Study protocol with rudimentary statistical analysis plan

A transdiagnostic course for common mental health problems in primary care

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Study protocol ([Swedish original] last revised on July 18th 2020)

Improved access to psychological interventions in primary care: feasibility and observational study of a transdiagnostic course for large groups

Summary
[In Sweden and many other countries,] primary care is tasked with assessing and treating patients with mild to moderate mental health problems, including the majority of patients with depression and anxiety disorders. Primary care is also tasked with offering prompt access to high quality care. Despite existing guidelines for the management and treatment of mental health problems in primary care, approximately one of three primary care clinics [in Sweden] do not offer assessment or treatment with a psychologist, and the effects of psychological interventions have rarely been evaluated empirically. The aim of this pilot study is to evaluate a transdiagnostic CBT-based large-group intervention in the primary care system of Sweden in terms of feasibility and preliminary efficacy, with British reference data.

Overview of the field (background)
The Swedish point prevalence for depression is 11%, and the point prevalence for clinically significant anxiety is about 15% (1). Common mental disorders such as depression and anxiety disorders have been found to be associated with functional impairment and reduced quality of life in a large number of studies (2, 3). A substantial proportion of these patients are in need of assessment and interventions in primary care, and some studies indicate that the majority of patients with mood disorders are found in primary care (4). Of patients seeking help in primary care, approximately 30-50% suffer from a mental health condition (5, 6).

Swedish national board of health and welfare targets dictate that at least 60% of patients with depression are to be offered psychological treatment ([cognitive behaviour therapy:] CBT or [interpersonal therapy:] IPT) and that 70% of patients with clinically significant anxiety are to be offered CBT (7). The task of primary care [in Sweden] is to assess and treat patients with mild to moderate mental health problems, i.e., the majority of patients with depression and anxiety disorders. Primary care is also tasked with offering easy access to high quality care (8). Region Stockholm guidelines prescribe that patients seeking help for mental health problems should be offered treatment with an expert clinician within 3 days (9). Despite this, only about half of primary care clinics [in Sweden] report being able to meet patient demand for mental health care (10) and the effects of psychological interventions have rarely been evaluated (11).

One way of ensuring access to psychological interventions in primary care could be to offer low-intensity interventions, i.e., psychological interventions that require relatively few resources, and interventions that are effective for a wide spectrum of psychiatric problems (12, 13). According to a meta-analysis from 2015 (13), transdiagnostic interventions for depression and anxiety commonly have large within-group effects on anxiety ($g = 0.85$) and depression ($g = 0.91$). In randomised controlled trials, according to the same source, controlled effect versus waitlist controls and attention control conditions are typically moderate to large on anxiety ($g = 0.70$ and 0.80 respectively) and moderate to large on depression ($g = 1.0$ and 0.69 respectively). This implies that a transdiagnostic intervention can be an adequate alternative for many patients where additional interventions are unnecessary.

One example of a widespread transdiagnostic low-intensity course based on CBT principles for patients with a wide spectrum of mental health problems is the Stress Control intervention (SC) (14, 15). This course is given in a large-group format and consists of six weekly sessions of 90-120 minutes with up to 100 participants. One potential advantage of this type of lecture-format intervention is being able to reach populations that rarely seek psychological care, such as men, individuals with low educational attainment and the elderly. The SC course primarily comprises education about common types of mental health problems including chronic stress disorders, anxiety, depressed mood and disordered sleep. Themes covered are: 1) stress and physical reactions to stress, 2) physical exercise and relaxation, 3) cognitions and how stress affects cognitions, 4) behavioural activation and problem solving, 5) managing panic attacks and 6) sleep and response prevention. (16) The SC intervention has been evaluated as part of the Improving Access to Psychological Therapies (IAPT) national initiative in England to improve access to psychological interventions for patients with mental health problems. Within IAPT, each year, about 537 000 patients are treated for depression and anxiety in accordance with British national guidelines. Interventions within IAPT are systematically evaluated, with pre- and post- treatment data available from 98% of patients (17). Within IAPT, the SC intervention has been found to have a moderate to large within-group effect on anxiety (d = 0.70), a moderate effect on depression (d = 0.59) and a moderate effect on work-related functional impairment (d = 0.47). About 42% of patients with clinically significant symptoms before SC have achieved a clinically significant and reliable improvement at treatment termination (12). This is only marginally lower than corresponding figures from interventions developed for specific mood and anxiety disorders (18, 19).

Research question (study aims)

The aim of this within-group study is to evaluate a CBT-based intervention similar to SC, focusing on feasibility and efficacy in Swedish primary care, with British reference data (12). The study includes a combination of patients with clinically significant levels of anxiety or depression and patients with subclinical symptoms, analyses concerning the clinical group being the primary focus of the study. The primary outcome is patient satisfaction, see below. Secondary outcomes include adherence to the protocol and effects on psychiatric symptoms in terms of anxiety and depression. Perceived stress, functional impairment and adverse events are also surveyed to make it possible to assess the relevance of the intervention for stress-related mental health problems, enable comparisons versus other protocols and ensure that the intervention is safe and does not result in unnecessary distress. Specific hypotheses are:

- Primary outcome: For patients with clinically significant symptoms, adequate satisfaction as measured using the 8-item Client Satisfaction Questionnaire (CSQ-8) and as evidenced by mean score of at least 22 points.
- Secondary outcome: For patients with clinically significant symptoms, adequate proportion of clinically significantly improved (12), in accordance with Jacobson and Truax (20). At least 1/3 of participants reporting a reliable reduction in anxiety (on the GAD-7) and a GAD-7 score below cut-off (8p) after the course. At least 1/3 of participants reporting a reliable reduction in depression (on the PHQ-9) and a PHQ-9 score below cut-off (10p) after the course.

Exploratory secondary outcomes also include:

- Adherence to the protocol, operationalised as the number of lectures attended.

- Self-reported lifestyle behaviours at baseline, and change in lifestyle behaviours. Due to limited power, this focuses on within-group effect sizes and not inferential statistics.
- The proportion of patients in need of additional mental health inventions, as determined by a clinician interviewer after the course.
- The proportion of patients who report a perceived need of additional interventions.
- Adverse events during the intervention

Description of the research project (methods)

Design and power

This study is a within-group trial (i.e., observational study) where 68 patients with common clinically significant psychiatric problems in terms of anxiety and depression are recruited in the primary care system of Stockholm[, Sweden]. The intervention is evaluated in terms of [satisfaction,]adherence and self-reported symptom outcomes. Power was determined to enable the analysis of data based on a general linear model with dependent means (pre-post) with 80% power in studying effects on symptoms corresponding to d=0.45 given alpha=0.05 and the expected data loss (no data at post intervention) of 40%. The effect size d=0.45 was chosen on the basis of effects reported by similar interventions in British primary care (12). Up to 25 patients with subclinical symptoms (PHQ-9<10 and GAD-7<8) are also recruited for an exploratory investigation of satisfaction and preliminary efficacy in this patient group.

Recruitment

Patients are continuously recruited from routine care at Liljeholmen academic primary care clinic[, Stockholm, Sweden]. Patients scheduled for assessment by the psychosocial team are informed by their physician or nurse about the possibility of taking part in a newly developed transdiagnostic intervention within the context of a study. The patient is then scheduled by a clinician not working as therapist in the study for an eligibility interview with a psychologist student or a mental health clinician at the primary care clinic. The clinician conducting the interview informs the patient about the voluntary nature of study participation and that the study is not part of routine health care. The patient is given a copy of the patient information when the eligibility interview is booked. This gives the patient time to think over the decision to apply for the study, and we therefore believe that there is a smaller risk of patient-therapist-dependency affecting this decision. For the eligibility interview, informed consent is provided before screening.

Eligibility criteria are the following:

1. (I) At least 8 points on the GAD-7 or at least 10 points on the PHQ-9 (n=68) – or (II) below 8 points on the GAD-7 and below 10 points on the PHQ-9 (up to n=25).
2. At least 18 years old
3. Based on a brief structured clinical interview developed specifically for the study, no severe psychiatric condition requiring further assessment or treatment in specialist psychiatry, for example a bipolar disorder, suicidal ideation or a psychotic disorder.
4. Medication with monoamine agonists[, primarily antidepressants, either non-existent or] stable since at least 6 weeks and planned to be stable during the intervention
5. No planned absence two weeks or more during the intended intervention period

Intervention
Patients are enrolled in a CBT-based intervention similar to SC, in a transdiagnostic format that enables shortened clinic waiting times. The course consists of six weekly lectures where up to 50 patients participate over 90 to 120 minutes.

The intervention is primarily based on psychoeducation about stress and how the body reacts to stressors, about exercise/activity and recuperation/relaxation, the impact of behaviours and thoughts on mental health, about anxiety, depression, how to manage sudden burst of intense anxiety (panic attacks) and techniques for improved sleep. The course comprises 6 lectures with corresponding themes: (1) ”Stress”, (2) ”Worry and anxiety”, (3) ”Low mood and depression”, (4) ”Sleep”, (5) ”Physical activity and mental health” and (6) ”Relationships and the importance of emotions”. The aim of the course is to improve the participants’ ability to identify what they need to feel better, and to provide the participants with the tools necessary for them to improve their mood for the better. Structured PowerPoint presentations will be used. The course also involves written material about each lecture theme and this material includes suggestions for tailored exercises (“homework”). Participants are encouraged to read and work with the written material before and between each lecture.

The psychological intervention is led by clinicians of the psychosocial team which consist of counsellors [“kuratorer”] and psychologists with training in cognitive behaviour therapy (CBT). In order to ensure competence, all therapists except the author of the course, Karoline Kolaas, attend a half-day introduction to the intervention and also sit in on at least one lecture led by a clinician already trained in delivering the course. All therapists receive regular supervision by the project leader Karoline Kolaas (and Karoline by another researcher in the project) about every other week over the course of the study. Adherence is ensured by the use of a structured manual and checklists completed by the therapist after each lecture.

At inclusion and during the course, participants are encouraged to contact clinicians working with the group intervention if symptoms deteriorate. Each week, participants rate their mood including suicidal ideation using validated instruments. Their responses are reviewed by researchers in the project, and participants who experience a substantial deterioration in symptoms are contacted for a discussion about their further participation in the course. Participants also have the opportunity to contact their course leader via the study web page, via a secure system reminiscent of email. If necessary, the intervention is terminated and the participant is referred to routine care services.

Measurements and psychometric instruments
Assessments in the study are: the screening (for the eligibility interview), the pre-intervention assessment, five weekly measurements during the course (w. 1-5) and the post-intervention assessment. A follow-up assessment will also take place after 3 months. Thus, in total, there are 9 assessment points. The measurements are conducted using online questionnaires that are stored in the patient’s digital record.

At the pre-intervention assessment, information is also collected during the eligibility interview. This interview involves questions about sociodemographic variables, a structured questionnaire for the assessment of suicidal ideation and severe psychiatric problems and questions concerning medication.

At each group session, the participation of each patient is registered. Post intervention, the patient also meets with a clinician of the psychosocial team. This appointment is booked 6 weeks from the planned start of the course. This assessment is conducted in a manner analogous to routine care assessment by the psychosocial team of the primary care clinic. During this assessment, all further necessary arrangements are registered (e.g., no need for further arrangements, referral to psychiatric services or additional help and if so of what kind). The patient also reports on adverse events, satisfaction with the course, changes to medication and other therapies. Lifestyle behaviours are surveyed over the course of the study because little is known about lifestyle behaviours in Swedish primary care patients, and the relation between lifestyle behaviours and mental health has been identified by the Swedish national board of health and welfare as a high-priority topic in primary care research.

Suicidal ideation is monitored during the course of the study. Each week, patients rate how much they are bothered by ”thoughts that [they] would be better off dead, or of hurting [themselves]”. Patients who score higher than ”not at all” are contacted for an individual assessment, and are offered additional support and/or are referred to specialist care in accordance with common practice and routine care guidelines. Each week, patients are also tasked with answering an open-ended question about adverse events. Adverse events are highlighted in the system for data collection and prompt subsequent review. In addition, all patients’ week-by-week change in mood is continuously reviewed, as is done in routine care for example at the Internet psychiatry unit of Region Stockholm.

In addition to questions about sociodemographic variables (such as age, sex, educational attainment, income and civil status), the following questionnaires are administered via the internet (the CSQ-8 in paper form [Note: All were administered online due to the covid-19 pandemic, see “Data safety and management” below.]):

Questionnaire	Outcome	Ref	SN	PRE	W	POST	3MFU
Client satisfaction questionnaire (CSQ-8)	Satisfaction with the course	(21)				x	
Generalised Anxiety Disorder 7-item Scale (GAD-7)	Anxiety	(22)	x	x	x	x	x
Patient Health Questionnaire 9 (PHQ-9)	Depression	(23)	x	x	x	x	x
Perceived Stress Scale 10 (PSS)	Stress	(24)		x		x	
12-item WHO Disability Assessment Schedule 2.0 (WHODAS 2.0)	Functional impairment	(25)		x		x	
Lifestyle behaviours	Lifestyle behaviours (tobacco, alcohol, physical activity, diet)	(26)		x		x	x

3MFU = 3-months follow-up, POST = post-intervention, PRE = pre-intervention, SN = screening, W = weekly during the course

Data safety and management

Information from self-report questionnaires are saved as part of the patient’s medical record, and also as research data using a secure data management service in accordance with the guidelines of Karolinska Institutet. Paper-form written consents and data from interviews pre- and post-intervention are stored in locked cabinets and are destroyed when transferred to a

secure digital form. Within 2 years, the interview guides are converted to digital documents stored in a safe manner, and the paper guides are then destroyed. Due to the covid-19 pandemic, as long as necessary, the study will be conducted without physical meetings. To make this possible, secure systems with encrypted data traffic are used. During this period, informed consent to take part in the study is given via a web-based form, via a secure web platform (128-bit encryption and a personal account with two-factor authentication) that has been used in several previous clinical trials (see for example [Regional ethics review board of Stockholm application] 2014/1530-31/2). [Note: This was written in early May of 2020. The course was eventually held entirely online in accordance with this clause.] Only researchers in the project have access to the raw data, and results are presented in a way that does not make it possible to identify individual participants. Personal information that is not necessary to characterise the sample or that does not constitute the outcome of the study will not be curated or used for publication.

Evaluation and statistical analysis
Primary outcome is the mean CSQ-8 score for patients completing this post-intervention questionnaire. Secondary outcomes that concern clinically significant improvement are based on the algorithm for reliable change as specified by Jacobson and Truax (20), combined with the established cut-offs for anxiety and depression of 8 points on the GAD-7 and 10 points on the PHQ-9 (27). Clinically significant improvement is calculated based on the last observation from each patient. Dose-response relationships and change over time are analysed using linear mixed models, if deemed suitable for the data. Linear regression is used for other continuous outcomes, and chi2 tests for nominal data. Within-group effect sizes are presented in terms of Cohen's d, and standardised effect sizes are compared to British reference data (12).

Time plan and feasibility
From the late summer or early autumn of 2020, recruitment for the study is expected to take ca 6-7 months. Then follows a follow-up period of 3 months, which implies that all data are expected to have been collected around the early summer of 2021. The curation of data, statistical analysis and manuscript writing is expected to take 3 months. In total, the study is expected to be completed in ca 12-15 months and to conclude around the end of 2021.

Liljeholmen primary care clinic is one of the largest primary care clinics in Sweden, with around 30 000 listed patients. The clinic is situated in central Stockholm, with a steady inflow of patients with mental health problems. There is currently a substantial waiting time to meet with a clinician of the psychosocial team. The primary care clinic hosts a large conference room housing up to 50 persons, and the front desk is staffed on the days and nights when the course is expected to take place. The psychosocial team consists of counsellors ["kuratorer"] and psychologists with competence in cognitive behaviour therapy. The project has been designed with the needs of the patients and staff of the primary care clinic in mind, and members of the psychosocial team, other professions and the management team have been involved in the planning of this study. This speaks for the study being completed as planned.

The research group
The researchers in this project have extensive experience of research in primary care. **Anne H Berman,** psychologist, associate professor and research group leader has long experience of treatment research in forensic healthcare, addiction healthcare and in later years also psychiatry. With her research group and other collaborators, she has developed and evaluated

several digital interventions: the eScreen, the PartyPlanner, the Alkoholhjälpen, the TeleCoach, the eChange and the ePlus programs. Dr. Berman has been responsible for an international research network for the development and evaluation of digital interventions for ANDTS behaviours, as financed by FORTE (2014-2017). She was also Editor-in-chief for the *Special Issue on E-health interventions for addictive behaviors* in the *International Journal of Behavioral Medicine* in the autumn of 2017. **Erik Hedman-Lagerlöf**, psychologist, associate professor in clinical psychology and head of academic proceedings at Gustavsberg primary care clinic has long experience as principal investigator of clinical trials of psychological treatment for primary care patients with mental health problems. **Erland Axelsson** has been involved in a number of clinical trials of psychological treatment in primary care, including chronic stress disorders and exhaustion (28), health anxiety (29) and other forms of pathological worry/anxiety (30). Erland has documented experience of developing psychological treatments, supervising clinicians in research methodology and designing and leading clinical trials in the primary care setting. [Note: Dr. Axelsson was the principal investigator of this trial.] **Karoline Kolaas** has extensive experience of clinical work in primary care and has made contributions to the psychosocial team of Gustavsberg primary care clinic, both in terms of personnel and improved access to psychological treatment. She has supervised clinicians in several large implementation studies, and has served as clinic-level project manager in two large clinical trials in primary care (ClinicalTrials.gov NCT01667822, NCT01636791). Karoline has been involved in the development and implementation of several group-format interventions that needed to be adapted for primary care. Kolaas is also well-acquainted with educating and supervising co-workers in group-format interventions, and with evaluating treatment results in a systematic manner. The study is intended to form part of the basis for Kolaas' ongoing doctoral studies.

Significance

This pilot study is expected to be of great significance in establishing whether the type of SC intervention that has been found successful in England is feasible also in the primary care system of Sweden. If the study is indicative of promising results, the research group is planning to evaluate the effects of the course versus relevant control conditions, probably within the context of a randomised controlled trial. The long-term research question may be whether the evaluated course protocol can serve a similar role as the SC protocol does in England, i.e., as a cost-effective intervention that makes it possible to improve access to psychological treatment in primary care whilst requiring relatively few resources.

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