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# Napping behaviour in sleep apnoea: a transcultural study in older people

**Submission date**
12/01/2012

**Recruitment status**
No longer recruiting

**Registration date**
28/02/2012

**Overall study status**
Completed

**Last Edited**
07/04/2016

**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
Obstructive sleep apnoea syndrome (OSAS) is a condition where the walls of the throat relax and narrow during sleep, interrupting normal breathing. These repeated sleep interruptions can make patients with OSAS feel very tired during the day, causing them to take frequent naps. OSAS can be treated with continuous positive airway pressure (CPAP). This involves wearing a mask that delivers a continuous supply of compressed air that prevents the throat from closing. The aim of this study is to examine the effect of CPAP on napping behaviour in OSAS patients in two different ethnic populations.

Who can participate?
Scottish and Taiwanese patients with OSAS, aged 60 and over, who nap at least 3 times per week with average nap duration of at least 30 minutes.

What does the study involve?
Patients are randomly allocated to one of two groups. One group is treated with CPAP and best supportive care for 12 weeks. The other group is treated with best supportive care for 6 weeks, then CPAP and best supportive care for another 6 weeks. Best supportive care includes normal medical treatment and information about weight loss, stopping smoking, drinking less alcohol, changing sleeping posture and sleep hygiene. Both groups undergo tests at the start of the study and at follow-up. The tests evaluate sleep behaviour, mood and anxiety, and quality of life. All participants undergo 2 weeks of actigraphy (sleep monitoring) before hospital visits. Sleep diaries are recorded over the study period.

What are the possible benefits and risks of participating?
All participants receive detailed advice on managing their OSAS with improved diet, exercise and regular sleep patterns. We may find during the tests that something needs further investigation or treatment that would not have otherwise been found. CPAP is generally very well tolerated. Sometimes it can cause nasal dryness/discomfort, nasal discharge, a dry mouth (and dribbling), facial discomfort and, rarely, ulceration due to poor mask fitting. These effects can be minimised by the use of humidification and careful mask fitting.

Where is the study run from?
1. Royal Infirmary of Edinburgh (UK)
2. Kaohsiung Medical University Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
February 2012 and October 2012

Who is funding the study?
National Science Council (Taiwan)

Who is the main contact?
Dr Chung-Yao Hsu

# Contact information

### Type(s)
Scientific

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Scientific

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# Additional identifiers

### Protocol serial number
N/A

# Study information

### Scientific Title
Napping Behaviour in Sleep Apnoea (NBSA): a randomised transcultural study in older people

## Acronym
NBSA

## Study objectives
Napping behaviour in obstructive sleep apnoea (OSAS) patients may reflect a compensatory reaction to sleep deprivation or sleep interruption. If sleep deprivation or sleep interruption due to disturbed breathing improve after continuous positive airway pressure (CPAP) treatment, napping behaviour may decrease.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
South East Scotland Research Ethics Committee 01, 21/02/2012, ref: 12/SS/0017

## Study design
Randomised single-blind parallel study

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Obstructive sleep apnoea syndrome (OSAS)

## Interventions
1. An early CPAP group: CPAP + best supportive care (BSC) for 12 weeks
2. A delayed CPAP group: BSC for 6 weeks initially then CPAP + BSC will be combined for another 6 weeks.

BSC includes normal medical treatment and information about weight reduction, smoking cessation, reducing alcohol consumption, change in sleeping posture and sleep hygiene.

## Intervention Type
Device

## Primary outcome(s)
Change in weekly nap frequency and duration every 6 weeks in both groups

## Key secondary outcome(s))
1. CPAP compliance during CPAP intervention in both groups
2. Change in Epworth Sleepiness Scale (ESS) and Pittsburgh Sleep Quality Index (PSQI) scores
3. Change in RAND-36 scores
4. Change in Hospital Anxiety and Depression Scale (HADS) scores
Measured every 6 weeks in both groups
5. Change in reaction time of Psychomotor Vigilance Task (PVT) assessed post intervention

## Completion date
31/10/2012

# Eligibility

### Key inclusion criteria
1. Aged 60 years and over
2. Have apnoea-hypopnoea index (AHI) ≥ 15
3. Nap at least 3 times per week with average nap duration of at least 30 minutes

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
All

### Key exclusion criteria
1. Have previous exposure to continuous positive airway pressure (CPAP) therapy
2. Are unable to give written informed consent or comply with the protocol
3. Are on central nervous system (CNS)-active drug treatment (e.g., hypnotic and antiepileptic drugs) that causes significant daytime sleepiness or cognitive impairment
4. Have an unstable medical or psychiatric illness
5. Have moderate to severe respiratory disease that affects activities of daily living or awake SpO2 less than 92%

### Date of first enrolment
15/02/2012

### Date of final enrolment
31/10/2012

# Locations

### Countries of recruitment
United Kingdom

Taiwan

### Study participating centre
**No.100, Tzyou 1st Road**
Kaohsiung
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80754

# Sponsor information

**Organisation**
Kaohsiung Medical University Hospital (Taiwan)

**Organisation**
Department of International Cooperation (Taiwan)

**Organisation**
Kaohsiung Medical University Chung-Ho Memorial Hospital

**ROR**
https://ror.org/02xmkec90

# Funder(s)

**Funder type**
Government

**Funder Name**
National Science Council (NSC 99-2911-I-037-004)

**Alternative Name(s)**
National Science Council, Taiwan, National Science Council of Taiwan, NSC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
Taiwan

# Results and Publications

**Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |