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Effect of narrative nursing combined with cognitive behavioral rehabilitation on cognitive function and anxiety in patients with Alzheimer's disease

Submission date
21/03/2025

Recruitment status
No longer recruiting

Registration date
27/03/2025

Overall study status
Completed

Last Edited
26/03/2025

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Alzheimer's disease (AD) is a progressive neurodegenerative disorder that significantly impacts cognitive function and quality of life. AD patients experience anxiety, which can exacerbate cognitive decline through stress-related mechanisms. This study aims to investigate the effect of narrative nursing combined with cognitive behavioral rehabilitation on cognitive function and anxiety in patients with AD.

Who can participate?
Patients with AD who meet the diagnostic criteria of AD in the 2018 Chinese guidelines for the diagnosis and treatment of dementia and cognitive impairment (II) attending the participating centre.

What does the study involve?
Narrative nursing combined with cognitive behavioral rehabilitation on cognitive function and anxiety in patients with AD. Cognitive behavioral rehabilitation includes: memory training, language communication skills training, computing ability training, and daily life ability training. The implementation of cognitive training is generally recommended to be 5-6 times a week, each time for 1 hour, lasting for 6 months, emphasizing the patient as the main body, and the time and intensity follow the principle of individualization. Cognitive behavioral rehabilitation training is designed and implemented by occupational therapists in hospitals.

What are the possible benefits and risks of participating?
Narrative nursing combined with cognitive behavioral rehabilitation may effectively increase cognitive function, reduce anxiety, and improve the ADL and QOL of patients with AD.

There are no possible risks in this study.

Where is the study run from?
Tianjin Medical University General Hospital, China

When is the study starting and how long is it expected to run for?
January 2020 to December 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dai Li, lidai_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
Effect of narrative nursing combined with cognitive behavioral rehabilitation on cognitive function and anxiety in patients with Alzheimer's disease

Study objectives
Narrative nursing combined with cognitive behavioral rehabilitation may effectively increase cognitive function, reduce anxiety and improve the ADL and QoL of patients with Alzheimer’s disease

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/04/2024, Ethics Committee of Tianjin Medical University General Hospital (No. 154, Anshan Road, Heping District, Tianjin, 300052, China; +86 022-60361044; zyyjgb_ll3@163.com), ref: IRB2024-YX-150-01

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Nursing care for patients with Alzheimer's disease

Interventions
Patients with AD were selected using a random sampling method and divided equally into the observation group and the control group using a random number table. Patients in the control group received conventional nursing care. Patients in the observation group received narrative nursing combined with cognitive behavioral rehabilitation in addition to conventional nursing care.

Cognitive behavioral rehabilitation includes: memory training, language communication skills training, computing ability training, and daily life ability training. The implementation of cognitive training is generally recommended to be 5-6 times a week, each time for 1 hour, lasting for 6 months, emphasizing the patient as the main body, and the time and intensity follow the principle of individualization. Cognitive behavioral rehabilitation training is designed and implemented by occupational therapists in hospitals.

Intervention Type
Behavioural

Primary outcome measure
The following primary outcome measures are assessed at baseline and 6 months:
1. Cognitive functions measured using Chinese versions of the MMSE and Montreal Cognitive Assessment (MoCA)
2. Anxiety measured using the Generalised Anxiety Disorder-7 (GAD-7) scale
3. Activities of Daily Living (ADLs) and quality of life (QoL) measured using the Alzheimer's Disease Cooperative Study (ADCS)-ADL and Quality of Life in Alzheimer's Disease (QoL-AD) scales

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
06/01/2020

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Meets the diagnostic criteria of AD in the 2018 Chinese guidelines for the diagnosis and treatment of dementia and cognitive impairment (II): Guidelines for the diagnosis and treatment of Alzheimer's disease
2. Basic language ability for simple communication
3. Meets the requirements of medical ethics in our hospital, and their family members signed the informed consent form

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
172

Total final enrolment
172

Key exclusion criteria
1. Severe psychiatric disorders that would prevent participation in cognitive behavioral therapy
2. Acute or unstable cardiovascular conditions requiring intensive medical management
3. Severe cognitive impairment (Mini-Mental State Examination [MMSE] score ≤10) that would preclude meaningful participation in the intervention

Date of first enrolment

10/01/2020

Date of final enrolment
08/11/2020

Locations

Countries of recruitment
China

Study participating centre
Tianjin Medical University General Hospital
Tianjin
China
300052

Sponsor information

Organisation
Tianjin Medical University General Hospital

Sponsor details
No. 154, Anshan Road, Heping District
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Sponsor type
Hospital/treatment centre

Website
https://www.tjmugh.com.cn/

ROR
https://ror.org/003sav965

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dai Li, lidai_2024@126.com.

IPD sharing plan summary
Available on request