Protocol Title：（Exploring the Clinical Value of an AI-Assisted Patient Self-Assessment App for Bowel Preparation: A Multicenter Study）

Informed Consent Form

Protocol No.：2025.09.01

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Please read the following information carefully

You are being invited to take part in a clinical research study. This informed consent form gives you information to help you decide whether or not to participate. Please read it carefully and feel free to ask the study staff any questions—you will receive detailed answers. You may take as much time as you need to decide, based on your own situation.

1. Study background and aims

Colonoscopy is the most effective way to screen for, diagnose, and even treat colorectal cancer. Finding and removing polyps early can greatly reduce both the medical burden and the personal cost of advanced cancer. The adenoma detection rate (ADR)—the percentage of colonoscopies in which at least one adenoma is found—is the main quality benchmark; every 1 % drop in ADR raises the chance of later cancer by about 3 %. Good bowel cleansing raises ADR and lowers the risk that lesions will be missed, whereas poor preparation lowers polyp and tumour detection, lengthens the procedure, increases endoscopist fatigue, and may raise complication rates. Yet studies show that 20 – 25 % of colonoscopies are still done under sub-optimal prep conditions.

How well the bowel is cleaned depends mainly on how well you follow the prep-drug regime instructions, so clear, practical education is essential. If you could check your own preparation and, if necessary, come to hospital early (out-patients) or alert the ward team (in-patients) for a "rescue" dose, you would be more likely to arrive with an adequate prep.

Artificial intelligence is now widely used in digestive endoscopy. In our earlier single-centre trial we built a smartphone app that uses AI to grade a photo of your stool after the last bowel movement. Patients who used the app had significantly higher adequate-prep rates (97 % vs 90 %, $P = 0.002$) and excellent-prep rates (86 % vs 60 %, $P < 0.001$) than those who received usual verbal instructions. Because that study was done in only one hospital, we are now expanding it to multiple centers so we can confirm the benefit. If you take part, the AI will help you self-check your prep; if the program thinks your prep is likely to be inadequate it will prompt you to come in

early or tell the staff so we can give you extra prep-drug regime and improve your cleansing before the colonoscopy.

2. Study procedure

If you agree to take part, you will be randomly assigned to either the “app” group or the “control” group.

Both groups follow the same 3-litre polyethylene-glycol dosing schedule; the only difference is how we check your preparation:

App group: After you finish the laxative, please photograph your last stool in the toilet and upload the picture through our app. The AI will score the image. If it shows “poor” or “inadequate” prep, the app will advise you to come to hospital early). A nurse or doctor will review the photo and decide whether you need one extra packet of polyethylene glycol.

Control group: Just before the examination, the clinical staff will ask you to describe your last bowel movement and will decide, based on your answers, whether you need the same rescue dose of one extra packet.

3. Risks and discomforts

All of your information will be kept strictly confidential. Your endoscopy and bowel preparation will be carried out by experienced endoscopists. Taking part in this study does not increase your risk compared with standard care.

4. Potential Benefits

This study uses a mini-program to help you check your bowel preparation at home. If the app thinks your prep may not be adequate, it will prompt you to come to the hospital early or tell the staff so we can give you a rescue dose and improve your preparation before the colonoscopy.

5. Study Costs

All examinations and treatments in this study are routine clinical care. If you agree to participate, you will be responsible for the costs; no study compensation is provided.

6. Responsibilities of Participants

As a study participant, you are expected to:

Give truthful information about your medical history and current health status;

Tell the study doctor about any discomfort you experience during the study;

Inform the study doctor if you have taken part in any other research recently or are currently enrolled in another study.

7. Voluntary participation

You are free to decline to take part or to withdraw from the study at any time simply by informing the investigator. Your data will then be excluded from the analysis, and your medical care and rights will not be affected in any way.

The study physician may also discontinue your participation if you require alternative treatment, fail to follow the study plan, suffer a study-related injury, or for any other medical or administrative reason.

8. Injury of Participants

If you are injured as a result of taking part in this study, you will receive immediate medical care. Any additional medical costs and compensation for damages will be provided in accordance with Chinese law.

This study protocol and the informed consent form have been reviewed and approved by the Institutional Ethics Committee of this hospital.

If you become aware of any protocol violations during the study, you may report them directly to the Ethics Committee. Tel: +86-20-3837 9764 E-mail: zslyllb@mail.sysu.edu.cn.

If you agree to participate voluntarily, you will be asked to sign this informed consent form to confirm that you have understood the study information and consent to take part.

You may obtain updated information about the study and its progress at any time.

For study-related questions, any discomfort or injury during the study, or issues concerning participants' rights, please contact Dr. Yi Lu at +86 13794353637.

Subject Informed Consent – Signature Page

I have read this informed consent form.

I have had the opportunity to ask questions and all my questions have been answered.

I understand that my participation is voluntary.

I may choose not to take part or may withdraw at any time simply by informing the researcher, without penalty or retaliation; my medical care and rights will not be affected.

The study physician may discontinue my participation if I require alternative treatment, fail to follow the study plan, suffer a study-related injury, or for any other reason.

I will receive a signed copy of this informed consent form.

Name of subject：_____

Signature of subject：_____

Signature of legally authorized representative：_____

Relationship of legally authorized representative to subject：_____

Date：_____

I have accurately explained this document to the participant, who has read the informed consent form, and I confirm that the participant had the opportunity to ask questions. I certify that his/her consent was given voluntarily.

Name of Investigator：_____

Signature of Investigator：_____

Date：_____

（*Note: If the participant is illiterate, a witness must also sign. If the participant lacks capacity, a legally authorized representative must sign.*）