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

Submission date
07/08/2019

Recruitment status
No longer recruiting

Registration date
28/08/2019

Overall study status
Completed

Last Edited
22/08/2019

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Contact name
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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"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 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
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Sponsor information

Organisation
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Sponsor type
University/education

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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)

IPD sharing plan summary
Available on request