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

Submission date
09/03/2014

Recruitment status
No longer recruiting

Registration date
04/04/2014

Overall study status
Completed

Last Edited
04/04/2014

Condition category
Nervous System Diseases

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

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Additional identifiers

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Other

Sex
All

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
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Sponsor information

Organisation
Kaohsiung Chang Gung Memorial Hospital (Taiwan)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration