

INFORMATION ON THE ONLINE PROGRAMME

HelloBetter Depression Prävention

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

- *HelloBetter Depression Prevention*
- *GET.ON Stimmung*
- *HelloBetter Wohlbefinden*
- *GET.ON Depression Prevention*
- *HelloBetter Stimmung*
- *GET.ON Depression Prävention*
- *GET.ON Mood Enhancer*
- *HelloBetter Depression vorstationär*
- *GET.ON Depression vorstationär*
- *HelloBetter Depression vorbeugen*
- *GET.ON Stimmung (angepasst für die grünen Berufe)*

This instruction provides guidance on the correct implementation of the *HelloBetter Depression Prävention* 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 Depression Prävention is a psychological online programme aimed at the prevention and sustained reduction of depressive symptoms as well as improve health-related quality of life in people with none or sub-threshold depressive symptoms. The online course consists of six units to be completed weekly, each lasting 45-60 minutes.

In addition to well-founded psychoeducation via text, videos and audios, the online programme teaches effective strategies from cognitive behavioral therapy according to the status quo of scientific findings. These include interactive exercises, problem-solving techniques, audio formats, and instructions for self-reflection. The exercises are learned within the course and can be integrated into daily life. Goals are formulated in such a way that they are individual, realistic and achievable. In addition, there is an online diary and recurring symptom checks to record, monitor and evaluate progress during the course.

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

HelloBetter Depression Prävention is intended for people with none or only subthreshold depressive symptoms, who are interested in positively impacting their mental health.

Conditions for use

HelloBetter Depression Prävention is available in an app-based and web-based version. The web-based version can be accessed through a computer or laptop with internet access. To use it through a browser (Google Chrome, Mozilla Firefox, Edge, or Safari), the browser must be in its latest version. Smooth operation with unsupported or mobile browsers cannot be guaranteed.

To use the app-based version on your mobile device, you will need the HelloBetter App. The HelloBetter App supports smartphones with at least Android 9 (API Version 28+) or iOS 12.2. For optimal performance, 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 programme. Previous psychotherapeutic experience is not necessary. Experience with navigating websites/and or apps is expected.

2. DESCRIPTION AND MODE OF OPERATION OF THE ONLINE PROGRAMME

Type and duration of the programme

The online course consists of six 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 keep an online journal and carry out regular symptom checks. 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 additional components (e.g. activity planner and diary) beyond that is possible multiple times a day.

Programme content

HelloBetter Depression Prävention includes well-founded psychoeducation and strategies of cognitive behavioural therapy according to the latest scientific findings. Knowledge about depression is taught as well as exercises, methods and techniques to improve depressive symptoms. This includes, among other things, instructions for behavioural activation, systematic problem solving, strengthening social

relationships as well as an ongoing online journal with which your own experience can be recorded and reflected upon.

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

Clinical benefit

The medical device *HelloBetter Depression Prävention* can help people with none or subthreshold depressive symptoms to prevent and/or reduce depressive symptoms as well as to improve health-related quality of life. 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 Depression Prävention* 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 (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 and 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 Depression Prävention 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 depressive symptoms helped to revise and improve *HelloBetter Depression Prävention*. In addition, regular focus groups with participants contribute to quality assurance.

4. SOURCES OF MEDICAL CONTENT

HelloBetter Depression Prävention has been tested for its effectiveness in several randomised controlled trials. The study results indicate the good effectiveness of the online programme. 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 subclinical depression with eCoaching

Study registration: [DRKS00004709](https://www.drks.de/DRKS00004709)

Study protocol: Buntrock, C., Ebert, D. D., Lehr, D., Cuijpers, P., Riper, H., Smit, F., & Berking, M. (2014). Evaluating the efficacy and cost-effectiveness of web-based indicated prevention of major depression: design of a randomised controlled trial. *BMC Psychiatry*, 14(25), 1–10. doi: 10.1186/1471-244X-14-25

Efficacy (6 months): Buntrock, C., Ebert, D., Lehr, D., Riper, H., Smit, F., Cuijpers, P., & Berking, M. (2015). Effectiveness of a web-based cognitive behavioural intervention for subthreshold depression: pragmatic randomised controlled trial. *Psychotherapy and psychosomatics*, 84(6), 348-358. doi: 10.1159/000438673

Efficacy (12 months): Buntrock, C., Ebert, D. D., Lehr, D., Smit, F., Riper, H., Berking, M., & Cuijpers, P. (2016). Effect of a web-based guided self-help intervention for prevention of major depression in adults with subthreshold depression: a randomized control trial. *JAMA*, 315(17), 1854–1863. doi:10.1001/jama.2016.4326

Cost-effectiveness: Buntrock, C., Berking, M., Smit, F., Lehr, D., Nobis, S., Riper, H., Cuijpers, P., & Ebert, D. (2017). Preventing depression in adults with subthreshold depression: health-economic evaluation alongside a pragmatic randomized controlled trial of a web-based intervention. *Journal of Medical Internet Research*, 19(1), e5. doi: 10.2196/jmir.6587

RCT on the efficacy in subclinical depression with eCoach on request

Study registration: [DRKS00005973](https://www.drks.de/DRKS00005973)

Efficacy: Ebert, D. D., Buntrock, C., Lehr, D., Smit, F., Riper, H., Baumeister, H., Cuijpers, P., & Berking, M. (2018). Effectiveness of web- and mobile-based treatment of subthreshold depression with adherence-focused guidance: a single-blind randomized controlled trial. *Behavior Therapy*, 49(1), 71–83. doi: 10.1016/j.beth.2017.05.004

Secondary analysis: Zarski, A. C., Berking, M., Reis, D., Lehr, D., Buntrock, C., Schwarzer, R., & Ebert, D. D. (2018). Turning good intentions into actions by using the health action process approach to predict adherence to Internet-based depression prevention: secondary analysis of a randomized controlled trial. *Journal of Medical Internet Research*, 20(1), e9. doi: 10.2196/jmir.8814

RCT on patients with depressive symptoms who are waiting for outpatient psychotherapy

Study registration: [DRKS00010282](https://www.drks.de/DRKS00010282)

Study protocol: Grünzig, S.D., Baumeister, H., Bengel, J. et al. Effectiveness and acceptance of a web-based depression intervention during waiting time for outpatient psychotherapy: study protocol for a randomized controlled trial. *Trials* 19, 285 (2018). <https://doi.org/10.1186/s13063-018-2657-9>

Efficacy: Krämer, L., Grünzig, S., Baumeister H., Ebert, D.D., & Bengel, J. (in press) Effectiveness of a guided web-based intervention to reduce depressive symptoms before outpatient psychotherapy: A pragmatic randomized controlled trial. *Akzeptiert in Psychotherapy & Psychosomatics*.

RCT on effectiveness in green professions

Study registration: [DRKS00014000](https://www.drks.de/DRKS00014000)

Study protocol: Braun, L., Titzler, I., Ebert, D.D., Buntrock, C., Terhorst, Y., Freund, J., Thielecke, J., & Baumeister, H. (2019). Clinical and cost-effectiveness of guided internet-based interventions in the indicated prevention of depression in green professions (PROD-A): study protocol of a 36-month follow-up pragmatic randomized controlled trial. *NBC Psychiatry*, 19(1), 1–16. <https://doi.org/10.1186/s12888-019-2244-y>

Efficacy: Braun, L., Titzler, I., Terhorst, Y., Freund, J., Thielecke, J., Ebert, D.D., Baumeister, H. Effectiveness of guided internet-based interventions in the indicated prevention of depression in green professions (PROD-A): Results of a pragmatic randomized controlled trial. *J Affect Disord.* 2021 Jan 1;278:658-671. doi: 10.1016/j.jad.2020.09.066. Epub 2020 Sep 15. PMID: 33096333.

RCT on the effectiveness of a problem-solving intervention for teachers

Study registration: [ISRCTN15635876](https://www.isrctn.com/ISRCTN15635876)

Efficacy: Ebert, D. D., Lehr, D., Boß, L., Riper, H., Cuijpers, P., Andersson, G., Berking, M. (2014). Efficacy of an internet- based problem-solving training for teachers: results of a randomized controlled trial. *Scandinavian Journal of Work, Environment & Health*, 40(6), 582–596. doi:10.5271/sjweh.3449

Secondary analysis: Junge, M. N., Lehr, D., Bockting, C. L. H., Berking, M., Riper, H., Cuijpers, P., & Ebert, D. D. (2015). For whom are internet-based occupational mental health interventions effective? Moderators of internet-based problem-solving training outcome. *Internet Interventions*, 2(1), 39–47. <https://doi.org/10.1016/j.invent.2014.11.007>

5. PATIENT SAFETY

Contraindications



The online programme *HelloBetter Depression Prävention* must not be used if suicidal tendencies are present. In this case, participants should obtain a medical and/or psychotherapeutic assessment and in crisis situations immediately contact the emergency number 112.

The online programme aims to reduce depressive symptoms. It must be weighed up whether there are any objections to the programme from a medical point of view. Therefore, it is necessary to clarify with a general practitioner whether participation is safe before starting the programme.

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 or psychotherapeutic contact should also be established if in the course of the online programme there is no reduction in the impairment caused by the depressive symptoms or if these worsen 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. Thus, not all participants may benefit equally from using *HelloBetter Depression Prävention*, 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. However, the points mentioned are typical temporary therapy processes. Should side effects occur and persist in connection with the use of the *HelloBetter Depression Prävention* online programme, we recommend seeking medical and/or psychotherapeutic advice or sending an email to support@helloworldbetter.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 Telefonseelsorge team knows the appropriate facilities and contact points for acute crises and suicidal tendencies. Clinics and other crisis services in your area in Germany 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 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 Depression Prävention includes the possibility for participants and health care practitioners to observe the course of the respective 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
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Information last updated

2023-07-26

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 Depression Prävention*, 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



2021-11-29

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.