

BMJ Open Impact of spiritual healing on moderate depression in adults: a study protocol of a pilot randomised controlled trial (RCT)

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ABSTRACT

Introduction Depression is a common mental disorder and the (global) leading cause of all non-fatal burden of disease worldwide. Currently, supported treatment for depression is antidepressant medication and different psychotherapeutic interventions. Many patients experience, however, adverse effects of antidepressant medication, while at the same time the access to psychotherapeutic interventions are limited. Many patients who suffer from depression turn to complementary medicine and among those modalities often spiritual healing. There is some evidence that consulting a spiritual healer can be beneficial for patients who suffer from depression, and that spiritual healing is associated with low risk. The aim of this protocol is to conduct a pilot randomised controlled trial (RCT) (spiritual healing as addition to usual care vs usual care alone) in preparation of a larger trial in adults with moderate depression, to examine feasibility and individuals' experience of spiritual healing.

Methods and analysis This study is a pilot RCT with two parallel groups. A total of 28 adult patients with moderate depression, diagnosed by the physician and according to the Montgomery and Åsberg Depression Rating Scale criteria will be randomised to spiritual healing in addition to usual care (n=14) or usual care alone (n=14). To determine if there is a statistical indication of an effect of healing warranting a full-scale study; the separation test will be used. To investigate participants' experience with spiritual healing, a qualitative study will be included using semistructured interviews. The data will be analysed based on a direct content analysis.

Ethics and dissemination This protocol was approved by regional committees for medical and health research ethics by the identifier (63692). The results will be disseminated through open-access, peer-reviewed publications, in addition to stakeholders' reporting and presenting at conferences.

Trial registration Norwegian Centre for Research Data (845302) and clinicaltrials.gov (ID: NCT04766242)

INTRODUCTION

Depression is a common mental disorder and is together with anxiety the (global) leading

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Several physicians will recruit patients to the trial providing insight into different methods of usual care.
- ⇒ Because of the COVID-19 lockdown, only one healer will be implementing the healing sessions as opposed to the two originally planned.
- ⇒ A multidisciplinary research team consisting of complementary medicine providers, physicians, psychiatrists and researchers safeguard a whole system research approach.
- ⇒ To enhance patient safety, the research team will record adverse effects of both healing and usual care.
- ⇒ Due to the overload of patients and COVID-19 protocols, the implementation of the trial has been negatively affected.

cause of all non-fatal burden of disease worldwide.¹ The core symptoms of depression are lowered mood, discouragement, loss of sense and meaning in life, lack of interest in other people and ordinary duties, and lack of energy and appetite. In addition, the patients often experience diminished self-esteem, self-reproach and a feeling of guilt. These symptoms may vary in intensity and duration.^{2,3} Nevertheless, around half of all people with depression worldwide do not receive appropriate treatment.⁴ Most mental disorders emerge before the age of 30,^{5,6} and lack of treatment might contribute to disability for many crucial years of an individual's life. In Norway, the 12-month prevalence and lifetime prevalence of depression is 10% and 20%, respectively, higher in women than in men.² Depression has been identified as a strong predictor for use of complementary medicine (CM).⁷⁻⁹ A recent Norwegian study demonstrates that only 10.9% of those with moderate depression and/or anxiety visited psychiatric outpatient services while 17.6% visited a CM provider.¹⁰ These facts

demonstrate that people with depression might be willing to seek help also from less established services, such as CM providers. Thus, it is possible that different CM modalities may serve as a substitute or an alternative when access to psychologist/psychiatric services is limited.¹⁰⁻¹²

Conventional medicine classifies depression as a mood disorder that manifests itself across a wide range of disease/symptom severity. Depression can be classified as mild, moderate or severe.¹³ Symptoms must have been persistent for at least 2 weeks and not be related to other medical or psychiatric diagnoses, or be due to substances.¹⁴ The World Health Organization (WHO) ranks the social costs of depression as the fourth highest of all diseases.¹⁵ Furthermore, by 2020 current trends indicate that depression will represent the highest cost for society of any disease.¹⁵ Clearly, prevention, early diagnosis and intervention of depression have huge significance.

The most commonly prescribed antidepressant drug, selective serotonin reuptake inhibitors (SSRIs), has recently been shown to have the best effect on severe depression, and no effect beyond placebo for mild and moderate depression.^{16 17} At the same time, SSRIs can be associated with serious adverse effects,¹⁸ and are associated with increased vulnerability to develop a depressive episode later in life.¹⁶ Thus, one of the most common treatment options for depression has been documented to be of little or no help beyond placebo for moderate depression while at the same time possibly inducing serious adverse effects.

The Competence Center for Lived Experience and Service Development, investigates the needs for individuals with mental health problems. According to the centre, many patients in psychological healthcare do not want to be treated with medication. These patients must be heard and taken seriously. We cannot force anyone to take medication as long as necessary care and treatment can be provided otherwise.¹⁹

Cognitive behavioural therapy (CBT) or structured psychological therapy²⁰ is a treatment option for patients who do not want pharmaceutical antidepressant treatment. However, waiting lists for such treatment are often long due to the lack of competent professionals (psychologists and psychiatrists), especially in rural communities, and at the district psychiatric centres.²¹ These centres have to prioritise patients with major depression, meaning that patients with moderate depression have less access to CBT.

Spiritual healing for depression

Spiritual healing is one of the most frequently used CM modalities in Norway.²² It is understood as an energy-based therapeutic approach to healing. A spiritual healer uses the hands to balance and harmonise the body and thereby place the client in a position of self-healing.²³ The healing treatment focuses on the whole person (physically, psychologically and emotionally) as well as the environmental factors (support from family,

friends, community). Scientific evidence indicates that users typically praise CM modalities for offering symptoms relief, reducing adverse effects of conventional treatment, enhancing their ability to cope physiologically and emotionally, providing an alternative to pharmaceuticals, and offering a close patient-practitioner relationship during treatment.²⁴

There is some evidence that spiritual healing can be beneficial for patients who suffer from depression,^{25 26} and spiritual healing is associated with low risk.²⁷ In a preliminary study conducted by the current research group, a mean decrease in depression score of 3.1 points (range 0–4) on a 7-point scale was found (n=9).²⁸ The symptom was rated on a scale from 0 to 6 where 0 was 'as good as it could be' and 6 was 'as bad as it could be' (Measure Yourself Medical Outcome Profile (MYMOP) Scale²⁹). Only one patient reported no change in depression symptoms after healing treatment. None of the patients experienced worsening of depression symptoms during the healing treatment, while the majority (n=5) had a reduction of 4 points.²⁸ More research is needed to confirm these findings and to identify modifications needed in the design of a larger randomised controlled trial (RCT).

Objectives

The objectives of this study are to conduct a pilot RCT (spiritual healing as addition to usual care vs usual care alone) in preparation of a larger trial in adults with moderate depression, and further to examine the feasibility of the study design and the participants' experience of spiritual healing.

METHODS AND ANALYSIS

This is a multicentre pilot RCT with two parallel arms. Nested within the trial is a qualitative arm.

Design

A total of 28 individuals with moderate depression will be randomised to a spiritual healing intervention as an adjunct to usual care (n=14) or to usual care alone (control) (n=14). We will study the entire spiritual healing package understood as everything a healer does in a consultation (visiting a healer), including the use of hands to balance and harmonise the body and sometimes offering lifestyle advice. Included in the treatment is the interaction between the patient and the therapist. A positive interaction between the patient and the therapist (alliance) is necessary for the patient to feel free to verbally express painful present and past experiences that may be related to the patient's psychological complaints^{30 31} (eg, pragmatic research approach).

Setting

In Norway, inhabitants receive treatment within the public healthcare system, while CM providers, including healers, operate outside this system. Patients generally cover the cost of these visits themselves. Since CM

practices are unregulated, anyone is allowed to use the term healer and treat patients. However, many healers are members of the Norwegian Healing Association that require a professional standard regarding healing skills. To ensure patient safety in cases of interventions related to health issues, members are required to obtain a professional insurance for injury to their patients caused by the treatment.

Study participants

Inclusion criteria

All patients must be 18 years or above. They have to suffer from depressive difficulties of moderate intensity and fulfil the criteria for depression diagnosed by the physicians included in the study, and score within the range of 20–29 on the Montgomery and Åsberg Depression Rating Scale (MADRS) Depression Rating Scale.^{32 33} Symptoms must have persisted for 2 weeks or more. In addition to a MADRS Score of 20–29, the physicians who include patients will decide whether the patient is suited for inclusion based on the following observations: (1) The patient is too healthy to be referred to a district psychiatric centre and (2) The patient is too ill to remain untreated.

Exclusion criteria

Patients are excluded for the following reasons: Chronic major or bipolar depression or any personality disorder (axis II); endocrine abnormality; suicidal potential; dementia; depression as direct physiological effects of a substance or a medical condition (such as Parkinson's disease, epilepsy and multiple sclerosis); substance abuse; history of psychosis or mania; heart valve disease; poorly controlled hypertension and diabetes mellitus; pregnancy;³⁴ or inability to complete study forms.

Recruitment

Patients who visit their physician for mood-related symptoms and fulfil the inclusion and do not fulfil any of the exclusion criteria will be asked by the physician if they want information about the study. If the patients agree, they will receive an information folder and informed consent. After that, the physician will send an Short Message Service (SMS) with contact information to the researchers at The National Center for Complementary Medicine (NAFKAM). Subsequently, NAFKAM will contact the patients, inform further about the study and include those who agree to participate. Before randomisation, participants must read and sign the informed consent. To collect baseline data, a link to the electronic Beck Depression Inventory (BDI) form will be forwarded to the participants.

Randomisation

We will use a randomisation system with block sizes, that vary from two to six, to eliminate confounders of a personnel or structural nature, thus balancing group allocation throughout the study period. Within each block, an equal number of patients will be randomly allocated

to either an intervention group with spiritual healing and usual care, or a control group with usual care alone.

Blinding

Patients will not be blinded regarding treatment allocation, in accordance with a pragmatic research approach. Neither the study physicians nor the study therapist will be blinded. The researchers will be blinded when analysing unidentified patient-reported data.

INTERVENTION

Primary outcome measures

The study outcome will be recruitment speed, willingness to be randomised, study adherence and implementation of healing compared with usual care for moderate depression.

Secondary outcome measures

Secondary outcomes will be change in severity of depression measured by BDI.³⁵ This questionnaire will be completed by the study patients at baseline, after 8 weeks and 16 weeks, and 6 months and 12 months after inclusion to the study. The separation test³⁶ will be used to investigate an indication of an effect of healing in a full-scale study.

An adverse effect form will be completed after 8 weeks and 16 weeks. The RELIS (a national network of four regional medicines information and pharmacovigilance centres in Norway) Adverse Effect Scale³⁷ will be used to measure adverse effects and the questions about adverse effects will be included at the end of the BDI form.

Measurements

The Beck Depression Inventory for Primary Care (BDI-PC)³⁵ is a screening instrument for depression that minimises the possibility of yielding spuriously high estimates of depression for patients with medical problems by focusing on symptoms of *sadness, pessimism, past failure, loss of pleasure (anhedonia), self-dislike, self-criticalness, and suicidal thoughts or wishes*. Each item is rated on a 4-point scale ranging from 0 to 3. The highest rating for each of the seven items constitute the total BDI-PC score.

To address the minimum Diagnostic and Statistical Manual of Mental Disorders IV requirement for the duration of moderate depression symptoms, respondents are asked to describe themselves for the 'past 2 weeks, including today'. We will also collect demographic data such as age, gender, education, household income and work, in addition to use of drugs and diary supplements/herbs for depression (questionnaire baseline). In intervention weeks 10 and 16, and 6 months and 12 months, adverse effects and change in use of drugs and diary supplements/herbs will be registered.

Qualitative study

In a qualitative study, nested within the trial, the investigators will investigate participants' experiences of spiritual

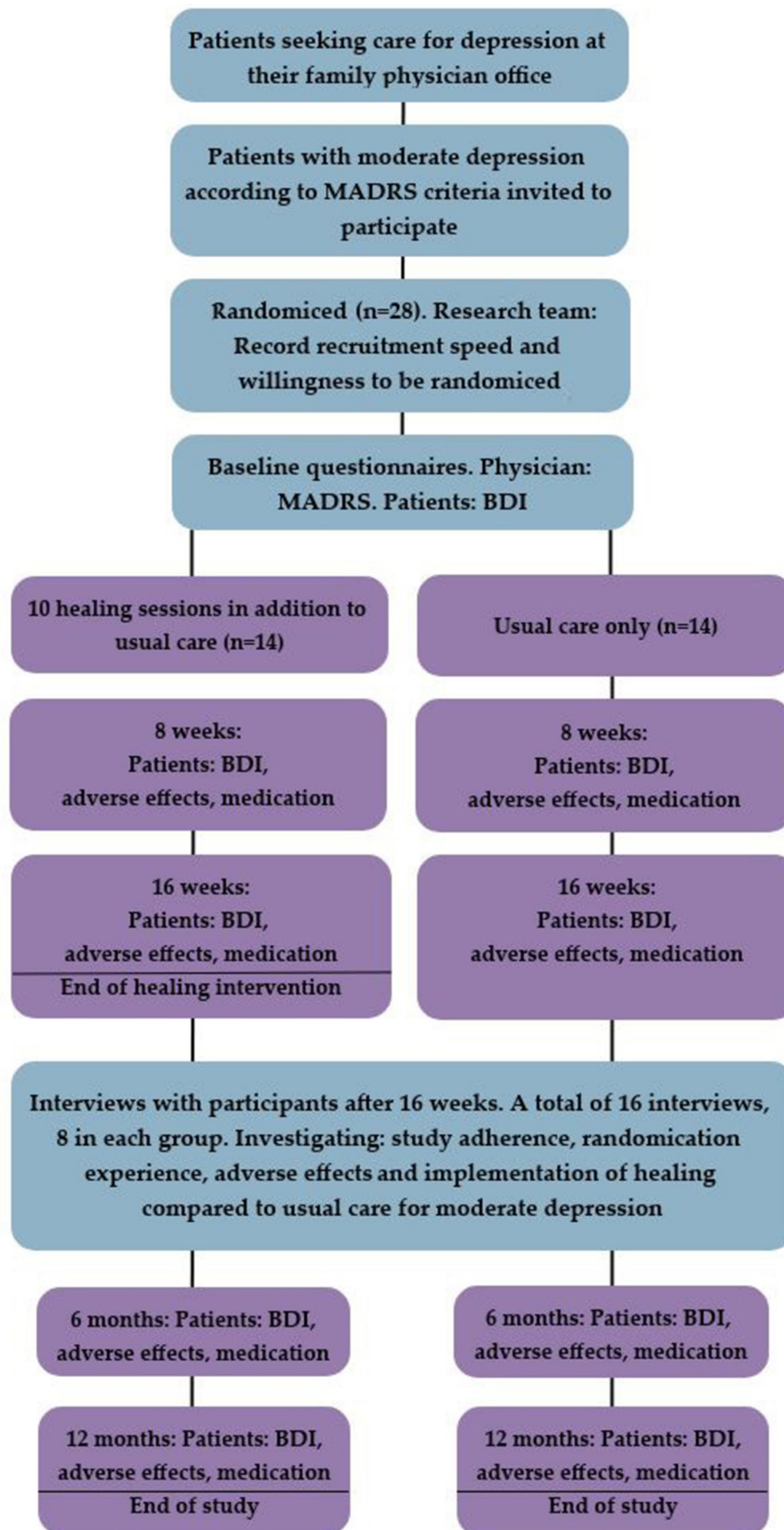


Figure 1 Flow chart of the schedule of enrolment, intervention and assessment. BDI, Beck Depression Inventory; MADRS, Montgomery and Åsberg Depression Rating Scale.

healing and usual care. The aim of the study is to collect information about the participants' lived experience of participating in the trial receiving healing and usual care interventions. The study is based on phenomenology as this study design explores what people experienced and focuses on their experience of a phenomenon³⁸ and will provide the investigators with more nuanced and in-depth data than data obtained only from the questionnaires.²⁴

The study will draw on data obtained through semistructured interviews³⁹ conducted with 16 participants ($n=16$), eight ($n=8$) in the intervention group and eight ($n=8$) in the control group on completion of the intervention period (week 16).

Based on an interview guide, the participants will be asked about their illness (severity, duration, previous treatment), how they experienced the treatment (advantages and disadvantages) provided during the study, if their expectations were met and their willingness to be randomised. Furthermore, we will ask about adverse effects from the treatment, and the patient-provider relationship. The control group will be interviewed and asked about their experiences with usual care. Moreover, we will observe and register recruitment speed, study adherence and implementation of healing compared with usual care.

Treatment plan

The study is planned to start in March 2022 and the end of the study (data collection) is in March 2023.

Intervention

Spiritual healing will be based on an assessment of the total health situation of the individual patient. Spiritual healing will mainly consist of a treatment where the healers hold their hands for some time at different parts of the patient's body, known as 'power points', outside the patient's clothing. The consultation might also include lifestyle advice. This can necessarily lead to slightly different treatment given to each patient. Each treatment will, however, last for 45–60 min.

The healer who will perform the healing is a trained member of the Norwegian Healer Association (Norges Healerforbund). She has been working full time as a spiritual healer for more than 20 years. As a member of the Norwegian Healer Association, she has liability insurance in cases of harmful effects of the treatment.

Usual care

All participants will be advised to follow the treatment plan given by the physician at five different clinics in a town south in Norway. Usual care may include regular consultations with physicians (every 14th day, duration 30–60 min) including counselling about sleep, activity, lifestyle, antidepressive medication and sick leave. The participants in the control group will be offered three healing sessions after the 10-week intervention period.

Implementation

The study nurse at NAFKAM will send the link to the questionnaire to the participants at baseline, weeks 8 and

16, and after 6 months and 12 months, asking them to complete the questionnaire.

1. When the patient has signed the informed consent, the researchers at NAFKAM will formally include the patient according to the randomisation system.
2. Included patients will be randomised to spiritual healing plus usual care (intervention group) or usual care alone (control group). Directly after randomisation and if assigned to healing, the name and phone number of the patients will be sent by SMS to the spiritual healer. The healer will then contact the patient who will receive the first healing session within 14 days after enrolment. The patient will be offered 10 healing sessions.
3. Patients in the control group will receive usual care as agreed with their physician.
4. Patients in the intervention group and control group are urged to follow the treatment recommendations given by the physician (eg, antidepressant medication).
5. The last follow-up healing treatment session must be completed by the end of week 16 of the study (the day of the first healing session is defined as week 0).

Follow-up

1. The study nurse will ask the participants to complete the electronic BDI Questionnaire in weeks 8 and 16. In addition, they will be asked to register information about adverse effects as part of the form.
2. The study nurse will contact the participants after 6 months and 12 months and remind them to complete the electronic BDI Questionnaire (follow-up data).
3. Interviews will be conducted with participants in both groups at the end of the intervention period (week 16). See figure 1.

Withdrawal and loss to follow-up

If a patient chooses to withdraw before week 16, all data collected will be permanently deleted. If the patient is lost to follow-up, data collected up to the day of dropout will be used for analysis.

Statistical analysis

Differences in BDI scores between groups as well as adverse effects will be described descriptively only, due to the pilot nature of the study. To investigate whether there is a statistical indication of an effect of healing indicating a later full-scale trial, we will apply the separation test, a statistical procedure for early phase research, to decide whether to pursue further research.³⁶ The separation test will be based on calculations regarding the mean reduction in symptoms, and the between-group difference from baseline to weeks 8 and 16, and from baseline to day 6 and 12 months for the intervention group (healing and usual care) versus the control group (usual care).

The last author (AEK) will perform the statistical analysis. Data analysis will be done using the IBM statistical package SPSS V.28 (<http://www.spss.com>).

Qualitative analysis

Qualitative data will be analysed based on a directed qualitative content analysis, because the field will benefit from further description.⁴⁰ Categories and codes will be developed inductively from the data and deductively according to themes of the structured interview guide and the research questions. Included themes will be supported by evidence in the form of participants' statement (quotations).

Patient and public involvement

In this study, patients will be interviewed about their study experiences and the main outcomes of this study are recruitment, willingness to randomisation and other feasibility measures.

Sample size

No sample size calculation is needed for a pilot RCT. The findings of this pilot study will be used to calculate the sample size in a potential future RCT. A study size of n=16 participants, n=8 in each group is chosen to generate sufficient interviews (saturation on that point is assumed) for the qualitative study.⁴¹

Data handling management

All patient data and the index that links trial numbers with individual participants will be kept under lock, and the key will be in the possession of NAFKAM. Trial number alone will identify all data.

Coding and punching

Data entry will be undertaken at NAFKAM. All data will be read twice to ensure against random bias in the coding and punching process. The first author (TS) will be responsible for obtaining and analysing the qualitative data.

ETHICS AND DISSEMINATION

The patients will be informed about the study through an information folder and verbally by the study nurse, and, if willing to participate, asked to give a written informed consent. The participants will be informed that they can withdraw from the study at any time without any consequences. All patients will follow usual care regardless of healing treatment, and adverse effects will be recorded at each treatment session. No systematic studies have been published on adverse effects of spiritual healing for depression. However, previous research has demonstrated that spiritual healing is associated with low risk.²⁷ The study will be conducted in accordance with the Helsinki declaration.⁴² This protocol was approved by The Regional Committees for Medical and Health Research Ethics (by the identifier 63692) and registered at the Norwegian Center for Research Data (845302) and clinicaltrials.gov (ID: NCT04766242).

The results of this protocol will be published in at least two scientific papers in peer-reviewed journals. In addition, results will be presented orally and on posters

at national and international conferences. Following the publication in scientific journals, the project will be communicated through the web portal of NAFKAM (www.nafkam.no). The Norwegian authorities will also be notified through written communication about the results of the study.

Data and safety monitoring

A steering group will be responsible for quality control and will meet on a regular basis throughout the study period. The steering group will be convened as an emergency in the event of serious adverse effects associated with the trial to decide on appropriate action to prevent recurrence. Regular meetings will concern any reported adverse effects, protocol violation, the recruitment rate, practical issues concerning local coordination, as well as any issues raised by the participants.

DISCUSSION

To the best of our knowledge, this is the first pilot RCT investigating the feasibility of the study design and the participants' experience of spiritual healing and usual care for patients with moderate depression in Norway. This research team has previously conducted an observational study investigating self-reported effect of healing, with a prepost design.²⁸ The rationale for the study was that Norwegian patients with chronic diseases and psychological problems reported frequent use of spiritual healing (14%–36%).⁴³ Moreover, 38% of patients with cancer in northern Norway reported having used spiritual healing.⁴⁴ Generally, most CM interventions are under-researched, taking into consideration that they are widely practised, and limited information is available about their clinical effectiveness and risk profile. Observational studies are well suited to investigate these questions in a real life setting.⁴⁵

Therefore, to get more nuanced information, we aimed to map the conditions patients reported when visiting a healer for the first time, and to evaluate the subjective benefits and risks from the intervention. Results from the above-mentioned observational study reported that a total of 23% of the participants reported psychological complaints such as anxiety and depression. These complaints were reduced from a pretreatment score of 4.7 to a post-treatment score of 2.3, measured by MYMOP.⁴⁶ This reduction was achieved after a mean of 4.1 spiritual healing sessions (ranges 1–17). Forty per cent of the participants reported one or more adverse effects after treatment. These were perceived by the participants as minor and transient. However, these results must be interpreted with care since no interference statistical analysis of effect was performed. Due to the lack of a control group, we cannot draw the conclusion that the findings are exclusively due to the spiritual healing treatment.

Based on the findings from the previous observational study, and in preparation for a larger RCT, we want to investigate the recruitment speed, participants'

willingness to be randomised, study adherence, and implementation of healing compared with usual care for moderate depression. We will also investigate the change in severity of depression measured by BDI.

Strengths and limitations

This protocol must be understood in light of the study limitations. Because of the COVID-19 pandemic and lockdown of the society, only one healer will be implementing the healing sessions as opposed to the two originally planned. Due to the overload of patients in clinical practice and implementation of pandemic protocols (such as vaccination of patients) the implementation of the trial has been negatively affected. The physicians who will recruit patients to the trial have been occupied with patients with COVID-19. However, several physicians working in five different conventional health clinics will recruit patients to the trial providing an insight on different methods of usual care. A multidisciplinary research team consisting of CM providers, physicians, psychiatrists and researchers will safeguard a methodology in line with a whole system research approach. Lastly, to enhance patient safety, the research team will record adverse effects of both healing and usual care.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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