

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	☐ Prospectively registered ☒ Protocol
Registration date 24/11/2025	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/11/2025	Condition category Cancer	☐ Individual participant data ☒ 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 confidence, self-care skills, 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-efficacy, self-management behaviours and quality of life among adults undergoing surgery for advanced gastric cancer

Acronym

GAIN-EPP

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

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. 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. 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 $\geq$ 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 intervention

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