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Continuous nursing at home for well-being after stomach cancer surgery

Submission date
31/10/2025

Recruitment status
No longer recruiting

Registration date
25/11/2025

Overall study status
Completed

Last Edited
05/11/2025

Condition category
Cancer

[_] 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
Gastric cancer (GC) is the fifth most common malignant tumor in the world in terms of incidence rate and the second most common malignant tumor in terms of mortality. The postoperative condition of patients with GC metastasis is still poor. How to effectively improve the quality of life (QoL) of postoperative patients has gradually become the key target of current treatment. This study aimed to explore the impact of continuous nursing care on the QoL of GC lung metastasis patients, to better implement treatment for GC patients and improve their QoL.

Who can participate?
Patients who have a confirmed diagnosis of stomach cancer that has spread to the lungs.

What does the study involve?
This study will compare two interventions: routine nursing care, which involves regular telephone follow-ups and continuous nursing care, which involves a structured program of telephone follow-ups, scheduled home visits, priority appointments at a specialist clinic, and support through an online health platform.

These measurements will be taken at the time of hospital discharge, and again at 3 months, 6 months, and 1 year after discharge using a questionnaire.

What are the possible benefits and risks of participating?
By enrolling, participants might gain access to a new and potentially better treatment that isn't available to everyone, all while receiving very close medical care from a team of experts. The research team will explain all the known risks, like tiredness or disturbance, in detail.

Where is the study run from?
The First Hospital of China Medical University, Shenyang, China.

When is the study starting and how long is it expected to run for?
June 2022 to October 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Yueyang Jiang, yueyang_jiang@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effect of continuous nursing care on postoperative quality of life in patients with gastric cancer lung metastasis

Study objectives
This study aimed to explore the impact of continuous nursing care on the quality of life (QoL) of gastric cancer (GC) lung metastasis patients, to better implement treatment for GC patients and improve their QoL.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/07/2025, Ethics Committee of the First Hospital of China Medical University (No. 155 Nanjing North Street, Heping District, Shenyang City, 110001, China; -; ethics@cmu1h.com), ref: 101022119

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Gastric cancer

Interventions
This was a 1-year follow-up study where 102 patients with GC lung metastasis in the First Hospital of China Medical University were randomized to routine telephone follow-ups (Control) or a comprehensive continuous nursing program involving phone calls, home visits, clinic services, and online support (Observation).The anxiety, depression and QoL scores of patients: physical function, role function, emotional function, cognitive function, and social function, were observed at the time of discharge, 3 months, 6 months and 1 year after discharge.

Control Group Protocol: the patents received regular telephone follow-ups conducted by a nurse specialist, which included: medication guidance, dietary counseling and mental health monitoring. All follow-up records were documented in a discharge follow-up logbook.

The randomization process was designed to ensure robustness and minimize bias, beginning with a computer-generated random number sequence created by an independent statistician uninvolved in patient care. Assignment occurred only after patients had provided informed consent and their eligibility was definitively confirmed. To enforce allocation concealment, sequentially numbered, opaque, sealed envelopes were used, and a research nurse opened each envelope solely after a participant’s baseline assessment was complete, thereby ensuring the enrolling team remained blinded to the upcoming group assignment throughout implementation.

Intervention Type
Behavioural

Primary outcome(s)
The following primary outcome measures were assessed at discharge, 3 and 6 months, and 1 year after discharge:
1. Anxiety measured using a simplified version of the General Anxiety Disorder-7 (GAD-7) questionnaire
2. Depression measured using a simplified version of the Patient Health Questionnaire-9 (PHQ-9)

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Pathologically confirmed diagnosis of gastric cancer with lung metastasis
2. Possessing self-awareness and ability to cooperate in answering questions
3. Patients who showed clinical improvement after surgical treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
80 years

Sex
All

Total final enrolment
102

Key exclusion criteria
1. Comorbidities with other severe systemic diseases
2. Patients with cognitive dysfunction
3. Patients unwilling to cooperate with home visits
4. Other reasons preventing participation

Date of first enrolment
01/06/2022

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
China

Study participating centre
First Hospital of China Medical University
No. 155 Nanjing North Street
Heping District
Shenyang

China
110001

Sponsor information

Organisation
First Hospital of China Medical University

ROR
https://ror.org/04wjghj95

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 will be available upon request from Mrs Yueyang Jiang (Yueyang_jiang@hotmail.com)

IPD sharing plan summary
Available on request