Trials

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Results of a randomized controlled superiority trial of the effect of modified collaborative assessment vs. standard assessment on patients' readiness for psychotherapy (CO-ASSM-RCT)

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Abstract

Background Avoidant personality disorder (AvPD) and social phobia (SP) are associated with high personal and societal costs. While psychotherapy can be efficient, many patients drop out during treatment. Little is known about what can be done to increase a patient's readiness for psychotherapy. However, research highlights the fields of collaborative and therapeutic assessment as a possible means to enhance readiness for psychotherapy.

Methods We conducted a randomized controlled feasibility and superiority trial on patients with SP or AvPD who were to initiate psychotherapeutic treatment in outpatient mental health services. Patients were randomized 1:1 to either assessment as usual or modified collaborative assessment (MCA), provided as a pre-treatment intervention before psychotherapy initiation. MCA included the collaborative administration of a battery of psychological tests designed to assess the patient's psychopathology more systematically. The tests were administered in collaboration with the patient, and detailed oral and written feedback was provided. We investigated the feasibility of the MCA intervention regarding acceptability, patient satisfaction, and adherence. We also investigated MCA's effect on readiness for psychotherapy, as assessed with the University of Rhode Island Change Assessment Scale (URICA), and outcomes relating to symptomatology and dropout rates.

Results All three prespecified feasibility outcomes were met. At the end of treatment, no significant difference was observed in any other outcome, except client satisfaction, which favored MCA (−7.42 (95% CI −11.75; −3.09; $p = 0.002$)).

Discussion We found that MCA was feasible, and patients were highly satisfied with the intervention. It is relevant to investigate another implementation of MCA.

Trial registration ClinicalTrials.gov NCT05018312. Registered on August 24, 2021.

Keywords Assessment, Personality disorders, Social phobia, Psychotherapy, Evasiveness, Collaborative assessment, Therapeutic assessment

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Background

Introduction and rationale

Anxiety disorders such as ICD-10 social phobia (SP) and anxious avoidant personality disorder (AvPD) represent a public health concern in the Western world [1, 2]. European epidemiological surveys estimate that between 14 and 19% of the population in Europe will fulfill the criteria for any anxiety disorder in their life [3, 4]. Anxiety disorders are associated with high socioeconomic costs and often a chronic, debilitating course for the affected person [5–7]. These disorders are one of the leading causes of the worldwide burden of disease, and their yearly costs in the European Union alone reached an estimated 74 billion euros in 2010 [8, 9]. Therefore, continuous initiatives to improve treatments for anxiety disorders are of high importance.

SP is the most frequent anxiety disorder and is characterized by a fear of being observed or negatively evaluated by others. This results in the affected patient avoiding social situations (such as jobs that include contact with other individuals, making new acquaintances, speaking or eating in front of others) or entering these situations with marked discomfort [10]. This evasiveness gravely impacts the affected individual's ability to function socially, impacts their ability to function socially and their quality of life, and can keep them from having a job [11, 12]. Similarly, patients with AvPD can experience feelings of inadequacy, have a consistent pattern of social inhibition, and be prone to feeling negatively evaluated by others. These feelings can result in avoidance of social interactions and marked evasiveness. AvPD patients regard themselves as isolated from others and unwanted [10]. AvPD is, therefore, also associated with a pronounced impairment in the ability to function for the affected individual and high socioeconomic costs [13].

These disorders are both, according to the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5), and the International Classification of Diseases, tenth edition (ICD-10) [10], regarded as distinct disorders. However, research suggests there is extensive overlap between SP and AvPD [14]. The exact link between these disorders is currently primarily a matter of discussion [15]. Still, the leading hypothesis is that the disorders are on a spectrum and are only different in terms of severity (the severity continuum hypothesis [16]). In the next edition of the International Classification of Diseases, the tenth edition (ICD-10), AvPD is expected to be discontinued as a diagnosis, which is in line with the proposed severity continuum hypothesis. Hence, the present study duly focuses on both SP and AvPD.

In Denmark, patients with SP and AvPD are offered outpatient, time-restricted, standardized, interdisciplinary treatment programs in the public Mental Health Services, funded by public health insurance, which is mandatory and paid via tax. According to Danish guidelines for treatment, the treatment programs consist of evidence-based mentalization-based therapy for AvPD and cognitive behavior therapy (CBT) for SP. The format and content of the standardized treatment programs for moderate-to-severe AvPD and SP are regulated per the Danish Health Authority guidelines. The treatment program for SP includes up to 42 h of clinician time, consisting of diagnostic assessment (3 h), psychopharmacological consultation (1 h), individual psychotherapy (7 h), or group psychotherapy with two therapists (28 h), relatives' support sessions (1½ h), and network consultation (1½ h) [17]. Correspondingly, the standardized outpatient treatment program for AvPD includes up to 78 h of clinician time, consisting first of diagnostic clinical assessment (2 h), then psychopharmacological consultation (2 h), and lastly, treatment with individual psychotherapy (11 h) or group therapy with two therapists (60 h), as well as network consultation (3 h) [18].

Despite the solid evidence base that supports the efficacy of CBT for SP, recent meta-analytic findings by Springer et al. [19] indicate that only 45% of patients who receive treatment for SP recover from their principal diagnosis as a result of treatment. Further, patients with SP experience an overall poorer outcome than patients who receive treatment for other anxiety disorders [19]. In addition, data from a Danish, multicenter randomized controlled trial ($n=291$) [20] investigating the relative efficacy of group diagnosis-specific CBT protocols versus a transdiagnostic CBT protocol for depression and anxiety disorders supports the meta-analytic findings on SP. The results of this trial indicated that only approximately half of the included subjects no longer fulfilled the diagnostic criteria for their illness at the end of the intervention [21]. For AvPD, the evidence for the effectiveness of psychotherapeutic treatment is limited, but reported remission rates vary between 40 and 80% [22]. No data exist on the effect of the Danish standardized treatment programs for AvPD. Moreover, considerable dropout is observed from current psychotherapy interventions, exemplified by the mentioned trial, where only 65% of patients completed treatment across conditions [21].

Readiness for psychotherapy

The scientific literature on psychotherapy highlights the pivotal role of patients' readiness for psychotherapy or readiness for change. The concept of "readiness for change" refers to the intentional aspect of a patient's change, which is described as the internal drive that precedes behavioral change prior to the beginning of therapy and the patient's ongoing engagement throughout therapy [23]. This includes domains such as willingness to

discuss personal matters [24], desire to change [25], preparedness to make reasonable sacrifices [26], and level of distress [27].

Theoretically, the concept is described by Prochaska and DiClemente as a fundamental component in the "stages of change" dimension of the Transtheoretical Model of Behavioral Change [28]. Herein, patients are regarded as varying in their overall readiness to change and are hypothesized to undergo the following four stages of change. First, they are considered to be in "precontemplation," where they are not yet contemplating change. Then, they enter "contemplation," where they are ambivalent about change. Next, they develop an intention to change ("preparation"), begin to change ("action"), and lastly, consolidate their changes ("maintenance").

Patients' readiness to change is described in the scientific literature as a moderator and predictor of outcomes from psychotherapeutic treatment [29]. Concerning anxiety disorders such as AvPD and SP, research has consistently indicated that patients' readiness to change prior to therapy not only reduces symptoms but also boosts important process variables, such as adherence to treatment and working alliance [30]. However, research also suggests that as many as 80% of patients are not ripe for change at the beginning of therapy [31].

Modified collaborative assessment

Currently, limited information exists on how a patient's readiness for psychotherapy can be enhanced. However, research highlights interventions in the field of collaborative assessment and therapeutic assessment (C/TA) as a possible means to increase process outcomes relating to psychotherapy [32]. In C/TA, a psychiatric assessment is not carried out solely to diagnose and propose. Instead, assessment is considered an important and integrative part of the treatment. C/TA allows psychotherapeutic treatment to begin with the diagnostic assessment at the clinic's intake instead of at the beginning of therapy.

C/TA employs brief, semi-structured therapeutic interventions in which a therapist administers an extensive battery of standardized psychological tests in collaboration with a patient. The results of these are interpreted collaboratively, and comprehensive feedback is given to the patient in a way that is helpful—and therefore therapeutic—for them [33–35]. Therapeutic assessment (TA) revolves around the patient's therapeutic question. This therapeutic question is something the patient finds meaningful to explore in the TA intervention, such as "Why do I get in trouble so much?" The patient and TA therapist then investigate this question utilizing one or more psychological tests, and the intervention ends with extensive, personalized written and oral feedback.

C/TA has been investigated in controlled trials and uncontrolled studies with adults and children. Herein, it has been shown to positively influence a wide range of process variables related to psychotherapy outcomes. These include compliance with treatment [36], therapeutic alliance with a subsequent therapist [32, 37], and the client's satisfaction with treatment [38], as well as recovery from anxiety symptoms [39, 40], improved self-esteem [41–43], and lower levels of self-criticism [39]. Poston and Hanson's [44] meta-analysis on 17 published C/TA studies, Durosini and Aschieri's meta-analysis on studies utilizing solely TA [45], and Aschieri's meta-analysis of C/TA applied to "clients" [46] all found support for the intervention, yet some shortcomings have been highlighted [47]. A systematic review of C/TA-style interventions in a clinical setting failed to find support for these interventions due to a lack of research [48].

In this paper, we report the results of an RCT comparing a modification of C/TA named modified collaborative assessment (MCA) with assessment as usual (AAU). Compared to C/TA, MCA is of shorter duration and more structured, and the MCA therapist needs less testing experience (i.e., it can be carried out by a junior doctor or psychologist, compared to the experienced psychologist who usually practices TA). In addition, MCA is designed to be less resource-intensive in terms of clinician time expenditure compared to standard TA. Therefore, we expect MCA to be more feasible in this trial and later implementation than C/TA.

As in standard TA, MCA includes the administration of standardized tests. However, in opposition to standard TA, MCA includes only a limited number of psychological tests to promote the intervention's feasibility. The battery of tests is specifically selected to collect extensive information on psychopathology, which a brief and unstructured diagnostic interview may not be able to detect (especially symptoms of incipient psychosis and autism spectrum disorders that have previously been undetected). MCA, like TA, emphasizes respect for the patients as "experts on themselves," the therapeutic question is envisioned as a means to assist the patient and the MCA assessor on their collaborative journey to gain more knowledge about the patient's resources and problems. Therefore, it includes respectful and thorough personalized feedback both orally and in writing. In short, MCA is a short, person-centered assessment of primary psychopathology, where assessment, psychotherapy, and psychoeducation are integrated into an individualized and novel intervention, all carried out collaboratively with the patient in focus.

We hypothesized that a trial exploring the effect of MCA versus AAU on patients' readiness for psychotherapy would be feasible in a Danish mental health service

setting regarding recruitment, acceptability, and patient satisfaction. We further hypothesized that MCA would be superior to AAU in increasing patients' readiness for psychotherapy, as assessed by the University of Rhode Island's Change Assessment Scale (URICA) (contemplation subscale) and the Readiness for Psychotherapy Index (RPI), and that it would increase engagement in psychotherapy as measured by early adherence.

Methods

Design

This was a two-armed, investigator-initiated, single-blinded, parallel, randomized, controlled feasibility and superiority trial comparing the effect of pre-treatment MCA with AAU. A protocol for the current trial was published prior to its finalization [49]. A flowchart is provided in Fig. 1. The trial was registered on the ClinicalTrials.gov website (ID NCT05018312). The study was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines [50] and the Template for Intervention Description and Replication (TIDieR) checklist [51].

Participants, recruitment, and procedure

In Denmark, patients are eligible to receive public-funded psychiatric outpatient treatment in the Mental Health Services (MHS) if they have a psychiatric disorder and the severity of the disease (in terms of symptom burden, level of functioning, or comorbidity) prohibits treatment in the primary sector. Patients included in the current trial were adults (18 + years) referred to treatment by general practitioners or private practice psychiatrists for treatment in the MHS. As part of the standard procedure in MHS psychotherapy clinics, patients receive their initial AAU as practiced in the given clinic with a diagnostic interview and possibly one or more diagnostic instruments, such as the SCID interview. Based on this interview, the patients receive a clinical diagnosis. They are either referred to treatment elsewhere or, if indicated, placed on a waitlist for group psychotherapeutic treatment in the clinics.

Patients from the waitlist were offered inclusion in the present study if they (a) were adults (18 + years old), (b) had a principal WHO ICD-10 diagnosis of either SP or AvPD, and (c) gave written consent to participate in the study. Patients were excluded if they had (a) a moderate or high risk of suicide, according to the investigator, (b) alcohol or drug dependency, or (c) a co-occurring eating disorder with BMI < 18 or psychotic illness.

Intervention

Patients randomized to MCA had already received AAU as described in the previous section. Following randomization to MCA, they first received a session of 1 h, in which they were asked to describe themselves and their life briefly, how and why, from their point of view, they had been referred to the clinic, and what their psychological/psychopathological issues were at present. This and the later sessions were conducted with an informal attitude. The first session resulted in the patient formulating one or more therapeutic questions in collaboration with ORH (e.g., "Why is it easy for me to get angry?" or "Why is it difficult for me to go to school?"). Based on this discussion, the therapist proposed psychological tests from the MCA test battery, which would be administered in collaboration at the next session to gather data informing the patient's question. This was not primarily to establish a diagnosis, but to give the patient more insight into his/her problems and what he/she needed to work on in future therapy. The intervention was carried out in person in the psychiatric clinics.

The MCA test battery included the following nine assessment instruments, of which the first three were obligatory, and the remaining six were only administered if indicated by the patient's therapeutic question. Present State Examination (PSE) is a standardized, semi-structured diagnostic that aims to give an thorough assessment of symptoms described in mental health disorders in the ICD-10 [10]. It contains 140 items, each rated on a 3- to 4-point scale [52]. The Structured Clinical Interview for DSM-5 (SCID-5) is an interview manual for evaluating the ten personality disorders described in the DSM-5. In Denmark, it is considered the gold-standard diagnostic interview to diagnose personality disorders. The Examination of Anomalous Self-Experience (EASE) is a clinician-administered interview designed for clinical

Fig. 1 Patients' flow into and through the clinic

phenomenological assessment of experiential disturbances ("self-disorders"). It is scored globally and has the following five sub-scores: self-awareness and presence, demarcation/transitive, cognition and stream of consciousness, existential reorientation, and lastly, bodily experiences [53].

EASE was obligatory because data on it was planned for another study. The Screen for Cognitive Impairment in Psychiatry (SCIP) is a short neuropsychological instrument designed for fast and unbiased assessment of possible cognitive dysfunction in patients with specific psychiatric disorders. The Danish version of the instrument has, in research, been found to have good validity for detecting cognitive impairment [54]. It assesses the following domains: delayed memory, verbal learning and memory, working memory, processing speed, and word mobilization [55]. The SCIP was used to judge if a patient needed more extensive neuropsychological testing with the Wechsler Adult Intelligence Scale—Fourth Edition (WAIS-IV), a test designed to assess cognitive ability and intelligence among adults [56]. The WAIS-IV can only be administered by a psychologist trained in the test and would, therefore, be administered by a psychologist in the given psychiatric clinic. The Personality Inventory for DSM-5, 36-item version (PID-36) is a condensed edition of the 100-item Personality Inventory for DSM-5 (PID-5). It has been designed to specifically assess the pathological trait specifiers found in the alternative model for personality disorders in DSM-5 Section III [57]. The Autism Diagnostic Observation Schedule (ADOS-2) module 4 is a test designed to assess psychopathology specific to the autism spectrum. It evaluates communication skills, social interaction, and the patient's ability to use materials creatively [58]. Conners'Adult ADHD Rating Scales (CAARS) is a psychological test designed to assess problems with attention specific to attention disorders [59]. The Level of Personality Functioning—Brief Form 2.0 (LPFS-BF) is a brief self-report instrument developed to evaluate a patient's levels of personality functioning quickly. Its 12 items assess impairment in both interpersonal functioning and self-functioning [60].

The MCA therapist administered the PSE at the next sessions, followed by the SCID-5, the EASE, and so forth, based on the patient's therapeutic question. These sessions included a discussion of the symptoms found by the instruments and how they related to the patient's clinical diagnosis. They also involved a discussion of which elements the patient did not have problems with (e.g., diagnostic criteria of AvPD that the patient did not fulfill), and thus, placed focus on the patient's resources. ORH administered the instruments. ORH was able to discuss the case with a senior psychiatrist. He could also get another judgment from a second senior psychiatrist in case of uncertainty regarding diagnosis. This step was included to ensure sound interpretation of test results and a correct diagnostic verification or alteration. If the MCA intervention detected psychopathology not previously described, the MCA therapist would confer with the staff in the clinic regarding the need for diagnostic reclassification of the patient. The patient was informed about this at the feedback session if this was agreed on. Here, the patient received detailed oral feedback on the findings of the administered tests. The oral feedback was based on a personal feedback letter written by the MCA therapist to the patient, and the patient was given a copy of this letter to bring home. Following the end of the MCU, the clinical staff in the given psychotherapy clinic were informed of the results of the MCA. This allowed the clinical staff to employ the additional information about the patient in the following treatment, which was completed following the completion of the primary endpoint.

Patients randomized to the control group received AAU, which was the standard psychopathological assessment that patients are administered in the clinic, administered in the usual manner, and which took place prior to enrollment in the trial, why they received no treatment while waiting for administration T1. Patients randomized to MCA were considered treatment completers if they completed the entire intervention and were administered T1. Patients randomized to AAU were considered treatment completers as per default.

Outcome measures

Baseline measures (T0) were gathered at the initial meeting, where the patient gave written consent to participate in the study before randomization. Post-treatment measures (T1) were collected within 1 week after the end of the intervention for patients randomized to MCA and 4 weeks after T0 for patients randomized to AAU. Follow-up data (T2) were gathered after the patient completed four group psychotherapy sessions. The completion time of outcome measures depended on logistics for treatment in the respective clinics, including the timing of the start of group psychotherapy onset. All outcomes were self-administered in the web-based data storage software REDCap © [61].

Feasibility outcomes

We utilized the following feasibility outcomes. Acceptability: The feasibility criterion for acceptability in patients was supported if 25% of patients who were found eligible for inclusion and had received formal information (an information meeting with ORH) about the trial agreed to participate. Satisfaction: The feasibility criterion for patient satisfaction was supported if the

mean CSQ-8 score was ≥ 3. Adherence: The feasibility criteria for adherence in patients were supported if 75% completed the MCA intervention (attended all MCA sessions, including the feedback session). Time spent on the intervention: Lastly, we evaluated the resources used to complete the study by recording the time spent in direct contact with each patient to complete the MCA intervention.

User evaluation

User evaluations of the present trial were conducted using the Client Satisfaction Questionnaire (CSQ-8), a self-reported, standardized instrument designed to evaluate individuals' satisfaction with services [62].

Adverse effects

We monitored for adverse events, particularly suicidal ideation and suicidal behavior. If a patient were admitted to a psychiatric ward during participation in the study, RB would decide if the patient could continue participating in the present trial.

Primary outcome

We used the University of Rhode Island Change Assessment Scale (URICA), contemplation subscale as the primary outcome assessed at T1. URICA is a 32-item self-reported instrument which includes four subscales. These are designed to quantify individual aspects of a patient's motivation for change. The four subscales are pre-contemplation, contemplation, action, and maintenance [63]. We used the score on the contemplation subscale as the trial's primary outcome to measure the patient's readiness to make changes in therapy.

Secondary outcomes

We employed the Liebowitz Social Anxiety Scale—Self-Report (LSAS-SR) as a measure of social anxiety. The self-administered 24-item LSAS-SR has been shown to have good convergent, discriminant validity and reliability [64]. In studies, the self-reported edition has been found to correlate to a high degree with the clinician-administered edition [65]. We assessed the patient's self-esteem with the Rosenberg Self-Esteem Scale (RSES), a 10-item measure. It includes five positive and five negative items, which are reverse-scored [66] and have been shown to have good convergent validity, test–retest reliability, and high internal consistency [67]. Lastly, we assessed the patient's self-efficacy with the General Self-Efficacy Scale (GSES), a 10-item self-reported instrument designed to evaluate optimistic beliefs about one's ability to cope with various difficult demands in life. It is specifically designed to assess personal agency (i.e., the belief that one's actions are responsible for successful outcomes in one's life) [68, 69].

Exploratory outcomes

We employed the Readiness for Psychotherapy Index (RPI) as an exploratory outcome. This 42-item self-report measure assesses seven dimensions of readiness for psychotherapy [70]. The other exploratory outcome was the National Patient-Reported Outcome Measures (PROM)—Psychiatry. It is a 19-item self-report designed to collect information on patients' views on both their somatic and physical health, as well as general well-being [71]. It includes the standardized instruments of the WHO Well-Being Index (WHO-5) [72] and the Work and Social Adjustment Scale (WSAS) [73]. The Danish WSAS has been validated in a sample of patients with anxiety and depression. Lastly, we employed data from patients' electronic health records (EHR) to monitor patients' adherence to therapy and, lastly, their possible diagnostic reclassifications by accessing the included patients' EHR.

Randomization and blinding

Patients were randomized 1:1 to either the MCA or AAU. The randomization was done and generated using the REDCap © software. Due to the nature of the intervention, neither the patients nor the researcher who administered it were blinded to allocation. However, the statistician was blinded.

Reliability

The intervention was carried out by ORH, a resident in psychiatry employed as a Ph.D. student. He was trained and received supervision on the test included in the assessment battery from national experts. KD, trained in therapeutic assessment at the Therapeutic Assessment Institute in Austin, TX, supervised the intervention.

Statistical methods

See the protocol for the trial for sample size calculations [49]. Prior to the finalization of the study, a detailed statistical analysis plan was published at ClinicalTrials.gov, which is also included as additional information added to the present paper (Supplementary material 2).

Briefly, we reported descriptive data such as percentages, means, and variation as standard deviations. We analyzed outcomes as continuous and categorical measures (i.e., responder status and new diagnosis). All statistical analyses were performed as intention-to-treat analyses (ITT). Missing data was handled by the use of multiple imputations. The pre- to post-treatment effects of the MCU or AAU were determined utilizing a series

of ANCOVA calculations. All analyses were based on blinded data.

Results

Protocol violations

Due to COVID restrictions, we failed to recruit a user panel and, due to a lack of human resources, failed to develop a fidelity checklist for the MCA intervention.

Demographics

From October 15, 2021, to September 8, 2022, 44 patients were considered eligible for inclusion and had a trial information meeting. Of these, 42 gave written consent and were included in the trial. They were randomly allocated 21 (50%) to MCA and 21 (50%) to the AAU condition. See Fig. 2, the CONSORT 2010 flow diagram. The sample was predominantly female (71.4%) and had a mean age of 29.5 (SD = 8.9) years. Five (11.9%) of the

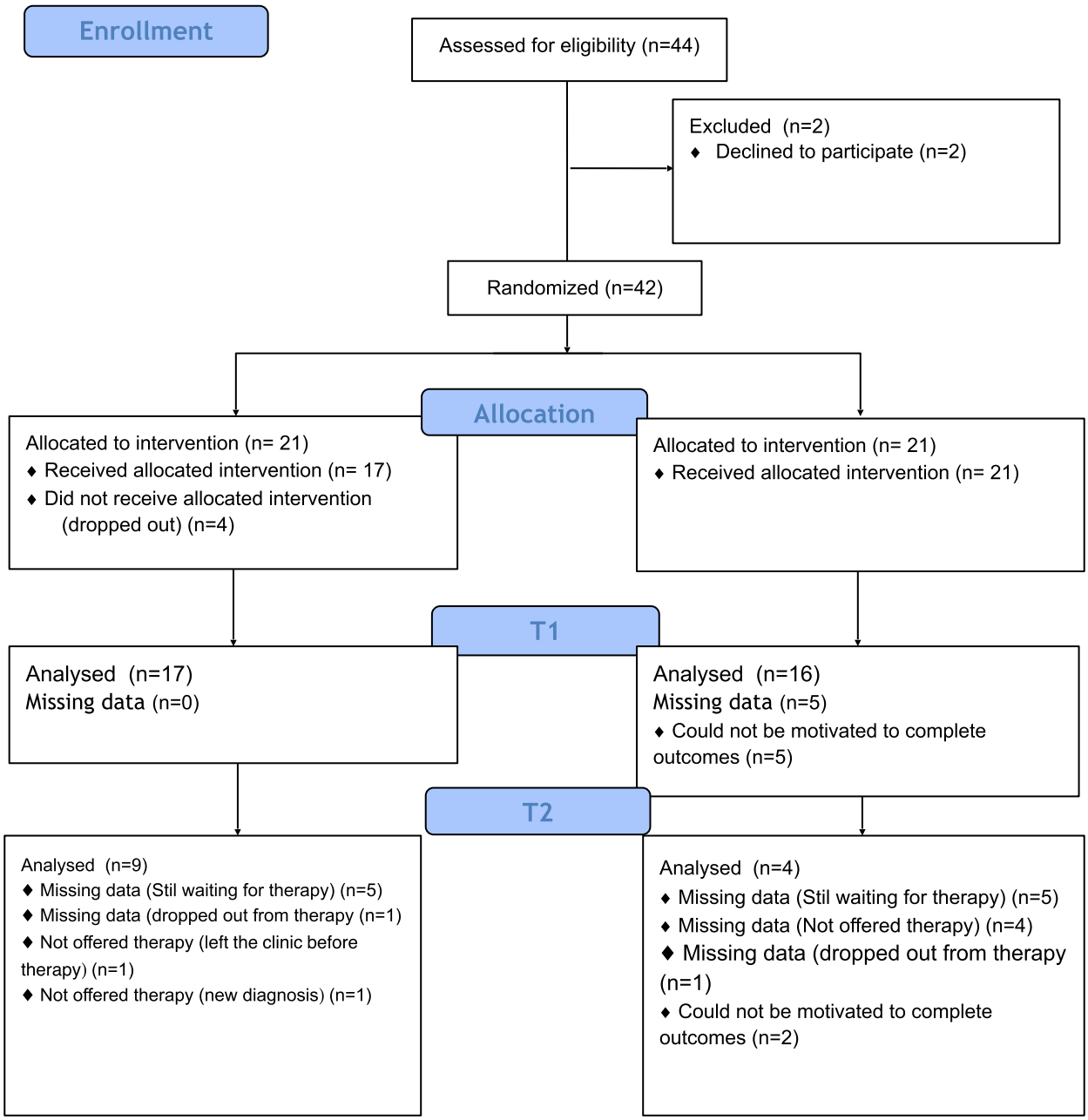

Fig. 2 CONSORT 2010 flow diagram

included patients had a principal ICD-10 diagnosis of SP, and the other 37 (88.1%) had a principal diagnosis of AvPD. Fifteen (35.7%) were not currently working or studying. More patients randomized to AAU were presently on sick leave ($p=0.02$), but no other demographic variable was different between the groups. See Table 1 for further demographic details.

Feasibility

The feasibility criterion for acceptability was met. Forty-four patients were given an information meeting, and 42 agreed to participate. The feasibility criterion for satisfaction was also met. At the end of the intervention, the estimated mean difference between conditions was −7.42 (95% CI −11.75; −3.09; $p=0.002$) points on CSQ8, mean score 3.3 for MCA. Time spent on the intervention was 6.07 (SD = 1.39) hours for intervention completers.

Adherence

Lastly, the feasibility criterion for adherence was also met, as 17/22 patients (80.9%) completed the MCA intervention. Post-treatment data were collected from these patients. Four (19.0%) patients randomized to MCA formally withdrew during treatment: two did so for lack of time, and two did not report the reason for withdrawal.

Table 1 Baseline demographic and diagnostic characteristics within and across conditions

	MCA	AAU	Total
Age	29.3 (9.3)	29.7 (8.7)	29.5 (8.9)
Gender			
Male	6 (28.6%)	6 (28.6%)	12 (28.6%)
Female	15 (71.4%)	15 (71.4%)	30 (71.4%)
Education			
Primary school	5 (23.8%)	5 (23.8%)	10 (23.8%)
Secondary school	11 (52.4%)	10 (47.6%)	21 (50.0%)
Short secondary education	0 (0%)	1 (4.8%)	1 (2.4%)
Bachelor's degree	4 (19.0%)	5 (23.8%)	9 (21.4%)
Master's degree	1 (4.8%)	0 (0%)	1 (2.4%)
Affiliation labor market			
Sick leave	4 (19.0%)	11 (52.4%)	15 (35.7%)
Studying/working/looking for work	17 (80.95)	10 (47.6%)	27 (64.3%)
Clinical diagnosis			
SP	1 (4.8%)	4 (19.0%)	5 (11.9%)
AvPD	20 (95.2%)	17 (80.9%)	37 (88.1%)
Comorbidity			
ADHD	3 (14.3%)	0 (0%)	3 (7.1%)
Anorexia nervosa	0 (0%)	2 (9.5%)	2 (4.8%)
PTSD	1 (4.8%)	0 (0%)	1 (2.4%)

Data are presented as n (%) or mean (SD) from data observed in the intention-to-treat population

MCA Modified Collaborative Assessment, *AAU* Assessment As Usual

Adverse effects

No patients were admitted during participation in the study. No patients experienced any suicidal behavior/ideation. No patients reported any discomfort with participation in the trial.

Primary endpoint (t1)

Primary outcome

At the end of treatment, the estimated mean difference between conditions was −0.49 (95% CI −3.51; 2.53; $p=0.74$) points on the URICA contemplation subscale, favoring MCA but failing to reach significance. See Table 2 for details.

Secondary outcomes

All secondary outcomes favored MCA but failed to reach significance. On the URICA RFC composite score, the estimated mean difference between conditions was −2.45 (95% CI −10.98; 6.08; $p=0.6$) at the end of treatment. The estimated mean difference between conditions on the LSAS was −3.16 (95% CI −20.11; 13.80; $p=0.7$). On the RSES, the estimated mean difference between conditions was −0.52 (95% CI −2.20; 1.16; $p=0.5$). On the GSES, the estimated mean difference between conditions was −1.06 (95% CI −5.14; 3.02; $p=0.6$). See Table 2 for details.

Exploratory outcomes

On the RPI RFC score, the estimated mean difference between conditions was −0.34 (95% CI −2.91; 2.22; $p=0.8$) at the end of treatment. On the WHO-5, the estimated mean difference between conditions was −12.54 (95% CI −26.12; 1.05; $p=0.1$) at the assessment. On the WSAS, the estimated mean difference between conditions was 3.00 (95% CI 1.25; 7.25; $p=0.2$) at end of treatment. See Table 2 for details.

MCA

All patients who completed the intervention were administered the SCID-5, PSE, and EASE. Further, one patient was also administered the Conners' and the SCIP. Other instruments were not administered. The mean length of the intervention was 6 h for MCA completers.

Follow-up (t2)

Primary outcome

At follow-up, the estimated mean difference between conditions with imputations on the LSAS was −26.96 (95% CI −90.33; 36.41; $p=0.37$). See Table 3 for details. The differences were not significant even with time spent waiting between T1 and T2 as a co-variable (Table 4).

Table 2 Means, estimated mean differences, and between-condition effect sizes for primary, secondary, and exploratory outcomes at T1 with imputations

				MCA			AAU			
	Diff	**95% CI**	***p***	**Est. mean**	**SE**	**95% CI**	**Est. mean**	**SE**	**95% CI**	***d***
Primary										
URICA cont	−0.49	−3.51; 2.53	0.74	35.11	0.95	33.16; 37.05	34.61	1.10	32.35; 36.89	−0.11
LSAS	−3.16	−20.11; 13.80	0.71	90.16	5.78	78.42; 101.89	87.00	6.04	74.69; 99.30	−0.12
RSES	−0.52	−2.20; 1.16	0.54	23.86	0.57	22.70; 25.01	23.34	0.61	22.08; 24.59	−0.19
GSES	−1.06	−5.14; 3.02	0.60	21.52	1.30	18.88; 24.16	20.46	1.52	17.32; 23.59	−0.17
CSQ8	−7.42	−11.75; −3.09	0.002	26.26	1.29	23.63; 28.89	18.84	1.63	15.42; 22.26	−0.97
URICA RFC	−2.45	−10.98; 6.08	0.56	85.35	2.64	79.99; 90.71	82.90	3.20	76.28; 89.51	−0.18
Exploratory										
URICA precnt	0.70	−1.33; 2.73	0.49	12.67	0.71	11.22; 14.12	13.37	0.71	11.92; 14.82	0.22
URICA action	−2.61	−5.47; 0.25	0.07	32.95	0.96	31.01; 34.90	30.34	1.03	28.22; 32.46	−0.56
URICA maint	1.50	−1.69; 4.68	0.34	30.05	1.02	27.98; 32.12	31.55	1.18	29.12; 33.97	0.30
RPI	−0.34	−2.91; 2.22	0.79	41.16	0.86	39.40; 42.92	40.82	0.91	38.94; 42.70	−0.08
WHO-5	−12.54	−26.12; 1.05	0.07	40.63	4.17	32.14; 49.11	28.09	5.19	17.30; 38.88	−0.56
WSAS	3.00	−1.25; 7.25	0.16	12.67	1.47	9.67; 15.67	15.67	1.45	12.71; 18.62	0.44

MCA Modified collaborative assessment, *AAU* Assessment as usual, *URICA* University of Rhode Island Change Assessment Scale, *LSAS* Liebowitz Social Anxiety Scale-Self-Report (LSAS-SR), *RSES* Rosenberg Self-Esteem Scale, *GSES* General Self-Efficacy Scale, *RPI* Readiness for Psychotherapy Index, *WHO-5* World Health Organization Well-Being Index, *WSAS* Work and Social Adjustment Scale, *CSQ8* Client Satisfaction Questionnaire 8

Table 3 Means, estimated mean differences, and between-condition effect sizes for primary, secondary, and exploratory outcomes at T2 with imputations

				MCA			AAU			
	Diff	**95% CI**	***p***	**Est. mean**	**SE**	**95% CI**	**Est. mean**	**SE**	**95% CI**	***d***
LSAS	−26.96	−90.33; 36.41	0.37	94.80	14.05	65.89; 123.70	67.84	24.72	9.19; 126.48	−0.29
RSES	1.24	−12.28; 14.77	0.84	23.29	5.46	8.66; 37.91	24.53	1.96	20.54; 28.53	0.07
GSES	1.04	−6.97; 9.05	0.78	19.10	2.72	13.21; 24.99	20.14	2.57	14.53; 25.75	0.09

See Table 2 for abbreviations

Table 4 Means, estimated mean differences, and between-condition effect sizes for primary, secondary, and exploratory outcomes at T2 with imputations. Data analyzed with time between T1 and T2 as a variable ($N=9$)

				MCA			AAU			
	Diff	**95% CI**	***p***	**Est. mean**	**SE**	**95% CI**	**Est. mean**	**SE**	**95% CI**	***d***
LSAS	−31.32	−75.61; 12.97	0.13	DNC	DNC	DNC	DNC	DNC	DNC	DNC
RSES	0.41	−3.98; 4.81	0.82	DNC	DNC	DNC	DNC	DNC	DNC	DNC
GSES	2.56	−3.73; 8.86	0.33	DNC	DNC	DNC	DNC	DNC	DNC	DNC

DNC Does not compute. See Table 2 for abbreviations

Secondary outcomes

On the RSES, the estimated mean difference between conditions with imputations was 1.24 (95% CI − 12.28; 14.77; $p=0.84$). On the GSES, the estimated mean difference between conditions with imputations was 1.04 (95% CI − 6.97; 9.05; $p=0.78$). See Table 3 for details. The differences were not significant even if time spent waiting between T1 and T2 was entered as a co-variable (Table 4).

Diagnostic reclassification and adherence to therapy

Three patients (14.3%) received another diagnosis as a result of the MCA intervention. One patient with a clinical diagnosis of SP was re-diagnosed with AvPD. Another patient with a clinical diagnosis of SP was re-diagnosed with borderline personality disorder. Lastly, one patient with a clinical diagnosis of AvPD was re-diagnosed with borderline personality disorder.

No differences were observed in patients' early adherence to psychotherapy between conditions ($p=0.9$).

Discussion

Our results supported the feasibility and acceptability of MCA in an outpatient population with anxiety and personality disorders. We demonstrated an excellent recruitment rate and a good MCA adherence rate. No adverse event was reported.

Participants randomized to MCA were significantly more satisfied with treatment than those randomized to AAU, but no significant effects were observed on any other outcome. This could be explained by the study's design, such that the patients randomized to MCA had already received AAU to receive their clinical diagnosis and be offered inclusion in the trial. This could reduce the impact of the MCA intervention, as some of the insight from the psychological tests in the MCA test battery might already have occurred from the standard administration of the test.

Both our primary outcome, the URICA, and one of our exploratory outcomes, the RPI, related to readiness for change. These or other outcomes relating to readiness for change had not been trialed in the context of C/TA-style interventions before the current trial. Other C/TA interventions have been shown to positively influence process outcomes, like therapeutic alliance with subsequent therapists [32, 37, 74], and increase compliance with treatment recommendations [36]. We, therefore, hypothesized that MCA would positively influence measures of readiness for change. However, as noted, we did not find that MCA had a significant positive effect on any of our outcomes related to readiness for change. A possible explanation could be that URICA and RPI are poor instruments for quantifying this outcome; Hovmand et al. (in review in the *Journal of Clinical Psychology*) [75] found that both the Danish URICA and the RPI had poor external validity regarding early adherence to psychotherapy.

Our main finding is that patients had higher satisfaction with MCA than AAU. Only one other study of C/TA-style interventions has published data on patient satisfaction with the intervention [74]. Therein, psychiatric inpatients awaiting group therapy received two CA sessions prior to therapy, which, regarding patient satisfaction, were superior to both a supportive psychotherapy condition and a treatment-as-usual condition, which had no individualized pre-treatment. Our findings are, therefore, in line with other trials on C/TA-style interventions administered as a pre-treatment to psychotherapy.

A number of reasons could explain patients' increased satisfaction with MCA. MCA could give patients a feeling of being met and that the clinician explicitly focuses on what is most important for them, as the therapeutic questions provide them with an opportunity to frame their key issues from their own perspective. This may provide patients with a feeling of empowerment [76]. The approach by which patients get a say in what questions should be answered is also in line with the concept of shared decision-making [77]. Further, the systematic approach of the MCA intervention and the considerable amount of clinician time involved could give patients a feeling of being taken seriously. The highly structured nature of MCA may provide patients a clear of actually undergoing an assessment, compared to the less structured standard diagnostic interview in AAU, which can be perceived as less structured. Finally, the personalized feedback letter that patients are given at the end of the MCA intervention could aid them in remembering the verbal feedback and make the assessment a lasting experience, which could also explain the increased satisfaction.

A number of interventions have been trialed as a means to enhance readiness for change. These include digital interventions [78] and those administered in person, such as motivational interviewing (MI), role induction, psychoeducation, and vicarious therapy pretraining [79, 80]. MI is especially relevant to discuss, as it is a relatively short intervention which, to a large extent, has been trialed as a means to prepare a patient for making changes in their life, and which we, therefore, could have opted to explore in this population instead of MCA and with the same endpoint. In MI, the therapist works with the patient to explore reasons for change, including weighing up the pros and cons of change and developing discrepancies between the patient's ideal and current states. In addition, they work towards building confidence and self-efficacy, as in T/CA [81]. MI was originally designed as a pre-therapy intervention for patients with alcohol overuse but has been applied for a wide range of mental health conditions, including anxiety disorders [82].

A recent meta-analysis evaluated existing trials on MI in clinical populations with a mental health diagnosis only [82]. Regarding patient motivation, MI did not result in greater increases in patient motivation when compared to a minimal control condition (7/12 studies), and the mean weighted effect size for the effect of

MI on patient motivation was small and non-significant ($d=0.18$, 95% CI [−0.05 to 0.42], $p=0.125$). This finding is in line with the present trial, which similarly did not show any increase in patient motivation. Likewise, regarding patient self-efficacy, the pooled effect size was negligible and non-significant ($d=0.04$, 95% CI [−0.54 to 0.62], $p=0.888$). This finding is thus also similar to current findings. Lastly, regarding adherence to future therapy, the majority of included studies (11/16 studies) found that patients receiving MI attended more treatment than those in a control condition (mean weighted effect size $d=0.38$, 95% CI [0.08 to 0.67], $p=0.012$). The meta-analysis provided no data on patient satisfaction, which, as noted, was the only significant finding in the present trial.

MCA is a time-consuming intervention, and one could ask if it would have been worth the resources, even if the intervention had shown any effect on the primary outcome. On average, the completers of the MCA intervention received 6 h of clinician time, which, in principle, could have been converted to extra psychotherapy. Routine clinical assessment, i.e., AAU, often takes 1–3 sessions, where the first interview is the longest, i.e., around 1.5–3 h. Consequently, applying MCA would mean doubling assessment time, which could be a grave impediment to implementation. It could only be justified if it improves outcome, whether mediated through reduced dropout or intrinsically through the patient's increased empowerment and insight. We also speculated that, although costly, saving wasted therapist time due to dropout might be cost-effective. Given the lack of difference in psychotherapy adherence, the current results do not support this. Certainly, cost-effectiveness would need to be investigated in a future trial.

Strengths and limitations

Intervention content

We used a shortened version of the standard TA intervention by the number of tests available for the MCA therapist to apply. The strength of using this scaled-down version of C/TA is that it is much more accessible to clinical staff in the MHS and, therefore, should be easier to implement in clinical practice than regular TA. In contrast to standard TA, which highly experienced psychologists often practice with access to many tests, the MCA intervention is accessible to junior staff, such as trainee psychiatrists or psychologists, who are still learning. The MCA therapist in the present trial was a junior psychiatrist who, with training in the MCA battery and supervision, could successfully carry out the collaborative approach while administering the assessment instruments and giving personalized written feedback. The MCA battery of tests was also designed to be able to detect psychopathology within different diagnostic categories (e.g., attention disorders, personality disorders, autism spectrum) and to uncover subtle psychopathology that an unstructured clinical interview might not be able to detect. As such, the battery consisted of tests that were more psychopathological than psychological and only allowed for discussions of non-psychopathology-related matters to a limited extent. It is, therefore, possible that some elements (e.g., the WAIS) are unable to promote readiness for psychotherapy. However, none of the patients randomized to MCA received the WAIS as it was not judged relevant from their therapeutic question and clinical presentation. Adding elements that are supposed to be closer related to readiness for psychotherapy change, such as symptom network [83], may have enhanced outcomes of the intervention in this study. Further, the tests applied in the MCA intervention are all well-known tests already widely applied in mental health services and in which many psychologists and psychiatrists are already trained. This, too, makes the MCA intervention easier to implement than regular therapeutic assessment. The intervention may also be less time-consuming than regular TA because of the limited number of tests.

Design

This study's major strength is that it relied on a robust methodological approach, including an RCT design with a protocol and statistical analysis plan published in advance, the use of an external statistician working with masked data, and the formulation of conclusions based on the masked data. Furthermore, the secondary mental health care setting with complex patients and broad inclusion criteria (in line with those used in the clinics) added external validity to the trial.

Limitations include the fact that the MCA intervention was administered by a single resident, a researcher and a therapist. Secondly, the MCA intervention was administered to a sample that already had completed AAU in the psychotherapy clinics to be eligible for inclusion. This might have reduced the therapeutic impact of the MCA intervention. Third, the MCA therapist was not the patients' future group therapist. It is possible that the MCA intervention would have shown a greater effect if the same person had administered both the MCA intervention and the following group psychotherapy. However, the fact that the C/TA therapist differed from the patients' later therapist is in line with standard practices in the therapeutic assessment community, where patients are usually referred to a therapeutic assessment [33, 34]. Fourth, we did not control for psychotropic medication in this RCT. Fifth, the potential effects of patient expectation biases were not assessed. Sixth, the trial did

not assess outcomes at the end of the following therapy, but only at the beginning of it (after four sessions). It is, therefore, possible that the MCA intervention could have had a long-term effect on the patients, which did not show so early in their treatment. Lastly, significantly fewer patients were randomized to MCA on sick leave. It is possible that this could have impacted the results of patients' treatment, as these patients could be regarded as having more resources and being higher functioning. However, we do not consider it likely that this would affect the primary outcomes of the present trial (feasibility and readiness). Another possible confounder could be that all included patients had already tried and failed at least one line of treatment. All patients could, therefore, be regarded as having had at least one frustrating experience of non-response, which could have negatively affected the outcome of the present study. However, this experience should be equally featured across treatment arms, and hence its possible effects should be equally experienced across them. Future research on MCA could evaluate patients' expectations for treatment at enrollment and apply this as a factor. However, our sample could also be regarded as one that, by default, was highly motivated to participate in treatment or had an exceptionally high level of discomfort from their symptoms. The first is exemplified by a score on the URICA, which was high at baseline and can suggest a ceiling effect. Future trials could utilize a high baseline score on the URICA or a similar instrument as an exclusion criterion. A third possible confounder is the period with symptoms and the period of treatment without effect experienced by the patients, which could influence the trial results. Future research on MCA could collect and investigate a possible moderating effect of this variable.

Implications for future research

MCA could be examined in a future large-scale trial where patients are enrolled prior to basic diagnostic assessment in the psychotherapeutic clinics and where high readiness for psychotherapy at inclusion could be applied as an exclusion criterion. This could increase MCA's effect on readiness for psychotherapy, as the patients allocated to MCA would not have already undergone AAU prior to MCA, as they had in the present trial. Future research should utilize other process outcomes, as the URICA and RPI might have limited relation to future adherence to psychotherapy.

Conclusion

This feasibility trial demonstrated that using a scaled-down version of TA in the Danish MHS was feasible in recruiting patients and patient retention in therapy. We observed no differences between MCA and AAU on patients' readiness to change as measured with the URICA contemplation subscale. No differences were observed in any secondary outcome, except patients who were more satisfied with the treatment in the MCA than in the AAU condition.

Our findings suggest that a future trial using a larger sample and adequate outcomes may be relevant to investigating the implementation of MCA, which is more integrated with clinical procedures in psychotherapy clinics.

Supplementary Information

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Supplementary Material 1.

Supplementary Material 2.

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Authors' contributions

SA conceived the study. SA, ORH, NR, and KD designed the study details. ORH collected data. RB assisted with the recruitment of patients. CH carried out statistical calculations. ORH was responsible for writing the first draft of this manuscript. SA contributed with significant analysis comments and guidance. All authors have discussed, reviewed, and approved the manuscript.

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Declarations

Ethics approval and consent to participate

The protocol was approved by the Ethics Committee Region Zealand (registration number: SJ-924) and Region Zealand Data Protection Agency (registration number: REG-050–2021) and has undergone full external peer review and accords with the European Union's data security regulations. All patients gave written informed consent following the National Danish Ethics Committee's guidelines prior to randomization and intervention allocation.

Competing interests

The authors reported no potential conflict of interest.

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