Trials

STUDY PROTOCOL

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Remote precise diet management intervention of defecation dysfunction among patients with rectal cancer after the sphincter-saving surgery: a study protocol for a randomized controlled trial

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Abstract

Background Different degrees of defecation dysfunction have emerged after the sphincter-saving surgery, which has made a significant influence on the quality of life of patients. Although diet adjustments were shown to be important for the management of defecation dysfunction, studies on the dietary management measures for defecation dysfunction after the sphincter-saving surgery are still scarce. This study aims to evaluate the effects of a "remote precise diet management intervention program" on patients with defecation dysfunction after the sphincter-saving surgery, providing a theoretical basis for clinical implementation of feasible diet management, and ultimately improving the quality of life of patients after the sphincter-saving surgery.

Methods This study will be a single-center, prospective, randomized controlled, non-blind trial involving rectal cancer patients after sphincter-saving surgery in a three tertiary general hospital who will be randomized into two groups. The intervention group will apply the "remote precise diet management intervention program" including one-on-one dietary instructions, a written booklet, app-assisted dietary recording and planning, and three times remote consolidating instructions and supervision every 2 weeks. The control group will receive a booklet that contains the same information as that provided in the "remote precise diet management program" and receive the standard counseling that is routinely provided by this hospital about the postoperative diet and Management of bowel symptoms. The intervention will begin from discharge until 6 months after surgery. The primary outcome will be the incidence of LARS after the sphincter-saving surgery. The secondary outcome is the quality of life and the dietary intake of participants after surgery. The occurrence of LARS will be evaluated by the Low Anterior Resection Syndrome Score (LARSS), quality of life, and dietary intake will be separately evaluated by the EORTC-QLQ-C30 questionnaire and Food Frequency Questionnaire(FFQ). Data will be collected three times: the baseline, 3rd month, and 6th month. Statistical analysis will be used to compare the outcomes between groups. Generalized estimating equations (GEEs) will be performed to evaluate the overall effect of the intervention on the incidence of LARS, quality of life, and dietary intake.

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Discussion The "remote precise diet management intervention program" in this study is designed with the characteristics of scientificity, precision, and feasibility aiming at controlling the bowel symptoms of patients after the sphincter-saving surgery. The findings of the study will provide a theoretical basis for the clinical implementation of feasible diet management, find effective ways to control defecation dysfunction, and ultimately improve the quality of life of patients after the sphincter-saving surgery.

Trial registration This study has been registered in the Chinese Clinical Trial Registry on March 22nd 2024 (the registration number is ChiCTR2400082167).

Keywords Rectal cancer, Sphincter-saving surgery, Low anterior syndrome, Dietetic intervention, Precise health

Introduction

Background

Colorectal cancer is one of the most common Malignant tumors of the digestive tract worldwide. According to the global cancer statistic report in 2022 [1], colorectal cancer ranks third and second in terms of cancer incidence and mortality worldwide. There were approximately 1.926 million new cases of colorectal cancer worldwide, accounting for 9.6% of all cancer cases. Due to the large population base in China, the number of cases and deaths from colorectal cancer has reached first place in the world [2]. In China, colorectal cancer represents the third most common Malignancy, comprising 10.7% of all cancer cases, with 517,000 newly diagnosed cases reported in 2022 [3]. Rectal cancer accounts for 30–35% of colorectal cases,and medium and low rectal cancer accounts for approximately 70% of total rectal cancer cases [4–7].

In recent years, with the deepening of rectal cancer research, surgical instruments, and treatment techniques are constantly improving, anal preservation surgery has gradually become the first choice for rectal tumor resection, accounting for more than 62–85% of the total number of rectal cancer operations [8–10]. However, the preservation of the anus does not mean that the normal bowel function of the anus can be fully preserved after surgery. Different symptoms of defecation dysfunction have emerged after the sphincter-saving surgery, including increased frequency of defecation, urgent defecation, frequent defecation, laborious defecation, and even liquid stool, gas stool, fecal incontinence, and other symptoms, which are also called low anterior excision syndrome (LARS) [11]. It is reported in research that the prevalence of LARS ranged from 55 to 91.6%, while the percentage of severe LARS ranged from 29 to 58.3% [12–16]. It was found in the longitudinal studies that patients still have LARS up to 15 years after surgery [17, 18]. The bowel symptoms after the sphincter-saving surgery have made a significant influence on the quality of life of patients. LARS is influenced by multiple factors, including the location and stage of the tumor, usage of radiotherapy and chemotherapy, surgical methods, and the time for temporary stoma repositioning [19]. The significant association between LARS and the decline in quality of life was shown in several studies. Patients with major LARS have significantly lower scores in many areas of quality of life (overall quality of life, physical function, emotional function, and social function) [20, 21], and how to manage defecation dysfunction among rectal cancer patients after surgery has become a problem that needs urgent attention and solution.

Diet is closely related to bowel function. It is reported in previous studies that after the sphincter-saving surgery, patients felt that the intake of certain foods would affect the occurrence of defecation dysfunction [22–24]. Our research group found in the previous observational study that both the intake of foods and nutrients of patients are related to defecation dysfunction, and the dietary intake of rectal cancer patients after the sphincter-saving surgery had changed a lot compared with that before surgery, but this change was not all conducive to the relief of defecation dysfunction. It was also found that the daily intake of Livestock and poultry meat, fats, milk and dairy products, vegetables, and Lipid nutrients within 6 months after the sphincter-saving surgery were the main dietary intake factors affecting the occurrence and relief of postoperative defecation dysfunction [25]. Thus, it is of great significance for the patients to have suitable dietary intake after operation to effectively control the defecation dysfunction.

Research showed that the management of defecation dysfunction of patients after the sphincter-saving surgery largely depends on patients'self-management, including dietary self-adjustments [26]. Several qualitative studies and investigative studies reflected that "trial and error" was the main method for patients' self-management of dietary management [22–24, 27]. Patients applied the most suitable dietary management measure through continuous attempts and avoided eating foods that would aggravate bowel symptoms. In the process of patient's self-management of dietary intake, the dietary adjustment measures adopted by different patients and the time for patients to find the most suitable diet measure were varied, meanwhile, so many patients were still unable to explore the dietary intake that could best alleviate

defecation dysfunction, which was not conducive to the relief of defecation dysfunction and the improvement of life quality [28–30].It was also reported that patients generally reported a lack of professional dietary management guidance after surgery, which could lead to malnutrition, low immunity, and unbalanced diets of patients [22, 30, 31]. The preliminary interviews of our research group also indicated that patients would also face information conflicts from different sources, which indicated that dietary management programs based upon professional guidance were in urgently needed [32].

However, there is no relevant research focusing on a doctor or nurse-led dietary guidance of defecation dysfunction until the last 2 years. Only two studies tried to explore the effects of nurse-led dietary management programs, and improvements in bowel symptoms after dietary interventions were found in both studies [33, 34]. In another prospective cohort study, Mette et al. (2023) found that dietitian-led dietary intervention aiming at controlling specific symptoms by moderating the intake of fiber or fat could improve gastrointestinal symptoms of patients with pelvic organ cancer in Denmark [35]. As to these three studies, two of them modified the intake of food fiber in the intervention group, and the other modified the patient's dietary intake according to their food and symptom diary. The existing studies all conducted dietary intervention follow-ups by phone. Therefore, some main points about the accuracy and precision of the dietary intervention, the possible interaction among different foods and nutrients, and the mobile technology used for remote intervention were not mentioned and not given enough concern. Meanwhile, relatively small sample sizes, variance evaluation tools for outcomes, and inconsistent effects reflected in different studies also limited dietary intervention's generalizability. In all, the descriptions of dietary management programs in the current limited studies are rather general, more focusing on type and frequency than on the specific consumption of foods and nutrient intake, quantitative dietary guidance, and the accuracy of dietary management is very insufficient now.

With the "Precision Medicine Initiative" put forward in 2015, precision medicine has become a hotspot in the field of health care [36–38]. In 2019, the National Institute of Nursing in the USA proposed the Nursing Science Precision Health model (NSPH). It consists of four parts: the precise measurement based on symptoms, the phenotypic characteristics based on living habits and the environment, the discovery of biomarkers based on genotypes, and the intervention design based on intervention target identification and self-management [39]. The concept of precision health has been applied in multiple fields. Existing studies have shown that precise management has achieved certain effects in lifestyle intervention, but no relevant research has been found in dietary management after sphincter-saving surgery [40, 41]. Therefore, more research focusing on precise management of the consumption of foods and nutrients based on the occurrence of bowel symptoms is needed to effectively control defecation dysfunction.

With the rapid development of digital technology, remote nutritional and dietary interventions (web page, mobile phone app, email, text messaging, and phone calls) are becoming more frequent at present [42]. In previous researches, remote interventions have shown significant effects on several aspects, including increasing intervention accessibility, helping optimize acceptability, adherence, and engagement [43–45]. In addition, remote interventions present advantages in terms of administrative convenience, efficiency in data collection, and flexibility in scheduling [45]. As to the limited research on the dietary management of defecation dysfunction, remote intervention is a better choice for the dietary management of cancer patients. On one hand, remote intervention could reduce the burden of medical treatment for patients and increase the accessibility of intervention; on the other hand, the patient's daily dietary intake at home needs to be recorded in a timely manner, and this can be achieved by using mobile tools.

More research with a large sample randomized controlled design, sufficient scientific basis dietary management, and quality-controlled remote intervention through mobile health tools are required to identify the effectiveness of more professional dietary guidance to promote the improvement of defecation dysfunction after the sphincter-saving surgery.

We present the protocol in accordance with the SPIRIT reporting checklist.

Objectives

This study aims to focus on the management of defecation dysfunction among rectal cancer patients after sphincter-saving surgery; and to evaluate the effects of precise diet management intervention programs on patients with defecation dysfunction and evaluate the primary effects on managing bowel symptoms, meanwhile the secondary effects on global quality of life (QoL). This study also aims at providing a theoretical basis for clinical implementation of feasible diet management, finding effective ways to control defecation dysfunction, and ultimately improving the quality of life of patients after sphincter-saving surgery.

Methods

Trial design and study setting

This is a single-center, prospective, randomized controlled, non-blind study conducted at a tertiary teaching hospital in China. This study was registered in the Chinese Clinical Trial Registry on March 22nd 2024 (the registration number is ChiCTR2400082167). https://www.chictr.org.cn/showproj.html?proj=223224. The study will be conducted in the colorectal surgery clinic in a tertiary hospital in China, which is one of the largest hospitals in Shanghai. The intervention group will receive the "remote precise diet management program" based on the scientific program construction. The control group will receive a booklet that contains the same information as that provided in the "remote precise diet management program" and receive the standard counseling that is routinely provided by this hospital about the postoperative diet and Management of bowel symptoms. The intervention will last 6 months, and this study will be conducted from 1 March 2024 to 30 June 2025. The flow chart of the study design is shown in Fig. 1.

Participants

Eligibility criteria

The inclusion criteria are as follows: (1) patients aged from 18 to 80 years; (2) patients diagnosed with primary rectal cancer by pathology; (3) patients who had undergone sphincter-saving surgery within 1 month; (4) the distance between the lower Margin of the tumor and the anal Margin is less than 15 cm; (5) patients who recovered well after surgery and began to eat semi-liquid, soft, or general food.

Exclusion criteria

Patients who meet any of the following criteria will be excluded: (1) patients with distant metastases; (2) patients with lactose intolerance; (3) patients who suffered complications (anastomotic fistula, rectovaginal fistula, etc.) after surgery; (4) patients who suffered from intestinal problems such as inflammatory bowel disease or irritable bowel syndrome before surgery; (5) patients who had undergone radiotherapy before surgery; (6) patients who had a history of anorectal surgery; (7) patients who had a temporary enterostomy in surgery; (8) patients with communication disorders.

Who will take informed consent?

Patients who are diagnosed with the rectal tumor and have undergone sphincter-saving surgery will undergo eligibility screening to determine their suitability for participation in this trial. Once the researcher has assessed the patient as eligible, the patient will receive recruitment information at the time of the first return to the outpatient clinic after surgery from the researcher. During this clinic, patients will have the opportunity to ask any questions they may have and sign the informed consent form.

Sample size calculation

The sample size estimation method for the comparison of two sample rates under a completely random design was applied in this study. The results from the previous study of our research group showed that the incidence of LARS was 60.9% among patients 6 months after the sphincter-saving surgery [46], and it was estimated that the incidence of LARS in the intervention group 6 months after surgery was 45%. Take both sides $\alpha = 0.05$, $\beta = 0.2$. The effect size is set to be 0.5. The sample size ratio between the intervention group and the control group was 1:1. The sample size was calculated to be 186 patients in each group. Considering the inevitable loss rate of follow-up, the sample size was expanded by 20% to ensure the supplementation of eliminated and dropped patients, and the sample size was finally set to 223 patients per group.

Assignment of interventions: randomization and allocation

The simple randomization method was adopted in this study, and all subjects meeting the inclusion criteria will be divided into the intervention group and control group by the random number table method. A random number table with 10,000 digits was used, and numbers were extracted in a left-to-right, top-to-bottom order. Subjects were assigned to the intervention group if the extracted number was an odd number and to the control group if it was an even number, ensuring a roughly 1:1 allocation ratio. As recruitment is finishing, participants can obtain a random code.

The execution of the allocation sequence was solely performed by the designated research assistant responsible for envelope preparation and storage. This assistant was not involved in any other study procedures, such as participant screening, intervention delivery, or follow-up evaluations, to minimize the risk of selection bias. This assistant randomly allocated the enrolled patients into the intervention group or the control group according to the computer-generated randomization scheme. For allocation concealment, opaque, sequentially numbered, and sealed envelopes were used. The envelopes were stored in a locked cabinet accessible only to this statistician until the time of allocation. When a participant met all eligibility criteria and provided informed consent, the next envelope in the sequence was opened in the presence of the participant's attending clinician, who was unaware of the envelope's contents before opening.

Meanwhile, the outcome assessors will be unaware of patient assignments to avoid selection bias.

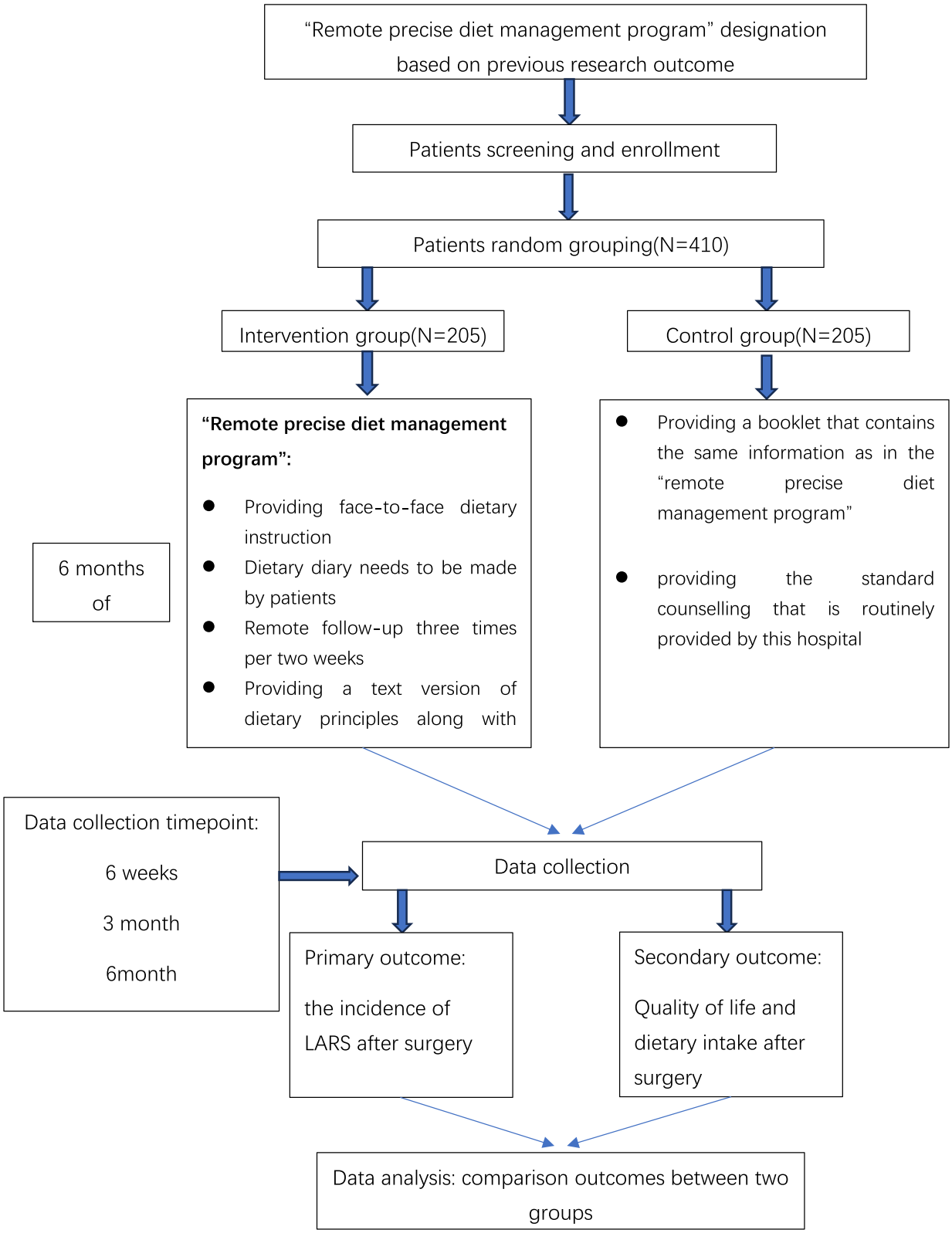

Fig. 1 The flow chart of the study

Assignment of interventions: blinding

Who will be blinded

Data collectors will be blinded. These assessors, who are in charge of collecting data at baseline and 6 weeks, 3, and 6 months of the study, will not be informed of the group information of the patients or the specific interventions they receive. All the data will be handed over to a statistician who is not involved in the intervention process to conduct data analysis. This statistician will remain blinded to the grouping information of the patients and the specific interventions they received until the data analysis is completed. This can reduce bias during the data analysis stage, thereby ensuring the objectivity of the analysis results.

Procedure for unblinding if needed

The patients enrolled in the two groups will be unblinded, as the complete separation cannot be achieved during the treatment process. The two researchers responsible for conducting the interventions will also be unblinded, as they need to clearly know the intervention protocols for each group to ensure the accurate implementation of the interventions.

Intervention

The research team and the "remote precise diet management program"

The research team includes 1 head nurse (group leader), 2 colorectal surgeons, 2 nurses with supervisor titles or above, 1 nutritionist, and 3 graduated students. The "precise diet management program" was constructed according to previous study results of our research group, combined with the consultation of experts and Dietary Guidelines for Chinese residents (2022). This program includes the following: the specific recommended intake range of different kinds of foods and nutrients, recommended types of foods and dietary patterns, specific dietary guidance plan including the timing and form of guidance, and the written instruction materials including the dietary survey photo gallery and knowledge about foods and nutrients. The content of "the precise diet management program" is shown in Table 1.

Intervention group

The intervention group will receive the "remote precise diet management program" based on the scientific program construction During the first 6 months after the sphincter-saving surgery. The whole intervention process includes 12 sessions over a 6 months' period.Each patient receives the first dietary instruction at their first postoperative clinic, and then the intervention team will do the remote follow-up (by regular phone call every 2 weeks) on randomly selected 3 days every 2 weeks to evaluate the implementation of the "remote precise diet management program" to answer their questions about the program, and to make timely corrections for patients.

Session 1 was administered at patients' first postoperative clinic. During this session, the guidance method combining one-to-one education and intensive education will be adopted. Knowledge about the methods of estimation of various nutrients in foods, the methods of converting the amount of nutrients into the weight of food, the methods of estimating the weight of foods, and the estimation of the volume of commonly used containers will be taught to patients in the intervention group. Meanwhile, the healthy lifestyle and disease-related knowledge after discharge will also be taught to patients. A text version of their dietary principles and precautions after surgery will be sent to the patient, along with accompanying dietary pictures. The usage of the "MINT HEALTHY" app, with the function of making precise records of every food intake and every meal intake per day, and the function of automatically calculating the intake of each food and nutrient based on three meals a day, will be provided to patients by the intervention team to make sure that during the first guidance, the "MINT HEALTHY" app has been installed in the phone of patients and the correct usage methods have been grasped by patients. The usage screenshots of the "MINT HEALTHY" app is shown in Fig. 2 below.

The main functions of the app include recording diet and diet analysis. Patients could choose every food of specific consumption by themselves for every meal and then the total daily intake of foods for patients could be recorded, calculated, and analyzed by this app. The records in the app also could be fully sent to other platforms like the WeChat app. Then researchers could supervise whether the daily intake of patients is correct or not. So that when patients go home after the clinic, they can make precise records of dietary intake and get the daily intake of foods and nutrients every day to make sure the dietary intake conforms to the principles in the "remote precise diet management program." In recent years, the "MINT HEALTHY" app has been widely used in China. In previous studies, it has been applied to self-diet recording during weight management and blood sugar management for diabetic patients and has demonstrated good accuracy and reliability in diet recording [47, 48]. Based on its powerful database and computing capabilities, it can help patients precisely record and Manage food and nutrition in research. During the pilot studies, 10 patients who had undergone sphincter-preserving surgery for rectal cancer began to use the "MINT HEALTHY" app to record their diet. The patients not only needed to upload screenshots of the types and quantities of healthy foods

Table 1 The content of "the precise diet management program"

Content of program	Remark
Recommended food intake: 1. Cereals: To ensure enough daily intake of an appropriate amount of cereals, the average intake of 250–400 g per day is more appropriate, pay attention to the proper match of coarse grain and fine grain 2. Livestock and poultry meat: The average intake of Livestock and poultry should not be too restricted after surgery. The intake of Livestock and poultry meat is 40–75 g per day is more appropriate, and poultry should be preferred, while the intake of red meat should be reduced 3. Aquatic products: The average intake of 40–75 g per day is more appropriate, and the intake of fish is preferred 4. Vegetables: It is necessary to pay attention to increasing the intake of vegetables, the recommended intake is 400–500 g/day, and it is recommended to take in all kinds of green leafy vegetables and to take vegetables every meal 5. Fruits: It is recommended to have fruit intake every day after surgery, and the recommended intake is 200–350 g per day 6. Dairy products: Appropriate intake of all kinds of milk and dairy products after surgery, but the intake should not be too much, the recommended intake is 100–110 ml per day 7. Soybeans and nuts: The recommended average intake of soybeans and nuts is 25–30 g/day 8. Eggs: To ensure the enough daily intake of an appropriate amount of eggs, the average intake of 40–50 g per day is more appropriate, and the egg yolk can also be ingested and should not be discarded 9. Oils and fats: After surgery, it is recommended not to take too Many oils and fats, the recommended intake is 22 g per day, no more than 30 g per day, and it is recommended to take vegetable oil 10. Salts: Low salt intake is recommended, and no more than 6 g per day 11. Avoiding alcohol intake 12. The barbecued, marinated animal foods are limited	1. Cereals: mainly including wheat, rice, corn, millet, sweet potato and so on 2. Livestock and poultry meat: Mainly includes pork, chicken, duck, beef, lamb and so on 3.Aquatic products: Mainly include fish, shrimp, crab, shellfish and other food 4. Vegetables: Mainly includes all kinds of rhizomes, fresh beans, eggplant fruits, melons, tender stems, leaves, cauliflower and so on 5. Fruits: Mainly includes berries, stone fruit, citrus, and all kinds of tropical and subtropical fruits 6. Dairy products: Including liquid milk, milk powder, yogurt, cheese, cream, etc 7. Soybeans and nuts: Soybeans include soybean milk, bean curd, bean curd, etc. Nuts include walnuts, peanuts, sunflower seeds, pistachios, etc 8. Eggs: Including eggs, duck eggs, quail eggs and so on 9. Oils and fats: Including animal fats and vegetable oils
Recommended range of nutrient intake: The intake of energy, lipids, protein, carbohydrates, dietary fiber and cholesterol should be based on the intake range in the "Dietary Guidelines for Patients with Malignant Tumors" and "Dietary Guidelines for Chinese Residents 2016 Edition"	
Food types: It is recommended to have a variety of foods, preferably more than 25 foods per week	
Recommended dietary pattern: it is recommended to avoid the dietary pattern of Livestock and poultry oils and fats -milk	
Timing of dietary guidance for patients: The first guidance for patients is the first postoperative clinic, patients will go to the first postoperative clinic about 2 weeks following surgery	
Forms of dietary guidance: Combine centralized education with individual guidance First of all, the researchers and nutritionists of the research group organized a centralized training and education for postoperative dietary guidance for patients, and their families. If each patient or family member has questions, the researchers will conduct one-on-one guidance to answer questions	
Supplemental dietary atlas provision: Each patient is provided with a map of common food quantities to help determine the amount of food consumed daily	
Information screening support: Providing patients with professional diet-related knowledge query resources, including websites, books, etc., to avoid finding unscientific diet-related information	

Table 1 (continued)

Content of program	Remark
Personalized adjustments about diet intake On the basis of meeting general dietary intake requirements, implement personalized dietary management as follows: 1. At enrollment, use the FFQ scale to investigate patients' previous dietary habits; identify priority food types and quantities to manage (referring to this protocol's dietary requirements) and monitor them during follow-ups 2. Instruct patients to keep a diet diary to record foods that worsen defecation dysfunction symptoms, feed back promptly to researchers; researchers will formulate a subsequent food replacement plan for such foods	
Remote support: To establish a complete remote support system for dietary guidance, in order to track the implementation of the dietary guidance program for patients, establish a WeChat group for patients and invite doctors and nutritionists to join in, provide timely guidance on the dietary intake of non-local patients by phone or WeChat app, and provide professional consultation and reply to patients' dietary problems	
Family support: Establishing a linkage support system for medical staff, patients and their families, explaining the implementation methods and precautions of the dietary guidance program to the families of patients in detail, so that they can help and supervise the implementation of the program. •	
Compliance guarantee: Check the compliance of the patient's dietary guidance program three times During 2 weeks, check the patient's dietary intake by checking the dietary diary from app, or pictures and videos from WeChat platform, and guide the patient to follow the fixed food recommended intake range in the program	

they consumed but also photos of all their meals within a day for researchers to compare. Through checking the differences and uniformity between them, researchers found that the dietary intake recorded by these patients was in good consistency with the actual food they consumed. It can be seen that the "MINT HEALTHY" app is reliable for recording dietary intake.

Sessions 2–12 will be the regular calls every 2 weeks. The researcher randomly selected 3 days every 2 weeks to evaluate the implementation of the "remote precise diet management program" to answer their questions about the program and to make timely corrections for patients. During these calls, the patient's daily diet records will be combined to assess whether they have followed the recommended dietary standards for this period of time, and the evaluation result during this period will be fed back to the patient. If the intake of some food types does not match the recommended range, the researcher will discuss with the patient, analyze the reasons, and conduct timely adjustments for patients. Meanwhile, the researcher will ask the patient about the types of food that may affect defecation dysfunction found based on daily records and discuss with the patient the dietary adjustments that need to be made on the basis of compliance with the "remote precise diet management program."

Strategies to improve adherence to interventions

Specific strategies were conducted to ensure the compliance of the intervention. First, the researcher will maintain a set of participants' records that include data from every dietary diary Made by patients and the date on schedule to collect records. So the researcher will regularly check the integrity and timeliness of the dietary diary sent back by patients. Second, the researchers will contact every patient and randomly select 3 days every 2 weeks to check the dietary review diary recorded by patients to ensure that the average daily intake of foods of patients in this group adheres to the instructions of the "remote precise diet management program" To guarantee that the dietary diary is consistent with the real situation, photographs of food intake for three meals a day will be taken by patients and sent to the researchers 3 days every 2 weeks. Third, regular reminders will be sent to every patient by WeChat app once a week since the intervention begins, including the dietary recording on the "MINT HEALTHY" every day and suggested daily intake of foods in the "remote precise diet management program." Some quantitative indicators of compliance were used to record their specific situations, including the completion ratio of the average daily intake of all food types in the "remote precise diet management program," as well as the integrity

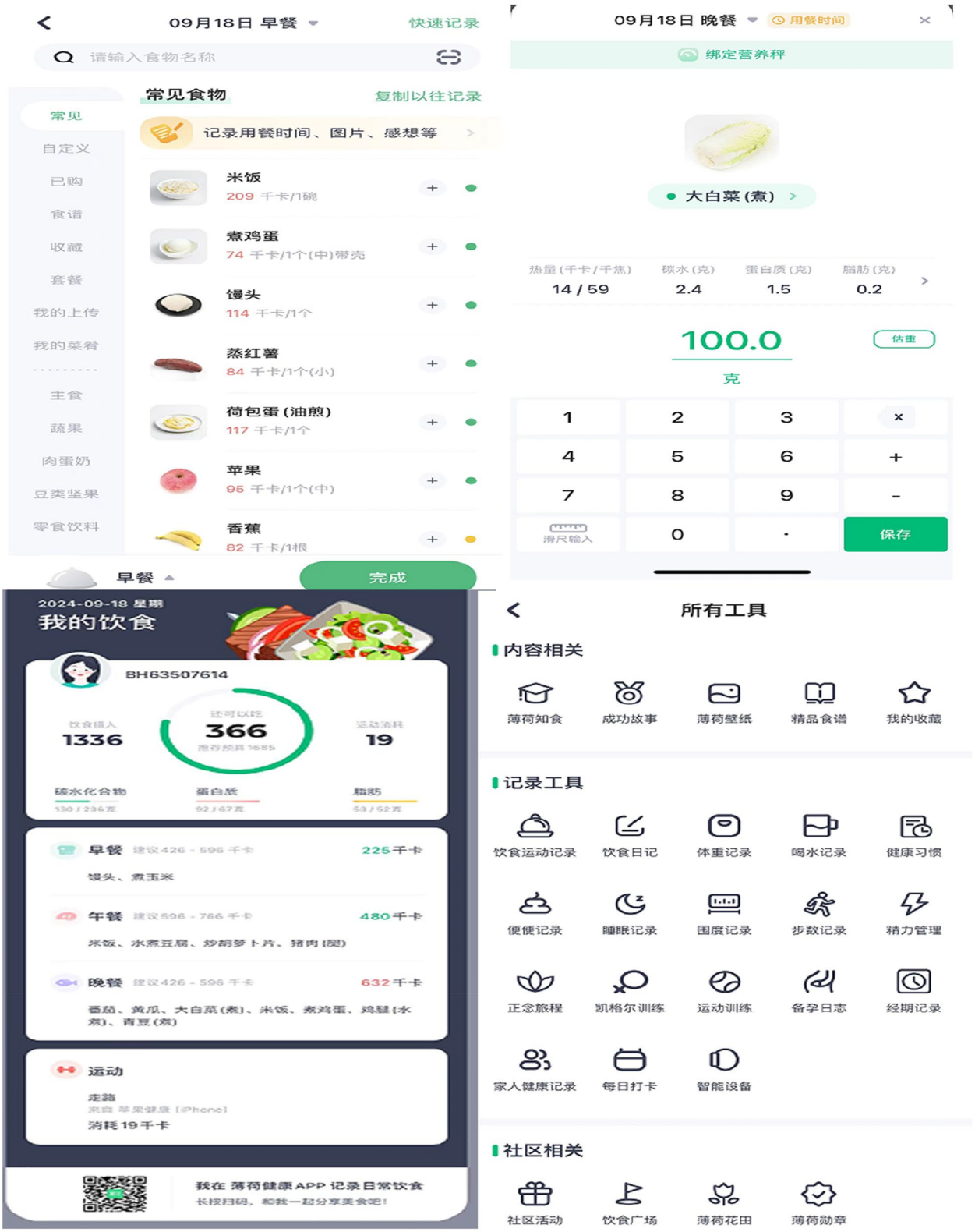

Fig. 2 The usage screenshots of the "MINT HEALTHY" app

and timely upload rate of the dietary diary sent back by patients.

Criteria for discontinuing or modifying allocated interventions

Subjects can withdraw from the study at any time for any reason. Considering the safety of the subjects, when the patient experiences situations where it is not appropriate to continue the study, including serious adverse events, poor compliance, experiencing lactose intolerance, and unwillingness to sign an informed consent form.

The researchers providing the intervention will be two registered nurses, and they need to have experience with cancer survivors and will be uniformly trained on "remote precise diet management program"-specific knowledge before the study begins, including knowledge about the background of the study and the intervention program, the methods of estimation of various nutrients in foods, the methods of estimating the weight of foods, the estimation of the volume of commonly used containers, the usage of the specific app, and the flow and schedule of intervention.

If Lactose intolerance emerges during the intervention process, which will be accessed by researchers, the trial will be stopped and the participant will discontinue the study.

Control group

Participants in the control group will receive a booklet that contains the same information as that provided in the "remote precise diet management program" and receive the standard counseling when they return to clinic for a follow-up visit. During standard outpatient consultations, doctors will answer patients' questions about dietary intake and tell them to avoid foods that may aggravate their intestinal symptoms based on patients' chief complaints. The estimation of the intake amount of each food mentioned in the "remote precise diet management program" and the conversion of nutrients will not be explained in detail.

The main difference between the two groups will be the following: (1) whether they receive the first one-to-one specific instructions at hospital about the estimation of various nutrients in foods, the methods of converting the amount of nutrients into the weight of food, the methods of estimating the weight of foods, the estimation of the volume of commonly used containers, and the usage and installation of the "MINT HEALTHY" app; (2) whether they make daily dietary records on the "MINT HEALTHY" app and send them back to researchers; (3) whether they receive remote one-to-one instructions every 2 weeks according to dietary records; (4) whether they make timely corrections according to instructions. Questionnaires for all participants will be sent in the same format and at the same time for both groups.

Treatment fidelity

Several approaches will be applied to ensure intervention rigor and validity. All telephone sessions will be audio-recorded and reviewed by the Research Chair. All screenshots on the WeChat app about the regular remote guidance and instruction will be checked by the Research Chair. Continuous monitoring will be initiated through random sampling of 15% of calls and instructions on the WeChat app in the first 2 weeks of the study and 5% monthly thereafter. A pilot randomized trial will be conducted to assess the preliminary efficacy, feasibility, and acceptability of the "remote precise diet management program" intervention. Feasibility will be defined as the percentage of consented participants who were successfully randomized.

Outcome

Primary outcome and assessment

The primary outcome is the incidence of LARS at 6 months after the sphincter-saving surgery. Data on postoperative experience of LARS will be obtained by the Low Anterior Resection Syndrome Score (LARS Score) questionnaire.

Secondary outcome and assessment

The secondary outcome is the quality of Life and the dietary intake of participants at the 3rd and 6th months after surgery. Data on postoperative quality of life will be obtained by the EORTC-QLQ-C30 questionnaire. The dietary intake will be obtained by the Food Frequency Questionnaire.

Two data collectors will be responsible for data collection throughout the research. They will be uniformly trained before the research to avoid subjective understanding deviations and ensure the consistency of the evaluation criteria during the questionnaire assessment process. Demographics and disease-related information are acquired through the General Information questionnaire and the Clinical Information questionnaire, which can be found in the database of the hospital. These questionnaires will be completed at different stages after surgery. The measurement tools and timing are shown in Table 2.

General information questionnaire

The general information questionnaire consisted of several items, including age, sex, employment status, education level, tobacco and alcohol use, and dietary habits before surgery.

Table 2 The content and timing of data collection

Outcome	Measurements	6th week	3rd month	6th month
Primary outcome				
Incidence of LARS	Low Anterior Resection Syndrome Score	√	√	√
Secondary outcome				
Quality of life	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30	√	√	√
Dietary intake	Food Frequency Questionnaire (FFQ)	√	√	√

Clinical information questionnaire

The clinical information questionnaire collected past medical information and data related to the treatment of rectal cancer, including the history of past chronic disease, history of personal and family cancer, history of past surgery, classification of the tumor, length of bowel removed, anastomotic site, lymphatic metastasis, and adjunct therapy before and after surgery.

Low anterior resection syndrome score(LARS score) [49]

This scale, developed by Emmertsen in 2002 to assess the low anterior resection syndrome of patients after sphincter-saving surgery, includes 5 items: (1) flatus incontinence; (2) shapeless stools and fecal incontinence; (3) frequency of defecation; (4) ability to control defecation; and (5) urgent defecation. The final score of this scale is the sum of the scores of all the items, with a total score of 0 to 42 points. The status of LARS can be divided into three levels according to the total scores: no LARS (0–20 points), minor LARS (21–29 points), and major LARS (30–42 points). Minor LARS and major LARS are collectively defined as the occurrence of LARS. The Chinese version of the LARS score was developed by Cao and was applied in this study [50].

Food frequency questionnaire

Dietary intake was assessed with a quantitative food frequency questionnaire (FFQ), reflecting the consumption of the Main food items by investigating the frequency of taking certain foods and the portion size taken every time. The FFQ was designed by the Chinese Center for Disease Control and Prevention in 2010 to monitor people's nutrition and dietary habits [51]. More than 100 food items were assigned to 11 food categories in FFQ. Intake frequency was measured by a scale of categories ranging from "times per day," "times per week," "times per month," and "times per year." By multiplying the frequency and portion size, the average consumed amount was calculated and expressed as the intake in grams per day. Based on the type and consumption of food collected by the FFQ questionnaire, nutritional analysis was conducted by the Nutrition Calculation Software in this study, which was developed based on the Chinese common food nutrition content table (version2023), to calculate the daily intake of different types of foods and nutrients and then the patients' nutrients database could be output from this software.

EORTC-QLQ-C30 questionnaire

This questionnaire was developed by the European Organization for Research and Treatment of Cancer (EORTC) The scale includes 30 items in 15 domains, which are aggregated into 1 global QoL scale, 5 functional scales, 3 symptom scales, and 6 single items. The higher the scores in functional scales and the global QoL scale, the better the functional status and quality of life of the patients; the higher the symptom scale of the respondent, the more symptoms the patient has and the worse their quality of life. The EORTC-QLQ-C30 has been well validated in patients with rectal cancer [11, 17, 52].

Data collection

Two data collectors will be responsible for data collection throughout the research. They will be uniformly trained before the research to avoid subjective understanding deviations and ensure the consistency of the evaluation criteria during the questionnaire assessment process. Demographics and disease-related information are acquired through the General Information Questionnaire and the Clinical Information Questionnaire, which can be found in the database of the hospital. Data on postoperative experience of LARS, quality of life, and dietary intake will be collected at different stages after surgery face-to-face or by phone calls, depending on whether the patient can reach the hospital conveniently. The content and timing of data collection are shown in Table 2.

Data management

The data will be recorded in the research electronic data collection (EDC) system, which will be used as an EDC system for long-term data storage and management.

The original data will be recorded timely and accurately. All data will be identified with a code number to ensure the confidentiality of the participants' data. The chief researcher can directly access the database. The Research Ethics Committee of the Zhongshan Hospital will be responsible for the data monitoring.

Statistical analysis

Statistical analysis for primary and secondary outcomes

SPSS 22.0 was applied for the statistical analysis, and the statistical significance was set at $P<0.05$ (2-tailed). Continuous variables are expressed as the mean (standard deviation), and categorical variables are described as numbers (%). Continuous outcomes in two groups will be compared using a t-test, and categorical outcomes will be compared using the Wilcoxon rank sum test.

To explore the relationships between participant demographics and incidence of LARS and describe potential confounders of LARS, a multiple logistic regression model will be built. The overall effect of the intervention on the incidence of LARS, quality of life, and dietary intake will be modeled using generalized estimating equations (GEEs) and the significant confounding factors were entered hierarchically per clinical and personal factors. To compare the differences between the changing trend of scores of LARS, FFQ, and EORTC-QLQ-C30 During the 6 months after surgery in two groups, the two-factor repeated measure analysis of variance will be performed. The reason why GEE is chosen is that it shows the within-subject correlations between responses at different time points, and it can still work when some of the data is missing. If there are baseline imbalances in the data, the mixed-effects model will be applied. It is more flexible in handling the baseline and can directly include the baseline values as covariates while retaining all repeated measurement data.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data

We allow patients to have 10% missing data, which will be deleted as blank. When the patient's data is missing by more than 10%, the patient will be deleted. If missing data occurs, we will take a sensitivity analysis by using the maximum bias strategy. No imputation will be performed for missing data.

Ethical approval

Ethical approval for this study was granted by the Zhongshan Hospital Medical Ethics Committee in January, 2024(NO:2024-019R). The study will adhere to the ethical principles stated in the Declaration of Helsinki.

Adverse events

We will document any adverse events that occur during the clinical trial. An adverse medical event that occurs after a patient or clinical trial subject receives an intervention, but is not necessarily causally related to the treatment, is called an adverse event. Serious adverse events are defined as events that require hospitalization, prolong hospitalization, cause disability, affect workability, endanger life, cause death, and cause congenital deformities during clinical trials. Clinical adverse events may occur during the subject's treatment. If an adverse event (including a major adverse event) occurs, the occurrence time, clinical Manifestations, treatment process and Duration, outcomes, and the related events of the adverse events will be recorded in detail on the case report form. If there are abnormal laboratory tests, the patients will be followed up until the test results return to normal, or to the level before the intervention, or until it is determined that the test results are not related to the research operation. Serious adverse events will be recorded in a serious adverse event form and reported to the Ethics Committee within 24 h.

Participant timeline

The participant timeline is listed in Table 3.

Discussion

This study focuses on evaluating the effectiveness of a "remote precise diet management program" on the management of LARS among rectal cancer patients after sphincter-saving surgery. It provides evidence on whether the diet intervention with precision, scientificity, and feasibility leads to better outcomes in patients with defecation dysfunction after surgery.

LARS has become an obvious health burden during the rehabilitation process of rectal cancer patients. As reflected in some previous research, according to patients' subjective feelings, the dietary intake was closely related to bowel symptoms among patients after the sphincter-saving surgery [22–2422]. However, the current dietary management methods of LARS are limited, and patients reflected that the scientific dietary instructions were scarce, which made it difficult to guarantee the scientific nature of patients' self-dietary management measures. The "remote precise diet management program" in this study was constructed with the theoretical basis of previous research finished by our study group [25, 32, 46]. The construction of "remote precise diet management program" was mainly based on the qualitative interviews based on patients' actual demands, the impact of food and nutrients on defecation dysfunction in the previous prospective cohort study, and the Literature review of the current dietary guidelines for rectal cancer patients. In

Table 3. The SPIRIT timeline of this trail

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT**	-1week	0	6weeks	3months	6months	
ENROLMENT:						
Eligibility screen	√					
Informed consent	√					
[List other procedures]	√					
Allocation		√				
INTERVENTIONS:						
[Intervention A]		◆—	—	—	—◆	
[List other study groups]		◆—	—	—	—◆	
ASSESSMENTS:						
[List baseline variables]	√	√				
[List outcome variables]			√	√	√	
[List other data variables]			√	√	√	

the previous prospective cohort study, the specific relationship between some food intake and nutrient intake and the incidence and severity of defecation dysfunction after surgery During the first 6 months after surgery had been explored, the optimal intake range of food types such as livestock and poultry meat, dairy products, and vegetables, and the dietary patterns to be avoided were also identified, which provided powerful and concrete evidence to support the scientificity of "remote precise diet management program" [25].In the previous descriptive qualitative study of our group, patients' dietary management concerns, needs, specific contents that require guidance, and preferred ways to receive guidance were explored, providing evidence to make the implementation details of the intervention plan match the demands of the patients so as to ensure the feasibility of "remote precise diet management program" [32]. A previous literature review of self-management methods applied by patients after the sphincter-saving surgery showed that knowledge about the characteristics of specific foods and the relationship between specific foods and bowel symptoms after surgery was urgently needed by patients [31]. Tylor et al. also pointed out that more attention needs to be paid to specific dietary adjustments for management of LARS [31]. In previous studies, the dietary adjustments were described in general terms and were not focused

on quantitative guidance of dietary intake, which led to an obvious lack of precision and effectiveness of dietary management [28–30]. In recent years, the concept of precision health has penetrated into many research fields [53–55]; however, no study has yet discussed the effects of precise diet management on patients suffering from LARS after sphincter-saving surgery.

Mobile health (mHealth) is defined by the World Health Organization (WHO) as "medical and public health practices supported by a mobile device,such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices [56]. mHealth is becoming increasingly common in healthcare and shows an important function in modifying dietary behaviors. A growing number of research studies have incorporated mHealth into lifestyle interventions, especially to modify dietary behaviors among cancer patients [45, 57, 58]. To make sure that patients are taking foods exactly as required in the intervention program, this study applied a remote LARS interaction management by use of an app "MINT HEALTHY" so that the specific data about the dietary intake every day could be recorded and collected timely, and the compliance of patients could be guaranteed as much as possible.

This study has several limitations. First, it is a single-center study and patients recruited in this study are from a large tertiary hospital, which may lower the representativeness of the results. In follow-up studies, our study group will conduct a multi-center trial to validate the results across different settings to further improve the representativeness of results. Second, this trial is limited to patients with smartphones and apps, which could possibly lead to selection bias of patients. In order to avoid selection bias, some family members living together with patients can make dietary records in their smartphones instead of patients themselves, so that patients meeting inclusion criteria can also be included in the study. Third, as to the restrictions of time and place of this study, patients cannot be completely separated from each other to avoid contamination. It is non-blind, which may lead to the possibility of subjective influence of researchers on the results of research. Several methods have been conducted to avoid the subject bias, including unified training of researchers, strict standardized intervention processes and supervision, and letting the data collectors and data statistician be blinded in the whole process of this research.

Trial status

The trial started patient recruitment in October 2024. The current protocol is version 1 of 22–3-2024. Currently (5th of August 2025). The recruitment process will persist for a Duration of 3 years, expected to be finished by 31 December 2027.

Abbreviations

HRQoL	Health-related quality of life
LARS	Low anterior resection syndrome
mHealth	Mobile health

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Authors' contributions

Liuwen conceived and designed the intervention program and the methodology of this trial. Xu Jian Min and Liu Wen will carry out the intervention and collect data. Liu Wen drafted the manuscript. Zhu Ai Yong and Xu Jian Min both provided a critical review of the manuscript. All authors read and approved the final manuscript.

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Data availability

The datasets generated and analyzed during the future study will not be publicly available due to the protection of patients' privacy but will be available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

This study has undergone full ethical review by the Zhongshan Hospital Medical Ethics Committee and was approved 23rd January 2024(B2024-019R). Informed written consent will be provided to participate before the study begins, which is the approved consent process by the ethics committee.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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