ISRCTN53553517 https://doi.org/10.1186/ISRCTN53553517

Does an app based short intervention improve quality of sleep?

Submission date
05/04/2019

Recruitment status
No longer recruiting

Registration date
08/04/2019

Overall study status
Completed

Last Edited
24/03/2023

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Two out of three adults in Germany have trouble sleeping at least occasionally, among employees the numbers rise up to 80%. Poor sleep quality can result in daytime fatigue and reduce performance, and is also associated with irritability and depressed mood. Only a few people with poor sleep quality seek professional help. Therefore, researchers have developed an app-based training to help people implement behaviour changes and improve sleep quality. The aim of this study is to find out whether this training helps improve sleep.

Who can participate?
German-speaking adults

What does the study involve?
Participants are randomly allocated to either receive access to the app-based training immediately or to wait for 6 months. The training is self-paced, but the recommended duration is 8 weeks (1 chapter per week). There are three assessments (start of the study, 8 weeks, 26 weeks).

What are the possible benefits and risks of participating?
Participants may improve their sleep quality. For some participants, thinking about their thoughts and feelings may be upsetting.

Where is the study run from?
Technische Universität Dresden, Institute of Clinical Psychology and Psychotherapy (Germany)

When is the study starting and how long is it expected to run for?
March 2019 to October 2020

Who is funding the study?
There is no external funding for the study

Who is the main contact?
Bianka Vollert

bianka.vollert@tu-dresden.de
(updated 03/07/2019, previously: Dr Ina Beintner
ina.beintner@tu-dresden.de)

Contact information

Type(s)
Public

Contact name
Ms Bianka Vollert

Contact details
Institute for Clinical Psychology and Psychotherapy
Chemnitzer Straße 46
Dresden
Germany
01187
+49 (0)351 463 38570
bianka.vollert@tu-dresden.de

Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Refresh - Does an app based short intervention improve quality of sleep? A randomised controlled feasibility study

Acronym
REFRESH

Study objectives
The current study seeks to examine the acceptability and efficacy of an app-based short intervention (Refresh) to improve sleep quality compared to a waitlist control group in the general population. The hypothesis is that Refresh will be efficacious, with significant improvements of sleep quality within the intervention group and differences at post intervention and follow-up between the intervention group and the waitlist control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/03/2019, Ethikkommission (IRB) an der TU Dresden (Fetscherstraße 74, 01307 Dresden, Germany; Tel: +49 (0)351 458 2992; Email: ethikkommission@mailbox.tu-dresden.de), ref: EK 111032019

Study design
Single-center unblinded randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Poor sleep quality

Interventions
Method of randomisation: stratified block randomization (strata: gender, sleep quality (RIS total score <12 vs >=12), use of sleep medication).

1. Refresh: an app-based short intervention to improve sleep quality
2. Waitlist control

The intervention is self-paced, but the recommended duration is 8 weeks (1 chapter per week). There are three assessments (baseline, post-intervention (+8 weeks), follow-up (+26 weeks).

Intervention Type
Behavioural

Primary outcome(s)
Sleep quality is measured using the Regensburg Insomnia Scale (RIS) Total Score at baseline and post-Intervention (8 weeks)

Key secondary outcome(s))
1. Sleep quality is measured using the Regensburg Insomnia Scale Total Score at baseline and follow-up (26 weeks)
2. Depression symptoms are measured using the depression scale from the Patient Health Questionnaire (PHQ-9) Total Score at baseline, post intervention (8 weeks) and follow-up (26 weeks)
3. Acceptance of the training is measured using the Working Alliance Scale adapted for Online Interventions at Post Intervention (8 weeks) and usage of the intervention (during intervention period)

Completion date
31/10/2020

Eligibility

Key inclusion criteria
1. Over 18 years of age
2. Fluent in German
3. Access to the Internet during the intervention period

Participant type(s)

Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
371

Key exclusion criteria
1. Current treatment for depression
2. History of psychotic or bipolar disorder
3. Suicidal ideation

Date of first enrolment
15/04/2019

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
Austria

Germany

Luxembourg

Switzerland

Study participating centre
Technische Universität Dresden, Institute for Clinical Psychology and Psychotherapy
Chemnitzer Straße 46
Dresden
Germany
01187

Sponsor information

Organisation
Technical University Dresden (Technische Universität Dresden)

ROR
https://ror.org/042aqky30

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
After the main results of the study have been published, anonymised participant level data can be shared for individual patient data meta-analyses upon request to Dr Ina Beintner (Ina.Beintner@tu-dresden.de), stating the purpose and methods of the planned project. ICMJE authorship recommendations apply. Participants give consent that their anonymised data can be used in research cooperation projects.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	outcome measure results	21/03/2023	24/03/2023	Yes	No
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