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# BMJ Open

## 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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Manuscripts

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4 **Mobile health-based remote interaction management intervention for patients**  
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6 **with low anterior resection syndrome: study protocol for a randomised**  
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8 **controlled trial**  
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53 **Note**

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56 Hui Li and Peng Zhou contributed equally to this work, should be considered joint  
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58 first author.  
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9 **Key Words:** rectal cancer; low anterior resection syndrome; mHealth; quality of life  
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11 **Words:** 3256  
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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

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4 mental and emotional well-being, impacts on social and daily activities, impacts on  
5 relationships and intimacy and/or impacts on roles, commitments and  
6 responsibilities).  
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9 The improvement in LARS largely depends on patient self-management  
10 behaviour.[8,9] However, variable bowel symptoms, receiving insufficient supportive  
11 care, and weak self-management awareness lead to poor patient  
12 self-management.[10,11] Based on a patient's symptom experience, developing  
13 targeted management plans and constantly improving them according to the patient's  
14 situation can help them effectively manage symptoms.[12] However, the intrinsic  
15 motivation of patients is often ignored and interventions rarely promote "effective  
16 participation", defined empirically as sufficient participation with the intervention to  
17 achieve the intended outcomes.[13] Motivational interviewing (MI) has been  
18 demonstrated to be an effective approach to help patients adopt positive health  
19 behaviours.[14] With the rapid development of information technology, mobile health  
20 has become an important means of patient health management, which can encourage  
21 patients to obtain timely symptom management measures and reduce the burden of  
22 symptoms.[15] The WHO defined mobile health as "medical and public health  
23 practices supported by mobile devices, such as mobile phones, patient monitoring  
24 devices, personal digital assistants, and other wireless devices".[16] Meanwhile  
25 experts advocate that in the current COVID-19 pandemic, public health departments  
26 should use multiple strategies to gain public trust and accelerate the adoption of tools  
27 such as digital contact tracing applications.[17] However, current online information  
28 on LARS is suboptimal, websites are highly variable, important content is often  
29 lacking and the material is too complex for patients.[18]  
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50 In 2017, Tencent officially released WeChat applet, defined as " a new way to  
51 connect users and services that is easy to access and spread, and provides a good  
52 experience". Compared with mobile apps, the WeChat applet does not need  
53 installation, occupies a small space and is widely used in patients' health.[19-21] In  
54 the early stage, we formed a multidisciplinary team to build a remote LARS  
55 interaction management based on a sound theoretical framework and symptom  
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4 management theory, and was vetted in a focus group and semistructured interviews  
5 involving 10 patients, 14 healthcare professionals. After optimization, 101 LARS  
6 patients and 113 healthcare professionals were selected by the convenience sampling  
7 method to complete the system usability questionnaire. The results of the  
8 questionnaire were good.[22] The WeChat applet has been registered with the China  
9 Copyright Protection Center (Registration Number: 2021SR1770686). We organized  
10 focus group interviews with LARS professionals, psychologists and patients on the  
11 remote LARS interaction management intervention based on the WeChat applet  
12 ("e-bowel safety") and MIs intervention program embeded "5W1H" principle. The  
13 final intervention version was ascertained by 26 LARS professionals from five large  
14 hospitals and universities. This intervention program aims to provide targeted,  
15 specialized, and individualized guidance to patients and improve the convenience and  
16 "effective participation" of patients in managing LARS. In addition, a semistructured  
17 interview will be conducted after the intervention to comprehend the patients'  
18 satisfaction, perceptions and their experiences with the intervention.  
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## 33 **METHODS AND DESIGN**

### 34 **Study setting**

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36 This will be a randomized, single-blind, two-arm pragmatic trial to evaluate the  
37 effects of LARS information, online counselling, peer support, pelvic floor muscle  
38 training and remote supervision for LARS patients based on "e-bowel safety" applet  
39 and MIs. The intervention group will receive LARS remote interaction management  
40 based on "e-bowel safety" applet and MIs. The control group will receive an  
41 information booklet that contains the same information as that provided in the  
42 "e-bowel safety" informational module and receive the standard LARS counselling  
43 that is routinely provided by their hospital. The intervention will last for 3 months,  
44 followed by three months of follow-up. The study will be conducted from 15 July  
45 2022 to 15 January 2023 in three tertiary grade A general hospitals.  
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### 56 **Eligibility and recruitment**

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58 The inclusion criteria are as follows:(1) patients aged 18–70 years; (2) patients who  
59 underwent SPS for rectal cancer or ostomy closure 1–3 months previously (0–15 cm  
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4 from the anal verge); (3) patients or primary caregivers who use WeChat; (4) LARS  
5 scores  $\geq 21$ ; and (5) patients who can identify their own condition and provide  
6 informed consent in this study. The exclusion criteria are as follows: (1) patients who  
7 participated in other clinical experiments; (2) patients with other chronic intestinal  
8 diseases; (3) patients who underwent major colonic resection in addition to  
9 proctectomy; and (4) patients who are unable to read and comprehend Chinese. When  
10 patients in the hospital databases meeting the inclusion criteria will receive  
11 recruitment information by telephone or mail.  
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### 19 **Sample size calculation**

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

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

53 The research team includes 1 head nurse (group leader), 2 gastrointestinal surgeons  
54 (intermediate titles or above), 1 clinical psychologist, 2 nurses with supervisor titles or  
55 above, 1 ostomy nurse, 1 nutrition support nurse, 1 pelvic floor rehabilitation nurse, 1  
56 software engineer and 3 graduate students. The team members will attend two training  
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4 sessions for the intervention program and the use of "e-bowel safety" applet provided  
5 by the group leader. The clinical psychologist will provide two training sessions for  
6 MIs, and all team members should pass the exam. One team member will be on shift  
7 each week to help patients, and others will be present throughout the duration of the  
8 study to support the team member if any undue problems occur.  
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11 The "e-bowel safety" applet content module includes the following: The symptoms  
12 experience module, which includes patients' stories, where patients can post their  
13 experiences in treating the disease or in self-management, and their peers will be able  
14 to respond to each post with comments and recommendations; A health diary, first  
15 daily landing and spontaneous pop-ups are provided for patients to record their diet,  
16 sleep, activity, and defecation on the previous day; The symptom management policy  
17 module, which includes the LARS informational module (LARS knowledge, daily life  
18 management strategies, and social communication strategies) that are presented in text  
19 and graphic form; Physical training which includes guiding patients in abdominal  
20 massage, pelvic floor muscle exercises and leg exercises in the form of videos; Online  
21 communication, where patients can always ask the intervention team questions; The  
22 Clock and Points module, where the system automatically generates points according  
23 to the length of time spent reading LARS knowledge and performing physical training  
24 hours; Intelligent reminders, which allows intervention team to push new messages to  
25 patients, and automatically or manually regularly remind patients about functional  
26 exercise. Patients can also set the reminder function according to their own time; The  
27 symptom management effect evaluation module: In the self-health assessment, such  
28 as bowel symptoms, nutrition assessment, the results of the check to upload  
29 automatically. The "e-bowel safety" applet function module will include the  
30 following: A voice broadcast, considering that the patients are older, with vision loss  
31 and low education levels, where the written content can be broadcast by voice; Audio  
32 guidance, with an animated video guide; and Collection and search, where important  
33 content can be clicked in the collection module, and patients can search for the target  
34 content according to the keywords. The medical terminal also has the functions of  
35 push information management, regular reminder management, interactive circle  
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4 management, user permission management and statistical analysis management. The  
5 communication board will be monitored on a daily basis. Figure 1 presents the  
6 "e-bowel safety" applet partial interface.  
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### 9 **Intervention group**

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

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38 Participants in the comparison group will receive a paper copy of the LARS patient  
39 information booklet that contains the same information as that provided in the  
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4 "e-bowel safety" informational module and an attached health diary and will have  
5 access to the standard LARS counselling that is routinely available at their hospital.  
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7 Both groups will receive phone/email reminders from data collectors to fill out the  
8 questionnaire and give feedback on the number and length of pelvic floor muscle  
9 exercises, providing feedback on the three-month intervention.  
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13 The main difference between the two groups will be whether they receive the  
14 "e-bowel safety" applet and MIs. The study flow chart is shown in Figure 3.  
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### 17 **Data collection methods**

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

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

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50 Quality of life will be measured by the EORTC-QLQ-C30. It consists of 30 questions,  
51 which are aggregated into one global QoL scale, five functional scales, three symptom  
52 scales and six single items. The EORTC-QLQ-C30 has been well validated in rectal  
53 cancer patients and is correlated with the severity of LARS.[25,26]  
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#### 58 **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]	√	√	√

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3	Social Support	Perceived Social Support Scale,	√	√	√	
4		PSSS[30,31]				
5						
6	Pelvic floor muscle	Duration				
7	exercise	Frequency				
8		Type ( Pelvic floor muscle exercise, fork		√	√	
9		and leg anal lifting exercise, hip and anal				
10		lifting exercise, leg exercise )				
11						
12	Patients' thinkings	Semistructured interview		√		
13		(Experience,Satisfaction)				
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### 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

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4 test, the applet was modified in combination with patient recommendations. In the  
5 construction of the intervention program, the duration, timing and form of the  
6 intervention were determined refer to the patients' opinions.  
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### 9 10 **ETHICS AND DISSEMINATION**

11 Ethics approval was granted by the Clinical Medical Research Ethics Committee of  
12 the First Affiliated Hospital of Anhui Medical University. All participants will be  
13 fully informed of the contents of this study before they are recruited and will sign an  
14 informed consent form. The results of this study will be presented at national and  
15 international conferences and published in peer-reviewed journals. Original data  
16 without personally identifiable information will be available after the article has been  
17 published.  
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### 20 21 22 23 24 25 **DISCUSSION**

26 This study focuses on the feasibility of a remote interaction intervention program for  
27 LARS patients based on "e-bowel safety" applet and MIs, provide supportive care  
28 information, and conduct regular MIs with dynamic, professional and personalized  
29 guidance to improve the "effective participation" of patients and improve their quality  
30 of life. After the intervention, semistructured interviews will be conducted to  
31 understand patient satisfaction and recommendations for the duration and form of the  
32 intervention.  
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35 At present, the common forms of patients' bowel management include brochures,  
36 lectures, telephone, SMS, and nursing clinics. Although they play a certain positive  
37 role, the above methods are time-consuming and laborious, have low patient  
38 acceptance, have a limited audience, and are not sustainable.[32] It is impossible to  
39 help patients solve existing problems in real time or remotely, and the COVID-19  
40 pandemic hindered the return of postoperative patients to the hospital for review. This  
41 study, considered from the patient perspective, provides patients with an accessible,  
42 comprehensive, and shared form of remote interaction intervention with health  
43 professionals–patient participation. On the basis of a literature review and clinical  
44 practice, our team improved health education information, showed and met the  
45 learning needs of different patients in various forms of text and audio to improve  
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4 patient acceptance. Health diaries and regular exercise clocking enable our team to  
5 remotely monitor patients' diets, exercise, management strategies and defecation in  
6 real time, provide personalized health guidance, and develop exercise programs with  
7 patients to increase their effective participation. Patients can post LARS management  
8 strategies to strengthen peer support. Providing points for gifts and other incentive  
9 systems, improving the completion rate of patient health diaries and the number of  
10 regular punching cards, improving the enthusiasm of patients to use "e-bowel safety"  
11 can help them better manage their bowel symptoms. Staged MIs, based on the  
12 patients' willingness to manage their bowel symptoms, mining patient and social  
13 motivational resources and reinforcing motivation allows patients to consciously  
14 combine their own motivational resources, psychological expectations and  
15 compliance with rehabilitation behaviour, which effectively drives patients to start  
16 and maintain their vitality and enthusiasm for the implemented behaviour.  
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### 29 **Limitations**

30 The trial is limited to patients with smartphones and WeChat, which could lead to  
31 selection bias. Although the participants will be recruited in one city and only patients  
32 with LARS scores of 21 points will be included, patients without LARS may also  
33 have bowel dysfunction.  
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40 **Contributors** All listed authors certified their contribution. SH, SY: Study design and revisions  
41 for important intellectual content. HL, PZ, XP, DY, TW, MF, HH: the First manuscript writing.  
42 All authors read and approved the final manuscript.  
43

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49

50 **Competing interests** There are no conflicts of interest to declare.  
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46 **Figure 1** "e-bowel safety" applet interface. A. home page; B. online consultation; C. Text and  
47 video to guide pelvic floor muscle training; D. Text and pictures to guide other trainings; E. LARS  
48 informational module; F. Personal homepage.

49 **Figure 2** System architecture diagram of Symptom Management Theory.

50 **Figure 3** Study flow chart.

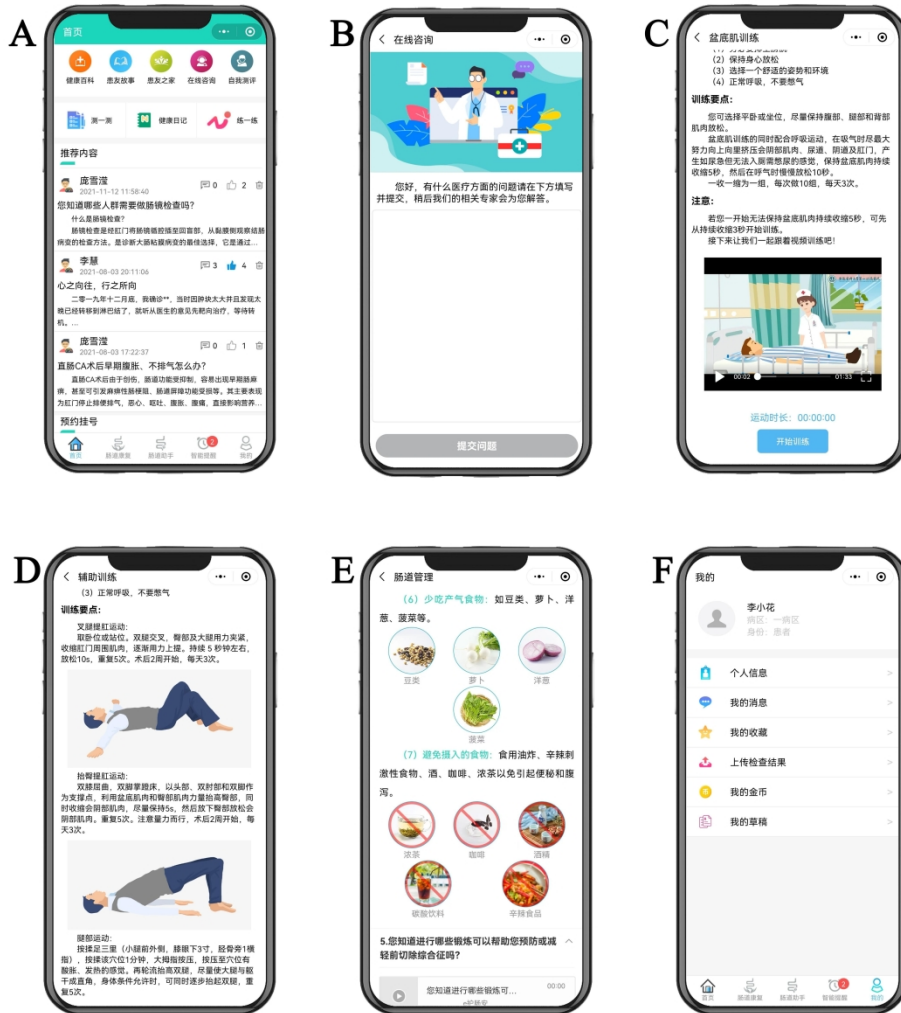


Figure 1 "e-bowel safety" applet interface. A. home page; B. online consultation; C. Text and video to guide pelvic floor muscle training; D. Text and pictures to guide other trainings; E. LARS informational module; F. Personal homepage.

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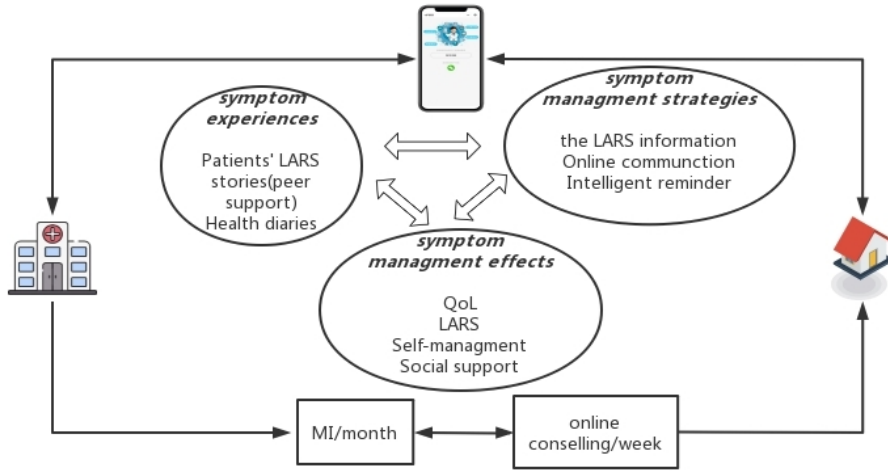


Figure 2 System architecture diagram of Symptom Management Theory.

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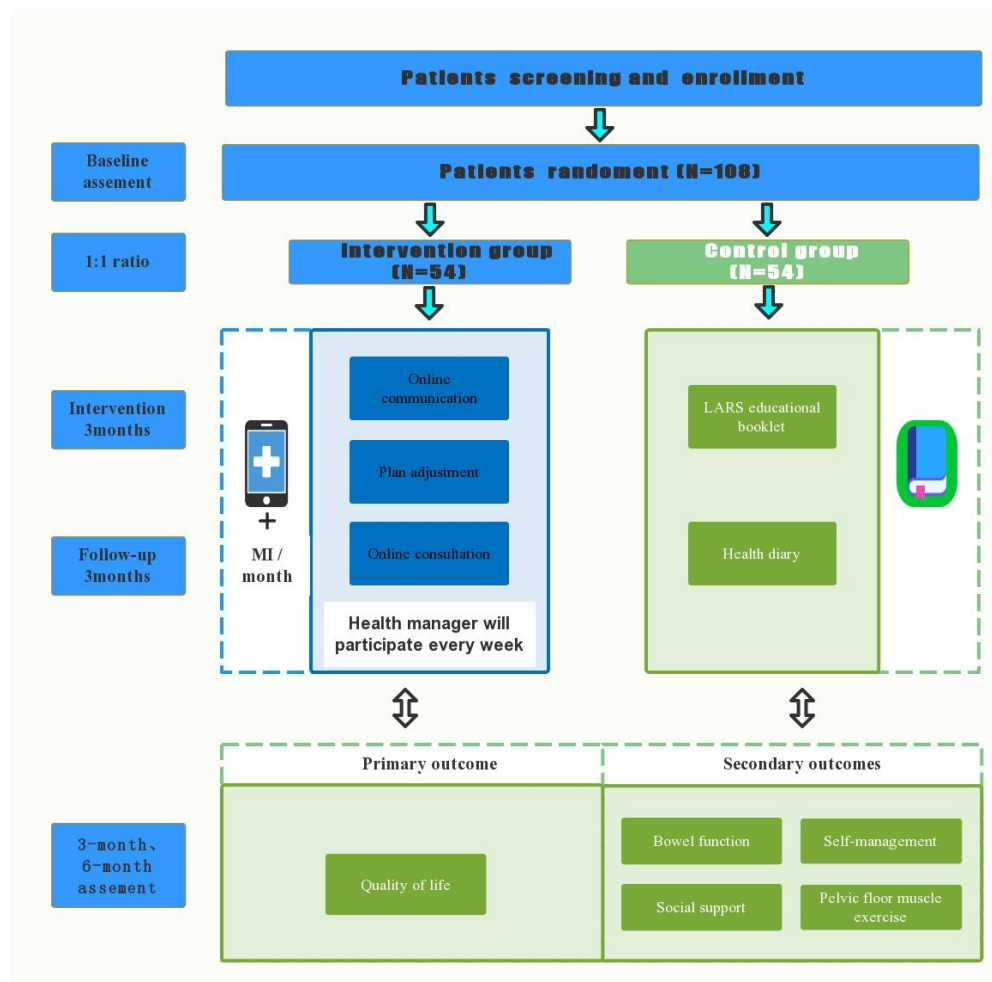


Figure 3 Study flow chart.

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# BMJ Open

## 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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Manuscripts

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4 **Mobile health-based remote interaction management intervention for patients**  
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11 **Authors:** Hui Li<sup>1, 2\*</sup>; Peng Zhou<sup>2\*</sup>; Xueying Pang<sup>1</sup>; Ting Wang<sup>2</sup>; Danqiao Yin<sup>2</sup>; Min  
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51 **Note**

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59 Shaohua Hu and Shihui Yu contributed equally to this work, should be considered  
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6 **Key Words:** rectal cancer; low anterior resection syndrome; mHealth; quality of life  
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9 **Words:** 3850  
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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

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

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

28  
29 In 2017, Tencent officially released WeChat applet, defined as "a new way to  
30 connect users and services that is easy to access and spread, and provides a good  
31 experience". Compared with mobile apps, the WeChat applet does not need  
32 installation, occupies a small space and is widely used in patients' health.[19-21] In  
33 the early stage, we formed a multidisciplinary team to build a remote LARS  
34 interaction management based on a sound theoretical framework and symptom  
35 management theory, and was vetted in a focus group and semistructured interviews  
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4 involving 10 patients, 14 healthcare professionals. After optimization, 101 LARS  
5 patients and 113 healthcare professionals were selected by the convenience sampling  
6 method to complete the system usability questionnaire. The results of the  
7 questionnaire were good.[22] The WeChat applet has been registered with the China  
8 Copyright Protection Center (Registration Number: 2021SR1770686). We organized  
9 focus group interviews with LARS professionals, psychologists and patients on the  
10 remote LARS interaction management intervention based on the WeChat applet  
11 (“e-bowel safety”) and MIs intervention program embeded "5W1H" principle. The  
12 final intervention version was ascertained by 26 LARS professionals from five large  
13 hospitals and universities. **Objectives**

14  
15 This intervention program aims to investigate the effects of the mobile health-based  
16 remote interaction management and MIs intervention on patients with low anterior  
17 resection syndrome and evaluate the primary effects on global quality of life,  
18 meanwhile the secondary effects of bowel function, social support, and  
19 self-management. We hypothesise that the participants with “e-bowel safety” and MIs  
20 for 3 months will significantly improve health-related QoL among individuals living  
21 with LARS.

## 22 **METHODS AND DESIGN**

### 23 **Study setting**

24 This will be a randomised, single-blind, two-arm pragmatic trial to evaluate the  
25 effects of LARS information, online counselling, peer support, pelvic floor muscle  
26 training and remote supervision for LARS patients based on “e-bowel safety” applet  
27 and MIs. The intervention group will receive LARS remote interaction management  
28 based on “e-bowel safety” applet and MIs. The control group will receive an  
29 information booklet that contains the same information as that provided in the  
30 “e-bowel safety” informational module and receive the standard LARS counselling  
31 that is routinely provided by their hospital. The intervention will last for 3 months,  
32 followed by three months of follow-up. The study will be conducted from 15 July  
33 2022 to 15 January 2023 in three tertiary grade A general hospitals. Figure 1 shows a  
34 flow chart of the study design. The study protocol conforms to the Standard Protocol  
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4 Items: Recommendations for Interventional Trials (SPIRIT) Statement.[23]

### 5 6 **Eligibility and recruitment**

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

### 18 19 20 21 22 23 24 25 26 27 28 29 **Sample size calculation**

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

### 39 40 41 42 43 44 45 46 47 48 49 **Randomisation**

50 Eligible participants will be randomised in a 1:1 ratio into one of two groups by a  
51 computer according to block sizes of 2, 4 or 6, stratified by the participant baseline  
52 LARS scores. Allocation will be performed by a statistician at the lead investigating  
53 site who is not directly involved in research design or participant enrolment so that  
54 researchers can analyse data without having access to information about the  
55 allocation. Meanwhile, the data collector will be unaware of patient assignments at  
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4 baseline and at 3 and 6 months of the study. To prevent contamination between the  
5 different groups, participants must use the code provided by the research team to log  
6 in, and participants will not be specifically encouraged to share the code to others.  
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8 Meanwhile, the research team will receive the patient's registration information and  
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10 can log off users who are not a participant at any time.  
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### 13 **The research team and “e-bowel safety” applet introduction**

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15 The research team includes 1 head nurse (group leader), 2 gastrointestinal surgeons  
16 (intermediate titles or above), 1 clinical psychologist, 2 nurses with supervisor titles or  
17 above, 1 ostomy nurse, 1 nutrition support nurse, 1 pelvic floor rehabilitation nurse, 1  
18 software engineer and 3 graduate students. The team members will attend two training  
19 sessions for the intervention program and the use of “e-bowel safety” applet provided  
20 by the group leader. The clinical psychologist will provide two training sessions for  
21 MIs, and all team members should pass the exam. One team member will be on shift  
22 each week to help patients, and others will be present throughout the duration of the  
23 study to support the team member if any undue problems occur.  
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26  
27 The “e-bowel safety” applet content module includes the following: The symptoms  
28 experience module, which includes patients’ stories, where patients can post their  
29 experiences in treating the disease or in self-management, and their peers will be able  
30 to respond to each post with comments and recommendations; A health diary, first  
31 daily landing and spontaneous pop-ups are provided for patients to record their diet,  
32 sleep, activity, and defecation on the previous day; The symptom management policy  
33 module, which includes the LARS informational module (LARS knowledge, daily life  
34 management strategies, and social communication strategies) that are presented in text  
35 and graphic form; Physical training which includes guiding patients in abdominal  
36 massage, pelvic floor muscle exercises and leg exercises in the form of videos; Online  
37 communication, where patients can always ask the intervention team questions; The  
38 Clock and Points module, where the system automatically generates points according  
39 to the length of time spent reading LARS knowledge and performing physical training  
40 hours; Intelligent reminders, which allows intervention team to push new messages to  
41 patients, and automatically or manually regularly remind patients about functional  
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4 exercise. Patients can also set the reminder function according to their own time; The  
5 symptom management effect evaluation module: In the self-health assessment, such  
6 as bowel symptoms, nutrition assessment, the results of the check to upload  
7 automatically. The “e-bowel safety” applet function module will include the  
8 following: A voice broadcast, considering that the patients are older, with vision loss  
9 and low education levels, where the written content can be broadcast by voice; Audio  
10 guidance, with an animated video guide; and Collection and search, where important  
11 content can be clicked in the collection module, and patients can search for the target  
12 content according to the keywords. The medical terminal also has the functions of  
13 push information management, regular reminder management, interactive circle  
14 management, user permission management and statistical analysis management. The  
15 communication board will be monitored on a daily basis. Figure 1 presents the  
16 “e-bowel safety” applet partial interface.

### 27 **Intervention group**

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

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

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

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56 The primary outcome will be the Global Quality of Life (QoL), as measured by the  
57 European Cancer Research and Treatment Organization Quality of Life  
58 Questionnaire-Core 30(QLQ-C30). Secondary outcomes will include bowel function  
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4 measured by the LARS score, bowel symptoms self-management behaviour measured  
5 by the Bowel Self-management Behaviour Questionnaire (BSSBQ), social support  
6 measured by the Perceived Social Support Scale (PSSS), and patients' thinkings. The  
7 scales all have been formally translated and culturally validated to Chinese  
8 populations. The measurement tools and timing are shown in Table 1.  
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#### 11 12 13 Quality of life

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15 Quality of life will be measured by the EORTC-QLQ-C30. It consists of 30 questions,  
16 which are aggregated into one global QoL scale, five functional scales, three symptom  
17 scales and six single items. The EORTC-QLQ-C30 has been well validated in rectal  
18 cancer patients and is correlated with the severity of LARS.[5, 6, 8, 9,26,27]  
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#### 21 22 23 Bowel function

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25 Bowel function will be measured by the LARS score, which contains five items aimed  
26 at symptoms of bowel dysfunction. The LARS score allows physicians to categorize  
27 patients as having major LARS (30~42 points), minor LARS (21~29 points) or no  
28 LARS (0~20 points). The LARS score has been well validated in rectal cancer  
29 patients in China.[28,29]  
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#### 32 33 34 Self-management

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36 The Bowel Symptoms Self-management Behaviours Questionnaire (BSSBQ) for  
37 Chinese rectal cancer patients after sphincter-preserving surgery will be used to test  
38 their bowel self-management behaviors. The BSSBQ consists of five functional scales  
39 and 20 items. The effect record is scored as follows: 0~3 points (0= no effect, 1=  
40 some effect, 2= some effect, 3= very effective).[30]  
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#### 43 44 45 Social support

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47 The Perceived Social Support Scale (PSSS) consists of 12 items, which mainly  
48 include three dimensions: family support, friend support, and other support. The  
49 Likert 7 scoring method is used, from "extreme disagreement" to "strong consent"  
50 with scores of 1 to 7, and the total score ranges from 12 to 84. A higher total score  
51 indicates that individuals feel more social support. The Cronbach's coefficient of this  
52 scale was 0.899.[31,32]  
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#### 60 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?

Table 1 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

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

### 15 **ETHICS AND DISSEMINATION**

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

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

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

## 7 **DISCUSSION**

9 This study focuses on the feasibility of a remote interaction intervention program for  
10 LARS patients based on “e-bowel safety” applet and MIs, provide supportive care  
11 information, and conduct regular MIs with dynamic, professional and personalized  
12 guidance to improve the “effective participation” of patients and improve their quality  
13 of life. After the intervention, semistructured interviews will be conducted to  
14 understand patient satisfaction and recommendations for the duration and form of the  
15 intervention.  
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18 At present, the common forms of patients’ bowel management include brochures,  
19 lectures, telephone, SMS, and nursing clinics. Although they play a certain positive  
20 role, the above methods are time-consuming and laborious, have low patient  
21 acceptance, have a limited audience, and are not sustainable.[34] It is impossible to  
22 help patients solve existing problems in real time or remotely, and the COVID-19  
23 pandemic hindered the return of postoperative patients to the hospital for review. This  
24 study, considered from the patient perspective, provides patients with an accessible,  
25 comprehensive, and shared form of remote interaction intervention with health  
26 professionals–patient participation. On the basis of a literature review and clinical  
27 practice, our team improved health education information, showed and met the  
28 learning needs of different patients in various forms of text and audio to improve  
29 patient acceptance. Health diaries and regular exercise clocking enable our team to  
30 remotely monitor patients' diets, exercise, management strategies and defecation in  
31 real time, provide personalized health guidance, and develop exercise programs with  
32 patients to increase their effective participation. Patients can post LARS management  
33 strategies to strengthen peer support. Providing points for gifts and other incentive  
34 systems, improving the completion rate of patient health diaries and the number of  
35 regular punching cards, improving the enthusiasm of patients to use "e-bowel safety"  
36 can help them better manage their bowel symptoms. Staged MIs, based on the patients'  
37 willingness to manage their bowel symptoms, mining patient and social motivational  
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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.

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

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38 **Figure 2** System architecture diagram of Symptom Management Theory.

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40 **Figure 3** Study flow chart.  
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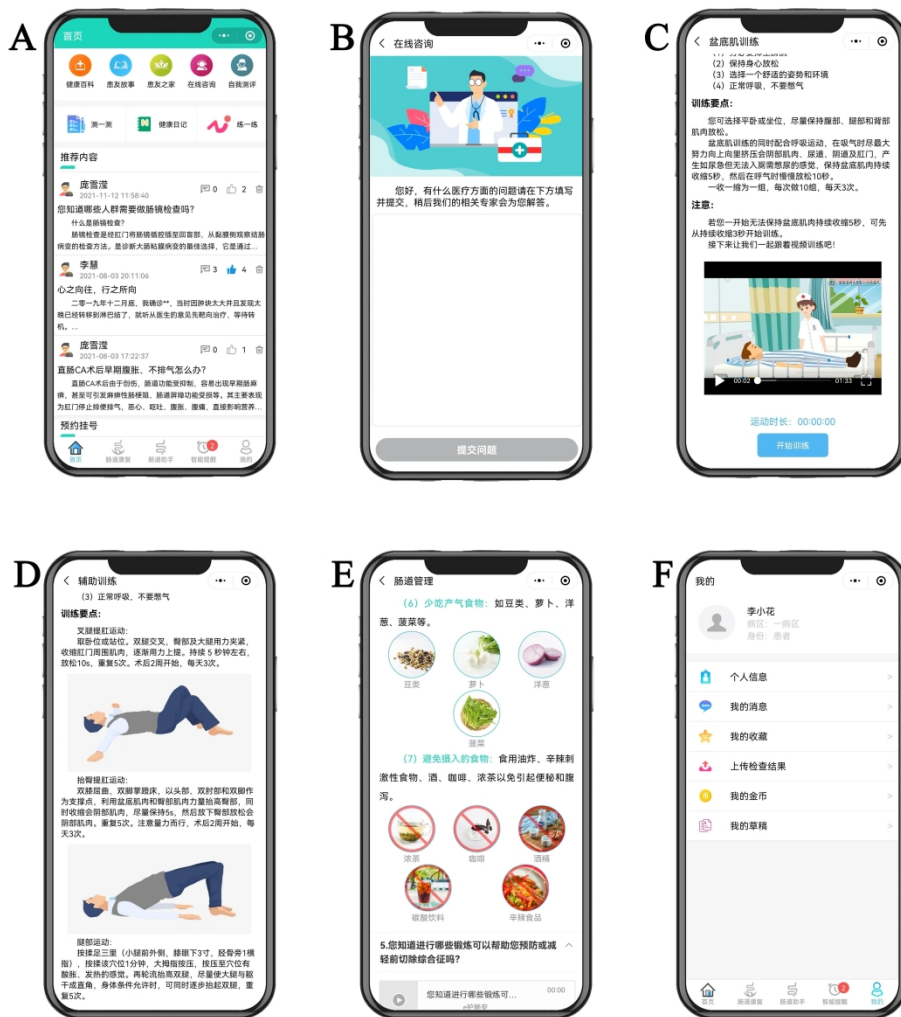


Figure 1 "e-bowel safety" applet interface. A. home page; B. online consultation; C. Text and video to guide pelvic floor muscle training; D. Text and pictures to guide other trainings; E. LARS informational module; F. Personal homepage.

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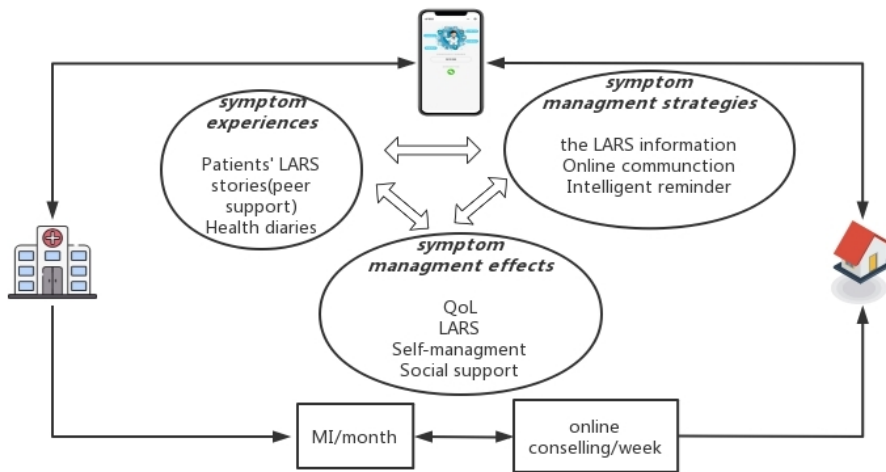


Figure 2 System architecture diagram of Symptom Management Theory.

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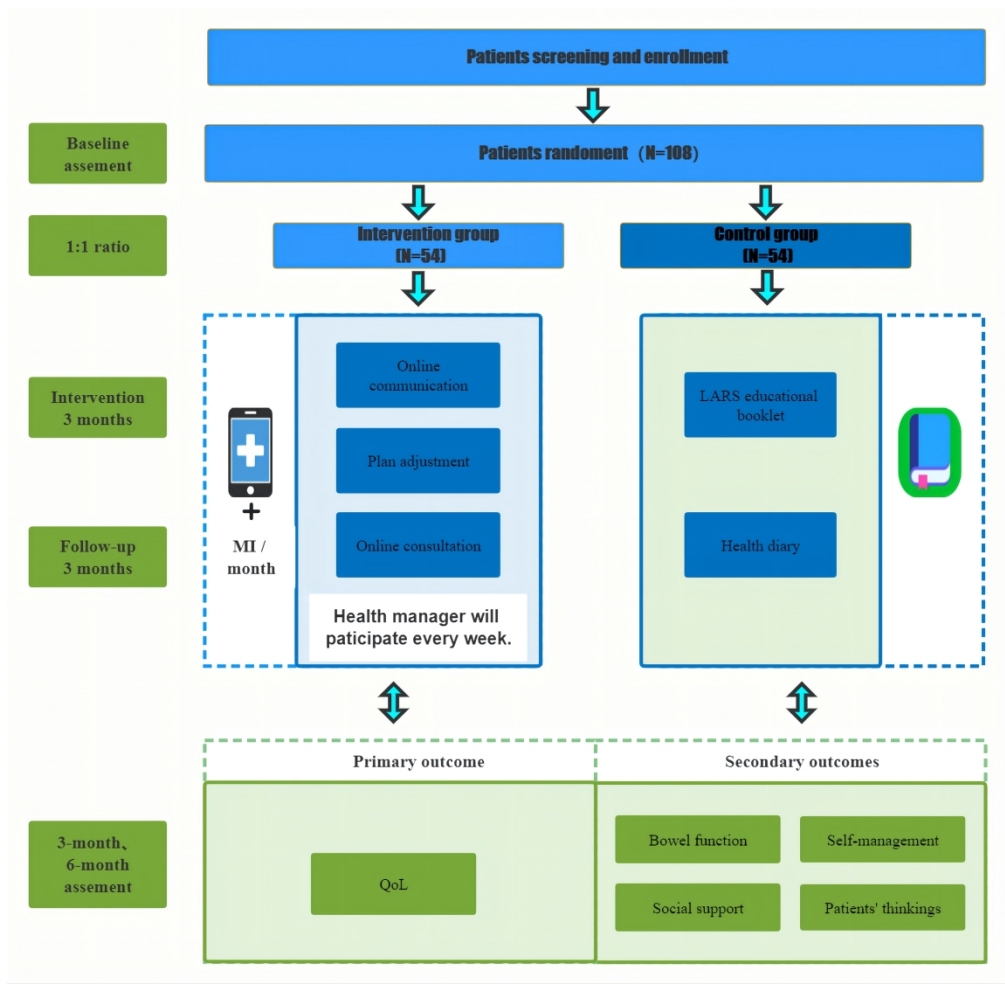


Figure 3 Study flow chart.

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