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Automatic abdominal/waist massage for managing chronic constipation in older adults

Submission date 29/05/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/05/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 30/05/2025	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to determine whether combining lifestyle education with the use of a heated massage device applied to the waist and abdomen can help relieve chronic constipation symptoms in older adults.

Who can participate?
We plan to recruit 90 individuals aged 65 and above who have symptoms of chronic constipation, as defined by the Rome IV criteria. Participants will be recruited from community-based long-term care facilities and the district public health center.

What does the study involve?
Participants will be randomly assigned to one of two groups:
Experimental group: Will receive lifestyle education on managing constipation and use a certified heated massager (BSMI certification number R53615) designed for safe use on the waist and abdomen. This device provides gentle heat at approximately 40°C and features rotating rollers to massage these areas.
Control group: Will receive the same lifestyle education and use a certified heating pad (BSMI certification number R54317) designed for safe use on the waist and abdomen. This device provides gentle heat at approximately 40°C to warm these areas but does not offer massage.
The intervention will last for four weeks, with sessions conducted five days per week. Each session will consist of 30 minutes, and participants can perform it either at home or at the facility. Before the intervention, we will collect baseline data and interview participants about their experiences with constipation. We will assess outcomes such as bowel movement frequency, use of laxatives, quality of life, and any side effects. Follow-up interviews will compare participants' experiences with the intervention to their previous constipation management strategies.

What are the possible benefits and risks of participating?
Participants may experience improved bowel movements, relief from constipation symptoms, and reduced reliance on laxatives. Potential risks are minimal but may include mild discomfort from the massage or heat application.

Where is the study run from?
The study is being conducted in community-based long-term care facilities and the District Public Health Center in Taichung City, Taiwan.

When is the study starting and how long is it expected to run for?
The study is expected to start in January 2025 and will run for approximately 18 months, including recruitment, intervention, and follow-up.

Who is funding the study?
This study is initiated and funded by the principal investigator, Shiou Yung Huang.

Who is the main contact?
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Study information

Scientific Title
Effects of automatic abdominal/waist massage in management of chronic constipation among older adults

Acronym
EAMCOA

Study objectives
Automatic abdominal/waist massage may stimulate intestinal peristalsis and relieve constipation symptoms in elderly individuals.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/01/2025, Institutional Review Board A of National Yang Ming Chiao Tung University (No. 155, Sec. 2, Linong St. Beitou Dist., Taipei City, 112304, Taiwan; +886-2-28239753; irb.ym@nycu.edu.tw), ref: NYCU113084AF

Study design
Two-arm parallel-group randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Constipation

Interventions
Participants were randomized into experimental and control groups. The experimental group received lifestyle modification education for constipation and a warm electric massage applied to the abdomen and waist. The control group received the same lifestyle education and warm compresses applied to the abdomen and waist. The intervention lasted four weeks, with sessions conducted five days per week. Each session included a 30-minute treatment, allocating 15 minutes each to the abdominal and waist regions.

Intervention Type
Mixed

Primary outcome(s)
Data are collected at baseline (one week before the intervention) and at the end of the fourth intervention week, using questionnaires, participant diaries, a stethoscope, and face-to-face interviews
1. Spontaneous bowel movement frequency per week
2. The Bristol Stool Form Scale
2. Patient Assessment of Constipation Symptoms, PAC-SYM
3. Bowel sounds per minute
4. Adverse events

Key secondary outcome(s))
Data are collected at baseline (one week before the intervention) and at the end of the fourth intervention week, using questionnaires, participant diaries, and MEAD meridian energy analysis device to evaluate participants' energy balance, and face-to-face interviews. The MEAD meridian energy device is certified under Taiwan FDA Medical Device License No. 002062.
1. Laxative usage
2. Patient Assessment of Constipation Quality of Life
3. Meridian energy

Completion date
14/06/2026

Eligibility

Key inclusion criteria
Adults aged 65 years and above who meet the Rome IV criteria for functional constipation.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit
90 years

Sex
All

Key exclusion criteria
1. Presence of tumors or vascular malformations in the lumbar or abdominal regions.
2. Cognitive impairment indicated by a score of less than 6 on the Short Portable Mental Status Questionnaire (SPMSQ).
3. Skin infections, injuries, bleeding, or thrombophlebitis in areas surrounding the lumbar or

abdominal regions that may contraindicate massage therapy.
4. History of abdominal surgery within the past six months.
5. Diagnosed coagulation disorders or platelet function abnormalities.
6. Use of a cardiac pacemaker.
7. Osteoporosis requiring medical treatment.

Date of first enrolment
07/01/2025

Date of final enrolment
14/05/2026

Locations

Countries of recruitment
Taiwan

Study participating centre
Wufeng District Public Health Center
No. 1-9, Minsheng Rd., Wufeng Dist., Taichung City
Taichung City
Taiwan
413006

Study participating centre
Enoch Peaceful Residence Community Long-Term Care Facility
Yongchun East 7th Road, Nantun District
Taichung City
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408

Sponsor information

Organisation
National Yang Ming Chiao Tung University

ROR
https://ror.org/00se2k293

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The individual participant data (IPD) collected during this study will not be made publicly available due to concerns regarding participant confidentiality. Given the sensitive nature of the data, there is a risk of re-identification. All data will be securely stored on encrypted servers at National Yang Ming Chiao Tung University and will be accessible only to authorized personnel.

IPD sharing plan summary
Not expected to be made available