ISRCTN33428260 https://doi.org/10.1186/ISRCTN33428260

Helping patients recovering from surgery for advanced gastric cancer to improve their self-management and quality of life through an expert patient support programme

Submission date
21/11/2025

Recruitment status
No longer recruiting

Registration date
24/11/2025

Overall study status
Completed

Last Edited
25/11/2026

Condition category
Cancer

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

Plain English summary of protocol
Background and study aims
People recovering from surgery for advanced stomach cancer often struggle with eating, managing symptoms, staying active, and coping emotionally. Many also feel unsure about how to look after themselves. This study looked at whether a programme called the Expert Patients Programme (EPP) – where trained former patients support new patients – could help improve self-care skills, confidence, and overall quality of life after surgery.

Who can participate?
Adults aged 18 to 80 years who have advanced stomach cancer and are having or have recently had surgery to remove part or all of the stomach, followed by chemotherapy. Participants needed to be able to give informed consent.

What does the study involve?
Participants were randomly placed into one of two groups:
Intervention group: Took part in a 3-month Expert Patients Programme. This included four weekly online sessions led by nurses and trained former patients, plus monthly follow-up support to help with recovery, nutrition, physical activity, and emotional wellbeing.
Control group: Received standard hospital care, including routine nursing, discharge advice, and monthly follow-up calls.
Everyone completed questionnaires at the start, one week after surgery, and three months after surgery.

What are the possible benefits and risks of participating?
Benefits could include practical recovery tips, emotional support, improved confidence in managing health, and possibly faster recovery.
There were no known medical risks. The main inconvenience was the extra time needed for online sessions and questionnaires, which some people might find tiring.

Where is the study run from?
The study was carried out at the Gastric and Intestinal Surgery Department of a large hospital in Guangzhou, China.

When is the study starting and how long is it expected to run for?
The study started in February 2024 and finished in May 2025, including recruitment and follow-up.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Xiaolu Yang, yangxiaolu@gdph.org.cn

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Ms Xiaolu Yang

ORCID ID
https://orcid.org/0009-0001-3464-4838

Contact details
Department of Gastrointestinal Surgery, Department of General Surgery, Guangdong Provincial People's Hospital (Guangdong Academy of Medical Sciences), Southern Medical University
Guangzhou
China
510080
+86 2083827812
yangxiaolu@gdph.org.cn

Additional identifiers

Study information

Scientific Title
A randomized controlled trial evaluating the effects of an Expert Patients Programme (EPP) on self-management behaviours, self-efficacy, and quality of life among adults undergoing surgery for advanced gastric cancer

Acronym
GAIN-EPP

Study objectives
Current study objectives 17/11/2026:
Primary objective:
To evaluate whether an Expert Patients Programme (EPP) improves self-management

behaviours, including: physical activity, cognitive symptom management, and communication with healthcare providers

Secondary objectives:
1. To determine whether the EPP improves self-efficacy in adults undergoing surgery for advanced gastric cancer
2. To assess the effect of the EPP on health-related quality of life (QoL) using the EORTC QLQ-C30 and QLQ-STO22

Previous study objectives:
Primary objective:
To evaluate whether an Expert Patients Programme (EPP) improves self-efficacy in adults undergoing surgery for advanced gastric cancer.
Secondary objectives
1. To determine whether the EPP improves self-management behaviours, including: physical activity, cognitive symptom management, and communication with healthcare providers.
2. To assess the effect of the EPP on health-related quality of life (QoL) using the EORTC QLQ-C30 and QLQ-STO22.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/01/2024, Ethics Committee of Guangdong Provincial People's Hospital (No.106, Zhongshan Second Road, Guangzhou, 510080, China; +86 2083827812; gdphgcp@gdph.org.cn), ref: KY2024-076-02

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Self-management and postoperative recovery in adults undergoing surgery for advanced gastric cancer

Interventions

Current interventions as of 25/11/2026:
1. Intervention arm: Expert Patients Programme (EPP)
Participants allocated to the intervention arm will receive a 3-month Expert Patients Programme (EPP) designed for adults undergoing surgery for advanced gastric cancer. The intervention is delivered jointly by trained expert patients (former gastric cancer patients who have undergone standardized training) and clinical nursing staff.

The programme consists of:
(1) Health education phase (Weeks 1–4):
Participants will attend weekly 60-90 minutes online sessions (via Tencent Meeting) covering: medical management (disease knowledge, treatment process, symptom monitoring), postoperative gastrointestinal symptom management, nutritional guidance and staged diet progression, physical activity and fatigue management, accessing and using health information resources, and psychological and emotional regulation.
Expert patients will provide personal experience sharing and peer support in each session.
(2) Follow-up and individualized guidance phase (Months 2–3):
Participants will receive monthly follow-up (via WeChat, phone, or in-person depending on patient preference). Each follow-up lasts approximately 10 minutes and will include:
assessment of recovery, symptoms, nutrition, physical activity, and self-management behaviours;
tailored guidance from nurses and expert patients;
and ongoing peer support and motivational encouragement.
Educational materials used in the intervention include the Gastric Disease Patient Self-Management Handbook and standardized EPP teaching slides.

2. Control arm: Routine perioperative and post-discharge care
Participants allocated to the control arm will receive standard clinical care, including:
routine perioperative nursing;
enhanced recovery after surgery (ERAS) measures;
standard discharge education (diet progression, wound care, activity guidance);
paper-based education materials;
and monthly telephone follow-up assessing wound status, diet, activity tolerance, and basic psychological wellbeing.

They will not receive any EPP peer-support sessions, expert patient involvement, or structured self-management training.

Randomisation / allocation
Participants will be assigned to either the intervention arm or the control arm in a 1:1 ratio using a randomized allocation sequence generated in SPSS. Allocation will follow the order of patient enrollment, with assignments stored in sequentially numbered, sealed, opaque envelopes opened at the time of group allocation.

Previous interventions:
1. Intervention arm: Expert Patients Programme (EPP)
Participants allocated to the intervention arm will receive a 3-month Expert Patients Programme (EPP) designed for adults undergoing surgery for advanced gastric cancer. The intervention is delivered jointly by trained expert patients (former gastric cancer patients who have undergone standardized training) and clinical nursing staff.

The programme consists of:
(1) Health education phase (Weeks 1–4):

Participants will attend weekly 40-minute online sessions (via Tencent Meeting) covering: medical management (disease knowledge, treatment process, symptom monitoring), postoperative gastrointestinal symptom management, nutritional guidance and staged diet progression, physical activity and fatigue management, accessing and using health information resources, and psychological and emotional regulation.
Expert patients will provide personal experience sharing and peer support in each session.
(2) Follow-up and individualized guidance phase (Months 2–3):
Participants will receive monthly follow-up (via WeChat, phone, or in-person depending on patient preference). Each follow-up lasts approximately 10 minutes and will include:
assessment of recovery, symptoms, nutrition, physical activity, and self-management behaviours;
tailored guidance from nurses and expert patients;
and ongoing peer support and motivational encouragement.
Educational materials used in the intervention include the Gastric Disease Patient Self-Management Handbook and standardized EPP teaching slides.

2. Control arm: Routine perioperative and post-discharge care
Participants allocated to the control arm will receive standard clinical care, including:
routine perioperative nursing;
enhanced recovery after surgery (ERAS) measures;
standard discharge education (diet progression, wound care, activity guidance);
paper-based education materials;
and monthly telephone follow-up assessing wound status, diet, activity tolerance, and basic psychological wellbeing.

They will not receive any EPP peer-support sessions, expert patient involvement, or structured self-management training.

Randomisation / allocation
Participants will be assigned to either the intervention arm or the control arm in a 1:1 ratio using a randomized allocation sequence generated in SPSS. Allocation will follow the order of patient enrollment, with assignments stored in sequentially numbered, sealed, opaque envelopes opened at the time of group allocation.

Intervention Type
Behavioural

Primary outcome(s)
1. Self-management behaviours measured using the Chinese Chronic Disease Self-Management Questionnaire (C-CDSMQ) at baseline (preoperative), 1 week after surgery, 3 months after surgery

Previous primary outcome as of 17/11/2026:
General self-efficacy measured using General Self-Efficacy Scale (GSES) at Baseline (preoperative), 1 week after surgery, 3 months after surgery

Key secondary outcome(s)
1. General self-efficacy measured using the General Self-Efficacy Scale (GSES) at baseline (preoperative), 1 week after surgery, 3 months after surgery

2. Health-related quality of life (global health status and functional domains) measured using EORTC QLQ-C30 at baseline, 1 week after surgery, and 3 months after surgery

3. Gastric cancer–specific symptoms measured using EORTC QLQ-STO22 at baseline, 1 week after surgery, and 3 months after surgery

Previous key secondary outcomes as of 17/11/2026:
1. Self-management behaviours measured using Chinese Chronic Disease Self-Management Questionnaire (C-CDSMQ) at baseline (preoperative), 1 week after surgery, 3 months after surgery
2. Health-related quality of life (global health status and functional domains) measured using EORTC QLQ-C30 at baseline, 1 week after surgery, and 3 months after surgery
3. Gastric cancer–specific symptoms measured using EORTC QLQ-STO22 at baseline, 1 week after surgery, and 3 months after surgery

Completion date
30/05/2025

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Diagnosed with advanced gastric cancer, meeting at least one of the following staging criteria:
cT1–2N1–3M0
cT3–4N0M0
cT3–4aN1–3M0
cT3–4bN0–3M0
3. Scheduled for or recovering from gastrectomy (partial or total) followed by adjuvant chemotherapy
4. Able to provide informed consent and voluntarily agree to participate
5. Adequate communication ability to complete questionnaires and participate in the interventio

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
70

Key exclusion criteria
1. Patients with another primary malignant tumour (non-gastric cancer)
2. Patients with severe cancer cachexia (late-stage wasting syndrome)

3. Pregnant or breastfeeding women
4. Patients unable to participate due to serious medical, cognitive, or psychological conditions preventing completion of the intervention or questionnaires
5. Patients who decline to participate or withdraw consent

Date of first enrolment
01/04/2024

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
China

Sponsor information

Organisation
Guangdong Provincial People's Hospital

ROR
https://ror.org/045kpgw45

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			21/11/2025	No	Yes
Protocol file			24/11/2025	No	No

Protocol file	17/11/2026	No	No
Protocol file	25/11/2026	No	No