

# BMJ Open Cognitive bias modification for interpretation (CBM-I) for post-traumatic stress disorder: study protocol of an app-based randomised controlled trial

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## ABSTRACT

**Introduction** Previous studies indicate that computerised trainings implementing cognitive bias modification (CBM) for interpretation bias might be promising treatments for trauma-related cognitive distortions and symptoms. However, results are mixed, which might be related to the implemented task (sentence completion task), setting, or training duration. Within the present study, we aim to evaluate the efficacy and safety of an app-based intervention for interpretation bias using standardised imagery audio scripts, which is designed as a standalone treatment.

**Methods and analysis** The study is a randomised controlled trial, implementing two parallel arms. 130 patients diagnosed with post-traumatic stress disorder (PTSD) will be allocated to either the intervention group or the waiting-list control group receiving treatment as usual. The intervention consists of 3 weeks of an app-based CBM training for interpretation bias using mental imagery, with three training sessions (20 min) per week. Two months after the last training session, 1 week of booster CBM treatment will be implemented, consisting of three additional training sessions. Outcome assessments will be conducted pretraining, 1 week post-training, 2 months post-training, as well as 1 week after the booster session (approximately 2.5 months after initial training termination). The primary outcome is interpretation bias. Secondary outcomes include PTSD-related cognitive distortions and symptom severity, as well as negative affectivity. Outcome assessment will be conducted by intention-to-treat analysis, as well as per-protocol analysis using linear mixed models.

**Ethics and dissemination** The study was approved by the Ethics Committee of the State Chamber of Physicians in Baden-Wuerttemberg, Germany (number of approval: F-2022-080). Scientific findings will be published in peer-reviewed journals informing future clinical studies, which focus on the reduction of PTSD-related symptoms using CBM.

**Trial registration number** German Clinical Trials Register (DRKS00030285; <https://drks.de/search/de/trial/DRKS00030285>).

## INTRODUCTION

Post-traumatic stress disorder (PTSD) is a physiological and psychological reaction

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Inclusion of 1 booster week of cognitive bias modification for interpretation.
- ⇒ Extended outcome assessments up to 2.5 months after treatment termination.
- ⇒ Low-threshold internet-based treatment, readily accessible from home.
- ⇒ Results may not generalise to inpatient post-traumatic stress disorder treatment settings.
- ⇒ Study does not include an active control group.

following the experiencing or witnessing of a traumatic event. Following the diagnostic guidelines described in the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-V,<sup>1</sup> p. 271), four hallmark features characterise PTSD: (1) symptoms of involuntary intrusions related to the traumatic event (eg, memories, flashbacks, nightmares), (2) persistent avoidance of trauma-related stimuli, (3) negative alterations of mood and cognition (such as persistent negative beliefs and expectations about the self, others and the world), and (4) marked alterations in arousal and reactivity associated with the trauma. Whilst past research indicates that a large amount of individuals exposed to a traumatic event recover spontaneously, around 15% display prolonged symptoms,<sup>2-4</sup> which are associated with internal (cognitive biases, emotional vulnerability) as well as external (eg., previous traumatic experiences, trauma type) factors.

Investigating the influence of cognitive alterations on the development and maintenance of PTSD symptomatology, various models summarised under the umbrella term *information processing theories* have been developed.<sup>5-8</sup> Each of these theories share the common notion that PTSD symptoms can be best elucidated by dysfunctional alterations in cognitive processes, which include

but are not limited to attention, interpretation and memory.<sup>9 10</sup>

Specifically, the cognitive model by Ehlers and Clark<sup>6</sup> proposes that individuals who are developing symptoms of PTSD are unable to evaluate the experienced trauma as a time-limited occurrence, which does not have global, negative implications for their future life (p. 320). Henceforth, the resulting negative cognitive interpretation biases commonly contribute to persistent feelings of imminent danger and threat, which can be of external (eg, 'The world is a dangerous place', 'Others will only cause harm to me') or internal (eg, 'I will not be able to master my life') valence.<sup>6</sup> Therefore, anxiety symptoms experienced within patients suffering from PTSD are maintained by dysfunctional cognitive interpretations regarding potentially threatening prospective situations. Once patients experience a sense of danger or threat, even in the presence of safety cues, common PTSD-related symptoms arise and uphold due to prevailing dysfunctional interpretations. This model has been confirmed by a vast amount of scientific studies, showing that cognitive distortions, such as interpretation and appraisal biases, have a strong correlation with, as well as predictive value of, PTSD symptomatology.<sup>11–14</sup> This theory indicates that the modification of interpretation biases might result in the reduction of PTSD symptoms. Nevertheless, current treatment approaches vary regarding their efficacy,<sup>15 16</sup> with treatments developed within the context of cognitive-behavioural therapy (CBT) being among the most promising approaches.<sup>17</sup> However, receiving the appropriate psychotherapeutic care is not always attainable, as waiting times for outpatient psychotherapeutic treatments within the German context vary between 3 and 9 months.<sup>18</sup> Therefore, there is a clear indication for improving and complementing current therapeutic approaches for the treatment of PTSD, specifically within the context of digital approaches. These digital applications could be used to bridge the gap between an initial psychotherapeutic assessment and the beginning of treatment.

Within the context of digital cognitive approaches treating PTSD, the method of cognitive bias modification (CBM) has been developed.<sup>19 20</sup> While this computerised training module has been initially established to merely assess cognitive biases, it has been altered to change dysfunctional cognitive biases by implementing cognitive tasks.<sup>10</sup> One of these tasks targets the change of interpretation-based appraisal biases in PTSD at hand of a computerised training programme.<sup>21–23</sup> Specifically, patients undergo a training session, where they are provided with various ambiguous sentences related to traumatic events and their implications, which end with a word fragment. Upon completion of the word fragment, the connected sentence is resolved in either a benign or a positive manner. Ideally, patients are trained by repeatedly practising to cognitively resolve trauma-relevant information in an equally positive (or benign) fashion. While initial scientific findings indicate that this

intervention results in more positive appraisal styles and a reduction in trauma-related symptomatology in healthy adults,<sup>21 22</sup> another study specifically targeting patients with PTSD by repeatedly implementing the same training across the course of 1 week was not able to confirm these results.<sup>24</sup>

Given these preliminary findings on CBM in targeting interpretation and appraisal biases, there is still space for improving CBM-based training programmes. For example, past studies solely provided ambiguous trauma-related sentences, which were resolved in a positive (or neutral) manner.<sup>10 25</sup> At the same time, in most cases, the training was only conducted once (with two studies implementing the training four to eight times over the course of 1–2 weeks<sup>10 24 26</sup>). As various research implementing CBM within other clinical disorders, such as anxiety disorders, shows that improvement usually occurs after 8–12 training sessions across a time span of 2–4 weeks,<sup>27–29</sup> we assume that extending the programme would additionally improve interpretation biases. Moreover, past research on learning and memory indicates that spaced repetition of learnt material further improves retention.<sup>30</sup> Henceforth, the inclusion of a booster training session after an extended period could further assist the maintenance of training effects. While the theory behind the development of an ambiguous sentence-based training for PTSD is sound and sensible,<sup>6</sup> within the third wave of CBT, it became apparent that the resolution of cognitive distortions is facilitated by the concurrent activation of emotional states (eg, by implementing imagery-based techniques<sup>31</sup>). To support this notion, a previous study by Williams and colleagues<sup>32</sup> showed that the usage of imagery-based stimuli, rather than merely verbal content in CBM, resulted in better training effects on negative interpretation bias and symptom improvement in patients with depression. Implementing these processes within the concept of CBM and PTSD therefore might further improve training outcomes.

Based on previous findings, the present study aims to evaluate the efficacy and safety of an app-based, standardised CBM training for interpretation bias, which can be used by patients with PTSD over the course of several weeks. We hypothesise that the invented app-based CBM training can successfully reduce PTSD-related interpretation biases in an outpatient setting. Additionally, we hypothesise that the training will reduce PTSD-related symptoms and dysfunctional cognition, as well as associated negative affective states. Furthermore, we hypothesise that the implemented intervention is a safe training programme for patients with PTSD. Lastly, we hypothesise that interpretation biases, PTSD-related symptoms and cognition, as well as negative mood states, can be further improved by the implementation of a booster training week 2 months after the termination of the initial training sequence.

## METHODS

### Study design

The study is designed as a single-blind (assessor) randomised controlled non-inferiority trial with two parallel arms, comparing the app-based CBM training with a waiting list control group (WL), which receives treatment as usual (TAU). Patients within the CBM arm receive 3 weeks of CBM training, with three training sessions à 20 min per week. Additionally, patients within the CBM condition receive 1 week of three booster CBM sessions, applied 2 months after initial training termination. Both patients within the WL group as well as patients within the intervention group will receive usual care, such as psychiatrist visits. After termination of the last assessment session, patients within the WL group will be granted access to the CBM training.

### Study setting

The study will be conducted at the Christophsbad Clinic, Goepfingen, Germany. The Christophsbad Clinic is a large psychiatric facility inheriting several inpatient units. Within the same facility, there are two psychiatric outpatient units, as well as two day units. Within both the inpatient and outpatient facilities, patients with a diagnosis of PTSD will be screened for eligibility during their ongoing treatment. After treatment termination, eligible patients will be invited for the diagnostic assessment (T0). Moreover, the study will be advertised through social media accounts and the webpage of the Christophsbad Clinic. After an initial diagnostic assessment, which will be conducted online by independent clinical psychologists through a certified medical provider (RedConnct), all patients will be provided with the CBM app. Patients within the intervention group will have access to the training after completing the diagnostic interview and assessments, while patients within the WL group will solely be granted access to the assessment questionnaires. Patients within the WL group will receive access to the treatment programme after study participation.

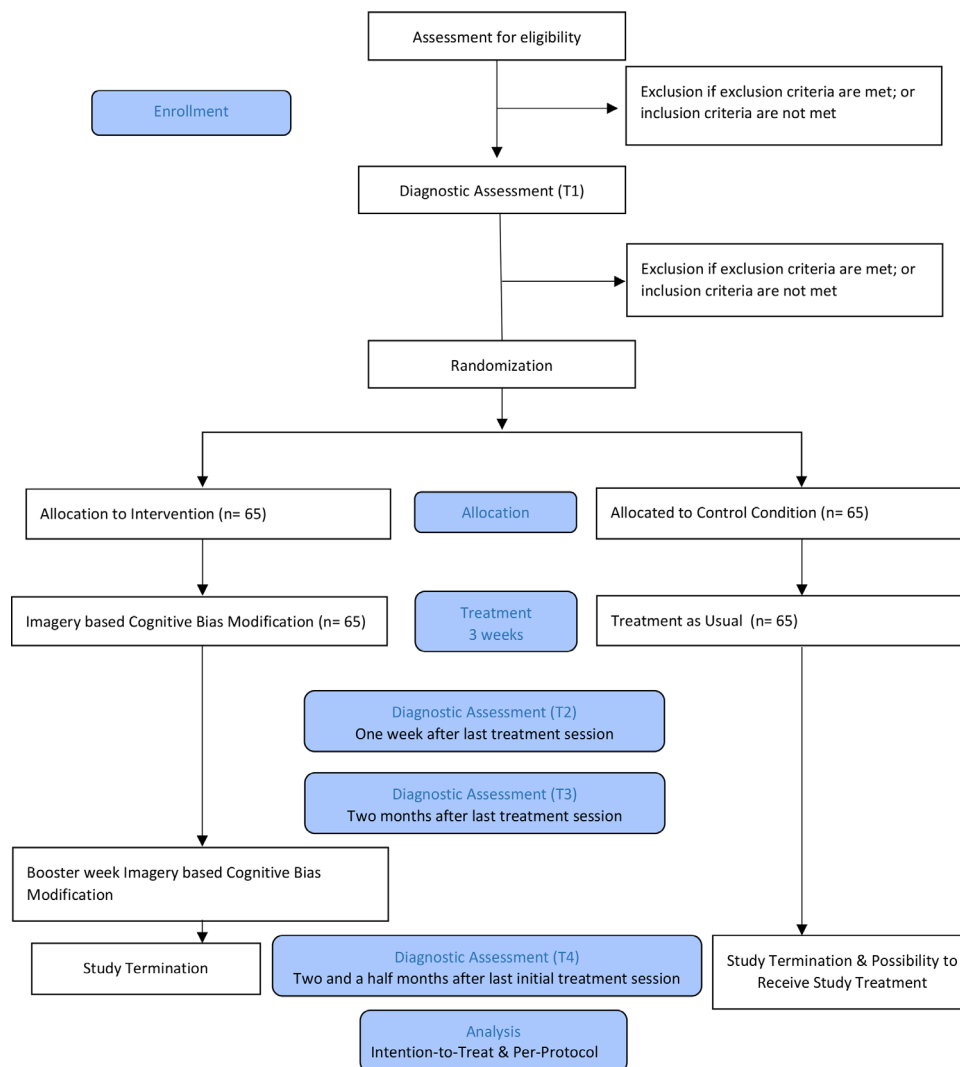
A total of 130 adult patients (65 per group) diagnosed with PTSD will be recruited at the inpatient and outpatient facilities of the Christophsbad Clinic. Patients recruited and screened within the inpatient and outpatient facilities will be contacted for study participation after treatment termination. Patients will be included if they meet eligibility criteria, provide written informed consent and are willing to take part in the study. Inclusion criteria: diagnosis of PTSD, age 18 years or older, fluent in written and spoken German. Exclusion criteria: current psychotherapeutic treatment, acute psychiatric medication (eg, benzodiazepines), severe comorbid psychiatric disorders (eg, psychotic disorder, bipolar disorder), acute suicidality, substance abuse/dependence. Primary diagnosis of PTSD will be established using the Structured Clinical Interview for DSM-V Axis I (SCID-I<sup>33</sup>), whereas other Axis I comorbidities will be evaluated using the Mini-International Neuropsychiatric Interview (MINI<sup>34</sup>).

Moreover, comorbid Axis II disorders will be evaluated using the SCID-II questionnaire.<sup>35</sup>

After an initial short information and screening for inclusion and exclusion criteria (eg., appropriate age; benzodiazepines), interested patients will be given an appointment with an independent clinical psychologist for the online diagnostic interview, within which participants will be provided with further information about the study (see [figure 1](#) for participant flow). After additional verbal and written information, participants provide written informed consent, which they will mail to the clinic address of the assessor. During the diagnostic assessment (T0), the following methods will be used to establish eligibility criteria: primary diagnosis of PTSD via SCID-I interview, adequate German language via the patient's ability to complete the diagnostic eligibility assessment and required questionnaires, current psychotherapeutic treatment and acute psychiatric medication via a self-developed questionnaire, acute suicidality via Columbia-Suicide Severity Rating Scale<sup>36</sup> and substance abuse/dependence via MINI (see [table 1](#)). Motivation to partake within the study will be assessed via self-report during the oral informed consent procedure, by providing the patients with extensive information about the demands of the study regarding time and effort, confirming their willingness to partake.

Patients were randomised to the intervention or WL group according to an allocation sequence, which was generated by an independent researcher who was not directly involved within study recruitment and assessment (JK) using a true randomisation process ([www.random.org](http://www.random.org)). We used a variable block length, in order to prevent the researchers involved in recruitment and assessment from predicting the allocation sequence. Randomisation will be centrally administered by JK. Patients will be allocated to either the intervention or WL group after completing the initial diagnostic interview, and prior to completing their baseline assessment and starting the first intervention session. Patients will be informed about their allocated condition at the end of the diagnostic assessment. Additionally, patients within the intervention group will be asked to start the CBM training after completing the first diagnostic assessment.

The study experimenter, clinical psychologist, as well as the patient, will be blinded about allocation until completion of the diagnostic assessment (T0). After this time point, patients will no longer be blinded about their group assignment, as one group will not receive any treatment within the study until the last assessment has been completed. Furthermore, the study experimenter will no longer be blind to the patient's allocation, as the patient will conduct all assessment points and training via the CBM app independently at home. Moreover, the study experimenter will need to contact patients within both arms, if they do not adhere to the study protocol, in order to improve adherence.



**Figure 1** Study flow chart.

### Intervention

The app-based CBM training comprises of a total of nine training sessions, which will be implemented within a course of 3 weeks. Each week, three training sessions will be held at the duration of 20 min each. Every training session comprises of three everyday scenarios, which are related to dysfunctional PTSD-related cognition, such as a negative view of the self, the world and others. Within each of the training sessions, patients are instructed to close their eyes and listen to a total of three prerecorded audio scripts, with duration of 5 min each. While listening, patients are instructed to imagine each recording with all their senses, as the usage of imagination, rather than merely verbal stimuli, has shown to increase training effects on improving negative interpretation bias and related symptoms in patients with depression.<sup>32</sup> After each scenario, patients will be asked several questions about the imagined scenario.

This intervention is based on previous research,<sup>10 24 25</sup> which implemented CBM for appraisal-based cognitive distortions in PTSD. Within these studies, patients are required to resolve ambiguous sentences in either a positive

or a neutral manner. However, results implementing this approach are mixed,<sup>24 25</sup> warranting an adaption of the implemented treatment. Therefore, within the present study, we provided patients with audio scripts consisting of initially ambiguous everyday scenarios, which were positively resolved across the course of the audio scenario to target PTSD-related interpretation bias. The scenarios were derived from the Posttraumatic Cognitions Inventory (PTCI) questionnaire,<sup>37</sup> containing cognitive distortions about the self, others and the future. Additionally, within each audio script, patients are instructed to close their eyes and imagine each scenario with all their senses. All scenarios are prerecorded and standardised across the treatment condition, to allow for comparability of test results.

### Outcome assessment

The study schedule is described in [table 1](#). Patients will be assessed at the following time points: baseline (T1: immediately before the beginning of the training sessions), post-intervention (T2: ~1 week after last training session), first follow-up (T3: ~2 months after last training session)

**Table 1** Schedule of enrolment, interventions and assessments

Timeline	Screening	Diagnostics	Post-allocation					
	-t <sub>1</sub>	t <sub>0</sub>	t <sub>1</sub>	CBM training	t <sub>2</sub>	t <sub>3</sub>	CBM booster week	t <sub>4</sub>
Eligibility screen	X							
Informed consent		X						
Demographics		X						
MINI		X						
SCID-I PTSD		X						
SCID-II questionnaire		X						
C-SSRS		X						
Treatment information and app usage		X						
Allocation (post-diagnostics)		X						
trSST			X		X	X		X
AST-D-II			X		X	X		X
PTCI			X		X	X		X
IES-R			X		X	X		X
BDI-II			X		X	X		X
BSI			X		X	X		X
Treatment acceptability and patient satisfaction						X		

AST-D-II, Ambiguous Scenarios Test relevant to Depressed Mood II; BDI-II, Beck Depression Inventory-II; BSI, Beck Scale for Suicidal Ideation; CBM, cognitive bias modification; C-SSRS, Columbia Suicidality Severity Rating Scale; DSM-V, Diagnostic and Statistical Manual of Mental Disorders Fifth Edition; IES-R, Impact of Events Scale-Revised; MINI, Mini-International Neuropsychiatric Interview; PTCI, Posttraumatic Cognitions Inventory; PTSD, post-traumatic stress disorder; SCID-I, Structured Clinical Interview for DSM-V Axis I; SCID-II, Structured Clinical Interview for DSM-V Axis II; t<sub>0</sub>, diagnostic assessment; -t<sub>1</sub>, eligibility screening; t<sub>1</sub>, assessment time point 1; t<sub>2</sub>, assessment time point 2; t<sub>3</sub>, assessment time point 3; t<sub>4</sub>, assessment time point 4; trSST, trauma-related Scrambled Sentence Test.

and second follow-up (T4: ~1 week after the end of the booster week, which is approximately 2.5 months after the end of the initial training sessions). All assessments will be app based following a standardised protocol, meaning that all patients will be able to complete the measurements from home according to a preset timed schedule. Upon completion, data will be encoded and automatically transferred to the experimenter (AG) by email. Patients will be reminded of the beginning of the training sessions, as well as the need for assessment completion via push notifications through their smartphones. If the assessments are not completed within the described time frame, patients will be reminded additionally by phone and/or email.

### Primary outcomes

The primary outcome will be the assessment of dysfunctional interpretation biases.

The *trauma-related Scrambled Sentence Test*<sup>38</sup> evaluates trauma-associated interpretation biases based on the concept of shattered assumptions.<sup>39 40</sup> The test displays various scrambled sentences, which can be reorganised into a grammatically correct sentence with either a positive or a negative valence. Based on the choice of building a positive or negative sentence, conclusions about underlying dysfunctional trauma-related assumptions can be drawn (eg., I am happy/sad about today).

The *Ambiguous Scenarios Test relevant to Depressed Mood II*<sup>41</sup> evaluates various aspects of interpretation biases at hand of 30 statements, which shall be imagined by the participant. After each imagination, the participant is

cued to indicate which emotions were elicited during the imagination, as well as to state on an 11-point Likert scale, whether the imagination was largely comforting or disconcerting.

### Secondary outcomes

Secondary outcomes include PTSD-related cognition and symptoms, as well as negative affectivity.

The PTCI<sup>37</sup> comprises of 33 statements, which represent typical PTSD-related cognition during the past week. Participants are instructed to indicate their agreement or disagreement with each of these statements on a 7-point Likert scale (1=strongly disagree to 7=strongly agree).

The *PTSD Checklist for DSM-5* (PCL-5<sup>42</sup>) is a 20-item self-report measurement assessing PTSD-related symptoms on a 5-point Likert scale (0=not at all to 4=extremely). Within the questionnaire, a sum score for overall PTSD symptom severity, as well as four subscales describing hyperarousal, avoidance, re-experiencing and negative alterations in cognition and mood, can be built.

The *Beck Depression Inventory-II*<sup>43</sup> will be used to measure symptoms of negative affectivity. The self-report questionnaire comprises of 21 items, which assess symptoms associated with negative mood and affect. Each item is rated on a 4-point Likert scale (0=never to 3=always).

### Acceptability and patient satisfaction

The *Client Satisfaction Questionnaire-8*<sup>44</sup> will be used to determine treatment satisfaction. The questionnaire entails eight items, with each item being answered on a 4-point Likert scale (0=not at all satisfied to 4=very

satisfied). Additionally, a *self-developed questionnaire* using visual analogue scales will be implemented to assess treatment acceptability (eg., 'I feel like I was able to benefit from the treatment', 'I would recommend this treatment to others with similar problems').

### Monitoring for adverse events

To assess adverse events, the *Beck Scale for Suicidal Ideation*<sup>45</sup> will be implemented. This self-report questionnaire assesses suicide risk at hand of 21 items, with each item being answered on a 3-point Likert scale (0=no suicidality to 2=strong indicator for suicidality). The measurement includes assessments for suicidal thoughts, ideation, planning, as well as various aspects of attempting suicide. It will be completed across all assessment time points (T1–T4). Within the measurement, the first five questions serve as a screening for suicidality. If patients report a value of 2 on question number four and/or five within the screening section, they will be contacted by the experimenter for further evaluation. Additionally, patients will have the experimenter's emergency contact information, as well as other emergency phone numbers (eg., acute psychiatric inpatient clinic, emergency telephone number, crisis line), available within the CBM app. If the patient is termed at risk of suicide during the contact with the experimenter, a referral to further care will be implemented (eg., referral to the psychiatric inpatient facility). Other adverse events include but are not limited to: worsening of PTSD symptoms (PCL-5), terminating study participation due to self-reported adverse effects of the training (acceptability questionnaire) and admission to an inpatient unit. Adverse events will be discussed within the study management group (JK, ZS-V and AG). Within this context, the group will discuss the relationship of the adverse event and the CBM training (0=not all related to 3=definitely related).

### Trial management and monitoring

The principal investigators (JK and ZS-V) are primarily responsible for the implementation of the study trial. Management as well as oversight of the trial implementation will be realised by biweekly meetings with the researchers involved within data collection (AG and MM). Due to the size and nature of the implemented study, there was no need for a data monitoring committee.

### Data collection and management

Data will be collected within the CBM app. Upon completion of each of the assessment points, the patients will be asked to transfer their data to the experimenter. If the patient indicates 'yes', data will automatically be transferred via email to the experimenter (AG). The app itself will create an automatic ID for each participant, which will be used to connect the various data points (T1–T4) to the respective patient. After receiving the pseudonymised data set, the experimenter will store the information continuously on an electronic database. To secure data retention, data will be regularly transferred to a

remote server. The electronic database will not hold identifiable information about the participating patients. This information will be accessed as needed from a separate password-protected electronic database prior to data analysis. Any data, which would lead to the identification of the participating patients, will be stored separately from the assessment data, with access granted solely to members of the research team.

### Patient and public involvement

Patients and/or public were not involved.

### Sample size

Previous studies implementing CBM in patients with PTSD found small to large effect sizes ranging between  $d=0.20$  and  $d=0.85$  (eg.,<sup>25 46</sup>). Based on a power of  $1-\beta=0.80$ , a medium effect size ( $f^2=0.15$ ) and a significance level of  $\alpha=0.05$ , using F-tests (multivariate analysis of variance), a sample size of  $N=92$  (46 patients per group) will be needed. Additionally, we expect a dropout rate of approximately 30%; therefore, we will include a total of  $N=130$  patients (65 per group) in the final sample. To reduce dropout rates and increase protocol adherence, patients will receive push notifications on their smartphones and receive phone calls/emails from the experimenter.

### Data analysis

Data will be analysed in SPSS (Version 28.0) and R using intention-to-treat, as well as per-protocol analysis. Linear mixed models will be implemented to allow for inclusion of patients displaying missing data. Specifically, we will use a repeated measures mixed-model design including analysis of variance across all time points (T1–T4), in order to assess within-effect and between-effect sizes (Cohen's  $d$ ), as well as contrasts. In order to test for possible between-group differences at baseline, t-tests, as well as  $X^2$  tests, will be implemented as appropriate. In case of significant findings, variables will be included as covariates.

### Ethics and dissemination

The study was approved by the Ethics Committee of the State Chamber of Physicians of Baden-Wuerttemberg, Germany (number of approval: F-2022-080). The central ethical considerations evolve around the informed consent, involvement of a TAU control group, as well as the implementation of equivocal imagery scenarios within the CBM for interpretation (CBM-I) training sessions. Participants will provide written informed consent before study participation. Before providing consent, all patients receive oral and written information about the content of the research project, data protection measures and about being able to withdraw without any further consequences at any time of the study. The duration of the study will be about 3.5 months. Within this period, neither participants within the intervention nor the control group will be able to receive psychotherapeutic treatment, in order to avoid confounding effects. However, previous data within the German healthcare system have shown that the waiting times for receiving a mental health provider

within an outpatient setting are 3–9 months.<sup>47</sup> As patients are usually recruited immediately after termination of their inpatient treatment, it is unlikely that they would be able to receive outpatient care within the period of the study. Moreover, patients within both conditions are allowed to schedule visits with their primary physician or psychiatrist. Regarding the implemented initially equivocal scenarios, we do not expect symptom exacerbation, as all scenarios will be positively resolved after the first view sentences, whereas the focus of each scenario is the activation of a positive image including all senses.

The scientific findings within the presented study protocol will be disseminated primarily by publications submitted to peer-reviewed journals. Results will also be presented at national as well as international scientific conferences. Furthermore, the collected data will be used within a doctoral thesis. The data set used and/or analysed during the current study will be available from the corresponding author upon reasonable request. If the stated hypotheses are confirmed, funding will be sought to conduct larger-scale randomised controlled trials, involving the provision of the intervention over longer time periods, as well as across different settings (ie, inpatient and outpatient).

### Clinical trial registry

The presented study is part of a large-scale scientific project registered within the German Clinical Trials Register (ID: DRKS00030285). While study A within this project focuses on evaluating the efficacy and safety of an imagery-based CBM-I intervention for patients with anxiety disorders, study B (the described study within this paper) aims to evaluate the efficacy and safety of an imagery-based CBM-I intervention tailored to patients with PTSD. Both projects share a similar study design; however, the imagery scripts are specifically designed for anxiety (study A) or PTSD (study B) symptomatology. Lastly, study C aims to validate a measurement assessing interpretation bias in patients with anxiety, as there is a lack of assessment tools thereof within the German context. Therefore, study C is directly connected to study A, as the in study C evaluated assessment tool is included as an outcome measurement within study A.

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### REFERENCES

- American Psychiatric Association. *Diagnostic and statistical manual of mental disorders*. 2013.
- Foa EB, Riggs DS. Posttraumatic stress disorder following assault: theoretical considerations and empirical findings. *Curr Dir Psychol Sci* 1995;4:61–5.
- Foa EB, Rothbaum BO. *Treating the trauma of rape: cognitive-behavioral therapy for PTSD*. Treatment manuals for practitioners. New York, NY, US: Guilford Press, 1998.
- Kessler RC, Sonnega A, Bromet E, et al. Posttraumatic stress disorder in the National comorbidity survey. *Arch Gen Psychiatry* 1995;52:1048–60.
- Dalgleish T. Cognitive approaches to posttraumatic stress disorder: the evolution of multirepresentational theorizing. *Psychol Bull* 2004;130:228–60.
- Ehlers A, Clark DM. A cognitive model of posttraumatic stress disorder. *Behav Res Ther* 2000;38:319–45.
- Foa EB, Steketee G, Rothbaum BO. Behavioral/cognitive conceptualizations of post-traumatic stress disorder. *Behavior Therapy* 1989;20:155–76.
- Resick PA, Schnicke MK. Cognitive processing therapy for sexual assault victims. *J Consult Clin Psychol* 1992;60:748–56.
- Bomyea J, Johnson A, Lang AJ. Information processing in PTSD: evidence for biased attentional, interpretation, and memory processes. *Psychopathology Review* 2017;a4:218–43.
- Woud ML, Verwoerd J, Krans J. Modification of cognitive biases related to posttraumatic stress: a systematic review and research agenda. *Clin Psychol Rev* 2017;54:81–95.
- Bryant RA, Guthrie RM. Maladaptive appraisals as a risk factor for posttraumatic stress: a study of trainee firefighters. *Psychol Sci* 2005;16:749–52.
- Bryant RA, Guthrie RM. Maladaptive self-appraisals before trauma exposure predict posttraumatic stress disorder. *J Consult Clin Psychol* 2007;75:812–5.
- Ehring T, Ehlers A, Glucksman E. Do cognitive models help in predicting the severity of posttraumatic stress disorder, phobia, and depression after motor vehicle accidents? A prospective longitudinal study. *J Consult Clin Psychol* 2008;76:219–30.
- Kleim B, Grey N, Wild J, et al. Cognitive change predicts symptom reduction with cognitive therapy for posttraumatic stress disorder. *J Consult Clin Psychol* 2013;81:383–93.
- Bosch J, Mackintosh M-A, Wells SY, et al. Ptsd treatment response and quality of life in women with childhood trauma histories. *Psychol Trauma* 2020;12:55–63.
- Nøhr AK, Eriksson H, Hobart M, et al. Predictors and trajectories of treatment response to sris in patients suffering from PTSD. *Psychiatry Res* 2021;301:113964.
- Schäfer I, Gast U, Hofmann A, et al. *S3-leitlinie posttraumatische belastungsstörung*. Berlin, Heidelberg: Springer Verlag, 2019.
- BPTK. BPTK-auswertung: monatelange wartezeiten bei psychotherapeut\*innen. 2021. Available: <https://www.bptk.de/bptk-auswertung-monatelange-wartezeiten-bei-psychotherapeutinnen/>
- Koster EHW, Fox E, MacLeod C. Introduction to the special section on cognitive bias modification in emotional disorders. *J Abnorm Psychol* 2009;118:1–4.
- Woud ML, Becker ES. Editorial for the special issue on cognitive bias modification techniques: an introduction to a time traveller's tale. *Cogn Ther Res* 2014;38:83–8.
- Woud ML, Holmes EA, Postma P, et al. Ameliorating intrusive memories of distressing experiences using computerized reappraisal training. *Emotion* 2012;12:778–84.
- Woud ML, Postma P, Holmes EA, et al. Reducing analogue trauma symptoms by computerized reappraisal training—considering a cognitive prophylaxis? *J Behav Ther Exp Psychiatry* 2013;44:312–5.
- Würtz F, Blackwell SE, Margraf J, et al. The world dangerous it is—the scrambled sentences task in the context of posttraumatic stress symptoms. *Journal of Experimental Psychopathology* 2022;13:204380872211247.
- de Kleine RA, Woud ML, Ferentz H, et al. Appraisal-based cognitive bias modification in patients with posttraumatic stress disorder: a randomised clinical trial. *Eur J Psychotraumatol* 2019;10:1625690.



- 25 Würtz F, Krans J, Blackwell SE, et al. Using cognitive bias modification-appraisal training to manipulate appraisals about the self and the world in analog trauma. *Cogn Ther Res* 2022;46:232–46.
- 26 Woud ML, Blackwell SE, Shkreli L, et al. The effects of modifying dysfunctional appraisals in posttraumatic stress disorder using a form of cognitive bias modification: results of a randomized controlled trial in an inpatient setting. *Psychother Psychosom* 2021;90:386–402.
- 27 Hirsch CR, Krahé C, Whyte J, et al. Internet-Delivered interpretation training reduces worry and anxiety in individuals with generalized anxiety disorder: a randomized controlled experiment. *J Consult Clin Psychol* 2021;89:575–89.
- 28 Beard C. Cognitive bias modification for anxiety: current evidence and future directions. *Expert Rev Neurother* 2011;11:299–311.
- 29 Lisk SC, Pile V, Haller SPW, et al. Multisession cognitive bias modification targeting multiple biases in adolescents with elevated social anxiety. *Cognit Ther Res* 2018;42:581–97.
- 30 Tabibian B, Upadhyay U, De A, et al. Enhancing human learning via spaced repetition optimization. *Proc Natl Acad Sci U S A* 2019;116:3988–93.
- 31 Young JE, Klosko JS, Weishaar ME. *Schema therapy: A practitioner's guide. (schema therapy: A practitioner's guide)*. New York, NY, US: Guilford Press, 2003.
- 32 Williams AD, Blackwell SE, Mackenzie A, et al. Combining imagination and reason in the treatment of depression: a randomized controlled trial of Internet-based cognitive-bias modification and internet-CBT for depression. *J Consult Clin Psychol* 2013;81:793–9.
- 33 First MB, Williams JBW, Karg RS, et al. *Structured clinical interview for DSM-5 disorders, clinician version (SCID-5-CV)*. Arlington, VA: American Psychiatric Association, 2016.
- 34 Margraf J, Cwik JC. *Mini-DIPS open access: diagnostic short-interview for mental disorders*. Bochum: Ruhr-Universität, 2017.
- 35 First MB, Williams JBW, Benjamin LS, et al. *Structured clinical interview for DSM-5 screening personality questionnaire (SCID-5-SPQ)*. Arlington, VA: American Medical Association, 2016.
- 36 Posner K, Brown GK, Stanley B, et al. The columbia-suicide severity rating scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *Am J Psychiatry* 2011;168:1266–77.
- 37 Foa EB, Ehlers A, Clark DM, et al. The posttraumatic cognitions inventory (PTCI): development and validation. *Psychological Assessment* 1999;11:303–14.
- 38 Viviani R, Dommes L, Bosch JE, et al. A computerized version of the scrambled sentences test. *Front Psychol* 2017;8:2310.
- 39 Janoff-Bulman R. Assumptive worlds and the stress of traumatic events: applications of the schema construct. *Social Cognition* 1989;7:113–36.
- 40 Janoff-Bulman R. *Shattered assumptions: towards a new psychology of trauma. (shattered assumptions: towards a new psychology of trauma)*. New York, NY, US: Free Press, 1992.
- 41 Rohrbacher H, Reinecke A. Measuring change in depression-related interpretation bias: development and validation of a parallel ambiguous scenarios test. *Cogn Behav Ther* 2014;43:239–50.
- 42 Weathers FW, Litz BT, Keane TM, et al. The PTSD checklist for DSM-5 (PCL-5)- standard (measurement instrument). 2013. Available: <https://ptsd.va.gov/>
- 43 Beck AT, Steer RA. Brown GK. BDI-II beck depression inventory-II. 1996. Available: <https://www.pearsonassessments.com/store/usassessments/en/Store/Professional-Assessments/Personality-%26-Biopsychosocial/Beck-Depression-Inventory-II/p/100000159.html> [Accessed 9 Apr 2019].
- 44 Attkisson CC, Zwick R. The client satisfaction questionnaire. psychometric properties and correlations with service utilization and psychotherapy outcome. *Eval Program Plann* 1982;5:233–7.
- 45 Beck AT, Steer RA. *Manual for the beck scale for suicide ideation*. San Antonio, TX: Psychological Corporation, 1991.
- 46 Woud ML, Blackwell SE, Shkreli L, et al. The effects of modifying dysfunctional appraisals in posttraumatic stress disorder using a form of cognitive bias modification: results of a randomized controlled trial in an inpatient setting. *Psychother Psychosom* 2021;90:386–402. 10.1159/000514166 Available: <https://www.karger.com/DOI/10.1159/000514166>
- 47 Bundespsychotherapeutenkammer. BPTK-auswertung: monatelange wartezeiten bei psychotherapeut\*innen. 2021. Available: <https://www.bptk.de/bptk-auswertung-monatelange-wartezeiten-bei-psychotherapeutinnen/> [Accessed 5 Dec 2022].