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The CCT-D Trial: Evaluating the efficacy of the app-based cognitive control training de:)press ® as an add-on to standard inpatient care for depression – Study protocol for a randomized controlled trial

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Study protocol

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developed and distributed the CE-certified medical device de:)press® with support from the University Hospital Tübingen. MS has received speaker fees from MEDICE Arzneimittel Pütter GmbH & Co. KG, Takeda, and Janssen-Cilag, and has served as an advisory board member for Takeda and Janssen-Cilag.

Abstract

Background

Depression is one of the most common and disabling mental health conditions. Despite evidence-based treatments, fewer than half of affected individuals achieve full remission. This may be due to limited targeting of cognitive vulnerabilities such as impaired control and negative information processing. Cognitive control training offers a promising add-on, with the adaptive Paced Auditory Serial Addition Task designed to activate prefrontal areas and promote neuroplasticity. Digital interventions, especially mobile apps, are increasingly recommended as adjuncts to standard care. This trial tests whether cognitive control training via the app *de:)press®* added to inpatient care reduces depressive symptoms more effectively and sustainably than a control condition in specialized wards for affective disorders.

Methods

This randomized, placebo-controlled trial will be conducted at two inpatient centers. A total of 106 adults diagnosed with unipolar depression will be randomly assigned to receive either standard inpatient care alone or standard care plus *de:)press®*. The app will be provided for six weeks. The primary outcome is clinician-rated symptom severity, measured four weeks after the intervention using the Hamilton Depression Rating Scale. Secondary outcomes include self-rated symptoms, well-being, neuropsychological functioning, and both trait and state rumination. Treatment expectations will be examined in relation to motivation, satisfaction, and outcome. Potential moderators such as age, gender, medication, cognitive style, and illness characteristics will also be analyzed.

Discussion

This trial examines whether app-based cognitive training can enhance treatment outcomes in inpatient depression care. If effective, it may offer a scalable, low-threshold tool to support recovery.

Trial registration

: German Clinical Trials Register: DRKS00037075 on 03 June 2025, last updated on 28 July 2025, https://www.drks.de/search/de/trial/DRKS00037075.

Introduction

Background and rationale

Major depression (MD) is one of the most prevalent and debilitating mental disorders globally, with a lifetime prevalence of approximately 16–20% worldwide (1, 2) and 11.6% in Germany (3–5). Standard

treatments include pharmacotherapy, psychotherapy, and neurostimulation (6) however, many individuals lack timely access to appropriate care, and only a fraction receive depression-specific treatment (7).

Internet- and mobile-based interventions (IMIs) have gained importance as adjunct treatments. The German National Clinical Practice Guideline for Unipolar Depression recommends guided IMIs as a first step within a stepped-care approach for mild depressive episodes; for moderate to severe episodes, IMIs may be offered additionally alongside psychotherapy and/or antidepressants (8). While most IMIs are based on cognitive-behavioral principles (9), less evidence exists for cognitive training approaches.

Cognitive deficits—particularly in memory, attention, and executive functions—are common in MD and represent a promising target for intervention (10). Dysfunctional cognitive processes in MD are associated with greater disease burden and duration(11), as well as treatment response (12). They are a key predictor of functional impairments and reduced quality of life (13). The neurocognitive model of depression highlights impaired cognitive control (CC) and the related preferential processing of negative information as critical factors in the development and maintenance of MD (14, 15). Neuroimaging studies support this model, showing reduced activity in prefrontal cognitive control regions leading to insufficient regulation of limbic processing of aversive stimuli. Improved control of biased cognitive processes is considered a key mechanism and common behavioral correlate of successful MD interventions (16).

Given the persistently high prevalence of MD, existing treatments may inadequately address neuropsychological impairments in attention, memory, executive function, and dysfunctional cognitive processing as vulnerability factors (17, 18). Cognitive control trainings (CCTs) have been proposed to modify cognitive processing biases and reduce depressive symptoms (19–22). CCT leverages neuroplasticity by targeted and repetitive training aimed at strengthening impaired neural circuits and restoring control mechanisms. Recent meta-analyses have shown significant improvements in mood and cognitive symptoms after CCT in MD (20, 23, 24).

A commonly used CCT paradigm is the adaptive Paced Auditory Serial Addition Task (aPASAT) (25). Originally developed for neuropsychological assessment of brain injury (26), the task requires continuous serial addition of the two most recent digits (one to nine [1–9]) which are held in working memory and subsequently responding with the result if the addition. The aPASAT demands sustained attention and the ability to overcome distractions and negative feedback. To maintain challenge across participants, the interstimulus interval (ISI) adapts individually based on performance.

Growing evidence supports the therapeutic potential of aPASAT in depressed individuals (27). However, evidence for CCT, particularly aPASAT-based training as a blended treatment for inpatients, remains limited. Siegle et al. (25) showed that a two-week aPASAT training (six sessions) added to treatment as usual (TAU) in depressed inpatients reduced rumination and symptom severity compared to TAU alone. These findings were replicated in outpatient samples (28, 29), with follow-up data indicating reduced clinical care needs up to one year post-intervention (29, 30). Contrarily, a recent inpatient study found no

significant differences immediately post-intervention between a two-week aPASAT (10 sessions) add-on and a sham training, although exploratory analysis showed significantly higher subjective well-being in the intervention group at one-year follow-up (31). This delayed effect aligns with earlier studies finding significant group differences only at three-month follow-up (28).

High dropout rates highlight that IMIs are not equally suitable for all patients: motivation, personal preferences, and technical access play key roles. For optimal effect, CCT must be conducted regularly over several weeks (6). Current studies suggest an optimal dose of 10–15 hours of training distributed over multiple weeks (21). To improve adherence and engagement, our study will utilize a gamified, app-based aPASAT training (*de:)press*®) that integrates depression-adapted gamification and information elements. A recent pilot study demonstrated the superiority of the gamified version regarding both depressive symptom relief and usage frequency compared to a non-gamified version of the CCT (6). Remarkably, the symptom reduction effect of *de:)press*® persisted up to three months post-training.

Given the need for accessible adjunctive treatments targeting cognitive dysfunction in depression, this trial tests a gamified, app-based cognitive control training (aPASAT via *de:)press*®) as an add-on to TAU in specialized inpatient units for affective disorders. TAU serves as the comparator to evaluate the specific benefit of the intervention, ensuring both clinical relevance and ethical acceptability, as all participants receive standard care. We expect greater symptom reduction four weeks post-intervention compared to TAU alone.

Objectives

Primary objective is to evaluate whether six weeks of CCT via the *de:)press*® app, in addition to TAU, leads to a greater reduction in depressive symptom severity compared to TAU alone in adults with unipolar depression treated on specialized inpatient units.

Secondary objectives are to assess additional benefits of the intervention, including improvements in subjective depressive symptoms, cognitive functioning, and patient-reported outcomes such as rumination, treatment satisfaction, and motivation. The study will also explore potential moderating factors, including treatment expectancy. Potential harms such as reduced adherence due to training burden or negative emotional reactions (e.g., frustration or demotivation) will also be monitored.

Methods

Patient and public involvement

Patients and members of the public were not involved in the design, recruitment, or conduct of this study. However, patient involvement is planned for the dissemination phase. After study completion, participants will be invited to provide feedback on their experience with the intervention and its

integration into inpatient care. This feedback will inform future adaptations of the app and its potential broader implementation in clinical practice.

Trial design and setting

The CCT-D trial is a prospective, randomized, controlled superiority trial with two parallel groups and a 1:1 allocation ratio.

The study will be conducted at two urban academic medical centers in Germany: the University Hospital Leipzig and the University Hospital Tübingen. Both sites include specialized inpatient units for affective disorders and operate within the public healthcare system. They provide multiprofessional care with physicians, nurses, psychologists, and therapists. Treatment includes pharmacotherapy, individual and group psychotherapy, digital interventions, and noninvasive neuromodulation (e.g., rTMS), complemented by relaxation, physical, and creative activities. Weekly social visits support discharge planning and ensure coordinated transition to outpatient care. The institutions have established infrastructures for clinical research and comply with national ethics and data protection regulations.

Eligibility criteria

Eligible participants must be 18 years or older, provide written informed consent, and have a confirmed primary diagnosis of unipolar major depression according to ICD-10 (F32.0, F32.1, F32.2, F33.0, F33.1, F33.2). Additional requirements include sufficient German language skills and the ability to operate a mobile device.

Exclusion criteria are acute suicidality, psychotic features (F32.3, F33.3), other major psychiatric conditions (e.g., bipolar disorder, schizophrenia spectrum, organic mental disorders), primary substance dependence (excluding nicotine), intellectual disability, or somatic/neurological disorders affecting cognitive functioning. Individuals currently using other cognitive training interventions, under legal guardianship, institutionalized, with insufficient compliance, or who are pregnant or breastfeeding will also be excluded.

Recruitment and data collection will take place locally at the participating university hospitals. Trained clinical staff in accordance with a standardized protocol (Version 1.2, 17. July 2025) will conduct interventions and assessments.

Interventions and comparator

Participants in the intervention group receive a six-week, app-based cognitive control CCT using the gamified *de:)press®* application, which is available for Android devices. The intervention is based on the aPASAT, implemented as a self-administered mobile app.

In each session, participants hear a sequence of single-digit numbers (one to nine) via auditory presentation. They are instructed to continuously add the two most recent digits and select the correct sum of each addition (two to eighteen) on a touchscreen. Immediate feedback is provided via a green screen for correct responses and a red screen for incorrect, delayed, or missing inputs. The ISI dynamically adapts based on performance: four consecutive correct responses reduce the ISI by 0.1 seconds; four consecutive errors increase it by 0.1 seconds. The ISI will be carried over from block to block, however it will be reset to the initial 3 s for each new training session. Each training session consists of three 5-minute blocks separated by 30-second breaks. Participants are instructed to complete at least three sessions per week, with a maximum of one session per day, over six weeks. App usage data is automatically recorded; however, the study staff will not monitor adherence or be able to access participants' performance data during the intervention period.

The app includes several gamification elements to enhance motivation and engagement: (a) psychoeducational content on cognitive mechanisms of depression and the rationale for CCT; (b) real-time performance feedback with graphical progress visualization; (c) unlockable levels and audio-guided imagery as adherence rewards; and (d) a virtual coach (animated avatar) providing guidance and encouragement. The app contains all necessary instructions, and no in-person training is required. Technical support is available if needed.

Participants may discontinue the intervention at any time or if clinically indicated (e.g., mental health deterioration or safety concerns). Unless consent is fully withdrawn, participation in follow-up assessments remains possible.

Control group participants receive standard inpatient TAU, including pharmacotherapy and/or psychotherapy in line with national guidelines (8). No restrictions apply to concomitant care. For ethical reasons, control participants are offered access to the *de:)press*® app after their final follow-up assessment.

Outcomes

Primary outcome

To examine whether six weeks of cognitive control training via the *de:)press*® in addition to inpatient TAU reduces depressive symptom severity more effectively than standard care alone, the score of the 21-item Hamilton Depression Rating Scale (HAMD-21) at end of study will be collected.

Key secondary outcomes

- The effects of cognitive control training with *de:)press*® on response and remission rates of depressive symptoms at four weeks post-intervention, as measured by the HAMD-21.

- Changes in subjectively reported depressive symptom severity, measured by the Beck Depression Inventory-II (BDI-II), at the end of the intervention and at end of study four weeks later.
- Changes in general well-being, as assessed by the WHO-5 Well-Being Index, at the end of the intervention and at end of study.

Other secondary outcomes

- Changes in subjective and objective cognitive performance using the app-based *THINC-it®* (32) neuropsychological test battery at end-of-intervention and end of study.
- Changes in trait and state rumination, as measured by the Rumination subscale of the Rumination-Reflection Questionnaire (RRQ) and an adapted version of the Perseverative Thinking Questionnaire (PTQ).
- Influence of treatment expectations, operationalized by an adapted version of the “General Treatment Expectation” (BE) subscale of the Questionnaire for Measuring Therapy Motivation (FMP), assessed prior to the start of the intervention.
- Influence of treatment motivation (indicated by the number of completed training sessions) and satisfaction (measured with an adapted version of the Client Satisfaction Questionnaire, ZUF-8).
- The role of a distorted cognitive pre-treatment style using the Lübeck Preoperative Thinking Questionnaire (LFPD), assessed before the intervention.
- Evaluation of the feasibility of implementing *de:)press®* into standard inpatient care based on participant uptake, usage rates, and reported barriers to usage.

Harms

Based on current evidence and prior use, CCT via the CE-certified *de:)press®*app is not associated with known adverse effects (AEs). To date, no AEs related to *de:)press®* have been reported in previous or ongoing studies. Transient frustration is an expected component of the task and is addressed through integrated psychoeducation and adaptive difficulty adjustment.

AEs will be assessed non-systematically via spontaneous self-reports and clinical observation by trained inpatient staff and monitored throughout the intervention period.

No ancillary or post-trial care is planned, as all participants are inpatients receiving standard hospital care. Any harm related to trial participation will be managed within the hospital setting, with costs covered according to institutional and legal regulations.

Participant timeline

Participation in the trial spans a total of 10 weeks per individual and includes three visits: the screening and baseline visit (V0), a visit at the end of the intervention (V1), and an end of study visit (V2), conducted four weeks after the intervention concludes. An overview of the visit schedule is provided in Table 1. The total planned duration of the clinical trial is 12 months.

Table 1. Schedule of interventions, and assessments

TIMEPOINT:	**Enrolment/Allocation**		**Post-allocation**	
Visit	V0		V1	V2
Study week	0		1 to 6	10
			End of Intervention	**End of Study**
ENROLEMENT:				
Eligibility screening	X			
Informed consent	X			
Sociodemographic and clinical data	X			
Allocation		X		
Randomization		X		
ASSESSMENTS:				
HAMD-21		X	X	X
BDI-II		X	X	X
WHO-5		X	X	X
PTQ		X	X	X
THINC-it®		X	X	X
RRQ		X		
BE		X		
LFPD		X		
Training adherence (app log data)			Continuous during Intervention	
ZUF-8			X	
Adverse events			X	X
INTERVENTION:			← →	
TAU + CCT (IG)			Weeks 1 to 6	
TAU (CG)			Weeks 1 to 6	

Note. V0, baseline visit; V1, end-of-intervention visit; V2, end-of-study visit; HAMD-21, 21-item Hamilton Depression Rating Scale; BDI-II, Beck Depression Inventory-II; WHO-5, 5-item World Health Organization Well-Being Index; PTQ, Perseverative Thinking Questionnaire; RRQ, Rumination-Reflection Questionnaire; BE, General Treatment Expectation; LFPD, Lübeck Preoperative Thinking Questionnaire; ZUF-8, Client Satisfaction Questionnaire; TAU, treatment as usual; CCT, cognitive control training; IG, intervention group; CG, control group.

Sample size

The sample size was calculated using G*Power (version 3.1.9.7) based on the primary outcome: depressive symptom severity, measured by the HAMD-21 at four weeks post-intervention. Assuming an

effect size of $d = 0.7$, derived from a previous pilot study of the *de:)press*® intervention in outpatients (6), a two-tailed independent samples *t*-test with 90% power and a significance level of $\alpha = 0.05$ yielded a required sample size of 44 participants per group. Accounting for an estimated 20% dropout rate, a total of 106 participants will be recruited from the specialized inpatient units for affective disorders at the participating university hospitals.

Recruitment

Participants will be consecutively approached by staff during their inpatient stay at the participating study sites and are provided with information on the study if interested. Eligible newly admitted patients will be invited to participate, subject to the availability of compatible (personal or provided) mobile devices. Recruitment will be supported through close coordination with clinical teams and ongoing monitoring of enrolment to ensure timely achievement of the target sample size.

Randomization

Stratified randomization is used to ensure balanced allocation across key demographic variables. Participants are stratified by gender (female, male, diverse; 45%, 45%, 10%) and age group (18–29, 30–49, 50–69, ≥70 years; 30%, 30%, 30%, 10%), resulting in 12 strata. To simulate the expected sample distribution, oversampled randomization matrices (n = 500 each) are created using MATLAB (2023b). Within each stratum, participants are randomly assigned (1:1 ratio) to the intervention or control group using SPSS (version 29, IBM) with a uniform random function (RV.UNIFORM(0,1)); values < 0.5 are assigned to the intervention group, values ≥ 0.5 to the control group.

The allocation sequence is embedded in the REDCap database (Research Electronic Data Capture) and automatically triggered upon entry of stratification variables. Allocation concealment is maintained by restricting access to group assignments within the system. Study personnel involved in generating the randomization syntax are not involved in outcome assessments and remained blinded to group assignments. Participants are enrolled and stratification variables entered by trained study staff. Group allocation is disclosed only to the intervention team after eligibility was confirmed.

Blinding

Due to the nature of the intervention, double-blinding is not feasible. Participants are aware of their group allocation. However, outcome assessors and data analysts responsible for evaluating the primary endpoint remain blinded to group assignment. To maintain blinding, both participants and unblinded study personnel are instructed not to share any information regarding group allocation with the blinded assessors.

Unblinding of outcome assessors will occur only after completion of all primary endpoint analyses. Premature unblinding is not planned, as no study procedures or safety monitoring require knowledge of group allocation. Should unblinding become necessary in exceptional cases (e.g., for clinical or organizational reasons), it will be documented and justified in the trial records.

Data collection, management, and analysis

The above-mentioned outcomes will be assessed using standardized clinician-administered and self-report measures, as well as an app-based neuropsychological test battery, all completed on a mobile device. Data will be collected on-site at three predefined study visits (screening/baseline, end of intervention, and end of study) for both groups. To promote retention, study visits will be scheduled during the inpatient stay whenever possible. After discharge, participants will be contacted in advance and offered flexible scheduling for the follow-up visit. Brief, user-friendly data collection procedures and technical support will be provided as needed. Participants who discontinue or deviate from the intervention will be encouraged to complete outcome assessments; remote completion will be offered if on-site visits are not feasible.

All personal and study-related data will be collected and stored in accordance with applicable data protection regulations. Participants will be assigned unique study IDs, with identifying information kept separate from study data. Data will be entered directly into REDCap on a mobile device, which applies range checks and validation rules to ensure data quality. REDCap also maintains a comprehensive audit trail, recording all changes to data entries, including creation, updates, or deletions. Access to the study database is restricted to authorized personnel, and data will be securely stored on institutional servers. Relevant study documents will be retained at each study site for at least 10 years after regular or early study termination and, after the archival period, stored in anonymized form. Any dissemination of results will use anonymized or aggregated data to maintain confidentiality. In case of technical difficulties, the assessments will be provided on paper and later transferred to REDCap.

An intention-to-treat (ITT) analysis will be conducted within the full analysis set of all randomized participants with at least one completed intervention. Missing HAMD-21 scores at the follow-up visit four weeks post-intervention will be imputed using multiple imputation. The primary outcome will be analyzed using an Analysis of Covariance (ANCOVA) with study arm as the main factor and baseline score as a covariate. Secondary outcomes will be analyzed similarly, using baseline-adjusted ANCOVAs, logistic regression for categorical variables, or proportional odds models for ordinal variables. Longitudinal trajectories will be evaluated using mixed models and illustrated with line graphs. Descriptive statistics will include means, standard deviations, ranges, medians, quartiles, and absolute and relative frequencies, with two-sided 95% confidence intervals. The number of completed training sessions will be analyzed using a Poisson regression model. Adverse events will be summarized in frequency tables and compared between groups using chi-square tests. Exploratory analyses will examine potential effects of additional therapies and BE.

Monitoring

Given the low-risk nature of the intervention and the close clinical monitoring inherent to the inpatient setting, no independent Data Monitoring Committee has been established. No interim analyses are planned. Individual participants may withdraw from the study at any time at their own request. Criteria for early termination of the entire study include insufficient recruitment, the emergence of unacceptable risks based on a risk–benefit assessment, or new scientific evidence contradicting continuation. The principal investigator will make decisions regarding study termination.

Dissemination plans

The results of the study will be reported and disseminated at international conferences and in peer-reviewed scientific journals, Guideline groups, and to the public via media communications, social networks, presentations at science festivals, charities, family and patient support groups, and clinics.

Discussion

This randomized controlled trial (RCT) will investigate the feasibility, acceptability, and efficacy of *de:)press®*, an app-based CCT, as an adjunct to specialized inpatient treatment for unipolar depression. The intervention aims to enhance cognitive control and reduce repetitive negative thought patterns - mechanisms implicated in depressive symptom persistence and relapse (11–15). Outcomes will be compared between CCT plus TAU and TAU alone, with assessments at the end of treatment and four weeks post-intervention.

CCT is a computerized cognitive remediation approach that has shown promising effects in remitted depression, particularly on residual symptoms and cognitive control, although findings vary between studies (20, 27, 33, 34). Evidence for its use in inpatient settings remains scarce (31). The present trial addresses this gap by integrating a standardized CCT protocol via *de:)press®* into daily clinical care. *de:)press®* is a gamified adaptation of the aPASAT, designed to increase engagement and adherence while preserving the core cognitive training mechanisms. This combination of evidence-based task structure and game elements aims to bridge the gap between experimental findings and scalable real-world applications.

In Germany, several approved Digital Health Applications (DiGAs) for unipolar depression are listed in the official DiGA directory maintained by the German Federal Institute for Drugs and Medical Devices (35), but most are grounded in cognitive behavioral therapy and focus on psychoeducation or behavioral activation. Digital interventions specifically designed to remediate cognitive deficits in depression are rare. By targeting cognitive control during acute treatment, this study explores a complementary

therapeutic pathway that may improve not only mood but also cognitive functioning and daily life outcomes—domains often still impaired after symptom reduction.

In addition to changes in depressive symptoms, the study will examine whether improvements in cognitive performance and rumination can serve as potential mediators of treatment response. Investigating individual differences—such as age, gender, medication, comorbid disorders, pre-existing cognitive distortions, use of neurostimulation, and severity or tendency to relapse—may help identify subgroups most likely to benefit, thus enabling a more individualized application of CCT in clinical practice.

From a healthcare perspective, CCT offers potential cost benefits: it is inexpensive to implement, can be standardized and digitally monitored, and could reduce the need for more resource-intensive in-person interventions. Patients' increasing familiarity with digital tools, accelerated by the COVID-19 pandemic, could further facilitate its adoption.

Despite these strengths, some limitations should be noted. Conducting the trial in inpatient units may limit generalizability to outpatient populations. Adherence could be influenced by symptom severity, hospitalization length, and digital literacy. Furthermore, the trial focuses on short-term outcomes; long-term maintenance of benefits remains to be examined.

In conclusion, this study will provide important insights into the feasibility and potential effectiveness of app-based CCT as an adjunct to inpatient depression treatment. If positive, the findings could support future large-scale implementation studies and inform clinical guidelines, ultimately contributing to more comprehensive recovery strategies in depression care.

Trial status

The trial is currently recruiting. Recruitment started in July 2025 and will last until the end of April 2026.

Abbreviations

AEs	Adverse effects
ANCOVA	Analysis of Covariance
aPASAT	adaptive Paced Auditory Serial Addition Task
BDI-II	Beck Depression Inventory-II
BE	General Treatment Expectation
CC	Cognitive control
CCT	Cognitive control training
FMP	Questionnaire for Measuring Therapy Motivation
HAMD-21	21-item Hamilton Depression Rating Scale
IMI	Internet- and mobile-based intervention
ISI	Interstimulus interval
ITT	Intention-to-treat
LFPD	Lübeck Preoperative Thinking Questionnaire
MD	Major depression
PTQ	Perseverative Thinking Questionnaire
RCT	Randomized controlled trial
RRQ	Rumination-Reflection Questionnaire
TAU	Treatment as usual
WHO-5	5-item Well-Being Index
ZUF-8	Client Satisfaction Questionnaire

Declarations

Ethics approval and consent to participate

The trial protocol and related documents have been reviewed and approved by the Ethics Committee at the Medical Faculty of the University of Leipzig (Ref: 163/23-ek) and the Ethics Committee at the University Hospital Tübingen (Ref: 793/2023BO2). Any substantial protocol amendments have been and will continue to be submitted to both ethics committees, updated in the study registry, and communicated to all investigators, study staff, and other relevant parties prior to implementation. Approvals were obtained prior to the initiation of participant enrollment.

Trained study staff (physicians or psychologists) will obtain written informed consent from all participants after providing verbal and written study information. Participants may withdraw at any time without consequences. No ancillary studies or additional data/specimen collection are planned.

Consent for publication

N/A.

Availability of data and material

The complete protocol, including the statistical analysis plan, will be registered in the German Clinical Trials Registry (DRKS, https://www.drks.de/search/de/trial/DRKS00037075) and will be updated in the event of any changes. The datasets generated and/or analyzed during the current study are not publicly available due to privacy and ethical restrictions but may be made available from the corresponding author on reasonable request.

Competing interests

NM, MK, JH, and CM declare that they have no competing interests. SW and CP are founders and shareholders of psykit GmbH, Tübingen, Germany. CP serves as managing director of psykit GmbH. The company developed and distributed the CE-certified medical device *de:)press*® with support from the University Hospital Tübingen. MS has received speaker fees from MEDICE Arzneimittel Pütter GmbH & Co. KG, Takeda, and Janssen-Cilag, and has served as an advisory board member for Takeda and Janssen-Cilag.

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Authors contributions

MS, NM, JH were responsible for the conception and design of study; NM, JH were responsible for statistics consultation; NM, MK were responsible for drafting the manuscript; MS, CM, JH were responsible for revising the manuscript critically for important intellectual content. All authors have read the manuscript and approval of the version of the manuscript to be published.

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