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AWAKE Check: A UK study assessing sleep disorder risk in adults using online and pharmacy-based screening

Submission date
30/09/2025

Recruitment status
Recruiting

Registration date
30/09/2025

Overall study status
Ongoing

Last Edited
03/11/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Sleep disorders such as insomnia and obstructive sleep apnoea (OSA) are common in the UK but are often under-recognised and untreated. Both conditions have major impacts on health, wellbeing, safety, and productivity. This study aims to estimate the proportion of UK adults at risk for insomnia, OSA, and comorbid insomnia and sleep apnoea (COMISA) using validated questionnaires delivered online. The project also seeks to raise awareness of sleep health by engaging people through community pharmacies, social media, and mass media.

Who can participate?
Adults aged 18 years and over who live in the UK and can complete an online survey in English. Participation is voluntary and open to both healthy volunteers and people who may already have sleep problems.

What does the study involve?
Participants complete a short web-based survey hosted on JotForm. The survey includes:
1. The Insomnia Severity Index (ISI) to assess insomnia risk
2. The STOP-Bang questionnaire to assess risk of obstructive sleep apnoea.
3. An optional Functional Outcomes of Sleep Questionnaire (FOSQ-10) to measure the impact of sleepiness on daily activities.
The survey takes about 5 minutes to complete. All questions are mandatory to ensure complete data, except for the optional field where participants may request an email copy of their responses. At the end, participants receive tailored feedback about their results and signposting to healthcare advice if at increased risk.

What are the possible benefits and risks of participating?
There are no direct health benefits to taking part, but participants may find it useful to learn more about their sleep health and possible next steps. The information gathered will help researchers and healthcare providers better understand the scale of sleep health needs in the

UK. Risks are minimal: the survey is anonymous and non-invasive, and no treatment is given. Some participants may find questions about their sleep sensitive, but they can withdraw at any time by choosing not to submit the survey.

Where is the study run from?
The study is organised and coordinated by the British Society of Pharmacy Sleep Services (BSPSS), a UK-registered charity based in Lincoln.

When is the study starting and how long is it expected to run for?
May 2025 to April 2026

Who is funding the study?
This is an unfunded investigator-initiated study coordinated by BSPSS
Sefam Medical UK Ltd: £500 unconditional grant to support participant prize fund

Who is the main contact?
Adrian Zacher, start@awakecheck.co.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Protocol: AWAKE v6.5, Ethics approval: Newcastle University REC Ref 63260/2023, OSF preregistration: https://osf.io/63c4u

Study information

Scientific Title
A prospective observational cross-sectional study assessing risk of insomnia and obstructive sleep apnoea in UK adults using validated screening tools (Insomnia Severity Index, STOP-Bang, and FOSQ-10)

Acronym
AWAKE

Study objectives
1. To determine the prevalence of risk for insomnia and obstructive sleep apnoea (OSA) in a UK adult population using validated screening tools (Insomnia Severity Index and STOP-Bang questionnaire).
2. To identify the proportion of participants at risk of comorbid insomnia and sleep apnoea (COMISA).
3. To compare the prevalence of sleep disorder risk across defined subgroups (e.g. occupation, sex, BMI, recruitment channel, and geographic location).
4. To assess the functional impact of sleepiness on daily living using the Functional Outcomes of Sleep Questionnaire (FOSQ-10) in a sub-sample of respondents.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/08/2025, Newcastle University Research Ethics Committee (King's Gate, Newcastle, NE1 7RU, United Kingdom; +44 (0)191 208 6000; res.policy@ncl.ac.uk), ref: 63260/2023

Study design
Prospective observational cross-sectional study

Primary study design
Observational

Study type(s)
Prevention, Quality of life, Screening

Health condition(s) or problem(s) studied
Insomnia disorder; Obstructive sleep apnoea (OSA); Comorbid insomnia and sleep apnoea (COMISA); Sleep-related functional impairment

Interventions
Participants will complete a single web-based survey (JotForm) including validated screening tools: the Insomnia Severity Index (ISI), the STOP-Bang questionnaire for obstructive sleep apnoea risk, and the optional Functional Outcomes of Sleep Questionnaire (FOSQ-10). On completion, participants receive tailored risk feedback and signposting to healthcare support if at elevated risk. Data collection occurs once at baseline, with no follow-up.

Intervention Type
Behavioural

Primary outcome(s)
1. Proportion of participants at high risk of insomnia, measured using the Insomnia Severity Index (ISI; score ≥15), assessed once at baseline (on survey completion).
2. Proportion of participants at high risk of obstructive sleep apnoea, measured using the STOP-Bang questionnaire (score ≥5), assessed once at baseline (on survey completion).

Key secondary outcome(s))
1. Proportion of participants at risk of comorbid insomnia and sleep apnoea (COMISA), defined by ISI score ≥15 and STOP-Bang score ≥3, assessed once at baseline (on survey completion).
2. Functional impairment due to sleepiness, measured using the Functional Outcomes of Sleep Questionnaire (FOSQ-10), assessed once at baseline (on survey completion).
3. Comparison of sleep disorder risk prevalence across subgroups (occupation, sex, BMI, recruitment channel, and geographic region), assessed once at baseline (on survey completion).
4. Geographic distribution of risk categories, analysed by the first three digits of participant postcodes, assessed once at baseline (on survey completion).

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Resident in the United Kingdom
3. Able to access and complete an online survey in English
4. Occupation may include employee or learner/student (18+ years)

Participant type(s)
Employee, Healthy volunteer, Learner/student, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Individuals under the age of 18 years
2. Non-UK participants, identified through IP address location at survey entry
3. Incomplete survey responses (missing core outcome data)

Date of first enrolment
01/10/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
British Society of Pharmacy Sleep Services
4 Waterford Lane
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United Kingdom
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Sponsor information

Organisation
British Society of Pharmacy Sleep Services (BSPSS)

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Sefam Medical UK Ltd. £500 unconditional grant to support participant prize fund

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant data will not be shared. Only aggregate, anonymised results will be published and reported in line with ethical approval.

IPD sharing plan summary
Not expected to be made available

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes