International Journal of Clinical Trials
Zhang J et al. Int J Clin Trials. 2026 Nov;13(4):423-435
https://www.ijclinicaltrials.com
pISSN 2349-3240 | eISSN 2349-3259

DOI: https://dx.doi.org/10.18203/2349-3259.ijct20263276

Protocol

Efficacy of artificial intelligence-integrated emotional granularity growth at improving resilience and quality of life in young and middle-aged colorectal cancer survivors: protocol for a pilot randomised controlled trial

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Received: 13 August 2026
Revised: 02 September 2026
Accepted: 09 September 2026

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ABSTRACT

Background: Young and middle-aged colorectal cancer survivors frequently experience emotional distress and difficulties adapting during the cancer trajectory. Emotional granularity, the ability to identify and differentiate emotional experiences, may represent a modifiable target for improving emotion regulation and resilience. However, interventions targeting emotional granularity among colorectal cancer survivors remain limited. The artificial intelligence-integrated emotional granularity growth program (AI-EGG), delivered via a WeChat mini program, was developed to enhance resilience and quality of life.
Methods: A two-arm pilot randomised controlled trial will evaluate the feasibility, acceptability, and preliminary efficacy of AI-EGG among young and middle-aged colorectal cancer survivors. Fifty-four participants will be randomly assigned (1:1) to either the intervention group or usual care across three teaching hospitals in Suzhou, China. The intervention group will receive a four-week AI-EGG intervention consisting of emotion identification and differentiation, selection of regulation strategies, implementation of regulation strategies, and maintenance and adaptation. Primary outcomes include recruitment, retention, adherence, ecological momentary assessment completion, and system usability. Secondary outcomes will include resilience, emotional granularity, emotion regulation, and quality of life. Assessments will occur at baseline, post-intervention, and one-month follow-up. Semi-structured interviews with a purposive subsample will explore acceptability and implementation experiences. Ethical approval has been obtained from the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University and participating hospitals.
Conclusions: This study will evaluate the feasibility, acceptability, and preliminary efficacy of AI-EGG for young and middle-aged colorectal cancer survivors and inform intervention refinement and a future definitive trial.
Trial Registration: The trial is registered at ClinicalTrials.gov (NCT07611071).

Keywords: Colorectal cancer, Emotional granularity, Resilience, Artificial intelligence, Randomized controlled trial, Protocol

INTRODUCTION

Colorectal cancer (CRC) is a malignancy originating in the colon or rectum.[1] According to the Global Cancer Observatory (GLOBOCAN) 2022, It is a significant public health concern worldwide, ranking as the third most commonly diagnosed cancer and the second leading cause of cancer-related deaths worldwide.[2] In China, CRC incidence and mortality continue to rise, making it a critical area for intervention.[3] Although advances in anticancer drugs and tumor resection have improved treatment response and 5 year survival rates, survivors increasingly face long-term and complex challenges during and after cancer treatment.[4]

Young and middle-aged patients experience particular difficulty adapting lifestyles after cancer and are at higher risk of emotional distress.[5,6] In China, early onset CRC incidence is projected to increase from 170.99 to 237.29 per 100,000 between 2022 and 2050.[7,8] Specifically, young and middle aged survivors under 60 years old with two or more comorbidities are more likely to experience severe physical and emotional symptoms, alongside financial stress and social isolation.[9-11] Despite their distinct needs, few structured programs currently exist to enhance resilience in this group or specifically target the emotional regulation processes underlying adaptation to cancer survivorship.

Resilience, defined as an adaptive individual response to a difficult life situation and a psychosocial outcome of growth, is crucial for CRC patients.[12,13] Effective emotion regulation is central to building this resilience.[14] While existing interventions, such as attention based and positive psychology approaches, effectively promote adaptive appraisal, most emphasize the provision of coping strategies rather than improving patients' underlying capacity to identify, differentiate, and effectively apply these strategies.[15,16]

Emotional granularity, the ability to differentiate and label emotional experiences with precision, is a fundamental mechanism enabling effective emotion regulation.[17,18] Evidence indicates that high emotional granularity enhances emotional control and psychological flexibility, thereby supporting resilience by allowing for the targeted use of emotion regulation strategies.[13,19-21]

However, traditional psychological interventions are often inflexible and struggle to meet heterogeneous emotional needs.[22] This is compounded by severe global mental health workforce shortages.[23] Artificial intelligence (AI) combined with mobile health platforms offers a highly scalable solution by providing continuous, personalized, and adaptive emotional support.[24-27] However, concerns remain regarding the safety, reliability, and appropriate clinical integration of AI-based mental health support, particularly regarding whether AI should complement rather than replace healthcare professionals. Crucially, rather than replacing clinical staff, AI can augment healthcare professionals. By providing real-time emotional identification, tailored strategy guidance, and continuous monitoring, the AI system empowers patients while enabling oncology nurses to act as a vital safety net. Nurses can deliver targeted support when high-risk emotional content is detected by the system or when patients voluntarily seek human assistance. Therefore, we hypothesize that enhancing emotional granularity through this AI-driven, nurse-supported approach will improve the effective use of emotion regulation strategies, thereby strengthening resilience. This study proposes the AI-integrated emotional granularity growth (AI-EGG) intervention to address this gap and evaluate its feasibility, acceptability, and preliminary efficacy.

The extended process model (EPM) of emotion regulation provides a comprehensive framework for understanding how individuals regulate emotions through dynamic and sequential processes.[21] The EPM conceptualizes emotion regulation as a dynamic, multi-stage valuation process with clear leverage points for intervention. It delineates sequential stages including identification, selection, and implementation. By highlighting potential difficulties at different stages of emotion regulation, the EPM provides a theoretical basis for designing targeted interventions. The AI-EGG intervention is therefore structured into a corresponding dynamic cycle consisting of emotion identification, strategy selection, implementation of regulation strategies, and maintenance.

During the identification stage, the intervention addresses poor emotional awareness by prompting participants to use a structured emotion wheel to describe daily experiences. By interacting with the AI assistant, participants are encouraged to distinguish among related emotional states, directly training their emotional granularity. In the selection stage, the AI facilitates reflection and provides tailored coping recommendations derived from evidence-informed knowledge cards and safety-bounded large language model suggestions. This aligns with the EPM's emphasis on contextual adaptability, as strategies are precisely matched to the participant's specific emotional triggers and survivorship challenges. During the implementation stage, the platform provides practical guidance and timeframes for the selected strategies, encouraging participants to apply them in daily life.

Finally, the dynamic nature of the EPM is supported by a maintenance and adaptation component. The platform generates longitudinal emotional summaries and automated follow-up prompts to evaluate strategy effectiveness, allowing participants to re-enter the identification cycle when emotional needs change. Throughout this entire process, a hybrid support system is maintained. The AI handles routine monitoring and engagement, while oncology nurses utilize a dedicated administrator interface to review AI-flagged high-risk emotional content or respond to voluntary requests. This ensures patient safety and provides timely clinical

intervention without demanding unsustainable human resources.

Therefore, this study aims to develop and preliminarily evaluate the AI-EGG intervention designed to enhance emotional granularity, with the goal of improving resilience and quality of life among young and middle-aged CRC survivors. Specifically, this study seeks to develop an AI-integrated intervention that supports dynamic emotion differentiation through an interactive emotion wheel, tailored strategy selection, and automated follow-up. Furthermore, it aims to assess the feasibility and acceptability of the intervention among the target population while evaluating its preliminary effectiveness in improving emotional granularity, resilience, and quality of life. Finally, the study will examine the usability of the AI system and its performance in tracking longitudinal emotional patterns, generating context-sensitive feedback, and effectively triaging high-risk emotional states to human clinical staff.

METHODS

Study design and setting

The study set up period commenced in May 2026 and included the development and testing of the AI-EGG platform, investigator training, refinement of study procedures, and quality assurance processes. No participants were recruited, enrolled, or randomized during this period. Participant recruitment and initial randomization commenced in June 2026, following the successful completion of regulatory filing requirements for the WeChat mini program. Recruitment is projected to conclude in July 2027. Participants will be recruited from three teaching hospitals in Suzhou, China. Although recruitment and outcome assessments will be coordinated through the participating hospitals, the intervention will be delivered remotely via the WeChat mini program, allowing participants to engage with the platform in their usual daily environments**.**

Eligibility criteria

Eligible CRC survivors will be recruited from two teaching hospitals in Suzhou, China. The inclusion criteria are: young and middle-aged adult patients (age in the range of 18-60 years); patients diagnosed with CRC; patients have completed primary curative-intent treatment for colorectal cancer, and are currently in a stable post-treatment or maintenance phase of care without evidence of active disease progression or acute treatment-related instability; and patients able to use a smartphone and agree to participate in the study. The exclusion criteria are: patients who are unaware of their cancer diagnosis due to family-related disclosure restrictions; patients suffering from severe comorbidities or conditions that may affect participation or assessment, such as significant cognitive impairment (e.g., dementia, severe memory loss), psychiatric disorders, or other serious medical complications; and those who are participating in other psychological intervention studies.

Recruitment and consent

Recruitment will be conducted by trained oncology nurses (Research Assistant 1) who have established rapport with patients through routine clinical care. These nurses will identify potential participants during outpatient visits or inpatient stays based on the inclusion criteria and will introduce the study purpose and procedures. Interested patients will then be referred to the research team for further eligibility screening and informed consent. To facilitate recruitment, oncology nurses will introduce the study during routine follow-up appointments and provide study information leaflets. Interested patients will be contacted by the research team for eligibility confirmation and informed consent procedures. Recruitment progress will be reviewed monthly throughout the study period. The overall study flow is shown in Figure 1.

Randomization and allocation concealment

An independent co-investigator who is not involved in participant recruitment, intervention delivery, or outcome assessment will generate the allocation sequence using R 4.5.2. Randomization will be performed using randomly permuted block sizes of 4 and 6 in a 1:1 ratio. The randomization sequence will be implemented through a blinded online electronic randomization tool to ensure allocation concealment and balanced group assignment throughout the enrollment process. Randomization will occur after completion of baseline assessments. Enrollment and assignment will be performed by a research coordinator who is not involved in the outcome assessment. The allocation sequence will be embedded within a secure web-based randomization system inaccessible to recruitment personnel. Allocation will only be revealed after completion of baseline assessments and participant enrolment. To avoid potential contamination between groups, participants in the intervention arm will be issued a unique login credential necessary to access the AI-EGG. Only those with valid credentials can log in and proceed. Participants will be requested not to share intervention content with individuals outside their group. question about whether the participants shared information with other groups will be included in the post-intervention questionnaire to assess contamination. Backend usage logs will be monitored to detect any crossover access.

Blinding

Due to the behavioral and digital nature of the intervention, blinding of participants and intervention personnel is not feasible. However, outcome assessors responsible for questionnaire administration and data verification will remain blinded to treatment allocation whenever possible. Statistical analyses will be conducted by an investigator blinded to group assignment using coded treatment groups.

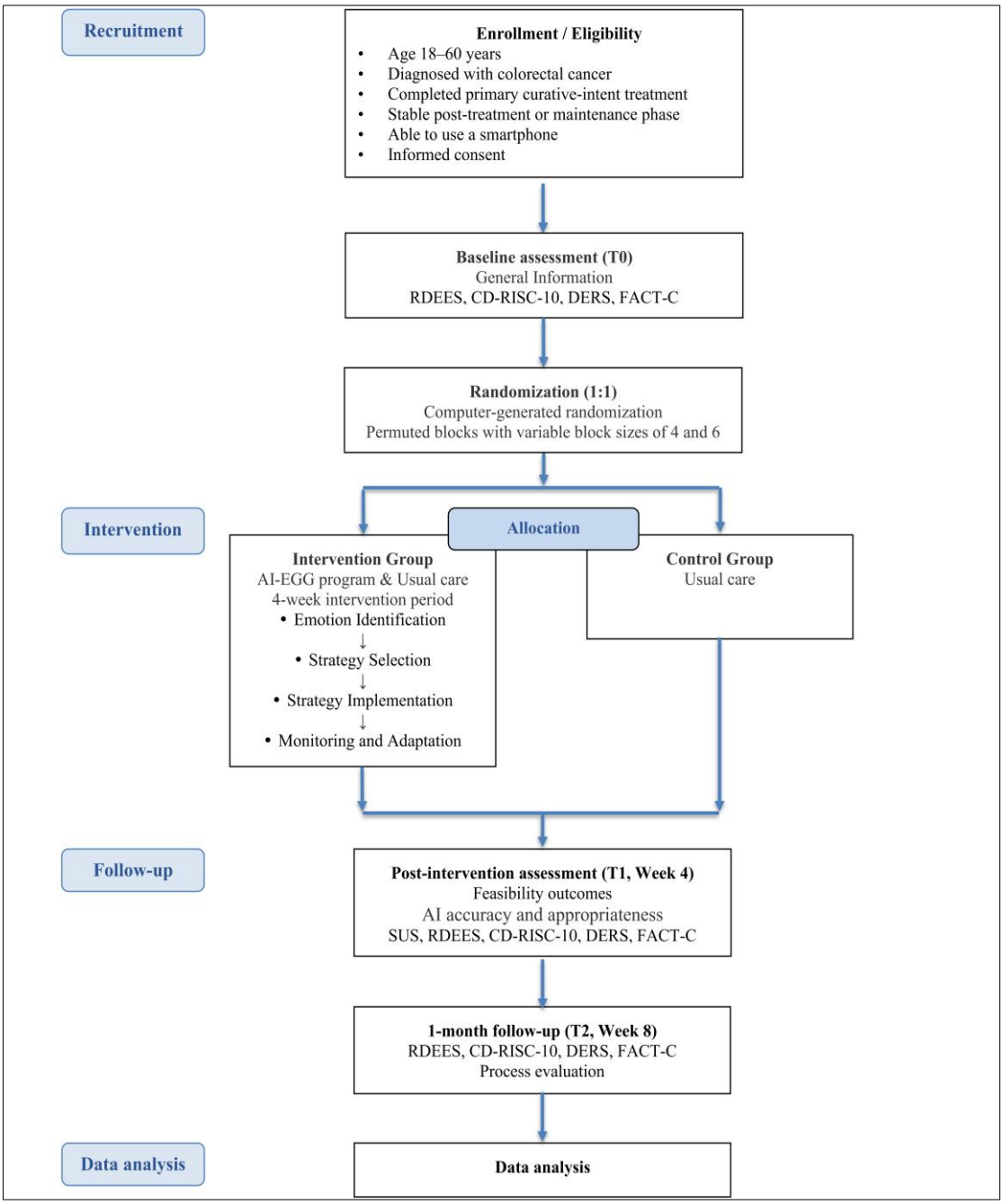


Figure 1: Study flow diagram.

AI-EGG: AI-integrated emotional granularity growth; CRC: colorectal cancer; CD-RISC-10: 10-item Connor-Davidson resilience scale; FACT-C: functional assessment of cancer therapy–colorectal; RDEES: range and differentiation of emotional experience scale; DERS: difficulties in emotion regulation scale; SUS: system usability scale

Intervention

Intervention group (IG): AI-EGG

Participants allocated to the intervention group will receive a four-week AI-EGG intervention delivered through a WeChat mini-program specifically developed for young and middle-aged colorectal cancer survivors. AI-EGG is an artificial intelligence assisted emotional support and self-management program developed based on Gross's EPM of emotion regulation, evidence synthesized from our previously published scoping review of emotional strategies for enhancing resilience among cancer survivors, and formative findings from an ongoing mixed-methods study exploring the relationships among emotional granularity, emotion regulation, and resilience, and patient preferences for AI-assisted emotional support.[21]

The intervention consists of four integrated components: emotion identification and differentiation, selection of regulation strategies, implementation of regulation

strategies, and maintenance and adaptation. These components are not delivered as a fixed linear sequence. Instead, they form a dynamic and iterative cycle that participants may enter and repeat throughout the intervention period according to their emotional experiences, needs, and ongoing interactions with the platform.

Participants may interact with the AI assistant ("eggshell") at their own pace throughout the intervention period. They will be encouraged to complete a full interaction cycle per week. A full interaction cycle consists of emotion identification and differentiation, selection of regulation strategies, implementation of regulation strategies, and follow-up maintenance and adaptation. To promote engagement, reminders will be sent to participants who have not logged into the platform for three consecutive days.

Emotion identification and differentiation

Participants are encouraged to describe daily experiences, concerns, and emotional reactions through text-based conversations and emotion diary entries. When emotional content is detected during interactions, the system prompts participants to identify and label their emotional experiences using a structured emotion wheel derived from the corrected Feeling Wheel by Dr. Albert Wong. (based on the original wheel by Gloria Willcox in 1982, and the adaptation by Geoffrey Roberts.[28] By encouraging participants to distinguish among multiple related emotional states, the intervention aims to enhance emotional granularity and improve awareness of emotional experiences. Participants may identify and record emotions either independently through the emotion wheel module or as part of an AI-assisted conversation. The emotion wheel therefore serves both as a standalone self-monitoring tool and as an entry point for subsequent AI-guided emotional support.

Selection of regulation strategies

Based on participants' selected emotions and narrative descriptions, the AI assistant facilitates reflection on emotional experiences through empathic responses and guided exploration of potential emotional triggers and reactions. Following this process, the AI assistant provides tailored coping recommendations that are appropriate for participants reported emotional experiences and current circumstances. Strategy recommendations are derived from two complementary sources. The first consists of evidence-informed knowledge cards developed from cancer survivorship guidelines, psycho-oncology literature, and findings from previous phases of the project. The second consists of context-sensitive suggestions generated by the large language model within predefined safety boundaries. These recommendations are tailored to the needs and circumstances of young and middle-aged colorectal cancer survivors and may address emotional experiences, cancer survivorship challenges, symptom self-management, interpersonal and family relationships, occupational and social demands, and broader issues encountered during adaptation to life after cancer. Participants retain autonomy in selecting whether and how to use the recommended strategies.

Implementation of regulation strategies

Once a strategy has been selected, the platform provides practical guidance to support implementation. For each recommended strategy, the system provides relevant instructions and an estimated completion timeframe. Participants are encouraged to apply the selected strategies in their daily lives and subsequently report their experiences through interactions with the AI assistant.

Maintenance and adaptation

To facilitate sustained engagement and adaptation of coping efforts, the platform provides ongoing emotional monitoring and follow-up support. In addition to participant-selected emotions, the system generates longitudinal summaries of emotional patterns based on conversational content using large language model–assisted analysis. These summaries are presented separately from intervention dialogues and are intended to support self-monitoring and reflection rather than emotion labeling. Participants may review emotional trend visualizations, identify recurring emotional themes, and evaluate the perceived accuracy of AI-generated emotional interpretations.

Automated follow-up prompts are delivered after a predefined delay period. These prompts encourage participants to report implementation experiences, perceived usefulness, and barriers encountered during strategy use. Based on participant feedback and ongoing conversations, the AI assistant may provide reinforcement, additional guidance, alternative coping suggestions, or support for re-entering a new cycle of emotion identification and strategy selection when emotional needs change.

Throughout the intervention period, participants may access support according to their individual needs and preferences. Human support remains available through a dedicated channel embedded within the mini-program and may be accessed voluntarily at any stage of the intervention. Oncology nurses access a dedicated administrator interface that receives real-time notifications of participants' high-risk emotional content identified by the AI system. Nurses can review participants' emotional trends, diary entries, and AI conversation history to assess psychological risk.

Participants may also voluntarily request human support by clicking a "contact nurse" button, which connects them directly to the nurse interface for live interaction. Nurses provide timely intervention, guidance, and, if needed, referral to appropriate mental health services.

Intervention dose and engagement

The intervention will be delivered over a four-week period. Participants will be encouraged to engage with the platform at least twice per week through emotion identification activities. Emotion identification may be completed either independently through the emotion wheel module or during conversations with the AI assistant. When emotions are selected before initiating a conversation, the AI assistant uses the selected emotions to guide subsequent interactions and support. All emotion identification activities are recorded within the platform and contribute to intervention engagement. To promote adherence, automated reminders will be sent to participants who have not logged into the platform for three consecutive days. Adherence will be defined as the completion of at least eight emotion identification activities during the four-week intervention period, regardless of whether these are conducted independently or within AI-assisted conversations. Each completed emotion identification activity, whether standalone or AI-mediated, will be recorded in the platform and contribute to overall intervention engagement.

Intervention delivery

The intervention will be delivered by a nurse researcher (Research Assistant 2) with extensive cancer care experience, who received study-specific training as an advanced care planning facilitator before participant recruitment. The training covered all components of the AI-EGG intervention to ensure competency in delivering emotional granularity and regulation training. Participants may discontinue the intervention if they withdraw consent, experience unacceptable distress, or request withdrawal. Decisions regarding continuation or discontinuation will be made in consultation with the research team. No planned modifications to the intervention content will occur during the trial; any unforeseen modifications required for participant safety or technical reasons will be documented and reported.

Control group (CG)

Participants in the control group will receive routine psychological care from oncology nurses, including standard educational materials on symptom management and basic emotional coping strategies consistent with clinical guidelines. The usual care group was selected as the comparator because it reflects the standard supportive care available to CRC survivors in clinical practice and enables evaluation of the added benefit of the AI-EGG intervention. Control participants will complete the same online questionnaires as the intervention group but will not access the structured emotional training program. Both groups will continue routine oncological follow-up and healthcare services throughout the study period, and any additional psychosocial support received will be recorded but not restricted.

Outcomes

Primary outcome

As this is a pilot randomized controlled trial, the primary outcomes will focus on feasibility and usability of the AI-EGG program. The primary outcomes will include recruitment rate, retention rate, intervention adherence, ecological momentary assessment (EMA) completion rate, feasibility of outcome assessment, and system usability.

Feasibility outcomes

Recruitment rates will be monitored using screening logs and the study CONSORT flow diagram. Retention rates will be assessed at T1 to measure short-term retention and at T2 to evaluate willingness to sustain participation one month after the intervention. Adherence and data completeness will be evaluated via automated data exports from the AI-EGG platform throughout the intervention period. Intervention adherence will be evaluated using automated data exports from the platform, based on participants' completion of the prescribed emotion identification activities throughout the four-week intervention period. EMA completion rate will be calculated as the proportion of completed EMA assessments relative to the expected number of EMA assessments during the intervention period. Outcome assessment feasibility will be evaluated using semi-structured interviews to confirm that all required assessments were acceptable and deliverable.

Usability, AI accuracy and appropriateness

Usability will be measured at T1 via the system usability scale (SUS).[29] Perceived accuracy of AI emotion interpretation will be assessed using a 0–10 visual analogue scale completed by participants after each emotion feedback episode. Higher scores indicate greater perceived agreement between the AI-generated emotional interpretation and participants' subjective emotional experience. Scores will be summarized as mean (SD) at the participant level. Perceived appropriateness of the AI feedback will be collected from both participants and nurses at T1.

Secondary outcomes

The secondary outcomes will assess preliminary efficacy and will include resilience, quality of life, emotional granularity, and emotion regulation. Additional outcomes will include the accuracy of AI-generated emotion identification and participants' perceptions of the acceptability, appropriateness, and suitability of the intervention.

Demographic and clinical characteristics will be collected at baseline. The general information questionnaire will be self-designed after literature review. The questionnaire includes age, sex, nationality, marital status, education,

occupation, religious beliefs, monthly per capita household income, payment method of medical expenses, and other diseases. CRC family history, cancer types, metastasis, treatments received, stoma-related information.

The Chinese version of 10-item Connor-Davidson resilience scale (CD-RISC-10)

Resilience will be measured at baseline (T0), immediately post-intervention at week four (T1), and four-week post-intervention (T2) using CD-RISC-10. The original version of the scale is a self-administered questionnaire with one single dimension, which originated from the original 25-item one.[30,31] It has 10 items with five response options (0=never; 4=almost always). The final score of the questionnaire is the sum of the responses of each item (range 0-40), where higher scores indicate higher resilience capacity. It was translated into Chinese in 2017.[32] The Chinese version of CD-RISC-10 retains its single dimension in the original English version. Cronbach's α for the entire scale was 0.88, and the test-retest was 0.73.

The Chinese version of the functional assessment of cancer therapy-colorectal (FACT-C)

Quality of life will be measured at baseline (T0), immediately post-intervention at week four (T1), and four-week post-intervention (T2) using FACT-C. The FACT-C is a disease-specific health-related quality of life questionnaire designed for colorectal cancer patients. It consists of 36 items, combining the 27-item general cancer core (FACT-G) with a 9-item colorectal cancer subscale (CCS), covering physical well-being, social/family well-being, emotional well-being, functional well-being, and colorectal cancer–specific concerns.[33] Each item is rated on a 5-point Likert scale from 0 ("not at all") to 4 ("very much") over the past 7 days, with higher scores indicating better quality of life. The Chinese version of the FACT-C has demonstrated good psychometric properties, including a Cronbach's α of 0.90 and Pearson and intraclass correlation coefficients ranging from 0.84–0.93 and 0.82–0.90, respectively, indicating high internal consistency and test–retest reliability.[34] We have obtained the Chinese version of the FACT-C from the official website (https://www.facit.org) and acquired permission to use it.

The Chinese version of range and differentiation of emotional experience scale (RDEES)

Emotional granularity will be measured at baseline (T0), immediately post-intervention at week four (T1), and four-week post-intervention (T2) using RDEES. It was developed by American scholars Kang and Shaver in 2004.[35] The original English version comprises 14 items across two subscales: Range and Differentiation. In 2013, Chinese researchers deleted 3 items from the original scale after translation and cultural adjustment, and finally obtained the Chinese version of the RDESS, which consists of 11 items, including the range of emotional experience and emotional experience differentiation dimensions, with a Cronbach's alpha coefficient of 0.82.[36]

The Chinese version of difficulties in emotion regulation scale (DERS)

Emotion regulation will be measured at baseline (T0), immediately post-intervention at week four (T1), and four-week post-intervention (T2) using DERS. The version of the scale was developed in 2004 with 36 items to assess multidimensional challenges in emotion regulation, including nonacceptance of emotions, difficulties engaging in goal-directed behavior, impulse control issues, lack of emotional awareness, limited access to regulation strategies, and lack of emotional clarity.[37] The English version has Cronbach's α of 0.93 and test-retest reliability (ICC=0.88) over four to eight weeks. Then the scale translated by Wang et al in 2007, The Chinese version has Cronbach's α of 0.87, and test-retest reliability (ICC=0.87).[38]

Process evaluation and acceptability

A process evaluation will be conducted to explore participant acceptability. At the end of the program, a purposive sub sample of 6 to 10 participants from the intervention group will be invited to participate in 30-minute semi-structured individual interviews. Conducted by a nursing researcher in a hospital interview room or via online meeting, these interviews aim to identify the strengths and limitations of the program, understand its perceived appropriateness, and gather insights to improve future delivery. The perceived accuracy of AI generated emotion identification and participant acceptability. The accuracy of AI interpretation will be assessed via participant self-report using a 1 to 10 visual analogue scale, completed after AI emotion feedback episode, with higher scores indicating greater subjective alignment between the AI interpretation and the participant's actual emotional experience. Scores will be summarized as mean and standard deviation at the participant level.

Participant timeline

The time schedule of enrollment, interventions, and outcome assessments for trial participants is outlined in Table 1. The timeline spans from the initial eligibility screening prior to baseline through the completion of the trial follow up at week eight.

Table 1: Participant timeline: schedule of enrollment, interventions, and assessments.

Timepoint	Trial period				
	Enrollment	Allocation	Intervention period	Post-intervention	Follow-up
	t−1 to 0	0	Weeks one to four	Week four (T1)	Week eight (T2)
Enrollment					
Eligibility screening	Yes				
Informed consent	Yes				
Demographic and clinical characteristics	Yes				
Baseline assessments	Yes				
Randomization		Yes			
Interventions					
AI-integrated emotional granularity growth (AI-EGG) program			Will be delivered		
Usual care			Will be provided		
Assessments					
Quantitative feasibility outcomes[a]	Yes		Yes	Yes	Yes
Resilience (CD-RISC-10)	Yes			Yes	Yes
Quality of life (FACT-C)	Yes			Yes	Yes
Emotional granularity (RDEES)	Yes			Yes	Yes
Emotion regulation (DERS)	Yes			Yes	Yes
System usability scale (SUS)				Yes	
Perceived accuracy of AI emotion interpretation				Yes	
Qualitative acceptability interviews[b]				Yes	

t−1 to 0: Screening and baseline period before randomization; 0, time of randomization; CD-RISC-10: 10-item Connor–Davidson resilience scale; FACT-C: functional assessment of cancer therapy–colorectal; RDEES: range and differentiation of emotional experience scale; DERS: difficulties in emotion regulation scale; SUS, system usability scale; [a] quantitative feasibility outcomes include recruitment rate, retention rate, intervention adherence, platform-generated engagement data completion rate, and feasibility of outcome assessment completion, derived from study records collected throughout the study period; [b] semi-structured interviews will be conducted with a purposive subsample of participants in the intervention group to explore the acceptability, appropriateness, and perceived usefulness of the AI-EGG program

Sample size estimation

As a pilot study, the sample size is intended to estimate feasibility parameters and generate preliminary estimates of treatment effects rather than formally test efficacy hypotheses. For the pilot RCT, 15 participants per arm (30 total completers) are required to achieve acceptable precision in estimating the standard deviation for future power calculations, assuming a medium standardized effect ($\delta \approx 0.50$) and a main trial powered at 90%.[39]

Given our primary progression criteria, retention ≥70% and intervention adherence ≥80%, the effective yield per enrolled participant is $0.70 \times 0.80 = 0.56$.

To ensure at least 15 participants per arm meet both criteria, we therefore plan to recruit 27 participants per arm ($15/0.56 \approx 26.8$). We will enroll a total of 54 patients.

Data collection and management

Questionnaire data will be collected electronically through the Wenjuanxing platform. Automated platform logs will capture intervention engagement, EMA completion, and system usage metrics. Data integrity will be ensured through range checks, completeness checks, and routine audits throughout the study period. The encrypted dataset will be stored on a designated password-protected computer within the department, with access restricted to the principal investigator, co-investigators, and institutional review boards after completion of data collection. Trial conduct will be monitored periodically by the research team, including review of recruitment progress, protocol adherence, participant safety, and data quality. Any protocol deviations will be documented and reported according to institutional requirements. The project coordinator and research assistants will oversee data entry and recruitment monitoring, particularly during the initial recruitment phase. Intervention fidelity will be

assessed through automated logs tracking login frequency, emotion identification activities, and strategy follow-up completion. Fidelity of nurse-delivered support for high-risk cases will be monitored using predefined management protocols. To promote retention, automated reminders for scheduled assessments and follow-up contacts from research assistants will be provided for incomplete questionnaires. For participants who discontinue the intervention, available outcome data collected before withdrawal will be retained and analyzed according to the statistical analysis plan.

Adverse events

Participation in this study is considered low risk. The intervention involves structured reflection on emotional experiences and cancer-related challenges, which may occasionally elicit transient emotional discomfort. The intervention also requires regular engagement with online activities during the four-week study period, which may impose a minor time burden. All adverse events (AEs) and serious adverse events (SAEs) related to study participation will be documented and reported to the relevant ethics committees in accordance with institutional requirements.

Safety monitoring procedures and quality assurance

Given the minimal-risk nature of this behavioral intervention, an independent data monitoring committee will not be established. Oversight will be provided by the principal investigator and research team through regular study monitoring meetings.

Participant safety will be supported through an automated risk monitoring system embedded within the AI-EGG platform. Participant inputs will be continuously screened using predefined keyword and semantic detection algorithms for indicators of psychological crisis, including self-harm, suicidal ideation, or severe emotional distress. When a potential risk is detected, an automated alert will be generated, and the participant will receive guidance to access appropriate support services. Simultaneously, designated oncology nurses will be notified to conduct follow-up assessment and facilitate referral where necessary. Participants identified as being at moderate or high risk will be referred to appropriate psychological or mental health services according to predefined escalation procedures.

Data quality will be maintained through electronic data capture, automated platform logs, routine data audits, completeness checks, and range checks.

Questionnaire data will be collected through the Wenjuanxing platform, while intervention engagement, EMA completion, and system usage metrics will be recorded automatically by the AI-EGG platform.

All study data will be encrypted and stored on password-protected institutional devices. Access will be restricted to authorized members of the research team and relevant ethics oversight bodies.

Intervention fidelity will be evaluated using automated platform-generated indicators, including login frequency, completion of emotion identification activities, and completion of strategy follow-up prompts. Fidelity of nurse-delivered support for high-risk cases will be monitored using predefined management protocols to ensure consistency of response and escalation procedures.

Data analysis

All quantitative analyses will be conducted using R statistical software (version 4.5.2). Data will first be examined for completeness and distributional assumptions. Normality of continuous variables will be assessed using graphical methods and the Shapiro–Wilk test. Descriptive statistics will be used to summarize all study variables. Categorical variables will be presented as frequencies and percentages, whereas continuous variables will be summarized using means and standard deviations for normally distributed data or medians and interquartile ranges for non-normally distributed data.

As this is a pilot randomized controlled trial, feasibility outcomes will constitute the primary focus of the analysis. Recruitment, retention, intervention adherence, EMA completion, and data completeness will be summarized using descriptive statistics. Proportions will be presented with corresponding 95% confidence intervals, where appropriate. System usability will be measured using the SUS, and participant-reported perceived accuracy of AI emotion interpretation will be summarized using means and standard deviations.

Secondary outcomes will be analyzed according to the intention to treat principle. Changes in outcomes over time between the intervention and control groups will be examined using linear mixed effects models, with group, time, and the group by time interaction included as fixed effects, and participant included as a random effect. Estimated mean differences, 95% confidence intervals, and effect sizes will be reported. Missing data will be examined for patterns, and linear mixed effects models will accommodate incomplete repeated measures data under the assumption that data are missing at random. Sensitivity analyses using complete case data may be conducted to assess findings robustness. Qualitative data from the process evaluation will be transcribed verbatim, managed using NVivo software, and analyzed via thematic analysis. Initial coding will commence immediately after each interview, with themes iteratively refined through team discussions to ensure credibility. Data triangulation will be used to enhance trustworthiness, and no subgroup analyses are planned due to the limited sample size of this pilot trial. No interim analysis or stopping guideline is planned for this pilot trial.

Ethical consideration

This study will comply with the Declaration of Helsinki. Ethical approval has been obtained from the Human Subjects Ethics Sub-Committee (HSESC) of the Hong Kong Polytechnic University (HSEARS20260427001). Furthermore, institutional ethical approval has been secured from Soochow University (SUDA20251015H10) covering its two affiliated teaching hospitals and from the Kunshan First People's Hospital (2025-03-073-H00-K01). Any protocol modifications will be reported to these ethics' committees for review before implementation. All participants will provide written informed consent prior to enrollment. The trial is registered at the ClinicalTrials.gov Protocol Registration and Results System (NCT07611071). Findings will be disseminated through peer reviewed journals and academic conferences.

Informed consent

Informed consent will be obtained from all participants before enrollment. Participation will be entirely voluntary, and participants may withdraw from the study at any time without any consequences to their medical care. The principles of respect for persons, beneficence, non-maleficence, and justice will be upheld throughout the study.

Ancillary and post-trial care

Participants requiring psychological support identified during the study will be referred to appropriate clinical services. No additional financial compensation or post-trial intervention access is planned. Given the psychological nature of the intervention, minimal risk of emotional discomfort may arise when participants reflect on their experiences. To mitigate this, participants will be allowed to skip any questions or discontinue participation, and referral pathways to appropriate psychological or clinical support services will be provided if needed.

Confidentiality and access to data

All study data will be stored on secure, password-protected, and encrypted servers. Personal identifiers (e.g., names and contact information) will be stored separately from research data and replaced with unique study identification codes. Only authorized members of the research team will have access to identifiable participant information. De-identified data will be used for analysis and reporting.

The AI-based conversational system will be integrated into the study platform through secure large language model (LLM) application programming interfaces (APIs). Only enterprise-grade or research-oriented API services with contractual data protection safeguards will be used. Participant data transmitted to the AI service will be de-identified or pseudonymized whenever feasible. In accordance with the provider's enterprise data-use policy, data submitted through the API will not be used for model training, secondary commercial purposes, or unauthorized retention.

All data management procedures will comply with institutional requirements and applicable data protection regulations. Access to the final trial dataset will be restricted to the principal investigator and authorized members of the research team.

Dissemination

Findings will be disseminated through peer-reviewed publications, conference presentations, and academic reports. Participants may request a summary of study findings upon study completion.

DISCUSSION

Young and middle-aged CRC survivors face unique survivorship challenges, including employment, family responsibilities, parenting, financial obligations, and social role expectations.[10,40-42] Consequently, they may experience greater psychological distress, fear of cancer recurrence, unmet supportive care needs, and poorer adjustment than older survivors.[9,43] Although resilience is associated with lower symptom burden and greater post-traumatic growth, how it can be effectively strengthened remains incompletely understood.[44-47]

Existing resilience-enhancing interventions, including cognitive interventions, positive psychological interventions, and attention and interpretation therapy (AIT), have demonstrated beneficial effects among cancer populations.[48] However, these interventions primarily target cognitive appraisals, coping styles, or psychosocial resources rather than underlying emotional processes.[16,49] Our recent scoping review identified emotion identification, emotion regulation, and emotional support as key emotional strategy domains, but found limited attention to interventions explicitly targeting emotional differentiation.[50] The present study therefore targets emotional granularity, defined as the ability to precisely distinguish among closely related emotional states, as a potentially modifiable target for resilience enhancement.[17,18,51]

The theoretical rationale for AI-EGG is grounded in Gross's extended process model of emotion regulation, which conceptualizes regulation as a dynamic sequence of emotion identification, strategy selection, implementation, and monitoring.[21] Difficulties in emotion identification may compromise subsequent strategy selection, whereas higher emotional granularity may facilitate contextually appropriate coping responses and reduce emotional distress.[51-53] Our preliminary mixed methods work further suggested that emotional granularity may contribute to resilience through improved emotion regulation.

A hierarchically organized emotion wheel was selected as the core intervention component. Although emotion wheels are widely used to support emotional awareness, their potential as an active training tool has received limited empirical investigation.[28] Emerging evidence suggests that increased emotion knowledge and repeated emotional self-monitoring can improve emotion differentiation.[54,55] By guiding participants from broad to more specific emotional labels, AI-EGG provides structured practice in distinguishing similar emotional states and expanding emotional vocabulary.

Furthermore, artificial intelligence is incorporated primarily to facilitate sustained engagement rather than as the therapeutic mechanism. Compared with traditional psychological therapies requiring substantial clinician involvement and repeated face-to-face sessions, mobile health technologies can provide personalized and scalable emotional support.[25,49,56-58] By integrating the emotion wheel, emotion diaries, emotional reflection, and AI-guided strategies, AI-EGG enables accessible emotional differentiation practice in everyday settings.

As a pilot randomized controlled trial, the primary purpose is to establish feasibility rather than definitive effectiveness.[59] Strengths include the systematic development of the intervention based on theoretical evidence, a scoping review, and qualitative exploration of patient needs, as well as the use of platform-generated engagement and emotional experience data to provide information on intervention use in real-world settings. Limitations include the small sample size, lack of participant and intervention personnel blinding, variable self-directed intervention exposure, uncertainty regarding implementation of AI-generated recommendations, and limited generalizability due to recruitment from three hospitals and smartphone requirements.

Despite these limitations, this pilot trial addresses a gap in oncology research by evaluating the feasibility, acceptability, and preliminary effects of an AI-assisted emotional granularity intervention for young and middle-aged CRC survivors. Findings will inform refinement of the AI-EGG platform and the design of a future definitive trial.

Trial status

Protocol version 1.0, dated 03 June 2026. The study set-up period started in June 2026 and included the development and testing of the AI EGG platform, investigator training, refinement of study procedures, and quality assurance procedures. Following the completion of regulatory filing requirements for the WeChat mini program, participant recruitment and randomization commenced in July 2026 and were recently completed across all three teaching hospitals in Suzhou, China. The study is currently in the intervention implementation phase, with participants receiving the four-week AI-EGG intervention remotely via the WeChat mini program. The trial is registered at the ClinicalTrials.gov, NCT07611071.

CONCLUSION

This study will be the first pilot randomized controlled trial to examine the feasibility and acceptability of an AI-assisted emotional granularity intervention among young and middle-aged colorectal cancer survivors. The study will provide evidence to evaluate the feasibility, acceptability, and preliminary efficacy of the AI-EGG intervention, including its potential effects on emotional granularity, emotion regulation, resilience, and quality of life. The findings will inform further refinement of the intervention and the design and implementation of a future definitive randomized controlled trial. This study may provide an important foundation for developing feasible and scalable technology-assisted emotional support in oncology nursing.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Zhang J, Chung JOK, Li J, Chen W, Li Y, Yorke J. Efficacy of artificial intelligence-integrated emotional granularity growth at improving resilience and quality of life in young and middle-aged colorectal cancer survivors: protocol for a pilot randomised controlled trial. Int J Clin Trials 2026;13(4):423-35.