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App-based unguided self-management for people with mild to moderate mental health impairments (APPSY). Study protocol for a randomised controlled trial.

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App-based unguided self-management for people with mild to moderate mental health impairments (APPSY). Study protocol for a randomised controlled trial.

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ABSTRACT

Introduction Mental disorders pose a huge burden to both individuals and health systems. Symptoms and syndromes often remain undetected and untreated, resulting in comorbidity and chronification. Besides limited resources in healthcare systems, the treatment-gap is—to a large extent—caused by within-person barriers impeding early treatment seeking. These barriers include a lack of trust in professionals, fear of stigmatization, or the desire to cope with problems without professional help. While unguided self-management interventions are not designed to replace psychotherapy, they may support early symptom assessment and recognition by reducing within-person barriers. Digital self-management solutions may also reduce inequalities in access to care due to external factors such as regional unavailability of services.

Methods and analysis: Approximately 1100 patients suffering from mild to moderate depressive, anxiety, sleep, eating, or somatization-related mental disorders will be randomized to receive either a low-threshold unguided digital self-management tool in the form of a transdiagnostic mental health app or care as usual (CAU). The primary outcomes will be mental health literacy, patient empowerment and access to care while secondary outcomes will be symptom distress and quality of life. Additional moderator and predictor variables are negative life events, personality functioning, client satisfaction, mental health care service use and application of self-management strategies. Data will be collected at baseline as well as 8 weeks and 6 months after randomization. Data will be analysed using multilevel mixed models with separate models for each primary and secondary outcome variable. Primary analyses will be performed using the completer sample, while secondary analysis will employ the intention-to-treat principle.

Ethics and dissemination Approval was obtained from the Ethics Committee of the Faculty of Educational Science and Psychology at the Freie Universität Berlin. The results will be submitted to peer-reviewed specialized journals and presented at national and international conferences.

STRENGTHS AND LIMITATIONS OF THE STUDY

- The APPSY study investigates an app based symptom and mood diary with automated feedback and a series of courses and exercises in which users can learn more about mental health problems and disorders as well as opportunities for self-help and treatment.
- This study is the first to systematically investigate treatment seeking attitudes and behaviors in a large population of users of an app-based mental health intervention.

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- The assessment of both predictors of treatment seeking and actual treatment seeking behavior enables the investigation of possible indicators for decision making in stepped care
- The inclusion of a control group, possible moderator variables and follow-up measurements will allow analyses to assess potential mechanisms of improvement
- The study may be limitated by a relatively high rate of attrition that is to be expected in unguided self-help solutions

INTRODUCTION

The number of people suffering from depression worldwide is estimated at over 300 million and more than 250 million suffer from an anxiety disorder [1]. In Germany, around one in ten people is affected by depression, while around one in five meets diagnostic criteria for an anxiety disorder [2]. One in twenty individuals suffers from chronic pain [2] or insomnia [3]. Depressive disorders are a major contributor to health loss, accounting for 7.5% of years lived with disability while anxiety disorders rank in the top ten among all known diseases[1,4] accounting for 4.5% of years lived with disability [1,4]. Furthermore, mental disorders are associated with high direct and indirect costs. In Germany, the direct costs in 2012 were estimated at 33 billion Euro [5] while estimates of indirect costs are almost equally high [6].

Further, comorbidity among mental disorders is high. For example, individuals with a mood disorder, e.g. depression, have a lifetime prevalence of 81% for anxiety disorders, with social phobia, obsessive compulsive disorder, generalized anxiety disorder, or post traumatic stress disorder being the most frequent comorbid disorders [7]. A review of 177 clinical studies with a total of 533,377 study participants revealed that only 14% of the cases could be clearly allocated to one specific mental disorder category such as depression, anxiety or personality disorders [8]. When affective and anxiety disorders are conceptualised under the overarching spectrum of *Internalizing Disorders,* predictive validity with respect to suicidal tendencies or future mental illness is improved significantly [9]. A similar approach is used in contemporary dimensional, hierarchical, and data-driven phenotypic definitions of psychopathology [10] which is also supported by recent findings concerning shared genetic covariance and polygenic risk scores [11].

Recent meta-analyses confirm the efficacy of app-supported smartphone interventions both for the reduction of common mental disorder symptoms as well as for improving quality of life [12]. These interventions are typically based on principles of cognitive behavioural therapy and are designed to teach the users skills to manage their symptoms as well as disorder related cognitions and behaviours [13].

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Typically, internet-based interventions consist of several sessions or modules and address one type of disorder [13]. Interventions targeting the same disorder tend to be very similar regarding their components and content, while they may differ in the way the content is presented (e.g., text vs. video based, length and reading level of text, inclusion of case vignettes and examples). Sessions or modules can be consecutive, i.e. users engage with the content in a preset order and/or at preset intervals, or users can determine the order of the content they engage with and self-pace through the intervention.

On the other hand, authors of an extensive analysis of the WHO World Mental Health Surveys conclude that "common causal pathways account for most of the comorbidity" [14]. This may explain why many pharmaceutical and psychosocial treatments show transdiagnostic effects on a range of mental disorders [15,16]. Contemporary mental health interventions and treatments such as the *Unified Protocol* [17] or the *Common Elements Treatment Approach* [18] therefore increasingly replace "single-disorder-protocols" with treatment elements that address the common underlying mechanisms of multiple disorders and have been proved to be transdiagnostically effective.

Based on these as well as the meta-analytical findings presented above we therefore expect a transdiagnostic unguided internet based self-management for mental health to have an impact on a range of mental disorder symptoms beyond anxiety and depression as well as on quality of life.

Most common mental disorders can be successfully treated if they are detected early and if appropriate treatment is provided in a timely manner. To this end, evidence-based therapeutic approaches are available but only reach about 28% (in high-income countries) of those with depression and 20% of those with an anxiety disorder [19]. Access to specialized care is often impeded by limited availability while treatment delays are associated with symptom deterioration and less favourable long-term outcomes, according to a study using longitudinal data from over half a million treatment-seeking individuals [20].

More importantly, within-person attitudinal barriers seem to constitute an even stronger obstacle for treatment seeking than structural barriers. Both a major national population study [21] and the WHO World Mental Health surveys [22] concluded that by far the largest treatment barriers are wanting to handle the problem on one's own and low perceived need for care. Although not considered to be stigma-related barriers, these factors may be influenced by stigma [23]. A systematic review of barriers and facilitators to mental health help-seeking showed the key barriers to be stigma, confidentiality issues, lack of accessibility, self-reliance, low knowledge about mental health services and fear/stress

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about the act of help-seeking or the source of help itself [24]. Consequently, stigma can be considered a part of a larger network of beliefs and other constraints deterring help-seeking behavior [25]. All of these factors reduce the chances of early detection, add to the issue of under-diagnosis, and increase the risk of long-term symptom deterioration and chronification [26].

Low threshold digital mental health interventions have been found to increase patients' self-management skills, improve the communication to health care providers, have the potential to reach non-treatment-seeking patient groups and could foster destigmatization [27,28]. The impact of psychoeducative or web-based self-help interventions on within-person attitudinal barriers has also been shown quantitatively [29,30]. A number of studies evaluating digital mental health interventions for depression and anxiety have shown a decrease in (self-)stigmatization [31–33]. Effects on help seeking attitudes and actual help seeking have been detected in several randomized controlled trials [33–36]. Those effects mostly are associated with effects on health literacy, which also has been shown in previous studies [31,33]. Apart from effects that may facilitate help seeking behavior, digital mental health interventions have been found to increase the application of self-management skills [34] and were found to have positive effects on subjective health-ratings [35].

A qualitative study investigating the potential utility of mental health app components on reducing help-seeking barriers [37], suggested that self-assessment with individualized feedback, informative videos by mental health professionals, testimonials from mental health service users, and a platform for an online connection with a professional have a potential to reduce within-person barriers to help seeking. Most of these components, especially psychoeducative elements, are central parts of the unguided app-based self-management mental health apps.

Based on these findings one can expect that the use of a transdiagnostic unguided internet based self-management for mental health may lead to significant improvements both in health literacy and variables that reflect patient empowerment, such as help-seeking, reduced stigma, and self-management behaviors.

While self-management interventions cannot replace psychotherapy and are not designed to do so, they can support assessment and recognition, reduce within-person barriers as well as treatment gaps and inequalities and facilitate self-management of symptoms and problems. The MindDoc App constitutes such a transdiagnostic, low-threshold monitoring and self-management application aimed at people with mild to moderate expressions of mental disorders from the internalizing spectrum. It provides automated tailored feedback

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and suggests psychological exercises based on reported symptoms and problems, but also allows users to access psychological exercises at their own discretion.

Taken together, we therefore hypothesize that the use of the MindDoc App in addition to care as usual is associated with an increase in mental health literacy, patient empowerment, and facilitation of access to care, compared with care as usual alone. Furthermore, this study aims to explore whether the use of the MindDoc App in addition to care as usual leads to a greater reduction of psychopathological symptom load of mental disorders of the internalizing spectrum and a stronger improvement in quality of life.

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METHODS AND ANALYSIS

Study design

To examine the effects of MindDoc App usage on health literacy, patient empowerment, access to care, symptom distress and quality of life, participants will be randomly assigned to either the intervention group or the care as usual group (CAU) following the baseline assessment. The intervention group will receive immediate access to all features and courses included in the MindDoc App. The care as usual group will receive access to the MindDoc App after 6 months (i.e., after the follow-up assessment).

In total, there will be 3 measurement points (aside from the continuous assessment of app usage behavior): Baseline (initial diagnostics), post (after 8 weeks), and follow-up (after 6 months). An overview on the measurements and measurement points is provided in Table 1, the study process is visualized in Figure 1.

Intervention

Users in the intervention group will get immediate access to the MindDoc App, which provides a monitoring tool that allows users to track symptoms of common mental health problems over long time periods. 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) biweekly automated feedback on general symptom load and level of functioning (Results), 3) continuous 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). Questions are asked within three blocks a day (morning, noon, evening), with each block consisting of three or more questions. 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. Every question block is followed 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 and 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 personal resources and suggest suitable disorder-specific and trans-diagnostic self-management courses and exercises to address symptoms

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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 by a specialist. Research on a previous version of the MindDoc App yielded good diagnostic accuracy compared to a gold standard measure for depression [38].

In case a user indicates suicidal ideation within the monitoring feature of the application, a crisis chat bot is immediately activated that directs the user to a national crisis helpline (in Germany: Telefonseelsorge) that can be called directly from the app.

Users in the care as usual group will get access to the MindDoc App after completing the final assessment. A detailed description of the MindDoc App can be found in the **supplementary material.**

Measures

Psychopathology

The **PHQ-9** is the depression module of the self-administered version of the PRIME-MD diagnostic instrument for common mental disorders. It scores each of the 9 DSM-5 diagnostic criteria as 0 (not at all) to 3 (nearly every day). The PHQ-9 is a reliable (Cronbach's alpha = .89) and valid measure of depression severity [39].

The **GAD-7** is a one-dimensional instrument designed to detect symptoms of generalized anxiety disorder as it is defined in the DSM-5. The item scores range from 0 (not at all) to 3 (nearly every day). The GAD-7 is a valid and efficient tool for screening for anxiety disorders and assessing its severity in clinical practice and research [40].

The **PHQ-15** is the module for the severity of somatic symptoms of the self-administered version of the PRIME-MD diagnostic instrument for common mental disorders. It comprises 15 somatic symptoms from the PHQ, each symptom scored from 0 ("not bothered at all") to 2 ("bothered a lot"). The PHQ-15 is a reliable (Cronbach's alpha = .80) and valid screening tool for somatization [41].

The **Regensburg Insomnia Scale** (RIS [42]) is a self-rating scale to assess cognitive, emotional and behavioural aspects of psychophysiological insomnia (PI) with ten items. It has good internal consistency with Cronbach's alpha = .89 and distinguishes well between controls and patients with PI.

The **PID5BF+** is a short form of the personality inventory for DSM-5 (PID-5) with 34 items, which is also compatible with the dimensional assessment of maladaptive personality expressions in the ICD-11. The **OPD-SFK** is a short 12-item assessment for the severity of

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personality dysfunction. Dimensional assessment of severity and style of personality dysfunction according to DSM-5 and ICD-11 are important predictors of treatment course, adherence, response, and general psychopathology [43]. Both the OPD-SFK (Cronbach's alpha = .89) and the PID5BF+ (average McDonald's Omega = .81) are validated and reliable measures [44–46].

Quality of Life

The **Assessment of Quality of Life** (AQoL)-8D is a multi-attribute 35-item self-rating scale which was constructed for the evaluation of health services that have an impact upon the psychosocial aspects of the quality of life. It comprises the assessment of 6 psychosocial functioning domains as well as the physical autonomy. It demonstrated good reliability (Cronbachs Alpha = .96) and convergent and predictive validity [47].

Mental Health Literacy, Patient Empowerment and Help-Seeking

The **Mental Health Literacy Questionnaire** (MHLq) is a 29-item scale which assesses mental health literacy on four dimensions (knowledge of mental health problems, erroneous beliefs/stereotypes, help-seeking and first aid skills, self-help strategies). Scores showed significant differences between individuals with more or less experience with mental health as well as good internal consistency (Cronbachs Alpha = .84) for the total score [48].

Assessment of Mental health related patient sovereignty and self management strategies (AMHPSSS): Based on a systematic review on self-management strategies for depression [49], a Delphi consensus study on self-help strategies for depression [50] as well as two studies on useful self management strategies for mood [51] and anxiety [52] disorders from the patient perspective, we identified 18 useful self-management strategies that were replicated at least once from expert and patient perspectives. We then formulated these strategies in questionnaire format asking for the frequency of application of the respective strategy in the last 8 weeks on a 5-point Likert scale, e.g. *"in the last 8 weeks, you engaged in activities that gave you a feeling of achievement".* We then further extracted strategies and behaviors that are indicators of patient sovereignty according to a conceptual framework for patient choice and empowerment in northern European health systems [53]. This resulted in 10 items in statement format asking how much participants agree or disagree on a 5-point Likert scale, e.g. "*I know well about the treatment options for my disease".*

The **Inventory of Attitudes Toward Seeking Mental Health Services** (IASMHS) is a 24-item scale assessing 3 internally consistent within-person barriers to seeking mental health services: Psychological openness, help-seeking propensity and indifference to stigma.

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Internal consistency (Cronbachs alpha = .87) and validity of the assessment could be confirmed in separate samples [54].

Mental Health Service Use Questionnaire (MHSq): Based on expert consensus between three licensed psychotherapists and one psychiatrist, a list comprising digital mental health interventions, alternative/complementary methods as well as preventive, psychosocial and therapeutic/curative/professional services with a total of 21 items was generated. Participants will be asked which services/interventions they used how often in the last 6 months.

Satisfaction with the App and Usage Behavior

The **Client Satisfaction Questionnaire adapted to Internet-based interventions** (CSQ-I) is a measure to assess satisfaction with web-based health interventions with a one-factorial structure and 8 items. It demonstrated good model fit, reliability (McDonalds Omega = .93) and correlated significantly with change in depressive symptoms and perceived stress [55].

Data assessed within the MindDoc App: Within the MindDoc App, usage data and responses within the monitoring system are stored and may be used for secondary analyses. Data from the two sources (MindDoc App, Study Survey) will be consolidated via a personalized deeplink which users in the intervention group receive after randomization.

Other Measures

The **Life Events Scale** (LES) is a list of 42 major life events such as divorce, change in residence or a child leaving home adapted from Holmes & Rahe (1967) and Hobson et al. (1998). Major life events are important predictors for occurence and relapse of mental health problems. Participants are asked to indicate whether a major life event occurred within the time of the study or in the 6 months before and how much they were affected by the life event.

Adverse events: If the crisis chat bot within the app is triggered, or if a participant scores >1 on the PHQ-9 suicidality item, this will be recorded as an adverse event (AE). Other adverse events (AEs) and serious adverse events (SAEs) will be collected via self-report during the post-intervention and follow-up assessments.

Table 1. Overview of assessments and study visits

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	Baseline	Post-Intervention (8 weeks after baseline)	Follow-up (6 months after baseline)
Questions assessing key sociodemographic variables	x		
Questions assessing whether inclusion and exclusion criteria are fulfilled	x		
PHQ-9	x	x	x
GAD-7 and MINI-SPIN	x	x	x
PHQ-15	x	x	x
RIS	x	x	x
PID5BF+ and OPD-SFK	x	x	x
AQoL 8-D	x	x	x
MHLq	x	x	x
Assessment of Mental Health Related Patient Sovereignty and Self Management Strategies	x	x	x
IASMHS	x	x	x
Health Care Service Use Questionnaire	x		x
CSQ-I		x	x
LES and (Serious) Adverse Events			x

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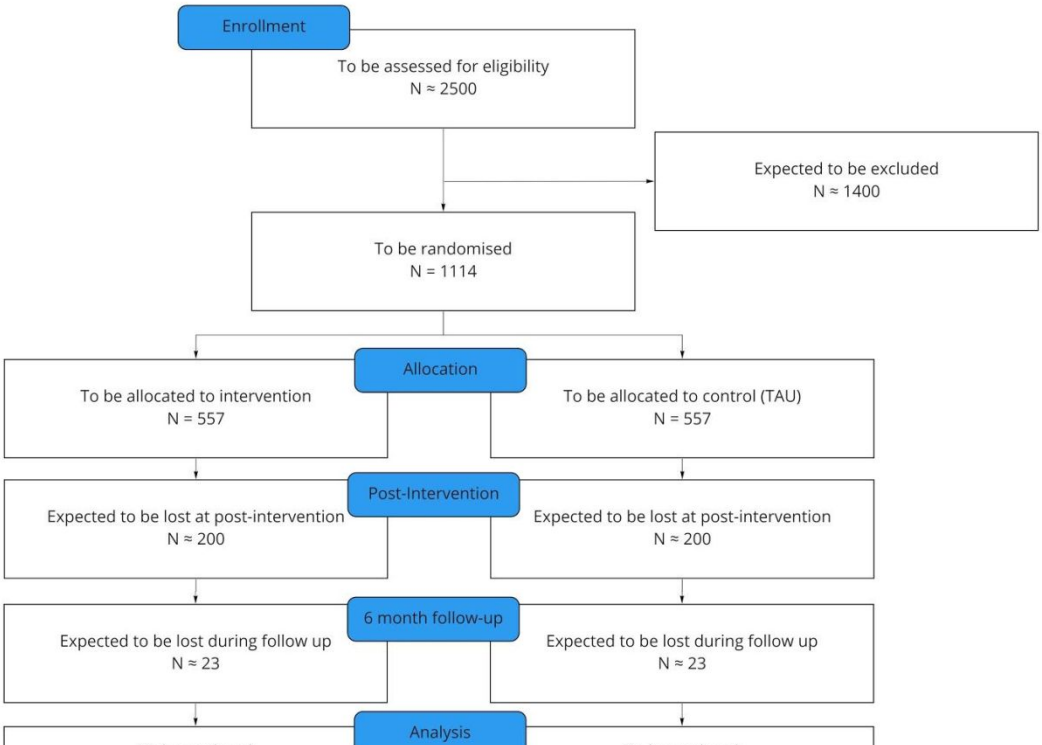

Figure 1. Study process and participant timeline.

Sample size

The primary endpoint is the change in mental health literacy (MHLq), self-management skills and patient sovereignty (AMHPSSS) and within-person barriers to help seeking (IASMHS) after 8 weeks and a change in actual help seeking behavior after 6 months compared to baseline. Based on a literature review and the findings of the pilot study, an effect of d = .3 (Cohen's d) and a dropout rate of 40% and an intercorrelation of .5 between these multiple primary endpoints is expected.

Using a multivariate (intersection-union) z-test to detect the expected difference between the intervention and the care as usual control group with a probability of 90% at a significance level of α = 2,5%, a total sample of N=1113 subjects is necessary.

Recruitment

Participants will be recruited via press releases and social media as well as health insurance member magazines and websites. Recruitment will take place over a period of at least 6 months. Participation in the study can be anonymous, but the participants must provide an

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(anonymous) e-mail address at which they can be contacted. Anonymous participation is associated with a lower threshold for engaging in mental health research.

Eligibility criteria

Inclusion criteria: Eligible for the trial are participants with symptoms of internalizing disorders indicated by scoring above the cutoff on one or more of the following scales: PHQ-9 score > 4 OR GAD-7 score > 4 OR MINI-SPIN score > 6 OR PHQ-15 score > 4 OR binge eating or compensatory behaviors > once/week OR BMI < 18.5 kg/m2 OR critical weight loss AND weight and shape concern OR RIS score > 12.
In addition, eligible participants need to have full legal capacity (self-disclosure), access to a smartphone (iOS or Android) and the internet (self-disclosure) and residence in Germany (self-disclosure).

Exclusion criteria: Not eligible for the trial are participants with too severe symptoms of internalizing disorders indicated by acute suicidality: Score > 1 on PHQ-9 item 9 OR answer "yes" to acute suicidality screening question OR PHQ-9 > 19 (severe depression according to [56]) OR GAD-7 > 15 (severe anxiety disorder according to [57]) OR PHQ-15 score > 14 (severe symptoms according to [41]) OR BMI < 15 kg/m2.
In addition, participants current in inpatient (self-disclosure) or ongoing psychotherapeutic treatment (self-disclosure) OR reported history of bipolar disorder, psychotic disorder, substance use disorder (self-disclosure) OR age < 18 are excluded.

Participants meeting these exclusion criteria are given detailed information on treatment options.

Procedures

All assessments will be carried out via online surveys. Before the baseline assessment, participants will receive written information about the study, the intervention, the randomization, the assessments and the data processing. Once they have given their consent, they are given access to the baseline assessment, which also includes questions that assess their eligibility to participate in the study according to the predefined inclusion and exclusion criteria. If a participant is eligible and the baseline assessment is complete, the participant will be randomly assigned to either the intervention or the control group in a 1:1 ratio. Participants in the intervention group then receive access to the MindDoc App and will be recommended to use it for 8 weeks. Eight weeks as well as sixmonths after the baseline assessment, the participants of both groups will receive an email invitation to the

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post-intervention or follow-up assessment.

Participants will not be financially compensated for participating in the study. However, participants in both study arms will receive free access to the intervention for 6 months after completing the follow-up assessments. In addition, participants who complete post-intervention and follow-up assessments will take part in a monthly drawing where they can win a universal 50€ voucher that can be redeemed in a number of online stores.

Outcome data for participants who discontinue from intervention protocols will comprise the completed survey assessments prior to discontinuation as well as possible app usage data.

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Data management

The study will be conducted in accordance with the EU General Data Protection Regulation (GDPR/DSGVO) and with the Berliner Datenschutzgesetz (BlnDSG). The data will be collected using the MindDoc App and Unipark/EFS Survey. Both data collection tools comply with the GDPR and have implemented state-of-the art data protection measures. During data collection, data will be stored on the respective servers of these tools. Upon completion of the data collection, the data will be securely transferred to an encrypted data storage at Freie Universität Berlin. The data will exclusively be processed by authorized project staff. Fully anonymized data will be shared upon request. Personal data will never be shared with third parties and will be deleted upon completion of the trial to fully anonymize the data. Prior to the anonymization, study participants can request the deletion of their data under their GDPR right. If a participant requests this, the data on Unipark will be deleted by the study team. Accounts and data on the MindDoc servers can be deleted in the settings of the app. Participant confidentiality will always be protected. All members of the research team will be required to maintain participant confidentiality and sign a confidentiality agreement. Acquired date after the completion of the trial can be obtained by reasonable request from the corresponding author.

Statistical methods

Randomization will be controlled by appropriate statistical tests on the baseline variables.

The study collective will be characterized by descriptive statistical methods such as relative and absolute frequencies, mean, median, standard deviation, and inter-quartile-range (IQR) and appropriate graphics such as histograms, box plots, and bar charts. Assumptions for the

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appropriate statistical tests will be checked for normality by histograms, skewness, and Kolmogorov-Smirnoff test, sphericity will be assessed through Mauchly test, (or any of the epsilon corrections in case it cannot be assumed), and the assumption of equality of variance-covariance matrices through Box test and Levene test.

Data will be analysed using multilevel mixed models. Separate models will be calculated for each primary and secondary outcome variable with significance levels adjusted to the amount of comparisons. Depending on the distribution of data in the various outcomes we will choose linear models (for normally distributed data) or negative binomial models (for left-skewed data). Each model will include group (intervention vs. TAU) and time (baseline, post-intervention, follow-up) as predictor variables. Additional predictors will be added to models as necessary following initial descriptive analyses, e.g. baseline characteristics of participants or variables associated with changes in outcomes or dropout.

Primary analyses will be performed using the completer sample, while secondary analysis will employ the intention-to-treat principle. This approach was chosen because in unguided interventions, substantial attrition is common. The results of the primary and secondary analyses will be presented by appropriate effect estimates and 95% confidence intervals.

ETHICS

This trial will be conducted in compliance with the protocol, the Declaration of Helsinki and good clinical practice. The trial has been registered in the DRKS trial register (DRKS00022531**)**. The local ethical committee of FU Berlin has approved the protocol (AZ 039/2020).

There will be no physical strain on the participants. The use of the MindDoc App requires a time expenditure of about 5 minutes per day for completing the assessment and additional time to engage with courses and exercises at the participants' convenience. These are not strains that exceed the usual level in studies with ambulatory assessment or mobile interventions. The app contains detailed information on how to access mental health care. Participants who report a high symptom load or functional impairment within the monitoring function of the app will be prompted to consult a health care professional within the automated feedback. Furthermore, individuals are repeatedly reminded that study participation doesn't substitute for diagnosis, counselling or treatment by a licensed physician or psychotherapist.

The questionnaire assessments could be perceived as a temporal emotional strain by some participants. The selection of questionnaires to assess primary and secondary outcomes

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was not only guided by psychometric properties, but also by the number of items in order to keep the burden at a minimum. In addition, individuals are informed that participation in all parts of the study is voluntary and can be terminated anytime without giving reasons.

Participants who report suicidal intent at baseline will be excluded from the study, but referred to crisis services (public telephone counselling) and provided with further information about treatment options. Participants who report suicidal intent at post-intervention or follow-up will be referred to crisis services (public telephone counselling, MindDoc counselling hotline) and provided with further information about treatment options. Participants who report suicidality at post or follow up assessments will be recorded as an adverse event (AE). If the "crisis-bot" within the app is triggered, or if a participant scores >1 on the PHQ-9 suicidality item, this will be recorded as an adverse event (AE). Other adverse events (AEs) and serious adverse events (SAEs) will be collected via self-report during the post-intervention and follow-up assessments. Participants with severe symptoms will be excluded from participating, but receive detailed information on treatment options.

DISSEMINATION

The MindDoc App will be available upon prescription by general practitioners for all German patients with mild to moderate internalizing disorders within the framework of the Digitales Versorgungsgesetz (DVG, "digital healthcare act", a new German law for digital health applications regulating the reimbursements of usage costs of digital health applications by German statutory health insurances.

The publication plan includes a main research report paper addressing the effects of the MindDoc App on all primary and secondary outcomes. In a secondary publications, predictors, moderators and mediators, such as personality functioning and negative life events, for the effectiveness of low-threshold mobile-based mental health interventions will be investigated. Results will be presented at national and international conferences.

DISCUSSION

Mental disorders pose a huge burden to both individuals and health systems. Many people who are affected suffer from more than one disorder. Thus, transdiagnostic approaches to screening, monitoring and treatment seem more suitable than disorder specific ones. Mental disorders often remain unrecognized and untreated. This is largely caused by within-person barriers such as lack of trust in professionals or the desire to cope with problems without professional help. Although there are effective psychological treatments for all common

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mental health disorders, their availability is limited. Average waiting times for psychotherapy are almost five months.

The study will contribute both to the growing evidence-base for closing gaps in mental health care through digital interventions and to the evidence-base for low-threshold mobile-based interventions. With a focus on mental health literacy, patient sovereignty, and facilitation of access to care, this study will provide important insights into how mental health care seeking can be supported through low-threshold digital approaches. To date, no other study systematically investigated these direct mental health care-related effects of app-based interventions using a RCT-design.

In addition, by including the assessment of potential moderators and predictors of treatment seeking behavior and treatment response while at the same time assessing the treatments actually used, this study enables the investigation of possible indicators for decision making in stepped care.

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REFERENCES

1 World Health Organization. Depression and Other Common Mental Disorders. Global Health Estimates. 2017. https://apps.who.int/iris/bitstream/handle/10665/254610/WHO-MSD-MER-2017.2-eng.pdf

2 Jacobi F, Höfler M, Strehle J, *et al.* Psychische Störungen in der Allgemeinbevölkerung: Studie zur Gesundheit Erwachsener in Deutschland und ihr Zusatzmodul Psychische Gesundheit (DEGS1-MH). *Nervenarzt* 2014;**85**:77–87. doi:10.1007/s00115-013-3961-y

3 Schlack R, Hapke U, Maske U, *et al.* [Frequency and distribution of sleep problems and insomnia in the adult population in Germany: results of the German Health Interview and Examination Survey for Adults (DEGS1)]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 2013;**56**:740–8. doi:10.1007/s00103-013-1689-2

4 Kessler RC, Bromet EJ. The epidemiology of depression across cultures. *Annu Rev Public Health* 2013;**34**:119–38. doi:10.1146/annurev-publhealth-031912-114409

5 Statista. Direkte Kosten psychischer Erkrankungen in Deutschland nach Krankheitsart in den Jahren 2002 bis 2012 (in Milliarden Euro). 2018.https://de.statista.com/statistik/daten/studie/246590/umfrage/direkte-kosten-

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psychischer-erkrankungen-in-deutschland-nach-krankheitsart/
6 Kamp L, Pickshaus K. *Regelungslücke psychische Belastungen schließen*. Düsseldorf: : Hans Böckler Stiftung, IG Metall 2011.
7 Brown TA, Campbell LA, Lehman CL, *et al.* Current and lifetime comorbidity of the DSM-IV anxiety and mood disorders in a large clinical sample. *Journal of Abnormal Psychology* 2001;**110**:585–99. doi:10.1037/0021-843X.110.4.585
8 Haslam N, Holland E, Kuppens P. Categories versus dimensions in personality and psychopathology: a quantitative review of taxometric research. *Psychol Med* 2012;**42**:903–20. doi:10.1017/S0033291711001966
9 Eaton NR, Krueger RF, Markon KE, *et al.* The structure and predictive validity of the internalizing disorders. *Journal of Abnormal Psychology* 2013;**122**:86–92. doi:10.1037/a0029598
10 Krueger RF, Kotov R, Watson D, *et al.* Progress in achieving quantitative classification of psychopathology. *World Psychiatry* 2018;**17**:282–93. doi:10.1002/wps.20566
11 Waszczuk MA, Eaton NR, Krueger RF, *et al.* Redefining phenotypes to advance psychiatric genetics: Implications from hierarchical taxonomy of psychopathology. *Journal of Abnormal Psychology* 2020;**129**:143–61. doi:10.1037/abn0000486
12 Linardon J, Cuijpers P, Carlbring P, *et al.* The efficacy of app-supported smartphone interventions for mental health problems: a meta-analysis of randomized controlled trials. *World Psychiatry* 2019;**18**:325–36. doi:10.1002/wps.20673
13 Blasko K, Ciulla R, Cavanagh R, *et al.* Internet-Based Mental Health Interventions: Evidence, Practical Considerations, and Future Directions. In: *Technology and Mental Health*. Routledge 2020. 38–55.
14 Kessler RC, Ormel J, Petukhova M, *et al.* Development of Lifetime Comorbidity in the World Health Organization World Mental Health Surveys. *Arch Gen Psychiatry* 2011;**68**:90. doi:10.1001/archgenpsychiatry.2010.180
15 Barlow DH, Sauer-Zavala S, Carl JR, *et al.* The Nature, Diagnosis, and Treatment of Neuroticism: Back to the Future. *Clinical Psychological Science* 2014;**2**:344–65. doi:10.1177/2167702613505532
16 Weitz E, Kleiboer A, van Straten A, *et al.* The effects of psychotherapy for depression on anxiety symptoms: a meta-analysis. *Psychol Med* 2018;**48**:2140–52. doi:10.1017/S0033291717003622
17 Barlow DH, Farchione TJ, Bullis JR, *et al.* The Unified Protocol for Transdiagnostic Treatment of Emotional Disorders Compared With Diagnosis-Specific Protocols for Anxiety Disorders: A Randomized Clinical Trial. *JAMA Psychiatry* 2017;**74**:875. doi:10.1001/jamapsychiatry.2017.2164
18 Murray LK, Dorsey S, Haroz E, *et al.* A Common Elements Treatment Approach for Adult Mental Health Problems in Low- and Middle-Income Countries. *Cognitive and Behavioral Practice* 2014;**21**:111–23. doi:10.1016/j.cbpra.2013.06.005
19 Chisholm D, Knapp MRJ, Knudsen HC, *et al.* Client Socio-Demographic and Service Receipt Inventory – European Version: development of an instrument for international research: EPSILON Study 5. *Br J Psychiatry* 2000;**177**:s28–33. doi:10.1192/bjp.177.39.s28
20 Clark DM, Canvin L, Green J, *et al.* Transparency about the outcomes of mental health services (IAPT approach): an analysis of public data. *The Lancet* 2018;**391**:679–86. doi:10.1016/S0140-6736(17)32133-5
21 Mojtabai R, Olfson M, Sampson NA, *et al.* Barriers to mental health treatment: results from the National Comorbidity Survey Replication. *Psychol Med* 2011;**41**:1751–61. doi:10.1017/S0033291710002291
22 Andrade LH, Alonso J, Mneimneh Z, *et al.* Barriers to mental health treatment: results from the WHO World Mental Health surveys. *Psychol Med* 2014;**44**:1303–17. doi:10.1017/S0033291713001943
23 Clement S, Schauman O, Graham T, *et al.* What is the impact of mental health-related stigma on help-seeking? A systematic review of quantitative and qualitative studies. *Psychol Med* 2015;**45**:11–27. doi:10.1017/S0033291714000129

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Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

24 Gulliver A, Griffiths KM, Christensen H. Perceived barriers and facilitators to mental health help-seeking in young people: a systematic review. *BMC Psychiatry* 2010;**10**:113. doi:10.1186/1471-244X-10-113

25 Schomerus G, Angermeyer MC. Stigma and its impact on help-seeking for mental disorders: what do we know? *Epidemiol Psichiatr Soc* 2008;**17**:31–7. doi:10.1017/S1121189X00002669

26 Halfin A. Depression: the benefits of early and appropriate treatment. *Am J Manag Care* 2007;**13**:S92-7.

27 Eichenberg C. Psychotherapie und Internet. *Psychotherapeut* 2011;**56**:468–74. doi:10.1007/s00278-011-0865-9

28 Musiat P, Tarrier N. Collateral outcomes in e-mental health: a systematic review of the evidence for added benefits of computerized cognitive behavior therapy interventions for mental health. *Psychol Med* 2014;**44**:3137–50. doi:10.1017/S0033291714000245

29 Levin ME, Krafft J, Levin C. Does self-help increase rates of help seeking for student mental health problems by minimizing stigma as a barrier? *Journal of American College Health* 2018;**66**:302–9. doi:10.1080/07448481.2018.1440580

30 Simmons L, Jones T, Bradley E. Reducing Mental Health Stigma: The Relationship between Knowledge and Attitude Change. *EJMH* 2017;**12**:25–40. doi:10.5708/EJMH.12.2017.1.2

31 Farrer L, Christensen H, Griffiths KM, *et al.* Web-Based Cognitive Behavior Therapy for Depression With and Without Telephone Tracking in a National Helpline: Secondary Outcomes From a Randomized Controlled Trial. *J Med Internet Res* 2012;**14**:e68. doi:10.2196/jmir.1859

32 Griffiths KM, Christensen H, Jorm AF, *et al.* Effect of web-based depression literacy and cognitive–behavioural therapy interventions on stigmatising attitudes to depression: Randomised controlled trial. *Br J Psychiatry* 2004;**185**:342–9. doi:10.1192/bjp.185.4.342

33 Taylor-Rodgers E, Batterham PJ. Evaluation of an online psychoeducation intervention to promote mental health help seeking attitudes and intentions among young adults: Randomised controlled trial. *Journal of Affective Disorders* 2014;**168**:65–71. doi:10.1016/j.jad.2014.06.047

34 Christensen H, Leach LS, Barney L, *et al.* The effect of web based depression interventions on self reported help seeking: randomised controlled trial [ISRCTN77824516]. *BMC Psychiatry* 2006;**6**:13. doi:10.1186/1471-244X-6-13

35 Klein B, Richards JC, Austin DW. Efficacy of internet therapy for panic disorder. *Journal of Behavior Therapy and Experimental Psychiatry* 2006;**37**:213–38. doi:10.1016/j.jbtep.2005.07.001

36 Kravitz RL. Patient Engagement Programs for Recognition and Initial Treatment of Depression in Primary Care: A Randomized Trial. *JAMA* 2013;**310**:1818. doi:10.1001/jama.2013.280038

37 Johnson JA, Devdutt J, Mehrotra S, *et al.* Barriers to Professional Help-seeking for Distress and Potential Utility of a Mental Health App Components: Stakeholder Perspectives. *Cureus* Published Online First: 28 February 2020. doi:10.7759/cureus.7128

38 Burchert S, Kerber A, Zimmermann J, *et al.* Screening accuracy of a 14-day smartphone ambulatory assessment of depression symptoms and mood dynamics in a general population sample: comparison with the PHQ-9 depression screening. (Manuscript submitted for publication). 2019.

39 Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;**16**:606–13.

40 Kroenke K, Spitzer RL, Williams JBW, *et al.* Anxiety Disorders in Primary Care: Prevalence, Impairment, Comorbidity, and Detection. *Ann Intern Med* 2007;**146**:317. doi:10.7326/0003-4819-146-5-200703060-00004

41 Kroenke K, Spitzer RL, Williams JBW. The PHQ-15: Validity of a New Measure for Evaluating the Severity of Somatic Symptoms. *Psychosomatic Medicine* 2002;**64**:258–66. doi:10.1097/00006842-200203000-00008

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

42 Crönlein T, Langguth B, Popp R, *et al.* Regensburg Insomnia Scale (RIS): a new short rating scale for the assessment of psychological symptoms and sleep in insomnia; Study design: development and validation of a new short self-rating scale in a sample of 218 patients suffering from insomnia and 94 healthy controls. *Health Qual Life Outcomes* 2013;**11**:65. doi:10.1186/1477-7525-11-65

43 Zimmermann J, Kerber A, Rek K, *et al.* A Brief but Comprehensive Review of Research on the Alternative DSM-5 Model for Personality Disorders. *Curr Psychiatry Rep* 2019;**21**:92. doi:10.1007/s11920-019-1079-z

44 Bach B, Kerber A, Aluja A, *et al.* International Assessment of DSM-5 and ICD-11 Personality Disorder Traits: Toward a Common Nosology in DSM-5.1. 2020.

45 Ehrenthal JC, Dinger U, Schauenburg H, *et al.* Entwicklung einer Zwölf-Item-Version des OPD-Strukturfragebogens (OPD-SFK)/Development of a 12-item version of the OPD-Structure Questionnaire (OPD-SQS). *Zeitschrift für Psychosomatische Medizin und Psychotherapie* 2015;**61**:262–74.

46 Kerber A, Schultze M, Müller S, *et al.* Development of a Short and ICD-11 Compatible Measure for DSM-5 Maladaptive Personality Traits Using Ant Colony Optimization Algorithms. *Assessment* Published Online First: 2020. doi:10.1177/1073191120971848

47 Richardson J, Iezzi A, Khan MA, *et al.* Validity and Reliability of the Assessment of Quality of Life (AQoL)-8D Multi-Attribute Utility Instrument. *Patient* 2014;**7**:85–96. doi:10.1007/s40271-013-0036-x

48 Dias P, Campos L, Almeida H, *et al.* Mental Health Literacy in Young Adults: Adaptation and Psychometric Properties of the Mental Health Literacy Questionnaire. *IJERPH* 2018;**15**:1318. doi:10.3390/ijerph15071318

49 Houle J, Gascon-Depatie M, Bélanger-Dumontier G, *et al.* Depression self-management support: A systematic review. *Patient Education and Counseling* 2013;**91**:271–9. doi:10.1016/j.pec.2013.01.012

50 Morgan AJ, Jorm AF. Self-help strategies that are helpful for sub-threshold depression: A Delphi consensus study. *Journal of Affective Disorders* 2009;**115**:196–200. doi:10.1016/j.jad.2008.08.004

51 van Grieken RA, Kirkenier ACE, Koeter MWJ, *et al.* Patients' perspective on self-management in the recovery from depression. *Health Expect* 2015;**18**:1339–48. doi:10.1111/hex.12112

52 Villaggi B, Provencher H, Coulombe S, *et al.* Self-Management Strategies in Recovery From Mood and Anxiety Disorders. *Global Qualitative Nursing Research* 2015;**2**:233393361560609. doi:10.1177/2333393615606092

53 Saltman RB. Patient Choice and Patient Empowerment in Northern European Health Systems: A Conceptual Framework. *Int J Health Serv* 1994;**24**:201–29. doi:10.2190/8WMP-RR2K-ABM7-NVNH

54 Mackenzie CS, Knox VJ, Gekoski WL, *et al.* An Adaptation and Extension of the Attitudes Toward Seeking Professional Psychological Help Scale. *J Appl Social Pyschol* 2004;**34**:2410–33. doi:10.1111/j.1559-1816.2004.tb01984.x

55 Boß L, Lehr D, Reis D, *et al.* Reliability and Validity of Assessing User Satisfaction With Web-Based Health Interventions. *J Med Internet Res* 2016;**18**:e234. doi:10.2196/jmir.5952

56 Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. *J Gen Intern Med* 2001;**16**:606–13. doi:10.1046/j.1525-1497.2001.016009606.x

57 Schalet BD, Cook KF, Choi SW, *et al.* Establishing a common metric for self-reported anxiety: Linking the MASQ, PANAS, and GAD-7 to PROMIS Anxiety. *Journal of Anxiety Disorders* 2014;**28**:88–96. doi:10.1016/j.janxdis.2013.11.006

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Misc Information

Author's contributions

AK and IB conceptualized and designed the study, wrote the first draft of the protocol and developed the statistical analysis plan. SB and CK and IB reviewed the manuscript, AK revised it based on these reviews and created the final version for submission.

Funding statement

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Competing interests statement

Ina Beintner is the Chief Science Officer of MindDoc Health GmbH, the app manufacturer.

Ethics approval: The study was reviewed and has received ethics approval from the ethics committee of the Faculty for Psychology of the Freie Universität Berlin (AZ 039/2020) and has been registered within the German Clinical Trial register (www.drks.de, DRKS00022531).

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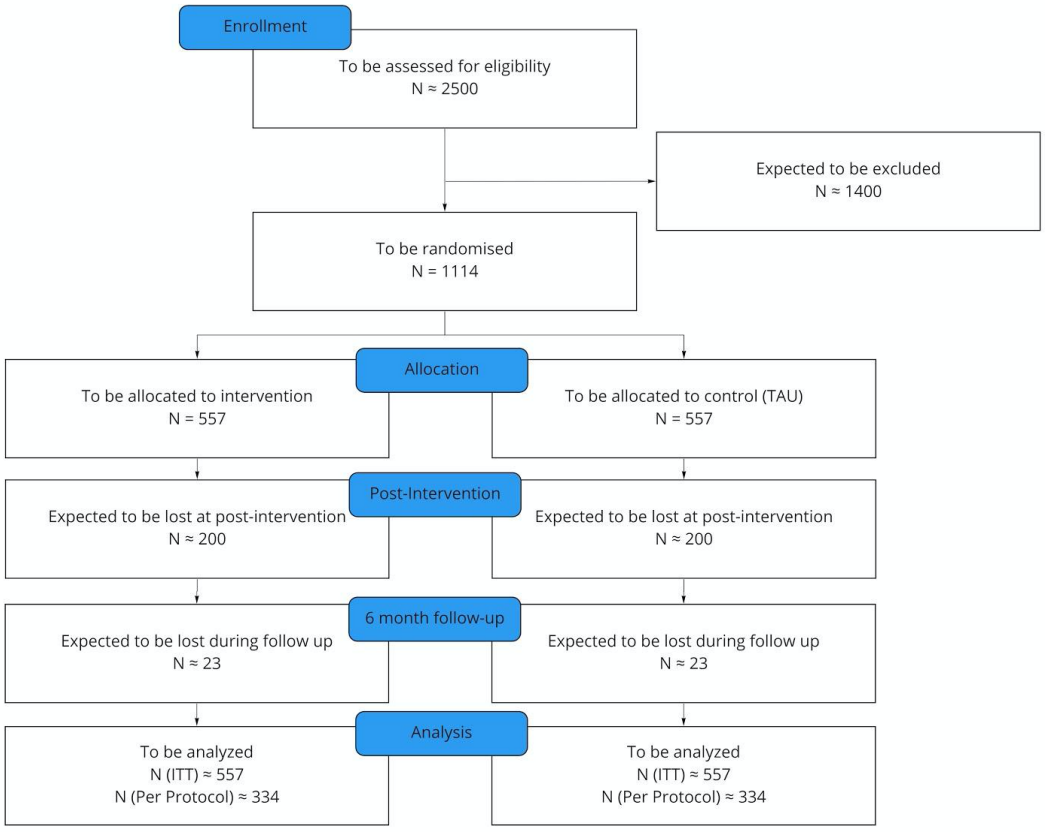

Figure 1. Study process and participant timeline.

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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

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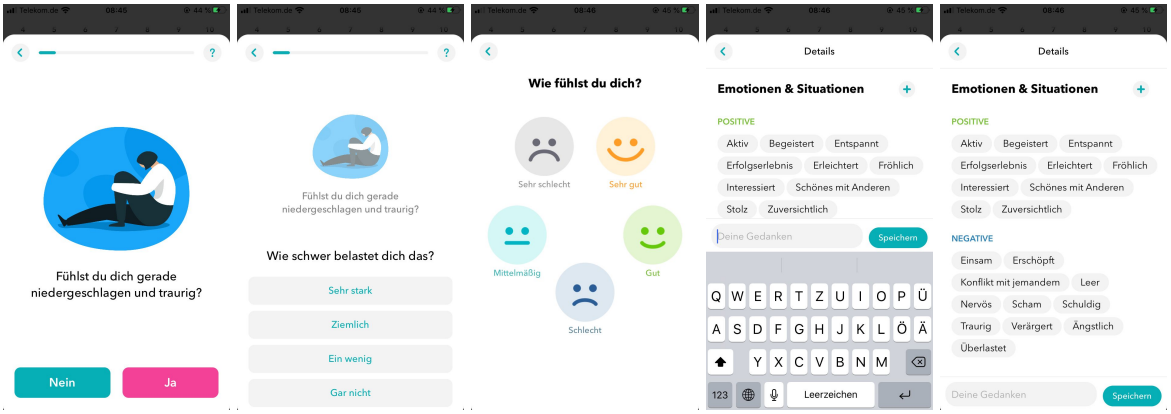
adaptive algorithm that takes into account previous answers of the user. Thus, the more questions are answered, the more individualized and relevant the questions become.

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.

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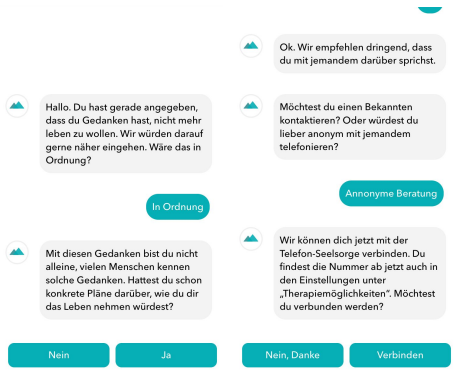
Users who report suicidal tendencies are instantly and automatically directed to an automated dialogue (crisis-bot) that culminates in a direct connection to a local crisis hotline if the user agrees. In Germany, this is the Telefonseelsorge, in other countries it is a comparable service. Alternatively,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

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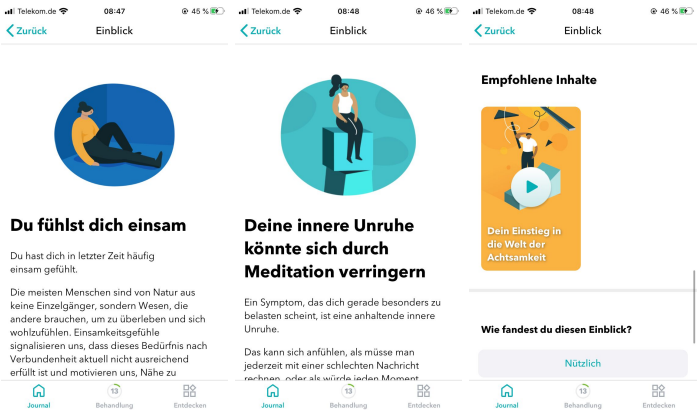

Self-management

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.

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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)

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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)

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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

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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),

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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.

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Does app-based unguided self-management improve mental health literacy, patient empowerment and access to care for people with mental health impairments? Study protocol for a randomised controlled trial.

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Does app-based unguided self-management improve mental health literacy, patient empowerment and access to care for people with mental health impairments? Study protocol for a randomised controlled trial.

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Abstract

Introduction Mental disorders pose a huge burden to both individuals and health systems. Symptoms and syndromes often remain undetected and untreated, resulting in comorbidity and chronification. Besides limited resources in healthcare systems, the treatment-gap is—to a large extent—caused by within-person barriers impeding early treatment seeking. These barriers include a lack of trust in professionals, fear of stigmatization, or the desire to cope with problems without professional help. While unguided self-management interventions are not designed to replace psychotherapy, they may support early symptom assessment and recognition by reducing within-person barriers. Digital self-management solutions may also reduce inequalities in access to care due to external factors such as regional unavailability of services.

Methods and analysis: Approximately 1100 patients suffering from mild to moderate depressive, anxiety, sleep, eating, or somatization-related mental disorders will be randomized to receive either a low-threshold unguided digital self-management tool in the form of a transdiagnostic mental health app or care as usual (CAU). The primary outcomes will be mental health literacy, patient empowerment and access to care while secondary outcomes will be symptom distress and quality of life. Additional moderator and predictor variables are negative life events, personality functioning, client satisfaction, mental health care service use and application of self-management strategies. Data will be collected at baseline as well as 8 weeks and 6 months after randomization. Data will be analysed using multiple imputation and analysis of covariance employing the intention-to-treat principle, while sensitivity analyses will be based on different multiple imputation parameters and a per protocol analysis.

Ethics and dissemination Approval was obtained from the Ethics Committee of the Faculty of Educational Science and Psychology at the Freie Universität Berlin. The results will be submitted to peer-reviewed specialized journals and presented at national and international conferences.

Strengths and Limitations of the Study

- This study is the first to systematically investigate treatment seeking attitudes and behaviors in a large population of users of an app-based mental health intervention.
- The assessment of both predictors of treatment seeking and actual treatment seeking behavior enables the investigation of possible indicators for decision making in stepped care
- The inclusion of a control group, possible moderator variables and follow-up measurements will allow analyses to assess potential mechanisms of improvement

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- The study may be limited by a relatively high rate of attrition that is to be expected in unguided self-help solutions

Introduction

The number of people suffering from depression worldwide is estimated at over 300 million and more than 250 million suffer from an anxiety disorder [1]. In Germany, around one in ten people is affected by depression, while around one in five meets diagnostic criteria for an anxiety disorder [2]. One in twenty individuals suffers from chronic pain [2] or insomnia [3]. Depressive disorders are a major contributor to health loss, accounting for 7.5% of years lived with disability while anxiety disorders rank in the top ten among all known diseases[1,4] accounting for 4.5% of years lived with disability [1,4]. Furthermore, mental disorders are associated with high direct and indirect costs. In Germany, the direct costs in 2012 were estimated at 33 billion Euro [5] while estimates of indirect costs are almost equally high [6].

Further, comorbidity among mental disorders is high. For example, individuals with a mood disorder, e.g. depression, have a lifetime prevalence of 81% for anxiety disorders, with social phobia, obsessive compulsive disorder, generalized anxiety disorder, or post traumatic stress disorder being the most frequent comorbid disorders [7]. A review of 177 clinical studies with a total of 533,377 study participants revealed that only 14% of the cases could be clearly allocated to one specific mental disorder category such as depression, anxiety or personality disorders [8]. When affective and anxiety disorders are conceptualised under the overarching spectrum of *Internalizing Disorders,* predictive validity with respect to suicidal tendencies or future mental illness is improved significantly [9]. A similar approach is used in contemporary dimensional, hierarchical, and data-driven phenotypic definitions of psychopathology [10] which is also supported by recent findings concerning shared genetic covariance and polygenic risk scores [11].

Recent meta-analyses confirm the efficacy of app-supported smartphone interventions both for the reduction of common mental disorder symptoms as well as for improving quality of life [12]. These interventions are typically based on principles of cognitive behavioural therapy and are designed to teach the users skills to manage their symptoms as well as disorder related cognitions and behaviours [13].

Typically, internet-based interventions consist of several sessions or modules and address one type of disorder [13]. Interventions targeting the same disorder tend to be very similar regarding their components and content, while they may differ in the way the content is

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presented (e.g., text vs. video based, length and reading level of text, inclusion of case vignettes and examples). Sessions or modules can be consecutive, i.e. users engage with the content in a preset order and/or at preset intervals, or users can determine the order of the content they engage with and self-pace through the intervention.

On the other hand, authors of an extensive analysis of the WHO World Mental Health Surveys conclude that "common causal pathways account for most of the comorbidity" [14]. This may explain why many pharmaceutical and psychosocial treatments show transdiagnostic effects on a range of mental disorders [15,16]. Contemporary mental health interventions and treatments such as the *Unified Protocol* [17] or the *Common Elements Treatment Approach* [18] therefore increasingly replace "single-disorder-protocols" with treatment elements that address the common underlying mechanisms of multiple disorders and have been proved to be transdiagnostically effective.

Based on these as well as the meta-analytical findings presented above we therefore expect a transdiagnostic unguided internet based self-management for mental health to have an impact on a range of mental disorder symptoms beyond anxiety and depression as well as on quality of life.

Most common mental disorders can be successfully treated if they are detected early and if appropriate treatment is provided in a timely manner. To this end, evidence-based therapeutic approaches are available but only reach about 28% (in high-income countries) of those with depression and 20% of those with an anxiety disorder [19]. Access to specialized care is often impeded by limited availability while treatment delays are associated with symptom deterioration and less favourable long-term outcomes, according to a study using longitudinal data from over half a million treatment-seeking individuals [20].

More importantly, within-person attitudinal barriers seem to constitute an even stronger obstacle for treatment seeking than structural barriers. Both a major national population study [21] and the WHO World Mental Health surveys [22] concluded that by far the largest treatment barriers are wanting to handle the problem on one's own and low perceived need for care. Although not considered to be stigma-related barriers, these factors may be influenced by stigma [23]. A systematic review of barriers and facilitators to mental health help-seeking showed the key barriers to be stigma, confidentiality issues, lack of accessibility, self-reliance, low knowledge about mental health services and fear/stress about the act of help-seeking or the source of help itself [24]. Consequently, stigma can be considered a part of a larger network of beliefs and other constraints deterring help-seeking behavior [25]. All of these factors reduce the chances of early detection, add to the issue of

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under-diagnosis, and increase the risk of long-term symptom deterioration and chronification [26].

Low threshold digital mental health interventions have been found to increase patients' self-management skills, improve the communication to health care providers, have the potential to reach non-treatment-seeking patient groups and could foster destigmatization [27,28]. The impact of psychoeducative or web-based self-help interventions on within-person attitudinal barriers has also been shown quantitatively [29,30]. A number of studies evaluating digital mental health interventions for depression and anxiety have shown a decrease in (self-)stigmatization [31–33]. Effects on help seeking attitudes and actual help seeking have been detected in several randomized controlled trials [33–36]. Those effects mostly are associated with effects on health literacy, which also has been shown in previous studies [31,33]. Apart from effects that may facilitate help seeking behavior, digital mental health interventions have been found to increase the application of self-management skills [34] and were found to have positive effects on subjective health-ratings [35].

A qualitative study investigating the potential utility of mental health app components on reducing help-seeking barriers [37], suggested that self-assessment with individualized feedback, informative videos by mental health professionals, testimonials from mental health service users, and a platform for an online connection with a professional have a potential to reduce within-person barriers to help seeking. Most of these components, especially psychoeducative elements, are central parts of the unguided app-based self-management mental health apps.

Based on these findings one can expect that the use of a transdiagnostic unguided internet based self-management for mental health may lead to significant improvements both in health literacy and variables that reflect patient empowerment, such as help-seeking, reduced stigma, and self-management behaviors.
While self-management interventions cannot replace psychotherapy and are not designed to do so, they can support assessment and recognition, reduce within-person barriers as well as treatment gaps and inequalities and facilitate self-management of symptoms and problems. The MindDoc App constitutes such a transdiagnostic, low-threshold monitoring and self-management application aimed at people with mild to moderate expressions of mental disorders from the internalizing spectrum. It provides automated tailored feedback and suggests psychological exercises based on reported symptoms and problems, but also allows users to access psychological exercises at their own discretion.

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Taken together, we therefore hypothesize that the use of the MindDoc App in addition to care as usual is associated with an increase in mental health literacy, patient empowerment, and facilitation of access to care, compared with care as usual alone. Furthermore, this study aims to explore whether the use of the MindDoc App in addition to care as usual leads to a greater reduction of psychopathological symptom load of mental disorders of the internalizing spectrum and a stronger improvement in quality of life.

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Methods and analysis

Study design

To examine the effects of MindDoc App usage on health literacy, patient empowerment, access to care, symptom distress and quality of life, participants will be randomly assigned to either the intervention group or the care as usual group (CAU) following the baseline assessment. The intervention group will receive immediate access to all features and courses included in the MindDoc App. The care as usual group will receive access to the MindDoc App after 6 months (i.e., after the follow-up assessment).

In total, there will be 3 measurement points (aside from the continuous assessment of app usage behavior): Baseline (initial diagnostics), post (after 8 weeks), and follow-up (after 6 months). An overview on the measurements and measurement points is provided in Table 1, the study process is visualized in Figure 1.

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research, although user/patient feedback was an important source for the development and improvement of the mental health app investigated in this trial.

Intervention

Users in the intervention group will get immediate access to the MindDoc App, which provides a monitoring tool that allows users to track symptoms of common mental health problems over long time periods. 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) biweekly automated feedback on general symptom load and level of functioning (Results), 3) continuous 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

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mental health disorders (Self-Management). Questions are asked within three blocks a day (morning, noon, evening), with each block consisting of three or more questions. 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. Every question block is followed 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 and 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 personal resources 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 by a specialist. Research on a previous version of the MindDoc App yielded good diagnostic accuracy compared to a gold standard measure for depression [38].

In case a user indicates suicidal ideation within the monitoring feature of the application, a crisis chat bot is immediately activated that directs the user to a national crisis helpline (in Germany: Telefonseelsorge) that can be called directly from the app.

Users in the care as usual group will get access to the MindDoc App after completing the final assessment. The MindDoc App was developed and is provided by MindDoc Health GmbH, a subsidiary of Schoen Clinic, which is a hospital group in Germany with one specialization in mental health. First published in 2016 under the name Moodpath, it was mainly directed at individuals with depressive disorders. Since 2019, the scope has been expanded to include other common mental disorders, resulting in an extension of both the monitoring system and the content library. Since October 2020, the App is available under the name MindDoc. All content was developed under the supervision of IB, who is a licensed clinical psychologist with a research background in e-mental-health. The theoretical foundation of the monitoring system is the Hierarchical Taxonomy of Psychopathology [39] , courses and exercises are based on national and international treatment guidelines. A detailed description of the MindDoc App can be found in the **supplementary material.**

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Measures

Psychopathology

The **PHQ-9** is the depression module of the self-administered version of the PRIME-MD diagnostic instrument for common mental disorders. It scores each of the 9 DSM-5 diagnostic criteria as 0 (not at all) to 3 (nearly every day). The PHQ-9 is a reliable (Cronbach's alpha = .89) and valid measure of depression severity [40].

The **GAD-7** is a one-dimensional instrument designed to detect symptoms of generalized anxiety disorder as it is defined in the DSM-5. The item scores range from 0 (not at all) to 3 (nearly every day). The GAD-7 is a valid and efficient tool for screening for anxiety disorders and assessing its severity in clinical practice and research [41].

The **PHQ-15** is the module for the severity of somatic symptoms of the self-administered version of the PRIME-MD diagnostic instrument for common mental disorders. It comprises 15 somatic symptoms from the PHQ, each symptom scored from 0 ("not bothered at all") to 2 ("bothered a lot"). The PHQ-15 is a reliable (Cronbach's alpha = .80) and valid screening tool for somatization [42].

The **Regensburg Insomnia Scale** (RIS [43]) is a self-rating scale to assess cognitive, emotional and behavioural aspects of psychophysiological insomnia (PI) with ten items. It has good internal consistency with Cronbach's alpha = .89 and distinguishes well between controls and patients with PI.

The **PID5BF+** is a short form of the personality inventory for DSM-5 (PID-5) with 34 items, which is also compatible with the dimensional assessment of maladaptive personality expressions in the ICD-11. The **OPD-SFK** is a short 12-item assessment for the severity of personality dysfunction. Dimensional assessment of severity and style of personality dysfunction according to DSM-5 and ICD-11 are important predictors of treatment course, adherence, response, and general psychopathology [44]. Both the OPD-SFK (Cronbach's alpha = .89) and the PID5BF+ (average McDonald's Omega = .81) are validated and reliable measures [45–47].

Quality of Life

The **Assessment of Quality of Life** (AQoL)-8D is a multi-attribute 35-item self-rating scale which was constructed for the evaluation of health services that have an impact upon the psychosocial aspects of the quality of life. It comprises the assessment of 6 psychosocial functioning domains as well as the physical autonomy. It demonstrated good reliability

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(Cronbachs Alpha = .96) and convergent and predictive validity [48].

Mental Health Literacy, Patient Empowerment and Help-Seeking

The **Mental Health Literacy Questionnaire** (MHLq) is a 29-item scale which assesses mental health literacy on four dimensions (knowledge of mental health problems, erroneous beliefs/stereotypes, help-seeking and first aid skills, self-help strategies). Scores showed significant differences between individuals with more or less experience with mental health as well as good internal consistency (Cronbachs Alpha = .84) for the total score [49].

Assessment of Mental health related patient sovereignty and self management strategies (AMHPSSS): Based on a systematic review on self-management strategies for depression [50], a Delphi consensus study on self-help strategies for depression [51] as well as two studies on useful self management strategies for mood [52] and anxiety [53] disorders from the patient perspective, we identified 18 useful self-management strategies that were replicated at least once from expert and patient perspectives. We then formulated these strategies in questionnaire format asking for the frequency of application of the respective strategy in the last 8 weeks on a 5-point Likert scale, e.g. *"in the last 8 weeks, you engaged in activities that gave you a feeling of achievement".* We then further extracted strategies and behaviors that are indicators of patient sovereignty according to a conceptual framework for patient choice and empowerment in northern European health systems [54]. This resulted in 10 items in statement format asking how much participants agree or disagree on a 5-point Likert scale, e.g. "*I know well about the treatment options for my disease".*

The **Inventory of Attitudes Toward Seeking Mental Health Services** (IASMHS) is a 24-item scale assessing 3 internally consistent within-person barriers to seeking mental health services: Psychological openness, help-seeking propensity and indifference to stigma. Internal consistency (Cronbachs alpha = .87) and validity of the assessment could be confirmed in separate samples [55].

Mental Health Service Use Questionnaire (MHSq): Based on expert consensus between three licensed psychotherapists and one psychiatrist, a list comprising digital mental health interventions, alternative/complementary methods as well as preventive, psychosocial and therapeutic/curative/professional services with a total of 21 items was generated. Participants will be asked which services/interventions they used how often in the last 6 months.

Satisfaction with the App and Usage Behavior

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The **Client Satisfaction Questionnaire adapted to Internet-based interventions** (CSQ-I) is a measure to assess satisfaction with web-based health interventions with a one-factorial structure and 8 items. It demonstrated good model fit, reliability (McDonalds Omega = .93) and correlated significantly with change in depressive symptoms and perceived stress [56].

Data assessed within the MindDoc App: Within the MindDoc App, usage data and responses within the monitoring system are stored and may be used for secondary analyses. Data from the two sources (MindDoc App, Study Survey) will be consolidated via a personalized download link which users in the intervention group receive after randomization.

Other Measures

The **Life Events Scale** (LES) is a list of 42 major life events such as divorce, change in residence or a child leaving home adapted from Holmes & Rahe (1967) and Hobson et al. (1998). Major life events are important predictors for occurence and relapse of mental health problems. Participants are asked to indicate whether a major life event occurred within the time of the study or in the 6 months before and how much they were affected by the life event.

Adverse events: If the crisis chat bot within the app is triggered, or if a participant scores >1 on the PHQ-9 suicidality item, this will be recorded as an adverse event (AE). Other adverse events (AEs) and serious adverse events (SAEs) will be collected via self-report during the post-intervention and follow-up assessments.

Table 1. Overview of assessments and study visits

	Baseline	Post-Intervention (8 weeks after baseline)	Follow-up (6 months after baseline)
Questions assessing key sociodemographic variables	x		
Questions assessing whether inclusion and exclusion criteria are fulfilled	x		
PHQ-9	x	x	x

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GAD-7 and MINI-SPIN	x	x	x
PHQ-15	x	x	x
RIS	x	x	x
PID5BF+ and OPD-SFK	x	x	x
AQoL 8-D	x	x	x
MHLq	x	x	x
Assessment of Mental Health Related Patient Sovereignty and Self Management Strategies	x	x	x
IASMHS	x	x	x
Health Care Service Use Questionnaire	x		x
CSQ-I		x	x
LES and (Serious) Adverse Events			x

Figure 1. Study process and participant timeline.

Sample size

The primary endpoint is the change in mental health literacy (MHLq), self-management skills and patient sovereignty (AMHPSSS) and within-person barriers to help seeking (IASMHS) after 8 weeks and a change in actual help seeking behavior after 6 months compared to baseline. Based on a metaanalysis on the efficacy of app-supported smartphone interventions for mental problems [12] as well as a review of the very few previous RCTs investigating the effects of digital mental health interventions on help seeking attitudes, GP visits and mental health literacy [33–36] we expected a small to moderate effect on the primary outcomes of d = .3 (Cohen's d). Based on a metaanalysis on attrition rate in smartphone-delivered interventions for mental health problems [57], we conservatively estimated adropout rate of 40%. .

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Using a multivariate (intersection-union) z-test to detect the expected difference between the intervention and the care as usual control group with a probability of 90% at a significance level of α = 2,5%, estimated intercorrelation of .5 between these multiple primary endpoints and a dropout rate of approx 40%, a total sample of N=1113 subjects is necessary.

Recruitment

Participants will be recruited via press releases and social media as well as health insurance member magazines and websites. Recruitment will take place over a period of approximately one year (2021). Participation in the study can be anonymous, but the participants must provide an (anonymous) e-mail address at which they can be contacted. Anonymous participation is associated with a lower threshold for engaging in mental health research.

Eligibility criteria

Inclusion criteria: Eligible for the trial are participants with symptoms of internalizing disorders indicated by scoring above the cutoff on one or more of the following scales: PHQ-9 score > 4 OR GAD-7 score > 4 OR MINI-SPIN score > 6 OR PHQ-15 score > 4 OR binge eating or compensatory behaviors > once/week OR BMI < 18.5 kg/m2 OR critical weight loss AND weight and shape concern OR RIS score > 12.
In addition, eligible participants need to have full legal capacity (self-disclosure), access to a smartphone (iOS or Android) and the internet (self-disclosure) and residence in Germany (self-disclosure).

Exclusion criteria: Not eligible for the trial are participants with too severe symptoms of internalizing disorders indicated by acute suicidality: Score > 1 on PHQ-9 item 9 OR answer “yes” to acute suicidality screening question OR PHQ-9 > 19 (severe depression [58]) OR GAD-7 > 15 (severe anxiety disorder [59]) OR PHQ-15 score > 14 (severe symptoms according to [42]) OR BMI < 15 kg/m2.
In addition, participants currently in inpatient (self-disclosure) or ongoing psychotherapeutic treatment (self-disclosure) OR reported history of bipolar disorder, psychotic disorder, substance use disorder (self-disclosure) OR age < 18 are excluded.

Participants meeting these exclusion criteria are given detailed information on treatment options.

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Procedures

All assessments described in this study protocol will be carried out via online surveys in a separate web-based platform outside of the mental health app investigated in this trial (Unipark / EFS Survey). Before the baseline assessment, participants will receive written information about the study, the intervention, the randomization, the assessments and the data processing. Once they have given their consent, they are given access to the baseline assessment, which also includes questions that assess their eligibility to participate in the study according to the predefined inclusion and exclusion criteria. If a participant is eligible and the baseline assessment is complete, the participant will be randomly assigned to either the intervention or the control group in a 1:1 ratio by an algorithm provided by the assessment platform (Unipark / EFS Survey).. Participants in the intervention group then receive access to the MindDoc App and will be recommended to use it for 8 weeks. Eight weeks as well as six months after the baseline assessment, the participants of both groups will receive an email invitation to the post-intervention or follow-up assessment.

Participants will not be financially compensated for participating in the study. However, participants in both study arms will receive free access to the intervention for 6 months after completing the follow-up assessments. In addition, participants who complete post-intervention and follow-up assessments will take part in a monthly drawing where they can win a universal 50€ voucher that can be redeemed in a number of online stores.

Outcome data for participants who discontinue from intervention protocols will comprise the completed survey assessments prior to discontinuation as well as possible app usage data.

Data management

The study will be conducted in accordance with the EU General Data Protection Regulation (GDPR/DSGVO) and with the Berliner Datenschutzgesetz (BlnDSG). The data will be collected using the MindDoc App and Unipark/EFS Survey. Both data collection tools comply with the GDPR and have implemented state-of-the art data protection measures. During data collection, data will be stored on the respective servers of these tools. Upon completion of the data collection, the data will be securely transferred to an encrypted data storage at Freie Universität Berlin. The data will exclusively be processed by authorized project staff. Fully anonymized data will be shared upon request. Personal data will never be shared with third parties and will be deleted upon completion of the trial to fully anonymize the data. Prior to the anonymization, study participants can request the deletion of their data under their

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GDPR right. If a participant requests this, the data on Unipark will be deleted by the study team. Accounts and data on the MindDoc servers can be deleted in the settings of the app. Participant confidentiality will always be protected. All members of the research team will be required to maintain participant confidentiality and sign a confidentiality agreement. Only members of the Freie Universität Berlin will have access to the final trial dataset and will be responsible for the data analyses described below.

Statistical methods

Data will be characterized by descriptive statistical methods such as relative and absolute frequencies, mean, median, standard deviation, and inter-quartile-range (IQR) and appropriate graphics such as histograms, box plots, and bar charts. Assumptions for the appropriate statistical tests will be checked for normality by histograms, skewness, and Kolmogorov-Smirnoff test, sphericity will be assessed through Mauchly test epsilon corrections will be applied if sphericity cannot be assumed, and the assumption of equality of variance-covariance matrices will be investigated through Box test and Levene test.

Potential significant differences between the intervention and control group which may occur despite the randomisation will be detected by with $\chi 2$ and variance analyses on the baseline variables. appropriate statistical tests on the baseline variables. and accounted for in all analyses.

Participants will be excluded if they were missing data from their baseline assessments. The main outcomes will be examined with intention-to-treat analyses (ITT), with missing data imputed using baseline scores on symptom severity, mental health literacy, patient sovereignty, help seeking attitudes, quality of life, severity of personality dysfunction and demographic information. Given that there are four primary outcomes, we will impute using multivariate normal regression with an iterative Markov Chain Monte Carlo method based on initial treatment assignment. The pre-specified covariates and baseline measurement of primary endpoints will be added to the baseline model for improved precision. Potential bias due to non-random missing outcome observations will be addressed by estimating Random Forest Lee bounds (RFLBs). Concerns of multiple testing error will be addressed by bonferroni correction. To compare intervention effects on all primary and secondary outcomes, we will use analysis of covariance (ANCOVA) between groups at posttreatment and at follow-up adjusting for baseline scores. To address potential heterogeneity, intervention effects will exploratorily be estimated for subgroups (depression, anxiety, eating,

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somatoform and sleep related disorders).

Sensitivity analyses will be performed exploiting different multiple imputation parameter settings, doing analyses with and without adjustment for baseline characteristics as well as by a per-protocol analysis excluding participants who violated the study protocol. The following protocol violations have been pre-specified: 1) failure to download the app and complete the onboarding process 2) use of the application before the randomization date, 3) reporting of using of the MindDoc app during the intervention and follow-up period in the waitlist condition, 4) reporting of regular psychotherapy during the 8-week intervention period, 5) non-completion of post-intervention or follow-up assessment.

Ethics

This trial will be conducted in compliance with the protocol, the Declaration of Helsinki and good clinical practice. The trial has been registered in the DRKS trial register (DRKS00022531**)**. The local ethical committee of FU Berlin has approved the protocol (AZ 039/2020). Amendments to the trial protocol will be immediately communicated to the local ethical committee as well as the trial registry by the corresponding author.

There will be no physical strain on the participants. The use of the MindDoc App requires a time expenditure of about 5 minutes per day for completing the assessment and additional time to engage with courses and exercises at the participants' convenience. These are not strains that exceed the usual level in studies with ambulatory assessment or mobile interventions. The app contains detailed information on how to access mental health care. Participants who report a high symptom load or functional impairment within the monitoring function of the app will be prompted to consult a health care professional within the automated feedback. Furthermore, individuals are repeatedly reminded that study participation doesn't substitute for diagnosis, counselling or treatment by a licensed physician or psychotherapist.

The questionnaire assessments could be perceived as a temporal emotional strain by some participants. The selection of questionnaires to assess primary and secondary outcomes was not only guided by psychometric properties, but also by the number of items in order to keep the burden at a minimum. In addition, individuals are informed that participation in all parts of the study is voluntary and can be terminated anytime without giving reasons.

Participants who report suicidal intent at baseline will be excluded from the study, but referred to crisis services (public telephone counselling) and provided with further

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information about treatment options. Participants who report suicidal intent at post-intervention or follow-up will be referred to crisis services (public telephone counselling, MindDoc counselling hotline) and provided with further information about treatment options. Participants who report suicidality at post or follow up assessments will be recorded as an adverse event (AE). If the “crisis-bot” within the app is triggered, or if a participant scores >1 on the PHQ-9 suicidality item, this will be recorded as an adverse event (AE). Other adverse events (AEs) and serious adverse events (SAEs) will be collected via self-report during the post-intervention and follow-up assessments. Participants with severe symptoms will be excluded from participating, but receive detailed information on treatment options.

Dissemination

The MindDoc App will probably be available after the study upon prescription by general practitioners for all German patients with mild to moderate internalizing disorders within the framework of the Digitales Versorgungsgesetz (DVG, “digital healthcare act”), a new German law for digital health applications regulating the reimbursements of usage costs of digital health applications by German statutory health insurances.

The publication plan includes a main research report paper addressing the effects of the MindDoc App on all primary and secondary outcomes. In a second publication, predictors, moderators and mediators, such as personality functioning and negative life events, for the effectiveness of low-threshold mobile-based mental health interventions will be investigated. Results will be presented at national and international conferences. Authorship eligibility will be oriented on the respective contributions while no member of MindDoc GmbH will be involved in the data analysis. We also do not intend to use any professional writers.

Discussion

Mental disorders pose a huge burden to both individuals and health systems. Many people who are affected suffer from more than one disorder. Thus, transdiagnostic approaches to screening, monitoring and treatment seem more suitable than disorder specific ones. Mental disorders often remain unrecognized and untreated. This is largely caused by within-person barriers such as lack of trust in professionals or the desire to cope with problems without professional help. Although there are effective psychological treatments for all common mental health disorders, their availability is limited. Average waiting times for psychotherapy are almost five months.

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The study will contribute both to the growing evidence-base for closing gaps in mental health care through digital interventions and to the evidence-base for low-threshold mobile-based interventions. With a focus on mental health literacy, patient sovereignty, and facilitation of access to care, this study will provide important insights into how mental health care seeking can be supported through low-threshold digital approaches. To date, no other study systematically investigated these direct mental health care-related effects of app-based interventions using a RCT-design.

In addition, by including the assessment of potential moderators and predictors of treatment seeking behavior and treatment response while at the same time assessing the treatments actually used, this study enables the investigation of possible indicators for decision making in stepped care.

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References

1 World Health Organization. Depression and Other Common Mental Disorders. Global Health Estimates. 2017. https://apps.who.int/iris/bitstream/handle/10665/254610/WHO-MSD-MER-2017.2-eng.pdf

2 Jacobi F, Höfler M, Strehle J, *et al.* Psychische Störungen in der Allgemeinbevölkerung: Studie zur Gesundheit Erwachsener in Deutschland und ihr Zusatzmodul Psychische Gesundheit (DEGS1-MH). *Nervenarzt* 2014;**85**:77–87. doi:10.1007/s00115-013-3961-y

3 Schlack R, Hapke U, Maske U, *et al.* [Frequency and distribution of sleep problems and insomnia in the adult population in Germany: results of the German Health Interview and Examination Survey for Adults (DEGS1)]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 2013;**56**:740–8. doi:10.1007/s00103-013-1689-2

4 Kessler RC, Bromet EJ. The epidemiology of depression across cultures. *Annu Rev Public Health* 2013;**34**:119–38. doi:10.1146/annurev-publhealth-031912-114409

5 Statista. Direkte Kosten psychischer Erkrankungen in Deutschland nach Krankheitsart in den Jahren 2002 bis 2012 (in Milliarden Euro). 2018.https://de.statista.com/statistik/daten/studie/246590/umfrage/direkte-kosten-psychischer-erkrankungen-in-deutschland-nach-krankheitsart/

6 Kamp L, Pickshaus K. *Regelungslücke psychische Belastungen schließen*. Düsseldorf: : Hans Böckler Stiftung, IG Metall 2011.

7 Brown TA, Campbell LA, Lehman CL, *et al.* Current and lifetime comorbidity of the DSM-IV anxiety and mood disorders in a large clinical sample. *Journal of Abnormal*

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Psychology 2001;**110**:585–99. doi:10.1037/0021-843X.110.4.585
8 Haslam N, Holland E, Kuppens P. Categories versus dimensions in personality and psychopathology: a quantitative review of taxometric research. *Psychol Med* 2012;**42**:903–20. doi:10.1017/S0033291711001966
9 Eaton NR, Krueger RF, Markon KE, *et al.* The structure and predictive validity of the internalizing disorders. *Journal of Abnormal Psychology* 2013;**122**:86–92. doi:10.1037/a0029598
10 Krueger RF, Kotov R, Watson D, *et al.* Progress in achieving quantitative classification of psychopathology. *World Psychiatry* 2018;**17**:282–93. doi:10.1002/wps.20566
11 Waszczuk MA, Eaton NR, Krueger RF, *et al.* Redefining phenotypes to advance psychiatric genetics: Implications from hierarchical taxonomy of psychopathology. *Journal of Abnormal Psychology* 2020;**129**:143–61. doi:10.1037/abn0000486
12 Linardon J, Cuijpers P, Carlbring P, *et al.* The efficacy of app-supported smartphone interventions for mental health problems: a meta-analysis of randomized controlled trials. *World Psychiatry* 2019;**18**:325–36. doi:10.1002/wps.20673
13 Blasko K, Ciulla R, Cavanagh R, *et al.* Internet-Based Mental Health Interventions: Evidence, Practical Considerations, and Future Directions. In: *Technology and Mental Health*. Routledge 2020. 38–55.
14 Kessler RC, Ormel J, Petukhova M, *et al.* Development of Lifetime Comorbidity in the World Health Organization World Mental Health Surveys. *Arch Gen Psychiatry* 2011;**68**:90. doi:10.1001/archgenpsychiatry.2010.180
15 Barlow DH, Sauer-Zavala S, Carl JR, *et al.* The Nature, Diagnosis, and Treatment of Neuroticism: Back to the Future. *Clinical Psychological Science* 2014;**2**:344–65. doi:10.1177/2167702613505532
16 Weitz E, Kleiboer A, van Straten A, *et al.* The effects of psychotherapy for depression on anxiety symptoms: a meta-analysis. *Psychol Med* 2018;**48**:2140–52. doi:10.1017/S0033291717003622
17 Barlow DH, Farchione TJ, Bullis JR, *et al.* The Unified Protocol for Transdiagnostic Treatment of Emotional Disorders Compared With Diagnosis-Specific Protocols for Anxiety Disorders: A Randomized Clinical Trial. *JAMA Psychiatry* 2017;**74**:875. doi:10.1001/jamapsychiatry.2017.2164
18 Murray LK, Dorsey S, Haroz E, *et al.* A Common Elements Treatment Approach for Adult Mental Health Problems in Low- and Middle-Income Countries. *Cognitive and Behavioral Practice* 2014;**21**:111–23. doi:10.1016/j.cbpra.2013.06.005
19 Chisholm D, Knapp MRJ, Knudsen HC, *et al.* Client Socio-Demographic and Service Receipt Inventory – European Version: development of an instrument for international research: EPSILON Study 5. *Br J Psychiatry* 2000;**177**:s28–33. doi:10.1192/bjp.177.39.s28
20 Clark DM, Canvin L, Green J, *et al.* Transparency about the outcomes of mental health services (IAPT approach): an analysis of public data. *The Lancet* 2018;**391**:679–86. doi:10.1016/S0140-6736(17)32133-5
21 Mojtabai R, Olfson M, Sampson NA, *et al.* Barriers to mental health treatment: results from the National Comorbidity Survey Replication. *Psychol Med* 2011;**41**:1751–61. doi:10.1017/S0033291710002291
22 Andrade LH, Alonso J, Mneimneh Z, *et al.* Barriers to mental health treatment: results from the WHO World Mental Health surveys. *Psychol Med* 2014;**44**:1303–17. doi:10.1017/S0033291713001943
23 Clement S, Schauman O, Graham T, *et al.* What is the impact of mental health-related stigma on help-seeking? A systematic review of quantitative and qualitative studies. *Psychol Med* 2015;**45**:11–27. doi:10.1017/S0033291714000129
24 Gulliver A, Griffiths KM, Christensen H. Perceived barriers and facilitators to mental health help-seeking in young people: a systematic review. *BMC Psychiatry* 2010;**10**:113. doi:10.1186/1471-244X-10-113
25 Schomerus G, Angermeyer MC. Stigma and its impact on help-seeking for mental disorders: what do we know? *Epidemiol Psichiatr Soc* 2008;**17**:31–7.

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Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

doi:10.1017/S1121189X00002669
26 Halfin A. Depression: the benefits of early and appropriate treatment. *Am J Manag Care* 2007;**13**:S92-7.
27 Eichenberg C. Psychotherapie und Internet. *Psychotherapeut* 2011;**56**:468–74. doi:10.1007/s00278-011-0865-9
28 Musiat P, Tarrier N. Collateral outcomes in e-mental health: a systematic review of the evidence for added benefits of computerized cognitive behavior therapy interventions for mental health. *Psychol Med* 2014;**44**:3137–50. doi:10.1017/S0033291714000245
29 Levin ME, Krafft J, Levin C. Does self-help increase rates of help seeking for student mental health problems by minimizing stigma as a barrier? *Journal of American College Health* 2018;**66**:302–9. doi:10.1080/07448481.2018.1440580
30 Simmons L, Jones T, Bradley E. Reducing Mental Health Stigma: The Relationship between Knowledge and Attitude Change. *EJMH* 2017;**12**:25–40. doi:10.5708/EJMH.12.2017.1.2
31 Farrer L, Christensen H, Griffiths KM, *et al.* Web-Based Cognitive Behavior Therapy for Depression With and Without Telephone Tracking in a National Helpline: Secondary Outcomes From a Randomized Controlled Trial. *J Med Internet Res* 2012;**14**:e68. doi:10.2196/jmir.1859
32 Griffiths KM, Christensen H, Jorm AF, *et al.* Effect of web-based depression literacy and cognitive–behavioural therapy interventions on stigmatising attitudes to depression: Randomised controlled trial. *Br J Psychiatry* 2004;**185**:342–9. doi:10.1192/bjp.185.4.342
33 Taylor-Rodgers E, Batterham PJ. Evaluation of an online psychoeducation intervention to promote mental health help seeking attitudes and intentions among young adults: Randomised controlled trial. *Journal of Affective Disorders* 2014;**168**:65–71. doi:10.1016/j.jad.2014.06.047
34 Christensen H, Leach LS, Barney L, *et al.* The effect of web based depression interventions on self reported help seeking: randomised controlled trial [ISRCTN77824516]. *BMC Psychiatry* 2006;**6**:13. doi:10.1186/1471-244X-6-13
35 Klein B, Richards JC, Austin DW. Efficacy of internet therapy for panic disorder. *Journal of Behavior Therapy and Experimental Psychiatry* 2006;**37**:213–38. doi:10.1016/j.jbtep.2005.07.001
36 Kravitz RL. Patient Engagement Programs for Recognition and Initial Treatment of Depression in Primary Care: A Randomized Trial. *JAMA* 2013;**310**:1818. doi:10.1001/jama.2013.280038
37 Johnson JA, Devdutt J, Mehrotra S, *et al.* Barriers to Professional Help-seeking for Distress and Potential Utility of a Mental Health App Components: Stakeholder Perspectives. *Cureus* Published Online First: 28 February 2020. doi:10.7759/cureus.7128
38 Burchert S, Kerber A, Zimmermann J, *et al.* Screening accuracy of a 14-day smartphone ambulatory assessment of depression symptoms and mood dynamics in a general population sample: comparison with the PHQ-9 depression screening. (Manuscript submitted for publication). 2019.
39 Kotov R, Krueger RF, Watson D. A paradigm shift in psychiatric classification: the Hierarchical Taxonomy Of Psychopathology (HiTOP). *World Psychiatry* 2018;**17**:24–5. doi:10.1002/wps.20478
40 Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;**16**:606–13.
41 Kroenke K, Spitzer RL, Williams JBW, *et al.* Anxiety Disorders in Primary Care: Prevalence, Impairment, Comorbidity, and Detection. *Ann Intern Med* 2007;**146**:317. doi:10.7326/0003-4819-146-5-200703060-00004
42 Kroenke K, Spitzer RL, Williams JBW. The PHQ-15: Validity of a New Measure for Evaluating the Severity of Somatic Symptoms. *Psychosomatic Medicine* 2002;**64**:258–66. doi:10.1097/00006842-200203000-00008
43 Crönlein T, Langguth B, Popp R, *et al.* Regensburg Insomnia Scale (RIS): a new short rating scale for the assessment of psychological symptoms and sleep in insomnia; Study

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design: development and validation of a new short self-rating scale in a sample of 218 patients suffering from insomnia and 94 healthy controls. *Health Qual Life Outcomes* 2013;**11**:65. doi:10.1186/1477-7525-11-65
44 Zimmermann J, Kerber A, Rek K, *et al.* A Brief but Comprehensive Review of Research on the Alternative DSM-5 Model for Personality Disorders. *Curr Psychiatry Rep* 2019;**21**:92. doi:10.1007/s11920-019-1079-z
45 Bach B, Kerber A, Aluja A, *et al.* International Assessment of DSM-5 and ICD-11 Personality Disorder Traits: Toward a Common Nosology in DSM-5.1. 2020.
46 Ehrenthal JC, Dinger U, Schauenburg H, *et al.* Entwicklung einer Zwölf-Item-Version des OPD-Strukturfragebogens (OPD-SFK)/Development of a 12-item version of the OPD-Structure Questionnaire (OPD-SQS). *Zeitschrift für Psychosomatische Medizin und Psychotherapie* 2015;**61**:262–74.
47 Kerber A, Schultze M, Müller S, *et al.* Development of a Short and ICD-11 Compatible Measure for DSM-5 Maladaptive Personality Traits Using Ant Colony Optimization Algorithms. *Assessment* Published Online First: 2020. doi:10.1177/1073191120971848
48 Richardson J, Iezzi A, Khan MA, *et al.* Validity and Reliability of the Assessment of Quality of Life (AQoL)-8D Multi-Attribute Utility Instrument. *Patient* 2014;**7**:85–96. doi:10.1007/s40271-013-0036-x
49 Dias P, Campos L, Almeida H, *et al.* Mental Health Literacy in Young Adults: Adaptation and Psychometric Properties of the Mental Health Literacy Questionnaire. *IJERPH* 2018;**15**:1318. doi:10.3390/ijerph15071318
50 Houle J, Gascon-Depatie M, Bélanger-Dumontier G, *et al.* Depression self-management support: A systematic review. *Patient Education and Counseling* 2013;**91**:271–9. doi:10.1016/j.pec.2013.01.012
51 Morgan AJ, Jorm AF. Self-help strategies that are helpful for sub-threshold depression: A Delphi consensus study. *Journal of Affective Disorders* 2009;**115**:196–200. doi:10.1016/j.jad.2008.08.004
52 van Grieken RA, Kirkenier ACE, Koeter MWJ, *et al.* Patients' perspective on self-management in the recovery from depression. *Health Expect* 2015;**18**:1339–48. doi:10.1111/hex.12112
53 Villaggi B, Provencher H, Coulombe S, *et al.* Self-Management Strategies in Recovery From Mood and Anxiety Disorders. *Global Qualitative Nursing Research* 2015;**2**:233339361560609. doi:10.1177/2333393615606092
54 Saltman RB. Patient Choice and Patient Empowerment in Northern European Health Systems: A Conceptual Framework. *Int J Health Serv* 1994;**24**:201–29. doi:10.2190/8WMP-RR2K-ABM7-NVNH
55 Mackenzie CS, Knox VJ, Gekoski WL, *et al.* An Adaptation and Extension of the Attitudes Toward Seeking Professional Psychological Help Scale. *J Appl Social Pyschol* 2004;**34**:2410–33. doi:10.1111/j.1559-1816.2004.tb01984.x
56 Boß L, Lehr D, Reis D, *et al.* Reliability and Validity of Assessing User Satisfaction With Web-Based Health Interventions. *J Med Internet Res* 2016;**18**:e234. doi:10.2196/jmir.5952
57 Linardon J, Fuller-Tyszkiewicz M. Attrition and adherence in smartphone-delivered interventions for mental health problems: A systematic and meta-analytic review. *J Consult Clin Psychol* 2020;**88**:1–13. doi:10.1037/ccp0000459
58 Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. *J Gen Intern Med* 2001;**16**:606–13. doi:10.1046/j.1525-1497.2001.016009606.x
59 Schalet BD, Cook KF, Choi SW, *et al.* Establishing a common metric for self-reported anxiety: Linking the MASQ, PANAS, and GAD-7 to PROMIS Anxiety. *Journal of Anxiety Disorders* 2014;**28**:88–96. doi:10.1016/j.janxdis.2013.11.006

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Misc Information

The manuscript was written according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.

Author's contributions

AK and IB conceptualized and designed the study, wrote the first draft of the protocol and developed the statistical analysis plan. SB and CK and IB reviewed the manuscript, AK revised it based on these reviews and created the final version for submission.

Data sharing statement

Researchers who provide a methodologically sound proposal can obtain deidentificated individual participant data and analysis code that underlie the results reported in this article to achieve aims in the approved proposal beginning 3 months and ending 5 years following article publication. Proposals should be directed to andre.kerber@fu-berlin.de. To gain access, data requestors will need to sign a data access agreement.

Funding statement

The Study is funded by MindDoc Health GmbH (Leopoldstraße 159, 80804 Munich, Germany) within the framework of a scientific cooperation agreement between Freie Universität Berlin and MindDoc Health GmbH. AK, SB and CK have ultimate authority over study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.

Competing interests statement

Ina Beintner is the Chief Science Officer of MindDoc Health GmbH, the app manufacturer.

Ethics approval:

The study was reviewed and has received ethics approval from the ethics committee of the Faculty for Psychology of the Freie Universität Berlin (AZ 039/2020) and has been registered within the German Clinical Trial register (www.drks.de, DRKS00022531).

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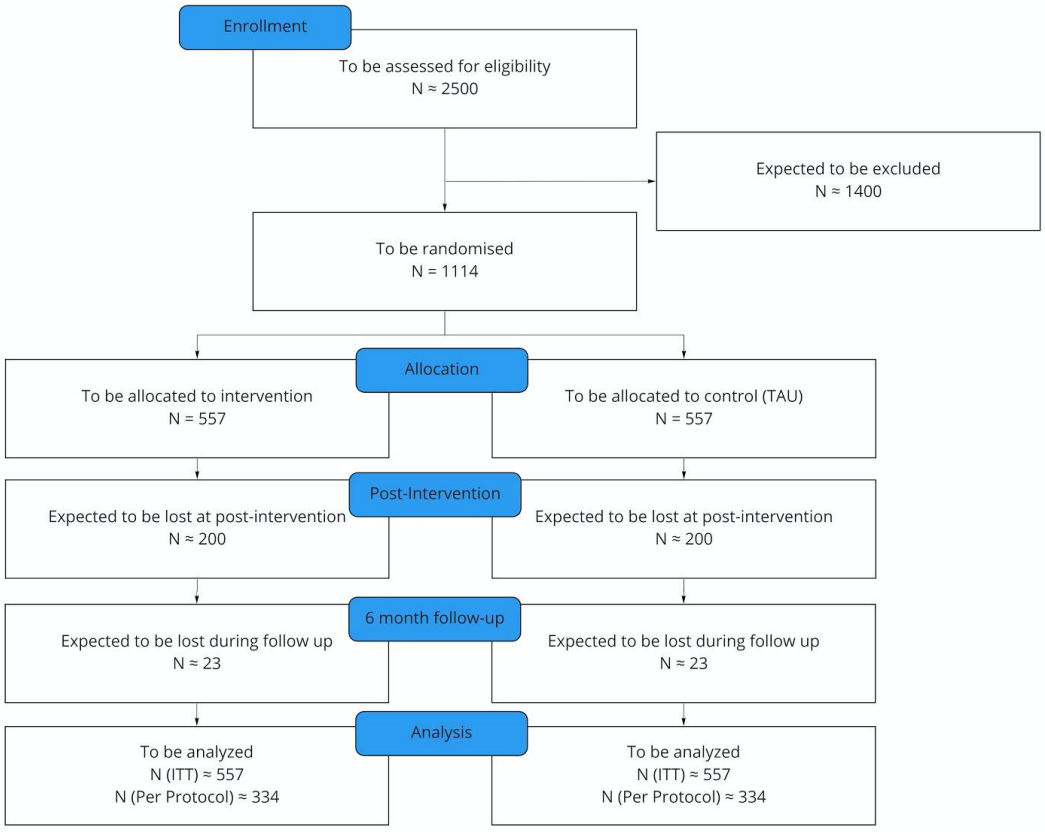

Figure 1. Study process and participant timeline.

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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

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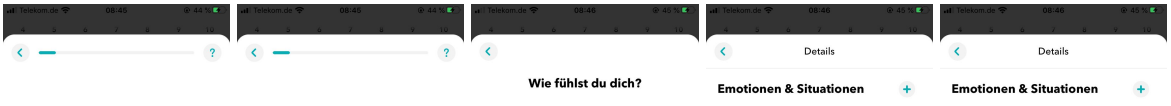
adaptive algorithm that takes into account previous answers of the user. Thus, the more questions are answered, the more individualized and relevant the questions become.

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.

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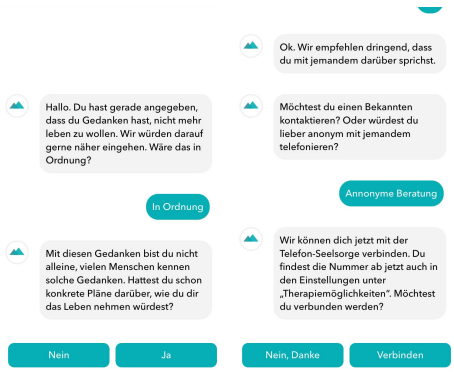
Users who report suicidal tendencies are instantly and automatically directed to an automated dialogue (crisis-bot) that culminates in a direct connection to a local crisis hotline if the user agrees. In Germany, this is the Telefonseelsorge, in other countries it is a comparable service. Alternatively,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

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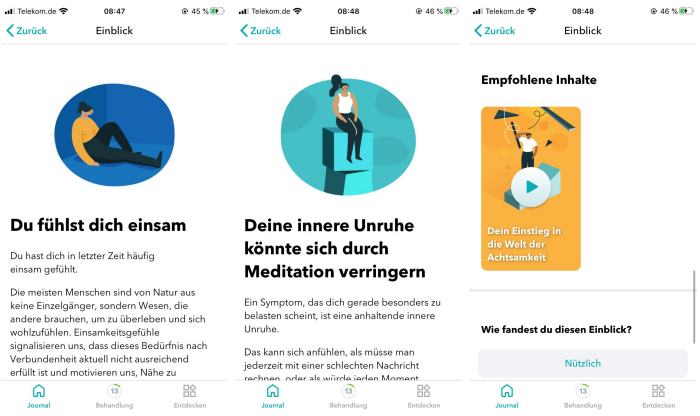

Self-management

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.

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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)

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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)

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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

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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),

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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.

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