ISRCTN15259166 https://doi.org/10.1186/ISRCTN15259166

Pilot randomized-controlled trial on the efficacy of acupuncture in people with an increased stress level

Submission date
24/08/2017

Recruitment status
No longer recruiting

Registration date
18/09/2017

Overall study status
Completed

Last Edited
11/10/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
It is well known that chronic (long-term) stress is a risk factor or intensifier for a variety of physical disorders or illnesses. Chronic stress has been demonstrated to increase cardiovascular (heart disease) risks, musculoskeletal disorders, and mental disorders such as depression. In Traditional Chinese Medicine acupuncture has been used to treat stress-related disorders. First studies have shown that acupuncture may serve as an adequate treatment for people with increased stress. However, well-designed studies demonstrating the effectiveness of acupuncture in chronic stress are still lacking. This study aims to assess the feasibility and acceptability of acupuncture in people with an increased stress level.

Who can participate?
Healthy adults aged 18 and over with an increased stress level

What does the study involve?
At the beginning of the study a diagnostic assessment is carried out for all participants. Afterwards participants are randomly allocated to one of three groups. One group receives verum (true) acupuncture treatment, one group sham acupuncture, and one group is put on a waiting list. Stress is measured at the start of the study, at the end of treatment and at three months after the end of treatment.

What are the possible benefits and risks of participating?
All participants are assessed closely by a professional team at the start of the study. Participants of all groups may benefit from the acupuncture treatment. Participation in this study involves no risks of physical injury or harm.

Where is the study run from?
University Hospital Heidelberg (Germany)

When is the study starting and how long is it expected to run for?
August 2017 to August 2018

Who is funding the study?
1. University Hospital Heidelberg (Germany)
2. Ministerium für Wissenschaft, Forschung und Kunst Baden-Württemberg (Germany)

Who is the main contact?
Prof. Beate Wild

Contact information

Type(s)
Scientific

Contact name
Prof Beate Wild

Contact details
Im Neuenheimer Feld 410
Heidelberg
Germany
69120

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Pilot randomized-controlled trial on the efficacy of acupuncture in people with an increased stress level

Acronym
AkuRest

Study objectives
This pilot study aims to assess the feasibility and acceptability of the study design and treatment.

Study hypotheses:
1. The study design is well accepted by those persons meeting the inclusion criteria. The rate of persons consenting to participation is over 50%, and more than 70% of the included persons complete the study.
2. Explorative: The acupuncture intervention leads to a reduction of the stress level measured by using the Perceived Stress Questionnaire (PSQ-20) and the Patient Health Questionnaire (PHQ

stress module).
3. Explorative: Acupuncture leads to alterations in psychoneuroimmunologic and psychophysiologic parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Heidelberg, 12/05/2017, ref: S-011/2017

Study design
Randomized controlled three-armed pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Adults with high self-reported stress levels

Interventions
At the beginning of the study a diagnostic assessment is done for all participants. Afterwards participants are randomized to one out of three groups. The randomization will conducted by using the randomization software “RANDI 2”. Randomization will be stratified by center. The randomization program will be applied by an independent assistant at the University Hospital Heidelberg.

1. Verum acupuncture group. The indicated points of the verum acupuncture are predefined according to literature research and the expertise of the acupuncturist and will be maintained throughout the 10 sessions. Eliciting a De Qi sensation is the aim of the treatment. The individual points may be chosen and altered during the course of treatment by the acupuncturist according to the leading clinical symptoms.
2. Sham acupuncture group. 4-6 standardized points of acupuncture are chosen that are not on acupuncture meridians. These will only be placed superficially without eliciting a so-called De Qi sensation. The control acupuncture points may analogous to the verum acupuncture be changed individually during the course of treatment.
3. Waiting list control group: a group that will, to begin with, not be treated for 3 months.

The intervention consists of 10 sessions (each between 20-30 minutes). Acupuncture will be carried out by a licensed acupuncturist. Intervals between treatments are dependent on the participant and according to plan and feasibility between 3 and 7 days. The total duration of

treatment will be up to three months. There will be a follow-up measurement at about three months after the end of treatment.

Intervention Type
Other

Primary outcome measure
Feasibility and acceptability: defined as the study design is well accepted by those persons meeting the inclusion criteria, the rate of persons consenting to participation is over 50% and more than 70% of these complete the study. Measured at the end of treatment.

Secondary outcome measures
1. Stress level, measured by the PSQ-20, the PSS, and the PHQ stress module
2. Heart rate variability, measured at all three centers with the same device using a standardized protocol
3. Psychoneuroimmunologic parameters, analysed using blood samples

Measured at baseline (at the beginning of the study), end of treatment, and at three months follow-up

Overall study start date
28/08/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. PSQ-20 score ≥ 60
2. Age ≥ 18
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
75

Total final enrolment
70

Key exclusion criteria
1. Suicidal ideation
2. Psychiatric disorder
3. Needle phobia
4. Insufficient knowledge of the German language

Date of first enrolment
31/08/2017

Date of final enrolment
15/06/2018

Locations

Countries of recruitment
Germany

Study participating centre
Department of General Internal Medicine and Psychosomatics, University Hospital
Im Neuenheimer Feld 410
Heidelberg
Germany
69120

Study participating centre
Institute of General Practice and Interprofessional Care, University Hospital Tübingen
Tübingen
Germany
72076

Study participating centre
Centre for Complimentary Medicine, University Hospital Freiburg
Freiburg
Germany
79106

Study participating centre
The Institute of Immunology, University Hospital Heidelberg
Heidelberg
Germany
69120

Sponsor information

Organisation
University Hospital Heidelberg

Sponsor details
Im Neuenheimer Feld 410
Heidelberg
Germany
69120

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/013czdx64

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Heidelberg (preparation, design planning, data management, organization, treatment)

Funder Name
Ministerium für Wissenschaft, Forschung und Kunst Baden-Württemberg (cooperation centers)

Alternative Name(s)
Ministry of Science, Research and Art Baden-Württemberg, MWK

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Germany

Results and Publications

Publication and dissemination plan
The German study protocol is available upon request. The trialists intend to publish the study results in a high-impact journal at about 6 months after the end of the study.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/07/2020	22/09/2020	Yes	No
Dataset			11/10/2023	No	No