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Nacadia Effect Study - studying the effect of garden Therapy in relations to people suffering from stress

Submission date	Recruitment status	[ ] Prospectively registered
22/05/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/08/2013	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/04/2019	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
In the Western world stress is considered as one of the main factors related to modern lifestyle diseases. This research project deals with stress treatment in the form of garden therapy in therapy garden Nacadia. Nacadia therapy can be described as a process where the patient's health and well-being is assumed to be improved by the presence of the natural environment and by participating in meaningful gardening activities. The therapy consists of individual and group activities in the garden, such as gardening, walking, resting and talk therapy. The effect of the garden therapy will be compared with the well-established therapy form Cognitive Behaviour Therapy (CBT). Half of the participants will receive garden therapy and the other half will receive CBT. The aim of this study is measure rate of return to work, frequency of use of healthcare, psychological measurements related to stress, health, quality of life and changes in medication use. A further aim is to see if the garden therapy is able to cure the participants just as successfully as the CBT.

Who can participate?
Men and women aged 20-60 years old who are suffering from prolonged stress and are on sick leave for that reason (3-24 months).

What does the study involve?
Participants will be randomly allocated to receive either garden therapy or CBT. The participants receiving garden treatment will visit the garden during ten weeks, two to three times a week for three hours in groups of eight. The participants receiving CBT will have individual sessions (20 hours in total) with a psychologist in a clinic during the same ten weeks. All participants will fill in five questionnaires (at the start, end and 3, 6 and 12 months after the treatment). The participants in the garden will also fill in log-books about their use of the garden and a researcher will do observation studies of the participants. Two of the participants will be interviewed after the observations.

What are the possible benefits and risks of participating?
Participating can be a demanding process and often requires that you challenge yourself mentally and physically. The benefit will be a better quality of life after the treatment.

Where is the study run from?
The study is run from the therapy garden Nacadia located in Hørsholm, as well as from two psychologist practices in Hillerød and Hørsholm, all north of Copenhagen, Denmark.

When is the study starting and how long is it expected to run for?
The study is starting in August 2013 and ends in April 2016. The last group will start in August 2014.

Who is funding the study?
The study is funded by the Tryg Foundation (Tryg Fonden Denmark).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01849718

Protocol serial number
NEST-704171

Study information

Scientific Title
Randomized controlled trial comparing two treatments of stress - Nacadia Therapy and Cognitive Behavioural Therapy - on repeated measurements of the same variables over a period of time

Acronym
NEST

Study objectives
Garden therapy, in a designed natural environment, will lead to improved health and well-being for people who are suffering from stress-related disorders and unable to maintain a job

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has been approved by the National Committee on Health Research Ethics, Copenhagen Region, Denmark, and has received the protocol number: H-1-2013-038. The study was approved 29/05/2013.

Study design
Randomized controlled trial. Exploratory studies of the garden therapy (observations and interviews)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stress-related problem

Interventions
The two intervention treatment options in this study is Nacadia-therapy (garden therapy) and cognitive behavioral therapy (CBT - control group). Because the Nacadia-therapy uses a large number of hours, it has been decided to compare it with the longest conventional treatment that can be offered through the public health insurance of stress-related disorders such as anxiety and depression.

1. Number of participants (N): 80
a. 40 (n) Nacadia Therapy
b. 40 (n) CBT

2.Type of environment
a. The therapy garden Nacadia (outdoors or greenhouse)
b. Clinic (indoors)

3.Therapists and staff
a. 2 psychologists and a gardener
b. 2 psychologists

4.Length of treatment
a. 10 weeks
b. 10 weeks

5.Treatment content
a. 96 hours of Nacadia-therapy (including 79 hours of gardening therapy, 10x½ hour individual conversations, and 4x3 hours of transition conversation)
b. 20 hours individual CBT (including 16 hours of treating converstaional therapy and 4x1 hour of transition conversation)

6.Treatment set-up
a. Group of 8
b. Individual

Consistent factors in the two treatment options:
1. The psychologists involved in both therapy types are authorized, and trained in CBT.
2. Conversational therapy: Psychotherapeutic conversations in both treatments are primarily based on CBT.
3. The treatments have the same length of time of 10 weeks

Diverging factors in the two treatment options:

1. Environment: In the Nacadia-therapy the treatment is taking place in a designed natural environment, and in CBT the treatment takes place in the psychologists' treatment rooms.
2. The number of hours: In Nacadia-therapy the individual sessions last three hours, with two sessions per week the first and last week and three sessions a week in week 2-9. This gives a total of 96 hours, including 4 x 3 hours transition conversation and 10 x ½ hour individual interviews. In CBT, the duration of the individual sessions are one hour, and there are 1-2 sessions per. week, totaling 20 hours, incl. 4 hours of transition conversations.
3. Treatment content: in Nacadia-therapy experiences and activities related to the garden environment are integrated with mindfulness exercises. The individual conversations in the Nacadia-therapy will be mindfulness-based CBT, whereas in the control group the conversations will be exclusively CBT-based.
4. Number of hours for conversational therapy: 20 hours of individual psychotherapy in CBT, 10 x ½ an hour for individual psychotherapy in Nacadia-therapy.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Ability to return to work
2. Use of medication
3. Use of Health Care

The outcomes are measured by treatment start and end (after 10 weeks) as well as 3, 6 and 12 months after the treatment has ended. Data on use of health care and medicine will be retracted from databases 3 years prior to the treatment and 1 year after the treatment.

Key secondary outcome(s))
Use of natural environments
The outcomes are measured by treatment start and end (after 10 weeks) as well as 3, 6 and 12 months after the treatment has ended.

Completion date
31/10/2015

Eligibility

Key inclusion criteria
The project is targeted at citizens who are severely burdened by stress (including ICD categories, F 43.0-9 [excluding Post-traumatic stress disorder (PTSD), and F45.3], which can be expected to correspond to 6-24 months sick leave.

Other inclusion criteria:
1. That you are between 20-60 years old, male and female
2. That you suffer from prolonged stress, and have been on sick leave for that reason in ½ -2 years
3. You have no other significant and untreated physical illness behind the symptoms
4. You have no other significant and untreated mental illness behind the symptoms, such as personality disorders, bipolar disorders, psychosis or a high degree of sociophobia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Suicidal tendencies or abuse problems

Date of first enrolment
01/08/2013

Date of final enrolment
31/10/2015

Locations

Countries of recruitment
Denmark

Study participating centre

Københavns Universitet
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Sponsor information

Organisation
Tryg Foundation (TrygFonden) (Denmark)

ROR
https://ror.org/02rcazp29

Funder(s)

Funder type
Charity

Funder Name
Tryg Foundation (TrygFonden) (Denmark)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2018	10/04/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes