The Effect of Virtual Reality-based Social Cognitive Training for Autistic Adults: A Study Protocol for STEPS (Social Cognitive Training Enhancing Pro-functional Skills), a Randomised Clinical Trial

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Abstract

Background: Autistic adults (AA) constitute a growing and largely overlooked population with limited clinical and research resources. Social cognitive impairments are key deficits faced by this population, significantly impacting social interactions, educational and vocational functioning, and quality of life. Interventions targeting social cognition in AA, have shown promising results. Recent studies investigating the effect of virtual reality (VR)-based interventions for AA have provided preliminary evidence supporting the feasibility and effectiveness of utilizing this innovative technology. These studies indicate that VR-interventions can enhance functional and social skills and improve specific neurocognitive and social cognitive functions. However, large scale, randomised, clinical trials are urgently needed to fully assess the effectiveness of VR-based interventions for AA.

Objective: This protocol aims to provide a comprehensive description of the design and methodology of the STEPS trial.

Methods: STEPS is a clinical, randomised, assessor-blinded, parallel-group superiority trial. A total of 140 participants will be allocated to receive either VR-based social cognitive training (VRSCT) + treatment as usual (TAU), or TAU alone. The experimental group will receive 12 weekly, one-hour sessions of VRSCT, aiming at improving psychosocial functioning and social cognition through exposure to virtual social environments. The intervention comprises three core modules: Emotions, Social Understanding, and Complex Social Interactions. The exact content and duration of TAU received by each participant will be mapped and documented upon trial completion. Assessments will be conducted at baseline, at cessation of the intervention (3 months post-baseline), and at 6 months post-baseline.

Results: The trial is currently recruiting participants. The first participant was enrolled in May 2024. Completion of recruitment

is expected in January 2026. Data analysis is expected to commence in summer 2026, following the final six-month follow-up assessment. Results are anticipated by fall 2026 and will be disseminated at international conferences and through peer-reviewed publications.

Conclusions: To our knowledge, STEPS is the hitherto largest randomised clinical trial globally investigating the effect of VRSCT for AA. The results of this innovative intervention approach may significantly advance research in the field of autism. VRSCT holds potential to improve psychosocial functioning, quality of life, co-occurring clinical symptoms and reduce social cognitive deficits in AA. Establishing evidence-based interventions is crucial for addressing the debilitating psychosocial challenges faced by this population, especially considering the absence of established gold-standard treatments. Clinical Trial: Registered at ClinicalTrials.gov (ID: NCT06438536). https://clinicaltrials.gov/study/NCT06438536?term=NCT06438536&rank=1

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Protocol

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Protocol Version

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Abstract

Background: Autistic adults (AA) constitute a growing and largely overlooked population with limited clinical and research resources. Social cognitive impairments are key deficits faced by this population, significantly impacting social interactions, educational and vocational functioning, and quality of life. Interventions targeting social cognition in AA, have shown promising results. Recent studies investigating the effect of virtual reality (VR)-based interventions for AA have provided preliminary evidence supporting the feasibility and effectiveness of utilizing this innovative technology. These studies indicate that VR-interventions can enhance functional and social skills and improve specific neurocognitive and social cognitive functions. However, large scale, randomised, clinical trials are urgently needed to fully assess the effectiveness of VR-based interventions for AA.
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Trial Registration: Registered at ClinicalTrials.gov (ID: NCT06438536). https://clinicaltrials.gov/study/NCT06438536?term=NCT06438536&rank=1

Keywords: Autism spectrum condition; Virtual reality; Psychosocial functioning; Social skills; Social cognitive training; Emotion recognition; Theory of mind.

Introduction

In this paper, we use the term Autistic Adults (AA), in line with international recommendations [1], to refer to adults on the autism spectrum. Additionally, we use the term autism spectrum condition as an equivalent to autism spectrum disorder, to minimize discriminatory language.

Autism

According to the American Psychiatric Association, autism is defined as a neurodevelopmental condition characterised *by persistent deficits in social communication*, such as difficulties with social-emotional reciprocity, communication and the development, maintenance and understanding of relationships. This is accompanied by *restricted, repetitive patterns of behaviour, interest, or activities*. These clinical characteristics must be present from early development (*but may not become fully manifest until social demands exceed limited capacities, or may be masked by learned strategies in later life*), cause significant impairment in psychosocial functioning, and cannot be better explained by other intellectual or developmental conditions [2]. Autism is a life-long condition affecting approximately 1-2% of the global population [3]. The prevalence rate is increasing [4,5] as well as the lifelong economic impact associated with the condition. In 2019 *the estimated lifetime social cost* of an individual on the autism spectrum was approximately $3.6 million in the United States, with the largest costs associated with lost productivity and adult care [6]. These costs should not be attributed to individuals on the autism spectrum but should rather be regarded as a consequence of inadequate support and accommodations in educational/occupational settings and lack of effective interventions that address the specific challenges faced by the autistic population. These obstacles are particularly pronounced for AA, as many experience lack of appropriate interventions and support [7], are being vastly underrepresented in the work force, and are at heightened risk of depression and suicidal actions compared to the general population [8–11]. Despite the critical need of interventions and support systems aimed at improving outcomes for AA, research on autism has primarily focused on children and adolescents overlooking the growing population of adults who face extensive unmet treatment needs [12].

Social Cognition in AA

Social cognitive impairments are key deficits faced by AA [13], which severely impact social interactions, hinder educational and vocational functioning, and compromise quality of life [14–16]. *Social cognition* can be defined as "(…) *the mental operations that underlie social interactions, including perceiving, interpreting, and generating responses to the intentions, dispositions, and behaviours of others*." [17]. The social cognitive deficits in autism encompass both the more basic functions such as recognizing emotions or making appropriate eye contact and higher order functions such as inferring others mental states (theory of mind) or understanding subtle aspects of social communication [18,19]. These functions are vital to understanding and reacting adequately to dynamic, complex social situations in all aspects of life, from making friends and building intimate relationships in private life, to being able to participate appropriately in an educational or professional settings.

Interventions Targeting Social Cognitive Impairments

Targeting social cognitive deficits in AA has been shown to improve psychosocial functioning [20,21]. While preliminary evidence supports the effectiveness of targeted social cognitive interventions for this population [22], the existing studies are limited in number and suffer significant methodological limitations such as not being randomised clinical trials, or having small sample sizes ($n \leq 17$) categorizing them as pilot studies.

VR in Mental Health

The use of VR holds great potential for mental health interventions by enabling researchers and clinicians to evoke psychological reactions to life-like scenarios in real-time within a controlled laboratory environment. VR serves as a powerful tool for delivering exposure therapy, as it creates a safe, flexible, and controlled space for immersive exposure to challenging situations. This approach allows individuals to practice confronting real-world challenges without facing the consequences of real-life situations, while also reducing the social pressure often associated with face-to-face interactions [23]. As a result, VR exposure is considered an effective tool for treating various psychological problems, with minimal risks of adverse side effects [24]. Additionally, creating in vivo exposure to challenging social situations in daily life is often difficult to arrange, nearly impossible to control, and can be overly stressful for participants, making engagement in such settings challenging. Interventions using VR exposure can overcome these obstacles by offering complete control over various scenarios and their elements, leading to greater user acceptance. As a result, participants may be more inclined to engage in exposure therapy when it is provided in a VR setting [25]. Additionally, VR enables the creation of highly personalised interventions by allowing control over the level of exposure, tailoring scenarios to individual needs, and making real-time adjustments.

VR-based Interventions for AA

By utilizing VR exposure in interventions targeting social cognitive challenges in AA, it becomes possible to assess real reactions and responses to life-like challenging social situations, allowing access to the real-time cognition of the participant in such situations. This approach might be of particular importance for intervention aimed at individuals on the autism spectrum, since self-awareness and self-insight are often compromised by alexithymia (difficulties in identifying and describing one's own emotional state) [26]. Alexithymia can hinder the accurate assessment of psychosocial difficulties in interventions, as more traditional approaches often require individuals to describe their own emotions. Therefore, using VR exposure might enhance assessment accuracy and, in turn, enable more personalised and effective interventions. Furthermore, individuals on the autism spectrum may prefer technology-based interventions [27], and preliminary evidence indicates that VR-based interventions leads to faster symptom reduction than traditional psychological interventions [28,29]. Research on VR-based interventions for individuals on the autism spectrum has gained significant momentum in recent years. Most previous studies have investigated interventions targeting specific functional domains, such as job interviewing skills, driving skills, and adaptive socials skills [30,31]. While some studies have examined the impact of VR-based interventions on cognition in individuals on the autism spectrum, these studies have primarily addressed specific neurocognitive domains and daily life skills [32], with comparatively fewer studies investigating social cognition [33,34]. The results of these studies have provided preliminary evidence supporting the feasibility of VR-based interventions for individuals on the autism spectrum. These studies have yielded promising results, indicating positive effects on specific functional and social skills, as well as neurocognitive domains like attention, memory, and executive functioning and social cognitive domains including emotion recognition and theory of mind. However, the findings are limited by small sample sizes, lack of randomised, clinical trials, and insufficient long-

term follow-up. Additionally, most research has focused on children and adolescents. Therefore, large-scale, methodologically rigorous trials are urgently needed to investigate the effectiveness of VR-based interventions for AA to draw more firm conclusions.

Objectives

The aim is to conduct the hitherto largest clinical randomised trial globally, comparing VRSCT + TAU to TAU for AA. The objective is to examine whether VRSCT is effective in improving psychosocial functioning, quality of life, co-occurring clinical symptoms and reducing social cognitive deficits in AA. Additionally, we will examine whether the VRSCT is cost-effective.
We hypothesize the following:

- VRSCT + TAU will be superior to TAU in improving psychosocial functioning, quality of life, co-occurring clinical symptoms and reducing social cognitive deficits in AA.
- VRSCT will be cost-effective in improving daily life functioning and reducing social cognitive deficits in AA.

Trial Design

STEPS is a randomised, assessor-blinded parallel-groups superiority clinical trial. A total of 140 participants will be allocated to receive either VRSCT + TAU or TAU alone. See figure 1 for a flow diagram of the trial. Assessments will be caried out at baseline, at cessation of intervention (3 months post-baseline), and at 6 months post-baseline. A stratified block randomisation with concealed randomisation sequence will be conducted with a 1:1 allocation. Independent assessors, blinded to the treatment, will evaluate outcomes. The analysis of outcomes will be carried out according to the intention-to-treat principle [35].

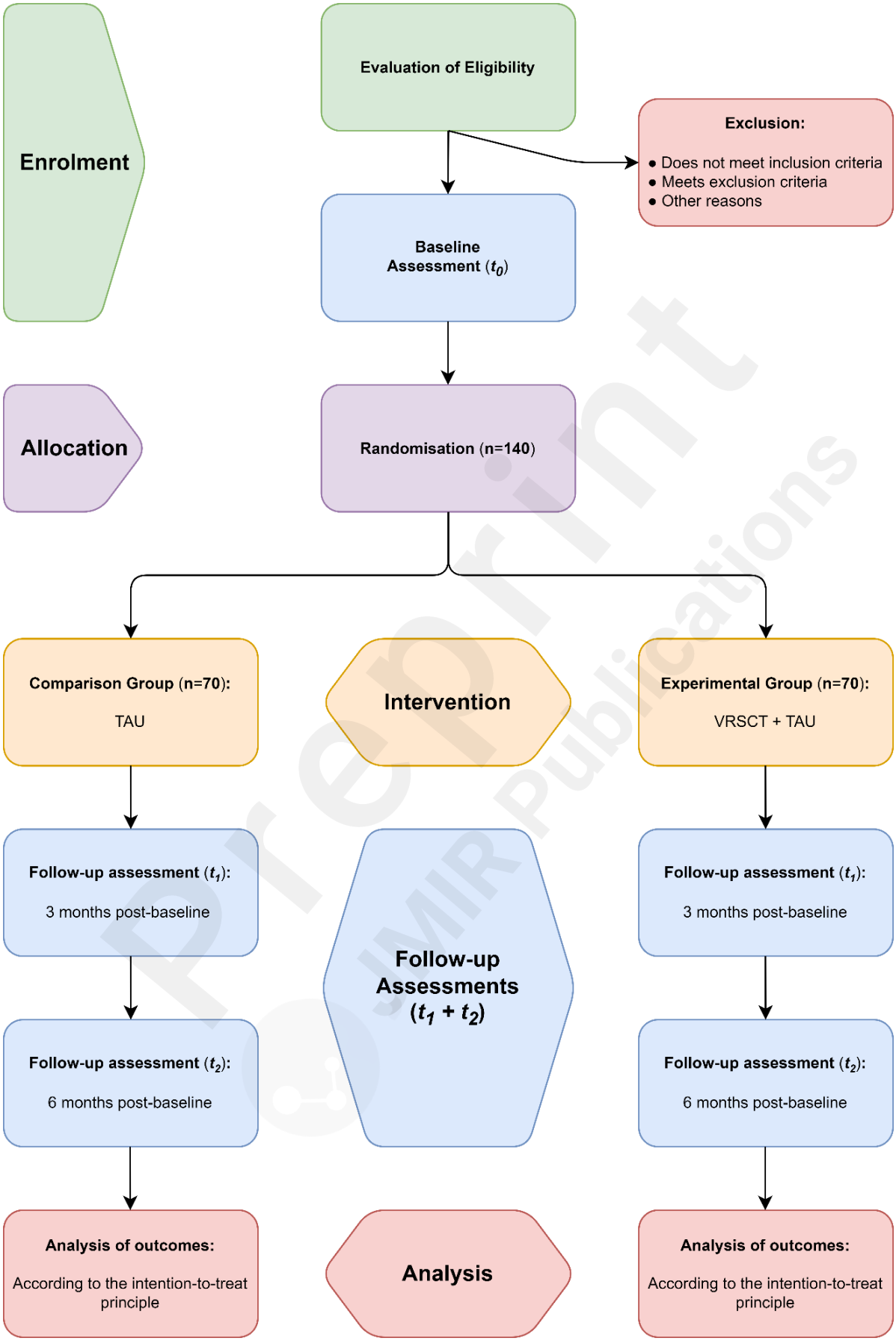

Figure 1: Flow diagram of the STEPS trial

Methods: Participants, Interventions, and Outcomes

Study Setting

The trial will enrol participants from public and private outpatient facilities in Denmark, that are specialising in the clinical assessment and diagnosis of autism in adulthood. The clinical staff at these sites, including nurses, psychologists, doctors, and social workers will approach relevant participants and refer them to the project group. Additionally, relevant participants from community-based social support services in the Capital Region of Denmark will be referred to the trial by the multidisciplinary staff at these locations, provided that a diagnosis of autism based on specialised clinical evaluation can be documented. Assessment, randomisation, experimental intervention, and analysis of outcomes will be carried out by the VIRTU Research Group located at Copenhagen Research Centre for Mental Health, 2900 Hellerup, Denmark.

Eligibility Criteria

Participants must provide written, informed consent prior to the initiation of any assessment or intervention in the STEPS trial. Inclusion and exclusion criteria are listed in table 1.

Inclusion Criteria:	Exclusion Criteria:
1. Age ≥ 18 years 2. Diagnosis of Autism (ICD-10: F84.0; 84.1; 84.5; 84.8) 3. T-*score* of ≥ 60 on the Social Responsiveness Scale Total Score, Second Edition, Adult Form, Self-report	1. A diagnosis of Organic Brain Disease (ICD-10: F00 - F09) 2. Intellectual disability (IQ < 70) 3. Inadequate command of spoken Danish or English for engaging in the assessments and intervention 4. Co-occurring ADHD with medically untreated symptoms 5. Immediate risk of homicide or suicide

Table 1: Inclusion and exclusion criteria of the STEPS trial

As no autism diagnostic assessment will be conducted during the trial, participants are required to provide documentation confirming an autism diagnosis (ICD-10 codes: F84.0; 84.1; 84.5; 84.8) obtained through specialised clinical evaluation. To ensure participants experience significant deficiencies in social interactions, the Social Responsiveness Scale, Second Edition, Adult Form, Self-report (SRS-2A) will be used to assess the level of social impairments. Gender-normed *T*-score of ≥ 60 on the SRS-2A Total Score is chosen as cut-off since a *T*-score of 60 is the lower threshold for mild deficiencies in social behaviours that are clinically significant and may lead to mild or moderate difficulties in daily social interactions [36]. Estimated full-scale IQ will be estimated using the two subtests, Vocabulary and Matrix Reasoning, from the Danish version of the Wechsler Adult Intelligence Scale, Fourth Edition (WAIS-IV) [37], which are known to correlate strongly with full-scale IQ [38]. Participants with co-occurring ADHD must demonstrate a preliminary satisfactory treatment response to ADHD medication at the time of enrolment. This determination will be based on mutual agreement between the participant and the clinician responsible for their ADHD treatment, confirming that targeted ADHD symptoms are well managed. Additionally, no changes in the type or dosage of ADHD medication are permitted within the 4 weeks preceding enrolment in the trial. The

type and dosage of ADHD medicine will be thoroughly mapped and documented at enrolment, and at follow-up assessments. See the section on concomitant care {11d} for further details of this criterion. Additionally, general psychopathology will be assessed with the Danish version of the Mini-International Neuropsychiatric Interview (M.I.N.I.) [39].

Interventions

Explanation for Choice of Comparator

This trial compares the effects of VRSCT + TAU to TAU alone offered to AA in Denmark. TAU usually includes short-term psychoeducation provided by specialised facilities for adults with autism, following psychiatric assessment and diagnosis. Additionally, TAU often involves supportive counselling or practical assistance in daily life situations, delivered in community settings. The exact content and duration of TAU received by each participant will be mapped and documented upon trial completion, enabling examination of potential between-group differences regarding the content and duration of TAU. This definition of TAU as a comparator was chosen, although its specific components are not strictly defined, because it represents the most common intervention currently offered to adults with autism in Denmark. To accurately assess the efficacy of VRSCT, it is essential to compare it against a standard treatment that represents routine, real-world care provided to this population.

Intervention Description

Participants in the *experimental group* will receive 12 weekly, one-hour sessions of VRSCT, with the primary aim of enhancing psychosocial functioning and social cognition through exposure to social environments in virtual reality. See figure 2 for an example of the VRSCT in STEPS.

Figure 2: VRSCT in STEPS; a participant (portrayed by a colleague from the Virtu Research Group) practices conversing with a stranger during a virtual bus ride. The therapist supports the participant while also controlling the stranger's voice and actions.

Relatives are invited to participate in the intervention. Participation of relatives is dependent on the participant's consent. Relatives will participate in one session at the beginning of intervention to add information to the assessment of the participants challenges. Relatives will also participate in one session at the end of intervention to support transfer of learned social skills into everyday life. If participants decline involvement of relatives, this will be registered, and the intervention will consist of 10 individual sessions. This 12-session format is in line with previous positive findings of other short-term interventions (10-14 sessions) targeting social cognition in adults with autism [40,41].

The VRSCT in the trial is a manualised cognitive behavioural therapy (CBT)-based intervention targeting social cognition. The intervention consists of three modules: Emotions, Social Understanding (including Theory of Mind), and Complex Social Interactions. Within these modules, the intervention is highly personalised to meet the specific needs of each participant. The intervention utilizes the *Social Worlds* VR software developed by CleVR. Originally developed for psychotic disorders, the *Social Worlds* software has been adapted to meet the needs of other clinical populations, including personality disorders and autism spectrum conditions [42]. The software enables exposure to different social environments, such as a bus, café, street, supermarket, park, classroom, waiting room, home environment, and an office/job setting. In these environments, social interactions, and roleplays, facilitated by the therapist, can take place. Additionally, the software allows for *perspective switching*, enabling the therapist to record and replay roleplays the participant engages in. These interactions can be replayed from multiple perspectives (e.g., from another person involved or an observer), allowing the participant to experience the situation from someone else's point of view and thereby stimulate theory of mind development. By addressing the participant's individual social interaction challenges through exposure to VR-based social situations and

roleplays, key social cognitive functions can be targeted. These include the speed and accuracy of emotion identification in complex life-like situations, distinguishing relevant from irrelevant social information, and theory of mind. Additionally, daily social communication and functioning are trained by engaging participants in virtual encounters with avatars (e.g., initiating conversations, engaging in small talk, etc.). The *Social Worlds* software allows for a highly individualised and tailored approach by having various daily life scenarios and 100 different avatars. The highly modifiable social interactions in VR allow for addressing social cognitive impairments across a broad range of severities. During virtual engagements, the therapist facilitates CBT-based dialogues to enhance psychosocial functioning, develop new coping strategies, and reduce avoidant behaviour, including social isolation.

Fidelity

All sessions of VRSCT will be audiotaped, and a selected number of sessions will be rated by an independent rater to ensure fidelity to the treatment protocol. Time spent in virtual reality will gradually increase during the first sessions, further building up during the intervention. The exact time spent in virtual reality will be mapped for each session.

Comparison Group

Participants in the *comparison group* will receive TAU alone, that typically comprises short-term psychoeducation provided by the clinical staff at the psychiatric facilities for AA, following psychiatric assessment and diagnosis. Additionally supportive counselling or practical assistance in daily life situations can be provided in community settings by social workers.

Criteria for Discontinuing or Modifying Allocated Interventions

Participants can choose to discontinue the interventions at any given time without any impact on their future psychiatric care. If participants experience a deterioration in their mental health condition during the intervention, this will be considered, and the intervention will be adjusted accordingly. Likewise, follow-up assessments and individual sessions in the intervention may be postponed if participants are unable to attend due to hospitalisation. Any psychiatric hospitalisation and its extent will be mapped upon trial completion.

Strategies to Improve Adherence to Intervention Protocols

Exposure to challenging social environments is a key component of the experimental intervention. Participants may encounter social situations that can provoke discomfort and anxiety. To prevent overwhelming the participant and reduce the risk of dropout, it is essential that the intervention is tailored to each participant’s optimal level of challenge. This ensures that difficult situations are addressed without exceeding their coping abilities. The therapists will maintain this balance through continuous dialogue with participants about their experiences and by promoting adherence to the intervention.

Relevant Concomitant Care and Interventions that are Permitted or Prohibited During the Trial

The prevalence of co-occurring psychiatric diagnoses is very high in AA, with ADHD (25.7%) being the most prevalent comorbid condition, followed by mood disorders (18.8%) and anxiety disorders (17.8%) [43]. The estimated prevalence of ADHD in the total autistic population is varying widely in the literature. Recent meta-analyses estimate the pooled point prevalence rate of ADHD in the autistic population to range from 28% (14) to approximately 38% [44,45]. To enhance the ecological validity of the trial, co-occurring psychiatric conditions and associated medical treatments will not constitute exclusion criteria apart from medically untreated ADHD. As previously mentioned,

participants with co-occurring ADHD must demonstrate a preliminary satisfactory treatment response to ADHD medication at the time of enrolment. This determination will be based on mutual agreement between the participant and the clinician responsible for their ADHD treatment, confirming that targeted ADHD symptoms are well managed. Additionally, no changes in the type or dosage of ADHD medication are permitted within the 4 weeks preceding enrolment in the trial. This criterion is essential due to the relatively high prevalence of co-occurring ADHD in individuals on the autism spectrum. Further many adults are often being assessed for (and diagnosed with) ADHD while undergoing evaluation for autism. As a result, many potential participants may be titrating ADHD medication while being referred to the trial. To be able to effectively distinguish the effects of the trial intervention from those of ADHD medication, this criterion is essential. Furthermore, all psychopharmacological treatments will be thoroughly mapped and documented upon trial completion.

Provisions for Ancillary and Post-trial Care

All participants have access to the Danish public healthcare system before, during, and after participation in the trial. The experimental intervention is considered an add-on treatment to the standard treatment. If post-trial care is needed, it will be provided by the healthcare system and will follow national standards. If participants experience a significant deterioration in their mental health during the trial, the project may initiate a referral for outpatient psychiatric follow-up and treatment. Additionally, participants in the trial are covered by the Danish Patient Compensation Association, which evaluates and covers injuries resulting from healthcare treatment.

Outcomes

See table 2 for an overview of the outcome measures and their assessment time points.

Primary Outcome

- The primary outcome is change of *social impairment* from baseline to intervention cessation, measured at 3-month follow-up. At follow-up assessments, the observation period will comprise the last two weeks, instead of the previous six months as at baseline assessment. The Social Responsiveness Scale, Second Edition, Adult Form, Self-report (SRS-2A) will be used to measure level of social impairment [36]. The SRS-2A is a 65-item self-report rating scale designed to assess social impairments related to autism spectrum conditions [46]. SRS-2A consist of 65-items, scored on a 4-point Likert Scale (0-3). Each item is scaled from 0 (never true) to 3 (almost always true), generating a total score ranging from 0 to 195. The SRS-2A provides a continuous measure of social impairment, where a higher score reflects a greater degree of difficulties with social interactions in everyday life. The SRS-2 has been extensively used in autism research across different age groups, and has demonstrated strong validity and reliability in both children [47,48] and adults [49–51].

Secondary Outcomes

- *Social skills performance* will be measured using the High-Risk Social Challenge task (HiSoC), a standardised performance-based task assessing social-interpersonal skills [52]. HiSoC scoring comprises three primary factors: Affect, Odd Behaviour and Language, and Social-Interpersonal skills. Additionally, an overall impression of the performance is rated. These three factors and the general impression are added to calculate the HiSoC total score.
- *Social impairment* will be measured using the Social Responsiveness Scale, Adult Form, Informant report (SRS-2AI) [36]. The SRS-2AI, a 65-item rating scale, assesses the level of social impairment based on informant observation. Items are rated on a 4-point Likert Scale,

from 0 (never true) to 3 (almost always true), generating a total score range of 0 to 195. The items, while similar in content to the self-report version, are adapted for informant perspective. The SRS-2AI provides a continuous measure of social impairment, with higher scores indicating more severe difficulties with social functioning in everyday life.

- *Social anxiety levels* will be measured by the Social Interaction Anxiety Scale (SIAS) [53]. The SIAS consists of 20 items rated on a 5-point Likert scale, from 0 (not at all characteristics of me) to 4 (extremely characteristic of me). Items 5, 9 and 11 are positively worded items and require reverse scoring. The total SIAS, ranging from 0 to 80, is calculated by summing all item ratings, with higher scores indicating greater social anxiety experienced in social interaction.
- *Emotion recognition* ability will be assessed using the Emotion Recognition Task (ERT) from the Cambridge Neuropsychological Test Automated Battery (CANTAB) [54]. The ERT outcome measures include the percentage and count of correctly and incorrectly identified emotions displayed in images of facial expressions, as well as overall response latencies. These measures can be assessed across individual emotions or as an aggregate across all emotions.
- Level of *empathy* will be assessed using the Empathy Quotient (EQ), a 60-item questionnaire designed to measure empathy in adults with normal intelligence [55]. Each item is scored on a 4-point scale (strongly agree, slightly agree, slightly disagree, strongly disagree), yielding a possible score from 0 to 80, with higher scores reflecting higher levels of empathy.

Exploratory Outcomes

Psychosocial functioning and quality of life

- *Daily life social functioning* will be assessed by the Personal and Social Performance Scale (PSP) [56].
- *Participation in community activities* will be assessed by the Temple University Community Participation Measure (TUCP) [57].
- *Everyday executive function* will be assessed by the Behaviour Rating Inventory of Executive Function - Adult Version, Self-Report (BRIEF-A) [58,59].
- *Perceived self-efficacy* will be assessed by the General Self Efficacy Scale (**GSE**) [60].
- *Defeatist performance attitudes* will be assessed by the Defeatist Performance Attitude Scale (DPAS) [61].
- *Subjective, psychological well-being* will be assessed by the WHO-5 Well-Being Index (WHO-5) [62].
- The EuroQOL five dimensions questionnaire (EQ-5D**)** will be used to assess *health-related quality of life* and to conduct cost-effectiveness analysis [63,64].

Clinical symptoms

- *Sensory reactivity* will be evaluated by the Sensory Reactivity in Autism Spectrum (SR-AS) questionnaire [65].
- Amount of *restricted and repetitive behaviours and interests* will be evaluated by the Repetitive Behaviour Questionnaire-3 (RBQ-3) [66].
- Level of *Intolerance towards uncertain events* will be evaluated by the Intolerance of Uncertainty Scale (IUS-12) [67].
- Level of *alexithymia* will be evaluated by the General Alexithymia Factor Score (GAFS-8) [68].
- *Social camouflaging behaviours* will be evaluated by the Camouflaging Autistic Traits Questionnaire (CAT-Q) [69].
- Level of *attention deficit hyperactivity disorder symptoms* will be evaluated by the Adult ADHD Self-Report Scale (ASRS) [70].

- Severity of *depressive symptoms* will be evaluated by the Beck Depression Inventory-II (BDI-II) [71].
- Level of *psychotic-like anomalous self-experiences* will be evaluated by the Inventory of Psychotic-Like Anomalous Self-Experiences (IPASE) [72].
- Level of *paranoid thinking* will be evaluated by the Green Paranoid Thought Scale (GPTS) [73].

Social cognition and performance

- *Theory of Mind and complex emotion comprehension* will be measured by the Awareness of Social Inference Test - Short Form, part 2 Social Inference, Minimal (TASIT-S**)** [74,75]**.**
- *Ability to infer others' intentions* behind indirect speech or social hints will be measured by The Hinting Task [76]**.**
- *Cognitive biases* will be measured by the Davos Assessment of the Cognitive Biases Scale (DACOBS) [77].
- *Social communication skills* (competence and appropriateness of conversational skills) will be measured by the Social Skills Performance Assessment (SSPA) [78].

Other measures

- Level of *satisfaction with the intervention* will be assessed with the Client Satisfaction Questionnaire (CSQ) [79].
- *Negative events and outcomes* in the participants life during the intervention period will be assessed with the Negative Effects Questionnaire (NEQ) [80].
- *Involvement and immersion into the virtual reality environments* will be assessed with the Multimodal Presence Scale, Modified Shortened Danish Version (MPS-MSDV) [81]**.** MPS-MSDV will be administered only to participants in the experimental group.
- Level of *simulator sickness* related to being in virtual reality will be assessed by the Simulator Sickness Questionnaire (SSQ) [82]. SSQ will be administered only to participants in the experimental group.
- *Attitudes and readiness for therapy aimed at resolving problems* will be assessed by The Readiness for Therapy Questionnaire (RTQ) [83]. The RTQ will be administered by the therapists in the intervention and only to participants in the experimental group.
- *Level of insight into challenges related to social interaction* will be assessed by utilizing a visual analogue scale (I-VAS). Participants and therapists will indicate, on a scale from 1 to 10, the extent to which the intervention has increased the participant's awareness of their challenges with social interaction, with 1 representing no increased awareness and 10 indicating the highest possible increase in awareness. This assessment of potential change in insight will be administered by the therapists in the intervention and only to participants in the experimental group upon completion of the intervention.

STUDY PERIOD						
Content	**Enrolment**	**Baseline Assessment**	**Allocation**	**Intervention**	**Follow-up assessment 3-month post-baseline**	**Follow-up assessment 6-month post-baseline**
TIMEPOINTS		t_0			t_1	t_2
Information about the trial	X					
Informed consent	X					
Eligibility evaluation:	X					
SRS-2A	X					
Vocabulary and Matrix Reasoning (WAIS-IV)	X					
M.I.N.I.	X					
Randomisation			X			
INTERVENTIONS						
Comparison Group (TAU)				X		
Experimental Group (VRSCT + TAU)				X		
ASSESSMENTS						
Primary Outcome:						
SRS-2A		X (administered at enrolment)			X	X
Secondary Outcomes:						
HiSoC		X			X	X
SRS-2AI		X			X	X
SIAS		X			X	X
ERT from CANTAB		X			X	X
EQ		X			X	X
Exploratory outcomes:						
PSP		X			X	X
TUCP		X			X	X
BRIEF-A		X			X	X
GSE		X			X	X
DPAS		X			X	X
WHO-5		X			X	X
EQ-5D		X			X	X
SR-AS		X			X	X
RBQ-3		X			X	X
IUS-12		X			X	X
GAFS-8		X			X	X
CAT-Q		X			X	X
ASRS		X			X	X
BDI-II		X			X	X
IPASE		X			X	X
GPTS		X			X	X
TASIT-S		X			X	X
The Hinting Task		X			X	X
DACOBS		X			X	X
SSPA		X			X	X
Other Measures:						
CSQ					X	X
NEQ					X	X
MPS-MSDV (Only experimental group, 3- and 10-weeks post-baseline)				X		
SSQ (Only experimental group, 3- and 10-weeks post-baseline)				X		
RTQ (Only experimental group, 1-week post-baseline)				X		
I-VAS (Only experimental group, 12-weeks post baseline)				X		

Table 2: Schedule of enrolment, intervention, and assessments

Participant Timeline

See figure 1 and table 2 for schematic presentations of the trial.

Sample Size and Power Calculation

The sample size calculation is based on detecting a between-group difference in the primary outcome, the SRS-2A, at cessation of the intervention (3 months post-baseline). Previous studies have reported considerable variation in the standard deviation (SD) of the social responsiveness scale total score when assessing social impairment in AA [34,49,51]. As a result, we have not been able to determine the minimal clinically significant difference. Therefore, we have based our sample size calculation on a medium effect size (Cohen's *d*=0.5), which corresponds to a difference of 0.5 SD between the experimental group (VRSCT + TAU) and the comparison group (TAU). With 80% power at a 0.05 significance level (two-sided), 63 participants are required in each group to detect this difference. To account for an anticipated 10% dropout rate, we plan to recruit a total of 140 participants.

Recruitment

The project group has established strong collaborations with several public and private outpatient facilities in Denmark, that are specialising in the clinical assessment and diagnosis of autism in adulthood. Based on the collaboration agreement, the multidisciplinary staff at these sites will routinely approach relevant participants and refer them to the VIRTU Research Group. To foster collaboration and ensure ongoing referrals to the trial, staff from VIRTU Research Group will regularly attend conferences and meetings at the various recruitment sites and invite clinicians to discuss potential participants.

Methods: Assignment of Interventions

Allocation

Sequence Generation

Participants who provide signed informed consent and meet the eligibility criteria will be randomly allocated to receive either TAU or VRSCT + TAU upon completion of the baseline assessment. Randomisation will be performed using a centralised, automated, computer-generated randomisation module in the online Research Electronic Data Capture (REDCAP) system (see Data Management section). A stratified block randomisation with a concealed randomisation sequence will be employed, with block sizes that are variable and unknown to the investigators. Randomisation will be stratified by site and gender. The allocation of the randomised intervention will remain concealed to investigators and assessors until the statistical analyses of outcome data have been completed.

Concealment Mechanism

When a participant has completed the baseline assessment, the trial assessor, who is responsible for conducting the assessment, will email one of the trial therapists responsible for generating the allocation sequence. The assessor will then receive a confirmation email acknowledging receipt only. The trial therapist has exclusive access to the randomisation module in REDCAP (see Data Management section), ensuring that assessors are blinded to intervention allocation.

Implementation

Allocation sequences are generated by one of the trial therapists. Enrolment and assignment to the interventions is carried out by the therapists who are conducting the interventions in the experimental group.

Blinding

Following the allocation to one of the interventions, the outcome assessors will be blinded to the participants group assignment. Due to the nature of the intervention in the experimental group (VRSCT) participants, therapists conducting the intervention, and the clinicians managing TAU will not be blinded to the received interventions. Participants will prior to follow-up assessments be instructed not to disclose their allocation to the outcome assessors. To maintain blinding, assessments and interventions will be conducted at separate locations, ensuring that the assessors remain unaware of group assignment. Assessors will be instructed to notify their supervisors immediately if they believe blinding has been broken. If unblinding of the outcome assessor occurs, another outcome assessor blind to the allocation of intervention will conduct the subsequent assessments.

Methods: Data Collection, Management, and Analysis

Data Collection Methods

Plans for Assessment and Collection of Outcomes

Assessments will be conducted at baseline (t_0), 3 months post-baseline (t_1), and 6 months post-baseline (t_2). An overview of assessments and outcome measures is provided in table 2. Outcome assessors will be psychologists who will receive comprehensive training before conducting assessments. To maintain data quality, assessors will participate in monthly supervision sessions focused on the administration and scoring of assessments. To ensure high psychometric reliability for rater-based outcomes, the following assessments will be evaluated through consensus rating: HiSoC, Hinting Task, and SSPA. These assessments will be video/audiotaped to enable subsequent consensus rating. Additionally, the scoring of PSP and the assessment of co-occurring psychopathology by the M.I.N.I. will be consensus-rated. Co-occurring psychopathology based on the M.I.N.I. will be diagnosed according to ICD-10 and ICD-11 criteria. Training, supervision, and consensus rating sessions will be facilitated by Jens Richardt Møllegaard Jepsen, a senior researcher and clinical expert in autism.

Plans to Promote Participant Retention and Complete Follow-up

To enhance participant retention and ensure follow-up assessments, several initiatives will be taken. Participants will be contacted by phone approximately one week before the planned follow-up assessments, and travel expenses for public transportation will be compensated to reduce financial burden associated with participation in the trial. Additionally, assessors can rearrange scheduled assessment times to accommodate participant's needs. In cases where participants leave the trial prematurely, efforts will be made to complete follow-up assessments. If participants are unable to complete the full assessment battery, priority will be given to obtain the primary and secondary outcomes.

Data Management

Data from evaluation of eligibility and assessments during the trial will be entered directly into the

electronic Case Report Form (CRF) using the data entry system REDCAP. REDCAP is an electronic data capture tool hosted by the Centre for IT, Medical Technology and Telephony (CIMT) in the Capital Region of Denmark. When electronic entry is not possible, data will be collected on paper and later transferred into REDCAP. Data on paper will be stored locally and secured. Using REDCAP, surveys can securely be distributed and returned via E-boks, a public Danish digital mailing system that all citizens possess, reducing the risk of data loss and unauthorised access. Data for each participant will be linked to a unique serial number, with only assigned researchers having access to REDCAP. REDCAP includes a complete audit trail of data transactions, detailed user rights, and access control management, ensuring compliance with Danish legislation (the Act on Processing Personal Data). Research data will be exported from REDCAP without personal identifiers. Data will be exported to well-known software packages (e.g., SPSS, SAS, Stata, R.) and put in logged folders on a network drive under the control of the CIMT. A data manager will ensure that all variables are properly defined with variable and value labels. All derived variables will be properly defined, and algorithms will be kept in special files. All data will be examined carefully to identify errors in data entry.

Statistical Methods: Analysis of Primary and Secondary outcomes

To evaluate the effectiveness of VRSCT, the potential differences in primary, secondary, and explorative outcomes between the two groups will be analysed using a generalized linear model adjusted for stratification variables. In the analysis of each outcome, baseline imbalances will be adjusted for, and skewed attrition will be accounted for as appropriate. As an important secondary assessment of this type of outcome, linear mixed model analyses with repeated measurements and an unstructured covariance matrix will assess the interaction between time and intervention. All analyses will follow the intention-to-treat principle, where all participants are analysed in the groups they were assigned to by randomisation; that is all participants irrespective of whether they attended follow-up assessments or not. Missing data will be addressed using linear mixed models and multiple imputations as appropriate. The primary efficacy analyses will be conducted by a blinded and independent statistician with no direct contact to the participants in the trial.

Methods: Monitoring and Oversight

Data Monitoring

The trial will be overseen by a Project Management Group (PMG). The PMG will comprise the primary investigator (PI) of the study, who is also the trial manager and daily leader of the trial, the principal therapist of the trial and the supervisor of the assessors. The PMG will hold monthly meetings throughout the recruitment period. There will be no data monitoring committee. The PMG will oversee trial safety and status of recruitment and retention.

Adverse Events

Although VR interventions are generally well tolerated with minimal to no severe side effects or adverse events [84], including among AA [34], some individuals may still experience cybersickness, which is not considered to be serious. Therefore, we do not expect to encounter any serious side effects or adverse events. Side effects and adverse events will be monitored and recorded throughout the study, as well as any complaints about the intervention. The following are considered as adverse events: 1) hospital admissions, 2) suicide attempts, 3) any violent incident necessitating police involvement (whether victim or accused), 4) self-harming behaviour and 5) all deaths. Any adverse events will be reported to the Committee on Health Research Ethics of the Capital Region Denmark.

Auditing Trial Conduct

The leading members of the PMG will continuously ensure that the trial is conducted according to protocol, that data is collected accurately and reliably, and that the safety and rights of the participants are protected. Any necessary revisions to the processes will be discussed at the monthly PMG meetings.

Ethical Considerations

Research Ethics Approval

The study was approved by the Committee on Health Research Ethics in the Capital Region of Denmark (Project ID: H-23055504) and by the Danish Data Protection Agency at the Capital Region of Denmark (project ID: p-2023-14488).

Protocol Amendments

Protocol amendments must be approved by the Committee on Health Research Ethics of the Capital Region Denmark. Any modifications to protocol will be documented in the trial registration at ClinicalTrials.gov (NCT06438536).

Consent

Trained psychologists from VIRTU Research Group will obtain signed informed consent for participation in the STEPS trial. Referred participants will initially receive information about the trial written in layman’s terms, covering the trial’s background, objectives, design, intervention, randomisation process, risks, confidentiality, and legal rights. Next, an appointment will be arranged with a trial researcher to ensure participants understand the information provided and accept random assignment to either VRCST + TAU or to TAU alone. If they decide to proceed, they will sign a consent form confirming they have received adequate written and verbal information about the trial's purpose, method, benefits, and risks, and agree to participate. Written, informed consent to participate will be obtained from all participants, and participants have the right to withdraw from the study at any time and for any reason. Written information about the trial aimed at the participants and the informed consent form are available from the corresponding author.

Privacy and Confidentiality

This protocol does not include any personal data or identifying images of participants, nor will such data be included in any subsequent publications reporting the trial results. All data presented in future articles will be fully anonymised to ensure participant confidentiality.

Dissemination

The results of the trial will be shared with the scientific community through presentations at national and international conferences. The findings will also be published in scientific articles submitted to relevant academic journals. Additionally, results will be communicated to trial participants. The implications of the results will be discussed with healthcare professionals and other stakeholders at clinical conferences. Furthermore, the findings will be presented to the public through meetings with interest groups and to the wider public at local meetings or seminars.

Compensation Details

Participants will not receive financial compensation. However, transportation expenses will be reimbursed, and meals will be provided on assessment days to ensure participant comfort and minimise any financial burden associated with participation.

Results

The trial is currently recruiting participants. The first participant was enrolled in May 2024. Completion of recruitment is expected in January 2026. Data analysis is expected to commence in summer 2026, following the final six-month follow-up assessment. Results are anticipated by fall 2026 and will be disseminated at international conferences and through peer-reviewed publications.

Discussion

AA constitute a growing and largely overlooked population, for whom few clinical and research resources have been allocated. Due to the limited evidence on effective interventions for AA, no national clinical guidelines have been developed for psychological interventions aimed at this population in Denmark. Sparse evidence from pro-functional studies conducted in England or Sweden is often referenced when attempting to guide psychological treatment approaches for this group [85]. To our knowledge, STEPS is the hitherto largest randomised clinical trial globally investigating the effect of VRSCT for AA. The results of this innovative intervention approach may significantly advance research in the field of autism. If the VRSCT intervention in the STEPS trial proves effective, it has the potential to improve psychosocial functioning, quality of life, co-occurring clinical symptoms and reduce social cognitive deficits in AA. Establishing evidence-based interventions is essential to address the debilitating psychosocial challenges encountered by this population, especially considering the absence of established gold-standard interventions. Enhancing pro-functional psychosocial skills can significantly impact the lives of these individuals, by enabling them to build more meaningful and intimate relationships, better maintain personal and professional relations, and improve educational and occupational functioning. Developing effective interventions for AA can further contribute to filling the critical gap in available support, and thereby contribute to alleviating the personal and social consequences, and the economic impact associated with autism. If proven effective, the manualised VRSCT intervention from this study could be implemented in mental health services across Denmark and potentially on an international scale supported by training and ongoing supervision. Additionally, the intervention could be adapted to fit the needs of other clinical populations experiencing social cognitive deficits, such as autistic adolescents, individuals with bipolar disorder, or individuals with psychosis [86]. This could help address the increasing demand for novel, effective interventions for psychiatric conditions globally.

Limitations

The participants in the comparison group will receive TAU, administered across multiple sites. It is expected that there will be variations in the content and duration of TAU among participants. Although the specific details of TAU for each participant will be documented at the end of the trial, this variability remains a limitation. The inconsistency in TAU introduces less control compared to an active control uniformly administered in the same setting as the experimental intervention. However, TAU was chosen as the comparator because it reflects current clinical practice available for AA in Denmark. Additionally, there is no established "gold standard" intervention specifically targeting social cognitive deficits in AA, which otherwise could have been an obvious choice of comparator.

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The authors express their sincere gratitude to the study participants and the staff at the recruitment

sites for their assistance in referring individuals to the trial. We extend our thanks to the focus group, consisting of AA, with lived experiences, whose insights were invaluable in developing the intervention manual. Finally, we acknowledge and thank all contributors to the development of the STEPS trial who may not have been specifically mentioned here.

Data Availability

Upon completion of the study, the following authors will have full access to the final dataset: Alberte C. E. Jeppesen, Johannes Andresen, Louise Birkedal Glenthøj, Jens Richard Møllegaard Jepsen, Carsten Hjorthøj, Merete Nordentoft, Lise Sandvig Mariegaard, and Anne Sofie Due. A fully anonymised dataset will be submitted to the Danish National Archive for scientific sharing purposes upon the study's full completion.

Authors' Contributions

Louise Birkedal Glenthøj is the PI, trial manager and daily leader of the trial. Louise Birkedal Glenthøj, Lise Sandvig Mariegaard, Jens Richard Møllegaard Jepsen, Rizwan Parvaiz, Amy Elizabeth Pinkham, and Merete Nordentoft have designed the STEPS trial. Carsten Hjorthøj contributed to the study design, conducted the power calculation, and authored the sections related to statistics. Lise Sandvig Mariegaard is the principal therapist of the VRSCT. The manual of VRSCT has been develop by Anne Sofie Due, Lise Sandvig Mariegaard and Louise Birkedal Glenthøj. Anne Sofie Due and Lise Sandvig Mariegaard are responsible for conducting the VRSCT in the trial. Alberte C. E. Jeppesen and Johannes Andresen are responsible for recruitment, enrolment, assessments, data collection and analysis and interpretation of data under the supervision of Louise Birkedal Glenthøj, Jens Richard Møllegaard Jepsen, and Carsten Hjorthøj. Johannes Andresen wrote the first draft of the manuscript, supervised by Louise Birkedal Glenthøj. All authors contributed to the manuscript and approved the final version.

Conflicts of Interest

None declared.

Abbreviations

AA: Autistic Adults; STEPS: Social cognitive Training Enhancing Pro-functional Skills; VR: Virtual Reality; VRSCT: Virtual Reality-based Social Cognitive Training; TAU: Treatment as Usual; SRS-2A: Social Responsiveness Scale, Second Edition, Adult Form, Self-report; WAIS-IV: Wechsler Adult Intelligence Scale, Fourth Edition; M.I.N.I.: Mini-International Neuropsychiatric Interview; CBT: Cognitive Behavioural Therapy: HiSoC: High-Risk Social Challenge task; SRS-2AI: Social Responsiveness Scale, Adult Form, Informant report; SIAS: Social Interaction Anxiety Scale; ERT: Emotion Recognition Task; CANTAB: Cambridge Neuropsychological Test Automated Battery; EQ: Empathy Quotient; PSP: Personal and Social Performance Scale; TUCP: Temple University Community Participation Measure; BRIEF-A: Behaviour Rating Inventory of Executive Function - Adult Version, Self-Report; GSE: General Self Efficacy Scale; DPAS: Defeatist Performance Attitude Scale; WHO-5: WHO-5 Well-Being Index; EQ-5D: EuroQOL Five Dimensions Questionnaire; SR-AS: Sensory Reactivity in Autism Spectrum; RBQ-3: Repetitive Behaviour Questionnaire-3; IUS-12: Intolerance of Uncertainty Scale; GAFS-8: General Alexithymia Factor Score; CAT-Q: Camouflaging Autistic Traits Questionnaire; ASRS: Adult ADHD Self-Report Scale; BDI-II: Beck Depression Inventory-II; IPASE: Inventory of Psychotic-Like Anomalous Self-Experiences; GPTS: Green Paranoid Thought Scale; CSQ: Client Satisfaction Questionnaire; NEQ: Negative Effects Questionnaire; MPS-MSDV: Multimodal Presence Scale, Modified Shortened Danish Version; SSQ: Simulator Sickness Questionnaire; RTQ: Readiness for Therapy Questionnaire; I-VAS: Insight Visual Analogue Scale; SD: Standard Deviation; REDCAP: Research

Electronic Data Capture; CRF: Case Report Form; CIMT: Centre for IT, Medical Technology and Telephony; PMG: Project Management Group; PI: Primary Investigator.

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