

Efficacy of acupuncture in post-COVID fatigue – A randomised controlled pilot study

Submission date 22/03/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/03/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/04/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Fatigue is one of the most common symptoms of post-COVID syndrome. The burden and distress caused by post-COVID fatigue are high. The present study is a randomized controlled (RCT) pilot study to evaluate the efficacy of acupuncture in post-COVID fatigue. The study is planned as a two-arm study with a semi-standardized acupuncture and a waiting control group. A total of 2 x 25 participants will be included. Clinical and psycho-neuro-immunological parameters, and heart rate variability will be examined before the start and after the end of treatment as well as at a 3-month follow-up. Validated questionnaires will be used to measure fatigue symptoms. The feasibility of the study protocol will be evaluated and effects of acupuncture will be estimated.

Who can participate?

Healthy adults aged 18 and over with persistent post-COVID fatigue symptoms (lasting over at least 2 months)

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 two groups. One group receives acupuncture treatment, and one group is put on a waiting list.

Fatigue and further variables are measured at the start of the study, at the end of treatment and at 3-month follow-up.

What are the possible benefits and risks of participating?

All participants are assessed comprehensively 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?

Department of General Internal Medicine and Psychosomatics, University Hospital Heidelberg (Germany)

When is the study starting and how long is it expected to run for?
January 2024 to December 2025

Who is funding the study?
Deutsche Ärztegesellschaft für Akupunktur (DÄGfA) (Germany)

Who is the main contact?
Prof. Dr. Beate Wild, beate.wild@med.uni-heidelberg.de

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Efficacy of acupuncture compared to a waiting control condition in patients with post-COVID fatigue - a randomised controlled pilot study

Acronym

ACU-POCO

Study objectives

The feasibility of the study protocol will be evaluated. The hypothesis is that the study design is well accepted by the patients with fatigue syndrome. The rate of persons consenting to participation is over 50%, and more than 70% of the included persons will complete the study. In

addition, the study hypothesis is that the acupuncture intervention will lead to a reduction in the fatigue symptomatology measured by the Chalder Fatigue Scale (CFS-11). An explorative hypothesis is that acupuncture leads to alterations in psychophysiologic and psychosomatic parameters.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 10/01/2024, Ethics committee of the University Hospital Heidelberg (Alte Glockengießerei 11/1, Heidelberg, 69115, Germany; +49 6221 562646-0; ethikkommission-l@med.uni-heidelberg.de), ref: S-752/2023

Study design

Randomized controlled pilot-study

Primary study design

Interventional

Study type(s)

Efficacy

Health condition(s) or problem(s) studied

Post-COVID fatigue

Interventions

The intervention group will receive acupuncture consisting of 10 treatment sessions. Each session will be between 20-30 minutes in length. Intervals between treatment sessions can vary from 3 to 7 days. However, according to feasibility and the circumstances of the participants (e. g., holidays or illness) longer intervals between sessions will be allowed. The treatment is semi-standardized, with 2-3 predefined and up to 15 other individually selectable acupuncture points. Acupuncture will be carried out by a licensed acupuncturist.

Participants in the control group will not receive acupuncture treatment for three months. After three months they will be offered the acupuncture treatment described above.

The randomisation will be done using REDcap (a web application for building and managing online surveys and databases).

Intervention Type

Other

Primary outcome(s)

Feasibility and acceptability measures:

The study design is well accepted by those persons meeting the inclusion criteria. This is defined by

1. The rate of persons consenting to participation is over 50% measured as the percentage of those who consent to the study out of those who have met the criteria (by using telephone interviews and questionnaires at baseline).

2. More than 70% of the included persons complete the study (measured as the percentage of persons who completed the study out of those who were included in the study using notes of the participation in treatment sessions at the end of treatment).

Primary outcome measure:

1. Fatigue measured by the Chalder Fatigue Scale (CFS-11) (by using the 0-3 scale for each item) at the end of acupuncture treatment

Key secondary outcome(s)

1. Fatigue measured by the FA12 and FAS at the end of treatment and at 3-months follow-up
2. Somatic and psychological outcomes such as pain, concentration, and health anxiety measured by using questionnaires at the end of treatment and at the 3-months follow-up
3. Heart rate variability measured using a portable HRV measurement instrument with high signal quality at the end of treatment and at 3-months follow-up
4. Psycho-neuro-immunologic parameters measured using blood sampling at the end of treatment and at 3-months follow-up

Completion date

01/12/2025

Eligibility

Key inclusion criteria

1. Post-COVID fatigue defined according to the WHO criteria: continuation or development of fatigue symptoms 3 months after a SARS-CoV-2 infection, with these symptoms lasting for at least 2 months with no other explanation
2. Actual CFS-11 Score of ≥ 4 using a binary coding (0/1) in the first 10 items
3. Age ≥ 18 years
4. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Acute diseases requiring treatment
2. Severe neurological diseases (severe persistent headache or cognitive impairment)
3. High-dose corticosteroid therapy
4. Immunosuppressive therapy

5. Pregnancy
6. Needle phobia
7. Insufficient understanding of the German or English language.

Date of first enrolment

02/04/2024

Date of final enrolment

01/11/2024

Locations

Countries of recruitment

Germany

Study participating centre

Department of General Internal Medicine and Psychosomatics, University Hospital Heidelberg

Im Neuenheimer Feld 410

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Germany

69120

Sponsor information

Organisation

University Hospital Heidelberg

ROR

<https://ror.org/013czdx64>

Funder(s)

Funder type

Research organisation

Funder Name

Deutsche Ärztegesellschaft für Akupunktur (DÄGfA)

Results and Publications

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