

# Effects of acupuncture and qigong meditation on non-motor symptoms of Parkinson's Disease

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/08/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 22/08/2019	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Background and study aims

The aim of this study is to investigate the effects of acupuncture and qigong meditation on non-motor symptoms of Idiopathic Parkinson's Disease (PD).

Who can participate?

Patients with idiopathic PD taking anti-Parkinson medications which remained unchanged until the end of this study

What does the study involve?

Participants are randomly allocated to be treated with either qigong meditation with acupuncture, or qigong meditation alone. The participants' level of discomfort in their daily lives caused by non-motor symptoms from idiopathic PD are evaluated before treatment, after the final treatment, and one month after the final treatment as a follow-up.

What are the possible benefits and risks of participating?

Participants may not benefit directly, but the study will help to increase the knowledge on acupuncture, meditation, and Asian medicine. By participating in this research it is possible that participants will be at greater risk than they would otherwise be. There is, for example, a risk that their condition will not get better and that the new medicine or treatment doesn't work. If, however, the medicine or treatment is not working, the researchers will give the medication or treatment routinely offered to make them more comfortable. While the possibility of this happening is very low, participants should still be aware of the possibility. Acupuncture can also cause pain, bleeding, blue and some temporary swelling around the place where the needles are injected. It is possible that it may also cause some problems that the researchers are not aware of. However, they will follow participants closely and keep track of any unwanted effects or any problems.

Where is the study run from?

South Baylo University (USA)

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

January 2018 to March 2019

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Dr Young Lee  
hobslee2001@southbaylo.edu

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Young Lee

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
SBU-010418RC

## Study information

**Scientific Title**  
Effects of acupuncture and qigong meditation on non-motor symptoms of Parkinson's Disease

**Study objectives**  
Acupuncture and qigong meditation help to improve neuro-degeneration issue.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Approved 04/01/2018, South Baylo University Institutional Review Board (IRB) (2727 W. 6th Street, Los Angeles, CA 90057, USA; Tel: +1 (0)714 533 6077; Email: edfollick@southbaylo.edu), ref: 050219-1

**Study design**

Randomised controlled double-blind trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Parkinson's disease

**Interventions**

Participants are randomized according to the stratified randomization method of Vickers. Participants are stratified into two types, that is, E group and C group. For each type, the Random Number Generator from random.org and relevant concealed envelope method will be used to allocate participants into group 'E' (n=10) treated with Qigong meditation with acupuncture for 5 minutes, and group 'C' (n=11) treated with Qigong meditation for 50 minutes. All of the participants and practitioners are blinded.

Four acupuncture points were used: GB-20, LI-4, DU-14, and DU-16. The Qigong meditation procedure consisted of breathing techniques, healing meditation practice, and qigong for transferring energy to areas of the olfactory tract through the mesolimbic and mesocortical pathway, for up to 50 minutes.

Participants with PD are assessed with a series of specialized scales before treatment, including nonmotor symptoms and quality of life like olfactory disorder. Participants in all groups were assessed prior to the first treatment, after the 12th treatment, and one month after treatment as a follow-up.

Statistical analysis was performed using R version 3.5.1 (2018-07-02) – "Feather Spray"<sup>49</sup>. after applying Kolmogorov-Smirnov test and Shapiro-Wilk Test to check normality, Paired t-test and Independent t-test or Wilcoxon signed rank test and Mann-Whitney U test were performed to evaluate the statistical significance. Generalised linear repeated mixed model was employed to analyse the missing data caused mostly due to noncompliance. The level set for statistical significance was 0.05.

**Intervention Type**

Mixed

### **Primary outcome measure**

Measured prior to the first treatment, after twelfth treatment, and one month after treatment:

1. Nonmotor symptoms measured using Unified Parkinson's Disease Rating Scale (UPDRS)
2. Olfactory function measured using Test of Smell Identification (TSI)

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

04/01/2018

### **Completion date**

30/03/2019

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosed with idiopathic PD based on UK Parkinson's Disease Society Brain Bank criteria
2. Taking anti-Parkinson medications which remained unchanged until the end of this study

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

21

### **Key exclusion criteria**

Does not meet inclusion criteria

### **Date of first enrolment**

04/01/2018

### **Date of final enrolment**

10/10/2018

## **Locations**

### **Countries of recruitment**

United States of America

**Study participating centre**  
**South Baylo University**  
2727 W 6th Ave  
Los Angeles  
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## **Sponsor information**

**Organisation**  
South Baylo University

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**Sponsor type**  
University/education

**Website**  
[www.southbaylo.edu](http://www.southbaylo.edu)

**ROR**  
<https://ror.org/0197qh103>

## **Funder(s)**

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

## **Results and Publications**

**Publication and dissemination plan**  
Planned publication in an open-access journal

**Intention to publish date**

30/12/2019

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Young Lee ([hobslee2001@southbaylo.edu](mailto:hobslee2001@southbaylo.edu))

**IPD sharing plan summary**

Available on request