China Clinical Trial Registry Registration Data Set

Data category	Information
Primary registry and trial	ChiCTR2300071703
identifying number	
Date of registration in	June 4 th , 2023
primary registry	
Source(s) of monetary or	the Research Project of Traditional Chinese Medicine
material support	in Zhejiang Province [grant number: 2023ZL224]
Public title	Research of acupuncture on motor function in patients
	with PIGD Parkinson's disease based on functional
	magnetic resonance imaging
Countries of recruitment	China
Health condition(s) or	Parkinson's disease
problem(s) studied	
Intervention(s)	acupuncture
active comparator	sham acupuncture
Key inclusion and	1. A primary PD diagnosis must be confirmed by the
	Parkinson's Disease Society Brain Bank.
	2. The Hoehn–Yahr level must be between 1.5 and
	3.0, based on the PD grading scale.
	3. There is no sex restriction; however, participants
	must be right-handed and aged between 50 and 85
	years (inclusive).
	4. According to the Uniform Parkinson's Disease
	Rating Scale III (UPDRS III), the PIGD criteria are met
	if the ratio of the mean postural instability and gait
	disturbance score to the tremor score is 0.90 or less.
	5. Maintenance of the original Western medicine
	treatment plan for 3 months or more.

	6. The Mini-Mental State Examination (MMSE) must
	demonstrate that participants do not have any cognitive
	impairment. Scores are based on educational level: >17
	for illiteracy, >20 for primary school, >22 for middle
	school, and >23 for university (including junior
	college).
	7. Normal vision, hearing, and language abilities.
	8. Informed consent and willing participation from
	participants.
Exclusion criteria	Presence of neurological diseases that significantly
	impact gait.
	Diagnosis of secondary Parkinson's syndrome or
	presence of cognitive impairment.
	Severely affected by hypertension, vascular disease,
	cardiac insufficiency, and bone and joint systemic
	diseases that affect walking ability.
	Contraindications for undergoing functional magnetic
	resonance imaging (fMRI).
	Patients who have a history of alcohol or narcotic
	abuse or are pregnant or breastfeeding.
Study type	Interventional study
Target sample size	AC:32; CO:32
Recruitment status	Prospective registration
Primary outcome(s)	Parkinson's disease-related scales (UPDRSIII,
	Unified-Parkinson's Disease Rating Scale III)
Key secondary outcomes	Berg Balance Scale; Gait analysis;
	rs-fMRI(resting-state functional magnetic resonance
	imaging); intestinal flora analysis; non-targeted
	metabolomics analysis
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