

Raising the head of the bed to 30 degrees for adults with snoring and obstructive sleep apnoea

Submission date 18/08/2026	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 18/08/2026	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 18/08/2026	Condition category Nervous System Diseases	☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Obstructive sleep apnoea (OSA) causes repeated pauses in breathing during sleep and loud snoring. Sleeping position affects how bad it is. This study tested whether raising the head end of an adjustable bed to 30 degrees reduces breathing pauses and snoring, and which patients benefit most.

Who can participate?

Adults aged 18 years and over with suspected or confirmed OSA

What does the study involve?

Each person had two overnight sleep studies on the same bed — one lying flat and one with the head of the bed raised to 30 degrees — in a random order, and the results were compared.

Possible benefits and risks

Possible benefit: fewer breathing pauses and less snoring on the raised night. Head-of-bed elevation is low-risk.

Where is the study run from?

Keeson Technology Corporation (China)

When did the study run?

November 2021 to December 2022

Who is funding the study?

Keeson Technology Corporation (China)

Who is the main contact?

Dr Yuan Dong, arthur.dong@keeson.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Sponsor protocol number

Keeson-Softide-PSG-MC-001

Study information

Scientific Title

Efficacy and safety of 30° head-of-bed elevation delivered by an electric smart-bed, versus a flat observation night, on the apnoea–hypopnoea index and whole-night snoring burden in adults with obstructive sleep apnoea: a multicentre randomised-order crossover study (HOBE-OSA)

Acronym

HOBE-OSA

Study objectives

1. To evaluate the efficacy of fixed 30° head-of-bed elevation on the apnoea–hypopnoea index (AHI) and whole-night snoring burden in adults with obstructive sleep apnoea
2. To identify the beneficiaries — which patients benefit and by how much, analysed by baseline severity and positional phenotype
3. To monitor safety (treatment-emergent adverse events on the intervention night). Reporting follows the SPIRIT/CONSORT guidance for crossover trials

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 30/10/2021, Ethics Committee of the Affiliated Hospital of Gansu University of Chinese Medicine (732 Jiayuguan West Road, Lanzhou, 730020, China; +86 (0)931 863 5928; arthurmyway@qq.com), ref: [2021]35

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Crossover

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Obstructive sleep apnoea and habitual snoring

Interventions

Softide Smart-Bed prototype — an adjustable ("smart") bed combining electric actuators with non-contact physiological sensing (Keeson Technology Corporation; developed 2020–2021; not a marketed device at the time of the study).

Within-patient randomised-order crossover. Each participant underwent two whole-night attended polysomnograms on the same study adjustable bed: (i) an observation night in the flat (0°) configuration (the within-patient control), and (ii) an intervention night with the upper half of the bed raised to a fixed 30° for the whole night (adaptive/closed-loop features disabled). The two nights were usually consecutive (median inter-night gap 1 night). Night order was assigned 1:1 from a computer-generated random sequence prepared centrally by the sponsor and disclosed to the site immediately before each participant's first study night. One centre (Qinhuangdao, n = 10) did not randomise (all observation-first) and is handled by a pre-specified sensitivity analysis.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Softide Smart-Bed prototype

Primary outcome(s)

1. Paired within-patient change in total apnoea–hypopnoea index (AHI) measured using two whole-night polysomnograms at intervention night and observation night
2. Paired within-patient change in whole-night snoring burden (co-primary) measured using two whole-night acoustic recordings at intervention night and observation night

Key secondary outcome(s)

1. Paired within-patient change in Oxygen Desaturation Index 3% (ODI3) and Oxygen Desaturation Index 4% (ODI4) measured using two whole-night polysomnograms at intervention night and observation night
2. Paired within-patient change in oxygen-desaturation morphology (duration/area/depth) measured using two whole-night polysomnograms at intervention night and observation night
3. Paired within-patient change in SpO₂ summary statistics (mean/median/variability) measured using two whole-night polysomnograms at intervention night and observation night
4. Paired within-patient change in positional behaviour, $\Delta\text{PHI} = \Delta\log_2(\text{supine/lateral minutes})$ measured using two whole-night polysomnograms at intervention night and observation night
5. Paired within-patient change in positional physiology, $\Delta\text{PSI} = \Delta\log_2(\text{supine/lateral AHI})$, measured using two whole-night polysomnograms at intervention night and observation night
6. Safety measured using treatment-emergent adverse events at on and after the intervention night

Completion date

31/12/2022

Eligibility**Key inclusion criteria**

1. Adults aged 18 years or older, male or female
2. Clinically suspected or polysomnography-confirmed obstructive sleep apnoea (no minimum apnoea-hypopnoea index [AHI] required for enrolment)
3. Able to undergo two whole-night polysomnograms on the study adjustable bed
4. Written informed consent

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

99 Years

Sex

All

Total final enrolment

63

Key exclusion criteria

1. Predominantly central sleep apnoea or another primary sleep disorder
2. Current obstructive sleep apnea (OSA) treatment that could confound posture/airway effects (continuous positive airway pressure [CPAP], oral appliance, or prior upper-airway surgery)
3. Unstable cardiopulmonary or neuromuscular disease, or any contraindication to head-of-bed elevation
4. Pregnancy
5. Inability to complete both study nights or to comply with study procedures

Date of first enrolment

01/11/2021

Date of final enrolment

31/12/2022

Locations**Countries of recruitment**

China

Study participating centre**Affiliated Hospital of Gansu University of Chinese Medicine**

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Study participating centre**Qinhuangdao Haigang Hospital**

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Study participating centre

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98 Wulanbuhe Road
Bayannur
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Study participating centre
Suzhou Guangji Hospital
11 Guangqian Road
Suzhou
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Sponsor information

Organisation
Keeson Technology Corporation

Funder(s)

Funder type

Funder Name
Keeson Technology Corporation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon request from Yuan Dong (arthur.dong@keeson.com). De-identified night-level data (posture, AHI, sleep-stage minutes, oxygen and snoring metrics) and the complete analysis/figure code are available on reasonable request. De-identified raw polysomnography (EDF) and whole-night snoring audio are retained and can be shared for independent re-scoring/audit, subject to participant-privacy and institutional data-sharing policy. Participants gave written informed consent; data are anonymised before sharing.

IPD sharing plan summary

Available on request