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)

Study website
https://tu-dresden.de/mn/psychologie/ikpp/e-mental-health/forschung/refresh

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
Not available in English

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

Secondary outcome measures
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)

Overall study start date
01/03/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
586

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)

Sponsor details
Institut für Klinische Psychologie und Psychotherapie
Chemnitzer Str. 46
Dresden
Germany
01187
+49(0)351-463-0
bianka.vollert@tu-dresden.de

Sponsor type
University/education

ROR
https://ror.org/042aqky30

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication of results in a high-impact peer reviewed journal. No additional documents will be publicly available.

Intention to publish date
31/03/2021

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