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Effectiveness of acupuncture for gastrointestinal dysfunction in Parkinson's disease

Submission date 01/03/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 14/03/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/11/2025	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is a common chronic progressive neurological disease in middle-aged and elderly people, accompanied by various movement and non-movement symptoms. Gastrointestinal dysfunction is one of the most common PD symptoms, and has often been neglected and has not been properly managed. Acupuncture has received attention as a promising intervention for gastrointestinal dysfunction, and some previous studies have reported that this intervention may be beneficial for treating PD patients with gastrointestinal dysfunction. This study aims to explore how practical and effective acupuncture is for PD patients with gastrointestinal dysfunction.

Who can participate?
Adults aged between 40 and 80 years with a diagnosis of Parkinson's disease and gastrointestinal dysfunction

What does the study involve?
Parkinson’s disease patients will be asked to join this study while they visit Beijing TCM Hospital’s acupuncture department. The trial will be explained to participants and will be asked to sign an informed consent form. Participants will be allocated to one of two groups with an equal chance of being in either group (like tossing a coin). One group will receive 12 sessions of acupuncture treatment over 4 weeks. The other group will receive 12 sessions of sham acupuncture treatment over 4 weeks using non-penetrating flat needles. The study lasts 1 month in total. Participants also complete online questionnaires and assessments before receiving treatment and after 4, 12 and 24 weeks. The gastrointestinal dysfunction of participants will be measured using a gastrointestinal electrograph scan before and after the treatment.

What are the possible benefits and risks of participating?
Relief of gastrointestinal dysfunction in PD patients may be a possible benefit while participating in this study. Improvements to the patient's gastrointestinal function are not guaranteed in the sham acupuncture group. If the symptoms are not improved due to the sham acupuncture treatment, normal acupuncture treatment can be provided after the test is

completed. The information obtained from this study could benefit patients with the same condition in the future.
The main risk of acupuncture would be temporary pain, a sense of itching or swelling, and other possible side effects such as slight bleeding, bruising, or fainting. Patients with any of these side effects will receive immediate medical care, and the study team will reassess whether they can continue to accept treatment.

Where is the study run from?
Beijing Traditional Chinese Medicine Hospital (China)

When is the study starting and how long is it expected to run for?
March 2023 to December 2025

Who is funding the study?
Beijing Traditional Chinese Medicine Hospital (China)

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
A clinical randomized controlled study of acupuncture for Parkinson's gastrointestinal dysfunction

Acronym
CRCSAPGD

Study objectives
A clinical randomized controlled study of acupuncture for Parkinson's gastrointestinal dysfunction

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/11/2023, Beijing Traditional Chinese Medical Hospital Ethics Committee (Beijing Traditional Chinese Medicine Hospital, No. 23, Art Museum Back Street, Dongcheng District, Beijing, 100010, China; +82 (0)10 8970 6734; website@bjzhongyi.com), ref: 2020BL02-072-02

Primary study design
Interventional

Study design
Single-center interventional randomized single-blinded parallel controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gastrointestinal dysfunction in patients with Parkinson's disease

Interventions
The random allocation sequence will be generated using a random number table method by a statistician not involved in the trial. Allocation sequences will be concealed in sequentially numbered, sealed, opaque (unrecoverable) envelopes to ensure sequence confidentiality.

Participants will be randomly allocated (1:1) to either the treatment or the control group. One group will receive 12 sessions of acupuncture treatment over 4 weeks. The other group will receive 12 sessions of sham acupuncture treatment over 4 weeks using non-penetrating flat needles. Treatment duration is 1 month with assessments at baseline (before the intervention), 4, 12, and 24 weeks.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Gastrointestinal dysfunction is measured using the electrogastrogram at baseline and 4 weeks
2. Blood Serum Index is measured using radioimmunoassay at baseline and 4 weeks
3. Gastrointestinal dysfunction is measured using the Rome IV functional gastrointestinal disorders (FGID) criteria at baseline and 4 weeks

Key secondary outcome(s)
1. Stool analysis by 16S-rRNA high throughput sequencing at baseline and 4 weeks
2. The extent of Parkinson's disease is measured using the Unified Parkinson's disease rating scale (UPDRS) and the Hoehn–Yahr Rating Scale at baseline, 4, 12 and 24 weeks

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Idiopathic PD diagnosis
2. Gastrointestinal dysfunction meeting Rome IV FGIDs criteria
3. Ability to provide written informed consent
4. Men or women aged 40 to 80 years
5. Liver function, kidney function, blood routine, urine routine, and stool routine are all normal

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
40 Years

Upper age limit
80 Years

Sex
All

Key exclusion criteria
1. Gastrointestinal dysfunction caused by other diseases
2. Severe heart, liver, kidney, or other organ dysfunction
3. Have been taking gastrointestinal motility drugs and laxative drugs for a long time
4. Severe cognitive impairment and language impairment who cannot cooperate with the rating
5. Inability to adhere to the study protocol as determined by the investigator

Date of first enrolment
01/04/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
China

Study participating centre
Beijing Traditional Chinese Medicine Hospital
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Sponsor information

Organisation
Beijing Hospital of Traditional Chinese Medicine

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beijing Traditional Chinese Medicine Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other