

Description of the Digital Health Application

The application provides an ecological momentary assessment tool which allows users to monitor symptoms of common mental health problems in real-time over long time periods. Questions are asked within three blocks a day (morning, noon, evening), with each block consisting of three or more questions. In contrast to a static mood-diary or the repeated completion of static questionnaires, the underlying algorithm adjusts the number and area of questions to the answers of the user as well as to the completion rate of previous questions blocks. In addition, every question block is finished by a general mood-tracking (very bad, bad, moderate, good, very good) as well as the opportunity to track emotions and situations via text entry, pre-defined or customized tags (positive, negative, neutral).

This information is then processed to continuously provide individualized automated feedback (insights) to the user that reflect symptoms as well as potential triggers and problem areas and suggest suitable disorder-specific and trans-diagnostic self-management courses and exercises to address symptoms and problems.

As soon as the user has answered the required minimum of questions, the application provides an individualized medical orientation regarding the need for assessment of their mental-mental condition which can be shared with a specialist.

This continuous approach to monitoring, mood-tracking and individualized recommendations for self-management exceeds the scope of existing mood diaries or stand-alone self-management programs that do either not adjust to the user's individual needs or symptoms or require personal guidance by a specialist.

The application has four core components which are interconnected to deliver the described benefit for the user.

1. Continuous monitoring of symptoms of common mental disorders, related problems, and personal resources (Journal).
2. Automated feedback on general symptom load and level of functioning (Results)
3. Automated feedback on symptoms, symptom clusters and relevant problem areas, along with recommendations for exercises and courses (Insights)
4. Structured self-management courses and exercises that address problems that commonly contribute to mental health disorders (Self-Management)

Journal

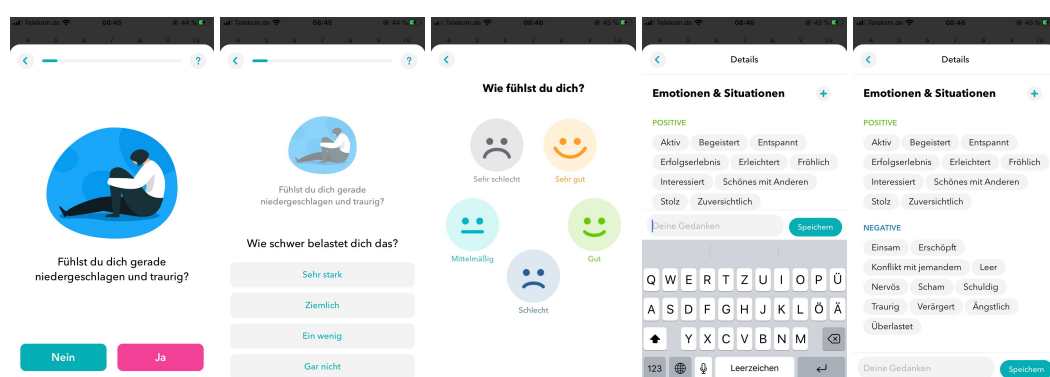
Users answer up to three blocks of questions per day on symptoms of common mental disorders, related problems and personal resources that can be helpful to address those symptoms and problems. Questions are chosen from a large question pool based on an

adaptive algorithm that takes into account previous answers of the user. Thus, the more questions are answered, the more individualized and relevant the questions become.

Questions typically require a dichotomous answer. If a symptom is confirmed, a follow-up question is asked to assess symptom severity (“How much does this bother you?”), which is rated on a four-point scale ranging from 1 to 4 with a visual anchor. Symptom ratings with a severity of 2 or higher are considered as clinically relevant.

At the end of each question block, users can rate their current mood on a simple 5-point scale (very bad, bad, neutral, good, very good). Users can also add personal notes as well as predefined and customized tags to their entries. The mood rating and the notes can be used independently of the question blocks, so users can make multiple entries per day.

A customizable alert function can be set to remind users to answer the question block at respective times via push notifications for higher response rates.



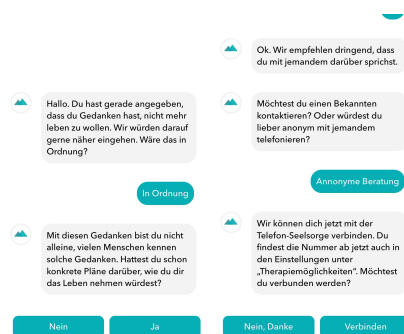
Results

If users have answered a minimum number of questions within a period of 14 days, they will get feedback on their answers regarding their symptom load. Users with a high symptom load, a high level of functional impairment or critical symptoms like suicidal tendencies are recommended to seek further assessment.

In addition to that recommendation, users are provided with summaries of their answers over predefined periods of time as well as weekly, monthly and yearly statistics. Some summaries can be exported in PDF format and can be shared with treatment providers.



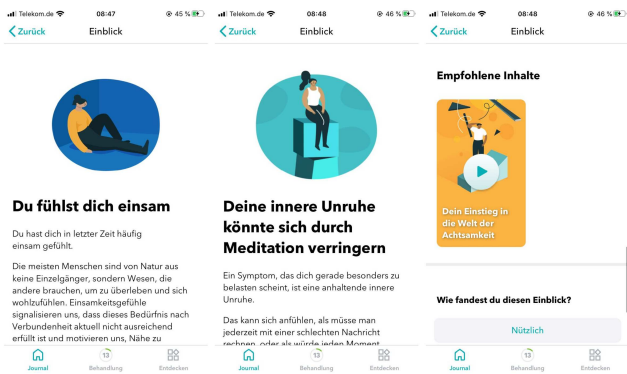
Users who report suicidal tendencies are instantly and automatically directed to an automated dialogue (crisis-bot) that culminates in a direct connection to a local crisis hotline if the user agrees. In Germany, this is the Telefonseelsorge, in other countries it is a comparable service. Alternatively, the user is guided to contact a friend or family member via text message to seek help.



Insights

If users report specific symptoms or problems, or combinations of symptoms and problems repeatedly, they will receive automated feedback via insights.

Insights provide general information about symptoms, about behaviour-health-links or about consequences of behaviors. They also provide an overview of possible strategies to address problems and prompt further engagement with related self-management exercises.



Self-management

The application provides a library of courses and exercises that are designed to enable the user to self-manage mental health problems. Courses can be accessed at the discretion of the user, and subscribed (i.e., full access) users have full access to the entire course library.

Courses consist of multiple exercises. For some courses it is advisable to complete the exercises in the set order, or to allow for time to implement behaviour changes between two exercises. If this is the case, this is explained to the user within the exercise.

The version of the application under evaluation contains the content described in the table below.



Course	Domain	Learning goals	Relevant treatment guidelines and evidence
Depression. (What is depression)	Psychoeducation	Knowledge about signs and symptoms, prevalence, etiology, treatment options.	(American Psychiatric Association, 2013; DGPPN et al., 2015)
Soziale Angststörung (What is social anxiety disorder)	Psychoeducation	Knowledge about signs and symptoms, prevalence, etiology, treatment options.	(American Psychiatric Association, 2013; Bandelow et al., 2014)
Generalisierte Angststörung (What is generalized anxiety disorder)	Psychoeducation	Knowledge about signs and symptoms, prevalence, etiology, treatment options.	(American Psychiatric Association, 2013; Bandelow et al., 2014; Becker & Hoyer, 2005)
Spezifische Phobien (What are specific phobias)	Psychoeducation	Knowledge about signs and symptoms, prevalence, etiology, treatment options.	(American Psychiatric Association, 2013; Bandelow et al., 2014)
Panikstörung und Agoraphobie (What is panic disorder and agoraphobia)	Psychoeducation	Knowledge about signs and symptoms, prevalence, etiology, treatment options.	(American Psychiatric Association, 2013; Bandelow et al., 2014; Lang et al., 2018)
Gesundheitsängste (What is health anxiety)	Psychoeducation	Knowledge about signs and symptoms, prevalence, etiology, treatment options.	(American Psychiatric Association, 2013; Bleichhardt & Weck, 2015)
Chronischer Schmerz (What is chronic pain)	Psychoeducation	Knowledge about signs and symptoms, prevalence, etiology, treatment options.	(American Psychiatric Association, 2013; Deutsches Kollegium für Psychosomatische Medizin & Deutsche Gesellschaft für Psychosomatische Medizin und Ärztliche Psychotherapie, 2018)
Essstörungen (What are eating disorders)	Psychoeducation	Knowledge about signs and symptoms, prevalence, etiology, treatment options.	(American Psychiatric Association, 2013; Deutsche Gesellschaft für Essstörungen (DGESS) et al., 2019; C. Jacobi et al., 2016)
Schlafstörungen (What is insomnia)	Psychoeducation	Knowledge about signs and symptoms, prevalence, etiology, treatment options.	(American Psychiatric Association, 2013; Deutsche Gesellschaft für Schlafforschung und Schlafmedizin, 2017)
Psychische Störungen in Schwangerschaft und Wochenbett (What are pre- and postnatal disorders)	Psychoeducation	Knowledge about signs and symptoms, prevalence, etiology, treatment options.	(American Psychiatric Association, 2013)
Psychotherapie (Psychotherapy)	Psychoeducation	Knowledge about different types of psychotherapy and how to get treatment	(H. U. Wittchen & Hoyer, 2011)

Stationäre Behandlung) Inpatient treatment)	Psychoeducation	Knowledge about different options of inpatient treatment (e.g., psychiatric, psychosomatic, rehabilitation) and indications	(H. U. Wittchen & Hoyer, 2011)
Wie entstehen psychische Erkrankungen? (Why do people get mental disorders)	Psychoeducation	Knowledge about the etiology of mental disorders	(H. U. Wittchen & Hoyer, 2011)
Gedanken, Gefühle, Verhalten (Thoughts, Emotions, Behavior)	Psychoeducation	Knowledge about the interrelation of thoughts, emotions, and behaviors, knowledge of ABC-Model, principles of CBT-based interventions	(J. Beck, 2013; Berking, 2015; Stavemann, 2014; H. U. Wittchen & Hoyer, 2011)
Dein Einstieg in die Welt der Achtsamkeit (Mindfulness Basic Course)	Self	Knowledge about the concept of mindfulness and meditation, practice mindfulness	(Michalak et al., 2012)
Trainiere 7 Tage Achtsamkeit (Mindfulness Course)	Self	Knowledge about the concept of mindfulness and meditation, practice mindfulness	(Michalak et al., 2012)
Wie du dich selbst akzeptierst (How to accept yourself)	Self	Learn about the role and practice self-compassion, strengthen self-esteem, cognitive restructuring of core beliefs about the self.	(Germer & Neff, 2013)
Denkmuster, automatische Gedanken und Grundüberzeugungen (Thinking styles, automatic thoughts, and beliefs)	Thinking	Identification of automatic thoughts, thinking styles, cognitive distortions, techniques of cognitive restructuring	(A. T. Beck et al., 2017; J. Beck, 2013; Stavemann, 2014)
So stoppst du Grübeln (How to stop rumination)	Thinking	Knowledge about rumination and strategies to interrupt or cope with it, application of those strategies	(Teismann, 2012)
Verstehe Deine Gefühle besser (Understanding your emotions)	Feeling	Knowledge about the role of emotions, the interrelation of emotions and needs, accept unpleasant emotions	(Berking, 2015; Eismann & Lammers, 2017)
So nimmst du Gefühle richtig wahr (Dealing with emotions)	Feeling	Knowledge about the interrelation between thoughts, emotions and actions	(Berking, 2015; Eismann & Lammers, 2017)
Aktiv werden (Getting more active)	Doing	Behavioral Activation	(Hoyer & Vogel, 2018)
Exposition, wie geht das?	Doing	Understanding the rationale of exposition, role of avoidance interoceptive exposition, graded in-vivo exposition)	(Bandelow et al., 2014; Lang et al., 2018)

Mit Problemen umgehen (Dealing with Problems)	Doing	Problem solving Radical Acceptance	(Bell & D'Zurilla, 2009; Kaluza, 2015; Stavemann, 2014)
Rückfällen vorbeugen (relapse prevention)	Doing	Relapse Prevention after treatment	(H. U. Wittchen & Hoyer, 2011)
Beziehungen und Kommunikation (Relationships and Communication)	Interpersonal	Improve social skills, achieving interpersonal goals	(Hinsch & Pfingsten, 2015)
Konflikte und Kritik (Dealing with Conflicts and Criticism)	Interpersonal	Improve social skills, handle conflicts	(Hinsch & Pfingsten, 2015)
So setzt du deine Muskeln zur Entspannung ein (Progressive Muscle Relaxation)	Body	Practice progressive muscle relaxation	(Kwekkeboom & Gretarsdottir, 2006; Manzoni et al., 2008)
Finde deine Ruhe mit autogenem Training (Autogenic training)	Body	Practice Autogenic Training	(Kwekkeboom & Gretarsdottir, 2006; Manzoni et al., 2008)
Besser schlafen (improve your sleep)	Body	Knowledge about sleep architecture, sleep cycles, sleep hygiene, instruction for sleep compression	(Deutsche Gesellschaft für Schlafforschung und Schlafmedizin, 2017; Marx, 2016)
Ausgewogene Ernährung (Balanced Eating)	Body	Knowledge about intuitive eating, balanced diet	(Hauner et al., 2012; R. E. Wilson et al., 2020; Wolfram et al., 2015)

Intended use and users

Intended use

The MindDoc monitoring and self-management application medical device provides continuous **long-term symptom monitoring for individuals with mental health problems. This enables users to recognize patterns in their symptom trajectories** which then can be shared with a mental health care provider or **used for self-management**. MindDoc thus

1. provides users **orientation regarding the need to consult a mental health care provider** who can use the monitoring data to prepare an actual diagnosis and support a follow-up therapy.
2. enables users to **self-manage symptoms and related problems by providing both transdiagnostic and disorder-specific evidence-based courses and exercises** which help them to recognize, understand, and cope with signs and symptoms of mental disorders.

The application explicitly does not replace a diagnosis of a doctor or a psychological psychotherapist, but can only prepare and support the way to a psychiatric or psychotherapeutic treatment.

Intended users

- Adults aged over 18 years
- All genders
- General ability to use a smartphone and a web-application (reading, listening)
- Internet access
- Access to a smartphone and a 3rd party Appstore (Apple Appstore, Google Play)
- Diagnosed or suspected common mental disorder (ICD-10) including
 - F32 Depressive episode
 - F33 Recurrent depressive disorder
 - F34 Dysthymia
 - F38 Other mood [affective] disorders
 - F39 Unspecified mood [affective] disorder
 - F40 Phobic anxiety disorders
 - F41 Other anxiety disorders
 - F43.2 Adjustment disorder
 - F45 Somatoform disorder
 - F48.0 Neurasthenia
 - F50 Eating disorders
 - F51 Nonorganic insomnia
 - F53 Postpartal depression and anxiety

The app may not be suitable for individuals with severe mental disorders including organic mental disorders (F0), most substance-related disorders (F1x.0, F1x.2, F1x.3, F1x.4, F1x.5, F1x.6., F1x.7), schizophrenia, schizotypal and delusional disorders (F2),

bipolar affective disorders (F30, F31, F34.0), dissociative disorders (F44, F48.1), mental retardation (F7), and disorders of psychological development (F8).

Though there is no direct harm to expect, under some circumstances and in specific cases, users with schizophrenia could misinterpret smilies or other forms of emotion-loaded illustrations which could lead to symptom deterioration. Also, for users with psychosis, parts of the self-management content (e.g., mindfulness, relaxation) could lead to an exacerbation of symptoms.

- The application explicitly does not replace the diagnosis by a mental health care provider, but can only give orientation on whether to consult a mental health care provider who then can include the results of the medical device in diagnostic processes.
- The application explicitly does not replace psychotherapy.