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Mobile health-based remote interaction management intervention for patients with low anterior resection syndrome: study protocol for a randomised controlled trial

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Note

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Key Words: rectal cancer; low anterior resection syndrome; mHealth; quality of life

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ABSTRACT

Introduction Low anterior resection syndrome (LARS) involves bowel dysfunction after sphincter-preserving surgery for rectal resection that significantly impacts patients' quality of life. The improvement of LARS largely depends on patient self-management behaviour; however, insufficient information about supportive care and weak awareness of self-management lead to poor self-management behaviour. Motivational interviews (MIs) explore and change patients' ambivalence during the conversation, thereby changing and maintaining healthy behaviours to enhance effective participation. In recent years, mobile health has been widely used in clinical practice, providing continuous information support and remote interaction. However, current online information on LARS is suboptimal, websites are highly variable, important content is often lacking and the material is too complex for patients. Therefore, this study will evaluate the impacts of a remote LARS interaction management intervention based on a WeChat applet ("e-bowel safety") and MIs on patients with LARS.

Methods and analysis This study will be a single-blind, two-arm randomized controlled trial involving patients with LARS in three tertiary grade A general hospitals who will be randomised into two groups. The intervention group will use the "e-bowel safety" applet and the intervention team will conduct a monthly MI about syndrome management. The control group will receive an information booklet that contains the same information as that provided in the "e-bowel safety" informational module. The intervention will last for 3 months, followed by three months of follow-up. The primary outcome will be global quality of life (QoL); the secondary outcomes will include bowel function , social support, self-management from baseline to 3 and 6 months, and pelvic floor muscle exercises, including the duration, frequency and type, from 3 and 6 months.

Ethics and dissemination Ethics approval was granted by the Clinical Medical Research Ethics Committee of the First Affiliated Hospital of Anhui Medical University(PJ2022-07-53).

Trial registration number ChiCTR2200061317

Strengths and limitations of this study

1.Our intervention is based on mobile health and can provide dynamic, remote, and personalized coaching to patients.

2.The trial, combined with motivational interviewing techniques, will provide insight into self-motivation and self-management willingness to improve compliance.

3.The trial will be limited to patients with smartphones and WeChat, which could lead to selection bias.

4.Participants will be recruited from hospital sites in one city, and only patients with LARS scores of 21 points will be included, although patients without LARS may also have bowel dysfunction.

INTRODUCTION

Colorectal cancer ranks third and second in terms of cancer incidence and mortality worldwide;[1] rectal cancer accounts for a higher proportion than colon cancer, and medium and low rectal cancer account for approximately 70% of rectal cancer cases.[2]With the progress of medical technology, patients' willingness and the development of neoadjuvant therapy, sphincter-preserving surgery (SPS) has become the first choice for resection of middle and low rectal cancer, avoiding the physical, psychological and social adverse effects on patients caused by artificial anus.[3,4]However, 70%~90% of patients have long-term bowel dysfunction after surgery, such as defecation urgency, gas and stool incontinence, stool fragmentation, obstructed defecation, and defecation aggregation, which are known as low anterior resection syndrome (LARS).[5] Longitudinal studies have found that patients still have LARS up to 15 years after surgery.[6] An international consensus study defined LARS as effects on patients after an anterior resection (sphincter-saving rectal resection).[7] Patients may experience at least one of the symptoms (variable and unpredictable bowel function, altered stool consistency, increased stool frequency, repeated painful stools, emptying difficulties, urgency, incontinence and/or soiling) resulting in at least one of the consequences (toilet dependence, preoccupation with bowel function, dissatisfaction with bowels, strategies and compromises, impacts on

mental and emotional well-being, impacts on social and daily activities, impacts on relationships and intimacy and/or impacts on roles, commitments and responsibilities).

The improvement in LARS largely depends on patient self-management behaviour.[8,9] However, variable bowel symptoms, receiving insufficient supportive care, and weak self-management awareness lead to poor patient self-management.[10,11] Based on a patient's symptom experience, developing targeted management plans and constantly improving them according to the patient's situation can help them effectively manage symptoms.[12] However, the intrinsic motivation of patients is often ignored and interventions rarely promote "effective participation", defined empirically as sufficient participation with the intervention to achieve the intended outcomes.[13] Motivational interviewing (MI) has been demonstrated to be an effective approach to help patients adopt positive health behaviours.[14] With the rapid development of information technology, mobile health has become an important means of patient health management, which can encourage patients to obtain timely symptom management measures and reduce the burden of symptoms.[15] The WHO defined mobile health as "medical and public health practices supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices".[16] Meanwhile experts advocate that in the current COVID-19 pandemic, public health departments should use multiple strategies to gain public trust and accelerate the adoption of tools such as digital contact tracing applications.[17] However, current online information on LARS is suboptimal, websites are highly variable, important content is often lacking and the material is too complex for patients.[18]

In 2017, Tencent officially released WeChat applet, defined as " a new way to connect users and services that is easy to access and spread, and provides a good experience". Compared with mobile apps, the WeChat applet does not need installation, occupies a small space and is widely used in patients' health.[19-21] In the early stage, we formed a multidisciplinary team to build a remote LARS interaction management based on a sound theoretical framework and symptom

management theory, and was vetted in a focus group and semistructured interviews involving 10 patients, 14 healthcare professionals. After optimization, 101 LARS patients and 113 healthcare professionals were selected by the convenience sampling method to complete the system usability questionnaire. The results of the questionnaire were good.[22] The WeChat applet has been registered with the China Copyright Protection Center (Registration Number: 2021SR1770686). We organized focus group interviews with LARS professionals, psychologists and patients on the remote LARS interaction management intervention based on the WeChat applet ("e-bowel safety") and MIs intervention program embeded "5W1H" principle. The final intervention version was ascertained by 26 LARS professionals from five large hospitals and universities. This intervention program aims to provide targeted, specialized, and individualized guidance to patients and improve the convenience and "effective participation" of patients in managing LARS. In addition, a semistructured interview will be conducted after the intervention to comprehend the patients' satisfaction, perceptions and their experiences with the intervention.

METHODS AND DESIGN

Study setting

This will be a randomized, single-blind, two-arm pragmatic trial to evaluate the effects of LARS information, online counselling, peer support, pelvic floor muscle training and remote supervision for LARS patients based on "e-bowel safety" applet and MIs. The intervention group will receive LARS remote interaction management based on "e-bowel safety" applet and MIs. The control group will receive an information booklet that contains the same information as that provided in the "e-bowel safety" informational module and receive the standard LARS counselling that is routinely provided by their hospital. The intervention will last for 3 months, followed by three months of follow-up. The study will be conducted from 15 July 2022 to 15 January 2023 in three tertiary grade A general hospitals.

Eligibility and recruitment

The inclusion criteria are as follows:(1) patients aged 18–70 years; (2) patients who underwent SPS for rectal cancer or ostomy closure 1–3 months previously (0–15 cm

from the anal verge); (3) patients or primary caregivers who use WeChat; (4) LARS scores≥21; and (5) patients who can identify their own condition and provide informed consent in this study. The exclusion criteria are as follows: (1) patients who participated in other clinical experiments; (2) patients with other chronic intestinal diseases; (3) patients who underwent major colonic resection in addition to proctectomy; and (4) patients who are unable to read and comprehend Chinese. When patients in the hospital databases meeting the inclusion criteria will receive recruitment information by telephone or mail.

Sample size calculation

The primary outcome measures were quality of life as the calculation standard. A large cross-sectional survey of patient quality of life measured by the EORTC-QLQ-C30 for rectal cancer showed an average patient score of 77±19.[23] According to the consensus guidelines for supporting randomized controlled trials using the EORTC-QLQ-C30, a mean difference of 10 points in global QoL is the most appropriate expected effect size for interventions aimed at improving QoL in cancer patients.[24] Therefore, if α=0.05 and 1-β=0.80, 45 patients will be needed in each group. Given the expected risk of 20% attrition during the study period, the adjusted final sample size is 54 patients per group (a total of 108 patients).

Randomisation

Eligible patients will be randomly assigned to the control and intervention groups using block sizes of 6, stratified by participant baseline LARS scores, hospital site and postoperative duration(1,2 or 3 months postoperative). The data collector will be unaware of patient assignments at baseline and at 3 and 6 months of the study. To prevent contamination between the different groups, "e-bowel safety" applet should be reviewed by the research team before patients logging in.

The research team and "e-bowel safety" applet introduction

The research team includes 1 head nurse (group leader), 2 gastrointestinal surgeons (intermediate titles or above), 1 clinical psychologist, 2 nurses with supervisor titles or above, 1 ostomy nurse, 1 nutrition support nurse, 1 pelvic floor rehabilitation nurse, 1 software engineer and 3 graduate students. The team members will attend two training

sessions for the intervention program and the use of "e-bowel safety" applet provided by the group leader. The clinical psychologist will provide two training sessions for MIs, and all team members should pass the exam. One team member will be on shift each week to help patients, and others will be present throughout the duration of the study to support the team member if any undue problems occur.

The "e-bowel safety" applet content module includes the following: The symptoms experience module, which includes patients' stories, where patients can post their experiences in treating the disease or in self-management, and their peers will be able to respond to each post with comments and recommendations; A health diary, first daily landing and spontaneous pop-ups are provided for patients to record their diet, sleep, activity, and defecation on the previous day; The symptom management policy module, which includes the LARS informational module (LARS knowledge, daily life management strategies, and social communication strategies) that are presented in text and graphic form; Physical training which includes guiding patients in abdominal massage, pelvic floor muscle exercises and leg exercises in the form of videos; Online communication, where patients can always ask the intervention team questions; The Clock and Points module, where the system automatically generates points according to the length of time spent reading LARS knowledge and performing physical training hours; Intelligent reminders, which allows intervention team to push new messages to patients, and automatically or manually regularly remind patients about functional exercise. Patients can also set the reminder function according to their own time; The symptom management effect evaluation module: In the self-health assessment, such as bowel symptoms, nutrition assessment, the results of the check to upload automatically. The "e-bowel safety" applet function module will include the following: A voice broadcast, considering that the patients are older, with vision loss and low education levels, where the written content can be broadcast by voice; Audio guidance, with an animated video guide; and Collection and search, where important content can be clicked in the collection module, and patients can search for the target content according to the keywords. The medical terminal also has the functions of push information management, regular reminder management, interactive circle

management, user permission management and statistical analysis management. The communication board will be monitored on a daily basis. Figure 1 presents the "e-bowel safety" applet partial interface.

Intervention group

The intervention group will receive a LARS remote interaction intervention program based on "e-bowel safety" applet combined with MIs. During the formal intervention, the intervention team will instruct the patients to sign the informed consent form and explain the precautions during the intervention; guide patients to register on the applet and explain the applet functions, modules, content and methods of use; and issue the applet use manual. The intervention team will evaluate the patients' bowel symptoms and self-management willingness every month from the beginning of the intervention to conduct MIs with the patients that will improve their self-management awareness. After the MIs,the team member will make a daily exercise duration and frequency plan with the patients ,set up the automatic clock-in reminder on the applet, read the symptom management strategy module to make a diet plan, and record a health diary and functional exercise clock-in every day. According to the arrangement of the group leader, the intervention team responds to the questions from the patient online consultation every Tuesday and Friday from 7 PM to 9 PM, provides personalized guidance for patients and feedback on patient functional exercise and health diaries, adjusts the patient management plan appropriately, and reports the weekly point rankings. The team will organize patients and their peers to communicate with home self-management skills online every week, understand the confusion of the patients, and build patient confidence in recovery through successful cases. Patients can also ask questions or share their self-management experiences in the "Peer Story" modules at any time or post comments to other patients, which will be officially released after review by the intervention team.Figure 2 shows System architecture diagram of Symptom Management Theory.

Control group

Participants in the comparison group will receive a paper copy of the LARS patient information booklet that contains the same information as that provided in the

"e-bowel safety" informational module and an attached health diary and will have access to the standard LARS counselling that is routinely available at their hospital. Both groups will receive phone/email reminders from data collectors to fill out the questionnaire and give feedback on the number and length of pelvic floor muscle exercises, providing feedback on the three-month intervention.

The main difference between the two groups will be whether they receive the "e-bowel safety" applet and MIs. The study flow chart is shown in Figure 3.

Data collection methods

Demographics (age, sex, BMI, marital status, education level, primary caregiver caregivers, residence), medical comorbidities and disease and treatment characteristics, including known predictors of poor bowel function [e.g., tumour height, neoadjuvant radiotherapy, type of proctectomy (total versus partial mesorectal excision)] will be acquired from the database of the patient treatment hospital. Data on quality of life and LARS scores will be obtained from questionnaires completed by the patients at different stages.

Outcome measures and data collection

The primary outcome will be the Global Quality of Life (QoL), as measured by the European Cancer Research and Treatment Organization Quality of Life Questionnaire-Core 30(QLQ-C30). Secondary outcomes will include bowel function measured by the LARS score, bowel symptoms self-management behaviour measured by the Bowel Self-management Behaviour Questionnaire (BSSBQ), social support measured by the Perceived Social Support Scale (PSSS), the pelvic floor muscle training. The measurement tools and timing are shown in Table 1.

Quality of life

Quality of life will be measured by the EORTC-QLQ-C30. It consists of 30 questions, which are aggregated into one global QoL scale, five functional scales, three symptom scales and six single items. The EORTC-QLQ-C30 has been well validated in rectal cancer patients and is correlated with the severity of LARS.[25,26]

Bowel function

Bowel function will be measured by the LARS score, which contains five items aimed at symptoms of bowel dysfunction. The LARS score allows physicians to categorize patients as having major LARS (30～42 points), minor LARS (21～29 points) or no LARS (0 ～20 points). The LARS score has been well validated in rectal cancer patients in China.[27,28]

Self-management

The Bowel Symptoms Self-management Behaviours Questionnaire (BSSBQ) for Chinese rectal cancer patients after sphincter-preserving surgery will be used to test its psychometric properties. The BSSBQ consists of five functional scales and 20 items. The effect record is scored as follows: 0-3 points (0= no effect, 1= some effect, 2= some effect, 3= very effective).[29]

Social support

The Perceived Social Support Scale (PSSS) consists of 12 items, which mainly include three dimensions: family support, friend support, and other support. The Likert 7 scoring method is used, from "extreme disagreement" to "strong consent" with scores of 1 to 7, and the total score ranges from 12 to 84. A higher total score indicates that individuals feel more social support. The Cronbach's coefficient of this scale was 0.899.[30,31]

Pelvic floor muscle training

The types of pelvic floor muscle training, such as pelvic floor muscle training, fork and leg anal lifting training, hip and anal lifting training,average daily exercise time, and exercise frequency, will mainly be recoded as pelvic floor muscle training.

Table1 Measurements for primary and secondary outcomes and data collection

Outcome	Measurements	Baseline	3 months	6 months
Primary outcome				
Quality of life	EORTC-QLQ-C30[25,26]	√	√	√
Secondary outcomes				
Bowel function	LARS score[27,28]	√	√	√
Self-management	Bowel Symptoms Self-management Behaviors Questionnaire(BSSBQ)[29]	√	√	√

Social Support	Perceived Social Support Scale, PSSS[30,31]	√	√	√
Pelvic floor muscle exercise	Duration Frequency Type （Pelvic floor muscle exercise, fork and leg anal lifting exercise, hip and anal lifting exercise, leg exercise）		√	√
Patients' thinkings	Semistructured interview (Experience,Satisfaction)		√	

Statistical analysis and data management

All data will be analysed using SPSS (V.23.0). Descriptive data will be computed, including means with standard deviations, medians with ranges, or frequencies with proportions, where appropriate. Continuous outcomes will be compared using t tests or Wilcoxon rank-sum tests, and categorical outcomes will be compared using chi-square tests. Analyses will be conducted on an intention-to-treat (ITT) and per-protocol population basis. First, the baseline survey data will be analysed to determine whether the differences in the basic characteristics of the two groups before the intervention are statistically significant. Outcomes will be collected at the times defined in the study protocol.

The Clinical Medical Research Ethics Committee of the First Affiliated Hospital of Anhui Medical University will be responsible for the data monitoring committee and for auditing trial conduct. The questionnaires will be collected by researchers and recorded in the research electronic data collection system, which will be used as an electronic data collection (EDC) system for long-term data storage and management. The original data will be recorded in a timely and accurate manner, and a copy of the report will be kept in the laboratory. All laboratory data will be identified with a code number to ensure the confidentiality of the subjects' data. The chief investigator can directly access the dataset, and the data scattered to the project team members cannot identify any participant identity information.

Patient and public involvement

Patient and public involvement (PPI) has played a vital role in this study. When building the applet, patients were interviewed through semistructured interviews to understand their willingness and needs for mobile health use. In the applet usability

test, the applet was modified in combination with patient recommendations. In the construction of the intervention program, the duration, timing and form of the intervention were determined refer to the patients' opinions.

ETHICS AND DISSEMINATION

Ethics approval was granted by the Clinical Medical Research Ethics Committee of the First Affiliated Hospital of Anhui Medical University. All participants will be fully informed of the contents of this study before they are recruited and will sign an informed consent form. The results of this study will be presented at national and international conferences and published in peer-reviewed journals. Original data without personally identifiable information will be available after the article has been published.

DISCUSSION

This study focuses on the feasibility of a remote interaction intervention program for LARS patients based on "e-bowel safety" applet and MIs, provide supportive care information, and conduct regular MIs with dynamic, professional and personalized guidance to improve the "effective participation" of patients and improve their quality of life. After the intervention, semistructured interviews will be conducted to understand patient satisfaction and recommendations for the duration and form of the intervention.

At present, the common forms of patients' bowel management include brochures, lectures, telephone, SMS, and nursing clinics. Although they play a certain positive role, the above methods are time-consuming and laborious, have low patient acceptance, have a limited audience, and are not sustainable.[32] It is impossible to help patients solve existing problems in real time or remotely, and the COVID-19 pandemic hindered the return of postoperative patients to the hospital for review. This study, considered from the patient perspective, provides patients with an accessible, comprehensive, and shared form of remote interaction intervention with health professionals–patient participation. On the basis of a literature review and clinical practice, our team improved health education information, showed and met the learning needs of different patients in various forms of text and audio to improve

patient acceptance. Health diaries and regular exercise clocking enable our team to remotely monitor patients' diets, exercise, management strategies and defecation in real time, provide personalized health guidance, and develop exercise programs with patients to increase their effective participation. Patients can post LARS management strategies to strengthen peer support. Providing points for gifts and other incentive systems, improving the completion rate of patient health diaries and the number of regular punching cards, improving the enthusiasm of patients to use "e-bowel safety" can help them better manage their bowel symptoms. Staged MIs, based on the patients' willingness to manage their bowel symptoms, mining patient and social motivational resources and reinforcing motivation allows patients to consciously combine their own motivational resources, psychological expectations and compliance with rehabilitation behaviour, which effectively drives patients to start and maintain their vitality and enthusiasm for the implemented behaviour.

Limitations

The trial is limited to patients with smartphones and WeChat, which could lead to selection bias. Although the participants will be recruited in one city and only patients with LARS scores of 21 points will be included, patients without LARS may also have bowel dysfunction.

Contributors All listed authors certified their contribution. SH, SY: Study design and revisions for important intellectual content. HL, PZ, XP, DY, TW, MF, HH: the First manuscript writing. All authors read and approved the final manuscript.

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Competing interests There are no conflicts of interest to declare.

REFERENCES

1 Siegel RL, Miller KD, Goding Sauer A, et al. Colorectal cancer statistics, 2020. *CA Cancer J Clin* 2020;70(3):145-164.

2 Liu ZCh, Li ZhX, Zhang Y, et al. 2020 Global Cancer Statistics Report Interpretation. *Electronic Journal of Comprehensive Treatment of Oncology* 2021;7 (02):1-14.

3 Heald RJ, Ryall RD. Recurrence and survival after total mesorectal excision for rectal cancer. *Lancet* 1986;1(8496):1479-1482.

4 Marwan K, Staples MP, Thursfield V, et al. The rate of abdominoperineal resections for rectal cancer in the state of Victoria, Australia: a population-based study. *Dis Colon rectum* 2010;53:1645-1651.

5 LARS TRENTI L, GALVEZ A, BIONDO S, et al. Quality of life and anterior resection syndrome after surgery for mid to low rectal cancer: a cross-sectional study. *Eur J Surg Oncol* 2018;44(7):1031-1039.

6 Pieniowski EHA, Palmer GJ, Juul T,et al. Low Anterior Resection Syndrome and Quality of Life After Sphincter-Sparing Rectal Cancer Surgery: A Long-term Longitudinal Follow-up. *Dis Colon Rectum* 2019;62(1):14-20.

7 Keane C, Fearnhead NS, Bordeianou LG, et al. International consensus definition of low anterior resection syndrome. *ANZ J Surg* 2020;90(3):300-307.

8 LAI X, WONG FK, CHING SS. Review of bowel dysfunction of rectal cancer patients during the first five years after sphincter preserving surgery: a population in need of nursing attention. *Eur J Oncol Nurs* 2013;17(5):681-692.

9 Pape E, Pattyn P, Van Hecke A, et al. Impact of low anterior resection syndrome (LARS) on the quality of life and treatment options of LARS-A cross sectional study. *Eur J Oncol Nurs* 2021;50:101878.

10 Luo MN, Chen YF, Wen XY, et al. Current status of intestinal function and its influencing factors in patients after anal preservation for rectal cancer. *Chinese Journal of Practical Nursing* 2021;37 (36):2801-2806.

11 Lu LC, Huang XY, Chen CC. The lived experiences of patients with post-operative rectal cancer who suffer from altered bowel function: a phenomenological study. *Eur J Oncol Nurs* 2017;31:69-76.

12 Wu HX, Wu Q, Chen JJ, et al. Case management practice in colorectal tumor patients based on symptom management theory. *Journal of Nursing* 2021;36(19): 28-31.

13 Yardley L, Spring BJ, Riper H, et al. Understanding and Promoting Effective Engagement With Digital Behavior Change Interventions. *Am J Prev Med* 2016;51(5):833-842.

14 Serio C, Gabarda A, Uyar-Morency F, et al. Strengthening the Impact of Digital Cognitive Behavioral Interventions Through a Dual Intervention: Proficient Motivational Interviewing-Based Health Coaching Plus In-Application Techniques. *JMIR Form Res* 2022;6(5):e34552.

15 Saeidzadeh S, Kamalumpundi V, Chi NC, et al. Web and mobile-based symptom management interventions for physical symptoms of people with advanced cancer: A systematic review and meta-analysis. *Palliat Med* 2021;35(6):1020-1038.

16 WHO guideline Recommendations on Digital Interventions for Health System Strengthening. Geneva: World Health Organization; 2019.

17 Grande D, Mitra N, Marti XL, et al. Consumer Views on Using Digital Data for COVID-19 Control in the United States. *JAMA Netw Open* 2021;4(5):e2110918.

18 Garfinkle R, Wong-Chong N, Petrucci A, et al. Assessing the readability, quality and accuracy of online health information for patients with low anterior resection syndrome following surgery for rectal cancer. *Colorectal Dis* 2019;21(5):523-531.

19 Zhao XD, Tao R. Comparison and Analysis of the four mobile application development modes. *Smart Computer and Applications* 2018;8(01):72-75.

20 Xu L, Li J, Zhang X, et al. Mobile health-based gamification intervention to increase physical activity participation among patients with coronary heart disease: study protocol of a randomised controlled trial. *BMJ Open* 2022;12(1):e054623.

21 Zhang X, Wen D, Liang J, et al. How the public uses social media wechat to obtain health information in China: a survey study. *BMC Med Inform Decis Mak* 2017;17(Suppl 2):66.

22 Pang XY, Hu ShH, Li H, et al. Development and availability evaluation of symptom management desk for low anterior resection syndrome in patients with rectal cancer. *Chinese Nursing Management* 2022;22(03):445-449.

23 Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158(3):200-7

24 Hibbard JH, Mahoney ER, Stockard J, et al. Development and testing of a short form of the patient activation measure. *Health Serv Res* 2005;40(6 Pt 1):1918-30.

25 Aaronson NK, Ahmedzai S, Bergman B, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst* 1993;85:365-376.

26 Wang JP, Chen ZhG, Lin WJ, et al. Determination of quality of life in Chinese cancer patients-Trial of EORTC QLQ-C30 in China. *Psychology Journal* 2000;32:438-342.

27 Emmertsen KJ, Laurberg S. Low anterior resection syndrome score: development and validation of a symptom-based scoring system for bowel dysfunction after low anterior resection for rectal cancer. *Ann Surg* 2012;255(5):922-928.

28 Yan JJ, Mou ShY, Tan RF, et al. Empirical study of the Chinese version of the low anterior resection syndrome score table for rectal cancer. *PLA Journal of Nursing* 2015;32(4):12-15.

29 Hou XT, Pang D, Lu Q, etc. Preparation of self-management behavior of rectal cancer and reliability validity test. *Chinese Journal of Nursing* 2016;51(09): 1059-1064.

30 Zimet GD, Powell SS, Farley GK,et al. Psychometric characteristics of the Multidimensional Scale of Perceived Social Support. *J Pers Assess* 1990;55(3-4):610-617.

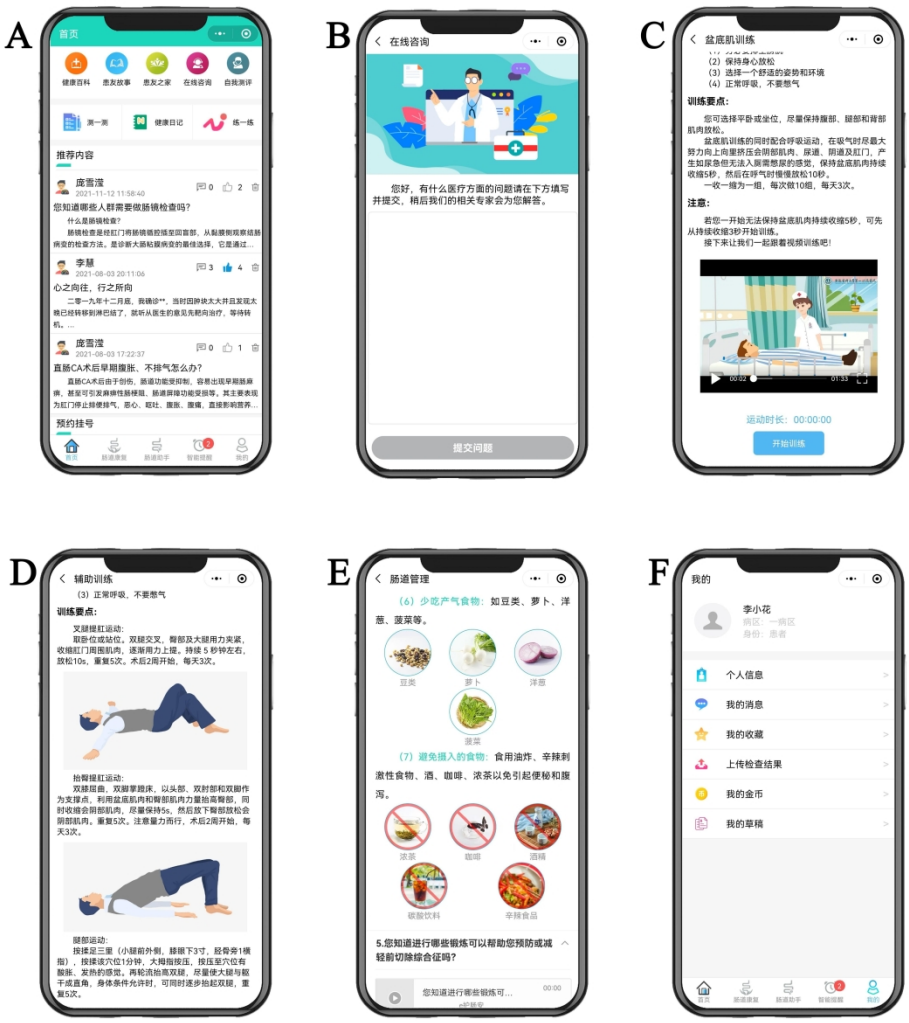
31 Huang L, Jiang QY, Ren WH. Association of coping style, social support and psychosomatic symptoms in cancer patients. *Chinese Journal of Mental Health* 1996;(04):160-161.

32 Cao Y. Effect of individualized health education on self-management ability and condition control in patients with chronic diseases. *International Infection Science (electronic edition)* 2020;9 (02):26-27.

Figure 1 "e-bowel safety" applet interface. A. home page; B. online consultation; C. Text and video to guide pelvic floor muscle training; D. Text and pictures to guide other trainings; E. LARS informational module; F. Personal homepage.

Figure 2 System architecture diagram of Symptom Management Theory.

Figure 3 Study flow chart.



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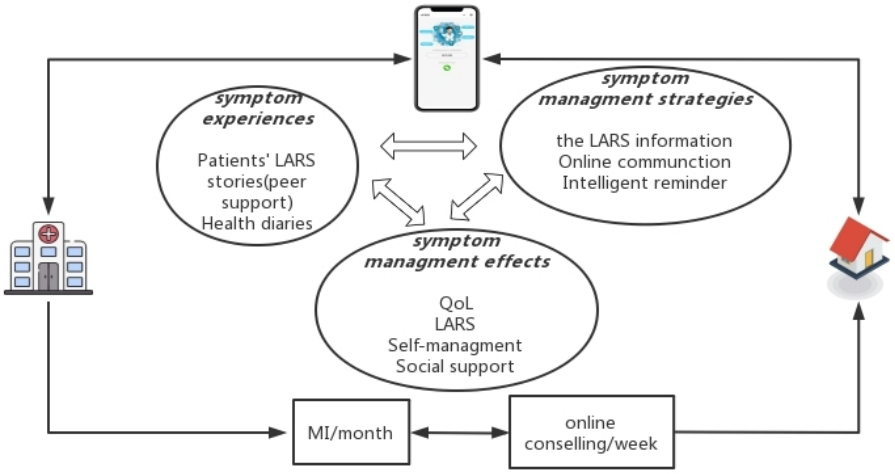

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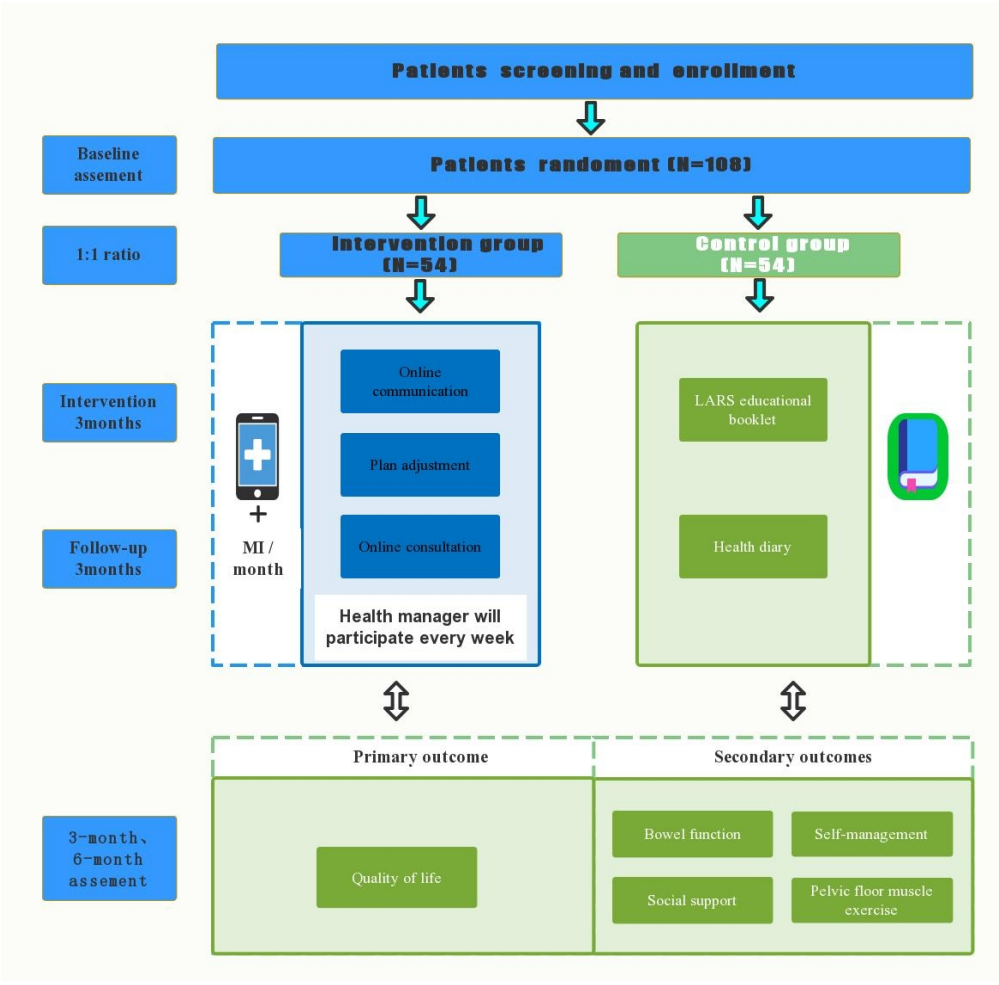

Figure 3 Study flow chart.

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Mobile health-based remote interaction management intervention for patients with low anterior resection syndrome: study protocol for a randomised controlled trial

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Mobile health-based remote interaction management intervention for patients with low anterior resection syndrome: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Low anterior resection syndrome (LARS) involves bowel dysfunction after sphincter-preserving surgery for rectal resection that significantly impacts patients' quality of life. The improvement of LARS largely depends on patient self-management behaviour; however, insufficient information about supportive care and weak awareness of self-management lead to poor self-management behaviour. Motivational interviews (MIs) explore and change patients' ambivalence during the conversation, thereby changing and maintaining healthy behaviours to enhance effective participation. In recent years, mobile health has been widely used in clinical practice, providing continuous information support and remote interaction. However, current online information on LARS is suboptimal, websites are highly variable, important content is often lacking and the material is too complex for patients. Therefore, this study will evaluate the impacts of a remote LARS interaction management intervention based on a WeChat applet ("e-bowel safety") and MIs on patients with LARS.

Methods and analysis This study will be a single-blind, two-arm randomised controlled trial involving patients with LARS in three tertiary grade A general hospitals who will be randomised into two groups. The intervention group will use the "e-bowel safety" applet and the intervention team will conduct a monthly MI about syndrome management. The control group will receive an information booklet that contains the same information as that provided in the "e-bowel safety" informational module. The intervention will last for 3 months, followed by three months of follow-up. The primary outcome will be global quality of life; the secondary outcomes will include bowel function, social support, self-management measured at the baseline, 3 months and 6 months for three times, and patients' thinkings at the end of the intervention(at 3 months).

Ethics and dissemination Ethics approval was granted by the Clinical Medical Research Ethics Committee of the First Affiliated Hospital of Anhui Medical University(PJ2022-07-53).

Trial registration number ChiCTR2200061317

Strengths and limitations of this study

1. Our intervention is based on mobile health and can provide dynamic, remote, and personalized coaching to patients.

2. The trial, combined with motivational interviewing techniques, will provide insight into self-motivation and self-management willingness.

3. The trial will be limited to patients with smartphones and WeChat.

4. Participants will be recruited from hospital sites in one city, and only patients with LARS scores of 21 points will be included, although patients without LARS may also have bowel dysfunction.

INTRODUCTION

Colorectal cancer ranks third and second in terms of cancer incidence and mortality worldwide;[1] rectal cancer accounts for a higher proportion than colon cancer, and medium and low rectal cancer account for approximately 70% of rectal cancer cases.[2]With the progress of medical technology, patients' willingness and the development of neoadjuvant therapy, sphincter-preserving surgery (SPS) has become the first choice for resection of middle and low rectal cancer, avoiding the physical, psychological and social adverse effects on patients caused by artificial anus.[3,4] However, 70%~90% of patients have long-term bowel dysfunction after surgery, such as defecation urgency, gas and stool incontinence, stool fragmentation, obstructed defecation, and defecation aggregation, which are known as low anterior resection syndrome (LARS).[5] Longitudinal studies have found that patients still have LARS up to 15 years after surgery.[6] An international consensus study defined LARS as effects on patients after an anterior resection (sphincter-saving rectal resection).[7] Patients may experience at least one of the symptoms (variable and unpredictable bowel function, altered stool consistency, increased stool frequency, repeated painful stools, emptying difficulties, urgency, incontinence and/or soiling) resulting in at least one of the consequences (toilet dependence, preoccupation with bowel function, dissatisfaction with bowels, strategies and compromises, impacts on mental and

emotional well-being, impacts on social and daily activities, impacts on relationships and intimacy and/or impacts on roles, commitments and responsibilities).

The improvement in LARS largely depends on patient self-management behaviour.[8,9] However, variable bowel symptoms, receiving insufficient supportive care, and weak self-management awareness lead to poor patient self-management.[10,11] Based on a patient's symptom experience, developing targeted management plans and constantly improving them according to the patient's situation can help them effectively manage symptoms.[12] However, the intrinsic motivation of patients is often ignored and interventions rarely promote "effective participation", defined empirically as sufficient participation with the intervention to achieve the intended outcomes.[13] Motivational interviewing (MI) has been demonstrated to be an effective approach to help patients adopt positive health behaviours.[14] With the rapid development of information technology, mobile health has become an important means of patient health management, which can encourage patients to obtain timely symptom management measures and reduce the burden of symptoms.[15] The WHO defined mobile health as "medical and public health practices supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices".[16] Meanwhile experts advocate that in the current COVID-19 pandemic, public health departments should use multiple strategies to gain public trust and accelerate the adoption of tools such as digital contact tracing applications.[17] However, current online information on LARS is suboptimal, websites are highly variable, important content is often lacking and the material is too complex for patients.[18]

In 2017, Tencent officially released WeChat applet, defined as " a new way to connect users and services that is easy to access and spread, and provides a good experience". Compared with mobile apps, the WeChat applet does not need installation, occupies a small space and is widely used in patients' health.[19-21] In the early stage, we formed a multidisciplinary team to build a remote LARS interaction management based on a sound theoretical framework and symptom management theory, and was vetted in a focus group and semistructured interviews

involving 10 patients, 14 healthcare professionals. After optimization, 101 LARS patients and 113 healthcare professionals were selected by the convenience sampling method to complete the system usability questionnaire. The results of the questionnaire were good.[22] The WeChat applet has been registered with the China Copyright Protection Center (Registration Number: 2021SR1770686). We organized focus group interviews with LARS professionals, psychologists and patients on the remote LARS interaction management intervention based on the WeChat applet ("e-bowel safety") and MIs intervention program embeded "5W1H" principle. The final intervention version was ascertained by 26 LARS professionals from five large hospitals and universities. **Objectives**

This intervention program aims to investigate the effects of the mobile health-based remote interaction management and MIs intervention on patients with low anterior resection syndrome and evaluate the primary effects on global quality of life, meanwhile the secondary effects of bowel function, social support, and self-management. We hypothesise that the participants with "e-bowel safety" and MIs for 3 months will significantly improve health-related QoL among individuals living with LARS.

METHODS AND DESIGN

Study setting

This will be a randomised, single-blind, two-arm pragmatic trial to evaluate the effects of LARS information, online counselling, peer support, pelvic floor muscle training and remote supervision for LARS patients based on "e-bowel safety" applet and MIs. The intervention group will receive LARS remote interaction management based on "e-bowel safety" applet and MIs. The control group will receive an information booklet that contains the same information as that provided in the "e-bowel safety" informational module and receive the standard LARS counselling that is routinely provided by their hospital. The intervention will last for 3 months, followed by three months of follow-up. The study will be conducted from 15 July 2022 to 15 January 2023 in three tertiary grade A general hospitals. Figure 1 shows a flow chart of the study design. The study protocol conforms to the Standard Protocol

Items: Recommendations for Interventional Trials (SPIRIT) Statement.[23]

Eligibility and recruitment

The inclusion criteria are as follows: (1) patients aged 18～75 years; (2) patients who underwent SPS for rectal cancer or ostomy closure 1～3 months previously (0～15 cm from the anal verge); (3) survival is more than 1 year; (4) patients or primary caregivers who use WeChat; (5) LARS scores≥21; and (6) patients who can identify their own condition and provide informed consent in this study. The exclusion criteria are as follows: (1) Patients undergoing chemotherapy or other clinical experiments; (2) patients with other chronic intestinal diseases; (3) patients with previous or current mental disorders, consciousness disorders and communication disorders or patients who are unable to communicate in Chinese and English. When patients in the hospital databases meeting the inclusion criteria will receive recruitment information by telephone or mail from his/her doctor who is not directly involved in research design.

Sample size calculation

The primary outcome measures were quality of life as the calculation standard. A large cross-sectional survey of patient quality of life measured by the EORTC-QLQ-C30 for rectal cancer showed an average patient score of 77±19.[24] According to the consensus guidelines for supporting randomised controlled trials using the EORTC-QLQ-C30, a mean difference of 10 points in global QoL is the most appropriate expected effect size for interventions aimed at improving QoL in cancer patients.[25] Therefore, if α=0.05 and 1-β=0.80, 45 patients will be needed in each group. Given the expected risk of 20% attrition during the study period, the adjusted final sample size is 54 patients per group (a total of 108 patients).

Randomisation

Eligible participants will be randomised in a 1:1 ratio into one of two groups by a computer according to block sizes of 2, 4 or 6, stratified by the participant baseline LARS scores. Allocation will be performed by a statistician at the lead investigating site who is not directly involved in research design or participant enrolment so that researchers can analyse data without having access to information about the allocation. Meanwhile, the data collector will be unaware of patient assignments at

baseline and at 3 and 6 months of the study. To prevent contamination between the different groups, participants must use the code provided by the research team to log in, and participants will not be specifically encouraged to share the code to others. Meanwhile, the research team will receive the patient's registration information and can log off users who are not a participant at any time.

The research team and "e-bowel safety" applet introduction

The research team includes 1 head nurse (group leader), 2 gastrointestinal surgeons (intermediate titles or above), 1 clinical psychologist, 2 nurses with supervisor titles or above, 1 ostomy nurse, 1 nutrition support nurse, 1 pelvic floor rehabilitation nurse, 1 software engineer and 3 graduate students. The team members will attend two training sessions for the intervention program and the use of "e-bowel safety" applet provided by the group leader. The clinical psychologist will provide two training sessions for MIs, and all team members should pass the exam. One team member will be on shift each week to help patients, and others will be present throughout the duration of the study to support the team member if any undue problems occur.

The "e-bowel safety" applet content module includes the following: The symptoms experience module, which includes patients' stories, where patients can post their experiences in treating the disease or in self-management, and their peers will be able to respond to each post with comments and recommendations; A health diary, first daily landing and spontaneous pop-ups are provided for patients to record their diet, sleep, activity, and defecation on the previous day; The symptom management policy module, which includes the LARS informational module (LARS knowledge, daily life management strategies, and social communication strategies) that are presented in text and graphic form; Physical training which includes guiding patients in abdominal massage, pelvic floor muscle exercises and leg exercises in the form of videos; Online communication, where patients can always ask the intervention team questions; The Clock and Points module, where the system automatically generates points according to the length of time spent reading LARS knowledge and performing physical training hours; Intelligent reminders, which allows intervention team to push new messages to patients, and automatically or manually regularly remind patients about functional

exercise. Patients can also set the reminder function according to their own time; The symptom management effect evaluation module: In the self-health assessment, such as bowel symptoms, nutrition assessment, the results of the check to upload automatically. The "e-bowel safety" applet function module will include the following: A voice broadcast, considering that the patients are older, with vision loss and low education levels, where the written content can be broadcast by voice; Audio guidance, with an animated video guide; and Collection and search, where important content can be clicked in the collection module, and patients can search for the target content according to the keywords. The medical terminal also has the functions of push information management, regular reminder management, interactive circle management, user permission management and statistical analysis management. The communication board will be monitored on a daily basis. Figure 1 presents the "e-bowel safety" applet partial interface.

Intervention group

The intervention group will receive a LARS remote interaction intervention program based on "e-bowel safety" applet combined with MIs. During the formal intervention, the intervention team will instruct the patients to sign the informed consent form and explain the precautions during the intervention; guide patients to register on the applet and explain the applet functions, modules, content and methods of use; and issue the applet use manual. The intervention team will evaluate the patients' bowel symptoms and self-management willingness every month from the beginning of the intervention to conduct MIs with the patients that will improve their self-management awareness. After the MIs,the team member will make a daily exercise duration and frequency plan with the patients ,set up the automatic clock-in reminder on the applet, read the symptom management strategy module to make a diet plan, and record a health diary and functional exercise clock-in every day. According to the arrangement of the group leader, the intervention team responds to the questions from the patient online consultation every Tuesday and Friday from 7 PM to 9 PM, provides personalized guidance for patients and feedback on patient functional exercise and health diaries, adjusts the patient management plan appropriately, and reports the weekly point

rankings. The team will organize patients and their peers to communicate with home self-management skills online every week, understand the confusion of the patients, and build patient confidence in recovery through successful cases. Patients can also ask questions or share their self-management experiences in the "Peer Story" modules at any time or post comments to other patients, which will be officially released after review by the intervention team.Figure 2 shows System architecture diagram of Symptom Management Theory.

Control group

Participants in the comparison group will receive a paper copy of the LARS patient information booklet that contains the same information as that provided in the "e-bowel safety" informational module and an attached health diary and will have access to the standard LARS counselling that is routinely available at their hospital. Questionnaires for all participants will be delivered through email, in the same format for both groups, and participants will provide feedback on the three-month intervention. The main difference between the two groups will be whether they receive the "e-bowel safety" applet and MIs. The study flow chart is shown in Figure 3.

Data collection methods

Demographics (age, sex, BMI, marital status, education level, primary caregiver caregivers, residence), medical comorbidities and disease and treatment characteristics, including known predictors of poor bowel function [e.g., tumour height, neoadjuvant radiotherapy, type of proctectomy (total versus partial mesorectal excision)] will be acquired from the database of the patient treatment hospital. Data on quality of life and LARS scores will be obtained from questionnaires completed by the patients at different stages. To reduce the potential risk of detection bias, outcome assessors will be blinded to treatment allocation.

Outcome measures and data collection

The primary outcome will be the Global Quality of Life (QoL), as measured by the European Cancer Research and Treatment Organization Quality of Life Questionnaire-Core 30(QLQ-C30). Secondary outcomes will include bowel function

measured by the LARS score, bowel symptoms self-management behaviour measured by the Bowel Self-management Behaviour Questionnaire (BSSBQ), social support measured by the Perceived Social Support Scale (PSSS), and patients' thinkings. The scales all have been formally translated and culturally validated to Chinese populations. The measurement tools and timing are shown in Table 1.

Quality of life

Quality of life will be measured by the EORTC-QLQ-C30. It consists of 30 questions, which are aggregated into one global QoL scale, five functional scales, three symptom scales and six single items. The EORTC-QLQ-C30 has been well validated in rectal cancer patients and is correlated with the severity of LARS.[5, 6, 8, 9,26,27]

Bowel function

Bowel function will be measured by the LARS score, which contains five items aimed at symptoms of bowel dysfunction. The LARS score allows physicians to categorize patients as having major LARS (30～42 points), minor LARS (21～29 points) or no LARS (0～20 points). The LARS score has been well validated in rectal cancer patients in China.[28,29]

Self-management

The Bowel Symptoms Self-management Behaviours Questionnaire (BSSBQ) for Chinese rectal cancer patients after sphincter-preserving surgery will be used to test their bowel self-management behaviors. The BSSBQ consists of five functional scales and 20 items. The effect record is scored as follows: 0～3 points (0= no effect, 1= some effect, 2= some effect, 3= very effective).[30]

Social support

The Perceived Social Support Scale (PSSS) consists of 12 items, which mainly include three dimensions: family support, friend support, and other support. The Likert 7 scoring method is used, from "extreme disagreement" to "strong consent" with scores of 1 to 7, and the total score ranges from 12 to 84. A higher total score indicates that individuals feel more social support. The Cronbach's coefficient of this scale was 0.899.[31,32]

Patients' thinkings

The researchers will ask the patients about the acceptance degree and opinions of the intervention one by one after the intervention, which mainly included: Can you accept the "e-bowel safety" applet guidance form? What do you think about health education needs to be added or deleted? What else do you think needs to be improved?

Table1 Measurements for primary and secondary outcomes and data collection

Outcome	Measurements	Baseline	3 months	6 months
Primary outcome				
Quality of life	EORTC-QLQ-C30[26,27]	√	√	√
Secondary outcomes				
Bowel function	LARS score[28,29]	√	√	√
Self-management	Bowel Symptoms Self-management Behaviors Questionnaire(BSSBQ)[30]	√	√	√
Social Support	Perceived Social Support Scale, PSSS[31,32]	√	√	√
Patients' thinkings	Semistructured interview (Experience,Satisfaction)		√	

Statistical analysis and data management

All data will be analysed using SPSS (V.23.0). Descriptive data will be computed, including means with standard deviations, medians with ranges, or frequencies with proportions, where appropriate. Continuous outcomes will be compared using t-test and categorical outcomes will be compared using Wilcoxon rank sum test.The overall treatment effect on global QoL, bowel function, self-management and social support will be modelled using generalised estimating equations (GEEs). The reason why GEE is chosen is that it shows the within-subject correlations between responses at different time-points and accounts for possible clustering of responses among participants from the same hospital. [33] And it can still work when some of the data is missing. The effect size, standard error and 95% CI for the estimate of the treatment effects at 6 months will be reported.

Patient and public involvement

Patient and public involvement (PPI) has played a vital role in this study. When building the applet, patients were interviewed through semistructured interviews to understand their willingness and needs for mobile health use. In the applet usability test, the applet was modified in combination with patient recommendations. In the construction of the intervention program, the duration, timing and form of the intervention were determined refer to the patients' opinions.

ETHICS AND DISSEMINATION

Ethics approval was granted by the Clinical Medical Research Ethics Committee of the First Affiliated Hospital of Anhui Medical University. All participants will be fully informed of the contents of this study before they are recruited and will sign an informed consent form by research team. We do not anticipate that participants will suffer harm from trial because we will monitor the online forum on a daily basis for any posts/comments that may affect users in a negative way (e.g. dissemination of false information, use of expletives, etc). All modifications will be communicated to co-investigators, REC, trial participants, trial registries and the journal. All questionnaires will be completed by the researcher's guidance or ghostwriting. The questionnaires will be distributed and collected on the spot to avoid data bias caused by different researchers. Two researchers will enter all the data to avoid objective typing errors.

The Clinical Medical Research Ethics Committee of the First Affiliated Hospital of Anhui Medical University will be responsible for the data monitoring committee and for auditing trial conduct. The questionnaires will be collected by researchers and recorded in the research electronic data collection system, which will be used as an electronic data collection (EDC) system for long-term data storage and management. The original data will be recorded in a timely and accurate manner, and a copy of the report will be kept in the laboratory. All laboratory data will be identified with a code number to ensure the confidentiality of the subjects' data. The chief investigator can directly access the dataset, and the data scattered to the project team members cannot identify any participant identity information. The results of this study will be

presented at national and international conferences and published in peer-reviewed journals.

DISCUSSION

This study focuses on the feasibility of a remote interaction intervention program for LARS patients based on “e-bowel safety” applet and MIs, provide supportive care information, and conduct regular MIs with dynamic, professional and personalized guidance to improve the “effective participation” of patients and improve their quality of life. After the intervention, semistructured interviews will be conducted to understand patient satisfaction and recommendations for the duration and form of the intervention.

At present, the common forms of patients’ bowel management include brochures, lectures, telephone, SMS, and nursing clinics. Although they play a certain positive role, the above methods are time-consuming and laborious, have low patient acceptance, have a limited audience, and are not sustainable.[34] It is impossible to help patients solve existing problems in real time or remotely, and the COVID-19 pandemic hindered the return of postoperative patients to the hospital for review. This study, considered from the patient perspective, provides patients with an accessible, comprehensive, and shared form of remote interaction intervention with health professionals–patient participation. On the basis of a literature review and clinical practice, our team improved health education information, showed and met the learning needs of different patients in various forms of text and audio to improve patient acceptance. Health diaries and regular exercise clocking enable our team to remotely monitor patients' diets, exercise, management strategies and defecation in real time, provide personalized health guidance, and develop exercise programs with patients to increase their effective participation. Patients can post LARS management strategies to strengthen peer support. Providing points for gifts and other incentive systems, improving the completion rate of patient health diaries and the number of regular punching cards, improving the enthusiasm of patients to use "e-bowel safety" can help them better manage their bowel symptoms. Staged MIs, based on the patients’ willingness to manage their bowel symptoms, mining patient and social motivational

resources and reinforcing motivation allows patients to consciously combine their own motivational resources, psychological expectations and compliance with rehabilitation behaviour, which effectively drives patients to start and maintain their vitality and enthusiasm for the implemented behaviour.

Limitations

The trial is limited to patients with smartphones and WeChat, which could lead to selection bias. Although the participants will be recruited in one city and only patients with LARS scores of 21 points will be included, patients without LARS may also have bowel dysfunction.

Contributors All listed authors certified their contribution. SH, SY: Study design and revisions for important intellectual content. HL, PZ, XP, DY, TW, MF, HH: the First manuscript writing. DZ: Information technology consulting and version upgraded of "e-bowel safety" applet. All authors read and approved the final manuscript.

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Competing interests There are no conflicts of interest to declare.

REFERENCES

1 Siegel RL, Miller KD, Goding Sauer A, et al. Colorectal cancer statistics, 2020. *CA Cancer J Clin* 2020;70(3):145-164.

2 Liu ZCh, Li ZhX, Zhang Y, et al. 2020 Global Cancer Statistics Report Interpretation. *Electronic Journal of Comprehensive Treatment of Oncology* 2021;7 (02):1-14.

3 Heald RJ, Ryall RD. Recurrence and survival after total mesorectal excision for rectal cancer. *Lancet* 1986;1(8496):1479-1482.

4 Marwan K, Staples MP, Thursfield V, et al. The rate of abdominoperineal resections for rectal cancer in the state of Victoria, Australia: a population-based study. *Dis Colon rectum* 2010;53:1645-1651.

5 LARS TRENTI L, GALVEZ A, BIONDO S, et al. Quality of life and anterior resection syndrome after surgery for mid to low rectal cancer: a cross-sectional study. *Eur J Surg Oncol* 2018;44(7):1031-1039.

6 Pieniowski EHA, Palmer GJ, Juul T,et al. Low Anterior Resection Syndrome and

Quality of Life After Sphincter-Sparing Rectal Cancer Surgery: A Long-term Longitudinal Follow-up. *Dis Colon Rectum* 2019;62(1):14-20.

7 Keane C, Fearnhead NS, Bordeianou LG, et al. International consensus definition of low anterior resection syndrome. *ANZ J Surg* 2020;90(3):300-307.

8 LAI X, WONG FK, CHING SS. Review of bowel dysfunction of rectal cancer patients during the first five years after sphincter preserving surgery: a population in need of nursing attention. *Eur J Oncol Nurs* 2013;17(5):681-692.

9 Pape E, Pattyn P, Van Hecke A, et al. Impact of low anterior resection syndrome (LARS) on the quality of life and treatment options of LARS-A cross sectional study. *Eur J Oncol Nurs* 2021;50:101878.

10 Luo MN, Chen YF, Wen XY, et al. Current status of intestinal function and its influencing factors in patients after anal preservation for rectal cancer. *Chinese Journal of Practical Nursing* 2021;37 (36):2801-2806.

11 Lu LC, Huang XY, Chen CC. The lived experiences of patients with post-operative rectal cancer who suffer from altered bowel function: a phenomenological study. *Eur J Oncol Nurs* 2017;31:69-76.

12 Wu HX, Wu Q, Chen JJ, et al. Case management practice in colorectal tumor patients based on symptom management theory. *Journal of Nursing* 2021;36(19): 28-31.

13 Yardley L, Spring BJ, Riper H, et al. Understanding and Promoting Effective Engagement With Digital Behavior Change Interventions. *Am J Prev Med* 2016;51(5):833-842.

14 Serio C, Gabarda A, Uyar-Morency F, et al. Strengthening the Impact of Digital Cognitive Behavioral Interventions Through a Dual Intervention: Proficient Motivational Interviewing-Based Health Coaching Plus In-Application Techniques. *JMIR Form Res* 2022;6(5):e34552.

15 Saeidzadeh S, Kamalumpundi V, Chi NC, et al. Web and mobile-based symptom management interventions for physical symptoms of people with advanced cancer: A systematic review and meta-analysis. *Palliat Med* 2021;35(6):1020-1038.

16 WHO guideline Recommendations on Digital Interventions for Health System Strengthening. Geneva: World Health Organization; 2019.

17 Grande D, Mitra N, Marti XL, et al. Consumer Views on Using Digital Data for COVID-19 Control in the United States. *JAMA Netw Open* 2021;4(5):e2110918.

18 Garfinkle R, Wong-Chong N, Petrucci A, et al. Assessing the readability, quality

and accuracy of online health information for patients with low anterior resection syndrome following surgery for rectal cancer. *Colorectal Dis* 2019;21(5):523-531.

19 Zhao XD, Tao R. Comparison and Analysis of the four mobile application development modes. *Smart Computer and Applications* 2018;8(01):72-75.

20 Xu L, Li J, Zhang X, et al. Mobile health-based gamification intervention to increase physical activity participation among patients with coronary heart disease: study protocol of a randomised controlled trial. *BMJ Open* 2022;12(1):e054623.

21 Zhang X, Wen D, Liang J, et al. How the public uses social media wechat to obtain health information in China: a survey study. *BMC Med Inform Decis Mak* 2017;17(Suppl 2):66.

22 Pang XY, Hu ShH, Li H, et al. Development and availability evaluation of symptom management desk for low anterior resection syndrome in patients with rectal cancer. *Chinese Nursing Management* 2022;22(03):445-449.

23 Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158(3):200-7.

24 Garfinkle R, Loiselle CG, Park J, et al. Development and evaluation of a patient-centred program for low anterior resection syndrome: protocol for a randomized controlled trial. *BMJ Open*. 2020 May 30;10(5):e035587.

25 Hibbard JH, Mahoney ER, Stockard J, et al. Development and testing of a short form of the patient activation measure. *Health Serv Res* 2005;40(6 Pt 1):1918-30.

26 Aaronson NK, Ahmedzai S, Bergman B, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst* 1993;85:365-376.

27 Wang JP, Chen ZhG, Lin WJ, et al. Determination of quality of life in Chinese cancer patients-Trial of EORTC QLQ-C30 in China. *Psychology Journal* 2000;32:438-342.

28 Emmertsen KJ, Laurberg S. Low anterior resection syndrome score: development and validation of a symptom-based scoring system for bowel dysfunction after low anterior resection for rectal cancer. *Ann Surg* 2012;255(5):922-928.

29 Yan JJ, Mou ShY, Tan RF, et al. Empirical study of the Chinese version of the low anterior resection syndrome score table for rectal cancer. *PLA Journal of Nursing* 2015;32(4):12-15.

30 Hou XT, Pang D, Lu Q, etc. Preparation of self-management behavior of rectal cancer and reliability validity test. *Chinese Journal of Nursing* 2016;51(09): 1059-1064.

31 Zimet GD, Powell SS, Farley GK,et al. Psychometric characteristics of the Multidimensional Scale of Perceived Social Support. *J Pers Assess* 1990;55(3-4):610-617.

32 Liang KY, Zeger SL. Longitudinal data analysis using generalized linear models. *Biometrika* 1986;73:13–22.

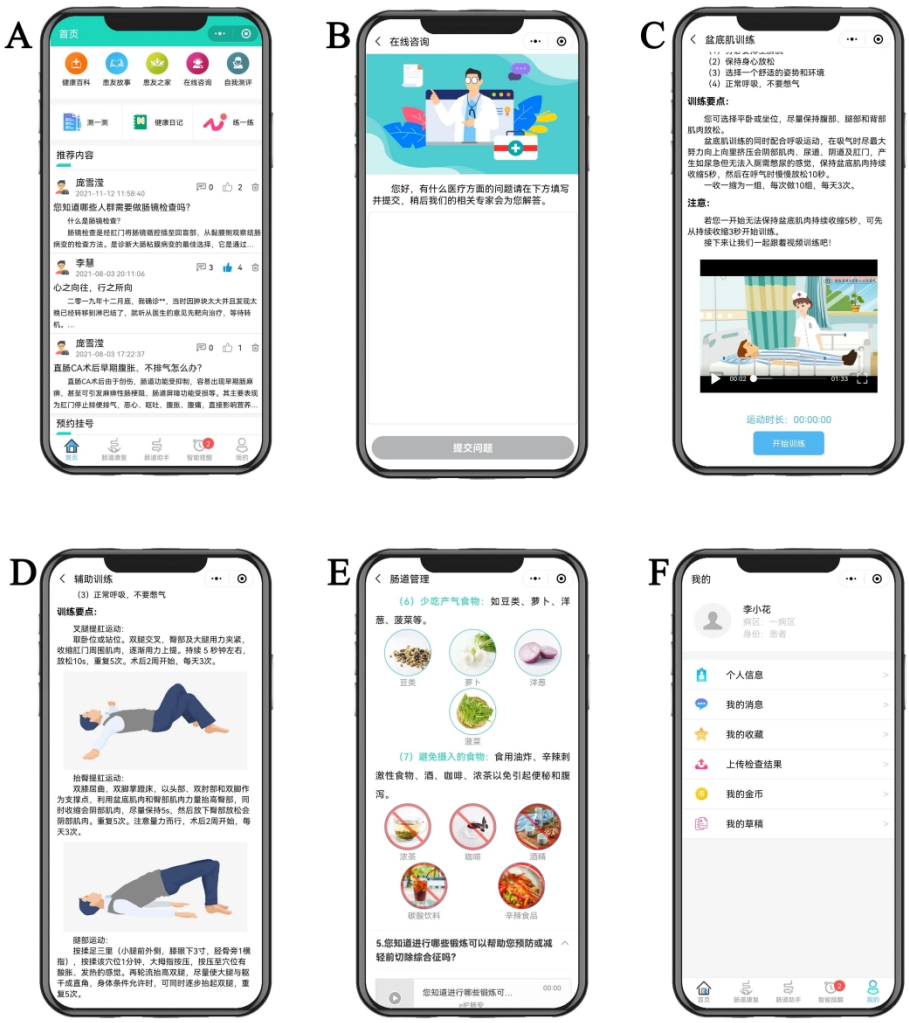
33 Huang L, Jiang QY, Ren WH. Association of coping style, social support and psychosomatic symptoms in cancer patients. *Chinese Journal of Mental Health* 1996;(04):160-161.

34 Cao Y. Effect of individualized health education on self-management ability and condition control in patients with chronic diseases. *International Infection Science (electronic edition)* 2020;9 (02):26-27.

Figure 1 "e-bowel safety" applet interface. A. home page; B. online consultation; C. Text and video to guide pelvic floor muscle training; D. Text and pictures to guide other trainings; E. LARS informational module; F. Personal homepage.

Figure 2 System architecture diagram of Symptom Management Theory.

Figure 3 Study flow chart.



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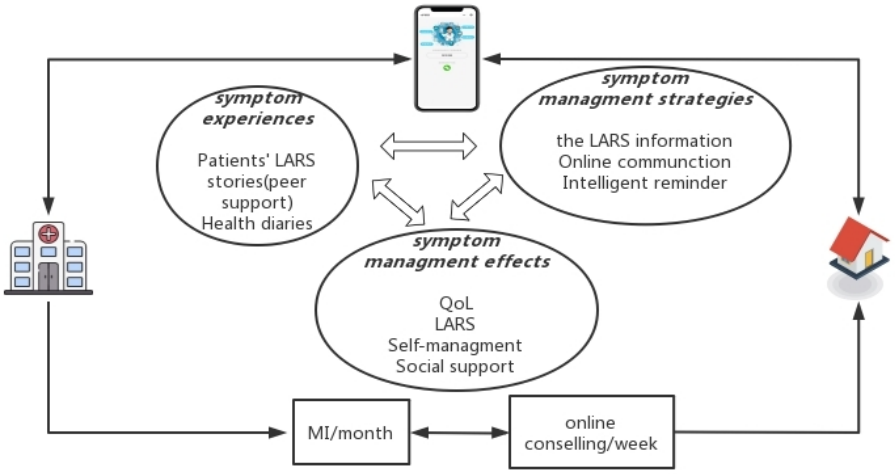

Figure 2 System architecture diagram of Symptom Management Theory.

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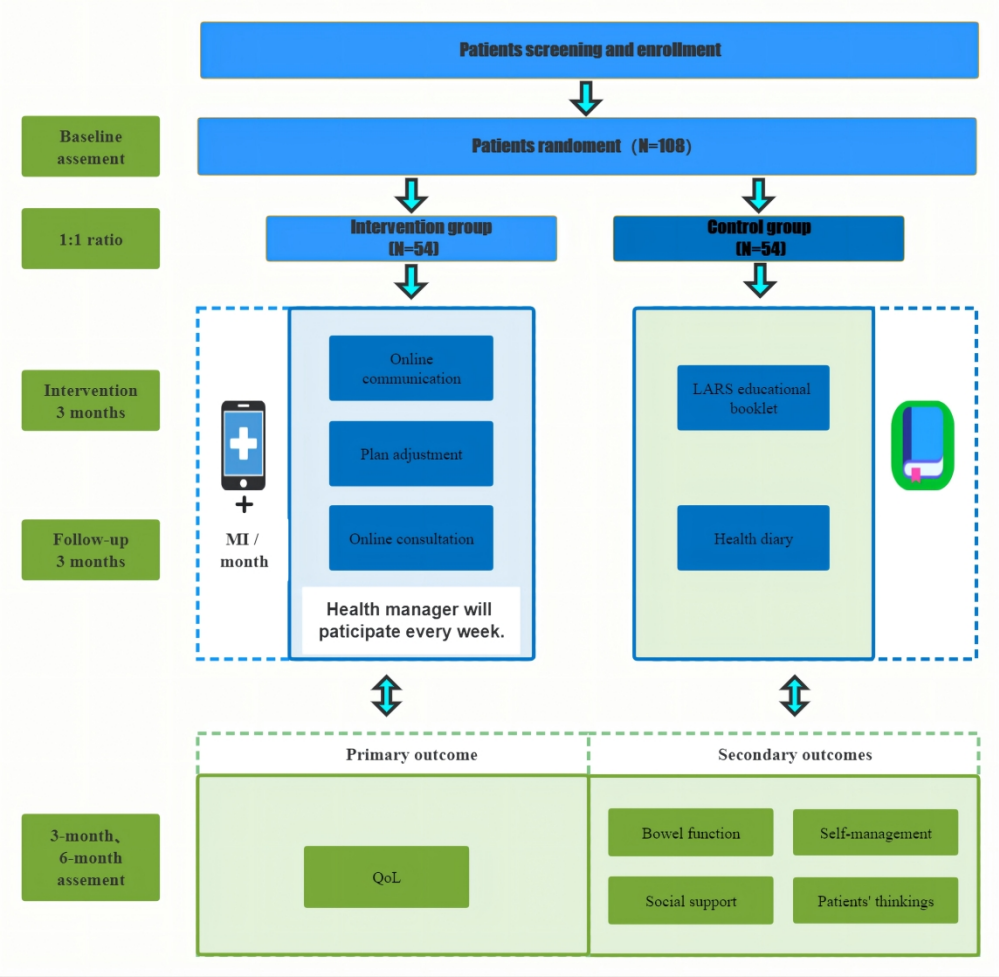

Figure 3 Study flow chart.

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