body weight/height2=kg/m2)

The subjective and objective outcome measures were checked pretreatment (baseline) and 3 months after treatment.

#### Secondary outcome measures

- 1. Medical outcomes study 36-item Short-Form Health Survey (SF-36)
- 2. Snoring intensity was evaluated by a ten-point visual analog scale
- 3. Epworth Sleepiness Scale (ESS)

The subjective and objective outcome measures were checked pretreatment (baseline) and 3 months after treatment.

#### Overall study start date

01/01/2010

#### Completion date

01/01/2011

# Eligibility

#### Key inclusion criteria

1. OSAHS patients who refused conservative therapies or surgery recruited from the outpatient clinic of the sleep center of Chang Gung Memorial Hospital (CGMH) Kaohsiung Medical Center 2. OSAHS confirmed by a full polysomnographic study

#### Participant type(s)

**Patient** 

#### Age group

Other

#### Sex

Both

#### Target number of participants

30

#### Key exclusion criteria

- 1. High alcohol intake (> 80 g/day)
- 2. Morbid obesity
- 3. Significant lung disease
- 4. Neurological disease
- 5. Intellectual deficits
- 6. Skeletal facial framework problems
- 7. Central apnea
- 8. Using of any hypnotic drugs or previous oropharyngeal surgery

#### Date of first enrolment

01/01/2010

#### Date of final enrolment

01/01/2011

## Locations

#### Countries of recruitment

Taiwan

#### Study participating centre

Kaohsiung Chang Gung Memorial Hospital , 123, Ta-Pei Rd., Niao-Sung District, Kaohsiung City, 833, Taiwan

Kaohsiung Taiwan 83311

# Sponsor information

#### Organisation

Kaohsiung Chang Gung Memorial Hospital (Taiwan)

#### Sponsor details

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#### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/00k194y12

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

Kaohsiung Chang Gung Memorial Hospital (Taiwan) (grant CMRPG 890341)

# **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