

INFORMATION ON THE ONLINE PROGRAMME

HelloBetter Stress and Burnout

1. INTENDED PURPOSE / INDICATION	3
Conditions for use	3
2. DESCRIPTION AND MODE OF OPERATION OF THE ONLINE PROGRAMME	3
Type and duration of the programme	3
Frequency of use	4
Programme content	4
Accompaniment	4
Operating	5
Interoperability	5
3. QUALIFICATION OF THE DEVELOPERS OF THE ONLINE PROGRAMME	5
4. SOURCES OF MEDICAL CONTENT	5
5. PATIENT SAFETY	7
Contraindications	7
Notes	8
Side effects	8
Interactions	8
Emergency information	8
6. DATA PROTECTION	9
Contact of the Data Protection Officer	9
7. COST	9
8. INTEGRATION INTO HEALTHCARE SUPPLY	9
9. MANUFACTURER AND PRODUCT INFORMATION	9
Manufacturer	9
State of information	9
Further information	9
Date of release	10
CE label	10
10. SIGNS AND SYMBOLS	10

The online programme has been labelled as a medical device since 28 May 2021 and is also known under the following names:

- *HelloBetter Stress und Burnout*
- *HelloBetter Burnout*
- *HelloBetter Stress et Burnout*
- *GET.ON Stress*
- *GET.ON Fit im Stress*

This information provides guidance on the correct implementation of the *HelloBetter Stress and Burnout* online programme. These instructions for use are 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. Upon registration, the HelloBetter support team at support@helloworldbetter.de is available for assistance if needed.

We employ numerous measures to secure 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 Stress and Burnout is a psychological online programme aimed at a sustained reduction of perceived stress in coping with life and work. Stress represents a risk factor for mental and physical diseases. With this online programme, perceived stress can provably be reduced and improvements in mental health (depression, anxiety, sleep, quality of life) and work-related health (emotional exhaustion, work commitment) can be obtained. The online course consists of seven units to be completed weekly as well as a booster unit scheduled four weeks after completing the course. Each unit takes about 45-60 minutes.

In addition to well-founded psychoeducation via texts, videos and audios, the online programme teaches effective strategies from cognitive behavioral therapy according to the status quo of scientific findings. These include problem-solving techniques, behavioural activation and emotion regulation strategies (in particular acceptance of negative feelings, self-support and relaxation). 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 diary and repeated 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 Stress and Burnout is designed for adults who meet criteria for the ICD-10 additional coding Z73 (Problems related to life-management difficulty).

Conditions for use

HelloBetter Stress und Burnout 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 online programme on a mobile device, 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 laypeople 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. Good knowledge of the German language is required. 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 seven course units plus a booster unit scheduled four weeks after the end of the programme, which are varied with 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. 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 helloworldbetter.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 Stress and Burnout includes well-founded psychoeducation and strategies of cognitive behavioural therapy according to the latest scientific findings. Knowledge about stress and burnout is imparted and exercises to reduce individual stress are learned. This includes problem-solving techniques, instructions for behavioural activation, exercises for emotion regulation (especially acceptance, self-support and relaxation) as well as an ongoing online journal to record and reflect on one's own experience.

In order to be able to observe a possible improvement or worsening of symptoms, participants are encouraged to take part in the bi-weekly evaluations regarding their stress levels as well as any depressive and anxiety-related complaints they may have. The individual input of the participants is taken into account so that an individualised experience can be ensured within the online programme.

Clinical benefit

The medical device *HelloBetter Stress and Burnout* can contribute to a proven reduction in stress levels as well as improvements in areas of mental health (depression, anxiety, sleep) and work-related health (emotional exhaustion, work engagement).

Risks potentially associated with the use of the medical device have been identified, controlled and consistently rated as acceptable.

Accompaniment

In case of technical questions and problems, participants receive support via the e-mail address support@hellobetter.de. A response will be provided as soon as possible.

Depending on the type of use, participants in the versions "guided" and "guidance on demand" receive written feedback within 24 hours on weekdays from a personal psychologist of 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 Stress and Burnout* 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 be continued at a later moment without any difficulties. The legal data protection requirements are met (see **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 Stress and Burnout was developed by experts from the fields of science, psychology and psychotherapy as well as together with those affected, its effectiveness was 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 affected by high stress helped to revise and improve *HelloBetter Stress and Burnout*. In addition, regular focus groups with participants contribute to quality assurance.

4. SOURCES OF MEDICAL CONTENT

HelloBetter Stress and Burnout has been tested for its effectiveness in various randomised controlled studies (conducted, among others, at the Friedrich-Alexander University Erlangen-Nuremberg and at the Leuphana University Lüneburg). The study results speak for a good effectiveness of the online programme. The studies report between-group effect sizes, intention-to-treat and completer analyses, dropout rates and reasons, and results on user satisfaction. 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 for employees with accompaniment

Study registration: [DRKS00004749](https://www.drks.de/DRKS00004749)

Study protocol: Heber, E., Ebert, D. D., Lehr, D., Nobis, S., Berking, M., & Riper, H. (2013). Efficacy and cost-effectiveness of a web-based and mobile stress-management intervention for employees: design of a randomized controlled trial. *BMC Public Health*, 13:655, <https://doi.org/10.1186/1471-2458-13-655>

Efficacy: Heber, E., Lehr, D., Ebert, D. D., Berking, M., & Riper, H. (2016). Web-based and mobile stress management intervention for employees: A randomized controlled trial. *Journal of Medical Internet Research*, 18(1), e21. doi: 10.2196/jmir.5112

Cost effectiveness (employer's perspective): Ebert, D. D., Kählke, F., Buntrock, C., Berking, M., Smit, F., Heber, E., Baumeister, H., Funk, B. Riper, H., & Lehr, D. (2017). A health economic outcome evaluation of an internet-based mobile-supported stress management intervention for employees. *Scandinavian journal of work, environment & health*, online first. doi:10.5271/sjweh.3691

Cost effectiveness (societal perspective): Kählke F., Buntrock C., Smit F., Berking M., Lehr D., Heber E., Funk B., Riper H., & Ebert D.D. (2019). Economic Evaluation of an Internet-Based Stress Management Intervention Alongside a Randomized Controlled Trial. *JMIR Mental Health*, 15(5). doi:10.2196/10866.

Secondary analysis: Weisel, K. K., Lehr, D., Heber, E., Zarski, A.-C., Berking, M., Riper, H., & Ebert, D. D. (2018). Severely burdened individuals do not need to be excluded from internet-based and mobile-based stress management: effect modifiers of treatment outcomes from three randomized controlled trials. *Journal of Medical Internet Research*, 20(6), e211. <https://doi.org/10.2196/jmir.9387>

Secondary analysis: Zarski, A. C., Lehr, D., Berking, M., Riper, H., Cuijpers, P., & Ebert, D. D. (2016). Adherence to internet-based mobile-supported stress management: a pooled analysis of individual participant data from three randomized controlled trials. *Journal of medical Internet research*, 18(6), e146. doi: 10.2196/jmir.4493

RCT on effectiveness in employees with accompaniment on request

Study registration: [DRKS00005112](https://www.drks.de/DRKS00005112)

Efficacy: Ebert, D. D., Lehr, D., Heber, E., Riper, H., Cuijpers, P., & Berking, M. (2016). Internet-and mobile-based stress management for employees with adherence-focused guidance: efficacy and mechanism of change. *Scandinavian journal of work, environment & health*, 42(5), 382-394. doi: 10.5271/sjweh.3573

RCT on the effectiveness for employees in a self-help setting

Study registration: [DRKS00005384](#)

Efficacy: Ebert, D.D., Heber, E., Berking, M., Riper, H., Cuijpers, P., Funk, B., & Lehr, D. (2016). Self-guided Internet-based and mobile-based stress management for employees: results of a randomised controlled trial. *Occupational and Environmental Medicine*, 73(5), 315-323.

RCT on effectiveness in the general population (universal prevention)

Study registration: [DRKS00005699](#)

Efficacy: Ebert D.D., Franke, M., Zarski, A., Berking, M., Riper, H., Cuijpers, P., Funk, B., Lehr, D. Internet-based and mobile-supported stress management as a universal prevention approach – Effectiveness and moderators from a large pragmatic randomized-controlled trial. *Journal of Medical Internet Research*. 17/05/2021:22107 (forthcoming/in press)

RCT on effectiveness in people with adverse working conditions

Study registration: [DRKS00005990](#)

Efficacy: *Studie abgeschlossen, Analyse & Publikation aktuell in Vorbereitung*

RCT on effectiveness in a three-arm study: accompaniment on demand / self-help / waiting group

Study registration: [DRKS00005687](#)

Study protocol: Ebert, D. D., Lehr, D., Smit, F., Zarski, A.-C., Riper, H., Heber, E., Cuijpers, & Berking, M. (2014). Efficacy and cost-effectiveness of minimal guided and unguided internet-based mobile supported stress-management in employees with occupational stress: a three-armed randomised controlled trial. *BMC Public Health*, 14(807), 1-11. doi: 10.1186/1471-2458-14-807

Efficacy: Nixon, P. et al. Impact of adherence-focused guidance on the efficacy of a web-based stress management intervention and investigating health impairing and promoting mechanisms of prevention: a three- armed randomized controlled trial. *Manuskript aktuell unter Begutachtung*

RCT on effectiveness in students with accompaniment on request

Study registration: [DRKS00010212](#)

Efficacy: Harrer, M., Adam, S.H., Fleischmann, R.J., Baumeister, H., Auerbach, R., Bruffaerts, R., Cuijpers, P., Kessler, R.C., Berking, M., Lehr, D., & Ebert, D.D. (2018). Effectiveness of an Internet- and App-based intervention for college students with elevated stress: randomized controlled trial. *Journal of Medical Internet Research*, 20(4), e136. doi:10.2196/jmir.9293

Qualitative Study: Fleischmann, R. J., Harrer, M., Zarski, A. C., Baumeister, H., Lehr, D., & Ebert, D. D. (2018). Patients' experiences in a guided Internet-and App-based stress intervention for college students: A qualitative study. *Internet Interventions*, 12, 130-140. doi:10.1016/j.invent.2017.12.001

RCT on effectiveness for distance learners with accompaniment on request

Study registration: [DRKS00011800](#)

Study protocol: Harrer, M., Apolinário-Hagen, J., Fritsche, L., Drüge, et al. (2019). Internet-and app-based stress intervention for distance-learning students with depressive symptoms: protocol of a randomized controlled trial. *Frontiers in Psychiatry*, 10 (361), 1-13. doi: 10.3389/fpsyt.2019.00361

Efficacy: Harrer, M., Apolinário-Hagen, J., Fritsche, L., et al. (2021). Internet-and app-based stress intervention for distance-learning students with depressive symptoms: results of a randomized trial. *Internet Interventions*, 24:100374. <https://doi.org/10.1016/j.invent.2021.100374>

5. PATIENT SAFETY

Contraindications



The *HelloBetter Stress and Burnout* online programme must not be used if suicidal tendencies, acute psychosis (ICD-10 F23) and/or dissociative disorder (ICD-10 F44) are present. In such cases, a medical and/or psychotherapeutic assessment should be obtained and in crisis situations, the emergency number 112 should be contacted immediately.

Furthermore, *HelloBetter Stress and Burnout* may only be used with accompaniment. This is ensured by a specially trained psychologist in our team (see **Accompaniment**).

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 medical and/or psychotherapeutic advice directly. If in the course of the online programme there is no reduction of perceived stress levels or if these worsen acutely, medical or psychotherapeutic contact should also be established. In addition, no changes should be made to any existing medication and/or therapy without consulting a doctor.

Side effects

The online programme *HelloBetter Stress and Burnout* can support participants to demonstrably reduce stress exposure and contribute to improvements in areas of mental health (depression, anxiety, sleep) and work-related health (emotional exhaustion, work engagement). This has been demonstrated in several randomised controlled trials (see **4. Sources of medical content**).

The success of the online programme depends on many influences and cannot be guaranteed in individual cases. Thus, not all participants may benefit equally from using *HelloBetter Stress and Burnout*, 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 online programme *HelloBetter Stress and Burnout*, 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 case of suicidal tendencies or an acute crisis, the emergency services should be informed:
Emergency numbers in Germany:

- general emergency service: 112
- police: 110

The telephone counselling service offers a sympathetic ear in life crises, around the clock, free of charge and anonymously.

- 0800 111 0 111 / 0800 111 0 222
- www.telefonseelsorge.de

The telephone counselling team knows the appropriate facilities and contact points for acute crises and suicidal tendencies. Clinics and other crisis services in your area can be found in the address list of the Stiftung Deutsche Depressionshilfe: 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 of 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 SUPPLY

HelloBetter Stress and Burnout includes the possibility for participants and accompanying persons to monitor the course of the respective physical and psychological complaints. Within the online

programme, multiple validated questionnaires are filled out that measure depressive symptoms, perceived stress levels and anxiety.

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

State of information

2024-03-22

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 product *HelloBetter Stress and Burnout*, please contact GET.ON Institut für Online Gesundheitstrainings GmbH. In addition, the competent authority BfArM must be informed, which will be taken over by the manufacturer.

Date of release



2024-03-22

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