Trials

STUDY PROTOCOL

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Formulation-based cognitive behavioral therapy compared to an active control and a waitlist in adult inmates with ADHD: study protocol for a randomized controlled trial

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Abstract

Background Recent literature suggests that ADHD is a risk factor for the development of antisocial behavior that is more severe and persistent than in community and other psychiatric populations. The combination of stimulant medication and psychotherapy (particularly cognitive behavioral therapy, CBT) is considered an evidence-based intervention for adults with ADHD. In contrast, few studies have evaluated the efficacy of medication in adult prisoners with ADHD, and the literature on the efficacy of psychotherapy is virtually nonexistent. Therefore, this article presents the protocol of a trial that will assess the efficacy of a formulation-based CBT program for inmates with ADHD.

Methods The study has a multicenter randomized controlled trial design. After screening and recruitment, participants will be randomly assigned to the CBT intervention, a general offender treatment program, or a waitlist. Pre- and post-treatment self-report and clinician-report assessments, as well as 6- and 12-month follow-up assessments will be conducted. These will include both clinical (e.g., ADHD symptoms, depression and anxiety symptoms, self-esteem, alcohol/drug abuse, treatment adherence, quality of life) and criminological (e.g., recidivism and risk of recidivism) measures. Linear mixed models will be used to assess differences between groups.

Discussion This study may be the first to evaluate the efficacy of a psychotherapy intervention in adult inmates with ADHD. It is expected that addressing the specific needs of ADHD would not only result in the previously reported clinical improvements (e.g., reduction in ADHD and comorbidity symptoms), but also reduce the risk and rate of recidivism compared to the general intervention or no intervention. However, the design may be limited by the difficulties inherent in the prison setting and in following up the sample after release.

Trial registration ClinicalTrials.gov NCT06080373. Registered on October 12, 2023.

Keywords ADHD; Cognitive behavioral therapy, Formulation-based psychotherapy, Inmates treatment

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Background

Attention-deficit/hyperactivity disorder (ADHD) is a childhood-onset neurodevelopmental disorder with an estimated adult prevalence of 2.6% to 2.8% [1, 2]. When persistent, the disorder is highly comorbid [3] and is associated with significant impairment in major domains of functioning, such as academic/occupational performance, social relationships, physical health, or socioeconomic outcomes [4, 5].

Relationship between ADHD and criminal behavior

Involvement in criminal behavior is another major area of impaired functioning often associated with adult ADHD [6]. Recent literature suggests that this antisocial behavior is one of the most serious long-term psychosocial consequences of living with ADHD since childhood [7]. Longitudinal studies have consistently found a significant association between childhood ADHD and increased risk of arrest, conviction, and incarceration in adulthood [8–10], at younger ages [11], and even with subthreshold ADHD [12]. Furthermore, the prevalence of ADHD is up to ten times overrepresented in the forensic population, with estimates ranging from 25.5 to 26.2% among inmates [13, 14]. Offenders with ADHD also reoffend more quickly and have higher recidivism rates [15], even when controlling for general risk factors (e.g., antisocial personality disorder) [16]**.** However, offenders with ADHD have significantly more risk factors than protective factors [17] and have higher levels of psychopathology compared to offenders without ADHD [18], with a higher risk of other concurrent psychiatric disorders that increase throughout adulthood [19]. In addition, they are at increased risk of becoming victims of criminal offenses [20]. Furthermore, while incarcerated, inmates with ADHD are at higher risk of exhibiting more frequent and more severe behavioral problems, which may hinder their rehabilitation and prolong their conviction. Compared to non-symptomatic inmates, are more likely to commit disciplinary infractions in prison [21] and engage in violent behaviors [22], such as verbal or physical aggression [23]. Also, according to Retz and Rösler's [24] classification, reactive-affective antisocial behaviors are more consistent with ADHD symptoms, as opposed to instrumental and premeditated violence, which is usually more associated with offenders with antisocial personality disorder traits without ADHD. Recent literature supports this hypothesis, suggesting that ADHD is a significant risk factor for the development of violent and impulsive offending [25], including intimate partner violence [26], physical abuse, shoplifting, and driving offenses [4]. In conclusion, individuals with ADHD are greatly overrepresented in the forensic population, and the disorder is associated with more difficult behavior in prison and an increased risk of recidivism.

Potential mechanisms underlying the increased rate of offending in ADHD

Although still far from fully understood, several potential underlying mechanisms have been proposed to explain this higher rate of criminal behavior in adults with ADHD. First, some neuroscientific explanations have been proposed. Neurocognitive deficits, such as delay aversion, impaired response inhibition, impairments in executive functions, and emotional dysregulation, have been consistently associated with ADHD [27–29] and play a key role in the development and persistence of antisocial behavior [30]. Similarly, certain genetic constellations, such as those involved in serotonergic circuits, which interact with certain adverse environmental conditions, could also increase the risk of antisocial behavior in ADHD patients [24]. Second, other possible explanations may come from criminology. One of the most relevant theories in this area is Moffit's Taxonomy of Crime [31]. Moffit's theory suggests that neuropsychological deficits, such as those underlying ADHD, may, in fact be a major cause of more pervasive, lifelong antisocial behavior. Furthermore, in their classic general theory of crime, Gottfredson and Hirschi [32] argued that deficits in self-control are involved in the etiology of criminal behavior, attributing low self-control primarily to inadequate parenting. There is also growing evidence supporting this theory in adults with ADHD, such as findings that parental supervision increases self-control and reduces the likelihood of adult delinquency [33], while parental incarceration, psychopathology, and ADHD symptoms increase the risk of later delinquent behavior [34]. Third, other psychosocial factors may also influence the trajectory from childhood ADHD symptoms to criminal behavior. Socialization problems have often been suggested as one of these important factors. For example, a cross-sectional retrospective study found that poor social connectedness may mediate the relationship between childhood ADHD symptoms and antisocial behavior [35]. Also, impaired academic functioning in children and adolescents with ADHD, which in turn is a general risk factor for delinquency [36], seems to be involved in the increased risk of antisocial behaviors in this population [37]. Additionally, the high comorbidity of ADHD with some externalizing disorders, such as substance abuse, seems to increase the risk of delinquency [6, 38]. However, the role of comorbidity between ADHD and conduct disorder in the development of antisocial behavior is still unclear. While some authors have found that ADHD no longer predicts adult offending when controlling for conduct disorders [26] and that conduct

disorder must mediate the relationship [39], others have found a direct effect of ADHD symptoms [4]. Fourth, the cognitive behavioral model of ADHD argues that neurobiological impairments hinder the development of adaptive compensatory behaviors and instead increase the likelihood of avoidant behaviors learned through negative reinforcement [40]. This dynamic, in turn, may be related to the differential reinforcement involved in learning criminal behavior [41]. In summary, there appear to be several neurobiological, criminological, psychosocial and behavioral factors that could explain the potential mechanism underlying the higher rate and severity of antisocial behaviors in ADHD individuals.

Treatment of adult ADHD

Stimulants are considered the first-line treatment for ADHD symptoms in adults [42]. In addition, there is recent preliminary evidence of their efficacy on offenders with ADHD. One retrospective study found that delinquency rates were significantly reduced during periods when patients were taking ADHD medication [43] or when they were treated during childhood [44]. Other experimental studies have found that methylphenidate reduced ADHD symptom severity, improved global functioning [45], and reduced drug relapse [46] in inmates with comorbid disorders, and these improvements were sustained for up to 3 years [47]. Nevertheless, other authors have warned of the potential risk of stimulant abuse in the prison setting, proposing to replace them with alpha-2 agonists such as clonidine or guanfacine [48]. However, these early results should be replicated with more rigorous methodologies and in combination with other evidence-based interventions, such as psychosocial treatments.

In addition to this pharmacological treatment, there is a growing body of literature suggesting that psychotherapy, particularly cognitive behavioral therapy (CBT), may help improve core ADHD symptoms [49], comorbid internalizing [50], and associated externalizing problems [51]. While manualized CBT programs have yielded positive results [52, 53], there is also growing evidence for the efficacy and feasibility of formulation-based approaches [54]. A formulation-based approach may be more appropriate to address the needs of ADHD offenders, given their high heterogeneity and comorbidity [55]. However, research on psychotherapy for offenders with ADHD is almost non-existent. CBT-oriented programs such as «Reasoning and Rehabilitation» (R&R) [56] have been proposed for use with prison inmates [57], but to our knowledge, it has not been studied in offenders with ADHD. Recently, an observational study evaluated a combination of a treatment based on the Risk Need Responsivity (RNR) model [58] for intimate partner violence and a more specific intervention for ADHD (psychoeducation, medication, and skills training) for 209 offenders with ADHD in a forensic psychiatry setting [59]. They found that improvements in intimate partner violence were primarily associated with reductions in ADHD symptoms. Thus, previous studies have found that cognitive-behavioral interventions are associated with improvements in core ADHD and comorbid maladaptive behaviors, but the efficacy of these interventions with ADHD offenders has not been thoroughly investigated.

Treatment as usual in European prisons

Despite the high prevalence of psychiatric disorders among inmates [60], rehabilitation interventions in most European prisons are either offense-specific (e.g., for sex offenders or domestic violence) or focused on severe mental disorders [61]. Nevertheless, according to the RNR model [58], offenders affected with psychiatric disorders may benefit from disorder-specific treatments [62]. In fact, a recent meta-analytic review found a significant effect of psychological interventions such as CBT on anxiety, trauma, and anger in the incarcerated population [63]. Since ADHD is one of the most prevalent and disabling conditions among inmates. Therefore, it may be reasonable to assume that ADHD symptom-specific treatment may be particularly effective for inmates diagnosed with this disorder, both for criminological and clinical outcomes.

Objectives

Thus, the main aim of this study is to examine the feasibility and potential efficacy of a formulation-based (i.e., not manualized, based on functional analysis) CBT intervention among inmates diagnosed with ADHD. We hypothesize that an intervention specifically targeting ADHD-related behaviors would not only improve clinical outcomes such as ADHD symptomatology and emotional comorbidities but would also reduce the likelihood of future antisocial behavior compared to standard offense-specific interventions or no intervention.

Methods/design

This study adheres to the principles stated in SPIRIT [64]. It has been registered in ClinicalTrials.gov with the number NCT06080373.

Trial design

The trial has a multicenter, three-arm design (see Fig. 1). There will be two study sites: Valencia (Spain), and Homburg (Germany). A sample of inmates diagnosed with ADHD will be randomly assigned to a CBT program specifically designed for ADHD offenders, to a generic treatment for general offenders, or to a waiting list control

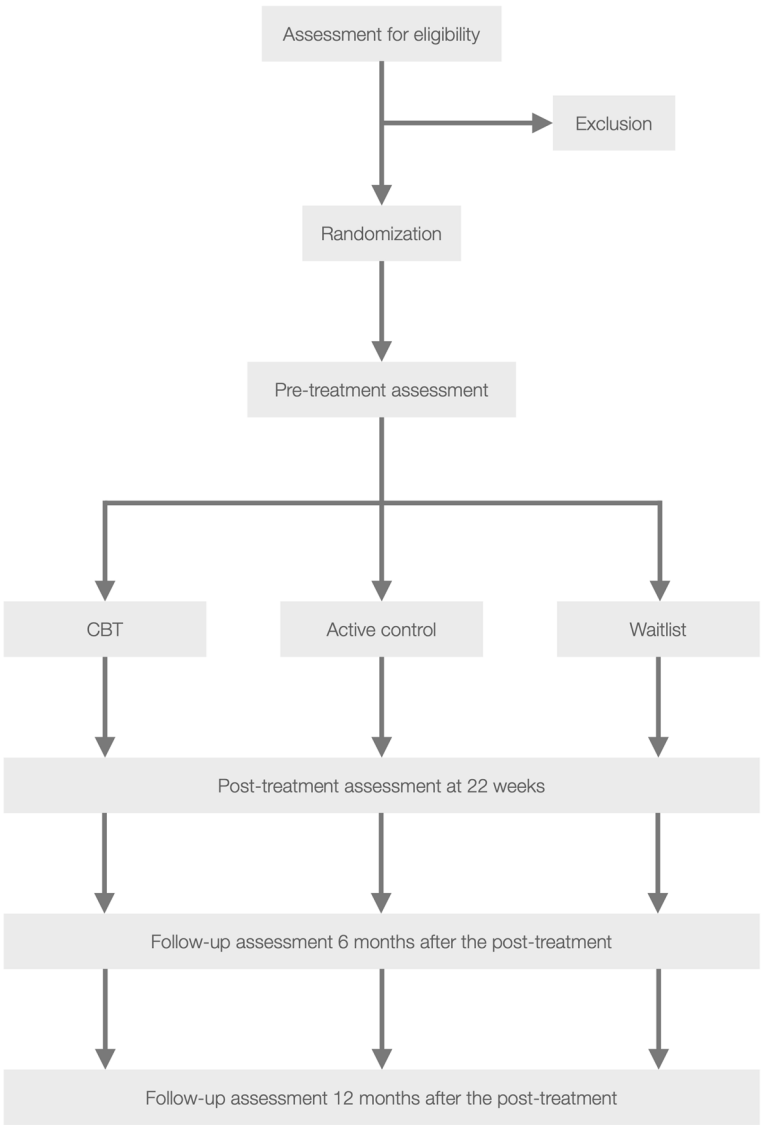

Fig. 1 Flowchart

group. The latter two will be used as control groups for the CBT program and will be referred to hereafter as the active control and waiting list control groups, respectively. Although international guidelines recommend a combined intervention of medication and psychotherapy for adults with ADHD [65], Prison Health Services indicated that prescribing ADHD medication was not possible for regulatory and logistical reasons. For ethical reasons, the CBT program will also be offered to participants in the waiting list group at the end of the study.

Ethics

This study adheres to the tenets of the Declaration of Helsinki [66] for research involving human subjects and will be conducted following the ethical approval (code number 23.318) of the Ethics Committee of the European University of Valencia. Participants will be asked to sign an informed consent form before participating in the study. The study is expected to be open for recruitment in 2024. Any further changes to the protocol must be approved by the Ethics Committee.

Although CBT is generally considered to be a safe and effective treatment for a variety of psychological problems, because this is a phase II study, adverse events and complications may occur and should be monitored. These could include an initial increase in anxiety or distress, substance withdrawal symptoms, and/or a decrease in self-esteem due to increased awareness.

These complications will be monitored by the therapists. In cases where these complications are more important than the potential benefits of the intervention, the therapists will meet with the principal investigator to decide whether the participant can continue or whether it is safer to discontinue the CBT intervention and offer him/her a more established intervention.

Eligibility criteria

Participants must meet the following criteria: (1) be between 18 and 65 years of age; (2) meet the DSM-5 diagnostic criteria for ADHD (American Psychiatric Association, 2013); (3) have been convicted of at least one crime under Spanish or German criminal law; and (4) have been incarcerated for at least 6 months and 3 or fewer years since the completion of the conviction at the time of eligibility assessment.

In addition, participants will be excluded if they meet any of the following criteria: (a) have a severe personality disorder (e.g., as primary diagnosis), psychotic disorder, or pervasive developmental disorder as their primary diagnosis, as the intervention would not meet their clinical needs; (b) have an IQ of 80 or less, as measured by a standardized IQ test (Raven et al., 1993), due to the complexity of the cognitive components in the CBT program; (c) have participated in a previous psychological intervention for ADHD; and (d) not be fluent in Spanish or German, depending on the study site.

Procedure

The schedule of enrollment, interventions, and assessments as recommended by SPIRIT is shown in Fig. 2.

Recruitment

First, a trained psychologist will explain all the details of the study to inmates who meet the inclusion/exclusion criteria. After reading and signing a written informed consent, they will be screened with the ADHD Rating Scale, ADHD-RS [67] for Spanish sites, and Conners Adult ADHD Rating Scale, CAARS [68] for German sites. Participants with a significantly high score will be further assessed for eligibility. Once a participant is enrolled or randomized, the study site will make every reasonable effort to follow up with the participant throughout the study period, contacting the participant every 3 months after treatment completion as a reminder of upcoming assessments.

Eligibility assessment

Participants will undergo a diagnostic assessment to confirm an ADHD diagnosis, conducted by trained psychologists and psychiatrists experienced in the assessment and treatment of this population. The DIVA-V structured interview [69] will be used to assess the presence of current and childhood ADHD symptoms, while differential diagnosis and assessment of comorbid symptoms will be conducted using the Mini-International Neuropsychiatric Interview-Plus (MINI-Plus) [70]. In addition, to increase reliability, information is required from at least one person significant to the participant (e.g., spouse, parent, sibling, offspring, close friend) using the ADHD-RS scale to assess current symptoms and the Wender-Utah rating scale [71] to assess childhood symptoms. In cases where the significant other and the participant disagree, the evaluator will assess the presence and intensity of symptoms based on all clinical information obtained during the diagnostic assessment.

Effectiveness assessments

Participants will be assessed before the beginning (t1) and after completing (t2) each treatment program. At least two follow-up assessments will also be conducted at 6 (t3) and 12 months (t4) after completion of the interventions (see Fig. 1). Primary independent assessments of clinical and criminological outcome measures (e.g., CAADID, CGI, HCR-20) will be performed by an independent assessor blinded to treatment assignment.

Randomization and allocation procedure

An independent researcher, not involved in the interventions or in the data analysis, will conduct the randomization and allocation. Participants will be randomly assigned to one of the three groups using a permuted block randomization algorithm in the Randomizer.at software [72], stratified by age, and the primary offense of conviction. Eligible participants will be allocated to groups by this independent investigator using a web-based service that is independent of the trial site and that conceals the order of allocation. The enrolling researcher will contact this independent researcher to receive the allocation after the participant is deemed eligible for the study. The allocation will be communicated to the CBT program and control group therapists via e-mail and securely recorded in an electronic file.

Outcome measures

Clinical outcomes—independent blinded evaluator

1. *Conners Adult ADHD Diagnostic Interview for DSM-IV (CAADID)* [73]. This is considered one of the primary outcomes. The CAADID is a structured interview divided into two parts. Part I may be self-administered or clinician-administered and collects information on the subject's demographic history, developmental history, associated risk factors, and comorbidity, while Part II must be administered by

		STUDY PERIOD					
		Enrol-ment	Allo-cation	Post-allocation			
	TIMEPOINT	$-t_1$	0	*Pre-treatment,* t_1	*Post-Treatment,* t_2	*Follow-up 6 months,* t_3	*Follow-up 12 months,* t_4
Enrolment	Eligibility screen	X					
	Informed consent	X					
	Allocation		X				
Interventions	CBT			←	→		
	Active control			←	→		
	Waitlist			←	→		
Assessment	DIVA	X					
	MINI-Plus	X					
	WURS	X					
	ADHD-RS	X		X	X	X	X
	CAADID			X	X	X	X
	CGI			X	X	X	X
	BDEFS			X	X	X	X
	BDI-II			X	X	X	X
	BAI			X	X	X	X
	RSES			X	X	X	X
	MAP			X	X	X	X
	AAQoL			X	X	X	X
	Reoffending rate				X	X	X
	HCR-20			X	X	X	X
	Homework compliance			X	X	X	X

Fig. 2 The schedule of enrolment, interventions, and assessments (as per Standard Protocol Items: Recommendations for Interventional Trials SPIRIT)

a trained clinician and assesses DSM-IV criteria for ADHD in adults. Only Part II will be used for the study, as information on patient history is not relevant for measuring response to interventions.

2. *Clinical Global Impression (CGI)* [74]. Is a three-item observer-rated scale that measures illness severity, global improvement or change, and therapeutic response. It is a widely used, robust measure of efficacy in clinical trials. The global functioning outcome provides a measure of the impact that symptoms have on daily functioning in various life domains (e.g., social, family, work, personal, and academic, among others).

Clinical outcomes—self-reported

3. *Attention-deficit/hyperactivity rating scale-IV (ADHD-RS)* [75]. This measure will be the primary self-reported outcome. The scale includes 18 items

that reference DSM-IV criteria [76], and it is used to determine the presence and severity of current ADHD symptoms. Each item is scored from 0 (*never, rarely*) to 3 (*often*). This measure has high validity and reliability and has been widely used both for clinical and research purposes.

4. *Beck depression inventory-II (BDI-II)* [77] and *Beck Anxiety Inventory (BAI)* [78]. These are some of the most commonly used self-report instruments to assess the severity of depressive and anxiety symptoms, respectively. A total score is obtained from the sum of its 21 items, with higher scores indicating higher levels of depression or anxiety.
5. *Rosenberg self-esteem scale (RSES)* [79]. This 10-item scale provides a unidimensional measure of global self-esteem and acceptance of self-worth.
6. *Adult ADHD Quality of Life Questionnaire (AAQoL)* [80]. It is an ecologically valid measure of the quality of life designed specifically for adults with ADHD. It consists of 29 items corresponding to four domains particularly relevant for patients with ADHD: productivity, psychological health, social relationships, and life perspectives.
7. *Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)* [81]. This questionnaire, endorsed by the World Health Organization (WHO), serves as a screening tool to assess different levels of problematic or risky substance use among adults. It consists of eight questions and covers a wide range of substances, including tobacco, alcohol, cannabis, cocaine, amphetamine-type stimulants (including ecstasy), inhalants, sedatives, hallucinogens, opioids, and other drugs. A risk score is determined for each substance, and these scores are categorized into three groups: "low risk," "moderate risk," or "high risk."

Clinical outcomes—therapist-reported

8. *Treatment adherence.* In order to measure adherence more objectively, attendance at treatment sessions and completion of homework assignments are systematically recorded by the therapist at each session.

Criminological outcomes

9. *Reoffending rate.* This will be the primary criminological outcome. Police records will be checked every 6 months after the end of treatment to look for new arrests. We will also try to check court and prison records for new convictions and incarcerations. However, access to this information may be very limited in European criminal justice systems, so it may be difficult to obtain.
10. *Historical Clinical Risk Management-20 (HCR-20)* [82]. This instrument is a guide to predicting violence risk in inmates and psychiatric patients, providing a probabilistic prediction of the risk of future antisocial behavior. A trained rater must assess the presence of 20 past, present, and future risk factors organized into three different scales. The HCR-20 includes both dynamic and static risk factors. Three levels of risk can be identified without initial reference to explicit tables, scales, or cutoff points: low, moderate, or high (and imminent).

Interventions

CBT intervention

Participants randomized to the CBT group will receive a minimum of 13 and a maximum of 22 sessions of individual formulation-based CBT. It will be delivered by psychologists trained in CBT, according to a manual that will be available soon. Prior to intervention, a behavioral assessment is conducted to operationalize each case's clinically relevant behaviors, antecedents, and maintenance stimuli. Based on the principles of Behavioral Functional Analysis, each case will be formulated and presented to the participant in simple and easy-to-understand language. To illustrate this, a schematic formulation of the typical case of an adult with ADHD is shown in Fig. 3. Specific behavioral goals will then be agreed upon for each participant. To achieve these goals, various treatment strategies will be presented in the following sessions. In contrast to more classic manualized CBT interventions, in our proposal, the choice of strategies, the order in which they are applied, and the duration of each module are customized for each participant according to the case formulation. In addition, the number of sessions will vary from 13 to 22 depending on the specific needs of every participant based in the case formulation. They are grouped into the following core modules:

A. *ADHD psychoeducation*. This module consists of providing basic information about the core characteristic behaviors of the disorder and its comorbidities, the underlying neurobiology, the various treatments available and what the current literature suggests about their efficacy, and the complex relationship between ADHD and antisocial behavior. When available, this information will be provided to at least one significant other (e.g., spouse, children, parents, close friends).
B. *Planning skills and distraction management.* The premise of these sessions will be to replace avoidance

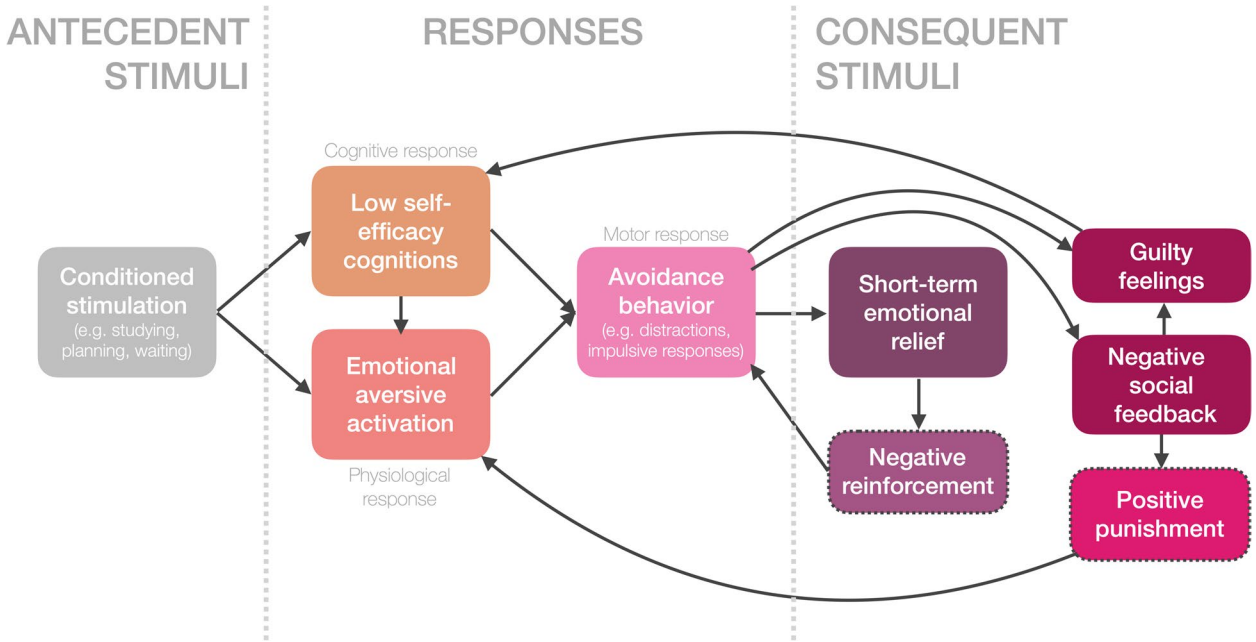

Fig. 3 Case formulation through behavior functional analysis

behavior (e.g., procrastination, distraction, impulsive decisions), which are negatively reinforced by a new one in which the participant performs actions in line with his or her values, and that this is positively reinforced. To achieve this, several strategies will be introduced. Participants will be taught to develop planning skills such as daily use of a to-do list and calendar, prioritizing urgent tasks, and breaking down long and overwhelming tasks into more manageable subtasks. In addition, according to Safren et al. [83], *distraction delay* will be presented. Participants will be asked to set a timer to break up a long task into shorter periods, depending on their attention span, and will be prompted to delay any internal distraction for the short break that follows. By adopting a stimulus control approach, unnecessary and potentially distracting stimuli will be removed from the environment. To maintain these new behaviors over time, the use of positive short-term self-reinforcement will be also introduced, according to their reinforcement system.

C. *Cognitive restructuring techniques.* Cognitive restructuring based on Ellis' Rational Behavioral Emotive Therapy [84] will be presented in these sessions. This is intended to be one of the most important skills for participants to improve emotional regulation and thus reduce impulsive behavior. First, through everyday examples, participants will be taught that in a given situation (element "A"), private verbal behavior (element "B") has a significant impact on emotional and operant behavior (elements "C"), and that by modifying irrational thoughts, they could regulate their own emotional and operant behavior. Participants then discuss the rationality of their thoughts with the help of the therapist using a Socratic approach. The aim of this discussion is to check whether such thoughts meet the four criteria of rationality: being based on objective information, producing a proportional emotional response, being useful to the participants' goals and values, and being expressed in flexible, moderate, and probabilistic language, expressing desires rather than strict demands. The discussion procedure will follow the proposal of Pastor and Sevillá [85]. These sessions will focus on recent episodes in which the participant presented a maladaptive emotional activation or behavior. Ultimately, the goal of this module is for participants to be able to identify and actively discuss potential irrational thoughts in their daily lives.

D. *Maintenance of treatment gains.* Finally, the extent to which the initial objectives have been achieved, both quantitatively and qualitatively, will be reviewed. Afterward, the risk factors present at the end of treatment and those that could eventually appear (e.g., release from prison, employment problems…) will be reviewed, and the participant will be helped to develop a concrete action plan to address them, based on the strategies seen in the previous modules.

To address the common comorbidities of ADHD, these core skills could be supplemented in some cases with some complementary modules, such as:

I. *Management of anxiety symptoms.* Evidence-based CBT strategies will be used to treat anxiety problems when necessary. According to recent literature [86], such intervention will be mainly based on the exposure therapy approach.
II. *Treatment of depression symptoms.* In line with recent evidence on the treatment of depression [87], these additional sessions will be based on the principles of behavioral activation, encouraging the participant to reconnect with positive environmental reinforcement. In addition, strategies from the cognitive techniques' module will be applied here for to manage depressive beliefs.
III. *Addictive behaviors.* This module introduces evidence-based CBT interventions based on relapse prevention strategies.

Active control—PROBECO and social therapeutic establishments

The Spanish participants assigned to the active control group will receive the PROBECO [88]. It is a group program designed by the Spanish Penitentiary Agency for its application with inmates convicted of different types of violent crimes (e.g., threats, theft, injuries, assaulting the police, economic and environmental crimes, animal abuse, among others). Its main goals are to eradicate criminal behavior and reduce recidivism, to modify the relevant dynamic risk factors related to general delinquency, and to introduce new social skills and prosocial values. It consists of four phases: (I) general intervention: aimed at the acquisition of social skills; (II) specific intervention: consists of four specific educational itineraries; (III) relapse prevention; (IV) follow-up.

Similarly, German participants will be assigned to a special type of prison known as a social therapeutic facility, where they will undergo compulsory psychotherapy focused primarily on relapse prevention.

Data analysis

All data will be entered electronically at each study site and shared with the main study site for data analysis. All assessment instruments or other documents related to the study will be identified only by a coded identification number to ensure participant confidentiality. This ID number will also be used in the electronic database. Original study assessment instruments and forms will be recorded and kept on file at the participating site. A subset will be requested later for quality control. It is anticipated that a data monitoring committee or interim analyses will not be necessary due to the minimal known risks of the interventions. At the end of each evaluation point, independent researchers will review a randomly selected sample of the data entered into the database for completeness and accuracy. There will be no restrictions on access to the final data set for anyone in the research group.

Data will be analyzed using a linear mixed model to estimate between-group differences over time. Independent, blinded evaluator and self-report measures of ADHD symptoms and reoffending rate will be considered primary outcomes. The remaining measures (e.g., clinical global impression, comorbid symptoms of anxiety, depression, substance abuse, self-esteem, treatment adherence, and risk assessment) will be considered secondary outcomes. Randomized intervention (CBT, active control, or waitlist), time (t0, t1, t2, and t3), and intervention*time interaction will be used as fixed effects. Clinical (treatment adherence; ADHD symptom severity and comorbid symptomatology at baseline) and criminological variables (sentence length at baseline, number of prior convictions) and within-subject change over time will be added as random factors. Effect sizes (ES) will be calculated for each outcome measure. In addition, a multiple regression analysis will be conducted with change in recidivism at t1, t2, and t3 as the dependent variable and change in ADHD symptoms measured by CAAID and ADHD-RS at t1, t2, and t3 as predictors. Clinical (treatment adherence; ADHD symptom severity and comorbid symptomatology at baseline) and criminological (length of sentence at baseline, number of prior convictions) variables will also be included as covariates in the analysis. The initial analysis will be conducted with completers, and an additional intent-to-treat analysis will be conducted using the last observation carried forward method. A significance level of $\alpha = 0.05$, two-tailed will be used for all the analyses. Following Cohen`s rule-of-thumb [89], ES values of 0.02, 0.05, and 0.08 will be considered small, moderate, and large, respectively. All statistical analyses will be performed using IBM SPSS Statistics, version 28, and R [90].

An a priori power analysis was performed using G*Power3 [91], with four measures for the primary outcomes. We set the ES at 0.3 and the alpha at 0.05. The results indicated that a total sample of at least 111 participants (approximately 37 participants in each arm) is required to achieve a power of 0.95.

Discussion

This article presents the protocol for a randomized controlled trial to assess the feasibility and acceptability of a psychological intervention for inmates diagnosed

with ADHD. To our knowledge, this will be the first trial to evaluate it in this subpopulation. We expect that this formulation-based CBT program may improve ADHD-related behaviors and other comorbidities, and thereby reduce the likelihood of recidivism, to a greater extent than the traditional offense-focused psychosocial intervention or no receive any intervention. This trial could also provide important preliminary information on the mechanisms of change of the intervention in this population, shedding some light on whether treatment of ADHD symptoms in this population could help them resocialize after their conviction, or whether treatment as usual or a general psychosocial intervention is sufficient. The results of this study will also help determine whether a more ambitious design with a larger sample size is appropriate.

However, the design of this study is not without some limitations that are important to note. First, it may be more difficult to deliver such a treatment due to the limitations of the prison setting. Second, it may be difficult to follow up with participants once they are released from prison, which could reduce the available data on the long-term effects of the treatment. Also, access to court and police records is very limited, so this measure of recidivism could be limited.

In conclusion, this study may provide further information on the feasibility and acceptability of formulation-based CBT treatment for inmates with ADHD. This could help those responsible for the reintegration of offenders to make evidence-based decisions, and offenders diagnosed with ADHD to have better resources to prevent recidivism and improve their clinical picture in a more targeted manner.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-024-08434-w.

Supplementary Material 1.

Trial status

The trial is currently in the pre-recruitment phase and is expected to start in the third quarter of 2024. Recruitment is expected to be completed in the first quarter of 2025. This is protocol version 1.0 (October 2023).

Authors' contributions

CLP, SMS, ECV, JMR, and WR contributed to the conception of the study. All authors contributed to the study design and CP was the study lead. CLP drafted the manuscript. All authors revised the manuscript for intellectual content and approved the final version.

Funding

The project is currently applying for funding from the European Union.

Availability of data and materials

The results of the study will be shared with interested participants and published in a peer-reviewed journal. They will also be disseminated through communications at scientific conferences. Since the sample consists of adult inmates, no data will be available after the study without the permission of the Spanish and German prison authorities.

Declarations

Ethics approval and consent to participate

This study will be conducted following the ethical approval (code number 23.318) of the Ethics Committee of the European University of Valencia. Any changes of the present protocol should be reported to the Ethics Committee. Informed consent materials are attached as supplementary materials.

Consent for publication

Not applicable—no identifying images or other personal or clinical details of participants are presented here or will be presented in reports of the trial results.

Competing interests

CLP, SMS, ECV, and JMR declare that they have no competing interests. WR has received honoraria from Medice, Takeda, and Janssen.

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