

A Single Arm Pilot Study of the Chinese Herbal Medicine Formula (SCD-2101) for the Functional Constipation in the Elderly

NCT06534996

Status	RECRUITING
Phase	Not Applicable
Sponsor	Hong Kong Baptist University
Enrollment	14 participants

Key Eligibility Criteria

Inclusion (1)

- (1) Age e 60 years old (2) Meet the Rome IV diagnostic criteria for functional constipation (3) Complete spontaneous bowel movements d 2 times per week, to be assessed based on a 2-week electronic diary record (CSBMs are defined as the number of times within a 24-hour period that the patient can defecate spontaneously without the use of laxatives or enemas and feels that the stool is completely evacuated) (4) Have colonoscopy results with a diagnosis of no significant abnormalities seen or no more than 3 colorectal polyps, each less than 0.5 cm in size (based on results within the last 5 years before screening) (5) Understand and be able to follow written and oral instructions in Chinese (6) Capable of independently using WhatsApp and an electronic diary, and completing a 2-week electronic diary record during the screening period (7) The subject is informed and voluntarily signs the informed consent form.

Exclusion (1)

- (1) Secondary constipation (constipation caused by drugs or other diseases); (2) Currently using or requiring continued use of medications that may affect the outcomes of the trial (including but not limited to: antibiotics, hormonal drugs, analgesics, neurotransmitter drugs, gut flora-regulating medications, etc.); (3) Colonoscopy or sigmoidoscopy reveals clinically significant abnormalities; (4) Clinically significant abnormalities in laboratory tests or imaging examinations within the last 6 months; (5) History of allergy to traditional Chinese medicine; (6) History of abdominal surgery within the past year (except for laparoscopic appendectomy); (7) Patients with psychiatric diseases or those requiring the use of psychotropic drugs; (8) Deemed by the researchers as unsuitable to participate in this study for psychological or physical reasons.

Locations (1 total)

Hong Kong Baptist University, Kowloon Tong, Hong Kong