ISRCTN12511434 https://doi.org/10.1186/ISRCTN12511434

# Efficacy of acupuncture for postprandial distress syndrome (PDS)

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| **Submission date**<br>16/02/2017 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>31/03/2017 | **Overall study status**<br>Completed | |
| **Last Edited**<br>02/12/2024 | **Condition category**<br>Digestive System | |

## Plain English summary of protocol

Background and study aims
Postprandial distress syndrome (PDS) is a form of indigestion that causes an unpleasant sense of fullness in the stomach after a eating a meal. PDS is related to pain and burning in the throat and stomach. Although PDS is not a life-threatening condition, people who suffer from PDS have higher rates of depression and anxiety. PDS is usually treated by prokinetics/antacids (tablets that are chewed or swallowed that control the acid in the stomach). However, there are very few studies that have looked at how these treatments actually work in treating PDS. Therefore, treatments by other methods should be examined. Some studies have shown that acupuncture therapy (an ancient Chinese treatment that inserts small needles into the skin) has been found to have helped relieve symptoms from other stomach disorders and could be successful in helping those with PDS. The aim of this study is to determine how well acupuncture works at treating PDS.

Who can participate?
Adults aged 18-65 who have PDS

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive verum acupuncture which consists of needles inserted into the skin at specific locations until a specific sensation is felt by the participant. Those in the second group receive minimal acupuncture which includes needles inserted lightly in the skin at nonspecific spots. Both groups receive 12 sessions that last 20 minutes over four weeks. Participants are followed up at four, six, eight and 12 weeks to see if the treatments affected their PDS symptoms.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in their symptoms. There are no notable risks with participating, however participants may feel some discomfort and temporary pain due to the acupuncture treatment.

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

When is the study starting and how long is it expected to run for?
June 2016 to September 2019

Who is funding the study?
Beijing Municipal Science & Technology Commission (China)

Who is the main contact?
Prof Cun-Zhi Liu
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# Contact information

### Type(s)
Public

### Contact name
Prof Cun-Zhi Liu

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# Additional identifiers

### Protocol serial number
Z161100000516007

# Study information

### Scientific Title
Efficacy of Acupuncture for Postprandial Distress Syndrome (PDS): a multi-centre, Randomized, Controlled Trial

### Acronym
APDS-RCT

### Study objectives
Acupuncture will produce a significant improvement in symptoms of PDS compared to minimal acupuncture

### Ethics approval required
Old ethics approval format

### Ethics approval(s)

Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, 02/12/2016, ref: 2016BL-073-02

## Study design
Two-arm multi-centre randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Postprandial distress syndrome (PDS)

## Interventions
Participants are randomly allocated to one of two groups using stratified block randomisation (generated by PROC PLAN in SAS, using the study site as the stratification factor).

Group one (Verum acupuncture group): Participants in this group receive acupuncture (insertion of small needles in the skin) at selected acupoints: Baihui (DU20), Zhongwan (RN12), Tianshu (ST25), Qihai (RN6), Neiguan (PC6), Danzhong (RN17), Zusanli (ST36) and Gongsun (SP4). In addition, according to participants symptoms, different needling points are inserted. These include needling for weakness of the qi of the spleen and stomach (Taibai SP3), depression of the qi of the liver (Taichong LR3), damp-heat in the stomach (Neiting ST44). Needles are stimulated by the clinician until patients feel a deqi sensation. Each session takes 20 minutes. Participant receive 12 treatment sessions in total over four weeks (three sessions per week).

Group two (control/minimal acupuncture group): Participants in this group receive acupuncture at non-acupoints with a superficial puncture (2mm in depth) in order to avoiding deqi sensation. The location of non-acupoints as following: NP1 Middle of Touwei (ST8) and Yuyao (EX-HN4) points, NP2 2.0 cun above the anterior superior iliac spine, NP3 2.0 cun below the umbilicus and 1.0 cun lateral to the anterior midline, NP4 Middle of the medial epicondyle of the humerus and the styloid process of ulna, NP5 3.0 cun below Yanglingquan (GB34) between the gallbladder and bladder meridian and NP6: Middle of Qiuxu (GB40) and Jiexi (ST41) points. Treatments consist of twelves sessions that take 20 minutes over four weeks (three sessions per week).

Participants are followed up after 12 weeks to see if they have any improvements with their PDS symptoms.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Acupuncture needles

## Primary outcome(s)

Current primary outcome measure as of 11/01/2018:
The overall treatment evaluation (OTE) and elimination rate of three meal-related symptoms (postprandial fullness, upper abdominal bloating and early satiation) are combined primary outcomes measured at four weeks.

Previous primary outcome measure:
The Overall Treatment Evaluation (OTE) (severity ratings of individual symptoms) is evaluated using a seven-point Likert scale at four weeks.

### Key secondary outcome(s))
1. Symptoms and global assessment are measured using a four-rate scale questionnaire-asymptomatic (0 point), mild (1 point), moderate (2 points) or severe (3 points) that evaluated eight symptoms including postprandial distension, early satiety, epigastric pain, epigastric burning, upper abdominal bloating, belching, nausea and vomiting at baseline, once every week in treatment period and at 8, 12, 16 weeks
2. Quality of life is measured using the 25-item Nepean Dyspepsia Index (NDI) at baseline, 4, 8 and 16 weeks after the first treatment.
3. Severity of anxiety and depression is measured using the Hospital Anxiety Depression Scale (HADS) at baseline, 4, 8 and 16 weeks
4. Number of participants with adverse events related to acupuncture is measured by safety assessment during the treatment at baseline, 4, 8 and 16 weeks

### Completion date
20/09/2019

## Eligibility

### Key inclusion criteria
Current inclusion criteria as of 06/02/2018:
1. 18-65 years old
2. If they have epigastric pain syndrome symptoms (epigastric pain or epigastric burning), then the symptoms that are causing distress have to be one of the following meal-related symptoms: postprandial fullness, upper abdominal bloating or early satiation
3. Normal esophagogastroduodenoscopy results within a year
4. No acupuncture treatment in previous 1 month
5. Never joined any other study in process in previous 2 months

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2. If they have epigastric pain syndrome symptoms (epigastric pain or epigastric burning), then the symptoms that are causing distress have to be one of the following meal-related symptoms: postprandial fullness, upper abdominal bloating or early satiation
3. Normal esophagogastroduodenoscopy results within a year
4. No acupuncture treatment in previous 1 month
5. No use of medicine for PDS during two weeks before enrollment
6. Never joined any other study in process in previous 2 months

### Participant type(s)
Patient

### Healthy volunteers allowed

No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
65 years

### Sex
All

### Total final enrolment
278

### Key exclusion criteria
Current exclusion criteria as of 06/02/2018:
1. Functional dyspepsia (FD) symptoms caused by any serious or malignant disease
2. Surgery related with the gastrointestinal tract
3. Taking drugs which might affect dyspepsia, such as anti-secretary drugs, antacids, prokinetics, non-steroidal anti-inflammatory drugs and antidepressant drugs before 1 month participating in the trial
4. Drug or alcohol abuse
5. Pregnant women or women in lactation period

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### Date of first enrolment
10/04/2017

### Date of final enrolment
15/03/2019

## Locations

### Countries of recruitment

China

**Study participating centre**
**Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University**
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**Study participating centre**
**Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine**
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# Sponsor information

### Organisation
Beijing Municipal Science & Technology Commission

### ROR
https://ror.org/034k14f91

# Funder(s)

### Funder type
Government

### Funder Name
Beijing Municipal Science & Technology Commission

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to confidentiality reasons.

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 16/06/2020 | 19/05/2020 | Yes | No |
| Results article | Hormones assessment in plasma | 20/11/2024 | 02/12/2024 | Yes | No |
| Protocol article | protocol | 18/01/2019 | 21/01/2019 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |