DEPRE-ST – A Randomized Controlled Trial of Schema Therapy for Patients with Chronic Treatment Resistant Depression

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(Danish title: DEPRE-ST – en randomiseret, kontrolleret undersøgelse af schematerapi for patienter med svært behandlelig depression)

We would like to ask if you would like to participate in a scientific study being carried out by PhD student and psychologist Ida-Marie Arendt and psychologist, associate professor and research leader Stine Bjerrum Moeller at the psychiatric center in Region of Southern Denmark and Capital Region Psychiatry. The study is affiliated with the University of Southern Denmark.

Before deciding whether to participate in the trial, you must fully understand what the trial is about and why we are conducting the trial. We would therefore ask you to read this participant information carefully. You will also get the information further elaborated before the first assessment, where you can ask any questions you have about the study. You are welcome to bring a family member, friend or acquaintance to the interview.

If you decide to participate in the trial, we will ask you to sign a consent form. Remember that you have the right to 24 hours of reflection before you decide whether you want to sign the declaration of consent. Participation in the study is voluntary. You can withdraw your consent at any time and without giving a reason by contacting the project manager, PhD student Ida-Marie Arendt, phone number 24658907, email: imarendt@health.sdu.dk, in writing or by phone. If you choose not to participate, or withdraw at a later stage, this will have no consequences for your further treatment in psychiatry. If you choose to withdraw after you have enrolled in the study, we will no longer contact you for follow-up measurements. However, we would like to be allowed to contact you one last time to hear your reasons for withdrawing, as this is very valuable information for the study.

Purpose of the study

In DEPRE-ST, we will investigate the effect of 30 sessions of individual treatment with the psychotherapy schema therapy compared to the treatment otherwise given in psychiatric settings in Denmark (e.g., group or individual treatment with other types of therapy). More precisely, we will look at the effect on difficult-to-treat depression, which is when depression has lasted more than 2 years or has been treated with more than 2 types of antidepressant medication without a sufficiently good effect.

Schema therapy is a particularly in-depth and vivid form of therapy that has shown promising results in the treatment of depression, and we will now investigate the therapy's effect more systematically.

We aim to recruit 129 participants who have been referred for depression treatment in psychiatry. You will be randomly assigned (through so-called randomization) as to whether you receive the usual psychiatric treatment or individual schema therapy. If you are assigned schema therapy, you still have the option of also receiving the treatment you would otherwise have received in psychiatry, e.g. with medication - it is only the psychotherapeutic treatment that is different.

We will also develop a model for understanding patients with difficult-to-treat depression, so that treatment providers can map out the nuances of problems in benefiting from the treatment and thus provide the right help.

Plan for the study

If you agree to participate in the study, we would like to make repeated measurements of your symptoms and your well-being. This is done by a short interview about your symptoms of depression and then filling

in a series of questionnaires. The first assessment is expected to last approximately 1½ hours in total. All measurements take place either at the psychiatric center or online and are carried out by trained psychologists. We make measurements at enrollment in the project and again after 6 months, as well as 1 and 2 years thereafter, as it is important to assess the effect of the treatment over a longer period of time. We measure: symptoms of depression, daily level of functioning, psychological well-being, anger management, personal assumptions about anger, anxiety symptoms, repeated negative thinking, personal recovery (perceived coping with life) after mental illness, labor market attachment, health-related quality of life, expectations for recovery from depression, and self-defined mental recovery. In addition, the first examination will uncover any previous depressions and treatments for depression, as well as education, marital status, schemas and schema modes (psychological phenomena that may underlie the depression) and whether there has been trauma in childhood. Experienced negative effects from the treatment are also measured.
It is important that you can set aside time to participate in all measurements. We agree on times for assessment according to your schedule. It is possible to meet online if you prefer.
The treatment itself takes place at the psychiatric center you are referred to, by the center's employed therapists. Treatment sessions will be recorded on video and used to internally assess the content and quality of the treatment.

Benefits of the study
Your participation will help in the attempt to further develop the treatment for depression in psychiatry. If schema therapy proves to be better than the treatment currently offered by psychiatry, this could be used in the planning of future psychiatric treatment. The study also provides important and valuable knowledge about the special group of patients with long-term or difficult-to-treat depression. This knowledge will potentially be used in research and treatment of depression worldwide.
If you are assigned schema therapy, you will receive individual psychotherapy adapted to you. Up to 30 sessions of schema therapy are given, which is more than is usually offered in psychiatry. Schema therapy is also a lively and engaging form of therapy that delves into emotional problems that can go all the way back to childhood.
No money or gifts are given for your participation in the study.

Side effects, risks, complications and disadvantages
We do not expect schema therapy to have other side effects than those already known in psychotherapy - for example temporary worsening of the condition when working with difficult emotional material. Only few people experience a permanent worsening due to psychotherapy itself.
Some people also experience being emotionally affected when they have to participate in research interviews and fill in questionnaires. If this happens, our experienced research staff will take care of you in the best possible way. You are also encouraged to talk to your therapist along the way if you experience getting worse, so you can deal with this together. The therapists who provide schema therapy receive frequent guidance (supervision) so that they can give you the best possible treatment.
However, there may be risks with the study that we do not yet know. We therefore ask you to let us know if you experience problems with your health while the trial is ongoing. If we discover side effects from the treatment that we have not already told you about, you will of course be informed immediately, and you will decide whether you want to continue with the trial.
Exclusion from and suspension of trials

There may be circumstances where we may need to discontinue your participation in the trial. This can be if your treatment is transferred to another treatment unit, for example if during the course you are in acute danger of suicide, if you develop mania or psychosis or are admitted to a psychiatric ward for a long period of time. The trial as a whole can be interrupted if - contrary to expectations - we find that there are previously unknown side effects from the treatment.

Access to electronic patient records

If you have given your consent after the initial interview at your psychiatric centre, the clinician will pass on your name, telephone number and status of depression treatment to the researchers. If you wish to participate in the study, we will also ask for your consent to direct access to your electronic patient record for, e.g., to be able to see what psychiatric treatment you have received before and during the study as well as measurements regarding your mental health. This is to be able to register and measure which treatment elements you have received and how they have worked, and also to keep an eye on the quality of the treatment. For more information, see below in the section: Information on the processing of personal data.

Access to trial results

The results of the trial will - in anonymized form - be made public on an ongoing basis in international journals and at scientific conferences, for the benefit of researchers and practitioners of mental illness. Relevant interest associations will also be involved in the project and its results.
The project is expected to be completed in January 2028. You have the opportunity to obtain information about the overall results of the study yourself when it has been completed. If you wish this, you can tick the attached declaration of consent.

Information about financial conditions

The study is financially supported with approx. DKK 6 million from Trygfonden, a private foundation which is independent of the study's initiators, Ida-Marie Arendt and Stine Bjerrum Moeller. Neither Trygfonden nor the initiators of the study have financial interests in the results of the study. In addition, the study is supported with DKK 592,000 from the Region of Southern Denmark's PhD fund.
The money is spent on PhD salary, salary for the study's research assistants, training and supervision of the participating clinicians, salary for statisticians, as well as overhead and PhD tuition fee to the University of Southern Denmark.

Information on the processing of personal data

In connection with the project 'DEPRE-ST - a randomized, controlled study of schema therapy for patients with chronic, difficult-to-treat depression', the Region of Southern Denmark would like to collect information about you. The Region of Southern Denmark is responsible for the protection of your personal data for use in research projects.

The collection takes place via clinical interviews and questionnaires (as described above) in connection with treatment for depression at the Region of Southern Denmark and the Capital Region of Denmark Psychiatry.

The project requests direct access to personal and health information in your electronic patient record in order to be able to assess your effect of treatment, as well as which and how much treatment you have received, both in connection to and within the project (talk therapy, medicine, etc.). In addition, access may be needed for quality checks by the project's researchers and research assistants and for monitoring of the study.

Purpose of the processing of personal data

The information that is processed is:

- Health information that appears from patient records regarding treatment for depression in psychiatry.

- Clinical interviews and questionnaires with a focus on mental health and psychological symptoms.

- Information on the reason for termination of treatment before originally planned, in the event of this

- Video recordings of your treatment sessions

- In addition, the researcher will be familiar with the name, e-mail address, social security number, number of attendances and medication in the psychiatric treatment as well as marital status, education and connection to the labor market.

How Region Southern Denmark handles the personal data

The information is processed in accordance with Section 10 of the Data Protection Act for sensitive personal data (e.g. diagnosis and health status) and in accordance with Article 6, paragraph 1, letter e of the Data Protection Regulation for the general personal data (e.g. name and email address). The Region of Southern Denmark will treat the personal data confidentially - in accordance with applicable law.

We make sure to store the data safely. The information is analyzed by our statisticians in Denmark and Austria, with whom we have entered into a formal cooperation agreement. The information will only be used for research. However, to the extent that it is relevant, the information will be recorded, cf. the Danish rules for record-keeping.

Deletion and storage of your personal data

Region Southern Denmark will delete or anonymize data when it is no longer relevant to store your personal data. This will most often be when the project has been completed, but can also be later, for

reasons of possible documentation of research results. This will happen no later than five years after the end of the project, i.e. no later than 31-1-2033.

You should be aware:

• that you can always revoke your consent to participate in the project. Note that revoking your consent to participate will not cause information already collected to be deleted.

• that you have the right to complain to the Data Protection Authority about the processing of the information via www.datatilsynet.dk.

There will be no publication of data where you can be identified, as all data published as research will be anonymized.

Additional information about personal data

If you have questions about data protection and your rights, you can contact the Data Protection Adviser of the Region of Southern Denmark on telephone number +45 24 75 62 90 (phone hours Mondays and Thursdays at 9-11 AM) or by email: databeskyttelsesraadgiver@rsyd.dk

You can also read more about our processing of your personal data and your rights here: https://regionsyddanmark.dk/om-region-syddanmark/sadan-behandler-vi-dine-data-og-personoplysninger/persondatapolitik-for-region-syddanmark

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We hope that with this information you have gained sufficient insight into what it means to participate in the trial and that you feel equipped to make the decision about your possible participation. We also ask you to read the attached material, "Participants' rights in a health science research project".

If you want to know more about the trial, you are very welcome to contact the project leader, PhD- student Ida-Marie T. P. Arendt, tel. 24658907, e-mail: imarendt@health.sdu.dk

With best regards

Ida-Marie T. P. Arendt, PhD, cand.psych.aut.

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Informed consent for participation in a health science research project

Title of the research project: 'DEPRE-ST - a randomized, controlled study of schema therapy for patients with chronic treatment resistant depression'

Statement from the subject:

- I have received written and oral information, and I know enough about the purpose, method, benefits and disadvantages in order to be able to agree to participate.
- I understand that participation is voluntary and that I can always withdraw my consent to participate without losing my current or future rights to treatment.
- I consent to participate in the research project and have received a copy of this consent form as well as a copy of the written information about the project for my own use.
- I understand that information about me will only be used for research.
- I also give consent for information to be obtained from my electronic patient record as described in the document 'Information on processing of personal data'.

Mark with x for consent to the above: _____

I am informed that I can withdraw my consent to participate in the project at any time by contacting the project manager Ida-Marie T. P. Arendt, e-mail: imarendt@health.sdu.dk, telephone +4524658907.

Name of participant: _____

Date: _____ Signature: _____

If new significant health information about you arises during the research project, you will be informed. If you would *not* to receive information about new important health information that arises during the research project, please tick here: _____ (mark with an x)

Do you wish to be informed about the results of the research project and any consequences for you?
Yes _____ (mark with an x) No _____ (mark with an x)

Declaration by the person providing the information:
I declare that the subject has received oral and written information about the study.

I confirm that sufficient information has been provided for a decision to be made regarding participation in the trial.
The name of the person providing the information: Ida-Marie T. P. Arendt

Date: _____ Signature: _____