Social Phobia and Evasiveness: Trial Protocol for a Feasibility, Superiority, Randomized Controlled Trial of the Effect of Modified Collaborative Assessment vs. Standard Assessment on Patients' Readiness for Psychotherapy (CO-ASSM-RCT).

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Study Protocol

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Abstract:

Background: Evasive personality disorder (EPD) and social phobia (SP) have substantial costs to the patients and their families, and great economic costs to the community. While psychotherapy can be an efficient treatment, a large percentage of patients drop-out during treatment. Little is known about what can be done in order to decrease dropout from psychotherapy in general, including how to increase a patient's readiness for psychotherapy.

Methods: We describe a feasibility randomized controlled trial of 42 individuals with a clinical diagnosis of either SP or evasive personality disorder, who are to initiate psychotherapeutic treatment in Danish outpatient mental health services. They will be randomized in a 1:1 ratio to either assessment-as-usual and receive no further assessment, or to a Modified Collaborative Assessment (MCA) provided as a pre-treatment intervention before psychotherapy initiation. MCA will included a battery of psychological tests designed to thoroughly assess the patients' psychopathology. The tests is administered in collaboration with the patient including a detailed oral and written feedback. We hypothesize that the patients randomized to MCA will reach higher levels of readiness for psychotherapy as assessed with the University of Rhode Island Change Assessment Scale (URICA) and have lower dropout-rates than assessment-as-usual.

Discussion: This protocol assess the feasibility, efficacy, acceptability, and safety of an intervention aimed at changing the readiness for participation in psychotherapy for patients with SP and EVP. Results from this feasibility study could guide the development of future large-scale trials of MCA and procedures for MCA treatment fidelity assessment.

Trial Registration: 2021001

Keywords: Assessment, personality disorders, social phobia, psychotherapy, evasiveness, collaborative assessment, therapeutic assessment

Background

Introduction and rationale

Anxiety disorders represent an important public health concern in the western world [1, 2]. Estimates from a large European epidemiological survey suggest that 14% of the European population will meet criteria for an anxiety disorder within their lifetime [3]. These disorders are often associated with a chronic, debilitating course for the affected individual as well as high socio-economic costs [4-6]. Anxiety disorders are among the leading causes of the global disease burden and the annual costs in Europe alone reached 74 billion Euros in 2010 [7, 8]. Continuous efforts to improve treatment programs for anxiety pathology is imperative.

Social phobia (SP) is the most common amongst anxiety disorders. The fear of being observed or negatively evaluated by other people is a prominent characteristic of individuals with social phobia. This fear leads the individual to avoid performance or social situations (e.g. speaking or eating in front of others, making acquaintances, and meeting authorities) or they enter such situations with substantial discomfort [9]. This evasiveness severely impacts the social functioning and quality of life for affected individuals [10, 11].

Similarly, avoidant personality disorder (AvPD) is characterized a pervasive pattern of social inhibition, feelings of inadequacy, and a hypersensitivity to negative evaluation, which result in marked evasiveness in terms of avoidance of social interactions, while perceiving themselves as unwanted and isolated from others [9]. The Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) [12] recognize a considerable overlap between AvPD and SP. Although the relationship between the disorders is a matter of debate[13], the dominant conceptualization is that the two disorders represent a spectrum, differing from each other only in severity (the severity continuum hypothesis[14]). In the upcoming revision of the International Classification of Diseases, tenth edition (ICD-10), AvPD will be removed as an independent diagnosis [15], which further support the severity continuum hypothesis. Similarly to the anxiety disorders, AvPD is associated with profound impairment in daily life for the affected individual as well as high socio-economic costs [16].

Hence, the present study protocol relevantly focus on SP and evasiveness.

Danish outpatient mental health services provide time-restricted, standardized, interdisciplinary treatment programs for social phobia and AvPDs. Following national clinical practice guidelines, the treatment programs offer evidence-based cognitive-behavioral therapy for social phobia and mentalization-based therapy for AvPD.

The content and format in the standardized treatment programs for moderate-severe SP and AvPD are regulated in accordance with the Danish Health Authority guidelines. The treatment program for SP amounts up to 15 hours of clinical assessment (3hrs), psychopharmacological consultation (1 hrs), individual psychotherapy (7 hrs) or group therapy with two therapists (28 hrs), relatives support (1½ hrs), and network consultation (1½ hrs) [17]. The standardized outpatient treatment program for AvPD include 34 hours of clinical assessment (2 hrs), psychopharmacological consultation (2 hours) individual therapy (11 hrs) or group psychotherapy with two therapists (60 hrs), and network consultation (3 hrs) [18].

Correspondingly, do the standardized outpatient treatment program for AvPD include 34 hours of clinician time, entailing approximately two hours of clinical assessment, two hour of psychopharmacological consultation, 11 hours of individual therapy and 15 hours of group therapy with two therapists and lastly three hours of contact with the general practitioner to other support-persons around the patient [18].

However, despite a solid evidence-base for the efficacy of cognitive-behavioral therapy for social phobia, recent meta-analytic data suggest that only 45% of patients suffering from social phobia remit from their principal diagnosis after treatment and patients with social phobia have a worse outcome than patients with other anxiety disorders[19]. The evidence-base psychological treatment for avoidant personality is limited in terms of number and quality of studies and the remission rates vary substantially from 40-80% [20].

Data from a recently finalized multicentre, randomized controlled trial [21] investigating the relative efficacy of group diagnosis-specific versus transdiagnostic cognitive-behavioral therapy for anxiety disorders or depression support the meta-analytic findings on social phobia. In this trial, 291 patients with anxiety disorders or depression received standardized treatment programs in three Danish mental health

services, and the results suggested that only half of the patients no longer met diagnostic criteria for their principal diagnosis by the end of treatment [22]. No data exists on the efficacy of the standardized programs for AvPD.

Modified Collaborative Assessment

Psychiatric assessment do usually aim to establish a diagnosis and plan the treatment, while it is not considered part of the treatment proper. We wish to alter this perspective by the introduction and exploration of a modification of Collaborative Assessment that we have chosen to name Modified Collaborative Assessment (MCA).

MCA takes off from Collaborative Assessment and Therapeutic Assessment (C/TA) [23-25]. These terms are used to describe a family of semi-structured, brief, therapeutic interventions, in which a therapist with a large battery of standardized diagnostic and psychological tests, administer these in a collaborative manner, and deliver feedback in a manner that is useful and enriching - and therefore therapeutic - for the patient.

C/TA have been explored in several controlled trials with adults, and have been shown to be able to increase a range of process-variables related to therapy outcomes. This includes self-esteem [26-29], compliance with treatment-recommendations [30], therapeutic alliance with subsequent therapist [31, 32], satisfaction with treatment [33], as well as decreased anxiety symptoms [34, 35] and levels of self-criticism [34]. In addition, Poston and Hanson (2010) [36] published a meta-analysis on 17 published C/TA-studies, which found favorable effects of this intervention in terms of overall effectiveness, when compared to assessment as usual.

We wish to apply a modification of C/TA, where the intervention is shorter, and slightly more structured and require less psychiatric expertise (i.e. can be carried out by trainee doctors and psychologists) which we therefore expect to be more feasible in the trial as well as in later implementation.

MCA will, similar to C/TA, include the administration of standardized diagnostic instruments, but we will in contrast to C/TA only include a smaller selection of tests, in order to secure feasibility. The bat-

tery of tests will be specifically designed to gather information on psychopathology, which a brief clinical interview might not detect, such as symptoms of previously un-detected developmental disorder or incipient psychosis. We have compiled a battery of tests with this focus because we find it most suitable for application in the Mental Health Service. The present study is further designed to establish diagnosis adhering to the current diagnostic systems (ICD-10 and DSM-5), but we expect it would be applicable if the Mental Health Service introduce the dimensional [37, 38] model of psychopathology, since the current MCA also includes a thorough personality assessment according to the DSM-5 alternative model of personality pathology..

MCA emphasize respect for the patients as "experts on themselves." The accessor will in collaboration with the patient formulate a list of therapeutic questions, which the patient would like to "ask the psychological test's" which will help guide the patient's and accessors collaborative quest to learn more about the patient's problems and personal resources. The results of the assessment and the answer to the therapeutic questions will be communicated, respectfully, to the patient both orally and in writing. It will further be communicated to the patient's future therapist in writing. In this manner, it should be possible to formulate personally relevant problems for the later psychotherapy. The MCA-accessor recognizes that diagnostic assessments is an interpersonal event, and that the relationship between assessor and patient is paramount both in relation to the validity of the result, and in relation to the patient's further treatment [25].

In short, MCA is a brief, individualized, and person-centered assessment of psychopathology, where assessment, psychotherapy and psychoeducation are integrated in a novel intervention, all carried out in collaboration with the patient.

Readiness for Psychotherapy

The fundamental role of patients' readiness to psychotherapy change (or client motivation) for outcome of therapy is widely recognized [39]. The concept overall refers to the intentional aspect of change, the internal drive preceding behavioral change before the initiation as well as the ongoing engagement

throughout therapy [40]. Theoretically the concept is most profoundly described as a core component in the 'stage of change'-dimension of the so-called Transtheoretical Model of behavior change set forward by Prochaska & DiClemente [41]. In the 'stage of change'-dimension, patients are assumed to vary in their overall readiness to change , and being on different levels of readiness to change ranging from 'pre-contemplation' over being ambivalent about change ('contemplation'), having intentions to change ('preparation'), and starting changes ('action') to consolidating changes ('maintenance).

Studies have consistently found patients' readiness to change to be an important factor in predicting and moderating psychotherapy outcomes for patients [42]. Regarding anxiety disorders, research indicate that patients' readiness to change reduces symptoms and improve other process variables such as working alliance and adherence to treatment [43]. However, data suggest that up to 80% of patients are not ready for change (to pursue treatment goals) when they enter treatment and they harness ambivalence about therapy [44].

We expect that MCA will increase patient's readiness for psychotherapy as assessed by the University of Rhode Island Change Assessment Scale (URICA) (contemplation subscale) and the Readiness for Psychotherapy Index (RPI), and increase engagement in psychotherapy as measured by attendance to psychotherapy. We expect that more than one mechanism of action is at play: (a) the patient will develop a relationship with the MCA-accessor and the outpatient clinic during the course of MCA, which will carry-over to the therapeutic-relationship with the psychotherapist; (b) due to the structural MCA format, the patient will be confident that her problems are seen and understood; (c) the patient will understand herself and her problems and personal strengths, and will more effectively be able to work on these in therapy, and (d) the therapists will have a greater knowledge of the patient's problems based on the summaries from the MCA.

Objectives

The study objectives are to (1) compare the effect of MCA vs Assessment As Usual (AAU) in patients referred to group therapy for social phobia or AVPD on levels of readiness for psychotherapy compared with AAU at end-of-intervention (T1) (main outcome) and after one month follow-up (T2); (2) compare

the effect of MCA vs AAU in patients referred to group therapy for social phobia or AVPD on diagnoses (number of diagnostic revisions) and treatment offered (number of patients offered other or additional treatment) as well as adherence to group therapy (adherence within the first four weeks); (3) explore the feasibility of MCA as intervention through patient satisfaction ratings and patient and therapist/clinician evaluations; (4) and develop a fidelity-checklist for the MCA intervention.

Hypotheses

We hypothesize that that MCA in patients with social phobia or AvPD is superior to AAU in increasing contemplation score (URICA, see below) at end of intervention (T1). (2) In addition to this, patients offered MCA have higher service satisfaction ratings (CSQ) than AAU prior to psychotherapy onset and user evaluation scores of MCA (purpose made) are positive (more than 3 on a 1-5 Likert Scale).

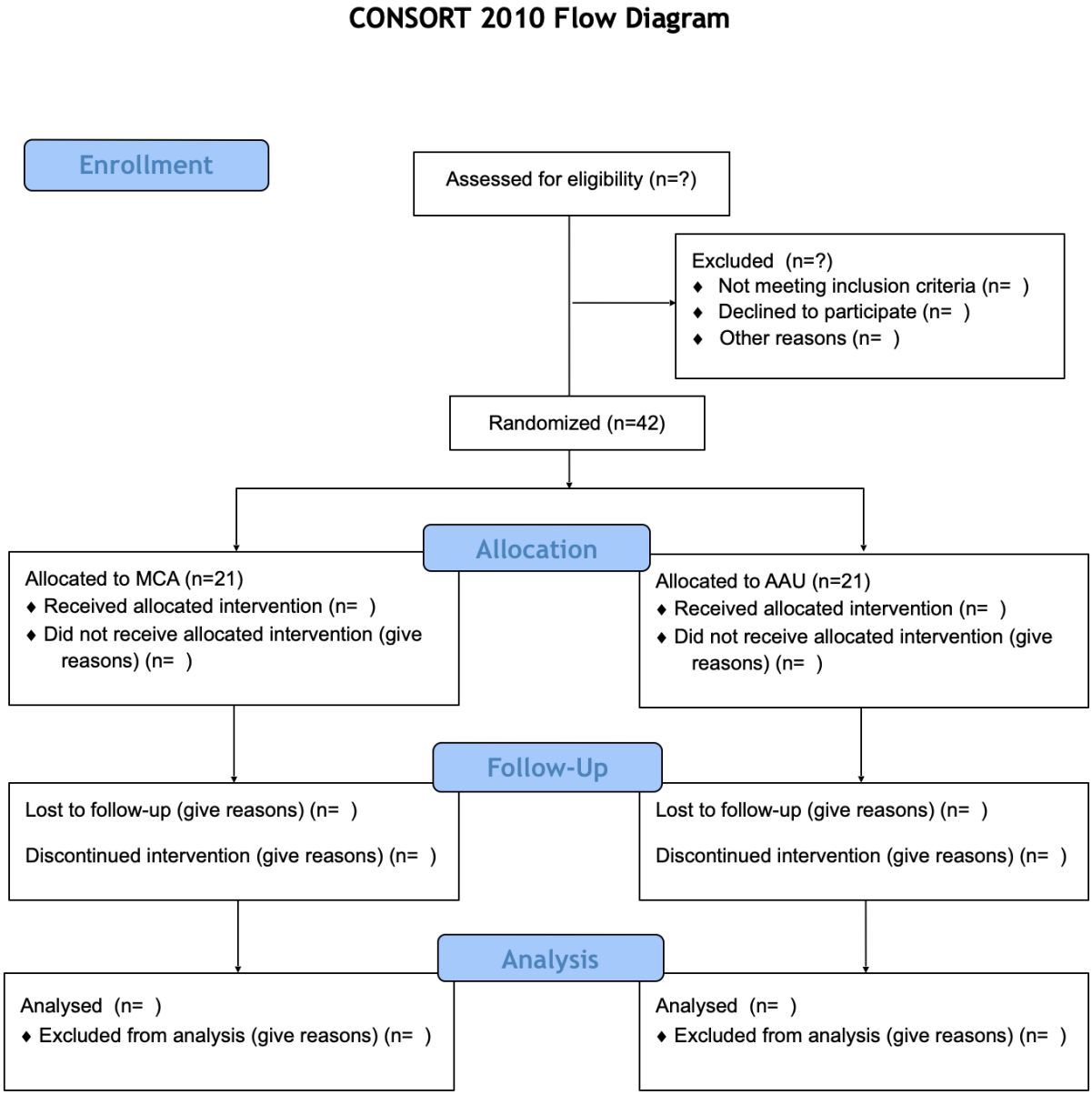
Methods/design

Trial design

A two-armed, parallel, superiority, randomized controlled trial comparing the effect of pre-treatment MCA with AAU.

A CONSORT diagram is provided in Fig. 1. A diagram of the proposed study and the outcome-assessment is provided in Fig. 2. The trial data collection and randomization, stratified by gender, will be carried out in the web-based data management system REDcap (https://www.project-redcap.org/). Self-ratings will be collected on the web-based REDcap platform.

Figure 1. **CONSORT flow diagram**



Settings

The setting of the study is Psychiatry South in Region Zealand, which is a rural-region with several medium-sized cities, according to Danish standards. Two of these cities have Psychiatric Outpatient Clinics, which carry out psychotherapeutic treatment of patients with emotional disorders, which are too serious to be manageable by family doctors and primary sector psychologist and psychiatrists. Patients are typically referred by general practitioners, when they have failed to respond to one or two different treatments (medication and/or psychotherapy). The services in these clinics are covered by the public

Danish health insurance, and involve both psychotherapy and psychopharmacological treatment, see also Introduction.

Participants and eligibility criteria

We aim to include 42 patients that satisfy the inclusion criteria: (1) a tentative ICD-10 diagnosis of either SP or AVPD, (2) who is going to be offered treatment in the before mentioned clinics, (3) are 18-65 years of age, (4) have given written consent to participate and (5) have sufficient knowledge of the Danish language.

Patients will be excluded if (1) risk of suicide is high or moderate according to the investigator, (2) they have alcohol or drug dependency, (3) they have co-occurring eating disorder with BMI < 18 or psychotic illness

Recruitment

In the first consultation in the psychiatric clinic, clinicians evaluate if the patient is eligible for psychotherapeutic treatment and stipulate a clinical diagnosis.

If patients are eligible for treatment in the clinic, they will be provided with information about the project and they will be invited to a meeting with a researcher, where the informed signed consent is gathered

Randomization and blinding

Patients will be randomized 1:1 to either the MCA or AAU. Allocation to experimental intervention or comparison intervention will be computer-generated using the software REDCap © [45].

Due to the nature of the intervention, neither participants nor the researcher who will administer the intervention, can be blinded to allocation. However, data will be re-coded for concealment and analyzed without access to information about allocation. The conclusion will be written prior to unblinding.

Experimental intervention

The MCA, as described in the Introduction will include at least the administration of the following nine assessment instruments:

Present State Examination (PSE). PSE is a semi-structured interview that intends to provide an objective evaluation of symptoms associated with mental disorders. It consists of 140 items, which is scored on a 3-point or 4-point scale [46]

Structured Clinical Interview for DSM-5 (SCID-5). SCID-5PD: A semi-structured interview guide for evaluation of the 10 DSM-5 Personality Disorders.

The Examination of anomalous self-experience (EASE). EASE is a semi-structured checklist for clinical-phenomenological exploration of experiential disturbances. Scores are summed up in a *global score*, with five *sub-scores*; Cognition and stream of consciousness, Self-awareness and presence, Bodily experiences, demarcation/transitivism and existential reorientation [47].

The Screen for Cognitive Impairment in Psychiatry (SCIP). SCIP is a neuropsychological test for quick and objective quantification of cognitive function in patients with psychiatric disorders. The Danish translation has demonstrated validity for detection of objective cognitive impairment [48]. It assesses verbal learning and memory, delayed memory, working memory, word mobilization and processing speed test [49].

Autism Diagnostic Observation Schedule (ADOS-2). ADOS-2, module 4 [50] is a a semi-structured and standardized observation of communication, social interaction and creative use of materials used to assess autism spectrum disorder pathology.

Wechsler Adult Intelligence Scale – Fourth Edition (WAIS-IV). The WAIS is an IQ test designed to measure intelligence and cognitive ability in adults and older adolescents [51]**.**

Conners´ Adult ADHD Rating Scales (CAARS). The CAARS is a test developed to diagnose attention problems, such as ADHD and ADD. It provides both Self-Report and Observer Report Forms, permitting multimodal assessment of adults with attention problems [52].

Level of Personality Functioning - Brief Form 2.0 (LPFS-BF). LPFS-BF is a brief 12-item self-report inventory developed to assess levels of personality functioning as defined in the alternative model for personality disorders in DSM-5 Section III. It measures impairment in personality functioning within the domains of self-functioning and interpersonal functioning [53].

Personality Inventory for DSM-5, 36 item version (PID-36). The PID-36 is an abbreviated version of the originally 100-item version of the Personality Inventory for DSM-5 (PID-5), developed to measure the pathological trait specifiers listed in the alternative model for personality disorders in DSM-5 Section III [54].

Material from the medical record and from the full MCA will be presented for case-supervision with a senior psychiatrist, with the option of getting additional opinion from another senior consultant in case of diagnostic uncertainty. This procedure is included in order to ensure solid diagnostic verification or alteration.

Therapists and team are informed of the results of the MCA, in order for them to use the extra information about the patient in the following psychotherapeutic intervention.

Comparison intervention

Patients allocated to the control-group will receive AAU, which is the standard assessment patients will receive in the clinic, administered in the manner the assessment usually is. Standard assessment could include diagnostic assessment with structured interviews (i.e. SCID-5 or PSE) if found indicated by the clinical assessment team.

Intervention fidelity

The intervention will be carried out by the researcher, a resident in psychiatry. He will receive training and supervision on the assessment battery from experts in the field, and he will likewise receive training and supervision in Therapeutic Assessment. Audio or video-recordings of MCA consultations will be used for supervision purpose, and to secure intervention fidelity.

Outcomes

Data are gathered through a number of questionnaires from patients prior to randomization (T0), at end of MCA (T1) and after four weeks of psychotherapy (T2) – absolute time depend on clinical logistics

and timing of group therapy onset.

An overview of outcome measures is given in Table 1, and instruments in each category are detailed below.

Primary outcome (objective 1)

University of Rhode Island Change Assessment Scale (URICA). URICA is a 32-item self-report measure that including 4 subscales designed to quantify the patients motivation for change: The four subscales are Pre-contemplation, Contemplation, Action, and Maintenance [55]. We will utilize Contemplation score as our primary outcome.

Secondary outcomes

The Liebowitz Social Anxiety Scale-Self-Report (LSAS). The self-administered 24-item LSAS-SR[55], which is highly correlated with the clinician-administered version [56] includes questions pertaining to social interaction and performance situations. The LSAS-SR have shown to have good convergent, discriminant validity, and reliability [57].

Rosenberg Self-Esteem Scale (RSES). The RSES is a 10-item measure of self-esteem that includes five positive items and five negative items which are reversed scored [58]. In general, the RSES has demonstrated good convergent validity and good test-retest reliability and in similar populations of adults with social phobia, the RSES has demonstrated high internal consistency [59].

General Self-Efficacy Scale (GSES). The GSES is a 10-item psychometric scale that is designed to assess optimistic self-beliefs to cope with a variety of difficult demands in life. In contrast to other scales that were designed to assess optimism, this one explicitly refers to personal agency, i.e., the belief that one's actions are responsible for successful outcomes [60, 61].

Exploratory Outcomes

Working Alliance Inventory (WAI). The WAI is a 36-item self-report psychometric scale that is designed to a assess the therapeutic alliance between a patient and a therapist [62]. It will access the working alliance between the group-therapists and the patients.

Readiness for Psychotherapy Index. The RPI is a 42-item self-report measure that uses a 5-point Likert scale to assess 7 dimensions of readiness for psychotherapy: level of distress, desire for change, willingness to work in therapy, recognition of problems as psychological, willingness to discuss personal matters, willingness to endure discomfort in therapy, and responsibility for change [63]. The questionnaire will be translated and validated for use in a Danish mental health service population, as part of the present study.

National Patient Reported Outcome Measures (PROM)-Psychiatry. The Danish National PROM is a 19-item, self-report measure covering patients own view on their mental and physical health, and level of general well-being [64]. It includes the WHO Well-Being Index (WHO-5), the Work and Social Adjustment Scale (WSAS) [65] and general items from the SF36

Data from Electronic Health Records (EHR). We will monitor number of no-shows and number of diagnostic re-classification by accessing the included patients EHR.

User Evaluations

Client Satisfaction Questionnaire (CSQ-8). The CSQ-8 is a self-report questionnaires constructed to measure satisfaction with services received by individuals and families [66].

Evaluation of the intervention (EQ). Questionnaire focusing on the patient's and therapist's evaluation of the intervention, which is purpose-made for the current study, will be distributed at the end of the intervention. Items will be constructed as Likert Scale feedback forms consisting of a list of statements about different aspects of the course of the intervention. Response possibilities are five categories ranging from very much in agreement to not at all.

Adverse effects

We monitor for adverse events, in particular suicidal behavior/ideation and will check for this at every visit to the clinic. If a patients is admitted during participation in the study, a senior consultant will decide whether the patient can continue to participate in the present study.

Table 1. Overview of measurements CO-ASSM-RCT

	Baseline (T0)	End of intervention (T1)	After 4 sessions group psychotherapy (T2)
URICA	x	x	
LSAS	x	x	x
RSES	x	x	x
GSES	x	x	x
WAI		x	x
CSQ-8		x	x
PROM	x	x	x
EHR			x
EQ		x	
RPI	x	x	

Patient and public involvement

We will throughout the present trial seek the feedback of users and next-of-kin, and we will establish a user-panel who will help interpret the findings of the study.

Statistical considerations

Sample size calculation is based on figures in Dozois et al. (2004) [67] of patients with panic anxiety, where the primary outcome “Contemplation stage score” in readiness for change. It was mean 37,3 (SD

1,9) for CBT responders and mean 34,4 (std 3,4) for non-responders, i.e. with significance level 5% and power 90%, it yields a total sample of 36 and 18 patients in each arm. We strive for 42 patients to account for attrition around 15%. We find it feasible to include the 42 patients since 64 patients annually are offered treatment packages (40 SP and 24 AVPD). A detailed statistical analysis plan will be published prior to data processing initiation. Briefly, we expect to analyze continuous outcomes by linear regression. Categorical outcomes will be analyzed using chi-square testing of frequency distribution. We will use multiple imputations to handle missing data.

Dissemination policy

The results of the present study will be disseminated by the Research Unit for Psychotherapy and Psychopathology's social media account and website. It will also be sought published through high-impact international peer-reviewed journals, and be presented at conferences for clinicians, commissioners, and researchers working in the mental health field. Both negative and positive findings will be published. The protocol is published at clinicaltrials.gov (Nr 2021001). Although steps will be taken to avoid it, protocol deviations may happen. Protocol deviations that occur after the start of trial recruitment will be communicated at https://clinicaltrials.gov and detailed in publications.

Trial Status

The trial is expected to begin recruitment October 2021. The last participant is expected to be included November 2022. The interventions session are expected to run from September 2021 to January 2023.

Discussion

The current study will be the first RCT investigating MCA in a Mental Health Services setting. It will be a feasibility study, and will test the study hypothesis in a small clinical sample. If the present study is successful, it might be followed up by other and larger clinical studies on MCA. The study will contribute to sparse existing research concerning the impact of clinical assessment and will provide important new knowledge about the effect of routine and systematic patient-centered clinical assessment and generate effect size measures for future power calculations. It will also generate data regarding patients

readiness for psychotherapy, and the percentage of patients who are wrongly-diagnosed in a prototypical Danish public healthcare psychotherapeutic clinic.

We believe the intervention will have a positive effect on the included patients, but there is however a potential risk that the patients receiving MCA may not benefit from the excess assessment, but that the treatment instead will increase dropout due to the patient becoming overwhelmed. There is also a possible risk of the patients become upset or disappointed due to the new knowledge, they receive about themselves. Ultimately, the MCA might yield an unexpected diagnosis which could severely change the way the patient sees herself, and the way society in general sees the patient. Many of these problems, may, however, also occur in AAU.

If the current project document feasibility of the approach, further studies should examine the incremental value of MCA as to patient outcome of total treatment course, persistence in and length of treatment and cost-effectiveness.

By the end of the present project, we will be able to decide whether the results are sufficiently promising to pursue a full trial (phase III)[68]. For that purpose, the study output also encompass development of a MCA protocol for clinicians and adjoining fidelity instrument.

Additional File

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents.

Declarations:

Ethics approval and consent to participate

The protocol was approved by Ethics Committee Region Zealand (Registration number: SJ-924) and Region Zealand Data Protection Agency (Registration number: REG-050-2021), and has thus undergone full external peer-review, and live up to the European Union's rules of data security.

All participants will give written informed consent following the National Danish Ethics Committee's guidelines, and do so prior to randomization and intervention allocation.

Consent for publication

Not applicable.

Availability of data and materials:

The datasets generated by the planned study will not be publicly available due to the rules of the Danish Data Protection Agency, but will be available from the corresponding author, after publication, on reasonable request and following signed confidentiality agreement with PI and the Danish Data Protection Agency Region Zealand.

Competing Interests

The authors declare there are no competing interests in this trial.

Funding:

The study have received funding from Psychiatry South, Region Zealand Mental Health Service (2.128.560 DKK) which is allocated to the PhD's salary, and the Region Zealand Phd Tuition og Annuum fond (180.000 DKK) which is allocated to the tuition fee to the University of Copenhagen and the PhD-students annum-funds. SA is affiliated with Region Zealand Mental Health Service, where she is employed. Furthermore, the study has received competitive funding from Trygfonden (997.259 DKR) and the AP Møllers Lægefond (50.000 DKR), which will cover the running costs of the study.

Authors contributions:

SMA is principal investigator and manager on the executive level as well as head academic supervisor. SMA conceptualized the study and ORH was responsible for writing the first manuscript draft which was supplemented with substantial input from NR and KD. All authors have discussed, reviewed and approved the manuscript.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents has been filled out, and is included as additional file 1.

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