

INFORMATION ON THE ONLINE PROGRAMME

HelloBetter Panik

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The online programme is labelled as a medical device and is also known under the following names: *HelloBetter Panic*, *HelloBetter Trouble Panique*, *GET.ON Panik*, *GET.ON Panik (angepasst für die grünen Berufe)*, *GET.ON Panic*.

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.

1. PURPOSE/ INDICATION

HelloBetter Panik is a psychological online programme aimed at reducing the symptom severity of panic disorder and agoraphobia with panic disorder. The online course consists of six units to be completed weekly. 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 behavioural therapy according to the status quo of scientific findings. These include e.g. repeated exposures to internal and external anxiety-provoking stimuli, cognitive restructuring, relaxation exercises and 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 a randomised controlled trial.

HelloBetter Panik is designed for adults with mild to moderate panic and agoraphobic symptoms who meet the criteria for one of the following ICD-10 diagnoses:

- F41.0 Panic disorder
- F40.01 Agoraphobia: With panic disorder

Conditions of use

HelloBetter Panik 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 all ages 18 years and older. It is equally suitable for female, male and non-binary people who are open to using web-based programmes. 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

Frequency of use

Based on scientific studies, the course units can be completed in a weekly rhythm to achieve the best possible success of the online programme. It is also 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 Panik includes sound psychoeducation and strategies of cognitive behavioural therapy according to the latest scientific findings. Knowledge about anxiety and panic is taught as well as helpful exercises to reduce the symptom severity of panic disorder and agoraphobia with panic disorder. These include repeated confrontations with internal and external fear-inducing stimuli, cognitive restructuring of fearful thoughts, relaxation exercises, relapse prophylaxis and an ongoing online diary with which one's own experience can be recorded and reflected upon.

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 anxiety-related symptoms as well as possible depressive and stress-related complaints. 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 Panik* may help to reduce the symptom severity of panic disorder and agoraphobia with panic disorder. Risks potentially associated with the use of the medical device have been assessed, controlled and consistently rated as acceptable.

Accompaniment

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

We attach great importance to the safety of our clients in all our services. Therefore, they receive written feedback from a trained psychologist in our team within 24 hours on weekdays after completing the individual course units. 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.

Interoperability

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

3. PATIENT SAFETY

Contraindications



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

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

- Mental illness due to brain dysfunction (F00-F09)
- Mental and behavioural disorders caused by psychotropic substances (F10-F16, F18, F19)
- Diseases of the schizophrenic type and psychotic disorders (F2, F32.3, F33.3)
- Presence of bipolar disorder and/or manic episode (F30, F31)
- Dissociative disorders (F44)

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

- Cardiovascular diseases (e.g. cardiac arrhythmias, angina pectoris)
- Diseases of the respiratory system (e.g. bronchial asthma)
- Metabolic diseases (e.g. hyper-/ hypothyroidism, diabetes mellitus)
- Neurological diseases (e.g. epilepsy, central vertigo)
- Known or suspected pregnancy

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

Notes

Suicidal thoughts that are tired of life 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 there is no improvement in the mental state of the participants in the course of the online programme or if it worsens acutely, medical and/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 *HelloBetter Panik* online programme can help participants reduce the symptom severity of panic disorder and agoraphobia with panic disorder. This was demonstrated in a randomised controlled trial.

However, the success of the online programme depends on many influences and cannot be guaranteed in individual cases. In the context of the confrontation exercises, there may be a risk of accident or injury when using public space or during certain physical exercises, even with prudent and proper behaviour. However, the online programme does not explicitly teach exercises that involve or deliberately provoke such a risk. In addition, the confrontation may temporarily cause unpleasant feelings and physical discomfort such as heart palpitations, dizziness or nausea. Such physical fear reactions are not inherently harmful and are quite desirable as a component of exposure procedures in order to achieve habituation to the fear. The participants are informed about each step of the confrontation, comprehensively explained and gradually introduced to fear-inducing stimuli. Potential stresses are thus made easy to manage. In addition, the participants are instructed not to go beyond their own physical limits.

In addition, not all participants may benefit equally from using *HelloBetter Panik*, 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 worsening"). 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 Panik* online programme, we recommend seeking medical and/or psychotherapeutic advice or emailing support@hellowebetter.de.

Interactions

So far, no interactions are known.

Details for emergencies

Emergency numbers in Switzerland:

- Rescue service: 144
- Police: 117

[The Offered Hand](#) offers a sympathetic ear in life crises, around the clock and anonymously.

- Phone: 143

4. DATA PROTECTION

More detailed information on the processing of personal data can be found in our privacy policy at hellowebetter.de/datenschutz-kurs.

Contact of the Data Protection Officer

Data Protection Officer
c/o GET.ON Institute for Online Health Training GmbH
Oranienburger Str. 86a
10178 Berlin
datenschutz@hellobetter.de

5. MANUFACTURER AND PRODUCT INFORMATION**Manufacturer**

HelloBetter is a brand of the
GET.ON Institute for Online Health Training GmbH
Schrammsweg 11
20249 Hamburg
<https://hellobetter.de>
kontakt@hellobetter.de
+49 (0)40 532 528 67

Status of the information

2024-03-22

Further information

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

Should serious incidents occur in connection with the use of the medical device *HelloBetter Panik*, 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.

Publication date

2024-03-22

CE marking

6. SYMBOL LEGEND



Medical device ISO/DIS 15223- 1:2020 Reference no. 5.7.7
This is a medical device.



CE marking Communauté Européenne
Product traded on the extended internal market of the European Economic Area (EEA), meets high standards of safety, health and environmental protection.



Follow the instructions for use ISO 7000-1641
The user must additionally observe the instructions for use.



Manufacturer ISO 7000-3082
Name and address of the manufacturer of the medical device



Publication date ISO 7000-2497
Date on which the medical device was published as such



Warning ISO 7000-0434A
Warnings and necessary precautions