ISRCTN77616219 https://doi.org/10.1186/ISRCTN77616219

Self-report and physiological measures of sleep quality

Submission date	Recruitment status	[ ] Prospectively registered
06/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/07/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/04/2008	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Andrew Krystal

Contact details
Duke University Medical Center
Box 3309
Durham, NC
United States of America
27710
kryst001@mc.duke.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Self-report sleep ratings reflect the formation of a global impression that colors all of the ratings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval details not yet received as of 24/05/2006

Study design
Randomised comparison of ratings of sleep in subjects led to the belief that they had good versus bad nights of sleep

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Sleep quality

Interventions
Patients were asked to score their sleep rating after being led to believe that they had either:
1. A bad nights sleep, or
2. A good nights sleep

Comparisons were run between the actual sleep activity and the percieved sleep activity.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
A single morning self-rating of:
1. Sleep latency

2. Time awake in the middle of the night
3. Total sleep time

Secondary outcome measures
1. Relationship of polysomnographic and self-reported measures of sleep latency
2. Time awake in the middle of the night
3. Total sleep time

Overall study start date
09/01/2005

Completion date
07/01/2006

Eligibility

Key inclusion criteria
1. Aged 18 - 64 years inclusive
2. Able to understand and cooperate with study procedures and give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Any symptom of daytime sleepiness
2. Any difficulty falling asleep or staying asleep in the last month
3. Any active medical or psychiatric disease that is likely to affect sleep
4. Taking any medication that might affect sleep within five half-lives of screening

Date of first enrolment
09/01/2005

Date of final enrolment
07/01/2006

Locations

Countries of recruitment
United States of America

Study participating centre
Duke University Medical Center
Durham, NC
United States of America
27710

Sponsor information

Organisation
Duke University Medical Center (USA)

Sponsor details
Box 3309
Durham, NC
United States of America
27710
+1 919 681 8788
kryst001@mc.duke.edu

Sponsor type
University/education

ROR
https://ror.org/03njmea73

Funder(s)

Funder type
University/education

Funder Name
Duke University Department of Psychiatry (USA)

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