

Effectiveness of a personality-oriented self-regulation training in rehabilitation patients with cannabis dependence: study protocol of a multicentre randomised controlled trial

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Title

Effectiveness of a personality-oriented self-regulation training in rehabilitation patients with cannabis dependence: study protocol of a multicentre randomised controlled trial

Short title

PSRT for cannabis dependence: study protocol

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Abstract

Background

Cannabis dependence is frequently associated with impairments in affective-volitional self-regulation processes that substantially influence rehabilitative change. Despite demonstrable effects of established psychosocial interventions, treatment outcomes often remain unstable. These observations suggest that sustainable behavioural change is less constrained by insufficient motivation than by difficulties in implementing and maintaining self-congruent goals under conditions of emotional strain. In particular, deficits in affect regulation, impulse control, and volitional action regulation are considered central mechanisms underlying these difficulties. The aim of the present study is to examine whether Personality-Oriented Self-Regulation Training (PSRT), delivered as an adjunct to standard rehabilitation, improves affective-volitional self-regulation competencies in inpatients with cannabis dependence compared with treatment as usual (TAU).

Methods

A multicentre, interventional, randomised, controlled trial (RCT) with two parallel treatment arms is being conducted. Inpatients with cannabis dependence (ICD-10 F12.2) are recruited from two specialised inpatient rehabilitation facilities in Germany. Pre-randomisation stratification is performed based on dispositional action versus state orientation as measured with the Action Control Scale (ACS-90), followed by random allocation to either PSRT in addition to TAU or TAU alone. The PSRT intervention is delivered as a manualised group programme over 11 weeks and integrates core assumptions of Self-Determination Theory, the Good Lives Model, and Personality Systems Interactions theory. Primary outcomes comprise affective-volitional self-regulation competencies measured using the Volitional Components Questionnaire – Short Form (VCQ-S), while secondary outcomes focus on selected facets of impulsive behaviour. Statistical analyses are performed according to the intention-to-treat principle using linear mixed models for repeated measures (MMRM).

Discussion

Within the context of inpatient addiction rehabilitation, this study evaluates a theory-driven, self-regulation-centred intervention approach. By explicitly targeting affective-volitional mechanisms of goal implementation under conditions of emotional strain, the findings are expected to contribute to the understanding of affective-volitional self-regulation as a hypothesised mechanism of sustainable behaviour change in cannabis dependence. In addition, the results may have impact on the further development of personalised, self-regulation-oriented rehabilitation programmes.

Trial registration German Clinical Trials Register (DRKS), DRKS00037137. Registered 12 June 2025, <https://drks.de/search/en/trial/DRKS00037137>, retrospectively registered.

Keywords: Cannabis dependence; affective-volitional self-regulation; action versus state orientation; self-regulation under stress; personality-oriented intervention; inpatient rehabilitation; randomised controlled trial

Background

Cannabis is the most widely used illicit drug worldwide and is also the most commonly used illegal or partially legalised substance in Germany [1–3]. Meta-analyses of therapeutic interventions aimed at reducing cannabis use or the severity of dependence indicate overall moderate effectiveness. The largest effect sizes have been observed for combined approaches integrating cognitive behavioural therapy and motivational interviewing [4]. Concurrently, these meta-analyses highlight comparatively low abstinence rates of approximately 25% as well as persistently high rates of treatment dropout [4]. In light of these findings, there has been an increasing focus on identifying core mechanisms that contribute to more stable treatment outcomes in substance use disorders. Self-regulation is regarded as a central factor in this context [5–8].

In particular, impairments in behavioural and emotional regulation are considered a transdiagnostic mechanism that is hypothesised to underlie different forms of addictive behaviour [9–12]. Accordingly, substance-related disorders are increasingly conceptualised not merely as disorders of consumption behaviour, but rather as expressions of complex dysfunctions in motivational, affective, and volitional self-regulation processes [5,13,14]. Empirical studies consistently demonstrate that individuals with addiction disorders exhibit pronounced deficits in emotion regulation and impulse control. Furthermore, impairments in goal persistence and interpersonal self-regulation have been observed compared with non-dependent control groups [6,15–17]. These limitations have been identified as both independent vulnerability and maintenance factors. In rehabilitative settings, they are frequently associated with reduced treatment adherence, an increased likelihood of premature discontinuation, and unstable abstinence outcomes [18,19]. Meta-analytic evidence further underscores self-regulation as a transdiagnostic core competence that is closely linked to long-term mental health and health-related behaviour [8].

Self-Determination Theory (SDT) constitutes a pivotal theoretical framework for understanding motivational processes. It posits that the quality of human motivation is contingent on the satisfaction of fundamental psychological needs for autonomy, competence, and relatedness [20,21]. When these needs are adequately satisfied, autonomous motivation emerges, which is associated with enhanced goal persistence, more effective emotion regulation, and more favourable treatment outcomes [22]. In contrast, chronic need frustration is linked to controlled motivation, heightened stress reactivity, and reliance on short-term, often maladaptive coping strategies [23,24]. In the context of substance use disorders, substance consumption can be understood as a short-term compensatory strategy aimed at regulating unmet psychological needs, particularly under conditions of low autonomous self-regulation [25,26].

The Good Lives Model (GLM) provides a complementary perspective by specifying the content of motivational goal orientations. Within this framework, problematic behaviour is not primarily conceptualised as a deficit, but rather as a misguided attempt to fulfil universal human needs and life goals, such as autonomy, meaning, relatedness, or inner stability [27,28]. From this perspective, the aim of rehabilitative interventions extends beyond the mere reduction of problematic behaviour to encompass the development of a life that is subjectively experienced as meaningful. In conjunction with SDT, GLM-oriented goals can be assumed to exert their regulatory potential especially when they are autonomously motivated and experienced as self-congruent [21].

Nevertheless, motivational approaches primarily account for the initiation of change and offer more limited explanatory power regarding the implementation and maintenance of behaviour change under conditions of stress. The discrepancy between intentions and actual behaviour, often termed the intention–behaviour gap, has been extensively documented. Within rehabilitative settings, this discrepancy frequently manifests as treatment dropout or relapse,

despite high readiness to change [29,30]. Research on self-regulation further indicates that this discrepancy becomes especially pronounced under conditions of affective strain, as stress and negative affect interfere with the initiation and maintenance of goal-directed action [14,31].

A differentiated framework for explaining these affective-volitional processes is provided by Personality Systems Interactions (PSI) theory. Within this strategy, self-regulation is understood as a dynamic interaction between affective, motivational, and cognitive functional systems, with affective states playing a central modulatory role [31,32]. Recent integrative work has further elaborated PSI theory by highlighting how affective strain dynamically modulates motivational and volitional systems, thereby undermining goal implementation under chronic stress conditions [33].

A core distinction within this framework is drawn between action orientation and state orientation. Action-oriented individuals are characterised by the ability to remain capable of action and to translate existing intentions into goal-directed behaviour even under conditions of stress. In contrast, state orientation is associated with perseverative, self-focused processes, such as rumination or emotional disengagement, which systematically impede the implementation of intended actions [34,35]. Empirical findings have indicated that action orientation is linked to effective affect regulation and stable goal pursuit, whereas state orientation is associated with reduced affect regulation capacity, increased impulsivity, and unstable self-regulation [36–38].

Taken together, SDT, the GLM, and PSI theory offer complementary explanatory perspectives on stable behaviour change. Within this integrative framework, SDT clarifies the motivational conditions under which goals are experienced as self-congruent, while the GLM specifies the content and personal meaning of these goals. PSI theory, in turn, explains how such goals are implemented—or fail to be implemented—under conditions of affective strain.

In contrast to established approaches that primarily target cognitive restructuring or motivational enhancement, this integrative framework highlights that sustainable behaviour change additionally depends on the capacity to maintain goal-directed action under affective strain — a process that existing interventions in cannabis rehabilitation typically do not systematically address.

Building on this theoretical foundation, the Personality-Oriented Self-Regulation Training (PSRT) was developed as a manualised, theory-based intervention. The programme was designed to foster self-determined motivation, explicitly integrate personally meaningful life goals, and systematically strengthen affective-volitional self-regulation competencies required for implementing these goals under conditions of stress.

This protocol is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2025 statement [39]; the completed SPIRIT 2025 checklist is provided as Additional file 1.

Primary objective

This randomised controlled trial (RCT) aims to evaluate the effectiveness of PSRT as an adjunct to standard rehabilitation (treatment as usual, TAU) in inpatients undergoing rehabilitation for cannabis dependence. Specifically, the study examines whether participation in PSRT is associated with improvements in affective-volitional self-regulation competencies, which are considered central prerequisites for initiating, maintaining, and flexibly adapting self-congruent behaviour under conditions of emotional strain.

Secondary objectives

Furthermore, the study investigates whether participation in PSRT is associated with changes in behavioural regulation-related indicators compared with TAU. In this context, the study examines the extent to which selected facets of impulsive behaviour – particularly affect-driven

impulsivity (urgency) and risk-taking – are influenced by the intervention, given their close links to substance-related consumption behaviour, affective dysregulation, and relapse processes.

Exploratory research questions (moderator analyses)

In addition, the study pursues an exploratory, theory-driven differentiation objective. Building on the assumptions of PSI theory, the study examines whether interindividual differences in dispositional affective-volitional self-regulation moderate the impact of the intervention. Specifically, it will be investigated whether state-oriented versus action-oriented rehabilitation patients benefit to different degrees from PSRT. Dispositional action versus state orientation is conceptualised as a pre-existing personal disposition rather than as a target of the intervention. It is assumed to influence the effectiveness of self-regulation-oriented interventions, particularly when affective demands are high.

Methods/Design

Study design

The present PSRT study constitutes the intervention-focused strand of the LEICa research project (“Lebenszielperspektive Erwerbstätigkeit – Intervention zur Verbesserung der Selbststeuerung bei Rehabilitanden mit Cannabisabhängigkeit”), a multicentre research programme examining self-regulation and life-goal perspectives in inpatient cannabis rehabilitation. Whereas LEICa provides the overarching organisational, infrastructural, and recruitment framework, the PSRT study is designed as a methodologically distinct intervention trial with its own research objectives, outcome measures, and analytical strategy.

Accordingly, the PSRT study is designed as a multicentre, interventional RCT with two parallel treatment arms evaluating the effectiveness of PSRT as an adjunct to TAU. The study follows a three-time-point assessment structure, including an initial assessment (T0) conducted exclusively for stratification purposes based on key dispositional self-regulation characteristics. Evaluation of the intervention is based on a pre–post design (T1–T2), with the post-intervention assessment (T2) performed immediately following completion of the intervention and not constituting a delayed follow-up assessment in the strict sense. This design explicitly accounts for the relevance of interindividual differences in affective-volitional self-regulation, as outlined in the theoretical background, while avoiding statistical distortion of the estimated intervention effect. Stratification based on dispositional self-regulation characteristics allows potential systematic differences between participants with varying competence levels to be controlled prior to randomisation.

The study employs a partially blinded design, with blinding implemented at the levels of data collection and statistical analysis. Blinding of participants and intervention providers is not feasible due to the nature of the intervention.

The trial is implemented across two inpatient rehabilitation facilities specialising in the treatment of substance use disorders. Facilities were selected according to predefined criteria to ensure comparable organisational and therapeutic conditions, as well as structured medical and psychotherapeutic rehabilitation. This approach aims to minimise potential centre effects and to enhance the generalisability of the study findings within the multicentre design. The schedule of enrolment, interventions, and assessments is presented in Figure 1.

Figure 1 Schedule of enrolment, interventions, and assessments (SPIRIT Figure)

TIMEPOINT	T0 <i>Stratification</i>	T1 <i>Baseline</i>	Weeks 1–11 <i>Intervention</i>	T2 <i>Post</i>
ENROLMENT				
Eligibility screen	X			
Informed consent	X			
Stratification (ACS-90)	X			
Randomisation		X		
INTERVENTIONS				
PSRT + TAU			↔	
TAU only			↔	
ASSESSMENTS				
Primary outcomes:				
VCQ-S (4 subscales)		X		X
Secondary outcomes:				
I-8 (urgency, risk-taking)		X		X
Stratification/moderator:				
ACS-90 (AOF, AOD)	X			
Process measures*:				
WAI-SR				X
Exercise adherence				X

Figure 1. Schedule of enrolment, interventions, and assessments. X = assessment administered; ↔ = intervention period; * = intervention group only. T0 = stratification assessment; T1 = baseline assessment; T2 = post-intervention assessment. PSRT = Personality-Oriented Self-Regulation Training; TAU = treatment as usual; ACS-90 = Action Control Scale; VCQ-S = Volitional Components Questionnaire – Short Form; I-8 = Impulsive Behaviour Scale – Short Form; AOF = Action Orientation after Failure; AOD = Action Orientation during Planning; WAI-SR = Working Alliance Inventory – Short Revised.

Study population

Eligible participants are rehabilitation inpatients aged 18 to 67 years with a primary or secondary diagnosis of cannabis dependence according to ICD-10 (F12.2) [40]. Recruitment takes place among patients routinely admitted for inpatient medical and psychotherapeutic rehabilitation at one of the two cooperating rehabilitation facilities between April 2025 and December 2026. Comorbid substance-related disorders (e.g., F10, F13–F17) do not constitute exclusion criteria, provided that cannabis dependence is documented as a primary or secondary diagnosis. For patients with a diagnosis of polysubstance use disorder (F19.1 or F19.2), inclusion requires documented evidence that cannabinoids are among the substances involved.

Patients are excluded if they present with a diagnosed schizophrenia-spectrum or other psychotic disorder (ICD-10 F20–F29). In addition, the presence of specific clinical features coded as supplementary qualifiers across substance-related diagnoses — including acute intoxication (Fxx.0), withdrawal state with delirium (Fxx.4), psychotic disorder (Fxx.5), amnesic syndrome (Fxx.6), residual or late-onset psychotic disorder (Fxx.7), or other or unspecified mental and behavioural disorders (Fxx.8, Fxx.9) — is evaluated on a case-by-case basis. In most of these cases, inclusion is not automatically precluded but is determined by the treating clinical team based on whether sufficient cognitive and affective stability is present to allow valid engagement in the group-based intervention and reliable self-report. This decision is documented as part of the eligibility screening procedure.

Severe affective disorders do not constitute a general exclusion criterion, provided that they are clinically manageable within the rehabilitation setting. This differentiated approach acknowledges the importance of adequate regulatory capacity for participation in self-regulation-oriented interventions while avoiding unnecessary restrictions on external validity.

The inclusion of patients with both primary and secondary diagnoses of cannabis dependence reflects the clinical reality of inpatient rehabilitation for cannabis-related disorders. In this population, polysubstance use patterns are highly prevalent, and the administrative distinction between primary and secondary diagnoses frequently reflects coding conventions rather than clinically meaningful differences in the centrality of cannabis dependence to the overall clinical presentation. Restricting inclusion to primary diagnoses alone would substantially limit recruitment feasibility without a corresponding gain in sample homogeneity, while reducing the external validity of the findings for the broader population of cannabis-dependent rehabilitation inpatients.

Retrospective data from the cooperating facilities indicate that the eligible population is predominantly male and relatively young. In the reference year 2023, inpatients admitted with a primary diagnosis of cannabis dependence ($N = 160$) were aged between 18 and 47 years, with 13.1% female patients. Polysubstance use patterns were documented in all cases (personal communication, cooperating facility). These characteristics are broadly consistent with national epidemiological data on cannabis dependence in rehabilitative settings [42] and inform expectations regarding sample composition in the present trial.

Potential participants are approached by specially trained clinical staff at the cooperating facilities during routine diagnostic procedures performed at admission to inpatient rehabilitation. Written study information detailing the objectives, procedures, and general conditions of participation is provided. This information explicitly addresses the voluntary nature of participation, potential intervention-related burdens (e.g., time and emotional burden), and the handling of personal data. Written informed consent is required prior to study participation. The decision to participate or not participate has no impact on the provision of standard rehabilitative care. Participants may withdraw their consent at any time without providing reasons and without experiencing any disadvantages. All recruitment and consent

procedures comply with established ethical standards for clinical intervention research and the principles of the Declaration of Helsinki [41].

Patient and public involvement

No formal patient and public involvement (PPI) was implemented in the design of this study. The development of the PSRT intervention was informed by established theoretical frameworks (SDT, GLM, PSI theory) and by clinical expertise within inpatient rehabilitation settings. Patients were not involved in the formulation of research questions, the selection of outcome measures, the design of recruitment strategies, or the preparation of the study protocol. The intervention was developed by the principal investigator and refined through consultation with clinical practitioners at the cooperating rehabilitation facilities. Prior to the main trial, a preliminary feasibility study was carried out with a non-clinical student sample ($n = 12$) to evaluate the comprehensibility, acceptability, and engagement motivation of the intervention materials. Based on this evaluation, the training manual was revised and finalised. The results of the study will be communicated to the participating rehabilitation facilities in an accessible format to facilitate transfer into rehabilitative practice. The absence of systematic patient involvement in the study design is acknowledged as a limitation.

Demographic and clinical baseline characteristics

Demographic and clinical baseline characteristics are collected at study entry to describe the study sample and to assess the comparability of treatment groups at baseline. Recorded variables include sex (categorised as male, female, or diverse, based on participant self-report), age, marital status, number of children, educational attainment, employment status, substance use history (including age of onset, duration, and consumption patterns), number of prior rehabilitation treatments, and the referral context (e.g., referral pursuant to the German Narcotics Act [BtMG]). These data are collected using a standardised study-specific questionnaire administered at the baseline assessment (T1). Demographic and clinical

characteristics will be reported descriptively for the total sample and separately by treatment group. Sex-disaggregated reporting of outcomes will be provided where sample sizes permit, in accordance with current reporting guidelines [43].

Interventions

Intervention group: Personality-Oriented Self-Regulation Training (PSRT) plus treatment as usual (TAU)

Participants in the intervention group receive PSRT in addition to TAU. PSRT is a manualised, theory-based intervention that integrates core assumptions of SDT, the GLM, and PSI theory, as outlined in the theoretical background. The intervention is designed to systematically strengthen affective-volitional self-regulation competencies relevant for the implementation of self-congruent goals within rehabilitative contexts.

An overview of the PSRT modules and their functional focus is presented in Table 1.

Table 1 Overview of the Personality-Oriented Self-Regulation Training (PSRT)

Module	Format	Core focus	Functional focus
1	Individual	Clarification of needs, values, and life goals	Clarifying personally meaningful goals
2	Group	Personality as a system of self-regulation	Developing self-regulatory understanding
3	Group	Perception and regulation of affective states	Enhancing affect awareness and regulation
4	Group	Differentiation of perception, appraisal, and interpretation	Reducing automatic affect amplification
5	Group	Impulsivity and stimulus–response patterns	Interrupting affect-driven impulses
6	Group	Self-congruent action and value-based decision-making	Aligning behaviour with core values
7	Group	Application of self-regulation in daily life	Applying self-regulation in everyday contexts
8	Group	Stressors and risk situations	Managing self-regulation under stress
9	Group	Maintaining self-regulation under emotional strain	Stabilising goal-directed action
10	Group	Dealing with setbacks as part of self-regulation	Developing adaptive responses to setbacks
11	Group	Integration and transfer	Consolidating self-regulation strategies

The intervention is conducted within the rehabilitative treatment framework of the cooperating institutions using a combined individual and group-based format. PSRT comprises 11 sequential modules conducted on a weekly basis over a period of 11 weeks. The first module is conducted in an individual setting, while modules 2–11 are carried out in small groups of up to eight participants. Each session has a duration of 90 minutes.

The training is fully manualised and conducted by the same psychologist at both study centres to ensure intervention fidelity and to minimise therapist- and centre-related effects. The development and preliminary evaluation of the intervention materials are described in the Patient and public involvement and Sample size sections. A detailed description of the intervention content and module structure is provided in Appendix A.

Intervention fidelity is supported through several procedures. First, standardised materials specify the core content, exercises, and procedural structure of each module. Second, the intervention provider completes structured session documentation after each module, recording the content delivered, session progression, and group-dynamic processes. This documentation allows for ongoing monitoring of adherence to the intervention manual. Third, the intervention provider receives regular supervision by the principal investigator to review session documentation, address implementation challenges, and ensure consistent delivery across both study centres. No independent fidelity rating based on audio or video recordings is conducted.

Control group: Treatment as usual (TAU)

Participants allocated to the control group receive TAU only. TAU comprises the multimodal, structured rehabilitation programme routinely provided at both cooperating facilities in accordance with the framework guidelines for substance-related rehabilitation of the German Pension Insurance (Deutsche Rentenversicherung). The programme follows a cognitive-behavioural orientation and is delivered over an approximate treatment duration of 22 weeks.

Core components of TAU include weekly individual psychotherapy (approximately 50 minutes per session), cognitive-behavioural group psychotherapy, and addiction-specific group interventions including relapse prevention and psychoeducation. In addition, patients receive occupational therapy, sports and exercise therapy, social counselling, and relaxation training as part of the standard rehabilitative programme. The treatment programmes at both cooperating facilities are comparable in structure, content, and intensity.

No additional structured self-regulation intervention is conducted in the control group. Participants in both the intervention and control groups receive the full TAU programme; PSRT is delivered as an adjunct to, not a replacement for, standard rehabilitative care.

An overview of TAU components is provided in Table 2.

Table 2 *Overview of treatment as usual (TAU) components*

Component	Format	Approximate frequency
Individual psychotherapy	Individual	1×/week, ~50 min
Cognitive-behavioural group therapy	Group	Regular, as per clinical schedule
Addiction-specific groups (relapse prevention, psychoeducation)	Group	Regular, as per clinical schedule
Occupational therapy	Group/individual	As per rehabilitation plan
Sports and exercise therapy	Group	As per rehabilitation plan
Relaxation training	Group	As per rehabilitation plan
Social counselling	Individual	As per rehabilitation plan

Outcomes and assessment instruments

Primary outcomes

The primary outcomes focus on self-regulation-related competencies assessed using the Volitional Components Questionnaire – Short Form (VCQ-S; German version: Selbststeuerungsinventar – Kurzform, SSI-K) [44]. The instrument is rooted in the volitional psychology tradition of PSI theory and operationalises central affective-volitional processes that are essential for initiating, maintaining, and flexibly adapting goal-directed behaviour in

demanding situations. Within the present study design, all four subdimensions of the VCQ-S are treated as equally weighted primary outcomes.

The decision to treat the four VCQ-S subscales as separate primary endpoints rather than aggregating them into a single composite score is based on theoretical and psychometric considerations. Within PSI theory, the four subdimensions reflect functionally distinct macro-systems of personality that serve different regulatory functions and may be differentially affected by the intervention. Specifically, self-regulation and self-control represent complementary but theoretically independent modes of volitional regulation, whereas volitional initiation and access to the self capture distinct aspects of action readiness and self-congruent goal pursuit. Aggregating these dimensions into a single score would obscure potentially differential intervention outcomes on theoretically distinct processes, thereby reducing the interpretive precision of the findings.

The assessed subscales comprise self-regulation, defined as the ability to affectively calm oneself and to integrate emotional states into goal-directed action, and self-control, defined as the ability to voluntarily inhibit impulsive tendencies in favour of superordinate goals. In addition, volitional initiation is evaluated as the ability to actively initiate actions despite motivational or emotional resistance, as well as access to the self, referring to the accessibility of implicit self-representations, values, and needs as a basis for self-congruent goal pursuit. According to the manual, VCQ-S subscales are scored as mean scale values, with higher scores indicating a stronger expression of the respective self-regulation competency. Intervention effects are evaluated based on changes between the baseline assessment (T1) and the post-intervention assessment following completion of the programme (T2).

Psychometric evaluations of the Volitional Components Questionnaire (VCQ) and its short forms demonstrate a replicable multifactorial structure, good to very good internal consistency

(Cronbach's alpha values typically ranging from 0.84 to 0.91), and theory-consistent construct and criterion validity [44–46]. The VCQ, originally developed by Kuhl and grounded in PSI theory, has been validated extensively, including its short form (VCQ-S). The VCQ-S subscales show theoretically expected associations with dispositional action versus state orientation, affective self-regulation, impulsivity, and psychological stress, supporting their suitability for use in the clinical rehabilitation context of substance-related disorders.

Secondary outcomes

Impulsive behaviour is assessed as a secondary outcome using the Impulsive Behaviour Scale–Short Form (I-8) [47]. The I-8 is an economical German-language short scale designed to assess core facets of impulsivity based on the UPPS (Urgency, Premeditation, Perseverance, and Sensation Seeking) model of impulsivity [48], which conceptualises impulsivity as a multidimensional construct comprising urgency, lack of premeditation, lack of perseverance, and sensation seeking. In the present study, two facets of impulsivity—urgency and risk-taking—are examined, as these dimensions are particularly closely associated with substance-related behaviour, affective dysregulation, and relapse processes. Since urgency reflects affect-driven action tendencies, improvements in affective self-regulation through PSRT may be expected to reduce this facet of impulsive behaviour. Each subscale consists of two items. Items are aggregated to form mean scale scores, with higher values indicating a stronger expression of the respective impulsivity dimension. Psychometric evaluations of the I-8 in German-speaking samples support its factorial structure as well as its convergent and discriminant validity and indicate acceptable to good internal consistency [47,49].

Further surveys and process measures

To assess dispositional action versus state orientation as a relevant moderator of intervention effects, the Action Control Scale (ACS-90) [50] is administered. The manual-compliant subscales Action Orientation after Failure (AOF) and Action Orientation during Planning

(AOD) are combined into a composite index, which is used in the moderator analyses. The scoring procedure and its role in stratification are described in the section on randomisation.

Extensive psychometric evidence supports the use of the ACS-90. Previous studies report satisfactory to good internal consistency for both subscales, with Cronbach's alpha coefficients ranging from approximately 0.70 to 0.86 for the AOF subscale and 0.72 to 0.88 for the AOD subscale, as well as a stable factorial structure corroborating the theoretically postulated distinction between action-oriented and state-oriented modes of self-regulation [50,51]. Construct validity is further supported by consistent associations with measures of affect regulation, goal attainment, inhibitory self-control as a component of self-regulation, and psychological stress. At the criterion level, expected relationships with behavioural indicators of action initiation under stress, persistence in goal pursuit, and adaptive coping with demanding situations have been demonstrated, underscoring the prognostic relevance of the instrument, particularly in clinical and rehabilitative contexts.

In addition to the primary and secondary outcome measures, two further instruments are collected in the intervention group for formative evaluation of the intervention. These measures are not intended to assess intervention efficacy in the narrow sense, but rather to evaluate implementation quality and relevant therapeutic process variables. First, adherence to the exercises between intervention sessions is assessed using a purpose-developed brief questionnaire comprising three items. This questionnaire retrospectively captures the extent and regularity with which prescribed exercises were completed between sessions and allows for descriptive and exploratory analyses of programme adherence. Second, the therapeutic alliance is assessed using the revised short form of the Working Alliance Inventory (WAI-SR, patient version). The German-language version of the WAI-SR demonstrates good psychometric properties and assesses the dimensions of goal agreement, task agreement, and therapeutic bond [52]. This assessment is conducted exclusively in the intervention group and

serves to evaluate the quality of the therapeutic relationship as a potentially relevant process and contextual factor.

Both measures are used exclusively for exploratory and interpretative purposes and are not included as dependent variables in the primary outcome analyses.

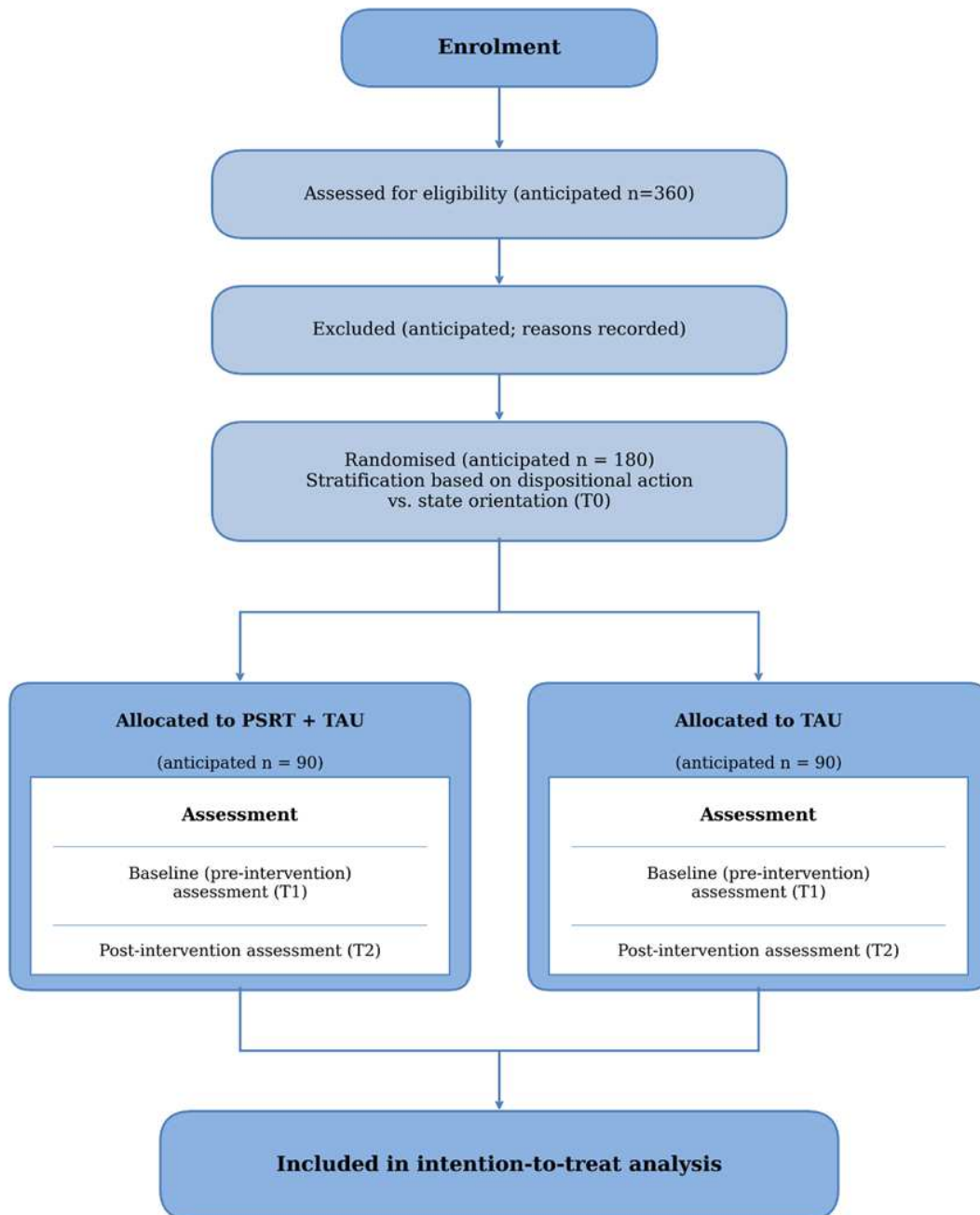
Sample size

Sample size planning was performed a priori with reference to the primary group comparison at the post-intervention assessment (T2) using linear mixed models for repeated measures (MMRM) with baseline adjustment. The sample size calculation was based on the expected intervention effect on the overarching construct of affective-volitional self-regulation. The four subscales of the VCQ-S were conceptualised as theoretically integrated dimensions of this construct. A preliminary, unpublished evaluation of an abbreviated version of PSRT (6 of 11 modules) in a non-clinical student sample ($n = 12$) yielded a large effect size (Cohen's $d = 0.80$) on self-regulation outcomes. Given the substantial differences in population characteristics, intervention dosage, and sample size, a medium standardised effect size (Cohen's $d = 0.50$) was adopted as a conservative planning assumption for the present trial. This assumption is supported by meta-analytic evidence from related fields. A meta-analysis of psychosocial interventions for substance use disorders reported an aggregate effect size of $d = 0.45$ across 34 RCTs [53]. A systematic review of self-regulation-based interventions found a pooled effect size of 0.42 (95% CI 0.32–0.53) on self-regulation outcomes, although based on non-clinical youth samples [54]. Furthermore, mindfulness-based interventions targeting self-regulatory mechanisms in substance use populations have yielded medium effect sizes on regulation-related outcomes ($d = 0.43$ – 0.68), with larger impacts for interventions specifically addressing affect regulation [55]. Taken together, these findings suggest that a medium effect size represents a plausible yet conservative planning assumption for a targeted self-regulation intervention in a clinical rehabilitation sample. The calculation was performed conservatively

using a two-sided significance level of $\alpha = 0.05$ and a target statistical power of 80%. This resulted in a required sample size of $n = 63$ participants per group for the primary two-group comparison at the post-intervention time point (T2). To account for an anticipated dropout rate of approximately 15%, the required sample size was increased accordingly, yielding a planned sample of $n = 75$ randomised participants per group. Although baseline-adjusted models such as analysis of covariance (ANCOVA) or MMRM can reduce required sample sizes depending on the correlation between baseline (T1) and post-intervention (T2) assessments, potential efficiency gains were deliberately not incorporated into the calculation. This decision was made in order to maintain a conservative planning approach. Considering remaining uncertainties regarding variance estimates, baseline–outcome correlations, and assumptions about missing data, the target sample size was ultimately set at approximately $n = 90$ participants per group.

This sample size is expected to provide sufficient statistical power to robustly estimate the intervention effect, even in the presence of moderate deviations from the underlying assumptions. In addition, it is expected to allow reliable detection of clinically meaningful effects of the intervention. Figure 2 illustrates the planned flow of participants through the study, including assessment for eligibility, stratification based on dispositional action versus state orientation (T0), randomisation, allocation to intervention conditions, baseline (pre-intervention) assessment (T1), post-intervention assessment (T2), and inclusion in the intention-to-treat analysis.

463 **Figure 2** Planned participant flow through the randomised controlled trial



464
 465 **Figure 2.** Planned participant flow through the randomised controlled trial. Numbers reflect
 466 anticipated sample sizes. Missing data at post-intervention assessment (T2) will be handled
 467 within the intention-to-treat framework using mixed models for repeated measures. PSRT =
 468 Personality-Oriented Self-Regulation Training; TAU = treatment as usual.

469

Randomisation and blinding

After provision of written informed consent, each participant is assigned a study-specific anonymisation code, which is used exclusively for pseudonymised identification within the study. As part of the preliminary assessment (T0), data required for stratification are collected.

Participants are stratified according to dispositional action versus state orientation, reflecting affective-volitional self-regulation, as assessed using the ACS-90. For this purpose, the manual-compliant subscales AOF and AOD are administered. Item responses from both subscales are aggregated into scale scores and subsequently combined into a composite index reflecting overall dispositional self-regulation. The composite index is computed as the sum of both scale scores (AOF + AOD). Based on normative reference values provided in the test manual, a predefined cut-off score of 11 points is applied to the composite index. Participants scoring above 11 are assigned to the action-oriented competence group, whereas participants scoring at or below 11 are assigned to the state-oriented competence group.

Following completion of the stratification procedure, participants are randomly allocated within each competence group to either the intervention condition (PSRT + TAU) or the control condition (TAU) using simple randomisation. The allocation sequence was generated by the principal investigator using a computer-based random number generator prior to the start of participant recruitment. Pre-generated allocation lists, stratified by competence group, were provided to the cooperating facilities for implementation. Allocation is disclosed only after completion of the baseline assessment (T1). However, as the full allocation sequence is available at the study sites, concealment of upcoming allocations from clinical staff involved in enrolment cannot be fully guaranteed. This procedural limitation is addressed in the Discussion.

Due to the nature of the intervention, blinding of participants and intervention providers with respect to group allocation is not feasible. However, data collection, data management, and statistical analysis are carried out blinded to treatment assignment. In addition, the intervention provider is not informed about participants' stratification status (action-oriented versus state-oriented), thereby minimising potential expectancy effects and differential treatment influences.

Data collection and data management

Data collection is carried out at the two cooperating rehabilitation facilities by specially trained clinical staff as part of routine rehabilitative care. Prior to study initiation, all personnel involved in data collection receive standardised written instructions regarding the administration and documentation of the assessments, complemented by uniform verbal training. This procedure is intended to ensure a high level of standardisation of data collection across both study centres.

Assessments are administered at the predefined measurement time points (T0, T1, and T2) using standardised instruments, including self-report questionnaires. Data collection is organisationally separated from intervention delivery. The intervention provider is not involved in data collection and has no access to the collected data. All study data are processed in a pseudonymised manner. The linkage between personal identifying information and study-specific pseudonymisation codes is stored separately from the study data and is accessible only to a strictly limited and authorised group of individuals. Data storage and processing are performed in accordance with applicable data protection regulations.

Data management and statistical analyses are performed independently by the Institute for Medical Epidemiology, Biometry and Informatics at University Medicine Halle. This organisational separation between intervention delivery, data collection, and data analysis is

intended to minimise the risk of systematic bias and to strengthen the internal validity of the study. The datasets generated within the study are used exclusively for study-related purposes.

Statistical analysis plan

Statistical analyses will be performed according to the intention-to-treat principle in order to include all randomised participants in the analyses, irrespective of the actual extent of their participation in the intervention. This approach allows for a realistic estimation of intervention effects and reduces bias resulting from selective study discontinuation.

The primary endpoints – the four subdimensions of affective-volitional self-regulation (self-regulation, self-control, volitional initiation, and access to the self) – will be analysed using MMRM. With two measurement occasions (baseline T1 and post-intervention T2), this approach is conceptually related to a longitudinal ANCOVA, while allowing explicit modelling of within-subject change over time. In the mixed-model framework, treatment group (PSRT versus TAU), time (T1, T2), study centre, and their interactions will be specified as fixed effects, with baseline values implicitly accounted for through the inclusion of the time factor. The models will be specified as random-intercept models; with only two measurement occasions, an unstructured variance–covariance matrix will be used.

Intervention effects will be tested using the group $\times$ time interaction term, which serves to assess whether changes in self-regulation competencies over time differ significantly between the two treatment groups. Missing data will be handled within the MMRM framework using maximum likelihood estimation under the assumption that data are missing at random. To examine the robustness of the findings with respect to alternative assumptions about missing data, additional sensitivity analyses using multiple imputation will be performed, and the primary analyses will be replicated in the imputed datasets.

To control for inflation of the type I error rate due to multiple primary endpoints, p-values obtained for the four VCQ-S subscales will be adjusted using the false discovery rate procedure according to Benjamini and Hochberg [56]. A nominal significance level of $\alpha = 0.05$ will be maintained.

The use of four equally weighted primary endpoints increases the risk of type I error inflation, which is addressed through the false discovery rate correction described above. This approach was chosen over a hierarchical testing strategy, as no a priori theoretical or empirical basis exists for prioritising one subdimension over the others.

Secondary outcomes will be analysed exploratively using analogous statistical models and interpreted with appropriate caution. In addition, moderator analyses will be performed to examine whether dispositional action versus state orientation moderates the intervention effect. For this purpose, interaction terms between treatment group, time, and the corresponding ACS-90 scale scores will be included in the models. These analyses are intended to test the theoretically derived assumption that interindividual differences in affective-volitional self-regulation contribute meaningfully to variation in intervention effectiveness.

Protection of participants and safety

The intervention under investigation is a non-pharmacological, behaviour-oriented programme with a low risk profile. No study-specific risks beyond those associated with routine rehabilitative treatment are anticipated. Any adverse events will be documented as part of standard clinical care and managed in accordance with the applicable internal institutional procedures. Given the low-risk nature of the intervention and the inpatient setting of the study, the establishment of an independent Data Safety Monitoring Board is not planned. Monitoring of trial conduct, including verification of informed consent procedures, completeness of

563 assessment data, and adherence to the study protocol, is performed on an ongoing basis by the
564 principal investigator.

565 **Access to protocol and data**

566 The study is registered in the DRKS (DRKS00037137). The full study protocol is made
567 publicly available through the present journal publication. The statistical analysis plan is
568 integrated into this protocol manuscript. De-identified participant-level data may be made
569 available upon reasonable scientific request, subject to applicable data protection regulations,
570 as described in the data availability statement.

571

Discussion

This randomised controlled study aims to provide a methodologically transparent evaluation of a theory-based, self-regulation-oriented intervention approach within the context of addiction rehabilitation. The primary focus lies on the investigation of affective-volitional self-regulation competencies as a hypothesised mechanism underlying sustainable behavioural change. In doing so, the study builds on current theoretical and empirical work conceptualising self-regulation as a transdiagnostic process whose effectiveness critically depends on the affective modulation of volitional control mechanisms [14,57,58].

A central feature of the study is the consistently theory-driven derivation of the intervention. By integrating core assumptions from SDT, the GLM, and PSI theory, the intervention is embedded within an integrative framework that systematically links motivational goal orientation, affect regulation, and volitional action control [20,28,31]. The study thereby contributes to the empirical examination of these theoretical assumptions within a clinically relevant rehabilitative setting. In addition, the study explicitly accounts for interindividual differences in dispositional self-regulation capacity. Planned moderator analyses examining action versus state orientation allow for an exploratory investigation of differential intervention effects as a function of participants' self-regulation profiles. This approach is theoretically well grounded and supported by previous findings demonstrating systematic differences in affect regulation and action initiation under conditions of stress between individuals with distinct self-regulation profiles [51].

From a methodological perspective, the study is characterised by a randomised, controlled, multicentre design with organisational separation of intervention execution, data collection, and statistical analysis, and the application of robust statistical methods within an intention-to-treat framework. Together, these features are intended to minimise potential sources of bias and to support the internal validity of the study [59–62]. At the same time, the design is

deliberately focused on the investigation of proximal self-regulation processes. The absence of a delayed follow-up assessment represents a conscious methodological decision intended to prioritise short-term changes in affective-volitional mechanisms. Future research may build on the present findings to examine the long-term stability and clinical relevance of the observed intervention effects [8]. To this end, a follow-up assessment extending beyond the post-intervention time point is currently being sought through additional funding.

Accordingly, substance-related outcomes, including abstinence motivation, are assessed within the broader LEICa research programme and will be reported in a separate analysis. This approach reflects the theoretical rationale that affective-volitional self-regulation competencies represent the hypothesised mediators of sustainable behaviour change, and that their independent evaluation is a necessary prerequisite before examining downstream effects on substance-related outcomes.

A further methodological limitation concerns the implementation of the randomisation procedure. Although allocation was based on a computer-generated random sequence stratified by dispositional self-regulation, the full allocation lists were provided to the cooperating facilities prior to the start of recruitment. This approach does not ensure adequate concealment of upcoming allocations from staff involved in participant enrolment, which may introduce selection bias. However, allocation is disclosed only after completion of the baseline assessment (T1), ensuring that baseline data are collected without knowledge of group assignment. This risk is further mitigated by the blinding procedures described in the Methods section, including blinded data collection and analysis and the intervention provider's unawareness of participants' stratification status. Nevertheless, future trials should implement central randomisation procedures to ensure full allocation concealment.

The assessment of intervention fidelity relies on structured session documentation and supervision by the principal investigator rather than on independent fidelity ratings based on recorded sessions. While this approach allows for ongoing monitoring of protocol adherence, it does not provide an objective, externally verified assessment of treatment fidelity. Future trials should consider implementing independent fidelity assessments to strengthen the evaluation of intervention integrity.

The delivery of PSRT by a single psychologist across both study centres ensures high intervention fidelity but limits the generalisability of the findings, as observed outcomes may partly reflect therapist-specific characteristics rather than the intervention itself.

Furthermore, funding is being sought for a subsequent study involving multiple intervention providers to examine the generalisability of the intervention across different therapists.

Given the exploratory nature of the moderator analyses, the study is not specifically powered to detect interaction effects between treatment group and dispositional action versus state orientation. Interaction effects typically require substantially larger sample sizes than main effects. Accordingly, moderator results will be interpreted with appropriate caution and considered as hypothesis-generating for future research.

Furthermore, based on available data from the cooperating facilities, the study population is expected to be predominantly male, which may limit the generalisability of the findings to female rehabilitation patients with cannabis dependence. This imbalance reflects the demographic composition of the target population in inpatient rehabilitation rather than a design-related selection bias. Nevertheless, sex- and gender-related differences in self-regulation processes and intervention responsiveness represent an important area for future research.

643 In addition, the study records sex based on self-reported legal categories (male, female, diverse)
644 but does not separately assess gender identity. This approach reflects standard clinical practice
645 in the German rehabilitation context but limits the ability to examine potential sex- and gender-
646 specific differences in intervention effects in accordance with current reporting
647 recommendations.

648 The results of the study will be disseminated through publication in peer-reviewed scientific
649 journals, irrespective of the magnitude or direction of the observed effects. In addition, the
650 findings will be presented at national and international scientific conferences. The results will
651 also be communicated to the participating cooperating rehabilitation facilities in an appropriate
652 format to facilitate transfer into rehabilitative practice.

653

Trial status

The study protocol presented in this manuscript corresponds to version 1.0, dated 31 December 2025. No amendments to the study design, primary outcomes, or statistical analysis plan are planned. Any future protocol amendments will be documented, communicated to the ethics committee, and updated in the trial registry.

Recruitment of study participants commenced in May 2025. At the time of manuscript submission, the study is in the active recruitment phase. Completion of participant recruitment is scheduled for December 2026.

The study is registered in the German Clinical Trials Register (DRKS00037137). Registration was completed retrospectively shortly after the start of participant recruitment. At the time of registration, the study design, intervention, primary and secondary outcomes, and statistical analysis plan had already been fully specified and were not modified following registration.

Abbreviations

ACS-90: Action Control Scale; ANCOVA: Analysis of covariance; AOD: Action Orientation during Planning; AOF: Action Orientation after Failure; BtMG: Betäubungsmittelgesetz (German Narcotics Act); DRKS: Deutsches Register Klinischer Studien (German Clinical Trials Register); DRV: Deutsche Rentenversicherung (German Pension Insurance); FDR: False discovery rate; GLM: Good Lives Model; I-8: Impulsive Behaviour Scale – Short Form; ICD-10: International Classification of Diseases, 10th Revision; LEICa: Lebenszielperspektive Erwerbstätigkeit – Intervention zur Verbesserung der Selbststeuerung bei Rehabilitanden mit Cannabisabhängigkeit; MMRM: Mixed models for repeated measures; PPI: Patient and public involvement; PSI: Personality Systems Interactions; PSRT: Personality-Oriented Self-Regulation Training; RCT: Randomised controlled trial; SAGER: Sex and Gender Equity in Research; SDT: Self-Determination Theory; SPIRIT: Standard Protocol Items:

Recommendations for Interventional Trials; SSI-K: Selbststeuerungsinventar – Kurzform (Volitional Components Questionnaire – Short Form); T0: Stratification assessment; T1: Baseline assessment (pre-intervention); T2: Post-intervention assessment; TAU: Treatment as usual; UPPS: Urgency, Premeditation, Perseverance, Sensation Seeking; VCQ-S: Volitional Components Questionnaire – Short Form; WAI-SR: Working Alliance Inventory – Short Revised

Declarations

Ethics approval and consent to participate

The study protocol was reviewed and approved by the Ethics Committee of the Medical Faculty of Martin Luther University Halle-Wittenberg (ethics approval no. 2024-212). Written informed consent is obtained from all participants prior to study enrolment. The study adheres to the ethical principles of the Declaration of Helsinki.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and analysed during the current study are not publicly available due to the sensitive nature of personal health data. Anonymised datasets may be made available by the corresponding author upon reasonable scientific request and subject to review of the applicable data protection requirements.

Competing interests

The authors declare that they have no competing interests.

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analysis, or interpretation of data, nor in the writing of the manuscript or the decision to submit for publication.

Authors' contributions

MSch designed the study and developed the intervention. MSch, JS, and TFa were responsible for the study design. MSch and TFa developed the statistical analysis plan. MSch wrote the first draft of the manuscript. UW, MSchn, JD, KW, and TFr supported the conduct of the study at the respective clinics. All authors contributed to the critical revision of the manuscript and approved the final version.

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Not applicable.

Additional files

Additional file 1: SPIRIT 2025 Checklist. Completed checklist of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2025 statement, indicating where each checklist item is addressed in the protocol.

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Appendix A. Detailed description of the Personality-Oriented Self-Regulation Training (PSRT)

This appendix provides a detailed description of the PSRT modules. The theoretical foundations and overall structure of the intervention are described in the Background and Interventions sections of this protocol.

PSRT is conducted over a period of 11 weeks and comprises 11 sequential modules. The first module is conducted in an individual setting, followed by 10 group-based modules. Group sessions are held weekly, have a duration of 90 minutes, and are conducted in groups of up to eight participants. The modular structure is explicitly sequential, with each module building on competencies acquired in preceding sessions.

Module 1: Clarification of needs, values, and life goals (individual session)

The initial module focuses on the individual clarification of core psychological needs, personal values, and meaningful life goals based on the GLM. Through a structured, guided interview, participants identify personally significant goal orientations and reflect on their relationship to previous substance use patterns. This module establishes an affectively and motivationally meaningful reference framework that serves as a stable anchor for subsequent self-regulation processes.

Module 2: Personality as a dynamic system of self-regulation

This module introduces the group format and provides a foundational understanding of personality as a dynamic system of interacting affective, motivational, cognitive, and volitional processes. Core assumptions of PSI theory are presented, with a particular focus on the role of affect in modulating access to self-related representations and goal-directed action.

Module 3: Perception and regulation of affective states

Participants learn to perceive and differentiate bodily and emotional signals and to reflect on their relevance for self-regulation. Affect regulation is conceptualised as a prerequisite for

907 maintaining access to self-related information and for enabling the integration of emotional
908 states into goal-directed behaviour.

909 **Module 4: Differentiation of perception, appraisal, and interpretation**

910 This module focuses on distinguishing situational perception from cognitive appraisal and
911 subjective interpretation. By explicitly separating these levels, automatic affect-amplifying
912 evaluation processes are reduced, cognitive relief is facilitated, and flexible regulation of
913 emotional responses is supported.

914 **Module 5: Impulsivity and stimulus–response patterns**

915 Building on enhanced affective awareness, participants analyse individual stimulus–response
916 patterns and identify early signals of impulsive action tendencies. Strategies for interrupting
917 impulsive behavioural chains at an early stage are developed and practised.

918 **Module 6: Self-congruent action and value-based decision-making**

919 Drawing on SDT and GLM, this module focuses on aligning behaviour with personally
920 significant values and needs. Participants reflect on incongruent action patterns and develop
921 alternative, value-based courses of action that support autonomous motivation and affective
922 stability.

923 **Modules 7–10: Application and consolidation in everyday contexts**

924 These modules aim to deepen and stabilise previously acquired self-regulation competencies.
925 Participants apply self-regulation strategies to individual everyday situations, identify stressors
926 and high-risk contexts, and develop personalised strategies for maintaining self-regulation
927 under emotional strain. Setbacks are explicitly addressed and conceptualised as an integral
928 component of a dynamic self-regulation process.

929 **Module 11: Integration and transfer**

930 The final module focuses on integrating and consolidating the competencies acquired
931 throughout the programme. Core contents are synthesised into an individual self-regulation

932 motto, which serves as a condensed, personally meaningful representation of the participant's
933 self-regulation strategy. This motto is intended to support the long-term transfer of self-
934 regulation competencies into everyday life beyond the intervention period.

935 Across all modules, PSRT emphasises experiential learning, reflective exercises, and
936 structured between-session tasks. The intervention is conducted strictly manual-based by a
937 trained psychologist, and fidelity is supported through standardised materials and structured
938 supervision.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Additionalfile1SPIRIT2025Checklist.xlsx](#)