

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

Submission date 07/08/2019	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 28/08/2019	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 22/08/2019	Condition category Nervous System Diseases	☐ Individual participant data
		☐ 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
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design

Randomised controlled double-blind trial

Study type(s)

Treatment

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"⁴⁹. 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(s)

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)

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United States of America

90057

Sponsor information**Organisation**

South Baylo University

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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)

IPD sharing plan summary

Available on request