ISRCTN15106165 https://doi.org/10.1186/ISRCTN15106165

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

Submission date	**Recruitment status**	[X] Prospectively registered
22/03/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/03/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/04/2024	Other	[ ] 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

Contact name
Prof Beate Wild

ORCID ID
https://orcid.org/0000-0002-2279-8135

Contact details
Im Neuenheimer Feld 410
Heidelberg
Germany
69120
+49 6221 568663
beate.wild@med.uni-heidelberg.de

Additional identifiers

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-I@med.uni-heidelberg.de), ref: S-752/2023

Primary study design
Interventional

Study design
Randomized controlled pilot-study

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
Heidelberg
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