病人专家项目（EPP）对中晚期胃癌患者自我管理的影响研究

一、研究背景

中晚期胃癌是我国常见且致死率高的消化系统恶性肿瘤。患者在术后面临长期康复、营养管理、症状管理、情绪调适等多重挑战。

传统护理模式以医护主导为主，患者在出院后缺乏持续的专业指导，难以有效开展自我管理。病人专家项目（Expert Patients Programme，EPP）是一种基于自我效能理论的自我管理干预模式，患者通过向康复经验丰富的“病人专家”学习，可显著提升自我管理能力、自我效能感与生活质量。本研究旨在构建并验证一套适用于中晚期胃癌术后患者的 EPP 干预方案。

二、研究目的

1. 构建基于自我效能理论的中晚期胃癌手术患者病人专家项目（EPP）干预方案；

2. 评价 EPP 对患者自我管理行为、自我效能与生活质量的干预效果；

3. 探索患者术后康复中的关键自我管理问题，为胃癌患者延续护理模式提供依据。

三、理论依据

本研究以班杜拉自我效能理论（Bandura Self-efficacy Theory）为核心理论框架。自我效能通过四种机制生成：掌握经验、替代经验、言语劝导、生理与情绪状态。EPP 通过病人专家经验分享与指导强化上述机制，从而提升患者的自我效能水平。

四、研究设计

1. 研究类型：混合方法研究（质性研究 + 随机对照试验 RCT）。

2. 研究流程包括：质性访谈 → 文献回顾 → 初稿构建 → 专家论证 → 预试验 → RCT 应用。

3. RCT 设计：平行分组、1:1 分配，共招募 70 例患者。

五、研究对象

1. 纳入标准：

- 年龄≥18 岁；

- 胃癌 TNM 分期满足：cT1-2N1-3M0，cT3-4N0M0，cT3-4aN1-3M0，cT3-4bN0-3M0；

- 接受胃部分或全胃切除术及辅助化疗；

- 知情同意，自愿参与。

2. 排除标准：

- 合并其他原发恶性肿瘤；

- 严重恶病质；

- 妊娠期及哺乳期；

- 无法执行随访者。

六、样本量与招募

按入院顺序和自愿原则，招募 2024 年 4 月至 10 月入住某三甲医院胃肠外科的患者，直到获得 70 例符合条件的病人。

按 SPSS 生成的随机序列采用密封信封法进行分配。

七、随机方法与盲法

采用随机分配方式，按照患者入组顺序打开密封信封确定组别。由于干预性质限制，本研究不进行盲法。

八、干预方案（EPP）

（一）总体结构

EPP 干预持续 3 个月，由护士+病人专家共同实施，分为健康教育阶段（4 周）和随访阶段（8 周）。

（二）第 1 个月：线上健康教育（每周 1 次，每次 60-90 分钟）

1. 课程主题：

- 胃癌基础知识

- 术后症状、营养与角色适应

- 伤口护理

- 康复锻炼

- 获取健康信息

- 心理调适

2. 授课团队：2 名护士 + 7 名病人专家

3. 支持材料：《胃疾病患者自我管理手册》及教学 PPT。

（三）第 2－3 个月：随访阶段（每月 1 次）

- 康复评估（症状、营养、活动、心理状态）

- 个性化指导

- 同伴支持

- 医院访视或微信、电话等远程方式进行。

九、对照组

接受常规护理，包括围手术期护理、ERAS 措施、出院健康教育以及每月电话随访，不包含 EPP 内容。

十、研究流程

1. 患者筛选与招募；

2. 签署知情同意；

3. 收集基线数据；

4. 按密封信封法随机分组；

5. 干预组实施 3 个月 EPP，对照组接受常规护理；

6. 于术前、术后 1 周、术后 3 个月进行随访测量；

7. 数据分析。

十一、结局指标

（一）主要结局：

自我管理行为（C-CDSMQ），时间点：术前、术后 1 周、术后 3 个月。

（二）次要结局：

1. 自我效能（GSES）

2. 生活质量（EORTC QLQ-C30）

3. 胃癌特异症状（QLQ-STO22）

时间点同上。

十二、数据管理

采用双人数据录入、核对方式。所有数据匿名化处理，电子数据存储于加密设备上。

十三、统计分析方法

1. 软件：SPSS 25.0， Stata 18.0，R 4.6.0
2. 基线组间比较：t 检验或 Mann－Whitney U 检验， χ^2检验
3. 组内比较：配对 t 检验或 Wilcoxon 符号秩检验
4. 随访期组间比较：重复测量资料的方差分析(Repeated-measures analysis of ANOVA)
5. 缺失值：采用 LOCF 法
6. 敏感性分析：协方差分析（ANCOVA）调整基线协变量
7. 显著性水平：双侧 $P<0.05$
8. 中期分析：无

十四、质量控制

1. 病人专家与护士均需接受统一培训；
2. 健康教育课程内容标准化；
3. 干预过程独立实施，避免干扰；
4. 数据收集者接受统一培训。

十五、伦理

本研究遵循相关伦理原则。所有参与者均须签署知情同意书。研究的所有程序均符合所在机构的伦理规范。

十六、时间计划

2024 年 2 月：质性研究

2024 年 3 月：EPP 方案构建与预试验

2024 年 4－10 月：招募与干预

2025 年 1 月：随访完成

2025 年 2－3 月：数据分析与报告撰写

Effects of an Expert Patients Programme (EPP) on self-management behaviours among adults undergoing surgery for advanced gastric cancer

(English Translation)

1. Background

Advanced gastric cancer is a common and highly lethal gastrointestinal malignancy in China. After surgery, patients face multiple long-term challenges, including rehabilitation, nutritional management, symptom management, and emotional adjustment.

Traditional care models are mainly led by healthcare professionals. After discharge, patients often lack sustained professional guidance, making it difficult to effectively engage in self-management.

The Expert Patients Programme (EPP) is a self-management intervention model based on self-efficacy theory. Through learning from "expert patients" with rich recovery experience, participants can significantly improve their self-management abilities, self-efficacy, and quality of life.

This study aims to develop and evaluate an EPP intervention tailored to patients undergoing surgery for advanced gastric cancer.

2. Study Objectives

1. To develop an EPP intervention programme based on self-efficacy theory for patients undergoing surgery for advanced gastric cancer.
2. To evaluate the effects of the EPP on patients' self-management behaviours, self-efficacy, and quality of life.
3. To explore key self-management challenges during postoperative recovery and provide evidence for improving continuity-of-care models for gastric cancer patients.

3. Theoretical Framework

This study adopts Bandura's Self-Efficacy Theory as the core framework. Self-efficacy is strengthened through four mechanisms: mastery experience, vicarious experience, verbal persuasion, and physiological/emotional states.

The EPP enhances these mechanisms through expert patient experience-sharing and guidance, thereby improving participants' self-efficacy.

4. Study Design

1. **Design:** Mixed-methods research, including qualitative research and a randomized controlled trial (RCT).

2. **Research process:** Qualitative interviews → literature review → preliminary framework development → expert consultation → pilot testing → RCT implementation.
3. **RCT characteristics:** Parallel-group design; 1:1 allocation; 70 participants enrolled.

5. Participants

Inclusion Criteria：

- Age ≥ 18 years.
- TNM staging consistent with any of the following: cT1-2N1-3M0, cT3-4N0M0, cT3-4aN1-3M0, or cT3-4bN0-3M0.
- Undergoing partial or total gastrectomy plus adjuvant chemotherapy.
- Provide informed consent and voluntarily participate.

Exclusion Criteria:

- Concurrent primary malignant tumours.
- Severe cancer cachexia.
- Pregnancy or breastfeeding.
- Unable to complete follow-up measurements.

6. Sample Size and Recruitment

Patients will be consecutively recruited from the gastrointestinal surgery department of a tertiary hospital between April and October 2024 until the target sample size of 70 eligible participants is reached.

Participants will be assigned using sealed, opaque envelopes based on a random sequence generated in SPSS.

7. Randomisation and Blinding

A randomised assignment method will be used. Participants will be assigned according to the order in which sealed envelopes are opened.

Due to the nature of the intervention, blinding is not feasible.

8. Intervention: Expert Patients Programme (EPP)

(1) Overall Structure

The EPP intervention lasts for **3 months** and is jointly delivered by nurses and expert patients.
It consists of:

- **4-week health education phase**, and
- **8-week follow-up phase**.

(2) Month 1 – Online Health Education (once weekly, 60-90 minutes each)

Course topics:

- Basic Knowledge of Gastric Cancer
- Postoperative Symptoms, Nutrition, and Role Adaptation
- Wound Care
- Rehabilitation Exercises
- Accessing Health Information
- Psychological Adjustment

Teaching team: 2 nurses + 7 expert patients
Materials: *Gastric Disease Patient Self-Management Handbook* and standardised teaching slides.

(3) Months 2–3 – Follow-Up (once monthly)

- Assessment of recovery (symptoms, nutrition, activity, psychological status)
- Individualised guidance
- Peer support
- Conducted via hospital visit, telephone, WeChat or other remote platforms

9. Control Group

Participants receive routine care, including perioperative nursing, ERAS measures, discharge education, and monthly follow-up calls.
No EPP content is provided.

10. Study Procedures

1. Screening and recruitment
2. Informed consent
3. Baseline data collection
4. Group allocation via sealed envelopes
5. 3-month EPP intervention for the intervention group
6. Routine care for the control group
7. Outcome assessments at:
    - Pre-surgery
    - 1 week post-surgery
    - 3 months post-surgery
8. Data analysis

11. Outcome Measures

Primary Outcome:

- **Self-management behaviours**, measured by the *Chinese Chronic Disease Self-Management Questionnaire (C-CDSMQ)*
    - Timepoints: baseline, 1 week postoperative, 3 months postoperative.

Secondary Outcomes:

1. **Self-efficacy**, measured by the *General Self-Efficacy Scale (GSES)*
2. **Quality of life**, measured by the *EORTC QLQ-C30*
3. **Gastric cancer-specific symptoms**, measured by *QLQ-STO22*
    - Timepoints same as above.

12. Data Management

Data are double-entered and cross-checked by two researchers. All data are anonymised and stored on encrypted devices.

13. Statistical Analysis

Statistical analyses will be performed using IBM SPSS 25.0, Stata 18.0, and R 4.6.0. Continuous variables will be summarized as means and standard deviations (SD) or medians and interquartile ranges (IQR), as appropriate. Categorical variables will be presented as frequencies and percentages. Baseline characteristics will be compared using independent-samples t-tests, chi-square tests, or Fisher's exact tests, as appropriate.
All randomized participants will be analysed according to their assigned groups, following the intention-to-treat principle. Repeated-measures analysis of variance (ANOVA) will be used to evaluate differences between the intervention and control groups over time. Missing values will be handled using last observation carried forward (LOCF) method. Additionally, analysis of covariance (ANCOVA) will be performed as a sensitivity analysis, adjusting for baseline covariates to assess the robustness of the intervention effects.
All tests will be two-sided, with a p-value < 0.05 considered statistically significant. No interim analyses are planned.

14. Quality Control

To ensure consistency and reliability, both expert patients and nurses will receive standardized training prior to intervention delivery. All health education content will be strictly standardized, and intervention procedures will be implemented independently to prevent cross-group contamination. In addition, data collectors will undergo uniform training to ensure accuracy and consistency in data collection.

15. Ethics

The study complies with ethical principles. Participants must sign informed consent forms. All procedures follow institutional ethical guidelines.

16. Study Timeline

- February 2024: Qualitative research
- March 2024: EPP development & pilot testing
- April–October 2024: Recruitment & intervention
- January 2025: Follow-up completion
- February–March 2025: Data analysis & report writing