

INFORMATION ON THE ONLINE PROGRAMME

HelloBetter Schlafen

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The online programme has been labelled as a medical device and is also known under the following names:

- *HelloBetter Sleep*
- *HelloBetter Regeneration für besseren Schlaf*
- *HelloBetter Insomnie*
- *GET.ON Regeneration*
- *GET.ON Insomnie*
- *HelloBetter Regeneration*
- *HelloBetter Recovery*
- *GET.ON Recovery training*
- *GET.ON Regeneration (angepasst für die grünen Berufe)*

This instruction provides guidance on the correct implementation of the *HelloBetter Schlafen* online programme. The information is based on the quality criteria for internet-based self-management interventions established by the task force of the German Psychological Society (DGPS) and the German Society for Psychiatry, Psychotherapy, Psychosomatics and Neurology (DGPPN; see publication by [Klein et al. in Der Nervenarzt, 2018](#)).

The information should be read carefully and the instructions contained therein followed. The HelloBetter support team at support@hellobetter.de is available during registration for assistance if needed.

We employ numerous measures to protect your data. However, please note that use of the online programme in potentially insecure environments may still result in risks in the form of possible data access by unauthorised persons. This includes, but is not limited to, using the online programme on a public or shared device and/or using public or unsecured networks or telecommunications connections monitored by government agencies. Please note that these risk factors are beyond our control. If you use our online programmes on public devices, we recommend that you use the private surfing mode and log out at the end of your session.

1. INTENDED PURPOSE / INDICATION

HelloBetter Schlafen is a psychological online programme aimed at reducing insomniac symptoms. The online course consists of eight units, each lasting 45-60 minutes.

In addition to well-founded psychoeducation via texts, videos and audios, the online programme teaches effective strategies from cognitive behavioural therapy for insomnia (CBT-I) according to the status quo of scientific findings. These include e.g. strategies for sleep hygiene, bedtime reduction and stimulus control, relaxation techniques, behavioural activation, strategies for dealing with dysfunctional thoughts and rumination as well as relapse prevention. The exercises are learned in the online programme and can be integrated into everyday life. Goals are formulated in such a way that they are individual, realistic and achievable. In addition, there is an online journal and recurring symptom checks to record, monitor and evaluate one's own progress.

The online programme has been developed over several years by leading experts in the field of e-mental health and has been extensively studied and found to be effective in multiple randomised controlled trials.

HelloBetter Schlafen is designed for adults who meet the criteria for one of the following ICD-10 diagnoses:

- F51.0 non-organic insomnia
- G47.0 Sleep onset and sleep maintenance disorder

Conditions for use

HelloBetter Schlafen can be used as an interactive online programme via a computer, laptop and/or mobile device with internet access. A current version of a browser (Google Chrome, Mozilla Firefox, Edge or Safari) is required to run the programme. Trouble-free operation with non-supported browsers cannot be guaranteed.

To use the mobile components, we recommend the HelloBetter app. The HelloBetter app supports smartphones that have at least Android 9 (API version 28 +) or iOS 12.2. For optimal use, Android 10 (API version 29 +) or iOS 13+ is recommended.

The online programme is designed for lay people of all age groups (from 18 years) and is equally suitable for female, male and non-binary participants who are open to the use of an online course. Previous psychotherapeutic experience is not necessary. Experience with website and/or app navigation is required.

2. DESCRIPTION AND MODE OF OPERATION OF THE ONLINE PROGRAMME

Type and duration of the programme

The online programme consists of eight course units, which variously include psychoeducation, interactive exercises, texts, videos and audios and can be completed flexibly, at one's own pace. Each unit takes about 45-60 minutes to complete. In addition, what has been learned can also be implemented in everyday life within the framework of a training plan. The duration of the exercises included depends on the individual course progress. In addition to the online course, participants can plan empowering activities, keep an online diary and do regular symptom checks, among other things. The structure is clear and concise throughout, so that participants are always informed about the course of the online programme. Further information on the length of use can be found at hellobetter.de.

Frequency of use

Based on scientific studies, we recommend completing the course units in a weekly rhythm to achieve the best possible success of the online programme. It is crucial for success that the everyday integration of the exercises is continuous and comprehensive. The use of the additional components (e.g. activity planner and diary) is possible several times a day. The symptom check is obligatory before the first unit and is scheduled fortnightly from then on.

Programme content

HelloBetter Schlafen includes well-founded psychoeducation and strategies of cognitive behavioural therapy according to the latest scientific findings. Knowledge content on sleep and models of sleep disorders are taught, as well as helpful exercises to reduce the severity of insomnia. These include strategies for sleep hygiene, bedtime reduction and stimulus control, relaxation exercises, behavioural activation, techniques for dealing with dysfunctional thoughts and ruminations, relapse prevention and an

ongoing online journal. This can be used to keep a personal sleep diary and to record and reflect on your own experience and sleep behaviour.

In order to be able to observe a possible improvement or worsening of symptoms, participants are encouraged to take part in the bi-weekly symptom checks regarding their sleep quality and impairment as well as any existing anxiety, depression and stress symptoms. The individual input of the participants is taken into account so that an individualised experience can be ensured within the online programme.

Clinical benefit

Medical device *HelloBetter Schlafen* can help people reduce the severity of their insomnia. Risks potentially associated with the use of the medical device have been identified, controlled and consistently rated as acceptable.

Guidance

In all our programs, we attach great importance to the safety of our users. In the event of technical questions and problems, participants receive support via the e-mail address support@hellobetter.de, a response is provided within 24 hours on weekdays.

Depending on the type of use, participants in the versions "guided" and "guidance on demand" receive written feedback after completing a course unit within 24 hours on weekdays from a personal psychologist in our team, who has been trained for this purpose. The feedback is always given by the same person. All communication within the framework of this security concept takes place on a web-based platform that is encrypted according to current data protection standards. After reading the feedback, participants can continue with the next course unit.

Operating

Access to *HelloBetter Schlafen* is encrypted. The online programme is available at any time via online login on the HelloBetter platform. This enables use that is largely independent of time, location and device. Progress made during the programme can be saved temporarily at any time so that the online programme can also easily be continued at a later point. The legal data protection requirements are met. More details can be found under section **6. Data protection**.

The operation and navigation of the technical platform are designed so that participants know at all times where they are in the online programme and how to get back to the overview. The system is error-tolerant, programme content is accessible via several paths.

The psychoeducational elements are conveyed in texts, pictures, videos or audios. The completion of the online programme is thus designed to be diverting and exciting. At the beginning of each exercise, the purpose is explained and at the end there is an opportunity for personal evaluation and self-reflection. Each unit contains several text fields, which the participants can fill in or tick to give them the opportunity to describe and discuss their personal situation. In addition, further information can be obtained at various points through fold-out contents, so that different needs and focal points can be addressed.

Interoperability

To ensure interoperability and portability, HelloBetter works with the open, internationally recognised FHIR standard (HL7 FHIR r4).

3. QUALIFICATION OF THE DEVELOPERS OF THE ONLINE PROGRAMME

HelloBetter Schlafen was developed by experts from the fields of science, psychology and psychotherapy, as well as together with those affected. Its effectiveness has been tested in various randomised controlled studies. Scientists, psychological psychotherapists and psychologists worked closely together to define the principles and procedures as well as the selection of exercises. Psychological psychotherapists and psychologists were involved in the formulation of the intervention content. Feasibility studies with people with insomnia helped to revise and improve *HelloBetter Schlafen*. In addition, regular focus groups with participants contribute to quality assurance.

4. SOURCES OF MEDICAL CONTENT

HelloBetter Schlafen has been evaluated for efficacy in several randomised controlled trials. The studies report intergroup effect sizes, intention-to-treat and completer analyses, dropout rates and reasons, and user satisfaction results. The studies were registered and accepted in an official study register prior to implementation. The study results are published and available in international journals:

RCT on the effectiveness in teachers with sleep problems (with eCoaching)

Study registration: [DRKS00004700](#)

Study protocol: Thiart, H., Lehr, D., Ebert, D.D., Sieland, B., Berking, M., & Riper, H. (2013). Log in and breathe out: efficacy and cost-effectiveness of an online sleep training for teachers affected by work-related strain—study protocol for a randomized controlled trial. *Trials*, 14(169), 1–10. doi:10.1186/1745-6215-14-169.

Effectiveness: Thiart, H., Lehr, D., Ebert, D. D., Berking, M., & Riper, H. (2015). Log in and breathe out: internet-based recovery training for sleepless employees with work-related strain—results of a randomized controlled trial. *Scandinavian Journal of Work, Environment & Health*, 41(2), 164–174. doi:10.5271/sjweh.3478

Cost effectiveness: Thiart, H., Ebert, D. D., Lehr, D., Nobis, S., Buntrock, C., Berking, M., Smit, F., & Riper, H. (2016). Internet-based cognitive behavioral therapy for insomnia: a health economic evaluation. *Sleep*, 39(10), 1769–1778. <https://doi.org/10.5665/sleep.6152>

RCT on the effectiveness in teachers with sleep problems (in a self-help setting)

Study registration: [DRKS00004984](#)

Effectiveness: Ebert, D. D., Berking, M., Thiart, H., Riper, H., Laferton, J. A. C., Cuijpers, P., Sieland, B., & Lehr, D. (2015). Restoring depleted resources: Efficacy and mechanisms of change of an internet-based unguided recovery training for better sleep and psychological detachment from work. *Health Psychology*, 34(Suppl), 1240–1251. <https://doi.org/10.1037/hea0000277>

RCT on the effectiveness in working professionals in the general population (in a self-help setting)

Study registration: [DRKS00007142](#)

Effectiveness: Behrendt, D., Ebert, D.D., Spiegelhalder, K., & Lehr, D. (2020). Efficacy of a self-help web-based recovery training improving sleep in workers: results of a randomized controlled trial in universal prevention. *Journal of Medical Internet Research*, 22(1), e13346. doi: 10.2196/13346

RCT on the effectiveness in students with sleep problems (with eCoaching)

Study registration: [DRKS00017737](#)

Effectiveness: in analysis (state 06/2021)

RCT on the effectiveness in international students with sleep problems

Study registration: [DRKS00018854](#)

Effectiveness: Spahnel, K., Lehr, D., Spiegelhalder, K., Bengel, J., Sander, L., & Ebert, D.D. Effectiveness of an internet-based intervention to improve sleep difficulties in a culturally diverse sample of international students: A randomised controlled study.

In progress (state 02/2022)

RCT on effectiveness for sleep disorders in the general population in the context of a stepped care model (GET.SLEEP)

Study registration: [DRKS00021503](#)

Study in progress (state 02/2022)

5. PATIENT SAFETY

Contraindications



The online programme *HelloBetter Schlafen* must not be used if suicidal tendencies are present. In this case, participants should seek medical and/or psychotherapeutic advice and, in a crisis situation, immediately contact the emergency number 112.

In addition, *HelloBetter Schlafen* is not intended for use with:

- Epilepsy (ICD-10 G40)
- Bipolar affective disorders (ICD-10 F31)
- Acute transient psychotic disorders (ICD-10 F23)

In the case of one or more of the following conditions, *HelloBetter Schlafen* may only be carried out if these have been carefully discussed **in advance** with the participant's family doctor and/or a specialist doctor and no objections to participation in the programme have been raised by the doctor.

- Sleep apnoea (ICD-10 G47.3)
- Sleepwalking (somnambulism) (ICD-10 F51.3)
- Severe cardiovascular diseases (e. g. cardiac arrhythmia, angina pectoris)
- Known or suspected pregnancy

Notes

Suicidal, world-weary thoughts can arise especially in particularly difficult phases of life. In some people these thoughts pass by themselves, in others they persist and are accompanied by impulses or actions to take their own lives. Such symptoms should be taken seriously in any case. We recommend seeking direct medical and/or psychotherapeutic advice. Medical and/or psychotherapeutic contact should also be established if in the course of the online programme there is no decrease of sleep impairment or if it worsens acutely. In addition, no changes should be made to any existing medication and/or therapy without consulting a doctor.

Side effects

The success of the online programme is influenced by many factors and cannot be guaranteed in individual cases. In the context of stimulus control and especially bedtime reduction, a so-called sleep deprivation syndrome can occur before sleep improvement occurs. Typical symptoms include headaches, excessive daytime sleepiness, an increase in blood pressure, nausea and restrictions in concentration and attention. This may impair the ability to participate in road traffic and to operate machinery. In the context of stimulus control and bedtime reduction, increased caution is therefore appropriate in the situations mentioned. Not all participants may benefit equally from using *HelloBetter Schlafen*, as not every exercise is equally suitable for everyone. This can cause a feeling of disappointment. In addition, it is possible that dealing with difficult topics can be stressful, which can initially lead to a worsening of symptoms ("initial deterioration"). Other negative effects that can occur in connection with the use of psychological techniques are, for example, a strain on social relationships or an increase in worry. In addition, relaxation exercises, such as those carried out in the online programme, do not always lead to a reduction in tension, but sometimes to the opposite effects, such as "relaxation-induced anxiety". However, the points mentioned are typical temporary therapy processes. Should side effects occur and persist in connection with the use of the *HelloBetter Schlafen* online programme, we recommend seeking medical and/or psychotherapeutic advice or sending an email to support@hellobetter.de.

Interactions

So far, no interactions are known.

Emergency information

In the event of suicidal tendencies or an acute crisis, the emergency services should be informed:

Emergency numbers in Germany:

- general emergency service: 112
- police: 110

The TelefonSeelsorge offers a sympathetic ear in life crises, around the clock, free of charge and anonymously. TelefonSeelsorge offers conversations in the German language only. You can find international helplines on their website.

- 0800 111 0 111
- 0800 111 0 222
- www.telefonseelsorge.de
- <https://www.telefonseelsorge.de/international-helplines>

The Telfonseelsorge team knows the appropriate facilities and contact points for acute crises and suicidal tendencies. Clinics and other crisis services in your area can also be found in the address list of the German Depression Aid Foundation: www.deutsche-depressionshilfe.de

6. DATA PROTECTION

Only the data that is absolutely necessary for the implementation of the online programme is collected. The legal data protection requirements are met. The content and the online programme are subject to the German Federal Data Protection Act and the General Data Protection Regulation (DSGVO). More detailed information on the processing of personal data can be found in our data protection declaration at <https://hellobetter.de/en/privacy-policy-training/>.

Contact details for the Data Protection Officer

Datenschutzbeauftragter
c/o GET.ON Institut für Online Gesundheitstrainings GmbH
Oranienburger Str. 86a
10178 Berlin
datenschutz@hellobetter.de

7. COST

Further information can be found at <https://hellobetter.de/>.

8. INTEGRATION INTO HEALTHCARE

HelloBetter Schlafen includes the possibility for the participants and health care practitioners to observe the course of the respective psychological complaints. Within the online programme, multiple validated questionnaires are filled out, which record the severity of the insomnia, perceived stress, anxiety and depressive complaints.

9. MANUFACTURER AND PRODUCT INFORMATION

Manufacturer



HelloBetter is a registered trademark of
GET.ON Institut für Online Gesundheitstrainings GmbH
Schrammsweg 11
20249 Hamburg
<https://hellobetter.de>
kontakt@hellobetter.de
+49 (0)40 532 528 67

Information last updated

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Further information

This stand-alone software is a medical device of risk class I according to rule 11 of EU regulation 2017/745. A free paper version of the instructions for use is available by e-mail at kontakt@hellobetter.de or by phone at +49 (0)40 532 528 67 (at appropriate landline and mobile phone rates).

Should serious incidents occur in connection with the use of the medical device *HelloBetter Schlafen*, please contact GET.ON Institut für Online Gesundheitstrainings GmbH. In addition, the competent authority BfArM must be informed. This will be undertaken by the manufacturer.

Date of release

2023-07-27

CE label

10. SIGNS AND SYMBOLS



Medical device indication ISO/DIS 15223- 1:2020 Reference no. 5.7.7
Indicates the item is a Medical Device.



CE marking Communauté Européenne
Product traded on the extended Single Market in the European Economic Area (EEA); has been assessed to meet high safety, health, and environmental protection requirements.



Consult instructions for use ISO 7000-1641
Indicates the need for the user to consult the Instructions for Use.



Manufacturer ISO 7000-3082
To identify the manufacturer of the Medical Device.



Date of manufacture ISO 7000-2497
To indicate the date on which the Medical Device was manufactured.



Caution ISO 15223-1, Clause 5.4.4
To indicate the need for the user to consult the Instructions for Use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the Medical Device itself.