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Effectiveness of mHealth-based survivorship programme on health-related quality of life among Vietnamese colorectal cancer survivors: A randomised controlled trial

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Introduction

The burden of colorectal cancer

Cancer is the second-leading cause of worldwide mortality (Siegel et al., 2024). Colorectal cancer (CRC) ranks third among common causes of cancer-related deaths and diagnoses in both sexes. About 153,020 CRC diagnoses and 52,550 deaths occurred in 2023 (Siegel et al., 2023). By 2030, the global burden of colorectal cancer is projected to increase by 60%, adding 2.2 million cases and 1.1 million deaths (Arnold et al., 2017). Despite these alarming statistics, advancements in CRC treatments, including surgery, chemotherapy, and radiation therapy, have significantly improved long-term survival rates (Kuipers et al., 2015). The overall 5-year survival rate for CRC ranges from 40% to 70% globally (Aguiar Junior et al., 2020; Onyoh et al., 2019). Vietnam had an average survival of 48.59 months, with a 3-year survival rate of 54.5% (Le et al., 2021). As survival rates continue to rise, this indicates an increasing number of individuals living in survivorship, highlighting the importance of providing ongoing support to these cancer survivors.

CRC survivorship

Mullan (1985) provided the first definition of cancer survivorship, identifying three distinct phases: acute (diagnosis to primary treatment), extended (watchful waiting with side effects), and permanent survival (long-term remission). Subsequently, the U.S. Institute of Medicine (IOM) (2006) expanded this concept to include the journey from diagnosis to end-of-life (Stovall et al., 2005). In contrast, most studies define survivorship as the period following the completion of active treatment (Dirven et al., 2015; Duijts & Spelten, 2021; El-Shami et al., 2015). This study adopts the widely accepted survivorship definition, focusing on individuals who have completed active treatment and are in the extended and permanent phases. This period emphasises the challenges CRC survivors face due to inadequate healthcare support, often leading to decreased quality of life (QoL) (Andreu et al., 2022).

QoL encompasses an individual's perception of their life across physical, mental, social and spiritual dimensions, aligning with the criteria outlined in WHO's health definition (Gurková, 2011; Schramme, 2023). This concept has become increasingly important due to the increasing number of CRC survivors. However, a systematic review found that long-term CRC survivors typically reported a lower overall QoL than the general population (Jansen et al., 2010). Several factors contribute to this lower QoL, including lower satisfaction with continuity of care, unmet

information needs and limited access to support from healthcare providers after treatment, particularly in distant areas (Drury et al., 2020). Moreover, CRC survivors often experience various psychological and physical symptoms such as depression (11.6%), anxiety (17.9%), distress (78.5%), fatigue (67%) and bowel dysfunction (49%) (Denlinger et al., 2009; El-Shami et al., 2015; Han et al., 2020; Mitchell et al., 2013; Simard et al., 2019), leading to a reduction of QoL. Therefore, implementing effective programmes that address these needs and improve QoL is essential.

Survivorship guidelines and programme for CRC

The IOM recommends developing survivorship programmes specifically for CRC survivors (IOM, 2006). Since then, various organisations, including the National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO), have issued guidelines focused on the prevention, addressing long-term/late effects on physical and psychological and management of symptoms, such as fatigue, anxiety, depression, and neuropathy, which adult cancer survivors commonly experience (Bower et al., 2014; Hershman et al., 2014; NCCN, 2013). Recognising the gaps in survivorship resources and clinical follow-up in posttreatment, the American Cancer Society (ACS) released its CRC Survivorship Care Guidelines, which emphasise surveillance for recurrence (1), managing long-term effects (2), promoting healthy behaviours (3), and coordinating care (4) (Shulman et al., 2015). A literature review identified survivorship programmes for CRC survivors in the post-treatment phase based on the ACS's guidelines. The results indicated an increasing focus on addressing ostomy issues and reducing distress, depression, and anxiety among survivors. Furthermore, evidence supports that exercise can reduce fatigue and enhance QoL. However, the review had several limitations, such as including various study designs, which made it difficult to evaluate the efficacy of the programme. Additionally, there was a lack of detailed information on specific programme components and their delivery (Luo et al., 2021).

mHealth-based programme for CRC survivors

Lack of resources and care coordination, particularly in distant areas, is the main cause of deficiencies in post-treatment follow-up care for cancer survivors (Lim et al., 2023). Since the COVID-19 pandemic, it has underscored the importance of technology for cancer survivors by promoting physical activity, meeting supportive care needs, and improving survival rates

(Koczwara, 2020). Technology-based interventions, including mobile apps, web platforms, video conferencing, and social media, have proven effective in supporting cancer survivors (Aapro et al., 2020; Marthick et al., 2021). Recent studies highlight the value of these tech-driven solutions in addressing multi-domains of survivorship care simultaneously (Lim et al., 2023; Wang et al., 2020). In Vietnam, a growing number of patients express willingness to use mobile apps for support (Dao et al., 2023), particularly given that 70% of the population uses Android smartphones (Nguyen, 2023) and internet access has risen from 72% in January 2021 to 79.1% in January 2024 (Kemp, 2024; Nguyen, 2021).

Ayyoubzadeh et al. (2020) found that mobile apps could enhance the health-related QoL for CRC survivors, recommending a framework to develop the app's layout. However, many studies address a wider range of cancer survivors, including those with CRC, which may be influenced when focusing solely on CRC survivors. Besides, the broad definition of "survivor" also encompassed individuals undergoing treatment, whose needs differ from those who have completed active treatments (Marthick et al., 2021). Given these gaps, it is essential to develop mHealth-based survivorship programmes aligned with ACS guidelines to enhance health-related QoL in this population.

Literature Review

The systematic review and meta-analysis were conducted to identify, analyse, and synthesise the available evidence on survivorship programmes that address health-related QoL among CRC survivors. This review followed the guidelines for reporting parallel group randomised trials based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Page et al., 2021). PROSPERO registration number: CRD42024580272.

A systematic search was performed across nine databases (PubMed, Cochrane Library, Scopus, CINALH Ultimate, Embase, OVID EMCARE, OVID Nursing, OVID Medline, and Web of Science) using specific search strategies to identify relevant articles from the databases' inception to June 2024, and manual searching by citation was included. The search utilised titles, abstracts, keywords, MeSH terms, and no date restrictions. The search keywords for the databases included the following: Colorectal cancer survivor, survivorship, post-treatment, follow-up, intervention, programme, Randomized Controlled Trial, and health-related quality of life. Further

details about the search strategy are presented in Appendix 1. The details of the inclusion and exclusion criteria followed by the PICO framework are shown in Supplement A.

Twenty studies were included in the review, and thirteen in the meta-analysis RevMan (version 5.4), and the study retrieval and selection process are provided in Figure 1. Data extraction encompassed the study population, participant demographics, settings, and intervention characteristics, including the theoretical basis, content, duration, frequency, format, deliverers, outcome measures, and results (Appendix 2). The Risk of Bias 2.0 tool was used to assess methodological quality. Overall, the studies ranged from having some concerns to having a high risk of bias (Figure 2). No trials were found to have impacts on the pooled results by sensitivity analysis. The results of this review are detailed in Supplement B. Briefly, we identified two key features of the available survivorship programmes and their efficacy in enhancing health-related OoL.

First, many programmes have methodological weaknesses, with few studies adequately reporting allocation concealment or non-blinding. Only 7 out of 20 studies were grounded in different theoretical frameworks, and none were conducted in developing countries.

Second, each programme was often treated in isolation, and the contents followed the ACS guidelines. They emphasise health promotion and managing late side effects over surveillance for second cancers and care coordination. Key components include: 1) CRC education on symptom management, nutrition, and exercise; 2) expert health coaching with survivorship care plans, delivered over 12 weeks, averaging 30-45 minutes, 6 to 12 sessions weekly; delivered mobile health, led by nurses. From these gaps, rigorous studies are warranted to integrate these contents to lay the foundation for future comprehensive interventions via mobile health, which can address multi-domains to improve the health-related QoL for this population.

Study Aim and Objectives

The study aims to examine the effectiveness of mHealth-based survivorship programme in enhancing health-related QoL among CRC survivors.

Feasibility and Piloting

A feasibility study will examine the feasibility, acceptability and preliminary effectiveness of the survivorship programme among CRC survivors in Vietnam.

Objective 1: To explore the feasibility and acceptability of the survivorship programme.

Objective 2: To examine the preliminary effectiveness of the survivorship programme on the same outcomes as the main study at baseline and immediately post-intervention.

Examine the effectiveness of the survivorship programme

A two-arm, single-blind, randomised controlled trial will evaluate the effectiveness of the survivorship programme in enhancing health-related QoL among CRC survivors.

Hypotheses

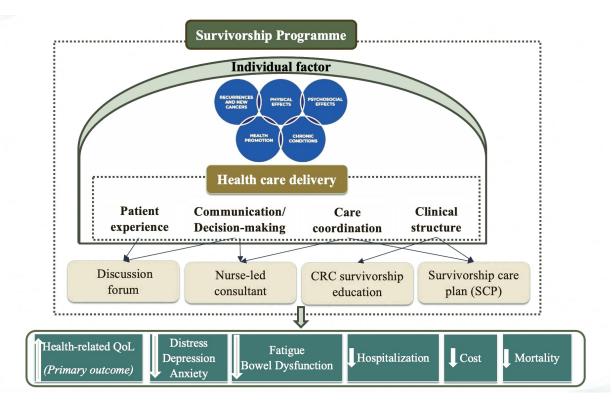
It is hypothesised that participants receiving the mHealth-based survivorship programme will report significantly higher levels of health-related quality of life and a lower level of distress, depression, anxiety, fatigue, and bowel dysfunction compared to those in the control group.

Theoretical framework

The Quality of Cancer Survivorship Care Framework, developed by Dr. Larissa Nekhlyudov at Harvard Medical School in collaboration with the National Cancer Institute (NCI), underpins this study (Nekhlyudov et al., 2019). This evidence-based framework, guided by the IOM, aims to improve cancer survivors' care by addressing recurrence, new cancers, physical and psychological effects, and chronic conditions. Most studies showed that nurse-led interventions effectively manage surveillance, side effects, and psychosocial support, improving care coordination and patient satisfaction while lowering costs; hence, this study adopted them (Gan et al., 2022; IOM, 2006; Vaz-Luis et al., 2022).

The framework identifies key factors influencing the quality of survivorship care, including clinical structure, care coordination, communication, and patient experiences (Nekhlyudov et al., 2019). To reflect this study, the CRC survivorship programme addresses five aspects of survivorship phases through healthcare delivery. The clinical structure will provide education and survivorship care plans (SCP), while the nurse will coordinate with oncologists to develop SCPs before patient discharge. Communication and decision-making will be enhanced through discussions facilitated by nurse consultants and the app forum, which also encourages survivors to share experiences. This comprehensive approach, whose indicators reinforce one another, aims to

improve the QoL and functionality of survivors, ultimately reducing hospitalisations, costs, and mortality rates.



Research Methodology

Development of CRC survivorship programme

Based on the results of a systematic review, meta-analysis, and framework, we developed this programme. It will be delivered over 12 weeks, averaging 30-45 minutes, in 6 sessions weekly via mobile health, and led by nurses. The modelling of intervention processes and outcomes was based on the results of the systematic review, qualitative study, ACS guidelines, oncology textbooks, and consultations with oncology professionals. The survivorship programme consists of four components: a survivorship care plan (SCP), CRC survivorship education, discussion forums (via a mobile application), and nurse-led consultations (via telephone). The SCP will provide general treatment information and pre-discharge care planning, while CRC survivorship education will focus on surveillance of second cancers, side effect management, and health promotion. Discussion forums encourage participants to interact and share their experiences. Nurse-led consultations will offer support and address any questions related to the intervention.

Mobile application:

The mobile app developed by a Vietnamese tech company will have two main layers: IT support and CRC survivor support. The former includes sign-up/sign-in, settings, and Help, while the latter offers CRC survivorship education, SCP, reminders, and discussion forums (Ayyoubzadeh et al., 2020). Designed for Android devices, the app will be built using Android Studio and Java, with a PHP (Hypertext Preprocessor) and JavaScript-based admin system (Nguyen, 2023). To ascertain privacy, data on the app are encrypted and can only be accessed by the software engineer and the researcher. Similarly, users can choose to remain anonymous by changing their display name and not displaying their personal picture. Moreover, the app was not available on social networking sites or public domains. Each participant was required to create a unique username and password, which they were instructed not to share with any other person. They could also change their passwords anytime they desire. Furthermore, the app also had a tracking function to monitor app usage. The tracking feature tallied the number of times the participants used the app, including the number of words and characters they used in the discussion forums.

It will feature a user-friendly interface with warm colours and images in audio or video formats, along with large black text on a white background for readability and guided navigation (Cole-Lewis & Kershaw, 2010). A tutorial video on usage will be provided. User data will be encrypted for privacy, allowing anonymity through display name changes and no personal photo uploads. The app will not be available on social media and will require unique usernames and passwords. Additionally, it will track usage, recording access frequency and discussion forum activity (Alzahrani et al., 2022).

Content validation

The content of the intervention was validated by an expert review and a layman review. A panel of experts—comprising an oncologist, an IT specialist, research professors, and two experienced oncology nurses—will evaluate for relevance, completeness, appropriateness, readability, and accuracy. They will have one week to review the mobile app before a meeting to discuss feedback and suggest improvements. For layman's review, three patients completing CRC treatment, with a variety of demographic characteristics, will be invited to evaluate the updated

content. They will be given access to the mobile application for one week, and their comments and suggestions will be collected.

Pilot study

Before the main RCT, a pilot study will assess the feasibility and acceptability of the CRC survivorship programme in Vietnam.

Setting

The study will be conducted at two oncology hospitals in Vietnam, being consistent with the proposed full-scale RCT setting.

Sample size

The sample size will be determined using the rules of thumb to find an appropriate sample size for continuous outcome measures. The pilot will include approximately 25 participants per group (Whitehead et al., 2016), based on recommendations for feasibility studies. The results will help refine and estimate the sample size for the full RCT.

Data collection

Quantitative data will be collected at baseline (T0) and immediately after the completion of the intervention (T1). Qualitative data will be collected from the intervention group at T1. Data collection will be carried out at the colorectal department and the outpatient department. A feasibility measure is based on the consent rate, attrition rate, adherence, and dose of the survivorship programme. Specifically, the consent rate measures agreement to participate, while adherence and dose reflect the extent and frequency of app usage among participants (Manojlovich & Sidani, 2008). The acceptability of the intervention is assessed through qualitative interviews between 15 and 20 minutes with participants in the intervention group at T1, focusing on their satisfaction and experiences, with the interview guide included in Supplement D.

Preliminary Effects of the Intervention

The preliminary effects of the survivorship programme are identified by measuring the health-related QoL, distress, anxiety, depression, fatigue, and bowel dysfunction outcome

variables. Details on the measurement instruments are the same as the ones presented for the main RCT.

Data Analysis

Quantitative data will be analysed using SPSS version 26.0. The sociodemographic and clinical data will be analysed using means, frequencies and percentages. The last observation carried forward (LOCF) method will be used to handle missing data (Robert M. Hamer & Pippa M. Simpson 2009). The homogeneity of the participants' socio-demographic characteristics is ensured using the Mann-Whitney U test for continuous variables and Fisher's exact test for categorical variables. A baseline assessment is conducted for all the outcomes before the intervention and is presented using median and interquartile ranges. The Mann-Whitney U test is conducted to compare the changes in outcome variables between the intervention and control groups from pre- to post-intervention. Verbatim transcription of the recorded interviews is performed by the researcher, after which the data are analysed using the NVivo 15 software programme.

Main study - RCT

Study design: A two-arm, parallel-group, single-blind RCT will be conducted, following the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines. The assessor will be blinded (Turner et al., 2012).

Setting: Participants will be recruited from the Hanoi Oncology Hospital and Can Tho Oncology Hospital in Hanoi and Can Tho city, which are the first-level cancer-specialized hospitals in the North and South of Vietnam (Hospital, 2024). The total number of hospital beds is 700 and 3200 respectively (Hospital, 2024; MOH, 2021).

Inclusion and exclusion criteria: Eligible participants will be 18 or older (1) Vietnamese-speaking CRC patients who have completed active treatment and are preparing for discharge (2); provide consent and complete questionnaires independently (3); no metastatic and second cancers (4), as well as using the Android smartphone (5). Exclusion will include mental health diseases, receiving anxiety or depression treatment or cognitive/learning problems.

Sample size: The sample size is calculated based on systematic review and meta-analysis findings for health-related QoL outcomes, with effect sizes of 0.75. To be conservative, the effect

size is estimated at 0.5. Using G*Power with 5% type 1 error, 80% power, and an effect size of 0.5, the target sample is 128. From the review, allowing for 20% attrition, 160 participants (80 per group) will be recruited.

Randomization and Blinding:

Block randomization with block sizes of four or six and a 1:1 allocation will be conducted by independent research using a computer-generated randomization list to ensure equal group sizes over time (Kang et al., 2008). An independent statistician will create the randomization sequences in advance using an online tool like www.randomizer.org. To achieve allocation concealment, these sequences will be transferred to sequentially numbered, opaque, sealed envelopes, which participants will open only after their baseline assessment (Dettori, 2010). While it is not feasible to blind participants or interventionists due to the study's nature, outcome assessors will be blinded to minimise any potential bias. Participants will be asked not to share their treatment allocation with others.

Intervention fidelity

Intervention fidelity refers to following the intervention protocol, which will be registered on ClinicalTrial.gov (Moncher & Prinz, 1991). The researcher ensures fidelity in this study by completing a 40-hour training coaching course and a 6.5-credit Cancer Survivorship Certification. The researcher will deliver all session interventions and monitor adherence by documenting attendance rates. RA who are research team members with bachelor's degree will be trained for one hour on quantitative data collection. To prevent contamination, eligible participants receive individual access links to the app, which are disabled after profile creation, and they are instructed not to share intervention content with others.

Outcome and **Instruments**

Primary outcomes include the health-related QoL. The second outcomes include distress, depression, anxiety, fatigue and bowel dysfunction (See Supplement E). The brief instruments are in the table below.

Outcomes	Description	Details
Socio- demographic	Age, gender, education level, occupation, nationality, religion, marital status, living conditions, personal income, insurance, etc.	
Clinical information	Follow in survivorship care plan (SCP), including diagnosis, treatment, nursing care, hospitalisation, cost	
Health- related QoL*	The Functional Assessment of Cancer Therapy-General (FACT-G)	Assesses health-related QoL, including physical function (consisting of 7 items), social and family relationships (7 items), emotional state (6 items), and functional abilities (7 items). Scores range from 0 to 100, with higher scores indicating better QoL. Cronbach's alpha of 0.89 for the scale, received the approval to use the FACT-G from the FACIT organisation
Distress	The distress thermometer screening tool (DT)	A self-report tool measuring distress on a scale from 0 (no distress) to 10 (extreme distress), focusing on a cutoff score of 4 (NCCN, 2024), with $\alpha = 0.87$ (Nguyen et al., 2021)
Depression & Anxiety	The Depression Anxiety Stress Scales (DASS-21) (Lovibond & Lovibond, 1995)	Consists of 21 items, with seven items for anxiety (DASS21-A), seven items for depression (DASS21-D) and seven items for stress (DASS21-S). It was validated for use in the Vietnamese population with good internal consistency (Cronbach's alpha: depression subscale-0.72; anxiety subscale-0.77; stress subscale-0.70, and overall scale-0.88) (Tran et al., 2013).
Fatigue	The Functional Assessment of Cancer Therapy- Fatigue subscale (FACT-F)	with 13 items, likert scales from 0 (not at all) to 4 (ver much), which has been validated for use in the Vietnamese version with Cronbach's alpha coefficient $\alpha = 0.93$ (Long et al., 2016).

Bowel Dysfunction

The Low anterior resection syndrome (LARS), which has been validated for use in the Vietnamese version (Mai-Phan & Pham, 2024)

A 5-question questionnaire evaluated bowel functional symptoms. Scores were assigned to responses, determining the LARS score, which categorized results into "no LARS" (0–20), "minor LARS" (21–29), and "major LARS" (30–42). Cronbach's alpha was from 0.874 to 0.934

Recruitment

Potential participants will be identified through informational posters, e-posters, and leaflets shared through hospital channels. RA will screen participants for eligibility and obtain signed informed consent on the last day of discharge preparation. Baseline data, including sociodemographics and clinical characteristics, will be collected before randomization. Consenting participants will be randomly assigned to either the intervention or control group.

Intervention

Intervention group: Participants will access a link that will be disabled after download to prevent sharing. They will be guided on creating usernames and passwords, and RAs will provide 10 to 15 minutes of app navigation training. In case of technical issues, a contact number of IT experts will be supplied. The app link will be disabled after intervention. The table below provides details of the intervention.

Session	Time point	Contents	Details	Mode of Delivery	Model construct
01	Week 1	introduces the SCP Chronic condition management	Conduct the SCP, then provide the tailed education about chronic disease (if available): Assist in downloading the application and registering an account. The account username and password will be maintained for subsequent visits.	Face to face, 30 minutes, nurse-led, before discharge	Clinical structure, Care coordination, Communication/ Decision-making
01	week 1	surveillance of recurrence and second cancer *	Covers risks of developing new cancers linked to: Genetic predisposition, Lifestyle choices, Treatment exposure Emphasizes the significance of: Regular follow-up appointments after treatment: Discussion forum: asking about the experiences of CRC survivors after these lessons	App, 30 minutes, nurse- led, communities	Clinical structure, Communication/ Decision-making Patient experience
02	Week 2	managing physical side effects *	Provides insights into common physical side effects and management strategies. Discussion forum: asking about the experiences of CRC survivors after these lessons.	App, 30 minutes, nurseled, communities	Clinical structure, Communication/ Decision-making Patient experience
03	Week 4	managing psychosocial side effects *	Provides insights into common psychosocial side effects and management strategies. Discussion forum: asking about the experiences of CRC survivors after these lessons.	App, 30 minutes, nurseled, communities	Clinical structure, Communication/ Decision-making Patient experience
04	Week 6	promoting healthy behaviours *	Information on benefits of exercise post-treatment, including: Aerobic, walking, stretching, and balance exercises Discussion forum: asking about CRC survivors' experiences with these exercises	App, 30 minutes, nurseled, communities	Clinical structure, Care coordination, Communication/ Decision-making
05	Week 8	promoting healthy behaviours *	Focus on meditation guides and deep breathing to control emotion. Discussion forum: asking about the experiences of CRC survivors after practicing these exercises.	App, 30 minutes, nurseled, communities	Clinical structure, Communication/ Decision-making Patient experience
06	Week 10	promoting healthy behaviours *	Learn about the importance of a balanced post-treatment diet, with various types of foods highlighted and examples provided. Tips for planning an effective diet after treatment, with emphasis on locally available food options in Vietnam.	App, 30 minutes, nurseled, communities	Clinical structure, Communication/ Decision-making Patient experience
	Week 12	Visiting check-up at hospital	• Re-assessment		

^{*}Short videos/lessons will be shown step-by-step, encouraging daily app access until all sections are completed

Nurse-led consultations aim to address participants' questions and provide informational support, conducted 15- to 20-minute phone calls at weeks 3, 5, 7, 9, and 11 by a principal investigator.

The control group will be provided with usual care, including a survivorship care plan and health counselling before discharge.

Data collection:

Participants will be assessed at three-time points: baseline (T0), post-intervention (T1), and 1-month follow-up (T2) by another RA. Data for T0 and T1 will be collected in hospitals, while T2 will occur online. The details of data collection are in the table below:

Outcomes	Description	Data collection procedures

		Baseline (T0)	Immediate post-intervention (T1)	1-month follow-up (T2)
Socio- demographic	Age, gender, education level, occupation, nationality, religion, marital status, living conditions, personal income, insurance, etc.			
Clinical	Follow in survivorship care plan (SCP),	V	V	V
information	including diagnosis, treatment, nursing care, hospitalisation, cost		hospitalisation, cost	hospitalisation, cost
Health- related QoL*	The Functional Assessment of Cancer Therapy-General (FACT-G)	$\sqrt{}$	$\sqrt{}$	
Distress	The distress thermometer screening tool (DT)	V	$\sqrt{}$	$\sqrt{}$
Depression & Anxiety	The Depression Anxiety Stress Scales (DASS-21) (Lovibond & Lovibond, 1995)	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
Fatigue	The Functional Assessment of Cancer Therapy-Fatigue subscale (FACT-F)		$\sqrt{}$	
Bowel Dysfunction	The Low anterior resection syndrome (LARS), which has been validated for use in the Vietnamese version (Mai-Phan & Pham, 2024)	$\sqrt{}$	$\sqrt{}$	

Data Analysis:

Statistical analysis, SPSS version 26, will be used, and an intention-to-treat analysis will be used in line with the CONSORT statement (Supplement F). The chi-squared test or Fisher's exact test, will be used for categorical data (e.g. family income, cancer stage), while the continuous variables (e.g. age) will use the independent T-test to test the homogeneity at baseline between groups. Categorical variables will be reported as frequencies and percentages and continuous

variables will be presented as mean± standard deviation. A two-tailed, two-sample T-test (normally distributed) or Mann-Whitney U test (non-normally distributed) will be used to compare the mean difference of FACT-G, DT, DASS-21, FACT-F, LARS of the intervention group and control group between T0, T1, and T2 respectively. Cohen's d will be used to measure the intervention effect size on the QoL, distress, anxiety, depression, fatigue, and bowel dysfunction of the intervention group and control group. The Generalized Estimating Equations (GEE) model will be used to compare the differential changes of each of the primary/ secondary outcomes at T1, T2 with respect to the baseline (T0) between groups.

Ethical consideration

The ethical principles of the Declaration of Helsinki (World Medical Association, 2013) are adhered to in this study. Ethics approval will be sought from the Chinese University of Hong Kong-New Territories Eastern Cluster Clinical Research Ethics Committee and the oncology hospitals in Vietnam This study will follow ethical principles for research involving human subjects, including autonomy, non-maleficence, and confidentiality. Participants will provide informed consent and can withdraw at any time, with an information sheet for the study. Each participant will be labelled with a code for confidentiality, and data will be secured. They will receive 200,000 VND (70 HKD) for internet fees, ensuring payment does not influence their participation. Approval for using instruments in Vietnamese will be obtained from the original authors.

Study plan

	2025											2026												2027												
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Qualitative study																																				
Ethical apply in Hong Kong																																				
Ethical apply in Vietnam																																				
Training Asistants																																				
Pilot study																																				
Main RCT data collection																																				
Data analysis																																				
Completion writing thesis and publication																																				

Project Significance and Value:

This study may provide evidence that supports oncology nurses in delivering mHealth survivorship programmes for CRC survivors. The findings can serve as a valuable resource for oncology nurses, enhancing survivorship care. In Vietnam, this study may be a pioneer for

oncology nurses to support CRC survivors, a population that has been neglected following treatment. Additionally, it is the first study in Vietnam to include technology in CRC nursing care, which aligns with the government's plans for healthcare digital transformation in the 2025–2030 period. Furthermore, this survivorship programme may extend support to other cancer survivors as well.

Reference:

- Aapro, M., Bossi, P., Dasari, A., Fallowfield, L., Gascón, P., Geller, M., Jordan, K., Kim, J., Martin, K., & Porzig, S. (2020). Digital health for optimal supportive care in oncology: benefits, limits, and future perspectives. *Supportive care in cancer*, 28, 4589-4612.
- Aguiar Junior, S., Oliveira, M. M., Silva, D., Mello, C. A. L., Calsavara, V. F., & Curado, M. P. (2020). Survival of Patients with Colorectal Cancer in a Cancer Center. *Arq Gastroenterol*, 57(2), 172-177. https://doi.org/10.1590/S0004-2803.2020000000-32
- Alzahrani, A., Gay, V., & Alturki, R. (2022). The evaluation of the usability in mobile applications. Proceedings of the 40th International Business Information Management Association (IBIMA), Seville, Spain, 23-24.
- Andreu, Y., Martinez, P., Soto-Rubio, A., Fernández, S., Bosch, C., & Cervantes, A. (2022). Colorectal cancer survival: prevalence of psychosocial distress and unmet supportive care needs. *Supportive Care in Cancer*, 30(2), 1483-1491. https://doi.org/10.1007/s00520-021-06513-1
- Arnold, M., Sierra, M. S., Laversanne, M., Soerjomataram, I., Jemal, A., & Bray, F. (2017). Global patterns and trends in colorectal cancer incidence and mortality. *Gut*, 66(4), 683-691. https://doi.org/10.1136/gutjnl-2015-310912
- Ayyoubzadeh, S. M., R. Niakan Kalhori, S., Shirkhoda, M., Mohammadzadeh, N., & Esmaeili, M. (2020). Supporting colorectal cancer survivors using eHealth: a systematic review and framework suggestion. *Supportive care in cancer*, 28(8), 3543-3555.
- Bower, J. E., Bak, K., Berger, A., Breitbart, W., Escalante, C. P., Ganz, P. A., Schnipper, H. H., Lacchetti, C., Ligibel, J. A., Lyman, G. H., Ogaily, M. S., Pirl, W. F., & Jacobsen, P. B. (2014). Screening, Assessment, and Management of Fatigue in Adult Survivors of Cancer: An American Society of Clinical Oncology Clinical Practice Guideline Adaptation. *Journal of Clinical Oncology*, 32(17), 1840-1850. https://doi.org/10.1200/jco.2013.53.4495
- Cole-Lewis, H., & Kershaw, T. (2010). Text messaging as a tool for behavior change in disease prevention and management. *Epidemiologic reviews*, 32(1), 56-69.
- Dao, H. V., Dao, Q. V., Lam, H. N., Hoang, L. B., Nguyen, V. T., Nguyen, T. T., Vu, D. Q., Pokorny, C. S., Nguyen, H. L., Allison, J., Goldberg, R. J., Dao, A. T. M., Do, T. T. T., & Dao, L. V. (2023). Effectiveness of using a patient education mobile application to improve the quality of bowel preparation: a randomised controlled trial. *BMJ Open Gastroenterol*, 10(1). https://doi.org/10.1136/bmjgast-2023-001107
- Denlinger, C. S., Barsevick, A. M., & Robinson, K. G. (2009). The Challenges of Colorectal Cancer Survivorship. *Journal of the National Comprehensive Cancer Network J Natl Compr Canc Netw*, 7(8), 883-894. https://doi.org/10.6004/jnccn.2009.0058
- Dettori, J. (2010). The random allocation process: two things you need to know. *Evid Based Spine Care J*, *I*(3), 7-9. https://doi.org/10.1055/s-0030-1267062
- Dirven, L., van de Poll-Franse, L. V., Aaronson, N. K., & Reijneveld, J. C. (2015). Controversies in defining cancer survivorship. *The lancet oncology*, *16*(6), 610-612. https://doi.org/10.1016/S1470-2045(15)70236-6
- Drury, A., Payne, S., & Brady, A.-M. (2020). Identifying associations between quality of life outcomes and healthcare-related variables among colorectal cancer survivors: A cross-sectional survey study. *International journal of nursing studies*, 101, 103434.
- Duijts, S. F. A., & Spelten, E. R. (2021). Cancer Survivorship Issues: Dissemination and Translation of Evidence-Based Knowledge. *Cancers* (*Basel*), 13(22). https://doi.org/10.3390/cancers13225794

- El-Shami, K., Oeffinger, K. C., Erb, N. L., Willis, A., Bretsch, J. K., Pratt-Chapman, M. L., Cannady, R. S., Wong, S. L., Rose, J., Barbour, A. L., Stein, K. D., Sharpe, K. B., Brooks, D. D., & Cowens-Alvarado, R. L. (2015). American Cancer Society Colorectal Cancer Survivorship Care Guidelines. *CA Cancer J Clin*, 65(6), 428-455. https://doi.org/10.3322/caac.21286
- Gan, T., Cheng, H.-L., & Tse, M. Y. M. (2022). A systematic review of nurse-led dietary interventions for cancer patients and survivors. *Asia-Pacific journal of oncology nursing*, 9(2), 81-87.
- Gurková, E. (2011). Issues in the definitions of HRQoL. *Journal of nursing, social studies, public health and rehabilitation*, *3*(4), 190.
- Hershman, D. L., Lacchetti, C., Dworkin, R. H., Smith, E. M. L., Bleeker, J., Cavaletti, G., Chauhan, C., Gavin, P., Lavino, A., Lustberg, M. B., Paice, J., Schneider, B., Smith, M. L., Smith, T., Terstriep, S., Wagner-Johnston, N., Bak, K., & Loprinzi, C. L. (2014). Prevention and Management of Chemotherapy-Induced Peripheral Neuropathy in Survivors of Adult Cancers: American Society of Clinical Oncology Clinical Practice Guideline. *Journal of Clinical Oncology*, 32(18), 1941-1967. https://doi.org/10.1200/jco.2013.54.0914
- Hospital, H. O. (2024). Hanoi Oncology Hospital. https://www.uicc.org/membership/hanoi-oncology-hospital
- IOM, I. o. M. a. N. R. C. (2006). From Cancer Patient to Cancer Survivor: Lost in Transition. . National Academies of Sciences, Engineering, and Medicine. https://nap.nationalacademies.org/read/11468/chapter/1
- Kang, M., Ragan, B. G., & Park, J. H. (2008). Issues in outcomes research: an overview of randomization techniques for clinical trials. *J Athl Train*, 43(2), 215-221. https://doi.org/10.4085/1062-6050-43.2.215
- Kemp, S. (2024). *Digital 2024: Vietnam*. DataReportal Global Digital Insights. <a href="https://datareportal.com/reports/digital-2024-vietnam#:~:text=Internet%20use%20in%20Vietnam%20in%202024&text=Vietnam's%20internet%20penetration%20rate%20stood,January%202023%20and%20January%202024
- Koczwara, B. (2020). Cancer survivorship care at the time of the COVID-19 pandemic. *The Medical Journal of Australia*, 213(3), 107.
- Kuipers, E. J., Grady, W. M., Lieberman, D., Seufferlein, T., Sung, J. J., Boelens, P. G., van de Velde, C. J., & Watanabe, T. (2015). Colorectal cancer. *Nat Rev Dis Primers*, *1*, 15065. https://doi.org/10.1038/nrdp.2015.65
- Le, D. D., Vo, T. V., & Sarakarn, P. (2021). Overall Survival Rate of Vietnamese Patients with Colorectal Cancer: A Hospital-Based Cohort Study in the Central Region of Vietnam. *Asian Pac J Cancer Prev*, 22(11), 3569-3575. https://doi.org/10.31557/apjcp.2021.22.11.3569
- Lim, J.-w., Zhang, A., & Zebrack, B. (2023). Technology-Based Cancer Survivorship Care Interventions: A Systematic Review and Meta-Analysis. *Research on Social Work Practice*, 34(7), 757-780. https://doi.org/10.1177/10497315231199940
- Long, N. H., Thanasilp, S., & Thato, R. (2016). A causal model for fatigue in lung cancer patients receiving chemotherapy. *European Journal of oncology nursing*, 21, 242-247.

- Luo, X., Li, J., Chen, M., Gong, J., Xu, Y., & Li, Q. (2021). A literature review of post-treatment survivorship interventions for colorectal cancer survivors and/or their caregivers. *Psychooncology*, 30(6), 807-817.
- Mai-Phan, T. A., & Pham, V. Q. (2024). Validation of the Vietnamese version of the low anterior resection syndrome score questionnaire. *Ann Coloproctol*, 40(6), 588-593. https://doi.org/10.3393/ac.2022.00514.0073
- Manojlovich, M., & Sidani, S. (2008). Nurse dose: what's in a concept? *Research in Nursing & Health*, 31(4), 310-319.
- Marthick, M., McGregor, D., Alison, J., Cheema, B., Dhillon, H., & Shaw, T. (2021). Supportive care interventions for people with cancer assisted by digital technology: systematic review. *Journal of medical Internet research*, 23(10), e24722.
- Mitchell, A. J., Ferguson, D. W., Gill, J., Paul, J., & Symonds, P. (2013). Depression and anxiety in long-term cancer survivors compared with spouses and healthy controls: a systematic review and meta-analysis. *The lancet oncology*, *14*(8), 721-732. https://doi.org/https://doi.org/10.1016/S1470-2045(13)70244-4
- MOH, M. o. H. (2021). Bach Mai Hospital 110 years of the largest special-class hospital in the North.

 https://moh.gov.vn/hoat-dong-cua-lanh-dao-bo/-/asset_publisher/TW6LTp1ZtwaN/content/bv-bach-mai-110-nam-benh-vien-hang-ac-biet-lon-nhat-mien-bac#:~:text=BV%20B%E1%BA%A1ch%20Mai%20l%C3%A0%20BV%C4%90K,PGS.
- Moncher, F. J., & Prinz, R. J. (1991). Treatment fidelity in outcome studies. *Clinical psychology review*, 11(3), 247-266.
- Mullan, F. (1985). Seasons of Survival: Reflections of a Physician with Cancer. *New England Journal of Medicine*, 313(4), 270-273. https://doi.org/doi:10.1056/NEJM198507253130421
- NCCN, N. C. C. N. (2013). NCCN clinical practice guidelines in oncology (NCCN GuidelinesTM). Prostate cancer. Version 4.2013. *Fort Washington, PA*.
- NCCN, N. C. C. N. (2024). NCCN Clinical Practice Guidelines in Oncology for Distress Management [v2.2024]. https://www.nccn.org/global/what-we-do/distress-thermometer-tool-translations
- Nekhlyudov, L., Mollica, M. A., Jacobsen, P. B., Mayer, D. K., Shulman, L. N., & Geiger, A. M. (2019). Developing a Quality of Cancer Survivorship Care Framework: Implications for Clinical Care, Research, and Policy. *JNCI: Journal of the National Cancer Institute*, 111(11), 1120-1130. https://doi.org/10.1093/jnci/djz089
- Nguyen, M. N. (2021). Internet usage in Vietnam-statistics & facts. In: Statista.
- $Nguyen, \quad M. \quad N. \quad (2023). \quad Mobile \quad apps \quad in \quad Vietnam \quad \quad statistics \quad \& \quad facts. \\ \quad \underline{https://www.statista.com/topics/8264/mobile-apps-in-vietnam/\#topicOverview}$
- Nguyen, T. Q., Do, T. M., & Pham, T. A. (2021). Screening for psychological distress in Vietnamese cancer patients: An evaluation of the distress thermometer. *Cancer Medicine*, 10(21), 7793-7803.
- Onyoh, E. F., Hsu, W.-F., Chang, L.-C., Lee, Y.-C., Wu, M.-S., & Chiu, H.-M. (2019). The Rise of Colorectal Cancer in Asia: Epidemiology, Screening, and Management. *Current Gastroenterology Reports*, 21(8), 36. https://doi.org/10.1007/s11894-019-0703-8
- Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., Shamseer, L., Tetzlaff, J. M., Akl, E. A., & Brennan, S. E. (2021). The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *bmj*, 372.

- Robert M. Hamer, P. D., & Pippa M. Simpson, P. D. (2009). Last Observation Carried Forward Versus Mixed Models in the Analysis of Psychiatric Clinical Trials. *American Journal of Psychiatry*, 166(6), 639-641. https://doi.org/10.1176/appi.ajp.2009.09040458
- Schramme, T. (2023). Health as complete well-being: The WHO definition and beyond. *Public Health Ethics*, 16(3), 210-218.
- Shulman, L. N., Ferris, L., Takanishi, D. M., & McKellar, D. (2015). Treatment Summaries and Survivorship Care Plans: The Approach by the Commission on Cancer to Increase Use. *Journal of Oncology Practice*, 11(1), 40-41. https://doi.org/10.1200/jop.2014.002329
- Siegel, R. L., Giaquinto, A. N., & Jemal, A. (2024). Cancer statistics, 2024. *CA Cancer J Clin*, 74(1), 12-49. https://doi.org/10.3322/caac.21820
- Siegel, R. L., Wagle, N. S., Cercek, A., Smith, R. A., & Jemal, A. (2023). Colorectal cancer statistics, 2023. *CA Cancer J Clin*, 73(3), 233-254. https://doi.org/10.3322/caac.21772
- Simard, J., Kamath, S., & Kircher, S. (2019). Survivorship Guidance for Patients with Colorectal Cancer. *Curr Treat Options Oncol*, 20(5), 38. https://doi.org/10.1007/s11864-019-0635-4
- Stovall, E., Greenfield, S., & Hewitt, M. (2005). From cancer patient to cancer survivor: lost in transition. National Academies Press.
- Tran, T. D., Tran, T., & Fisher, J. (2013). Validation of the depression anxiety stress scales (DASS) 21 as a screening instrument for depression and anxiety in a rural community-based cohort of northern Vietnamese women. *BMC Psychiatry*, 13(1), 24. https://doi.org/10.1186/1471-244X-13-24
- Turner, L., Shamseer, L., Altman, D. G., Weeks, L., Peters, J., Kober, T., Dias, S., Schulz, K. F., Plint, A. C., & Moher, D. (2012). Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals. *Cochrane Database of Systematic Reviews*(11). https://doi.org/10.1002/14651858.MR000030.pub2
- Vaz-Luis, I., Masiero, M., Cavaletti, G., Cervantes, A., Chlebowski, R. T., Curigliano, G., Felip, E., Ferreira, A. R., Ganz, P. A., Hegarty, J., Jeon, J., Johansen, C., Joly, F., Jordan, K., Koczwara, B., Lagergren, P., Lambertini, M., Lenihan, D., Linardou, H., . . . Pravettoni, G. (2022). ESMO Expert Consensus Statements on Cancer Survivorship: promoting high-quality survivorship care and research in Europe. *Annals of Oncology*, *33*(11), 1119-1133. https://doi.org/https://doi.org/10.1016/j.annonc.2022.07.1941
- Wang, Y., Lin, Y., Chen, J., Wang, C., Hu, R., & Wu, Y. (2020). Effects of Internet-based psychoeducational interventions on mental health and quality of life among cancer patients: a systematic review and meta-analysis. *Supportive care in cancer*, 28, 2541-2552.
- Whitehead, A. L., Julious, S. A., Cooper, C. L., & Campbell, M. J. (2016). Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat Methods Med Res*, 25(3), 1057-1073. https://doi.org/10.1177/0962280215588241