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Mindfulness meditation on blood pressure and quality of life in patients with intradialytic hypertension

Submission date	**Recruitment status**	[_] Prospectively registered
23/10/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/10/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/10/2024	Circulatory System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to observe the effects of mindfulness meditation on blood pressure changes and quality of life in hypertensive patients suffering from intradialytic hypertension (IDH) during hemodialysis.

Who can participate?
Patients aged 18 years or older with maintenance hemodialysis and IDH

What does the study involve?
The control group received routine care (hemodialysis and health education), while the intervention group received mindfulness meditation in addition to routine care. Blood pressure and quality of life changes were evaluated at enrollment and three months post-intervention.

What are the possible benefits and risks of participating?
Mindfulness meditation may improve blood pressure during dialysis and enhance patients' quality of life.
The intervention group may experience inauthentic self-perceptions and increased sensory perceptual sensitivity.

Where is the study run from?
Blood Purification Center of Lihuili Hospital in Ningbo City

When is the study starting and how long is it expected to run for?
May 2023 to November 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Jiang Liu, liujiang_2024@126.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Mindfulness meditation on blood pressure and quality of life in patients with intradialytic hypertension during hemodialysis

Study objectives
Mindfulness meditation may improve blood pressure during dialysis and enhance patients' quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/08/2023, Ethics Review Committee of Lihuili Hospital in Ningbo City (No. 57, Xingning Road, Yinzhou District, Ningbo, 315040, China; +86 0574 87018834; lihuiliethics@163.com), ref: KY2023PJ204

Study design
Single-center interventional double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Blood pressure control and recovery in hemodialysis patients

Interventions
The patients are randomly assigned to an intervention group and a control group using a random number table. The control group received standard antihypertensive drug treatment and routine care (including hemodialysis and health education), while the intervention group additionally received mindfulness meditation intervention.

The intervention was 3 times a week, about 63 minutes each time, for a total of 12 weeks, including: 1.Observe the body (15 minutes); 2.Observe the breathing (5 minutes); 3.Dialysis visualization (5 minutes); 4.Sound wave therapy (30 minutes); 5.Stress release (8 minutes), a total of 5 parts (total 63 minutes).

After the intervention, the subjects' experiences and problems encountered during meditation are discussed in the group through the WeChat platform, and medical staff will provide relevant answers and guidance.

Intervention Type
Behavioural

Primary outcome measure
1. Blood pressure measured using the blood pressure monitoring module on the dialysis machine before dialysis, at 1, 2, and 3 hours during dialysis, and after dialysis
2. Quality of life measured using the Kidney Disease and Treatment-related Quality of Life (KDTA) and the general health-related quality of life (SF-36) scales before and 12 weeks after the intervention

Secondary outcome measures
Fasting venous blood was collected from the elbow to measure hemoglobin (Hb), inflammation markers (IL-6, CRP), nutritional indicators (ALB), homocysteine (Hcy), Parathyroid hormone (PTH) and dialysis adequacy (KT/V) before and 12 weeks after the intervention.
1. Hb measured using advanced photoelectric detector
2. CRP measured using chemiluminescence
3. IL-6 measured using enzyme-linked immunosorbent assay (ELISA).

4. ALB measured using ultraviolet spectrophotometer
5. HCY measured using radioenzyme assay
6. PTH measured using fluorescent immunochromatography

Overall study start date
25/05/2023

Completion date
16/11/2023

Eligibility

Key inclusion criteria
1. Meeting the diagnostic criteria for hypertension during dialysis, that is, the blood pressure increased by more than 15 mmHg during dialysis
2. Aged between 18 and 75 years old, with good overall health status
3. Demonstrating good treatment compliance and being able to actively cooperate with the doctor's treatment and guidance
4. The weekly dialysis time was 9 - 12 hours, the KT/V value was at least 1.2, and the hemoglobin (Hb) level was between 10 - 13 g/dL
5. Being able to accurately measure blood pressure in the upper limbs

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
69

Total final enrolment
69

Key exclusion criteria
1. Patients whose blood pressure could only be measured in the lower limbs
2. Patients with mental disorders or other diseases that affected their cooperation in the study
3. Patients with other serious diseases that might affect the study results

Date of first enrolment
02/07/2023

Date of final enrolment
14/08/2023

Locations

Countries of recruitment
China

Study participating centre
Ningbo Medical Center Li Huili Hospital
No. 1111, Jiangnan Road, Yinzhou District
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Sponsor information

Organisation
Ningbo Medical Center Lihuili Hospital

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Sponsor type
Hospital/treatment centre

Website
http://www.nblhlyy.com/

ROR
https://ror.org/030zcqn97

Funder(s)

Funder type
Other

Funder Name
Investigator funded and initiated

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
16/11/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the corresponding author, Jiang Liu, liujiang_2024@126.com.

IPD sharing plan summary
Available on request