

EFFECTS OF ABDOMINAL VIBRATION COMBINED
WITH WALKING EXERCISE AS AN ADJUNCT TO
STANDARD BOWEL PREPARATION IN OLDER PATIENTS
WITH CONSTIPATION

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FACULTY OF MEDICINE
UNIVERSITI MALAYA
KUALA LUMPUR

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PATIENTS WITH CONSTIPATION**

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**THESIS SUBMITTED IN FULFILMENT OF THE
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**EFFECTS OF ABDOMINAL VIBRATION COMBINED WITH WALKING
EXERCISE AS AN ADJUNCT TO STANDARD BOWEL PREPARATION IN
OLDER PATIENTS WITH CONSTIPATION**

ABSTRACT

High-quality bowel preparation is an important prerequisite for a successful colonoscopy. However, older patients with constipation are at high risk for inadequate bowel preparation. This study aimed to evaluate the effectiveness of an abdominal vibration combined with walking exercise (AVCWE) programme compared with walking exercise (WE) and standard bowel preparation regimens for bowel preparation in older patients with constipation. A prospective, single-blinded, three-arm randomised controlled trial was conducted between February and August 2023. Older patients with constipation who underwent colonoscopy at a tertiary hospital in China were prospectively enrolled and randomly assigned to one of the three groups: the AVCWE group, the WE group, or the control group. During the period of laxative ingestion, patients assigned to the AVCWE group were asked to walk independently for at least 5,500 steps at no more than moderate intensity and received two cycles of moderate-intensity abdominal vibrations. Patients in the WE group were required to walk independently for at least 5,500 steps at no more than moderate intensity, whereas patients in the control group received only the standard bowel preparation regimen. The primary outcome was the quality of bowel preparation assessed by the Boston Bowel Preparation Scale (BBPS). The secondary outcomes included adenoma detection rate, caecal intubation rate, caecal intubation time, adverse events, satisfaction, and willingness to repeat the same preparation. Additionally, logistic regression analysis was performed to identify risk factors for inadequate bowel preparation. A total of 271 patients were randomly divided into AVCWE group (n = 90), WE group (n = 90), and control group (n = 91). The total BBPS score in the AVCWE

group ($M = 6.99$, $SD = 0.93$) was significantly higher compared with both the WE group ($M = 6.58$, $SD = 1.08$) and the control group ($M = 5.96$, $SD = 1.14$) ($p < 0.001$). Similarly, compared with other groups, the AVCWE group also had significant advantages in improving adenoma detection rate (AVCWE group vs WE group vs control group: 42.2% vs 24.4% vs 20.9%, $p = 0.003$), satisfaction score (91.98 [$SD = 5.93$] vs 89.39 [$SD = 7.48$] vs 87.37 [$SD = 8.25$], $p < 0.001$) and reducing the incidence of bloating (22.2% vs 38.9% vs 40.7%, $p = 0.016$). However, there were no significant differences in caecal intubation rate, caecal intubation time, and willingness. Besides, the first colonoscopy (OR, 2.329; 95% CI, 1.210–4.485; $p = 0.011$), laxative use ≥ 3 times per week (OR, 2.675; 95% CI, 1.452–4.931; $p = 0.002$), and poor dietary compliance (OR, 2.249; 95% CI, 1.142–4.430; $p = 0.019$) were found to be significant predictors of inadequate bowel preparation in older patients with constipation. The AVCWE programme significantly improved the quality of bowel preparation, adenoma detection rate, satisfaction, and significantly reduced the incidence of bloating in older patients with constipation. Healthcare providers are recommended to adopt this strategy to optimise the detection of colorectal diseases and elevate the standard of healthcare services for this ‘difficult-to-prepare’ population.

Keywords: Bowel preparation, Constipation, Walking exercise, Abdominal vibration, Older persons.

**KESAN GABUNGAN GETARAN ABDOMEN DENGAN SENAMAN
BERJALAN SEBAGAI TAMBAHAN KEPADA PROSEDUR PIAWAI
PERSEDIAAN USUS UNTUK PESAKIT WARGA EMAS DENGAN MASALAH
SEMBELIT**

ABSTRAK

Pembersihan usus yang berkualiti tinggi adalah penting untuk kolonoskopi yang efektif. Namun, pesakit yang berumur yang mengalami sembelit kerap menghadapi masalah melakukan pembersihan usus dengan sempurna. Kajian ini bertujuan menilai keberkesanan getaran abdomen yang digabungkan dengan rejimen senaman berjalan (*abdominal vibration combined with walking exercise; AVCWE*) berbanding dengan hanya senaman berjalan (*walking exercise; WE*) dan rejimen pembersihan usus rutin untuk pesakit yang berumur yang mengalami sembelit. Ini adalah kajian ‘*randomised controlled trial*’ (RCT) yang prospektif, dijalankan dari Februari hingga Ogos 2023. Pesakit berumur yang mengalami sembelit dan menjalani kolonoskopi di hospital tertiar di China telah didaftarkan secara prospektif dan diagihkan secara rawak ke salah satu daripada tiga kumpulan: kumpulan AVCWE, kumpulan WE, atau kumpulan kawalan. Pesakit dalam kumpulan AVCWE diarahkan untuk berjalan secara bebas sekurang-kurangnya 5,500 langkah dan menerima dua kitaran peranti getaran intensiti sederhana ke abdomen. Pesakit dalam kumpulan WE dikehendaki berjalan secara bebas sekurang-kurangnya 5,500 langkah, manakala pesakit dalam kumpulan kawalan hanya menerima rejimen pembersihan konvensional. Objectif utama adalah kualiti pembersihan usus yang dinilai mengikut Skala Pembersihan Usus Boston (*Boston Bowel Preparation Scale; BBPS*). Objektif lain termasuk menilai dan membandingkan kadar pengesanan adenoma, kadar intubasi cecum, masa intubasi cecum, kesan sampingan, kepuasan, dan kesiediaan untuk mengulangi pembersihan di antara ketiga kumpulan tersebut. Selain itu, analisis

regresi logistik dilakukan untuk mengenal pasti faktor risiko pembersihan usus yang tidak mencukupi di kalangan pesakit yang berumur yang mengalami sembelit. Sejumlah dua ratus tujuh puluh satu ($n = 271$) pesakit diagihkan secara rawak ke kumpulan AVCWE ($n = 90$), kumpulan WE ($n = 90$), dan kumpulan kawalan ($n = 91$). Skor BBPS yang lebih tinggi diperolehi dalam kumpulan AVCWE ($M = 6.99$, $SD = 0.93$) berbanding dengan kumpulan WE ($M = 6.58$, $SD = 1.08$) dan kumpulan kawalan ($M = 5.96$, $SD = 1.14$) ($p < 0.001$). Selain itu, kumpulan AVCWE menunjukkan kadar pengesanan adenoma yang lebih tinggi daripada kumpulan lain (kumpulan AVCWE vs kumpulan WE vs kumpulan kawalan: 42.2% vs 24.4% vs 20.9%, $p = 0.003$) dan kepuasan pembersihan usus yang lebih tinggi (91.98 [SD = 5.93] vs 89.39 [SD = 7.48] vs 87.37 [SD = 8.25], $p < 0.001$) manakala kadar kesan sampingan distensi abdomen adalah lebih rendah (22.2% vs 38.9% vs 40.7%, $p = 0.016$). Walau bagaimanapun, tiada perbezaan signifikan dari segi kadar intubasi cecum, masa intubasi cecum, dan kesiediaan untuk mengulangi pembersihan usus. Selain daripada itu, kolonoskopi pertama (OR, 2.329; 95% CI, 1.210–4.485; $p = 0.011$), penggunaan julap ≥ 3 kali seminggu (OR, 2.675; 95% CI, 1.452–4.931; $p = 0.002$), dan kegagalan mengikuti diet yang diarahkan (OR, 2.249; 95% CI, 1.142–4.430; $p = 0.019$) didapati faktor-faktor penting bagi pembersihan usus yang tidak mencukupi. Program AVCWE meningkatkan kualiti pembersihan usus, kadar pengesanan adenoma, kepuasan pembersihan usus, dan mengurangkan kejadian distensi abdomen pada pesakit berumur yang mengalami sembelit. Strategi ini seharusnya dipraktikkan untuk meningkatkan pengesanan kanser kolorektal pada populasi berumur.

Kata kunci: Pembersihan usus, Sembelit, Senaman berjalan, Getaran abdomen, Orang yang berumur.

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LIST OF SYMBOLS AND ABBREVIATIONS

| | | |
|-------------------|---|--|
| ACG | : | American College of Gastroenterology |
| ASGE | : | American Society for Gastrointestinal Endoscopy |
| ADR | : | Adenoma Detection Rate |
| AVCWE | : | Abdominal Vibration Combined with Walking Exercise |
| ANOVA | : | Analysis of Variance |
| AMR | : | Adenoma Miss Rate |
| ADLs | : | Activities of Daily Living |
| BBPS | : | Boston Bowel Preparation Scale |
| BPCS | : | Bowel Preparation Compliance Scale |
| BMI | : | Body Mass Index |
| CRC | : | Colorectal Cancer |
| CIT | : | Caecal Intubation Time |
| CIR | : | Caecal Intubation Rate |
| CCT | : | Clinical Controlled Trial |
| CI | : | Confidence Interval |
| ESGE | : | European Society of Gastrointestinal Endoscopy |
| FC | : | Functional Constipation |
| HR | : | Heart Rate |
| HR _{max} | : | Maximal Heart Rate |
| IBS-C | : | Irritable Bowel Syndrome with Constipation |
| IQR | : | Interquartile Range |
| ICC | : | Intraclass Correlation Coefficient |
| L | : | Liters |
| MD | : | Mean Difference |

| | | |
|-----|---|------------------------------|
| OR | : | Odds Ratio |
| PEG | : | Polyethylene Glycol |
| QoL | : | Quality of Life |
| RCT | : | Randomised Controlled Trial |
| RR | : | Relative Risk |
| SD | : | Standard Deviation |
| SE | : | Standard Error |
| SMD | : | Standardised Mean Difference |
| VAS | : | Visual Analogue Scale |
| WBV | : | Whole-body Vibration |
| WE | : | Walking Exercise |

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CHAPTER 1: INTRODUCTION

1.1 Introduction

Chronic constipation is a globally prevalent condition characterised by difficult, infrequent, or incomplete evacuation of the bowel, with symptoms lasting for over three months (Deb et al., 2020; Zhang et al., 2024a). It is reportedly one of the most common gastrointestinal disorders in older patients worldwide and is widely recognised as an independent predictor of poor bowel cleansing for colonoscopy (Lin et al., 2024; Popovic & Filipovic, 2024). A notably high proportion (30%–60%) of older patients with constipation globally have inadequate bowel preparation, which often results in a range of negative consequences for colonoscopy, including missed diagnosis of colorectal disease, failed caecal intubation, prolonged procedure time, and increased risk of procedure-related complications, such as bleeding and perforation (Fostier et al., 2023; Sharma et al., 2020; Tiankanon & Aniwani, 2024). Therefore, it is imperative to optimise the quality of bowel preparation for colonoscopy in this high-risk population (Song & Kim, 2024; van Riswijk et al., 2024). Furthermore, most patients undergoing colonoscopy consider bowel preparation to be the worst part of the colonoscopy procedure and report various intolerable adverse events during bowel preparation (Di Leo et al., 2021; Kimpel et al., 2022; Woo et al., 2018). Consequently, patient satisfaction with bowel preparation and willingness to repeat the same bowel preparation are generally low in current medical practice (Hatoum et al., 2016; Vemulapalli et al., 2022).

Despite the poor quality of bowel cleansing in older patients with constipation, this particular demographic has not received adequate attention from medical practitioners, and current bowel preparation guidelines do not recommend targeted regimens for this group (Digestive Endoscopy Special Committee, 2019; Hassan et al., 2019). Recent studies have demonstrated that certain non-pharmacological methods, such as walking

exercises and abdominal vibration, can markedly improve the quality of bowel cleansing and optimise the detection of adenomas (Gao et al., 2023; Noh et al., 2020; Rezamand et al., 2023). However, so far, there have been no comparable investigations carried out on older Chinese individuals suffering from constipation. Furthermore, prior research has predominantly focused on examining the individual effects of walking exercise and abdominal vibration on the quality of bowel preparation. Given the slower colonic transit times and gastrointestinal motility experienced by older patients with constipation, interventions including walking exercise or abdominal stimulation alone might not have significant positive impacts on bowel preparation quality. Based on available evidence, a more intensive approach that integrates these two strategies may be promising for achieving optimal bowel preparation in this ‘difficult-to-prepare’ demographic. Therefore, this study hypothesised that a regimen combining abdominal vibration and walking exercise would be more effective than either walking exercise or a standard bowel preparation regimen in ensuring adequate bowel preparation for this demographic.

1.2 Background

Population ageing refers to the process in which the proportion of older people in the total population continues to increase (Ismail et al., 2021; Partridge et al., 2018). Currently, as human life expectancy increases and fertility levels decline, most countries worldwide are experiencing population ageing (Fang et al., 2020; Sahoo et al., 2023; Wang et al., 2023). This demographic shift towards an ageing global population presents notable challenges and opportunities for healthcare systems worldwide (Rosenberg et al., 2022; Wang et al., 2022a). According to the World Social Report 2023, the number of individuals aged 65 years and above in 2021 was 761 million, and this number is expected to surpass 1.6 billion by 2050, which underscores a pressing need for healthcare adaptations (United Nations, 2023). Consistent with this, the proportion of the world population aged 65 years and over is expected to increase from 10% in 2021 to about

16.7% in 2050 (United Nations, 2023). This trend, most pronounced in regions like Western Asia, sub-Saharan Africa, and North Africa, necessitates a reappraisal of healthcare strategies to address age-associated conditions, particularly chronic constipation (Mahmood & Dhakal, 2022; Miles, 2023; United Nations, 2023).

Constipation, especially chronic constipation, has emerged as a prevalent and burdensome condition among older individuals, significantly exacerbating healthcare utilisation and economic burden (Hungin, 2022; Tomita et al., 2021). Chronic constipation is a common condition characterised by difficult, infrequent, or perceived incomplete evacuation of bowel, with symptoms lasting for more than three months (Aziz et al., 2020; Diaz et al., 2024). According to recent statistics, the global prevalence of constipation among older people is 18.9% (95% CI: 14.7%–23.9%), highlighting an urgent need for effective management strategies (Barberio et al., 2021; Rao & Brenner, 2022; Salari et al., 2023). This is particularly critical as the prevalence of chronic constipation strongly correlates with ageing, highlighting the need for healthcare systems to adapt to the specific needs of the geriatric population (Al Nou'mani et al., 2023; Yamamoto et al., 2022; Yurtdaş et al., 2020).

In clinical practice, chronic constipation is not merely a discomfort but a complex geriatric syndrome influenced by multifactorial elements, including diet (e.g. low-fibre diet, inadequate fluid intake, and low-calorie diet), decreased physical activity, comorbidities (e.g. severe hypothyroidism and Parkinson's disease), and polypharmacy (e.g. opioids, antipsychotics, calcium channel blockers, and iron supplements) (Lim et al., 2021; Mari et al., 2020; Włodarczyk et al., 2021; Zheng & Yao, 2018). The persistence and exacerbation of constipation in the ageing population sheds light on a critical gap in current geriatric care and patient management strategies, emphasising the necessity for

innovative, non-pharmacological interventions to alleviate this condition (Deb et al., 2020; Güven Ş, 2023; Mari et al., 2020).

The varied prevalence of constipation among older adults globally, with the highest rates observed in Africa and the lowest in Asia, not only reflects geographical and possibly cultural differences in diet, lifestyle, and healthcare access but also highlights the complex interplay of factors contributing to the condition's manifestation (Oh et al., 2020; Sperber et al., 2021; Yurtdaş Depboylu et al., 2023). The significant negative impact of chronic constipation on quality of life (QoL), from severe complications such as perforation and rectal bleeding to increased healthcare costs, underscores an overlooked but critical aspect of geriatric health that necessitates a nuanced approach to management and prevention strategies (Arco et al., 2022; Lucak et al., 2021; Zhang et al., 2023a).

Colorectal cancer (CRC) is a significant global health issue, ranking as the third most common cancer and the second leading cause of cancer-related deaths worldwide (Marcellinaro et al., 2023; Siegel et al., 2023). It predominantly affects older adults, with most cases occurring in individuals aged 50 and over (O'Donnell et al., 2024; Ozluk et al., 2023). Regular screening is essential for preventing CRC, with colonoscopy being widely recognised as the most reliable and accurate screening method (Diedenhofen et al., 2024; Jain et al., 2022; Ladabaum et al., 2020). This procedure serves both diagnostic and therapeutic purposes, enabling the early detection and removal of precancerous lesions, thereby significantly reducing the incidence and mortality of CRC (Corley et al., 2023; Montminy et al., 2020). CRC mortality rates were reported to be more than 60% lower in patients who underwent screening colonoscopy than in those who did not undergo colonoscopy (Cenin et al., 2022; Doubeni et al., 2018; Tanaka et al., 2023). The endorsement of colonoscopy across global gastroenterology practices underscores its

importance in contemporary medical care (Gupta, 2022; Lin et al., 2021). In clinical practice, colonoscopy is performed for various indications, including abdominal pain, change in bowel habits, abdominal distension, constipation, diarrhoea, haematochezia, physical examination, weight loss, and surveillance after colorectal polypectomy (Abu Baker et al., 2023a; Mangas-Sanjuan et al., 2020).

Given the elevated risk of CRC with ageing, current guidelines strongly advocate for regular colonoscopies among older adults (Chinese Society of Colorectal Surgery, 2022; Shaukat et al., 2021). This recommendation aligns with the growing demand for colonoscopies, driven by both the implementation of national CRC screening programmes and the ageing global population (Calderwood et al., 2022; Nee et al., 2020; Ravindran et al., 2022). The significant representation of older individuals in colonoscopy patient demographics, as noted in studies by Maida et al. (2022) and Amitay et al. (2021), further emphasises the procedure's relevance to this population. Notably, chronic constipation, a common condition among older adults, presents unique challenges in this context, affecting a substantial portion of this patient cohort (Mari et al., 2020; Wang et al., 2022b).

Effective bowel preparation is pivotal for the success of a colonoscopy, ensuring the intestinal mucosa is sufficiently visible for examination (Haydel et al., 2024; Malkin et al., 2023). Any residue in the patient's colon will make it difficult for endoscopists to view the details of the intestinal mucosa during an examination, leading to missed diagnosis of intestinal lesions (Gimeno-García et al., 2024; van Riswijk et al., 2024). However, achieving optimal bowel preparation, which involves dietary restrictions and laxative use, is often a challenge, particularly among older adults with constipation (Mamula & Nema, 2021; Millien & Mansour, 2020; Parekh et al., 2019). The critical link between bowel preparation regimen compliance and bowel preparation quality

underscores the need for effective strategies to enhance patient adherence (Chen et al., 2023; Mahadeva, 2023; Zhu et al., 2023).

Dietary restrictions, considered a crucial component of standard bowel preparation, play an important role in determining the quality of bowel preparation (Ahumada et al., 2022; Nam et al., 2018). Accumulating evidence suggests that a low-residue diet, as recommended by the European Society of Gastrointestinal Endoscopy (ESGE), leads to better patient compliance, satisfaction, and willingness to repeat the same preparation, compared with traditional clear-liquid diets (Chen et al., 2020; Hassan et al., 2019; Samarasena et al., 2022; Wu et al., 2021). This finding not only highlights the evolving landscape of pre-colonoscopy preparation but also calls for a nuanced understanding of dietary regimens' impact on older individuals, particularly those with constipation (Digestive Endoscopy Special Committee, 2019).

The development of various laxatives, including polyethylene glycol (PEG) and others, reflects advancements in pre-colonoscopy bowel preparation (Liu et al., 2021a; Sharma et al., 2020). PEG-based solutions are the preferred bowel cleansing agent for their efficacy and safety (Di Leo et al., 2021; Jaiswal & Chaudhary, 2020). Current guidelines recommend the use of 4 L or 3 L PEG solution as the standard laxative regimen for colonoscopy, with the last dose administered within five hours before the procedure (Digestive Endoscopy Special Committee, 2019; Migaly et al., 2019). Compliance with the prescribed laxative regimen is of key importance in ensuring adequate bowel preparation (Martel et al., 2018; Zhang et al., 2024a). However, recent studies have reported high rates of non-adherence to prescribed regimens, particularly among older individuals (Kang et al., 2024; Ramprasad et al., 2020; Shin et al., 2019).

This backdrop of extensive preparation protocols raises a critical question: How do these regimens serve the older population, particularly those with constipation, a

demographic already at a disadvantage owing to physiological and medication-induced challenges? Approximately 20% to 50% of older patients undergoing colonoscopies experience unpleasant adverse events such as nausea, vomiting, bloating, and abdominal pain after ingesting PEG solutions (Cheng et al., 2022; Huh et al., 2018; Sun et al., 2023). The reported discomfort and adverse effects from PEG solutions indicate a significant area for improvement, especially considering the impact on patient satisfaction and willingness to participate in future screenings (Hao et al., 2020; Kamran et al., 2020; Yang et al., 2018).

Studies demonstrating a significant correlation between older age and poor bowel preparation outcomes compel a comprehensive and in-depth assessment of current practices (Komori et al., 2024; Sadeghi et al., 2022; Zad et al., 2020). The rate of inadequate bowel preparation in older patients undergoing colonoscopy ranges from 30% to 40%, which does not satisfy the minimum criteria for an adequate bowel preparation rate of $\geq 90\%$ recommended by the ESGE Quality Committee (Amitay et al., 2021; Hu et al., 2021; Kaminski et al., 2017; Maida et al., 2022). The presence of chronic constipation significantly exacerbates the difficulty of achieving adequate preparation, suggesting a need for protocols that address the specific challenges faced by older patients (Occhipinti et al., 2023; Shahini et al., 2023). The stark disparity in bowel preparation quality between older adults with constipation and their counterparts without this condition amplifies the urgency for targeted interventions (Xun et al., 2022; Zhang et al., 2024a; Zhang et al., 2018).

Inadequate bowel preparation is strongly associated with decreased adenoma detection rate (ADR), prolonged caecal intubation time (CIT), decreased caecal intubation rate (CIR), increased rates of adverse events, and increased healthcare costs due to frequent repeat colonoscopies (shorter than the recommended interval) (Millien & Mansour, 2020;

Niedermaier et al., 2020). In addition, it may result in lower patient satisfaction and willingness to repeat bowel preparation in the future (Kimpel et al., 2022; Tontini et al., 2021). This situation not only places a burden on the healthcare system but also diminishes the quality of patient care, underscoring a pressing need for innovation in bowel preparation practices tailored to the needs of older patients with constipation.

The highlighted challenges present an opportunity for critical reflection on current bowel preparation guidelines and practices. Especially for vulnerable populations, such as older patients with constipation, it is critical to develop and implement strategies that prioritise patient comfort, safety, and compliance. As the demand for colonoscopies continues to rise with the ageing global population, the healthcare community is called upon to critically evaluate and adapt bowel preparation protocols to enhance patient outcomes and screening effectiveness, ultimately aiming to improve CRC detection and treatment in this high-risk group.

In the realm of clinical practice, the endeavour to optimise bowel preparation for colonoscopy in older patients with constipation reveals a complex interplay of physiological and treatment-related challenges (Ho et al., 2017; Luo et al., 2022). The inherent slower intestinal motility and extended colonic transit times characteristic of this demographic significantly hinder effective bowel cleansing (Kunz & Gillespie, 2017; Mandolesi et al., 2017; Tangvoraphonkchai et al., 2023). Attempts to address these challenges have led researchers to explore intensive regimens combining traditional methods with additional stimulant laxatives or prokinetic agents (Ding et al., 2022; Ichijima et al., 2021; Lu et al., 2016; Mandolesi et al., 2017). Despite achieving some level of success in bowel cleansing, the resultant adverse effects have raised concerns over tolerability and compliance, leading to a cautious stance in current guidelines against their routine use for constipated patients (Digestive Endoscopy Special Committee, 2019;

Hassan et al., 2019; Migaly et al., 2019). Heretofore, there is a lack of consensus on standard bowel preparation regimens for older patients with constipation.

This ongoing challenge underscores a significant gap in the provision of safe, effective, and patient-friendly bowel preparation methods for older patients with constipation. The exploration of non-pharmacological strategies, notably walking exercise and abdominal vibration, introduces a promising paradigm shift (Noh et al., 2020; Zhang et al., 2023b). These interventions have demonstrated efficacy in enhancing bowel preparation quality without the burden of adverse effects, providing feasible strategies for optimising bowel preparation practice. Notably, recent meta-analyses and randomised controlled trials (RCTs) have offered promising evidence supporting the effectiveness of these approaches in enhancing bowel preparation outcomes and patient experiences. This represents a significant advancement towards improving current bowel preparation practices (Gao et al., 2023; Huang & Zhou, 2021; Rezamand et al., 2023).

However, the primary focus of these studies was on the general population rather than older patients with constipation, which highlights a critical research gap. The lack of targeted investigations into the effectiveness of walking exercise and abdominal vibration for this high-risk group signals an urgent need for further investigations. The potential of these non-pharmacological interventions to transform bowel preparation practices for older patients with constipation—not only in improving clinical outcomes but also in enhancing patient tolerability and satisfaction—warrants a focused inquiry. Such research could provide the necessary evidence to inform practice guidelines and ultimately improve the quality of care for older adults undergoing colonoscopy, a crucial step in advancing CRC screening and prevention strategies within this demographic.

1.3 Problem Statement

As China emerges as the world's second-largest economy, it concurrently grapples with the profound demographic challenge of an ageing population (Sun & Li, 2023; Zhao & Li, 2024). This issue is exacerbated by significant declines in fertility and mortality rates, setting the stage for unique public health dilemmas (Chen et al., 2022a; Thomas et al., 2020; Ye et al., 2021). China's Seventh National Population Census in 2020 highlighted a striking demographic shift, revealing that individuals aged 60 years and above now exceed 264 million, representing an 18.7% share of the national population (Akimov et al., 2021; Payne & Xu, 2022). Projections suggest a dramatic increase to 402 million by 2040, accounting for 28% of the population (Gu et al., 2021; Wang & Chen, 2022). Such demographic trends place unprecedented pressures on China's public health infrastructure and necessitate innovative management strategies for ageing-related health issues, notably constipation—a widespread concern among older individuals (Han et al., 2020; Lundberg et al., 2020; Yang et al., 2021). Older patients with constipation are more prone to severe complications, such as haemorrhoids, rectal bleeding, faecal impaction, volvulus, incontinence, and perforation (Du et al., 2022; Lyu et al., 2022). These issues significantly reduce their QoL and escalate healthcare costs, warranting considerable attention and improvement (Deng et al., 2023; Song et al., 2021a).

Current cross-sectional studies estimate that constipation affects 15%–20% of China's older population, positioning it as a significant public health concern with profound implications for CRC screening practices (Chen et al., 2022b; Du et al., 2022; Zheng et al., 2023). National guidelines recommend screening colonoscopies beginning at age 40, a protocol with high compliance among China's older adults (National Cancer Center, 2021; Zhang et al., 2023d; Zhu et al., 2024). However, the frequent occurrence of constipation in this age group complicates these efforts, significantly impacting the effectiveness of bowel preparation for colonoscopy (Hu et al., 2021; Lin et al., 2019).

Constipation is recognised as a significant independent risk factor for inadequate bowel preparation among older adults (Feng et al., 2024; Zhang et al., 2024a). This is evidenced by a 34.6% rate of inadequate bowel preparation among older individuals, alarmingly increasing to 61.7% among those with constipation, underscoring the urgency for targeted interventions (Feng et al., 2024; Guo et al., 2020a; Martel et al., 2018; Zhang et al., 2018).

Currently, standard bowel preparation protocols in China do not offer tailored regimens specifically for older patients with constipation. It typically involves a one-day low-residue diet combined with the consumption of a 3 L PEG solution (Digestive Endoscopy Special Committee, 2019). This one-size-fits-all approach has proven insufficient, revealing a significant gap in the tailored preparation strategies required for this specific patient population and underscoring the need for targeted research to address this oversight (Luo et al., 2022; Wang et al., 2022b; Zhang et al., 2024a).

In light of these challenges, emerging research into non-pharmacological strategies such as walking exercise and abdominal vibration presents new potential for enhancing bowel preparation quality (Gao et al., 2023; Noh et al., 2020). However, the application of these findings to high-risk groups, particularly older patients with constipation in China, has not been adequately explored. The extant literature primarily focuses on broader populations and varying regional contexts, indicating a glaring research gap in understanding the efficacy of these methods in the targeted demographic (Rezamand et al., 2023; Zhang et al., 2020a). In addition, prior research has only investigated the impact of abdominal vibration or walking exercise separately on the quality of bowel cleansing. Due to the slower gastrointestinal motility and delayed colonic transit time observed in older adults with constipation, the effectiveness of either approach alone in improving the quality of bowel cleansing might be somewhat restricted.

This study seeks to address this gap by assessing the efficacy of abdominal vibration combined with walking exercise (AVCWE) in optimising bowel preparation among older Chinese patients with constipation. It is hypothesised that AVCWE will be more effective than walking exercise (WE) or the standard bowel preparation regimen in achieving adequate bowel cleansing for this demographic. This pioneering research aims to evaluate the synergistic potential of these interventions within the specific context of older Chinese patients with constipation, striving to optimise CRC screening protocols and enhance patient care outcomes amidst China's ageing crisis.

1.4 Research Questions

This research attempted to answer the following questions:

1. Is the developed AVCWE programme feasible and safe for older patients with constipation?
2. Are there any differences in colonoscopy quality indicators (bowel preparation quality, ADR, CIR, and CIT) between the intervention (AVCWE group and WE group) and control groups?
3. Are there any differences in adverse events during bowel preparation between the intervention and control groups?
4. Are there any differences in patient satisfaction between the intervention and control groups?
5. Are there any differences in patient willingness to repeat the same bowel preparation between the intervention and control groups?
6. Are there any differences in the primary outcome (bowel preparation quality) among older patients with different background characteristics and bowel preparation compliance?

1.5 Research Objectives

The general and specific objectives of the study are mentioned in the following sections, offering a comprehensive overview of the study's aims and the specific goals it seeks to achieve.

1.5.1 General Objective

The general objective of this study was to compare the effects of the AVCWE programme with the WE programme and the standard bowel preparation regimen on colonoscopy quality indicators (bowel preparation quality, ADR, CIR, and CIT), adverse events, patient satisfaction, and willingness to repeat the preparation among older patients with constipation.

1.5.2 Specific Objectives

The specific objectives of the study were as follows:

1. To evaluate the feasibility and safety of a developed AVCWE programme for older patients with constipation.
2. To compare the effects of three bowel preparation regimens (AVCWE programme, WE programme, and standard bowel preparation regimen) on colonoscopy quality indicators in older patients with constipation.
3. To compare the effects of the three bowel preparation regimens on adverse events, patient satisfaction, and willingness to repeat the same bowel preparation in older patients with constipation.
4. To determine the association between background characteristics, bowel preparation compliance, and bowel preparation quality in older patients with constipation.

1.6 Hypotheses

The following null hypotheses guided this study:

H₁: There are no statistically significant differences in colonoscopy quality indicators, adverse events, patient satisfaction, and willingness to repeat the same bowel preparation between the intervention and control groups.

H₂: There are no statistically significant associations among background characteristics, bowel preparation compliance, and bowel preparation quality in older patients with constipation.

1.7 Significance of the Study

Building on the context of the identified challenges and proposed methodologies, the significance of this study extends across multiple dimensions of healthcare, as detailed below:

1.7.1 Direct Implications for Patient Care, Healthcare Efficiency, and Broader Health Outcomes

This study represents a pivotal advancement in patient care for older patients with constipation, addressing a critical gap in the literature by providing empirical evidence on non-pharmacological interventions aimed at improving bowel preparation quality. By integrating the physical therapies of walking exercise and abdominal vibration, this research promises to enhance the efficacy of colonoscopy screenings while elevating the overall patient experience by allaying discomfort and adverse effects. This comprehensive approach not only reduces the need for repeat procedures due to inadequate preparation but also directly improves healthcare efficiency by streamlining the diagnostic process and effectively allocating resources. Additionally, by facilitating earlier and more accurate detection of colorectal abnormalities, this approach can significantly improve health outcomes, potentially lowering the incidence and mortality

of CRC within this vulnerable population. The inclusion of patient satisfaction and willingness measurements provides valuable insights into the acceptability and effectiveness of these interventions from the patient's perspective, enhancing the study's pertinence and applicability in real-world clinical settings.

1.7.2 Application in Practice and Policy-Making

The findings from this study are critical in bridging the gap between current practices and optimised protocols for bowel preparation, particularly for older patients with constipation. By proposing tailored protocols that incorporate walking exercise and abdominal vibration, this research could transform standard preparatory measures in clinical settings. Prospective applications include structured pre-colonoscopy programmes delivered through face-to-face guided sessions or patient education materials, designed to optimise bowel cleanliness without compromising safety or comfort. From a policy perspective, these insights could lead healthcare administrators to amend existing guidelines, advocating for the incorporation of these non-pharmacological strategies into routine practice. Additionally, the knowledge gained could inspire public health campaigns aimed at enhancing awareness among older persons about effective bowel preparation practices, thereby improving compliance and screening outcomes.

1.7.3 Paradigm Shift in Management Across Healthcare Settings

By demonstrating the efficacy of a regimen combining abdominal vibration with walking exercise in bowel preparation for older patients with constipation, this study champions a paradigm shift from conventional pharmacological reliance to a more holistic, patient-centred approach. It challenges existing practices and offers a new framework for pre-colonoscopy preparation that could redefine standard care practices across various healthcare settings, from primary care to specialised gastroenterology units. Such a shift would ensure that older persons receive care that not only aligns with their

physiological needs but also respects their preferences and tolerances. Moreover, the adoption of these non-pharmacological interventions could catalyse further innovation in the management of other age-related conditions, underscoring the study's broad significance in advancing geriatric care and influencing healthcare policies and practices.

1.8 Conceptual Framework

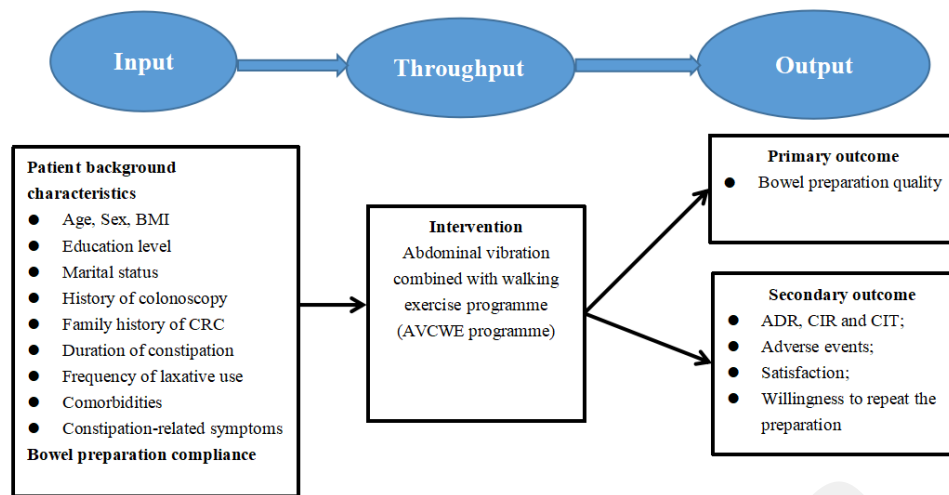
The conceptual framework adopted for the study is predicated on the general system theory by Ludwig Von Bertalanffy (1969). Overall, general system theory is a general science of wholeness that aims to unify scientific thinking across disciplines and provide a framework for analysing the integrity of any system (Johnson, 2019). General system theory describes how to break the whole apart and then learn how the parts work together (Adhikari & Shrestha, 2017). The fundamental concept of this theory is that a system is a whole composed of independent components that are interrelated and share a common purpose or goal (Pokharna & Bobra, 2016). More specifically, the system has the following components: input, throughput, and output (Anderson, 2016; Garner, 2018). Input is the component that includes varying types and amounts of matter, material or human energy, and information received from the environment. Throughput is the process whereby the system transforms, creates, and organises for its ready use. Finally, the output is the final product of the system (Masters, 2014).

Nursing is based on a holistic approach and is a continuous process (Boswell & Cannon, 2022). Like all systems, the nursing process has a specific purpose or goal of organising and delivering patient-centred care (Gray & Grove, 2020). In nursing, general system theory means that patient safety and health are a result of the structure of the healthcare system (Constantino, 1979). The entire nursing system needs to be dedicated to improving the lives of patients (Beckstead & Beckstead, 2006). To date, general system

theory has been widely applied in nursing research to improve the quality of care and promote patient health (Glennister, 2011; Meyer & O'Brien-Pallas, 2010).

From a nursing research perspective, input generally refers to the general characteristics of the patient. In this study, input was the background characteristics of older patients with constipation, including age, sex, body mass index (BMI), education level, marital status, history of colonoscopy, family history of CRC, duration of constipation, frequency of laxative use, comorbidities, exercise habits, and constipation-related symptoms. Additionally, patient compliance with bowel preparation was a key input. Throughput usually refers to the process of transforming input into the output of a system through the application of nursing interventions. In this study, throughput referred to the study intervention, namely, the AVCWE programme. In nursing practice, output generally refers to patient outcomes resulting from nursing intervention. In this study, the output was patient outcomes, including primary outcome (bowel preparation quality) and secondary outcomes (ADR, CIR, CIT, adverse events during bowel preparation, satisfaction, and willingness to repeat the same bowel preparation).

In summary, the main independent variable of this study was the AVCWE intervention, whereas the dependent variables were patient outcomes. Furthermore, patient background characteristics and bowel preparation compliance represented covariates in the analysis (Figure 1.1).



➤ Note: Colonoscopy quality indicators include bowel preparation quality, ADR, CIR and CIT.

Figure 1.1: The conceptual framework based on general system theory

1.9 Conceptual and Operational Definitions

To clarify and ensure a better understanding of the terms used in this study, the following conceptual and operational definitions are provided.

1.9.1 Constipation

Constipation is a common gastrointestinal complaint usually defined as difficulty or infrequent bowel movements (Aziz et al., 2020; Jani & Marsicano, 2018). In this study, constipation referred to functional constipation according to the Rome IV diagnostic criteria, and screening was performed by a senior gastroenterologist (Mearin et al., 2016). The following criteria should be fulfilled for the last three months with symptom onset at least six months prior to diagnosis:

a. Must include two or more of the following symptoms:

- (i) Straining more than 25% of defecations.
- (ii) Lumpy or hard stools more than 25% of defecations.
- (iii) Sensation of incomplete evacuation of more than 25% of defecations.
- (iv) Sensation of anorectal obstruction/blockage of more than 25% of defecations.

(v) Manual manoeuvres to facilitate more than 25% of defecations.

(vi) Fewer than three spontaneous bowel movements per week.

b. Loose stools are rarely present without the use of laxatives.

c. There are insufficient criteria for irritable bowel syndrome (IBS).

(Patients with functional constipation do not fulfil the criteria for IBS because abdominal pain is absent/not predominant or occurs less than one day per week.)

1.9.2 Older Patients

Definitions of older persons vary globally, influenced by cultural and socioeconomic factors (Eurostat, 2020). Older persons in developed world economies are commonly defined as those aged 65 years or older (Eurostat, 2020). However, the United Nations and China's definitions align more closely, considering individuals aged 60 years or older as older persons (Liu et al., 2021b; United Nations, 2013). Older patients in this study referred to individuals aged 60 years or older, diagnosed with functional constipation according to the Rome IV diagnostic criteria who are recipients of healthcare services provided by healthcare professionals.

1.9.3 Bowel Preparation Compliance

Compliance is the act of obeying an order, rule, or request (Cambridge University Press, n.d.). Cleansing the colon before a colonoscopy is called 'bowel preparation', which involves taking medications and restricting diet to empty the colon with frequent, loose, watery bowel movements (Argyriou & Parra-Blanco, 2022). Bowel preparation compliance refers to the degree to which a patient adheres to a standard bowel preparation regimen, including medication compliance and dietary compliance (Gwag & Yoo, 2022). In this study, medication compliance referred to the degree or extent of conformity to a laxative regimen that required patients to consume a full dose of 3 L of PEG solution at a rate of 250 mL every 10 minutes between 8:00 am and 10:00 am on the day of the

colonoscopy. Besides, dietary compliance in this study referred to the degree or extent of conformity to a dietary regimen that required patients to eat a low-residue diet the day before the colonoscopy and fast on the day of the colonoscopy until the end of the procedure. This study used the Chinese version of the Bowel Preparation Compliance Scale (BPCS) to assess patients' bowel preparation compliance (Kong, 2019).

1.9.4 Walking Exercise

Exercise is planned, structured, and repetitive physical activity designed to maintain or improve one or more components of physical health (Farlex, n.d.). Walking is an activity in which the body moves forward at a slow-to-moderate speed by moving the feet in a coordinated manner (Collins, n.d.). Walking exercise is the activity of taking walks for exercise (Bullo et al., 2018). In this study, walking exercise was defined as walking for at least 5,500 steps at no more than moderate intensity within two hours of consuming PEG solution on the day of the colonoscopy.

1.9.5 Abdominal Vibration

Vibration is the mechanical oscillations of an object around an equilibrium point (Lei et al., 2016). The abdomen is the part of the body between the chest and pelvis in humans and other vertebrates (Wikipedia, n.d.). Abdominal vibration is a method of delivering mechanical oscillations to an individual's abdominal region using an automatic vibration equipment of different amplitudes, frequencies, and accelerations to promote gastrointestinal motility and reduce colonic transit time (Wu et al., 2012). The abdominal vibration in this study was implemented with an abdominal vibration belt (MK9301-02, Mike Sports, Guangdong, China). Specifically, abdominal vibration began simultaneously with walking exercise and consisted of two cycles of moderate-intensity vibration, each consisting of 10 minutes of stimulation and 10 minutes of rest.

1.9.6 Colonoscopy Quality Indicators

Colonoscopy is the endoscopic examination of the large bowel and the distal portion of the small bowel using a fibre-optic camera on a flexible tube passed through the anus (Engin et al., 2015). It can provide a visual diagnosis (e.g. ulcers, polyps) and provide the opportunity to biopsy or remove suspicious intestinal lesions (Hong & Baek, 2023). Quality is defined as the standard of something compared with other similar things, or how good or bad something is (Britannica, n.d.). Indicator can be defined as a measurement or value that helps to understand what something is like (Longman, n.d.). Quality indicator refers to any measure of the process, performance, or outcome of healthcare delivery (Campbell et al., 2015). Colonoscopy quality indicators are defined as specific parameters associated with colonoscopy procedure (Shaukat et al., 2022). In clinical practice, colonoscopy quality indicators play a critical role in improving colonoscopy performance and outcomes (Park & Cha, 2022). Colonoscopy quality indicators can be divided into three categories in chronological order: preprocedural colonoscopy quality indicators, intraprocedural colonoscopy quality indicators, and postprocedural colonoscopy quality indicators (May & Shaukat, 2020). In this study, colonoscopy quality indicators referred to intraprocedural colonoscopy quality indicators, including bowel preparation quality, ADR, CIR, and CIT (Rex et al., 2015). These parameters were documented using a standard colonoscopy quality indicator form.

1.9.6.1 Bowel Preparation Quality

Bowel preparation is a procedure commonly performed before starting the diagnosis or treatment of certain colorectal conditions to empty and clean the patient's large intestine (Martens & Bisschops, 2014). Bowel preparation quality is defined as the degree to which the colonic mucosa is visualised during colonoscopy and may also be described as 'bowel cleanliness' or 'bowel cleansing' (Park & Cha, 2022). In this study, bowel preparation quality was the primary outcome, assessed using the Boston Bowel

Preparation Scale (BBPS) (Lai et al., 2009). In clinical practice, the BBPS is a commonly used and well-validated method for assessing bowel cleanliness (Kastenberg et al., 2018). According to the BBPS scoring system, only a total score of BBPS ≥ 6 can be defined as adequate bowel preparation; otherwise, it will be regarded as inadequate bowel preparation (Calderwood et al., 2014). This criterion was applied to assess the quality of bowel preparation in this study.

1.9.6.2 Adenoma Detection Rate

Adenomas are benign tumours of epithelial tissue with glandular origin, glandular characteristics, or both (RxList, n.d.). Colorectal adenomas are benign glandular tumours of the colon and rectum that are precursors to colorectal adenocarcinoma (colon cancer, CRC) (Aceto et al., 2020). Figure 1.2 shows the colonoscopy image of representative colorectal adenomas. Adenoma detection rate, or ADR, is the proportion of colonoscopies in which at least one colorectal adenoma is detected (Wieszczy et al., 2017). The detection of adenomas is crucial because they can be removed endoscopically, thereby preventing the development of colorectal carcinoma (Hossain et al., 2022; Waldmann et al., 2021). In clinical practice, ADR is largely affected by the quality of bowel preparation (Rai et al., 2016). In this study, the number of adenomas was recorded by trained researchers who were blinded to study allocation. The ADR for each group was calculated by the researchers at the end of the study as the number of patients with one or more adenomas divided by the total number of patients in the group.



Figure 1.2: Colonoscopy image of representative colorectal adenomas

1.9.6.3 Caecal Intubation Rate

The caecum is a large pouch located at the beginning of the large intestine, situated in the lower right-hand side of the abdomen (Oxford University Press, n.d.). Figure 1.3 displays the anatomical image of the caecum. Caecal intubation is defined as the successful insertion of the colonoscope tip into the proximal part of the ileocecal valve until the caecal caput, medial caecal wall, and appendiceal orifice are visible (May & Shaukat, 2020). Caecal intubation rate, or CIR, refers to the percentage of colonoscopies that successfully insert the colonoscope tip into the proximal part of the ileocecal valve (Park & Cha, 2022). Inadequate bowel preparation may result in an inability to complete the colonoscopy, resulting in a lower CIR (Hoff et al., 2017). In this study, caecal intubation status was recorded by trained researchers who were blinded to study allocation. The CIR for each group was calculated by the researchers at the end of the study as the number of patients with successful caecal intubation divided by the total number of patients in the group.

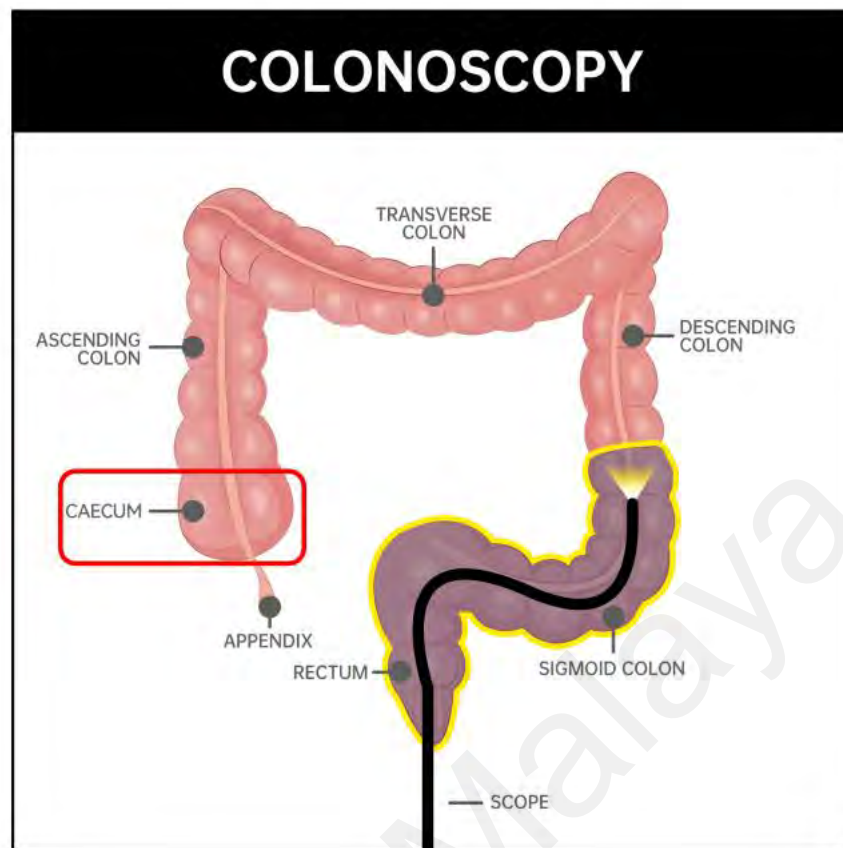


Figure 1.3: Anatomical image of the caecum

1.9.6.4 Caecal Intubation Time

Caecal intubation time, or CIT, is defined as the time from the insertion of the colonoscope tip into the anal verge until reaching the proximal portion of the ileocecal valve (Kim, 2021). Inadequate bowel preparation was found to be significantly associated with longer CIT (Jaruvongvanich et al., 2018). In this study, CIT was recorded during insertion colonoscopy using a calibrated timer by a researcher who was blinded to the study assignment.

1.9.7 Adverse Events

An adverse event can be defined as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment (National Cancer Institute, n.d.).

In the current study, adverse events referred to any undesirable gastrointestinal discomfort associated with the use of high-volume laxatives (3 L PEG solution), such as abdominal pain, bloating, nausea, or vomiting (Guo et al., 2020b).

1.9.8 Patient Satisfaction

Satisfaction is the fulfilment or gratification of a desire, need, or appetite (Vocabulary.com, n.d.). Patient satisfaction is defined as the extent to which an individual regards a healthcare service or product or the manner in which it is delivered by its provider as useful, effective, or beneficial (National Library of Medicine, n.d.). Patient satisfaction in this study referred to satisfaction with the bowel preparation process, assessed on a 100-point Satisfaction Visual Analogue Scale (VAS; 0 = complete dissatisfaction, 100 = complete satisfaction) (Chen et al., 2021).

1.9.9 Willingness to Repeat the Bowel Preparation

Willingness can be defined as the quality of being happy to do something if it is needed (Merriam-Webster, n.d.). In this study, willingness to repeat the bowel preparation referred to the extent to which patients are willing to undergo the same preparation regimen for a future colonoscopy, assessed on a three-point Likert scale ranging from 1 to 3 (1 = unwilling, 2 = maybe/uncertain, 3 = willing) (De Silva et al., 2016).

1.10 Structure of the Thesis

This thesis is structured into six chapters to facilitate clarity and understanding of the study. Chapter One provides an introduction and focus of the study. This chapter begins with the background information of bowel preparation before colonoscopy in older patients with constipation and briefly introduces abdominal vibration and walking exercise. Subsequently, a problem statement identifying the research gap justifies the need to conduct this research. This chapter also includes the research questions that

identify the study variables and evaluate the effects of the AVCWE intervention, as well as the objectives that provide clear direction for the research findings. The significance of the current study demonstrates the benefits of the findings to nursing services, public health services, and future investigations. Furthermore, this chapter describes the theoretical and operational definitions of the relevant terms, and the conceptual framework of the study to ensure an in-depth understanding of the current research. Finally, the structure of the thesis is outlined.

Chapter Two provides a critical and extensive review of the relevant literature exploring the impact of abdominal vibration or walking exercise on bowel preparation for colonoscopy to elucidate the basis for this study. The statements of this chapter also provide a valuable reference for a more comprehensive analysis and discussion of the data in subsequent chapters.

Chapter Three elaborates on the methodology used in this study. The chapter outlines the study design, research setting and sample, study instruments, sampling methods, and data collection procedures. Additionally, this chapter delves into the various phases of this study. The details of the pilot study, data analysis, and ethical considerations are also described.

Chapter Four presents the findings from Phase 1 of this study, which includes the development of the AVCWE programme, validation by a multidisciplinary expert panel, and feasibility study. The results of Phase 1 provide an important basis for the implementation of the RCT in Phase 2.

Chapter Five describes the main findings from Phase 2 of this study. It presents the effectiveness of the AVCWE intervention on colonoscopy quality indicators, adverse

events, patient satisfaction, and willingness to repeat the preparation by comparing these outcomes between the intervention and control groups. Additionally, factors influencing the primary outcome (bowel preparation quality) in older patients with constipation are also presented.

Chapter Six presents a discussion of the study findings, where the results of previous studies are used to corroborate the findings. Subsequently, research conclusions are drawn, along with implications and recommendations for clinical practice. The chapter also reflects on the limitations and the strengths of the study. The chapter concludes with an overview of the study findings.

1.11 Summary

This chapter briefly describes the background of research on abdominal vibration and walking exercise aimed at optimising bowel preparation for colonoscopy. As stated in the problem statement, there is a large research gap in non-pharmacological strategies to improve bowel preparation in older patients with constipation in the Chinese context. As the demand for colonoscopies among older patients in China continues to rise, effective management strategies are needed to promote healthcare adaptation. In the face of China's ageing crisis, an intensive intervention that integrates abdominal vibration and walking exercises may contribute to optimising CRC screening and improving patient care outcomes. Furthermore, this chapter mentions the research objectives and questions, significance of the study, definition of terms, and conceptual framework for an in-depth understanding of this study. Finally, this chapter presents the structure of the thesis.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter presents an extensive review of the extant literature to clarify the foundation of this study. The literature review and background presented at the beginning of the study can help to better understand the existing knowledge on the topic and underscore the importance of the new research (Denise & Cheryl, 2013; Snyder, 2019). Therefore, this chapter delves deep into previous literature on the effect of walking exercise or abdominal vibration on bowel preparation for colonoscopy.

First, the process of literature search and screening based on inclusion and exclusion criteria are described. Then, the specific contents of the literature review are summarised, including constipation among older patients, colonoscopy for older patients with constipation, bowel preparation for colonoscopy, bowel preparation in older patients with constipation, outcomes associated with bowel preparation, and walking exercise or vibration stimulation for improving colonic motility. Importantly, this chapter offers a comprehensive review of articles that explore the impact of abdominal vibration or walking exercise on colonoscopy quality indicators, adverse events during bowel preparation, patient satisfaction, and willingness to repeat the same bowel preparation. The chapter concludes with a critical appraisal of current research evaluating the impact of abdominal vibration or walking exercise on bowel preparation for colonoscopy.

2.2 Search Strategy

The literature search was performed using English databases including the Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, and Web of science. In addition, three Chinese databases (WanFang database, China National Knowledge Infrastructure [CNKI], and VIP database) were searched. Truncation symbols (*),

Medical Subject Heading Terms (MeSH), and entry terms were also used to determine keywords related to the objectives of the study. Specific keywords were used to retrieve relevant literature for this review such as ‘exercise therapy (MeSH)’, ‘exercise therap*’, ‘exercise (MeSH)’, ‘exercise*’, ‘walking (MeSH)’, ‘ambulation’, ‘vibration (MeSH)’, ‘vibrations’, ‘colonoscopy (MeSH)’, ‘colonoscop*’, ‘bowel preparation’, and ‘bowel cleansing’. These keywords were searched as individual words and combined using Boolean operators (‘AND’, ‘OR’, and ‘NOT’). The relevant articles were reviewed, and valuable information was extracted based on the study objectives and methodology.

2.2.1 Inclusion and Exclusion Criteria

The inclusion criteria for this literature review were as follows: (i) published in English or Chinese, (ii) describe the effect of walking exercise or abdominal vibration on bowel preparation for colonoscopy, (iii) the full text is available, (iv) quantitative or qualitative studies, and (v) recent 10 years of publication (2015–2024). Meanwhile, the exclusion criteria were a book or book chapter, a review, and a guideline.

2.2.2 Results of Study Selection

Figure 2.1 illustrates the process of identifying eligible studies for this literature review. After conducting a thorough search of three Chinese databases and three English databases, 1,142 records were identified and retrieved through keyword combinations, of which 401 were retrieved from the Chinese databases, and 741 were obtained from the English databases. In the initial screening, 544 duplicate studies and 570 irrelevant documents were removed. After conducting an in-depth review of the whole texts of the remaining 28 studies, 13 were removed because they were reviews or the intervention did not include walking exercise or abdominal vibration. Finally, 15 eligible full-text articles (2,864 participants) published between 2016 and 2023 were used for the critical appraisal. This literature review also reveals the absolute dominance of quantitative research

methods in this field of research, as all included studies were experimental or quasi-experimental. In contrast, qualitative and mixed research methods were rather underutilised.

The general characteristics of the included studies are specified in Appendix A. Overall, the topic of the effects of walking exercise or abdominal vibration on bowel preparation for colonoscopy has not been extensively studied, with a relatively small number of publications ($n = 15$). Specifically, 10 randomised controlled trials (RCTs) and five quasi-experimental studies were included and analysed. All relevant evidence comes from studies in Asian countries (Iran, South Korea and China). All included studies examined the effectiveness of walking exercise for bowel preparation before colonoscopy, with only one study additionally assessing the impact of abdominal vibration on the quality of bowel preparation. Most studies focused on the general adult population ($n = 10$), while only a few specifically examined the effects of interventions in children ($n = 1$) or older adults ($n = 4$). In terms of measurement tools for assessing bowel preparation quality, 14 studies (93.3%) used well-validated and reliable scales such as the Boston Bowel Preparation Scale (BBPS) and the Ottawa Bowel Preparation Scale (OBPS). In contrast, only one study used an unvalidated scale, the 3-point bowel preparation scale. As for study outcomes, all studies included the quality of bowel preparation, 10 studies mentioned the incidence of adverse events during bowel preparation, six studies focused on patient satisfaction with bowel preparation, and four studies involved patient willingness to repeat the same bowel preparation. Furthermore, only three studies mentioned adenoma detection rate (ADR), caecal intubation rate (CIR), or caecal intubation time (CIT).

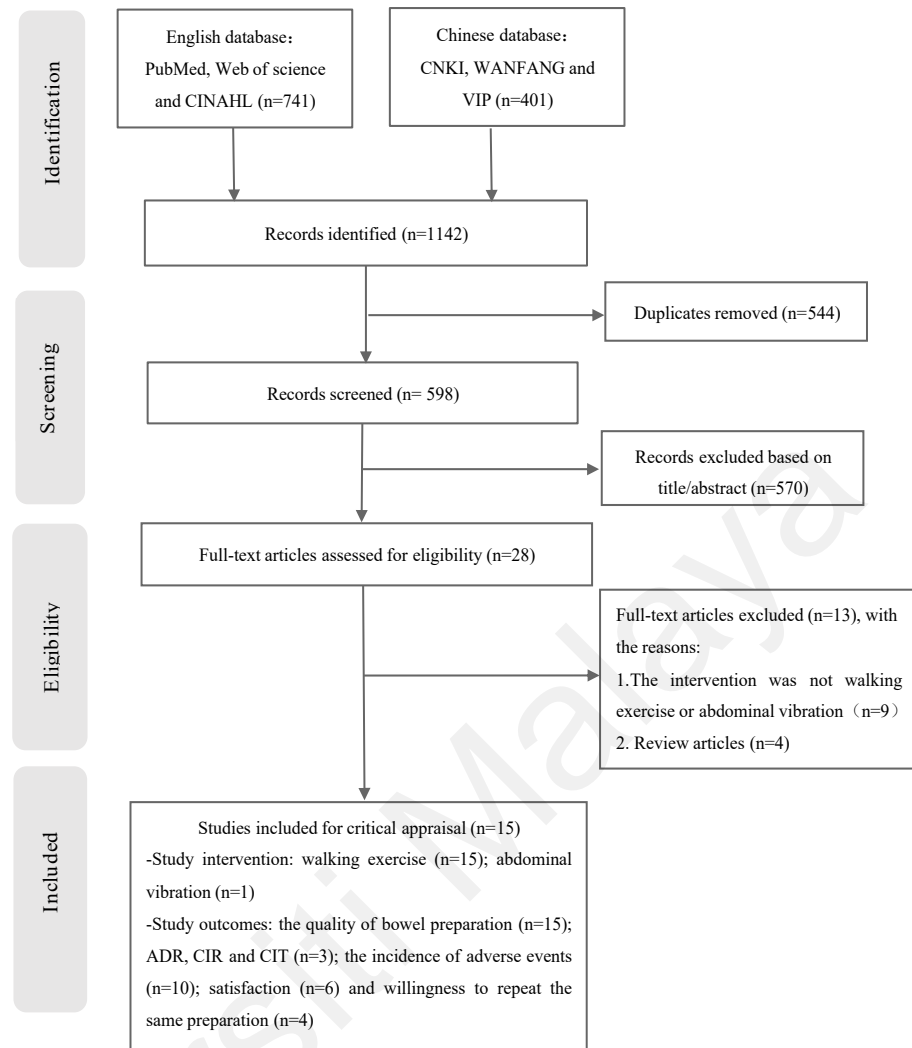


Figure 2.1: Flow chart of the literature search

2.3 Constipation among Older Patients

Constipation, a gastrointestinal motility disorder characterised by difficulty in defecation or infrequent bowel movements, has become a global public health problem (Kessoku et al., 2024; Serra et al., 2020). Chronic constipation is usually defined as constipation-related symptoms lasting at least three months (Bharucha & Wald, 2019; Cho et al., 2023). According to the Rome IV criteria, disorders of chronic constipation can be categorised into four subtypes: (a) functional constipation (FC), (b) irritable bowel syndrome with constipation (IBS-C), (c) opioid-induced constipation (OIC), and (d) functional defecation disorders (Aziz et al., 2020). FC is similar to IBS-C, but people with FC do not have other IBS symptoms, such as abdominal pain (Schmulson & Drossman,

2017). Overall, the global prevalence of chronic constipation in the general population is estimated to be 12%–17%, with the vast majority having FC and only a minority having other chronic constipation subtypes (Barberio et al., 2021; Bharucha & Lacy, 2020).

The incidence of constipation in older people is significantly higher than in younger individuals due to decreased activity, psychological impairment, pelvic floor dysfunction, comorbidities, and polypharmacy (Deb et al., 2020; Emmanuel et al., 2017; Jani & Marsicano, 2018). This phenomenon can be seen in almost every country in the world (Abdul Wahab et al., 2022; Konradsen et al., 2022; Yamamoto et al., 2022). However, the prevalence of constipation in older persons varies slightly across countries and regions due to environmental, cultural, ethnic, dietary, or genetic factors (Barberio et al., 2021; Kang et al., 2021). An Australian longitudinal study reported that the prevalence of self-reported constipation in older adults increased from 14% to 21% over a decade, with this number increasing with age (Werth et al., 2015). Furthermore, a longitudinal study involving 899 older people from different communities in Korea found that the prevalence of FC diagnosed according to the Rome IV criteria was 19.6% (Jeong et al., 2021). A recent cross-sectional study involving 5,222 participants in four cities in China reported that 17.6% of older adults were diagnosed with constipation, with older age, female gender, and shorter nighttime sleep duration being independent predictors of constipation (Du et al., 2022). According to the findings of a recent large meta-analysis of 45 population-based studies involving 275,260 participants from 43 different countries, the global prevalence of chronic constipation was 15.3% (95% CI: 8.1%–24.4%) (Barberio et al., 2021). In recent years, as population ageing has rapidly become the most significant demographic trend worldwide, constipation in older adults has become particularly prominent (Feng et al., 2020; Lobanov-Rostovsky et al., 2023; Peng, 2023). This issue places a significant burden on global healthcare resources (Deb et al., 2020; Güven Ş, 2023; Mari et al., 2020).

In clinical practice, constipation has a significant negative impact on health-related quality of life (QoL), and this impairment is predominated in the psychological and emotional aspects (Arco et al., 2022; Wlodarczyk et al., 2021). Specifically, the impact of constipation on QoL is comparable to other common chronic conditions, such as diabetes mellitus, chronic allergies, osteoarthritis, and rheumatoid arthritis (Abdul Wahab et al., 2020; Ohkubo et al., 2021). In addition, constipation has been found to be closely associated with high medical costs and a huge financial burden on individuals (Albu et al., 2019; Shah et al., 2021). Moreover, older patients with constipation are more likely to suffer from severe complications (e.g. haemorrhoids, rectal bleeding, faecal impaction, volvulus, incontinence, and perforation), further exacerbating medical expenses. According to a large cross-sectional study of 30,001 Japanese people, patients with chronic constipation had significantly lower QoL and work productivity and significantly higher indirect costs compared with patients without chronic constipation (Tomita et al., 2021). Additionally, a recent systematic literature review assessed the economic burden of patients with chronic constipation in the United States and found that patients with constipation had significantly higher direct medical costs than those without constipation owing to frequent use of healthcare services such as outpatient services, hospitalisations, and prescription medications (Nag et al., 2020). In the United States, the total direct costs of per patient with chronic constipation are estimated to be between \$1,912 and \$7,522 per year (Nellesen et al., 2013). From 1997 to 2010, there was a 129% increase in the number of constipation-related hospitalisations and a 353% increase in aggregate costs (Sethi et al., 2014). In addition, between 2006 and 2011, the number of emergency department visits due to constipation in the United States also increased by 41.5%, and related medical expenses increased by 121.4% (Sommers et al., 2015). Considering that these cost figures are outdated, it is reasonable to believe that the current financial burden of patients with constipation may be much greater.

2.4 Colonoscopy for Older Patients with Constipation

Colonoscopy is widely recognised as an efficacious diagnostic tool for intestinal diseases, given its high detection rate and capability to remove precancerous lesions during the procedure (Read et al., 2021; Shaukat & Levin, 2022). The American College of Gastroenterology (ACG) strongly recommends regular screening colonoscopies for average-risk individuals starting at age 50 years to decrease the prevalence of advanced adenomas and colorectal cancer (CRC) (Shaukat et al., 2021). In comparison, Chinese guidelines recommend an earlier starting age for CRC screening. According to the National Cancer Centre guidelines, the average-risk Chinese population over the age of 40 years are recommended to undergo a screening colonoscopy for the early detection and treatment of CRC (National Cancer Center, 2021). Due to the recommendations of CRC screening guidelines and the vigorous promotion of CRC screening programmes, screening or diagnostic colonoscopies in older adults have increased significantly in recent years (Smith et al., 2019; Wang et al., 2022b).

According to recent statistics, a considerable number of patients undergoing colonoscopy in actual clinical practice are older persons (Ray-Offor & Jebbin, 2021; Tajika et al., 2021). A prospective, multicentre, observational study of 1,289 Italian patients undergoing colonoscopy showed that 44.8% of patients were older than 65 years (Maida et al., 2022). Similarly, according to results from a recent German CRC screening cohort study involving 8,125 participants, the mean age of patients undergoing colonoscopy was 63.3 years (SD = 6.9), with 39.5% being older adults (Amitay et al., 2021). A retrospective study of 315 patients undergoing colonoscopies at a teaching hospital in the United States reported that the median patient age was 67 years, with an interquartile range of 58 to 76 years (Poola et al., 2020). A similar phenomenon was observed in South Korea, Japan, and China, with older adults accounting for a larger proportion of patients undergoing colonoscopies (Gwag & Yoo, 2022; Okamoto et al.,

2022; Zhang et al., 2024a). Since chronic constipation is a prevalent gastrointestinal symptom among older persons, older patients with constipation are an important representative of the patient population undergoing colonoscopy (Ding et al., 2022; Mari et al., 2020; Nee et al., 2020). According to the findings of several Chinese studies, over 50% of adults undergoing colonoscopy were older persons, and about one-fourth of them displayed symptoms of constipation (Dong et al., 2021; Yuan et al., 2022; Zhang et al., 2018).

2.5 Bowel Preparation for Colonoscopy

Bowel preparation is a preparation procedure performed prior to a diagnostic procedure or treatment to remove faecal material from the intestinal lumen (Argyriou & Parra-Blanco, 2022; Sun et al., 2023). Currently, bowel preparation is considered an important and essential procedure before a colonoscopy to achieve a sufficient level of bowel cleansing for a successful colonoscopy (Baker et al., 2019; Niedermaier et al., 2020). In clinical practice, the standard bowel preparation regimen involves a combination of dietary restrictions and laxative administration (Gkolfakis et al., 2019; Millien & Mansour, 2020). Based on available evidence, good compliance with dietary restrictions is significantly associated with adequate bowel preparation (Adamek et al., 2022; Wang et al., 2024a). According to the findings from an observational study of 715 Korean patients undergoing colonoscopies, non-compliance with dietary instructions was a significant risk factor for suboptimal bowel preparation (OR, 2.111; 95% CI, 1.375–3.242; $p = 0.001$) (Shin et al., 2019). Consistent with this finding, a multicentre prospective cohort study involving 575 older Italian patients demonstrated that patients who strictly adhered to a prescribed dietary regimen were more likely to achieve high-quality bowel cleansing (OR, 2.45; 95 % CI, 1.42–4.24; $p = 0.001$) (Maida et al., 2022). Therefore, improving patients' compliance with dietary regimens has always been an important research goal for medical practitioners in bowel preparation practice (Cheng et

al., 2020; Shahini et al., 2023). Dietary restrictions, as recommended by the current guidelines, include eating a low-residue diet the day before the colonoscopy and fasting on the day of the colonoscopy until the end of the procedure (Digestive Endoscopy Special Committee, 2019; Hassan et al., 2019).

To date, several laxatives for pre-colonoscopy bowel preparation have been developed, including polyethylene glycol (PEG), oral sodium phosphate, oral sulphate solution, magnesium citrate, senna, bisacodyl, and mannitol. The European Society of Gastrointestinal Endoscopy (ESGE) guideline recommends 4 L of PEG solution as the standard laxative regimen for bowel preparation (Hassan et al., 2019). Specifically, a split-dose regimen is recommended for morning colonoscopies (half the PEG solution the night before colonoscopy and half the dose the morning of colonoscopy), while a same-day regimen is recommended for afternoon colonoscopies (full dose of PEG on the day of the colonoscopy) [Strong recommendation, high-quality evidence] (Hassan et al., 2019). Additionally, it is recommended that the time interval between the last ingestion of PEG solution and the start of colonoscopy should be less than five hours [Strong recommendation, high-quality evidence] (Hassan et al., 2019). However, poor palatability and large volume are the main disadvantages of the traditional 4 L PEG regimen (Jung et al., 2022a; Soh & Kim, 2016). Based on a comprehensive review of existing evidence and considering China's national conditions, the Chinese bowel preparation guideline recommends 3 L PEG solution as the standard bowel cleansing regimen for patients undergoing colonoscopy (Digestive Endoscopy Special Committee, 2019). Specifically, patients are recommended to take 250 mL of PEG solution every 10 minutes four to six hours before their colonoscopy and to complete it within two hours [Strong recommendation, high-quality evidence] (Digestive Endoscopy Special Committee, 2019). Currently, non-compliance with the prescribed laxative regimens has been recognised as an important predictor of suboptimal bowel preparation (Martel et al., 2018;

Zhang et al., 2024a). Zhang et al. (2018) conducted a prospective observational study of 240 older patients undergoing colonoscopies and found that incomplete intake of PEG solution was strongly associated with suboptimal bowel cleansing (OR, 4.576; 95% CI, 1.855–11.287; $p = 0.001$). Similarly, a recent meta-analysis of seven observational studies ($N = 1,350$) found that patients who did not consume a full dose of laxatives were more likely to experience poor bowel preparation (OR, 2.43; 95% CI, 1.60–3.67; $p < 0.001$) (Zhang et al., 2024a). Therefore, it is crucial for healthcare professionals to ensure that patients undergoing colonoscopy strictly adhere to the prescribed laxative regimen (Ramprasad et al., 2020; Shin et al., 2019).

Adequate bowel cleansing is essential for a successful colonoscopy as it provides the optimal visualisation of the colonic mucosa and optimises the detection of colonic lesions (Sharma et al., 2020; Tontini et al., 2021). Nevertheless, a significant proportion of individuals (about 20%–40%) undergoing colonoscopies are unexpectedly found to have inadequate bowel preparation. This percentage exceeds the suggested upper limit of 10% set by the American Society for Gastrointestinal Endoscopy/American College of Gastroenterology (ASGE/ACG) (Baker et al., 2019; May & Shaukat, 2020; Sadeghi et al., 2022). Mahmood et al. (2018) conducted a meta-analysis of 24 retrospective and prospective observational studies involving 49,868 participants and found that 19.9% of patients had inadequate bowel cleansing for colonoscopy. Similarly, Gandhi et al. (2018) performed a meta-analysis of 67 studies ($N = 75,818$) published between 1994 and 2015 and found that the proportion of inadequate bowel cleansing was as high as 26%, ranging from 5% to 57%. A prospective observational study of 461 Chinese patients undergoing colonoscopy found that 23.9% of them showed inadequate bowel preparation during colonoscopy (Yuan et al., 2022). A high rate of poor bowel preparation was also reported in other countries, such as Italy (32%), France (25%), Egypt (39%), and the United States (26.0%) (Afify et al., 2022; Agrawal et al., 2022; Berger et al., 2021; Fuccio et al., 2021).

Recent data indicate that inadequate bowel preparation for colonoscopy is a significant challenge worldwide, suggesting that the current standard bowel preparation regimen used in clinical practice is insufficient for adequately clearing the bowels of patients undergoing colonoscopy (Damjanovska et al., 2024; Sninsky et al., 2024; Wang et al., 2022b; Wang et al., 2024b). Inadequate bowel cleansing can adversely affect various aspects of the colonoscopy procedure, including reduced CIR, prolonged CIT, and decreased ADR (Alvi et al., 2019; Baker et al., 2019; Wong et al., 2016). In addition, poor preparation quality may aggravate the risk of procedural-related complications (e.g. perforation, bleeding, and infection) and increase healthcare costs and patient discomfort due to the need for re-examination (Kim et al., 2019; Millien & Mansour, 2020). Notably, inadequate bowel preparation significantly impairs the colonoscopic detection of non-polypoid colorectal neoplasms, thereby contributing to the development of post-colonoscopy CRC (Iwatate et al., 2017; Oh et al., 2015). A recent study analysing 335,466 colonoscopies from a large population-based screening programme in Austria found that individuals with fair or poor bowel preparation during screening colonoscopy faced significantly higher hazards of post-colonoscopy CRC death (Hazard Ratio, 2.56; 95% CI, 1.67-3.94; $p < 0.001$), indicating more than a twofold increase in risk compared to individuals with better preparation (Zessner-Spitzenberg et al., 2024). These facts emphasise the crucial role of adequate bowel preparation in enhancing the accuracy and effectiveness of colonoscopy screenings.

The current situation of suboptimal bowel cleansing urgently requires attention and improvement from healthcare providers (Gimeno-Garcia et al., 2017; Hernandez et al., 2019). In clinical practice, identification of potential predictors of inadequate bowel preparation plays a critical role in preventing failed colonoscopy (Berger et al., 2021; Sadeghi et al., 2022). To date, patient characteristics identified as significant risk factors for inadequate bowel preparation can be classified into three categories, including

sociodemographic characteristics (older age, male sex, obesity, and lower socioeconomic status), clinical characteristics (hospitalisation, constipation, diabetes, hypertension, stroke/dementia, cirrhosis, history of abdominal/pelvic surgery, and medication use), and poor bowel preparation compliance (Fuccio et al., 2021; Gandhi et al., 2018; Martel et al., 2018). Therefore, it is imperative for healthcare providers to identify specific high-risk patients with poor bowel cleansing early and provide them with intensive bowel preparation regimens before colonoscopy.

2.6 Bowel Preparation in Older Patients with Constipation

Chronic constipation and older age have been identified as two important and highly prevalent factors associated with inadequate bowel preparation for colonoscopy (Gandhi et al., 2018; Zhang et al., 2024a). According to the pooled results of a meta-analysis conducted by Mahmood et al. (2018), older age (OR, -1.20 ; 95% CI, -2.20 to -0.19 ; $p = 0.02$) and constipation (OR, 0.61 ; 95% CI, 0.49 – 0.76 ; $p < 0.001$) were significantly associated with an increased risk of poor bowel preparation. Furthermore, constipation was identified as a significant risk factor associated with poor bowel cleansing in both European and Asian populations, regardless of the bowel preparation regimen adopted (Mahmood et al., 2018). Similarly, Fuccio et al. (2021) prospectively collected data on 1,016 hospitalised patients who had a colonoscopy at 12 hospitals in Italy and indicated that constipation was a significant risk factor for inadequate bowel preparation (OR, 2.16 ; 95% CI, 1.55 – 3.00 ; $p < 0.05$). Additionally, a prospective observational study of 240 older patients undergoing colonoscopy showed that 34.6% of older Chinese patients had inadequate bowel preparation, and older patients with constipation were three times more likely to have poor colon cleansing than those without constipation (Zhang et al., 2018). This issue may largely be attributed to the prolonged colonic transit time and reduced intestinal motility commonly seen in older adults with constipation, which makes it challenging for this population to adequately cleanse their bowels using standard

preparation protocols (Beran et al., 2024; Ho et al., 2017; Luo et al., 2022). Overall, the above findings suggest that older patients with constipation are at higher risk for poor bowel cleansing. Therefore, there is a pressing need to develop targeted bowel preparation regimens to optimise the quality of bowel preparation in this ‘difficult-to-prepare’ population.

Disappointingly, the current bowel preparation guidelines do not recommend specific preparation regimens for older patients with constipation (Digestive Endoscopy Special Committee, 2019; Hassan et al., 2019). In real-world clinical practice, these patients typically receive the same standard bowel preparation regimen as the general population, that is, a one-day low-residue diet and ingestion of 3 L PEG solution (Luo et al., 2022). Although older patients with constipation have a higher incidence of poor bowel cleansing, this demographic currently receives insufficient attention and emphasis in gastrointestinal practice in China (He et al., 2024; Zhang et al., 2024a).

Over the past few decades, in an effort to improve the quality of bowel preparation for patients with constipation, several experimental studies have tested different intensive regimens that combine conventional preparation methods with additional stimulant laxatives (bisacodyl and senna) or prokinetic agents (mosapride, itopride, and lubiprostone) to help patients empty their bowels in a short period of time (Ding et al., 2022; Ichijima et al., 2021; Lu et al., 2016; Mandolesi et al., 2017). Although adequate bowel cleansing can be achieved, patients with constipation who received these additional bowel cleansing regimens exhibit poor tolerability and low compliance due to significant adverse events (e.g. diarrhoea, headache, abdominal pain, nausea, and vomiting) (Kunz & Gillespie, 2017; Tangvoraphonkchai et al., 2023). Therefore, current bowel preparation guidelines do not recommend routine use of these supplemental preparation regimens in patients with constipation due to safety concerns (Digestive Endoscopy Special

Committee, 2019; Hassan et al., 2019; Migaly et al., 2019). This situation emphasises the importance of developing safe, effective, and patient-friendly non-pharmacological interventions tailored for older patients with constipation.

2.7 Outcomes Associated with Bowel Preparation for Colonoscopy

2.7.1 Colonoscopy Quality Indicators

The primary goal of colonoscopy is to detect and facilitate the removal of precancerous lesions of the colon and rectum (Ladabaum et al., 2020; Saito et al., 2021). Quality assessment of colonoscopies includes intubation of the entire colon and detailed mucosal examination to identify adenomas (Bishay et al., 2020; Macken et al., 2018). Successful caecal intubation eliminates the need for repeat colonoscopies, thereby avoiding waste of medical resources (Kozan et al., 2018; Zhang et al., 2020b). In addition, adequate visualisation of the colonic mucosa is critical for effective detection of precancerous lesions (Guo et al., 2019; Kim et al., 2024). The ASGE/ACG identifies nine intraprocedural colonoscopy quality indicators (Rex et al., 2015). Among them, bowel preparation quality, ADR, and CIR are of vital importance (May & Shaukat, 2020). Notably, the quality of bowel preparation has been reported to be closely associated with ADR and CIR (Alvi et al., 2019; Spada et al., 2021).

According to the colonoscopy quality indicators guidelines, the performance target for the CIR should be at least 90% for all colonoscopies and at least 95% for screening colonoscopies (May & Shaukat, 2020; Tiankanon & Aniwan, 2024). Caecal intubation is defined as deep intubation into the caecum so that the tip of the colonoscope can contact the appendiceal orifice (Dekker & Rex, 2018; Naeem et al., 2023). In real-world clinical practice, caecal intubation is a key step to evaluate the performance of colonoscopy and the basis for ensuring the completion of colonoscopy (Matyja et al., 2018; Park & Cha, 2022). In fact, caecal intubation is mainly based on visualisation of the caecal valve and

appendix orifice (Muslim & Al-Obaidi, 2021; Shine et al., 2020). Therefore, the CIR depends largely on the quality of bowel preparation (Belderbos et al., 2015; Kuga et al., 2023). A retrospective cohort study of 2,519 patients undergoing screening colonoscopy in the United States found that the CIR in patients with fair preparation (75.4%) or poor preparation (72.1%) was significantly lower than the 95% performance goal ($p < 0.001$) (Rai et al., 2016). Furthermore, a retrospective study of 315 hospitalised patients undergoing colonoscopy demonstrated that caecal intubation failure was most likely to occur with inadequate bowel preparation compared with adequate preparation (36% vs 11%, $p = 0.014$) (Poola et al., 2020).

Similarly, ADR, a critical colonoscopy quality indicator, also depends largely on visualisation of the entire colon (Groza et al., 2022; Yousaf et al., 2020). ADR is defined as the percentage of colonoscopies in which at least one adenoma is detected and is considered a strong quality measure of effective colonoscopies (Ishtiaq et al., 2023; Tjaden et al., 2018). In a prospective cohort study involving 5,470 Chinese patients undergoing screening colonoscopy, it was observed that individuals with fair or poor bowel cleansing were significantly less likely to have adenomas detected than those with good bowel cleansing (OR, 0.619; 95% CI, 0.420–0.911; $p < 0.05$) (Wong et al., 2016). The missed adenoma is defined as an adenoma detected during the second colonoscopy but not during the first colonoscopy (Zhao et al., 2019a). The adenoma miss rate (AMR) is typically calculated as the number of adenomas detected during the second colonoscopy divided by the total number of adenomas found during the first and second colonoscopy (Han et al., 2022; Seo et al., 2020). In clinical practice, inadequate bowel preparation is an independent predictor of higher AMR (Chang et al., 2018; Wang et al., 2018). According to a retrospective analysis of 872 Chinese patients who underwent a second colonoscopy within one year after the first colonoscopy, the AMR was 15.8%, and suboptimal bowel preparation was significantly associated with missed adenomas (OR,

2.37; 95% CI, 1.111–5.056; $p = 0.026$) (Dong et al., 2021). Similarly, a retrospective study of 309 patients who underwent repeat colonoscopies at less than six-month intervals at the same tertiary hospital also found that patients with inadequate bowel preparation had significantly higher AMR than those with adequate bowel preparation (35.6% vs 21.6%, $p = 0.001$) (Wang et al., 2018). Notably, since colorectal adenomas are well-known precursors to CRC, missed diagnosis of adenomas and therefore lack of timely treatment may result in poor patient prognosis and reduced survival (Chang et al., 2018; Padilla-Ruiz et al., 2022).

CIT is the time required for the colonoscope tip to travel from the anal verge to the caecal end (Kim, 2021; Matyja et al., 2018). In routine clinical practice, rapid caecal intubation should be an ideal performance target for high-quality colonoscopy (Allescher & Weingart, 2019; Goksoy et al., 2021). Prolonged caecal intubation indicates difficulty in reaching the caecum with the colonoscope and is considered an important determinant of difficult colonoscopy (Aday, 2020; Hamada et al., 2023a). Additionally, prolonged caecal intubation is a painful and unpleasant experience from the patient's perspective (Jaruvongvanich et al., 2018; Wang et al., 2021). In addition, as the duration of caecal intubation increases, patients may need to be administered additional sedative and analgesic medications, and therefore, the risk of complications may be markedly increased (Hamada et al., 2023b; von Renteln et al., 2017). Kim (2021) retrospectively analysed data from 1,229 subjects who underwent screening colonoscopy at a tertiary hospital in South Korea and found that poor bowel preparation was a significant risk factor for prolonged CIT (OR, 3.817; 95% CI, 1.866–7.808; $p < 0.001$). This finding suggests that adequate bowel preparation is key to a successful colonoscopy as it helps endoscopists clearly visualise the mucosal surface for quick and smooth insertion of the colonoscope tip into the patient's colon and rectum (Hsieh et al., 2022; Weng et al., 2023). Similarly, a meta-analysis of nine cohort studies involving 7,131 patients found poor

bowel preparation to be a significant predictor of prolonged CIT (MD, 200.24; 95% CI, 73.86–326.63; $p = 0.002$) (Jaruvongvanich et al., 2018). A retrospective study of 346 patients undergoing colonoscopy in Turkey also revealed a significant negative correlation between bowel cleanliness score and CIT ($r = -0.371$, $p < 0.001$) (Yilmaz et al., 2021).

2.7.2 Adverse Events during Bowel Preparation

To date, the most commonly used laxative for bowel preparation before colonoscopy is PEG because of its favourable safety profile and few restrictions (Digestive Endoscopy Special Committee, 2019; Hassan et al., 2019). Specifically, PEG acts as an osmotic laxative to cleanse the intestines through the intake of large amounts of fluids (Harrison & Hjelkrem, 2016; Schneider et al., 2022). PEG solutions are non-absorbable isotonic solutions that do not cause significant fluid shifts or electrolyte imbalances (Jagdeep et al., 2021; Rutherford & Calderwood, 2018). Noteworthy, this specific laxative is the preferred option for patients with inflammatory bowel diseases (Pellegrino & Gravina, 2023). This preference stems from its ability to avoid altering the histological appearance of the intestinal mucosa, ensuring that the diagnosis of the patient's condition remains unaffected (Gravina et al., 2023; Restellini et al., 2017). In addition, PEG-based solutions are the first choice for bowel cleansing in patients with cardiac, renal, or liver dysfunction since they do not cause electrolyte imbalances (Htet & Segal, 2020; Tangvoraphonkchai et al., 2023). Currently, the most commonly used bowel cleansing regimens, whether in European or Asian countries, require patients to drink large volumes (≥ 3 L) of PEG solution within a specific period (Seo et al., 2019; Zhang et al., 2021a). However, PEG solutions have a poor taste due to its high sodium and sulphur content (Di Leo et al., 2021; Li et al., 2019). Therefore, despite the high efficacy and safety profile of PEG solutions, their large volume and poor taste are their major limitations, as this may lead to low

patient tolerance and a high incidence of adverse events during bowel preparation (Gravina et al., 2023; Millien & Mansour, 2020).

In routine clinical practice, both the 4 L PEG solution recommended by the international bowel preparation guidelines and the 3 L PEG solution recommended by the Chinese guidelines are large-volume bowel cleansing regimens that are often intolerable to most patients (Jung et al., 2022a; Tian et al., 2019b). Adverse events caused by PEG regimens mainly include gastrointestinal symptoms, such as vomiting, nausea, bloating, and abdominal pain, which bring unpleasant experiences to patients undergoing colonoscopy (Hao et al., 2020; Yan et al., 2021). Based on available evidence, patients often consider adverse events during bowel preparation as the most stressful and anxiety-provoking aspect of colonoscopy and a major barrier to adherence to screening and diagnostic colonoscopies (Bhise et al., 2016; Collatuzzo et al., 2022). According to a Chinese population-based study, about 24% of patients undergoing colonoscopy reported nausea or vomiting during bowel preparation (Guo et al., 2020b). Similarly, a prospective study by Wang et al. (2019) indicated that bloating was also a common adverse event during bowel preparation, with an incidence rate of 17.3%, and therefore, it should not be ignored. This discomfort, along with other adverse symptoms during preparation, can substantially diminish patients' readiness to undergo CRC screening in the future (Sharara et al., 2016; Yang et al., 2018). According to the findings of a previous systematic review, the majority of patients cited bowel preparation as the most burdensome part of colonoscopy, highlighting its significant adverse events as a key reason for their reluctance to undergo the procedure (McLachlan et al., 2012). Therefore, this current situation emphasises that interventions aimed at reducing adverse events should be developed to optimise patients' subjective experience during bowel preparation.

2.7.3 Patient Satisfaction and Willingness to Repeat the Preparation

According to recommended surveillance guidelines, individuals who have had precancerous polyps completely removed should undergo a follow-up colonoscopy every three to five years, depending on the size, type, and number of polyps (Abu-Freha et al., 2021; Gupta et al., 2020). Patients treated for CRC should undergo a colonoscopy within one year of cancer removal to facilitate early detection of recurrence, new cancers, or precancerous polyps (Maida et al., 2024; Stephens & Fahy, 2021). Studies found that high patient satisfaction with bowel preparation and their willingness to repeat the same preparation are key factors in ensuring compliance with follow-up guidelines (Brotons et al., 2019; Selva et al., 2021). Therefore, these two subjective factors should be recognised and improved to strengthen patient adherence to surveillance colonoscopy recommendations, thereby maximising CRC prevention. As mentioned previously, frequent adverse events are a common problem in patients receiving PEG preparation regimens (Soh & Kim, 2016; Spadaccini et al., 2020). However, mounting evidence suggests that the prevalence of adverse events and poor tolerability associated with conventional preparation regimens significantly reduces patient satisfaction with bowel preparation and their willingness to repeat the same preparation regimen (Decruz et al., 2021; Hao et al., 2020; Kamran et al., 2020; Yang et al., 2018).

The patient's overall satisfaction with bowel preparation regimen is a major component of the bowel preparation process as it may play an important role in ensuring that patients fully ingest the laxatives as directed, which may help achieve a better colon cleansing (Hatoum et al., 2016; van der Zander et al., 2021). However, in actual clinical practice, patients undergoing colonoscopy have reported that bowel preparation is the most uncomfortable and challenging experience and a barrier to future CRC screening (Kimpel et al., 2022; Shamim et al., 2021). Vemulapalli et al. (2022) conducted a prospective survey involving 405 adult patients who had recently undergone

colonoscopies at two outpatient endoscopy centres in the United States. Their findings revealed that 71% of patients considered adverse events during bowel preparation as the most unpleasant aspect of the colonoscopy experience. Besides, 55% of patients identified these adverse events as the primary factor likely to deter them from undergoing future colonoscopies. Additionally, Hatoum et al. (2016) conducted a multicentre survey study of 1,211 patients scheduled for elective outpatient colonoscopy in the United States and found that only 77% of subjects were satisfied with their bowel preparation protocol. Importantly, subjects who were more satisfied with their current bowel cleansing regimen expressed a greater willingness to undergo the same preparation regimen in the future (Hatoum et al., 2016; Zhao et al., 2019b). Therefore, strategies aimed at reducing adverse events during bowel preparation may enhance patient satisfaction and willingness to repeat the preparation, thereby improving their overall experience and increasing adherence to CRC surveillance guidelines.

2.7.4 Other Consequences of Inadequate Bowel Preparation

In addition to the above, inadequate bowel preparation can result in increased medical expenses and an increased risk of procedural complications (Kingsley et al., 2016; Ray-Offor & Jebbin, 2021). A prospective cohort study of 6,196 patients undergoing colonoscopy at an endoscopy centre in Hong Kong indicated that inadequate bowel preparation was an independent predictor of immediate perforation during colonoscopy (OR, 3.5; 95% CI, 1.7–7.3; $p = 0.001$) (Chan et al., 2015). According to a systematic review of 14 observational studies in five European countries, the proportion of repeat colonoscopies due to poor bowel preparation was 63% in Spain, 27.5%–35.9% in Italy, and 24.5% in the United Kingdom (Murphy et al., 2019). Additionally, the decision analytic model of this study suggests that increasing the rate of adequate bowel cleansing at first colonoscopy may result in healthcare cost savings and potential economic benefits to the healthcare system (Murphy et al., 2019).

In addition, due to the increasing number of repeat colonoscopies due to inadequate preparation, the burden on endoscopy departments is increasing, and demand exceeds current capabilities, resulting in longer appointment waiting times for patients and greatly reducing the quality of medical services (Agrawal et al., 2022; Hotta, 2022). A cohort study of 524 hospitalised patients in the United States demonstrated that compared with adequate bowel preparation, inadequate bowel preparation increased hospitalisation time by approximately 25% and hospitalisation costs by 30%, resulting in a huge waste of medical resources (Yadlapati et al., 2015). Although there is currently a lack of cost analysis of repeat colonoscopies due to poor bowel preparation in China, this figure is not expected to be lower than that in Western countries. In real-world clinical practice, improving the quality of bowel preparation for colonoscopy is a formidable challenge that plagues medical professionals worldwide (Chen et al., 2024; Kutyla et al., 2021). These findings highlight that improving the quality of bowel preparation may be an important and effective strategy to reduce the risk of colonoscopy-related complications and avoid wasting healthcare resources.

2.8 Walking Exercise for Improving Colonic Motility

Exercise therapy is a simple and safe strategy to improve patients' physical fitness and relieve the symptoms of diseases (De Giorgio et al., 2021; Luan et al., 2019; Song et al., 2018b). Recently, there has been increasing interest in the impact of exercise therapy on constipation management, with researchers suggesting that walking exercise can reduce the severity of symptoms and improve the QoL in patients with constipation (Daniali et al., 2020; Nimrouzi & Zarshenas, 2019). Walking is an activity that moves the body forward at a slow to moderate speed by moving the feet in a coordinated manner to maintain physical health or achieve certain therapeutic purposes (Gao et al., 2019; Ungvari et al., 2023).

Tantawy et al. (2017) randomly assigned 125 obese middle-aged Egyptian women with chronic constipation to a walking exercise group and a control group (receive routine care for constipation) to explore the impact of physical activity on constipation in this population. In this study, the intervention group received a 60-minute walking training programme, which included a 10-minute warm-up, a 40-minute walk, and a 10-minute recovery period. Participants were asked to perform the programme three times per week for 12 weeks. The results of this study showed that 12 weeks of walking exercise significantly improved constipation symptoms and QoL in premenopausal women with constipation. Gao et al. (2019) conducted a meta-analysis of nine RCTs including 680 participants to scientifically analyse the effects of walking exercise on chronic constipation. The results of this meta-analysis demonstrated that symptoms of constipation were significantly improved after 4–12 weeks of walking intervention (RR, 1.98; 95% CI, 1.05–3.73; $p = 0.035$). Although this study suggests that exercise may be a feasible and effective treatment option for patients with constipation, there are some significant methodological limitations that may compromise the reliability of the findings. Overall, the included studies exhibited a relatively high risk of bias and a low methodological quality. Specifically, limitations of the study include incomplete description of the random sequence, lack of detailed information about allocation concealment, and absence of blinding in outcome assessment. Moreover, there was considerable heterogeneity among the included studies ($I^2 = 87.8\%$, $p = 0.000$). These factors may influence the interpretation and generalisability of the study findings. Thus, conducting more rigorous future studies is imperative to accurately assess the effectiveness of walking interventions in treating constipation.

Intestinal peristalsis can pull food towards the distal end of the intestine, and the frequency and amplitude of peristaltic waves can enhance the flow of food (Gaskell et al., 2023; Park et al., 2015). Research findings indicate a strong correlation between

prolonged colonic transit time and poor bowel cleansing (Zhai et al., 2019). According to a retrospective study of 404 adults undergoing colonoscopy in South Korea, infrequent bowel movement ($< 3/\text{week}$) was a strong predictor of inadequate bowel preparation (OR, 5.00; 95% CI, 1.91–13.1; $p = 0.001$) (Lee et al., 2017). Therefore, intervention aimed at enhancing intestinal motility may improve bowel cleansing for colonoscopy (Martel et al., 2018; Panigrahi et al., 2023). Recent studies suggest that exercise is a promising strategy as it significantly increases the amplitude of intestinal peristaltic waves (Duboc et al., 2020; Kim et al., 2014). Inadequate exercise during bowel preparation has been identified as an independent risk factor significantly associated with poor bowel cleanliness (Zhang et al., 2024a; Zhang et al., 2020a).

Kumar et al. (2016) performed a prospective observational study of 88 older adults (age ≥ 65 years) undergoing colonoscopies at a gastrointestinal endoscopy unit in the United States to determine the association between the functional status and the quality of bowel preparation. In this study, functional status was assessed based on patients' self-reports of their ability to perform activities of daily living (ADLs) and ambulate. As a result, difficulty with ambulating (OR = 4.83, $p < 0.001$), difficulty with ADLs (OR = 2.93, $p = 0.001$), and history of diabetes mellitus (OR = 2.88, $p = 0.007$) were identified as significant univariate factors for predicting poor bowel preparation. After adjusting for the three variables, only 'difficulty with ambulating' was an independent risk factor for inadequate bowel preparation in older patients undergoing colonoscopy (adjusted OR = 5.78, $p = 0.004$). This new finding highlights the need for healthcare professionals to focus on patients who have difficulty walking because they are at risk for poor bowel preparation (Zhang et al., 2023b). Besides, a prospective observational study by Zhang et al. (2018) investigated 240 Chinese older adults scheduled for elective colonoscopy to identify risk factors for inadequate bowel preparation. According to the findings of this

study, walking less than 30 minutes during preparation was a strong predictor of inadequate bowel preparation (OR, 2.474; 95% CI, 1.261–4.855; $p = 0.008$).

Shi et al. (2021) conducted a prospective cross-sectional study collecting clinical data from 150 outpatients undergoing colonoscopy at a university hospital in China to investigate factors influencing the quality of bowel preparation for colonoscopy and to examine the correlation between walking steps and bowel cleanliness. The multivariate ordinal logistic regression analysis indicated that the number of steps walked before colonoscopy was a significant factor affecting the quality of bowel preparation ($\beta = 0.018$, $p = 0.004$). A curvilinear relationship was observed between bowel cleansing scores and the number of steps walked, suggesting that at least 5,270 steps during bowel preparation are needed for achieving high-quality bowel cleansing. This is the first study to demonstrate a strong correlation between the quantity of steps taken and the quality of bowel preparation and the first to suggest the minimum exercise intensity required to obtain optimal bowel cleansing. However, the relatively small sample size may be a shortcoming of this study, and more multicentre studies with large samples are needed in the future to validate this valuable and novel finding.

2.9 Vibration Stimulation for Improving Colonic Motility

Clinically, the use of laxatives is the most common strategy in the management of constipation (Forootan et al., 2018; Sharma et al., 2021). However, prolonged use of laxatives can result in serious adverse effects, including faecal impaction and aggravation of symptoms related to constipation (Alsalimy et al., 2018; Sharma & Rao, 2017). Abdominal massage, as a non-invasive, non-pharmacological method, is widely used by clinical medical staff to manage constipation (Aydinli & Karadağ, 2022; Doğan İ et al., 2022). Abdominal massage refers to the regular and rhythmic movement of hands on the abdomen, which stimulates intestinal peristalsis and changes intra-abdominal pressure

through mechanical and reflexive methods, thereby accelerating the excretion of stool from the gastrointestinal tract (Hasanshahi et al., 2022; Li, 2022). Based on available evidence, abdominal massage has been widely proven in clinical practice to be effective in reducing constipation symptoms and improving the QoL of patients with constipation (Chen et al., 2014; Faghihi et al., 2022).

An RCT involving 35 older patients with constipation in a Turkish nursing home demonstrated that 30 minutes of daily abdominal massage over eight weeks effectively improved patients' QoL and alleviated constipation issues (Birimoglu Okuyan & Bilgili, 2019). Similarly, Yildirim et al. (2019) conducted an RCT involving 204 Turkish adult patients with constipation, revealing that administering abdominal massage twice daily for four weeks led to a 13% increase in bowel movements and a notable reduction in constipation severity. A meta-analysis of 13 RCTs (N = 830) by Gu et al. (2023) demonstrated that abdominal massage could significantly increase the frequency of defecation (SMD, 1.05; 95% CI, 0.63–1.46; $p < 0.001$), reduce the symptoms of difficult defecation (SMD, -1.51; 95% CI, -2.35 to -0.68; $p = 0.0004$), and improve the QoL (MD, -13.24; 95% CI, -25.83 to -0.65; $p = 0.04$) of patients with functional constipation. Wang et al. (2022c) reviewed the scientific evidence for abdominal massage in the treatment of chronic constipation and found that abdominal massage increases the frequency of bowel movements and reduces the severity of constipation by accelerating gastrointestinal motility and reducing colonic transit time.

However, manual massage, while effective, can be time-consuming and requires precise technique to yield significant positive results (Mari et al., 2020; Robertson et al., 2018). This may pose challenges, particularly for older patients with constipation who may find self-massage difficult due to their weaker physical condition (Hagbini et al., 2024; Mari et al., 2020). In addition, clinical nurses usually need to invest a lot of energy

and time when using massage techniques to treat constipation, which significantly increases their workload and reduces clinical work efficiency (McClurg et al., 2020; Zhu et al., 2022). Considering the limitations and difficulties in applying manual massage technique to treat constipation in older adults, it is necessary to develop a method that has similar effects but is more convenient for this population.

In recent years, several studies have found that vibration stimulation may be an effective and easy-to-use therapy to increase gastrointestinal motility and reduce the severity of constipation symptoms (Elfatah Elhosary et al., 2023; Xu et al., 2020). Abdominal vibration is a safe and non-invasive method of delivering mechanical oscillation to the colon using automatic vibrating devices of different frequencies, amplitudes, and accelerations to reduce colonic transit time and increase gastrointestinal motility, thereby alleviating constipation symptoms without any side effects (Noh et al., 2020).

Xu et al. (2020) recruited 150 hospitalised older patients with constipation from a tertiary hospital in China to evaluate the effectiveness and safety of an abdominal vibration device (CAVORTINE, Jiangsu Yuyue Medical Equipment & Supply Co., Ltd, Chongqing, China) in treating constipation symptoms. During the study period, patients in the control group received only conventional constipation treatment. However, patients in the intervention group received external mechanical vibration therapy twice a day for 30 minutes each time in addition to conventional treatment. After four weeks of treatment, compared with the control group, the severity of constipation in the intervention group was significantly reduced, and the QoL was significantly improved ($p < 0.05$). The results of this study provide valuable evidence that abdominal mechanical vibration can positively reduce colonic transit time and promote gastrointestinal motility in older

patients with constipation. However, the relatively high price of this vibration device (about \$ 2,700) may hinder its widespread use in clinical practice.

Similarly, Elfatah Elhosary et al. (2023) conducted a single-blinded, pre–post RCT in 40 women with postnatal constipation at a university hospital in Egypt to evaluate the effects of whole-body vibration (WBV) induced by a non-invasive oscillation platform (AV-001; Body Green, Taipei, Taiwan) on constipation symptoms and health-related QoL. In this study, patients in the control group received only routine care, including pelvic floor exercises, static abdominal exercises, and dietary instructions. However, the intervention group received low-intensity WBV treatment thrice a week for six weeks in addition to usual care. Specifically, each vibration lasted for 15 minutes, and patients were asked to adopt a semi-squatting position on the WBV platform while receiving the vibrations to avoid adverse reactions such as dizziness. The results of this study demonstrated that six weeks of WBV treatment had a significant positive effect on reducing constipation severity and improving the QoL in postpartum women. In conclusion, available research evidence suggests that vibration intervention is a promising strategy for the management of constipation because it significantly promotes gastrointestinal motility and is easy to perform (Jiang & Li, 2015; Uwawah et al., 2024).

2.10 Effect of Walking Exercise or Abdominal Vibration on Colonoscopy Quality

Indicators (Bowel Preparation Quality, ADR, CIR, and CIT)

Recently, several experimental studies have demonstrated that walking exercise during bowel preparation can significantly improve bowel cleanliness in patients undergoing colonoscopies (Gao et al., 2023; Noh et al., 2020). Walking exercise is known to improve gastrointestinal motility and promote bowel movements through specific walking intensity, time, or number of steps (Rezamand et al., 2023; Zhang et al., 2023b).

Zhang et al. (2017) conducted a prospective quasi-experimental study to examine the effect of walking exercise on bowel preparation for colonoscopy. They recruited 220 Chinese outpatients scheduled for elective colonoscopy and assigned them to a walking exercise group ($n = 110$) and a control group ($n = 110$) according to the order of outpatient visits. In addition to the standard preparation regimen, patients in the exercise group were required to walk for 15 minutes after each ingestion of 600 mL of PEG solution until the entire 3 L volume was consumed. However, patients in the control group received only a conventional bowel preparation regimen. Finally, this study found that bowel cleanliness scores were significantly higher in the intervention group compared with the control group ($p < 0.001$). Therefore, this study recommends that walking exercise be an important component of standard bowel preparation for outpatients undergoing colonoscopy owing to its proven advantages in improving bowel preparation quality. However, as patient grouping in the study by Zhang et al. (2017) was not randomised, the estimated effects may be biased. Furthermore, the study did not specify whether the outcome measurers were aware of the patient groupings; therefore, the reliability of the study results is questionable.

Similarly, Gao et al. (2023) performed an RCT in Chinese patients undergoing colonoscopy to determine appropriate walking steps for high-quality bowel cleansing. In this study, 300 patients scheduled for colonoscopy were randomised into three groups: 0 step, 5,000 steps, and 10,000 steps during bowel preparation. Four to six hours before colonoscopy, patients in all three groups were instructed to drink 2 L of PEG solution at a rate of 250 mL every 15–20 minutes within two hours. Then, the 5,000-step group and the 10,000-step group were asked to start walking one hour after taking the full dose of PEG solution and reach the prescribed number of steps. A pedometer was attached to the patient's ankle to ensure that the number of steps taken was within the prescribed range. The primary outcome of this study was the adequacy of bowel cleansing, as assessed by

endoscopists using the BBPS during colonoscopy. In addition, endoscopists recorded other colonoscopy quality indicators such as ADR, CIR, and CIT. All outcome assessors were unclear about the grouping of patients. According to the findings, the 10,000-step group had significantly higher rates of adequate bowel preparation than the other two groups (0-step group vs 5,000-step group vs 10,000-step group: 51% vs 59% vs 89%; $p < 0.001$). Furthermore, the 10,000-step walking group exhibited significantly higher ADR and lower CIT compared with the 0-step and 5,000-step groups, although there was no significant difference in the CIR between the three groups. Therefore, this study recommends an exercise regimen of 10,000-step prior to colonoscopy to achieve high-quality bowel preparation. However, the study's primary limitation is that the participants were all under the age of 65 years, thus limiting the generalisability of the findings. In other words, the suggested 10,000-step walking exercise programme may only be appropriate for patients who can tolerate long-distance walking but may not be feasible for all patients undergoing colonoscopy, particularly those with mobility issues or elderly individuals.

Recently, a single-centre, investigator-blinded RCT was conducted in 262 Iranian patients undergoing colonoscopy to ascertain the effectiveness of walking exercise for bowel preparation (Rezamand et al., 2023). Specifically, patients in the walking group ($n = 131$) were asked to walk for 5 minutes after each 250 mL of PEG solution until the full 3 L volume was consumed. Patients in the control group ($n = 131$) received the same bowel preparation regimen as the walking group but were not required to walk. Patients' bowel cleanliness scores were assessed by an endoscopist using the BBPS, and CIT was recorded by two trained nurse assistants. All researchers involved in outcome assessment were blinded to patient assignment. The results of this study demonstrated that although walking exercise did not show the benefits in improving the quality of bowel preparation and shortening the CIT, patients who walked more than 6,900 steps had significantly

higher BBPS scores ($M = 6.62$, $SD = 1.8$) compared with those who walked less than 6,900 steps ($M = 5.92$, $SD = 1.9$) ($p = 0.003$). However, this study has some limitations that cannot be ignored. First, only one endoscopist determined bowel cleanliness scores for all participants, which may have reduced the accuracy of the study results to some extent. Second, the walking exercise programme in this study was not rigorously formulated and lacked scientific basis.

Despite numerous studies demonstrating the beneficial effects of walking exercise on improving the quality of bowel preparation, there are still studies that draw inconsistent conclusions. An RCT involving 330 participants conducted by Qin et al. (2016) found that exercise after drinking PEG solution did not show a significant advantage in improving bowel preparation for colonoscopy (rate of adequate bowel preparation, exercise group vs control group: 60.1% vs 66.4%; $p = 0.495$). In this study, participants in the exercise group were asked to exercise for more than 10 minutes after ingesting each litre of PEG solution until the full 3 L volume was consumed. However, this study has some shortcomings that need to be strengthened. First, this study did not provide a detailed description of random sequence generation, allocation concealment, and blinding of outcome assessment. Therefore, the methodological quality of this study remains unclear. Second, this study did not describe the specific exercise regimen, so the intervention in this study is difficult to be referenced by other studies. Third, the patients in the intervention group could only exercise after taking a large dose of PEG solution (1 L), which might be a burden for them. Whether this type of exercise affects the quality of bowel preparation remains to be further elucidated. Finally, this study did not consider participants' characteristics, including body mass index (BMI), history of abdominal surgery or colonoscopy, medication used, and comorbidities. However, it is worth noting that these characteristics are important risk factors that directly affect the quality of bowel preparation for colonoscopy.

Although several previous RCTs have examined the effect of walking exercise on bowel preparation for colonoscopy, study conclusions have been inconsistent due to limited sample sizes and variability in study interventions (Zhang et al., 2023b). Therefore, Huang and Zhou (2021) performed a meta-analysis of five RCTs and three controlled clinical trials (CCTs) including 1,486 participants to systematically evaluate and analyse the effects of exercise intervention on bowel preparation for colonoscopy. The pooled analysis of this meta-analysis demonstrated that quantitative exercise intervention can significantly improve the rate of adequate bowel preparation (RR, 1.25; 95% CI, 1.05–1.49; $p = 0.012$). Despite the positive findings, this meta-analysis has several limitations that should be accounted for when interpreting the results. First, most included studies were deficient in terms of allocation concealment and blinding of the participants and personal, and 37.5% of included studies did not use randomisation. Second, although different exercise regimens were used in the included studies, no further subgroup analyses were performed in this meta-analysis. Overall, the methodological quality of eligible trials in this meta-analysis was not high. In the future, more multicentre and high-quality RCTs are required to draw more accurate and reliable conclusions. Similarly, a recent systematic review including five experimental studies ($n = 1,109$) also found that exercise therapy is a feasible and promising non-pharmacological strategy to improve the quality of bowel preparation and should become an important component of bowel preparation regimens (Zhang et al., 2023b). However, this review noted that the amount of exercise (3,000–10,000 steps or 0.5–1.9 hours) and the exercise timing (during or one hour after taking laxatives) varied widely between studies, limiting the broad generalisation of the findings into clinical practice. Therefore, it is crucial to establish a standardised and well-structured exercise regimen aimed at improving the quality of bowel preparation in future studies.

In recent years, based on favourable findings from previous studies exploring the efficacy of vibrational stimulation in the treatment of chronic constipation, some researchers have speculated that abdominal vibration may be beneficial in optimising bowel preparation for colonoscopy. Noh et al. (2020) conducted a prospective, investigator-blinded CCT to assess the clinical feasibility and effectiveness of abdominal vibration in bowel preparation for colonoscopy. In this study, 300 Korean patients scheduled to undergo therapeutic colonoscopy were equally divided into a walking group, a vibrator group, and a control group ($n = 100$ per group). Patients in the walking group were asked to start walking one hour after taking 4 L of PEG solution the day before and on the day of colonoscopy and were required to walk at least 3,000 steps before colonoscopy. While the study failed to set a maximum number of steps for the walking group, patients were limited to walking one hour before their colonoscopy. Patients in the vibrator group were administered abdominal vibration intervention (up to eight cycles, each of which lasted for 10 minutes and was followed by 20 minutes of rest) one hour after ingesting the PEG solution the day prior to and on the day of their colonoscopy. In the vibrator group, patients were allowed to self-adjust the stimulation intensity but were instructed to remain in the rest room to minimise walking. It is important to note that the vibrator application was limited to one hour before the colonoscopy. The primary outcome of this study was the quality of bowel preparation, as measured by the BBPS. The results showed that abdominal vibration could achieve high-quality bowel cleansing similar to walking exercise but better than the control group (BBPS scores: control group vs walking group vs vibrator group, 6.17 [SD = 1.15] vs 7.39 [SD = 1.55] vs 7.38 [SD = 1.55]; $p < 0.001$). Furthermore, the abdominal vibration group showed a significant advantage over the walking and control groups in reducing the CIT (control group vs walking group vs vibrator group, 7.68 [SD = 2.39] vs 7.93 [SD = 5.05] vs 5.96 [SD = 2.63]; $p < 0.001$). However, this study also has some drawbacks that need to be addressed.

First, the lack of randomisation in grouping may lead to bias. Second, since this study only included patients who underwent therapeutic colonoscopy, most precancerous lesions had already been identified on previous examinations. Therefore, the relationship between the quality of bowel preparation and ADR could not be determined. Therefore, future studies should consider also including patients undergoing screening or diagnostic colonoscopy to further explore the impact of abdominal vibration on ADR. Finally, this study used 4 L of PEG solution as the bowel cleansing regimen. However, high-volume solutions have been shown to be significantly associated with poor tolerability, higher rates of adverse events, and lower willingness to repeat the regimen (Ma & Fang, 2023; Tian et al., 2019a). Currently, the Chinese Bowel Preparation Guideline recommends that 2–3 L PEG solution be used as the standard bowel cleansing regimen for colonoscopy based on patient compliance and safety considerations (Digestive Endoscopy Special Committee, 2019). Therefore, the use of smaller volumes of PEG formulations (2 L or 3 L) should be considered in future studies to reduce bowel cleansing discomfort in patients undergoing colonoscopy.

2.11 Effect of Walking Exercise or Abdominal Vibration on Adverse Events

Walking exercise during bowel preparation has been reported to have significant benefits in reducing discomfort associated with laxative ingestion (Chen et al., 2018b; Fang, 2017; Zhang et al., 2017). Fang (2017) conducted an RCT involving 68 Chinese patients undergoing colonoscopy and randomised them to a walking group or a control group. Patients in the walking group were instructed to walk for 30 minutes after each meal for three days before colonoscopy and walk one hour after ingesting the full-dose laxatives on the day of colonoscopy. Consequently, the incidence of adverse events during bowel preparation in the walking group was significantly lower than that in the control group (8.82% vs 44.12%, $p = 0.001$). However, some limitations should be considered. First, the sample size of this study was relatively small. Second, the random

sequence generation and blinding of outcome assessments were not described in this study. Similarly, another study involving 100 Chinese adults scheduled for colonoscopies found that a walking exercise regimen (walking for 10–15 minutes after each ingestion of 600 mL of PEG solution until the entire 3 L volume was consumed) significantly reduced the overall adverse events ($p < 0.05$) (Chen, 2018a). However, it should be noted that this study was not a randomised trial. Furthermore, the researcher who assessed adverse events during bowel preparation was not blinded to patient assignment. Therefore, the reliability of the outcome assessments remains unclear. More rigorous RCTs with large sample sizes are required to confirm this finding.

In contrast, some studies have found that walking exercise has no significant positive effect on reducing adverse effects during bowel preparation. For instance, Noh et al. (2020) found no statistically significant difference in the incidence of adverse events between the vibrator group, walking group, and control group ($p > 0.05$). This finding is consistent with the RCT conducted by Gao et al. (2023). Considering this controversy, several meta-analyses were recently performed to objectively evaluate the effect of walking exercise on the incidence of adverse events during bowel preparation in patients undergoing colonoscopy. A meta-analysis conducted by Huang and Zhou (2021) showed that walking exercise substantially reduced the occurrence of adverse events associated with the use of laxatives, including nausea (RR, 0.52; 95% CI, 0.37–0.74; $p = 0.000$), vomiting (RR, 0.36; 95% CI, 0.23–0.56; $p = 0.000$), abdominal pain (RR, 0.50; 95% CI, 0.28–0.89; $p = 0.019$), and bloating (RR, 0.60; 95% CI, 0.36–0.99; $p = 0.047$). Similarly, Zhang et al. (2020a) performed a meta-analysis of five RCTs and CCTs involving 984 participants to explore whether walking exercise could reduce adverse events during bowel preparation. The pooled results revealed that the incidence of abdominal pain (RR, 0.51; 95% CI, 0.29–0.90; $p < 0.05$) and vomiting (RR, 0.39; 95% CI, 0.23–0.68; $p < 0.01$) in the exercise group were significantly lower than that in the control group. However,

most of the studies included in the above two meta-analyses were Chinese articles, and there were many flaws in the quality of research methodologies. Therefore, these findings need to be verified by more high-quality studies.

2.12 Effects of Walking Exercise or Abdominal Vibration on Patient Satisfaction and Willingness to Repeat the Bowel Preparation

A few prior studies focused on the impact of abdominal vibration or walking exercise on patient satisfaction and the willingness to repeat the same bowel preparation. In an RCT conducted by Gao et al. (2023), a principal researcher assessed patient satisfaction with bowel preparation and willingness to repeat the regimen through a 100-point questionnaire after the examination. The findings of this study revealed no significant differences in patient satisfaction and willingness to repeat the same bowel preparation between the walking exercise group and the control group ($p > 0.05$). Similarly, Noh et al. (2020) used a five-point scale to evaluate patient satisfaction with bowel preparation and patient self-reported 'yes' or 'no' responses to assess patient willingness to repeat the preparation. The results of this study also indicated that abdominal vibration or walking exercise interventions had no significant advantage in improving these subjective outcomes.

However, some Chinese researchers have reached the opposite conclusion. Li et al. (2021) conducted an RCT of 74 older Chinese patients undergoing colonoscopy and instructed patients in the walking exercise group to walk for 15 minutes after ingesting each 600 mL of PEG solution until the full 3 L volume was consumed. The result of this study demonstrated that walking exercise significantly improved patient satisfaction with bowel preparation ($p < 0.05$). Additionally, an RCT including 110 Chinese adults undergoing colonoscopies found that walking exercise significantly improved patients' willingness to repeat the same preparation (Ding, 2022). However, these Chinese

publications lacked the use of validated tools to assess patient satisfaction and willingness. Therefore, the reliability of these subjective outcome assessments remains unknown.

Chai et al. (2019) conducted a meta-analysis of 11 RCTs involving 2,067 participants and noted that quantitative exercise intervention was effective in improving patient satisfaction with bowel preparation (OR, 4.97; 95% CI, 2.31–10.67; $p < 0.0001$). However, approximately half of the included studies did not describe the random sequence generation and blinding of outcome assessment. Therefore, more well-designed, large-sample, multicentre RCTs are recommended to be conducted in the future to assess the actual effects of walking exercise or abdominal vibration on patients' subjective perception of bowel preparation.

2.13 Gap Identification

Constipation is one of the most common gastrointestinal disorders among older adults worldwide, with an overall prevalence of 14.7%–23.9% (Forootan et al., 2018; Salari et al., 2023). Additionally, constipation is a common risk factor for inadequate bowel cleansing for colonoscopy (Shahini et al., 2023; Zhang et al., 2024a). As a frequent population undergoing colonoscopy, older patients with constipation have a higher risk of inadequate bowel preparation, which negatively affects various aspects of the colonoscopy procedure (AlAmeel, 2018; Gwag & Yoo, 2022). These negative consequences in turn place significant stress and challenges on patients and the healthcare system (Shaukat et al., 2021; Tiankanon & Aniwani, 2024).

The association of chronic constipation with increased risk of inadequate bowel preparation brings to light the essential need for tailored approaches in managing bowel preparation among older adults. This scenario underscores a broader implication: the necessity for healthcare strategies that not only address the physiological aspects of

ageing but also accommodate the complex interplay of conditions like constipation, which can significantly impact the effectiveness of crucial diagnostic procedures like colonoscopy.

Studies have suggested that those experiencing constipation should consider the additional use of bowel laxatives, such as lubiprostone, lactulose, and bisacodyl, to ensure adequate bowel preparation and the effectiveness and accuracy of the procedure (Banerjee et al., 2016; Li et al., 2020; Lu et al., 2016). However, the use of additional cleansing agents was found to result in higher rates of adverse events, lower tolerability, and reduced patient satisfaction (Kamran et al., 2020; Kunz & Gillespie, 2017). Despite the high risk of inadequate bowel preparation in older patients with constipation, current guidelines do not provide specific recommendations for this population due to a lack of sufficient high-quality evidence (Hassan et al., 2019; Martel et al., 2018). This situation emphasises the importance of innovative, non-pharmacological interventions aimed at enhancing bowel preparation quality and patient comfort, particularly within this vulnerable population.

Although several previous studies have demonstrated the effectiveness of non-pharmacological strategies such as abdominal vibration or walking exercise in optimising bowel preparation for colonoscopy, the overall methodological quality of these studies was not very high due to a lack of randomisation or failure to blind the outcome assessors (Gao et al., 2023; Noh et al., 2020; Qin et al., 2016). In addition, previous studies were mainly conducted in the general population, thereby limiting the generalisability of these findings to populations at higher risk with poor bowel preparation. Moreover, previous literature only analysed the influence of abdominal vibration or walking exercise on bowel cleansing separately, without exploring their synergistic effects. Since it is difficult for older patients with constipation to achieve satisfactory bowel cleansing, it can be

hypothesised that a combination of abdominal vibration and walking exercise may be beneficial for these ‘difficult-to-prepare’ individuals. Therefore, based on the existing evidence in this field, this study aimed to compare the effects of the abdominal vibration combined with walking exercise (AVCWE) programme versus walking exercise (WE) programme and the standard bowel preparation regimen on colonoscopy quality indicators, adverse events during bowel preparation, patient satisfaction, and willingness to repeat the bowel preparation among older patients with constipation.

2.14 Summary

This chapter reviews the extant literature regarding the impact of abdominal vibration or walking exercise on bowel preparation for colonoscopy. Colonoscopy is widely considered a highly effective procedure for preventing, screening, and diagnosing CRC. Ensuring adequate bowel cleansing is paramount for an effective colonoscopy. To improve bowel cleanliness in patients undergoing colonoscopy, it is crucial to identify high-risk individuals with inadequate bowel cleansing early so that targeted strategies can be implemented before colonoscopy.

Constipation has been identified as a critical clinical variable significantly associated with inadequate bowel preparation. Additionally, it is reported as one of the most prevalent comorbidities among older patients scheduled for colonoscopy. However, in clinical practice, a significant proportion of older patients with constipation experience poor bowel cleansing due to slower colonic motility and delayed colonic transit time. As the global population continues to age rapidly, addressing the issue of inadequate bowel preparation in these patients warrants significant attention.

Recently, non-pharmacological approaches like abdominal vibration and walking exercise have demonstrated potential in enhancing bowel cleanliness and minimising

adverse events during preparation. However, as these studies were mainly carried out among the general population, it remains unclear whether these interventions are appropriate for the 'difficult-to-prepare' population, such as older patients with constipation. Furthermore, the only study on abdominal vibration was conducted in South Korea, and the effectiveness of this intervention in the Chinese population remains to be confirmed. Considering the difficulties in achieving adequate bowel preparation in older patients with constipation, the positive effects of either strategy alone on bowel cleansing might be restricted. Based on the current evidence, this study hypothesises that a more intensive intervention combining both strategies might be more promising in obtaining the ideal bowel cleaning for colonoscopy in this high-risk group of patients.

CHAPTER 3: METHODOLOGY

3.1 Introduction

This chapter elucidates the research methodology utilised in the current study. First, the research design of randomised controlled trial (RCT) is discussed. Then, the research setting where this study was conducted is introduced. The population, sample, and sample size calculation used in the study are also highlighted. Next, the phases of the current study are described. Then, the tools or instruments used to collect data are delineated. Subsequently, the data collection procedures are elaborated on. Ethical considerations for conducting this study and the pilot study to assess the reliability of research tools are also presented. Finally, the statistical methods used in this study are summarised.

3.2 Study Design

This study used a quantitative method to address the research questions. The quantitative paradigm is based on positivism, in which this approach tends to emphasise objective measurement and numerical analysis of data (Grove & Gray, 2022; Tappen, 2023). Quantitative research is often considered to have higher reliability and objectivity compared to other research types (Claxton & Barthlow, 2023; Williams et al., 2022). This is because statistics can be used to generalise a finding, so complex problems are often simplified and restructured into a limited number of variables (Creswell & Creswell, 2022; Gray & Grove, 2020). Given that all measured variables, including sociodemographic data, bowel cleanliness score, adenoma detection rate (ADR), caecal intubation rate (CIR), caecal intubation time (CIT), incidence of adverse events, satisfaction score, and willingness score, are numerical, a quantitative design is deemed suitable for this study.

Specifically, an RCT was considered the most appropriate quantitative design for achieving the objectives of this study. In clinical research, RCTs are widely regarded as

the gold standard for assessing the effectiveness of new interventions or treatments because they provide the strongest evidence of cause-and-effect relationships (Baldi et al., 2017; Fernainy et al., 2024). The design of RCT follows three basic principles, namely, randomising subjects into different groups, establishing a control group, and applying blinding (Houser, 2021; Machin et al., 2021). Randomising patients in a clinical trial involves assigning them to an experimental or control group in a random manner, ensuring that each participant has an equal and unbiased chance of being placed in any group (Sverdlov et al., 2024). Generally, the experimental group receives the intervention being tested, while the control group receives the current standard care or a placebo (Boswell & Cannon, 2022; Schulz & Grimes, 2018). According to the research objectives, multiple groups can be established within either the experimental group or the control group (Bédécarrats et al., 2020; Ramthun, 2022). Blinding reduces bias and maximises the validity of results by ensuring that those involved in the study are unaware of participants' treatment assignments (Monaghan et al., 2021). It can be applied to various groups involved in a study, including participants, researchers, healthcare providers, and outcome assessors (Juszczak et al., 2019; Polit & Beck, 2020; Sil et al., 2019).

The parallel-group design, the most prevalent type of RCTs, aims to demonstrate the superiority, equivalence, or non-inferiority of a new intervention (Nair, 2019). Under this design, participants are randomly assigned to one or more study groups, each of which receives a distinct intervention (Murray et al., 2020). After randomisation, each participant will remain in their assigned treatment group for the duration of the study. The parallel-group design can be applied across various diseases and facilitates the simultaneous execution of experiments in multiple groups, even across different locations (Fain, 2020). In parallel-group randomised trials, it is essential to ensure that participants in one group do not inadvertently influence the other group through unplanned co-interventions or crossovers (Kim et al., 2021). The steps involved in a parallel-group trial

design include: (i) assessing the eligibility of study subjects, (ii) recruiting participants after obtaining consent, (iii) randomisation, and (iv) allocation to either the test group or the control group (Figure 3.1).

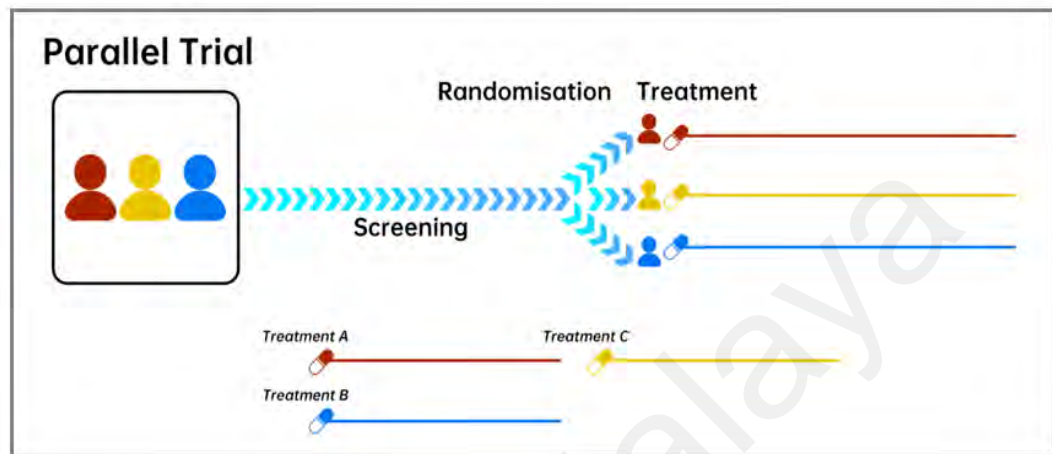


Figure 3.1: Parallel-group design

In light of the aforementioned details, a parallel-group RCT design was employed in this study to evaluate the comparative effects of the AVCWE programme versus the WE programme and the standard bowel preparation regimen on colonoscopy quality indicators (bowel preparation quality, ADR, CIR, and CIT), adverse events, patient satisfaction, and willingness to repeat the same preparation among older patients with constipation. To ensure randomisation of this study, a co-researcher not involved in data collection and analysis employed a lottery method to randomly assign eligible patients to one of three groups at a 1:1:1 allocation ratio. Specifically, patients were assigned to either a control group (C group), a walking exercise group (WE group), or an abdominal vibration combined with walking exercise group (AVCWE group) by selecting an opaque envelope containing a piece of paper indicating 'C', 'WE', or 'AVCWE'. Each sealed opaque envelope contained only one sheet of paper, and there were no markings or labels on the outside of the envelope. Furthermore, to mitigate the risk of detection bias,

researchers responsible for collecting outcome data were blinded to patient group assignment. Additionally, all participants were asked not to disclose their group details to any researcher, endoscopist, or assistant nurse. Notably, patients in different groups of this study were scheduled for colonoscopies on different days to avoid possible contamination between groups. This study strictly complied with the CONSORT (Consolidated Standards of Reporting Trials) 2010 explanation and elaboration for reporting parallel-group randomised trials (Schulz et al., 2010). The CONSORT item checklist was used for reporting the details of this study (Appendix B).

3.3 Study Setting

Study setting refers to a place where a study is conducted (Melnik & Fineout-Overholt, 2023; Polit & Beck, 2020). This prospective, investigator-blinded, three-arm RCT was conducted at the Digestive Endoscopy Centre of Changzhou Second People's Hospital, Changzhou City, Jiangsu Province, China. This hospital was chosen because it is a well-known tertiary teaching hospital affiliated with Nanjing Medical University and one of the largest hospitals in Changzhou. It has 2,200 inpatient beds and an annual outpatient volume of approximately 2.39 million. The hospital's digestive endoscopy centre, established in 1970, performs approximately 12,000 colonoscopies annually. About half of these patients are older adults, ensuring a sufficient sample size during the study period. The centre has a well-structured medical team, comprising ten physicians and eight nurses. All physicians in this digestive endoscopy centre hold master's or doctorate degrees, with more than 90% having pursued advanced studies for over a year in developed countries such as the United States, Germany, France, Canada, and Japan. All colonoscopies at this centre are performed by senior endoscopists, each with experience in over 3,000 procedures.

3.4 Population and Sample

The population refers to all types of elements (individuals, objects, events, or substances) that satisfy the inclusion criteria in a particular study (Lobiondo-Wood & Haber, 2021). There are two types of population, namely, target population and accessible population (Creswell & Clark, 2017). The target population comprises the entire group of people or objects to which the researcher aims to generalise the study results (Martien & Nelligan, 2019). In contrast, the accessible population represents a representative unit or subset of the target population that the researcher can obtain (Monsen, 2024). The sample refers to the selected elements (people or objects) chosen for participation in a study (Houser, 2021; Tappen, 2023).

The target population for this study comprised all older patients with constipation scheduled for outpatient colonoscopy, while the accessible population included older patients with constipation scheduled for outpatient colonoscopy from February to August 2023 in this study setting. The sample of this study was obtained from the accessible population using universal sampling. Universal sampling refers to the selection of sample where not all the people in the population have the same probability of being included in the sample, and for each one of them, the probability of being selected is unknown (Avron et al., 2019). Accessible patient samples were identified by a trained co-researcher based on the following inclusion and exclusion criteria.

Inclusion criteria

Patients who fulfilled the following criteria were included in the study:

1. Diagnosed as functional constipation according to the Rome IV diagnostic criteria (Mearin et al., 2016). A senior gastroenterologist (L.M.) conducted the functional constipation screening. Criteria fulfilled for the last three months with symptom onset at least six months before diagnosis:

- a. Must include two or more of the following symptoms:
 - (i) Straining more than 25% of defecations.
 - (ii) Lumpy or hard stools more than 25% of defecations.
 - (iii) Sensation of incomplete evacuation of more than 25% of defecations.
 - (iv) Sensation of anorectal obstruction/blockage of more than 25% of defecations.
 - (v) Manual manoeuvres to facilitate more than 25% of defecations.
 - (vi) Fewer than three spontaneous bowel movements per week.
 - b. Loose stools are rarely present without the use of laxatives.
 - c. There are insufficient criteria for irritable bowel syndrome.
2. Aged 60 years and above;
 3. Outpatients scheduled to undergo screening or diagnostic colonoscopy;
 4. Can walk independently without any assistance.

Exclusion criteria

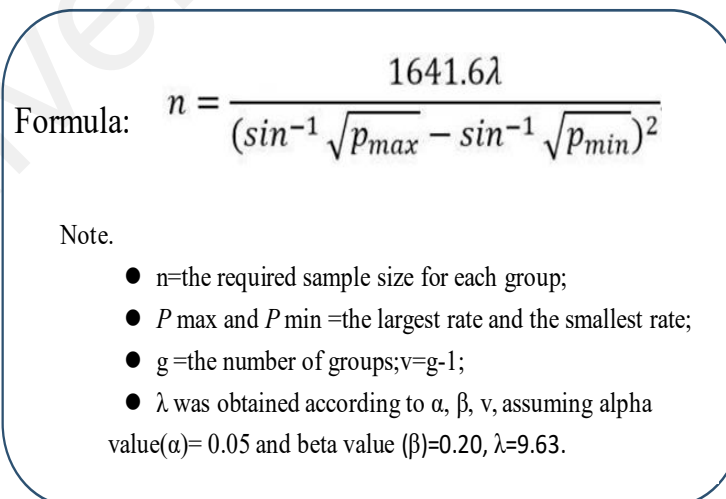
Patients with the following criteria were excluded from the study:

1. Scheduled for therapeutic colonoscopy, such as endoscopic mucosal resection or polypectomy;
2. Suspected colon obstruction, stricture, or perforation;
3. Had the following causes of secondary constipation: severe hypothyroidism, Parkinson's disease, spinal cord injury, long-term opioid use, etc.
4. Had serious health conditions, such as heart failure, kidney failure, liver failure, dyspnoea, and dementia;
5. Had an abdominal mass, such as an abdominal aortic aneurysm;
6. Allergy to the laxatives used in this study;
7. Other situations in which the study protocol cannot be followed.

3.5 Sample Size Calculation

As this was an RCT, each subject was randomly assigned to one of three groups following enrolment and eligibility assessment (Moule et al., 2017). The calculation of sample size is crucial, as it directly affects the statistical power required to determine the appropriate number of participants needed to detect clinical treatment effects (Grove & CIPHER, 2024; Wang & Ji, 2020). Existing literature suggests that sample size calculations can be informed by previous studies, pilot studies, and past clinical experience (Althubaiti, 2023; Das et al., 2016).

The sample size for this study was determined based on findings from a prior study involving older adults with constipation (Wei & Chen, 2023). The sample size calculation was specifically based on the primary outcome variable, defined as the adequate bowel preparation rate, which refers to participants with a total score of ≥ 6 points on the Boston Bowel Preparation Scale. The following formula was used to calculate the sample size for this study (Yang & Xu, 2015) (Figure 3.2).



Formula:
$$n = \frac{1641.6\lambda}{(\sin^{-1}\sqrt{p_{max}} - \sin^{-1}\sqrt{p_{min}})^2}$$

Note.

- n =the required sample size for each group;
- P_{max} and P_{min} =the largest rate and the smallest rate;
- g =the number of groups; $v=g-1$;
- λ was obtained according to α , β , v , assuming alpha value(α)= 0.05 and beta value (β)=0.20, $\lambda=9.63$.

Figure 3.2: Sample size calculation formula

Wei and Chen (2023) reported that the rate of adequate bowel preparation was 93% in the intervention group and 75% in the control group. Based on these findings, this study estimated the proportion of older adults with adequate bowel preparation to be 93% ($P_{\max} = 0.93$) in the intervention group and 75% ($P_{\min} = 0.75$) in the control group. A beta value (β) of 0.20 and an alpha value (α) of 0.05 were assumed, with a degree of freedom (ν) of 2 based on the current three groups. This results in a λ value of 9.63. These values were then substituted into the formula (Figure 3.3):

$$n = \frac{1641.6 \times 9.63}{(\sin^{-1} \sqrt{0.93} - \sin^{-1} \sqrt{0.75})^2} \approx 74$$

$$n_1 = n_2 = n_3 = 74$$

Figure 3.3: Sample size calculation for this study

Based on the calculation results from the above formula, a minimum of 74 subjects per group was required. However, accounting for a 20% attrition rate, at least 93 subjects per group were necessary to detect a difference in treatment success, with a 5% Type-I error rate and 80% power for a two-tailed test. A total of 279 eligible patients were ultimately recruited for this study, with 93 patients in the AVCWE group, 93 in the WE group, and 93 in the control group. Therefore, the sample size for this RCT was deemed sufficient.

3.6 Phases of Study

As shown in Figure 3.4, the study was divided into two main phases: Phase 1 involved the development, validation and feasibility study of the AVCWE programme, whereas Phase 2 focused on the implementation of the AVCWE programme.

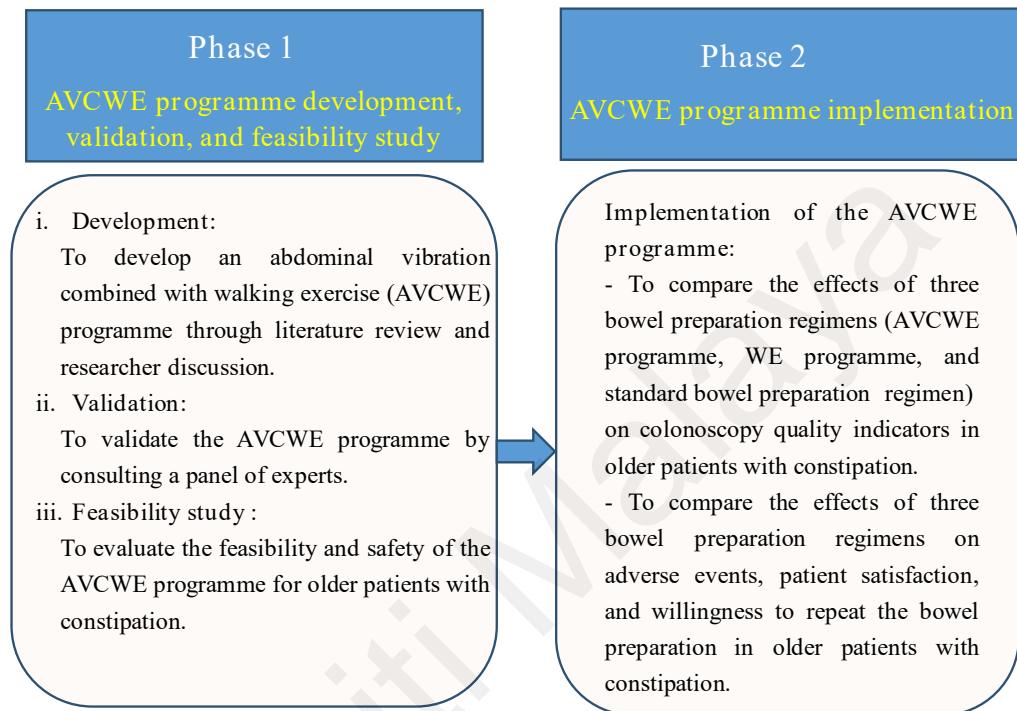


Figure 3.4: Flow chart of study phases

3.6.1 Phase 1: AVCWE Programme Development, Validation, and Feasibility Study

Phase 1 involved the development, validation, and feasibility study of the AVCWE programme for older patients with constipation. The AVCWE programme was initially developed by three experienced researchers: the main researcher (a nursing educator with 10 years of experience in geriatric care research), a senior gastroenterology professor with 21 years of experience in bowel preparation research, and a physical education scholar with 16 years of experience in physical exercise research. A detailed text description and demonstration video of the initial AVCWE programme were subsequently presented to a multidisciplinary expert panel for comprehensive evaluation. The experts were asked to

evaluate the programme using the exercise programme evaluation form designed by Chen et al. (2013).

During this phase, a feasibility study was conducted to examine the feasibility and safety of the developed AVCWE programme for older patients with constipation. All findings from Phase 1 formed the basis for the actual implementation of the AVCWE programme in Phase 2. Figure 3.5 depicts a flow chart of the study process and procedure for Phase 1, including the development, validation, and feasibility study of the AVCWE programme.

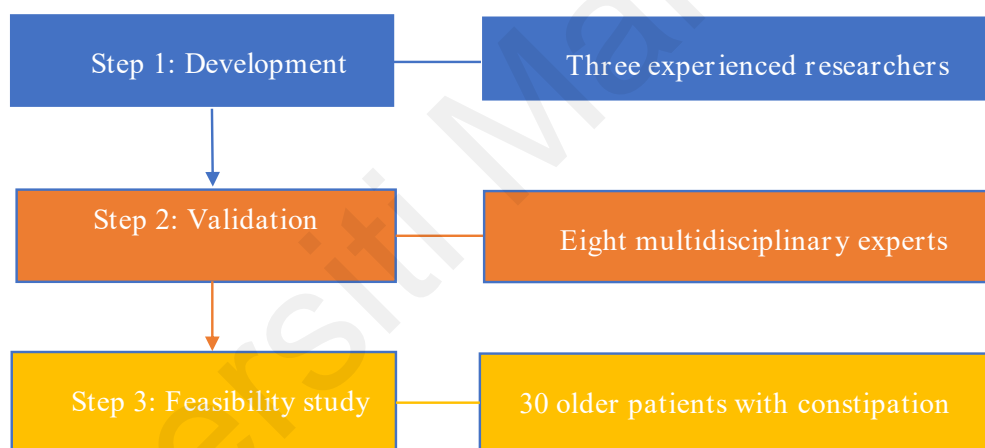


Figure 3.5: Flow chart for Phase 1 of the study

Step 1. Development

The main researcher, in collaboration with the senior professor of gastroenterology and the physical therapist, conducted a comprehensive search and review of the literature on non-pharmacological interventions to improve bowel preparation for colonoscopy. This provided an evidence-based basis for the initial development of the AVCWE protocol. The literature provided definitions, benefits, and techniques for implementing relevant strategies. The researchers first developed a preliminary AVCWE programme based on their substantial clinical experience and the existing literature. The results of the

originally developed AVCWE programme are shown in Table 4.1 in the subsequent Chapter 4.

Step 2. Validation

In this step, the Delphi technique was employed to collect the viewpoints of a group of specialists to validate the tailored AVCWE programme for older patients with constipation (Niederberger & Köberich, 2021; Zhao et al., 2024). A group of eight specialists from three varied fields—gastroenterology, geriatrics, and physical therapy—was recruited using the purposive sampling method. The preliminary AVCWE protocol was thoroughly described in text and demonstrated in video form, and the expert panel provided extensive feedback through an email survey. In order to mitigate arbitrary bias in perspectives and improve the reliability of the consultation process, a minimum of two experts from each of the three disciplines were involved. The following criteria were used to determine the inclusion of specialists in the panel: (i) a minimum of 10 years of work experience in one of the three aforementioned fields, (ii) holder of a higher professional title, and (iii) voluntary engagement.

Experts assessed the preliminary AVCWE programme using the exercise programme evaluation form designed by Chen et al. (2013) (Appendix D). This evaluation form included four essential elements to evaluate the programme:

- i. **Simplicity:** This measured the level of challenge older patients with constipation faced while performing the programme. Experts were asked to assess the degree of complexity or simplicity.
- ii. **Safety:** The safety evaluation aimed to determine whether the programme posed any risks or possible hazards to older patients with constipation. Experts assessed its safety and potential dangers.
- iii. **Suitability:** Suitability was defined as the programme's feasibility and appropriateness

for older patients with constipation. Specialists evaluated whether the programme was well-suited for this particular demographic.

iv. Helpfulness: This criterion evaluated the programme's overall efficacy by determining whether it facilitated intestinal cleansing in older patients with constipation.

According to the study by Chen et al. (2013), the Cronbach's α coefficients for these criteria in this assessment scale were 0.93, 0.93, 0.94, and 0.94, respectively. Experts utilised this grading system relying on their expertise, allocating ratings to each procedure under the AVCWE programme. The rating ranged from '1', representing a procedure that was very challenging, extremely dangerous, completely unsuitable, and ineffective (implying it should be eliminated), to '2', indicating that the procedure needed considerable adjustments. A score of '3' demonstrates that the procedure was overall satisfactory but need some small modifications, whilst a score of '4' indicates that the procedure was very easy, safe, suitable, extremely effective for bowel cleansing, and of utmost significance (implying that it should not be excluded) (Chen et al., 2013). Experts were asked to offer suggestions for improvements if they rated an item as 3 or lower. Based on feedback from the expert panel, some modifications were made to the AVCWE programme. The details of the revised programme are presented in Table 4.4 (Chapter 4).

Kendall's coefficient of concordance (W) is a statistical measure used to evaluate the level of agreement among multiple experts' ordinal assessments of the same samples (Kramer et al., 2018). Kendall's W ranges from '0' (no agreement) to '1' (complete agreement), with higher values indicating stronger inter-rater reliability (Venugopal et al., 2023; Wu et al., 2024). A p -value < 0.05 from the Kendall's W test indicates a significant level of concordance and consistency in the opinions of the experts involved (Yang et al., 2023b; Zhao et al., 2022b). In this study, Kendall's W was utilised to ascertain inter-rater reliability in evaluating the AVCWE programme.

Step 3. Feasibility study

Feasibility study aims to determine the practicality of implementing a large-scale formal study design in an actual clinical setting and fully determine the potential problems that may arise during the study to evaluate whether the intervention in the formal study is appropriate and can be successfully conducted (Lobiondo-Wood & Haber, 2021; Pearson et al., 2020).

A single-arm feasibility study of the AVCWE programme was performed prior to the commencement of Phase 2 to ascertain the successful execution of this strategy in a formal study context. The study involved 30 older patients with constipation. After the intervention, each participant was requested to evaluate the programme protocol according to their own perspectives. The feasibility study was performed in February 2023 at the Digestive Endoscopy Centre of Changzhou Second People's Hospital. This centre conducts approximately 12,000 colonoscopies annually, with approximately half of the individuals undergoing colonoscopies being older persons. The feasibility study used a convenience sampling method to recruit 30 older adults suffering from constipation from this specific location. The eligibility criteria for participants in the feasibility study were identical to those for the subsequent formal study, including: (i) diagnosed as functional constipation according to the Rome IV diagnostic criteria (Mearin et al., 2016), (ii) aged 60 years and above, (iii) outpatients scheduled to undergo screening or diagnostic colonoscopy, and (iv) can walk independently without any assistance. In addition, this study excluded individuals with the following conditions: scheduled for therapeutic colonoscopy, suspected colon obstruction, stricture, or perforation, had causes of secondary constipation, had serious health conditions, had abdominal masses, and those with an allergy to the laxative used in this study.

The two elements of the AVCWE programme, namely, abdominal vibration and walking exercise, were assessed by the subjects following the same criteria (simplicity, helpfulness, safety, and suitability) provided by Chen et al. (2013). According to the study by Tsai et al. (2020), study participants were asked to rate each criterion using a 10-point Cantril ladder scale. A score of '0' on this scale implied that older patients with constipation recognised the procedure very challenging, hazardous, unsuitable, and ineffective. Conversely, a score of '10' indicated that they perceived the procedure as highly simple, safe, suitable, and extremely useful. A lower score signifies more negative views, whilst higher values suggest more favourable attitudes (Tsai et al., 2020).

In addition, participants were prompted to offer qualitative input by contemplating their actual experiences in conducting the AVCWE programme and answering the following open-ended inquiries: (i) What are your feelings throughout the execution of the AVCWE programme? (ii) What recommendations do you have for improving the programme? (iii) If you have previously had a colonoscopy, how did your bowel preparation experience differ this time? The suggestions and feedback provided by respondents at this stage were collected and used as a helpful guide for making modifications to the programme. Patients' ratings and suggestions for the AVCWE items are presented in Chapter 4.

In summary, in Phase 1, this study developed and validated the AVCWE programme and evaluated its practicality within older patients with constipation. All results from Phase 1 are detailed in Chapter 4. In the following phase, an RCT was conducted to comprehensively evaluate the impact of the AVCWE programme on bowel preparation for colonoscopy in older patients with constipation.

3.6.2 Phase 2: AVCWE Programme Implementation

Phase 2 was a parallel-group RCT aimed at comparing the effectiveness of the AVCWE programme with the WE programme and the standard bowel preparation regimen on colonoscopy quality indicators, adverse events during bowel preparation, patient satisfaction, and willingness to repeat the same bowel preparation in older patients with constipation. This was a crucial phase involving the actual implementation of the study intervention. In this phase, patients who fulfilled the inclusion criteria were prospectively randomised into one of three groups in a 1:1:1 ratio: a control group, a walking exercise group (WE group), or an abdominal vibration combined with walking exercise group (AVCWE group), using a lottery method. The specific process of Phase 2 is depicted in Figure 3.6.

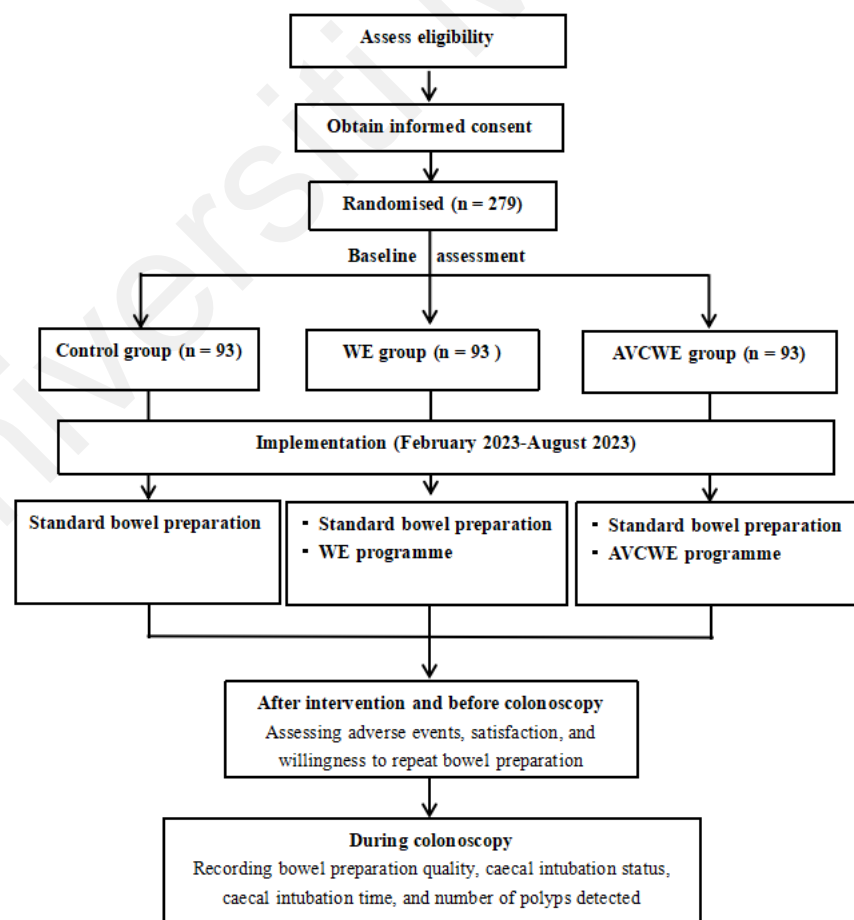


Figure 3.6: Flow chart for Phase 2 of the study

This was a single-blinded, parallel, three-arm RCT. The actual implementation period of the study was from February to August 2023. The specific procedures are as follows:

i. On the day the patient arrived at the hospital for an outpatient colonoscopy appointment, the co-researcher (L.M.) performed a comprehensive evaluation of participants based on a checklist of inclusion and exclusion criteria.

ii. The purpose and process of the study, along with the voluntary nature of participation, were explained to patients who met all criteria. Additionally, written informed consent was obtained from patients prior to enrolment.

iii. The co-researcher (W.L.N.) then asked eligible patients to select a sealed opaque envelope from a box containing an equal number of envelopes for each group. As the calculated sample size was 93 patients per group, a total of 279 envelopes were prepared for this study, with 93 envelopes allocated to each group. Recruitment to a group ceased once the required 93 patients had been enrolled. Each envelope contained only a piece of paper labelled with either 'C', 'WE', or 'AVCWE', with no markings or labels on the outside. Eligible patients were therefore randomly assigned to a group based on their self-selection.

iv. After patients were assigned to a group, the co-researcher (W.L.N.) scheduled their colonoscopy dates. To avoid contamination, patients from different groups were scheduled for colonoscopies on different days.

v. On the day of the patient's colonoscopy, the patient was required to arrive at the endoscopy centre before 8 a.m. The main researcher (Z.Y.Y.) then instructed the patients to implement the following preparation regimen according to their group.

3.6.2.1 Control Group

If the piece of paper in the envelope randomly selected by the patient had the letter 'C' written on it, the patient was assigned to the control group and did not receive any intervention other than the standard bowel preparation regimen. The standard preparation

regimen recommended by the Chinese Bowel Preparation Guideline, including laxative ingestion and dietary restriction, was equally applied to all patients in the three groups (Digestive Endoscopy Special Committee, 2019). Specifically, on the day of the appointment, once patients were scheduled for a specific colonoscopy date, they received a standard verbal explanation of bowel preparation instructions from the co-researcher (W.L.N.). In addition, patients were provided with standardised instructions in written form so that they could better understand and adhere to the bowel preparation regimen (Appendix F).

In accordance with the standard bowel preparation regimen, patients were asked to follow a low-residue diet the day before the colonoscopy and drink only water on the day of the colonoscopy until the end of the procedure. Since all eligible patients in this study underwent colonoscopies in the afternoon, patients were asked to arrive at the endoscopy centre before 8 a.m. on the day of their colonoscopy and take the PEG solution according to the same standards under the guidance of the main researcher. Specifically, each patient was instructed to take a full dose of 3 L of PEG solution at a rate of 250 mL every 10 minutes between 8:00 and 10:00 a.m. on the day of colonoscopy (Digestive Endoscopy Special Committee, 2019). The PEG solution used in this study was made by mixing 3 L warm water with three bags of PEG powder (Heshuang, Shenzhen Wanhe Pharmaceutical Co., Ltd.). All patients in the three groups followed the same standard of dietary restrictions and laxative intake. However, patients in the control group were instructed to remain in the waiting area during laxative administration, except for walking to the bathroom, until the whole 3 L volume was consumed.

A high-resolution adult video colonoscope (CF-H290I, Olympus, Japan) was used for the single-person colonoscopy, and the specific parameters of the colonoscopy procedure were precisely documented. All procedures were performed separately in the afternoon

by three senior endoscopists, each with experience in performing more than 8,000 colonoscopies. They were blinded to the hypotheses and objectives of the study and the randomisation of the patients. Furthermore, all participants were asked not to disclose their group details to any researchers, endoscopists, or nurse assistants.

3.6.2.2 Walking Exercise Group (WE group)

If the piece of paper in the envelope randomly selected by the patient had ‘WE’ written on it, the patient was assigned to the WE group and received a walking exercise intervention in addition to the same standard bowel preparation regimen as the control group. The walking exercise intervention was implemented based on the walking exercise procedure from the developed AVCWE programme, the content of which is described in detail in Table 4.4 in Chapter 4.

A smartwatch (Honor Band 5, Huawei, Shenzhen, China) was used in this study to ensure that the parameters of walking exercise were within the specified range (Figure 3.7). Currently, smartwatches are widely used in the daily life of Chinese citizens to accurately monitor real-time heart rate and record exercise distance during multi-sports, running, and fitness. Smartwatches are easy to buy online or in physical stores and are not expensive (about 100–200 RMB, equivalent to USD 14–28). Therefore, smartwatches have high sales and are gaining popularity in China.



Figure 3.7: Schematic diagram of the smartwatch

3.6.2.3 Abdominal Vibration Combined with Walking Exercise Group (AVCWE group)

If the piece of paper in the envelope randomly selected by the patient had ‘AVCWE’ written on it, the patient was assigned to the AVCWE group and received abdominal vibration combined with walking exercise as an intervention in addition to the same standard bowel preparation regimen as the control group. The AVCWE intervention was implemented according to the AVCWE programme developed in Phase 1, with its content detailed in Table 4.4 (Chapter 4).

As shown in Figure 3.8, in addition to using the above-mentioned smartwatch to record walking parameters, an abdominal vibration belt (MK9301-02, Mike Sports, Guangdong, China) was used for patients in the AVCWE group to implement abdominal vibration intervention. In general, abdominal vibration belts are not considered medical devices and are widely sold in the Chinese market for weight loss and fitness. Their average price is around 200–300 RMB (equivalent to USD 28–41). They are easily available and cheap, making them popular among the Chinese people.



Figure 3.8: Schematic diagram of the abdominal vibration belt

3.7 Study Instruments or Tools

The instruments used to collect data on study variables were inclusive of sociodemographic and clinical information form, Boston Bowel Preparation Scale (BBPS), colonoscopy quality indicators recording form, satisfaction Visual Analogue Scale (VAS), and three-point Likert willingness scale.

3.7.1 Sociodemographic and Clinical Characteristics

Sociodemographic and clinical data were collected through a standardised data collection form, including the patient's age, gender, body mass index (BMI), education level, marital status, monthly income, exercise habits, history of abdominal surgery, history of colonoscopy, family history of colorectal cancer (CRC), comorbidities, duration of constipation, frequency of laxative use, and constipation-related symptoms. These variables were incorporated based on previous studies to examine the homogeneity of patients across the intervention and control groups (Fostier et al., 2023; Mahmood et al., 2018; Martel et al., 2018) (Appendix H).

3.7.2 Bowel Preparation Compliance Scale (BPCS)

Patient compliance with bowel preparation was a covariate in this study and was compared among the three groups to determine 'pure' causal effects. The Bowel Preparation Compliance Scale (BPCS) was used to measure this variable. The BPCS was developed by Back et al. (2018) and subsequently adapted to Chinese version by Kong (2019). The Chinese version of the BPCS consists of two dimensions and eight items: medication compliance (three items) and dietary compliance (five items). The BPCS has undergone extensive testing in the Chinese population, demonstrating satisfactory reliability, with a Cronbach's α coefficient of 0.850 (Kong, 2019). Each item was scored 1 point for a 'yes' answer and 0 point for a 'no' answer. The maximum score for BPCS is 8 points, comprising 3 points for medication compliance and 5 points for dietary

compliance (Appendix J). According to previous literature, a total BPCS score of 8 points indicates good bowel preparation compliance, whereas a lower score suggests poor compliance (Kong, 2019).

3.7.3 Boston Bowel Preparation Scale (BBPS)

The BBPS, developed by Lai et al. (2009), is widely recognised as the global standard method for assessing bowel preparation quality. The Chinese version of BBPS was translated and validated by Gao et al. (2013). The total BBPS score ranges from 0 to 9, with higher scores indicating better bowel preparation quality (Kastenberg et al., 2018). A total score of BBPS ≥ 6 was defined as adequate bowel preparation; otherwise, it was regarded as inadequate bowel preparation (Calderwood et al., 2014). The total BBPS score was calculated as the sum of the three segments of the colon (left colon, transverse colon, and right colon). Specifically, each segment of the colon was scored on a 4-point scoring system:

- i. 0 (poor)—there is a large amount of residual solid stool, and intestinal mucosa cannot be observed;
- ii. 1 (fair)—most of the colon is covered with stool or opaque fluid, and only a small part of colonic mucosa is visible;
- iii (good)—a small part of the colon is covered with stool or opaque fluid, but most of the colonic mucosa can be seen;
- iv. 3 (excellent)—the entire intestinal mucosa is clearly visible.

According to the survey results of 49 medical professionals in seven hospitals in China, the intraclass correlation coefficient (ICC) of inter-observer and intra-observer for the Chinese version of BBPS were 0.987 (95% CI, 0.949–1.000) and 0.713 (95% CI, 0.452–0.849), showing satisfactory reliability (Gao et al., 2012). Furthermore, a BBPS score greater than 5 was found to be significantly associated with a higher polyp detection rate

among 1012 screening colonoscopies ($p < 0.05$), demonstrating high validity of BBPS in the Chinese population (Gao et al., 2013).

Therefore, in this study, the Chinese version of the BBPS was used to evaluate the quality of bowel preparation in older patients with constipation (Appendix L). Boston University Medical Centre, the developer of BBPS, has affirmed that the BBPS scoring method is easy to learn and can be fully mastered by medical professionals worldwide with just a simple instructional video (Lai et al., 2009). Therefore, this study used a 15-minute free instructional video provided by Boston University Medical Centre to help researchers master BBPS quickly and effectively (available at <https://www.bmc.org/gastroenterology/research>). All researchers involved in assessing the quality of bowel preparation received training in the BBPS scoring method before the start of the study. In addition, colourful BBPS pictures of representative colonoscopy images based on the BBPS scores were displayed on the walls of the endoscopy room to assist researchers accurately assess the quality of bowel preparation (Figure 3.9).

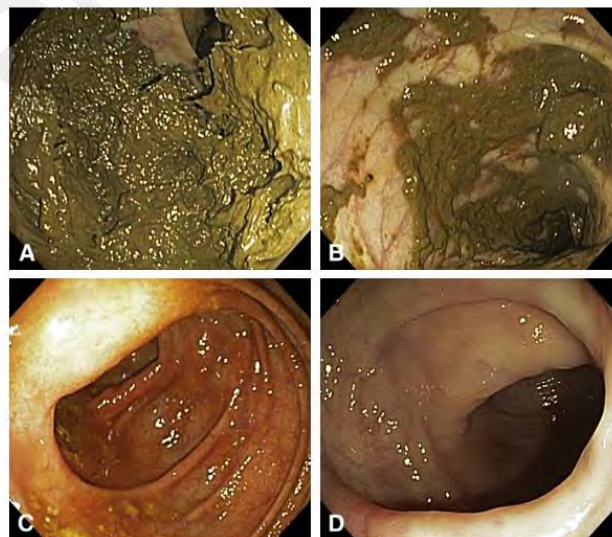


Figure 1. The BBPS. **A**, Segment score 0, unprepared colon segment with mucosa not seen because of solid stool that cannot be cleared. **B**, Segment score 1, portion of mucosa of the colon segment seen, but other areas of the colon segment not well seen because of staining, residual stool, and/or opaque liquid. **C**, Segment score 2, minor amount of residual staining, small fragments of stool and/or opaque liquid, but mucosa of colon segment seen well. **D**, Segment score 3, entire mucosa of colon segment seen well with no residual staining, small fragments of stool and/or opaque liquid.

Figure 3.9: The coloured BBPS picture (Lai et al., 2009)

3.7.4 Colonoscopy Quality Indicators Recording Form

In addition to bowel preparation quality, the quality indicators of colonoscopy include the ADR, CIR, and CIT (May & Shaukat, 2020). The three colonoscopy quality parameters were collected using a standardised form commonly used in this study setting (Appendix N). Specifically, ADR refers to the proportion of colonoscopies in which at least one colorectal adenoma is detected (Huang et al., 2021). Researchers recorded the presence of adenomas in each patient based on colonoscopy pathology reports and calculated the ADR for each group at the end of the study as the number of patients with one or more adenomas divided by the total number of patients in the group. CIR is the percentage of colonoscopies in which the colonoscope tip is successfully inserted into the proximal portion of the ileocecal valve (Park & Cha, 2022). The researchers recorded the caecal intubation status of each patient based on the actual examination conditions and calculated the CIR of each group at the end of the study, that is, the number of patients with successful caecal intubation divided by the total number of patients in the group. CIT is the time from the insertion of the colonoscope tip into the anal verge until reaching the proximal portion of the ileocecal valve (Kim, 2021). In this study, researchers recorded each patient's CIT during colonoscopy insertion using a calibrated timer.

3.7.5 Adverse Events during Bowel Preparation

After completing the bowel preparation, patients were asked to report any adverse events experienced during the procedure, such as abdominal pain, bloating, nausea, or vomiting, by answering 'yes' or 'no' (Guo et al., 2020b) (Appendix P).

3.7.6 Satisfaction Visual Analogue Scale (VAS)

The VAS, first used by Hayes and Patterson in 1921, is a well-known, simple, and commonly used method for assessing pain intensity in clinical practice (Delgado et al., 2018). Additionally, the VAS proved to be a simple and reliable tool for quantifying

patient satisfaction with medical procedures (Sims et al., 2021; Voutilainen et al., 2016). A study by Brokelman et al. (2012) demonstrated that the test–retest reliability of the Satisfaction VAS was high, with an ICC of 0.95. Furthermore, the Satisfaction VAS also demonstrated good validity as it was significantly correlated with several objective outcomes (Brokelman et al., 2012). The Chinese version of the Satisfaction VAS also has good reliability and is widely used to determine Chinese patients’ satisfaction with medical services (Chen et al., 2021; Fu et al., 2008).

In this study, patient satisfaction with bowel preparation was assessed using a 100-point Satisfaction VAS, with higher scores indicating greater satisfaction (Gao et al., 2023). The Satisfaction VAS is a 100 mm long horizontal line numbered 0 to 100. There are two descriptors indicating the degree of satisfaction at the beginning and end of the line (0 means complete dissatisfaction, while 100 indicates complete satisfaction). Patients rated their satisfaction level by making a vertical mark on the 100 mm line. The VAS score was then determined by measuring the number of millimetres from the beginning of the line to the point marked by the patient, with the value ranging from 0 to 100 points (Appendix R).

3.7.7 Three-point Likert Willingness Scale

Likert (1932) introduced a psychometric rating scale to measure an individual’s attitude or opinion towards a particular statement, now known as the Likert scale. The Likert scale is the most widely used method of measuring response in psychology and the social sciences (Sullivan & Artino, 2013). Likert scale provides a series of possible answers to a statement or question, allowing respondents to indicate their degree of agreement or the strength of their feeling with the question or statement (Jamieson, 2004). A three-point Likert scale is a scale that provides agree and disagree as extremes as well as a neutral option, often used to assess a patient’s willingness/likelihood to do something

(De Silva et al., 2016). It has been shown to have good reliability and validity and is also widely used in the Chinese setting (Fang et al., 2011; Jacoby & Matell, 1971). In this study, patients were asked to indicate their willingness to repeat the same bowel preparation by selecting one of three options on the three-point Likert willingness scale (1 = unwilling, 2 = maybe/uncertain, 3 = willing) (Appendix T).

3.8 Data Collection

Data collection for this study took place from February to August 2023. It included collecting information on patient characteristics, compliance with bowel preparation, quality of bowel preparation, ADR, CIR, CIT, adverse events during preparation, satisfaction, and willingness to repeat the same preparation. Specifically, the sociodemographic and clinical information form, BPCS, satisfaction VAS, and three-point Likert willingness scale were completed by researchers through interviews with the patients, while the BBPS and colonoscopy quality indicators recording form were completed by researchers based on the procedure conditions. As shown in Figure 3.10, data collection for each patient in this study was divided into three time points:

T1. On the day of the patient's colonoscopy appointment (usually one week before the scheduled colonoscopy date), the patient was examined and fully screened by a co-researcher (L.M.) in accordance with the inclusion and exclusion criteria. After explaining the purpose and procedures of the study to eligible patients, another co-researcher (W.L.N.) obtained their written informed consent and then randomly assigned patients to one of three groups using a lottery method. This co-researcher then collected the patient's baseline data based on the sociodemographic and clinical information form through face-to-face interviews with patients. The collected data were then immediately entered into a secure online database.

T2. After the patients completed the prescribed bowel preparation regimen (10 a.m. on the day of colonoscopy), co-researchers (H.X.Y., Z.S.) who were unaware of the patients'

group assignment interviewed the patients using validated questionnaires to obtain information on their bowel preparation compliance, adverse events during preparation, satisfaction, and willingness to repeat the same preparation.

T3. During the colonoscopy (usually between 1:30 and 2 p.m. on the day of colonoscopy), three trained co-researchers (C.Q.Q., D.Y.X., Z.M.), who were blinded to study allocation, assessed bowel preparation quality using the BBPS and recorded caecal intubation status, caecal intubation time, etc.

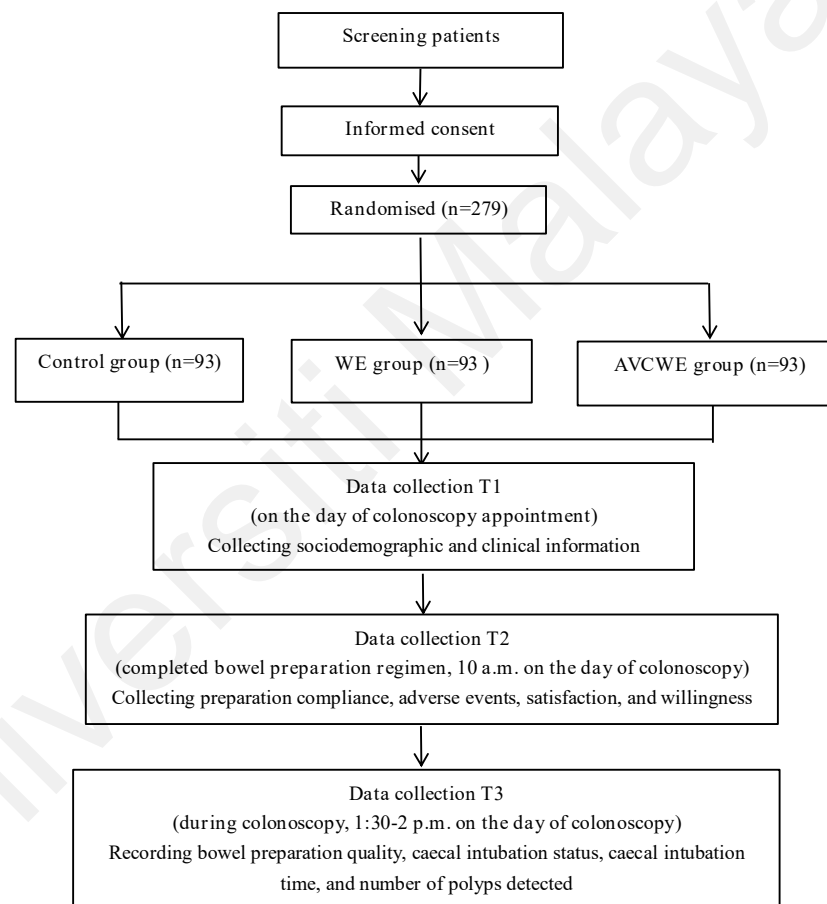


Figure 3.10: Data collection flow chart for this study

3.9 Pilot Study

A pilot study aims to test the reliability and clarity of the research instruments intended for use in the formal study (Gray & Grove, 2020). A research tool with good reliability is a necessary condition for rigorous research (Tappen, 2023). Reliability is defined as the

degree to which a research instrument produces stable and consistent results (Houser, 2021). Basically, there are three types of reliability: over time (test–retest reliability), across items (internal consistency), and across different researchers (inter-observer reliability) (McClure, 2020). The Cronbach’s α is the most common measure of internal consistency, and a value of 0.80 and above usually indicates that the reliability of the research instrument is satisfactory (DeVellis & Thorpe, 2021). Moreover, the ICC is commonly used as a measure of test–retest reliability and inter-observer reliability (Kumar, 2020). An ICC value of 0.75 and above indicates good reliability of the research instrument (Bobak et al., 2018).

All instruments in this study have well-established Chinese versions and have been validated and widely used in Chinese setting. To assess the appropriateness and clarity of these instruments for the current study, a pilot study involving 30 older patients with constipation was conducted in February 2023 in the same research setting as the actual study. However, participants in the pilot study were not included in the subsequent actual study. This study conducted an internal consistency test on the reliability of the BPCS and found that Cronbach’s α was 0.857, indicating that the BPCS has good reliability. To assess the test–retest reliability of the satisfaction VAS and three-point Likert willingness scale, this study administered the same test twice (two weeks apart) to these 30 participants. The correlation between the scores at the two time points was then calculated to assess the stability or consistency of the scores over time. The ICC values of satisfaction VAS and three-point Likert willingness scale were 0.923 and 0.940, respectively. To assess the inter-observer reliability of the BBPS, 13 members of this endoscopy centre were invited to use the BBPS to rate the quality of bowel preparation in three colonoscopy videos. Subsequently, the consistency of the results obtained between observers was analysed. The ICC of BBPS in this study was 0.922. In summary,

the reliability of the instruments used in this study was generally satisfactory and therefore remains unchanged.

3.10 Ethical Considerations

This study obtained ethical approval from the Institutional Review Board and Ethics Committee of Changzhou Second People's Hospital (No. [2022] KY312-01) (Appendix U) and was registered with the Chinese Clinical Trial Registry (Registration No. ChiCTR2300067667). The research also followed the ethical guidelines outlined in the 2013 Declaration of Helsinki (World Medical Association, 2013). Before their involvement, all participants were given comprehensive information on the research. The participants were notified that their participation in the research was completely voluntary and that their choice to discontinue at any time would not affect their medical care in the hospital. Prior to the start of the trial, each participant provided written informed consent (Appendix W). Furthermore, all information and data were handled in an anonymous and secret manner, only for the goal of conducting research. All data related to this study will be retained for five years for record keeping and audit purposes.

The study instruments used in this study were obtained with permission from the original authors. In addition, patient safety was fully considered during the study. Patients were closely monitored by the main researcher during the implementation of the intervention. If any patient experienced severe discomfort such as dizziness, palpitations, headache, dyspnoea, and chest pain, the patient would be asked to stop walking or abdominal vibration immediately.

This study is dedicated to upholding ethical standards in research and academic writing, consistently adhering to the principles of academic integrity and honesty. Specifically, it

maintained ethical research practices through strict adherence to APA citation style, acknowledgement of original sources, and the utilisation of plagiarism detection software.

3.11 Data Analysis

The quantitative data obtained from the questionnaire were analysed using the SPSS software (Version 22.0; SPSS Inc., Chicago, Illinois, USA). All data were entered into the SPSS software to conduct statistical procedures including descriptive and inferential statistics. The questionnaires were checked for completeness prior to data entry.

Continuous variables with normal distribution were expressed as the mean (standard deviation [SD]), while non-normal variables were reported as the median (interquartile range [IQR]). Categorical variables were presented as frequencies and percentages. All data were analysed according to the per-protocol (PP) analysis (Tripepi et al., 2020). To assess the differences in colonoscopy quality indicators (bowel preparation quality, ADR, CIR, and CIT) between the intervention and control groups, the Pearson chi-square test and one-way analysis of variance (ANOVA) were used. Additionally, differences in adverse events during bowel preparation and willingness to repeat the same preparation between the intervention and control groups were assessed using the Pearson chi-square test. One-way ANOVA was used to measure differences in satisfaction scores between the intervention and control groups. If the differences among the three groups were statistically significant, post-hoc analysis was used to identify exactly which groups differed from each other.

Both univariate and multivariate logistic regression analyses were performed to identify significant predictors of inadequate bowel preparation ($\text{BBPS} < 6$). Only variables with a *p*-value less than 0.10 in the univariate analysis were included in the multivariate logistic regression analysis (Chowdhury & Turin, 2020; Walters et al., 2021).

Results of multivariable logistic regression analyses were expressed as odds ratios (OR) and respective 95% confidence intervals (CI). All analyses are two-sided, and p -values < 0.05 were considered to be statistically significant. Table 3.1 summarises the statistical analysis used to answer the research questions.

Table 3.1: Summary of statistical analysis used

| Research questions | | Measured variables | Statistical analysis |
|--|---|--|---|
| 1. Is the developed AVCWE programme feasible and safe for older patients with constipation? | ✓ | The ratings of the AVCWE programme | • Descriptive statistics (mean [SD]) |
| 2. Are there any differences in colonoscopy quality indicators between the intervention and control groups? | ✓ | CIR, ADR, the rate of adequate bowel preparation (categorical data) | • Descriptive statistics (frequency and percentage) |
| | ✓ | BBPS score, CIT (continuous data) | • Chi-square test |
| | | | • Descriptive statistics (mean [SD]) |
| | | | • ANOVA |
| 3. Are there any differences in adverse events during bowel preparation between the intervention and control groups? | ✓ | Adverse events (categorical data) | • Descriptive statistics (frequency and percentage) |
| | | | • Chi-square test |
| 4. Are there any differences in patient satisfaction between the intervention and control groups? | ✓ | Satisfaction score (continuous data) | • Descriptive statistics (mean [SD]) |
| | | | • ANOVA |
| 5. Are there any differences in patient willingness to repeat the same bowel preparation between the intervention and control groups? | ✓ | Willingness to repeat the same preparation (categorical data) | • Descriptive statistics (frequency and percentage) |
| | | | • Chi-square test |
| 6. Are there differences in the primary outcome (bowel preparation quality) among older patients with different background characteristics and bowel preparation compliance? | ✓ | The independent variables: demographic data and bowel preparation compliance | • Logistic regression analysis |
| | ✓ | The dependent variable: inadequate bowel preparation | |

Note. AVCWE, Abdominal vibration combined with walking exercise; BBPS, Boston Bowel Preparation Scale; CIR, caecal intubation rate; CIT, caecal intubation time; ADR, adenoma detection rate; SD, standard deviation; ANOVA, one-way analysis of variance.

3.12 Summary

This chapter focuses on the research methodology used to address the questions related to this study. It includes a description of the study design and setting, population sample

size, study phases, measurement tools, data collection, and statistical analysis. Furthermore, in addition to assessing the reliability of the research instruments, ethical considerations were also addressed before the study began. The next chapter presents the results of Phase 1, including the development, validation, and feasibility study of the AVCWE programme.

Universiti Malaysia

CHAPTER 4: RESULTS (PHASE 1)

4.1 Introduction

This chapter elaborates on the results of Phase 1. Specifically, the first section describes the results of the development of the AVCWE programme, and the second section involves the validation results by a multidisciplinary expert panel. Finally, the feasibility study results of the AVCWE programme are presented in detail.

4.2 Research Question 1:

The first phase research question is: Is the developed AVCWE programme feasible and safe for older patients with constipation? To fully address this question, this section first introduces the detailed results of the development of the AVCWE programme.

4.2.1 AVCWE Programme Development

The research team initially developed a prototype of the AVCWE protocol that included two procedures: abdominal vibration and walking exercise, which were performed during laxative ingestion, with the assistance of available research and a multitude of practical knowledge. Specifically, the walking exercise procedure requested participants to walk at least 5,500 steps within two hours of consuming the PEG solution on the colonoscopy day (from 8:00 am to 10:00 am). Moreover, the walking exercise intensity was required to be moderate, with the target heart rate (THR) ranging between 65% and 75% of the maximum heart rate (HRmax). During bowel preparation, each participant was provided with the same type of smartwatch to monitor and record data related to their walking exercises.

According to the preliminary AVCWE protocol, the abdominal vibration procedure was scheduled to commence 30 minutes after the completion of the walking exercise. The main researcher was responsible for assisting the patient in wearing the abdominal

vibration belt and ensuring that the belt was activated and deactivated according to the prescribed vibration cycle. Specifically, the abdominal vibration procedure was set at a moderate intensity and consisted of two cycles, each lasting 15 minutes, with 10 minutes of stimulation followed by 5 minutes of rest. Patients were instructed to sit and rest in the waiting room during the abdominal vibration procedure (from 10:30 am to 11:00 am), with the exception of bathroom breaks. A detailed description of the preliminary AVCWE programme is presented in Table 4.1.

Table 4.1: Descriptions of the preliminary AVCWE programme

| Procedure | Descriptions |
|----------------------------|--|
| Walking exercise | <ul style="list-style-type: none"> i. Type of exercise: Walking independently without any assistance. ii. Duration and frequency: Walk at least 5,500 steps within two hours of ingesting PEG solution on the day of colonoscopy (8:00 am to 10:00 am). iii. Intensity: Moderate intensity (HR during walking ranging from 65% to 75% of HRmax). iv. Monitoring method: A smartwatch was used to accurately record walking steps and HR during walking exercises. |
| Abdominal vibration | <ul style="list-style-type: none"> i. Vibration method: A vibrating abdominal belt was worn half an hour after the walking exercise, and the researchers then helped turn on the switch. ii. Duration and frequency: Two vibration cycles, each consisting of 10 minutes of stimulation and 5 minutes of rest. During the abdominal vibration intervention, patients were asked to sit in the waiting room unless going to the bathroom (10:30 am to 11:00 am). iii. Intensity: Moderate vibration intensity (set halfway between the highest and lowest settings). |

Note. AVCWE: Abdominal vibration combined with walking exercise; PEG: Polyethylene glycol; HR: Heart rate; HRmax: Maximal heart rate; $HR_{max} = (220 - \text{age})$ (Hofmann & Tschakert, 2010).

4.2.2 AVCWE Programme Validation

Afterwards, a detailed explanation and demonstration video of the initial AVCWE protocol were sent to eight qualified specialists from three professional fields for critical evaluation. The demographic information of the expert panel is specified in Table 4.2. The average age of the eight specialists was 41.63 years ($SD = 3.70$), with a range of 35 to 47 years. The majority of the experts (62.5%) were female, and 72.5% hold a master's degree or above. Gastroenterology comprises the majority (50.0%) of the professional background, with physical therapy (25.0%) and geriatrics (25.0%) following behind. The

working experience of the experts ranged from 11 to 28 years ($M = 19.13$, $SD = 6.40$). There are four individuals that occupy the position of chief nurse, which accounts for exactly 50.0% of the whole group.

Table 4.2: The demographic information of experts (n = 8)

| Variables | n (%) | Range | Mean (SD) |
|----------------------------|----------|-------|--------------|
| Age (years) | | 35–47 | 41.63 (3.70) |
| 30–40 | 3 (37.5) | | |
| 41–50 | 5 (62.5) | | |
| Gender | | | |
| Male | 3 (37.5) | | |
| Female | 5 (62.5) | | |
| Education level | | | |
| Bachelor's degree | 3 (37.5) | | |
| Master's degree | 2 (35.0) | | |
| Doctoral degree | 3 (37.5) | | |
| Professional background | | | |
| Gastroenterology | 4 (50.0) | | |
| Geriatrics | 2 (25.0) | | |
| Physical therapy | 2 (25.0) | | |
| Job title | | | |
| Professor | 2 (25.0) | | |
| Chief nurse | 4 (50.0) | | |
| Chief physician | 2 (25.0) | | |
| Working experience (years) | | 11–28 | 19.13 (6.40) |
| 10–20 | 4 (50.0) | | |
| 21–30 | 4 (50.0) | | |

Note. SD: Standard deviation.

All experts were asked to rate each procedure within the AVCWE programme based on their best judgment using a 4-point exercise programme evaluation form. As depicted in Table 4.3, the average expert ratings for the four criteria of walking exercise were consistently greater than 3 points. In particular, the simplicity score was 3.50 ($SD = 0.54$), the safety score was 3.25 ($SD = 0.46$), the suitability score was 3.63 ($SD = 0.52$), and the helpfulness score was 4.00 ($SD = 0.00$). For the abdominal vibration procedure, experts evaluated it based on the same four criteria as the walking exercise, yielding scores that ranged from 3.75 ($SD = 0.46$) to 4.00 ($SD = 0.00$) (Table 4.3). Overall, the Kendall's W

value for the AVCWE programme was 0.416 ($p = 0.002$). This suggests a significant degree of agreement among experts regarding their assessment.

Table 4.3: Expert ratings of the preliminary AVCWE programme (n = 8)

| Procedure | Simplicity, mean (SD) | Safety, mean (SD) | Suitability, mean (SD) | Helpfulness, mean (SD) |
|---------------------|--------------------------|----------------------|---------------------------|---------------------------|
| Walking exercise | 3.50 (0.54) | 3.25 (0.46) | 3.63 (0.52) | 4.00 (0.00) |
| Abdominal vibration | 4.00 (0.00) | 3.75 (0.46) | 4.00 (0.00) | 3.75 (0.46) |

Note. AVCWE: Abdominal vibration combined with walking exercise; SD: Standard deviation.

However, six out of eight experts (75.0%) believed that the moderate-intensity requirements for walking exercise in the original AVCWE protocol were somewhat strict, especially when considering the feasibility of such exercise for older patients. They proposed that a minimum requirement of 5,500 steps would suffice, eliminating the need to set a lower limit for exercise intensity. Therefore, considering expert feedback and prioritising patient safety, the walking exercise procedure was appropriately adjusted, determining that the intensity of walking exercise should not exceed moderate levels. In particular, participants' HR during walking exercise should be kept below 75% of their HR_{max}.

Additionally, 62.5% of experts noted the necessity for minor adjustments to abdominal vibration procedure. First, experts believed that the original protocol of scheduling abdominal vibration half an hour after the walking exercise was not conducive to the synergy between these two interventions. Based on the experts' suggestions, the onset of abdominal vibration was synchronised with the initiation of the walking exercise. In other words, the combined effect of the AVCWE programme was optimised by performing abdominal vibration in conjunction with walking exercise. Second, based on the physiological and comfort considerations of older patients, experts believed that the rest time for abdominal vibration could be extended from the original 5 minutes to 10 minutes

per cycle. This recommendation has been fully accepted based on its rationale. Given the high reliability of the inter-expert ratings and the minor suggestions provided, a second round of assessment for the modified AVCWE programme was deemed unnecessary. Detailed information regarding the revised AVCWE programme is provided in Table 4.4.

Table 4.4: Descriptions of the revised AVCWE programme

| Procedure | Descriptions |
|----------------------------|--|
| Walking exercise | <ul style="list-style-type: none"> i. Type of exercise: Walking independently without any assistance. ii. Duration and frequency: Walk at least 5,500 steps within two hours of ingesting PEG solution on the day of colonoscopy (8:00 am to 10:00 am). iii. Intensity: No more than moderate intensity (HR during walking < 75% of HR_{max}). iv. Monitoring method: A smartwatch was used to accurately record walking steps and HR during walking exercises. |
| Abdominal vibration | <ul style="list-style-type: none"> i. Vibration method: A vibrating abdominal belt was worn while initiating a walking exercise, and the researchers then helped turn on the switch. ii. Duration and frequency: Two vibration cycles, each consisting of 10 minutes of stimulation and 10 minutes of rest (8:00 am to 8:40 am). iii. Intensity: Moderate vibration intensity (set halfway between the highest and lowest settings). |

Note. AVCWE: Abdominal vibration combined with walking exercise; PEG: Polyethylene glycol; HR: Heart rate; HR_{max}: Maximal heart rate; HR_{max} = (220 – age) (Hofmann & Tschakert, 2010).

In summary, according to the revised AVCWE programme, patients were required to complete walking exercises and abdominal vibration procedures during the period of laxative ingestion on the day of their colonoscopy (8:00 am to 10:00 am). As for the walking exercise procedure, patients were required to walk independently for at least 5,500 steps at no more than moderate intensity between 8:00 am and 10:00 am. They were provided with smartwatches to accurately record relevant data and ensure compliance with walking exercises. The abdominal vibration procedure commenced simultaneously with the walking exercise and lasted for two cycles, each comprising 10 minutes of vibration and 10 minutes of rest (from 8:00 am to 8:40 am). The main researcher assisted the patient in wearing the abdominal vibration belt, adjusting it to moderate vibration intensity, and ensuring that the belt was activated and deactivated according to schedule. Figure 4.1 provides an in-depth understanding of the AVCWE programme.

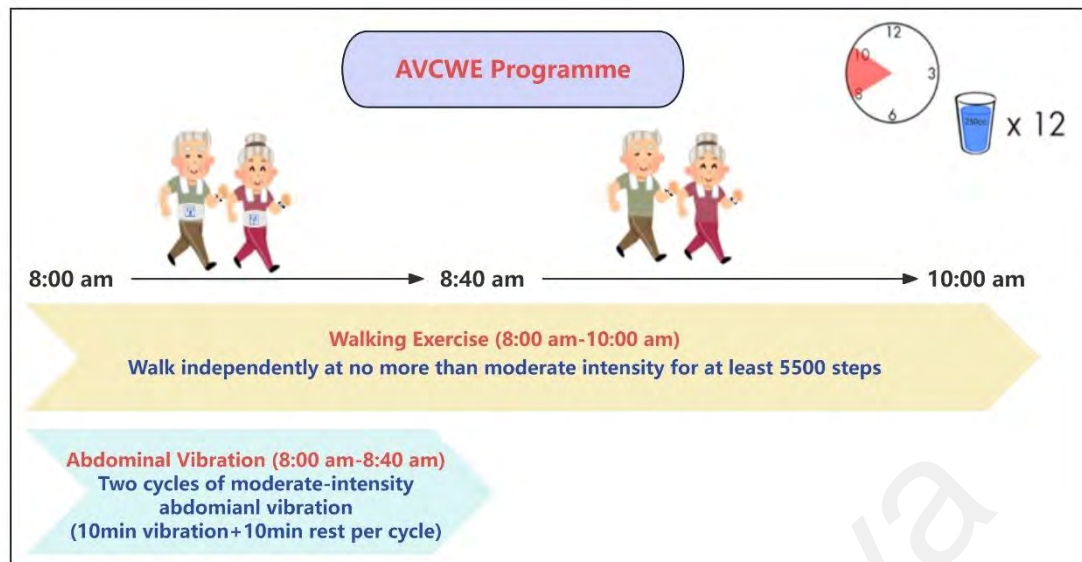


Figure 4.1: Schematic diagram of the AVCWE programme

4.2.3 Feasibility Study of the AVCWE Programme

Subsequently, a single-arm feasibility study was performed on 30 older patients with constipation to assess the practicality and viability of the AVCWE programme. Specifically, this group of patients were instructed to walk at least 5,500 steps at no more than moderate intensity within two hours of taking laxatives, and at the same time, they received two cycles of moderate-intensity abdominal vibration (10 minutes of vibration + 10 minutes of rest per cycle).

All participants (100%) successfully completed the AVCWE programme. As shown in Table 4.5, the average age of the participants was 67.00 years (SD = 5.80, range = 60–79). The gender distribution was equitable, with an equal ratio of males and females, and 40% of participants had attained a minimum of a secondary school education. Besides, 16.7% of the patients stated that they were divorced or widowed. Among this group, the median duration of constipation was 2.50 years (IQR = 5.00, range = 1–20). Furthermore, over one-third (43.3%) of the participants had a history of colonoscopy.

Table 4.5: Demographic information of participants in feasibility study (n = 30)

| Variables | n (%) | Range | Mean (SD) / median (IQR) |
|----------------------------------|-----------|-------|--------------------------|
| Age (years) | | 60–79 | 67.00 (5.80) |
| 60–70 | 22 (73.3) | | |
| 71–80 | 8 (26.7) | | |
| Gender | | | |
| Male | 15 (50.0) | | |
| Female | 15 (50.0) | | |
| Education | | | |
| Primary school and below | 18 (60.0) | | |
| Secondary school | 11 (36.7) | | |
| College and above | 1 (3.3) | | |
| Marital status | | | |
| Married | 25 (83.3) | | |
| Divorced / widowed | 5 (16.7) | | |
| Duration of constipation (years) | | 1–20 | 2.50 (5.00) |
| 1–10 | 25 (83.3) | | |
| 11–20 | 5 (16.7) | | |
| History of previous colonoscopy | | | |
| Yes | 13 (43.3) | | |
| No | 17 (56.7) | | |

Note. SD: Standard deviation; IQR: Interquartile range

After the intervention, participants were requested to assess the AVCWE programme based on their actual experience using a 10-point evaluation form, with higher scores reflecting more positive attitudes. Participants provided highly positive ratings for both the abdominal vibration and walking exercise procedures, with scores ranging from 9.07 (SD = 0.74) to 9.73 (SD = 0.52) (Table 4.6). These results suggest that older patients with constipation recognised this programme as easy, safe, appropriate, and advantageous for bowel preparation. Subsequently, participants were motivated to offer qualitative feedback by contemplating their experiences, and all reported encountering no difficulties during implementation. Furthermore, they stated that the programme did not require modification.

Thirteen participants with a history of colonoscopy were asked to compare their experiences with this bowel preparation to their prior ones. Twelve patients (92.3%)

stated that the discomfort associated with ingesting the PEG solution was considerably reduced this time, and 11 patients (84.6%) said the AVCWE programme boosted their bowel movements. Furthermore, out of the 30 participants involved in the feasibility study, 25 participants (83.3%) demonstrated high levels of confidence in obtaining high-quality bowel preparation with the AVCWE programme. Additionally, 27 individuals (90.0%) expressed a strong willingness to repeat the same preparation if a future colonoscopy were needed.

Table 4.6: Feasibility evaluation of the AVCWE programme (n = 30)

| Procedure | Simplicity, mean (SD) | Safety, mean (SD) | Suitability, mean (SD) | Helpfulness, mean (SD) |
|---------------------|----------------------------------|------------------------------|-----------------------------------|-----------------------------------|
| Walking exercise | 9.07 (0.74) | 9.73 (0.45) | 9.60 (0.50) | 9.17 (0.75) |
| Abdominal vibration | 9.27 (0.69) | 9.73 (0.52) | 9.40 (0.72) | 9.50 (0.57) |

Note. AVCWE: Abdominal vibration combined with walking exercise; SD: Standard deviation.

4.3 Summary

In conclusion, in Phase 1, the AVCWE programme was initially developed by the research team, subsequently validated by eight multidisciplinary experts, and implemented in 30 older patients with constipation. Based on input from the researchers and experts, the programme includes an exercise regimen of at least 5,500 walking steps and two cycles of moderate-intensity abdominal vibrations during laxative ingestion. The feasibility study confirms the simplicity, appropriateness, safety, and possible benefit of the AVCWE programme in improving the bowel preparation process in this particular demographic. In the next chapter, the effects of this programme on study variables are presented one by one.

CHAPTER 5: RESULTS (PHASE 2)

5.1 Introduction

This chapter presents the findings of the data analysis from Phase 2. The chapter first describes patient response rates and normality test for continuous dependent variables and then compares the background information and bowel preparation compliance among the three groups. Finally, the research outcomes are presented one by one according to the following research questions:

Question 2: Are there any differences in colonoscopy quality indicators (bowel preparation quality, adenoma detection rate [ADR], caecal intubation rate [CIR], and caecal intubation time [CIT]) between the intervention (abdominal vibration combined with walking exercise [AVCWE] group and walking exercise [WE] group) and control groups?

Question 3. Are there any differences in adverse events during bowel preparation between the intervention and control groups?

Question 4. Are there any differences in patient satisfaction between the intervention and control groups?

Question 5. Are there any differences in patient willingness to repeat the same bowel preparation between the intervention and control groups?

Question 6. Are there any differences in the primary outcome (bowel preparation quality) among older patients with different background characteristics and bowel preparation compliance?

5.2 Response Rates for Patients

Patient samples were selected from older patients with constipation scheduled for colonoscopy in the research setting from February to August 2023. Of the 360 older patients with constipation who underwent colonoscopies during the study period, six patients refused to participate in the study, and 75 patients did not fulfil the inclusion

criteria. The exclusion reasons included scheduled to undergo therapeutic colonoscopy (n = 55), inability to walk independently (n = 15), and severe health conditions (n = 5).

As a result, a total of 279 eligible patients were randomly assigned to three groups (Control group: 93 patients; WE group: 93 patients; AVCWE group: 93 patients). However, 8 patients (Control group: 2 patients; WE group: 3 patients; AVCWE group: 3 patients) cancelled their colonoscopy appointments for personal reasons and consequently did not receive the allocated regimen. Finally, a total of 271 participants (Control group: 91 patients; WE group: 90 patients; AVCWE group: 90 patients) completed the study and were included in the analyses. During the study period, all patients successfully completed the prescribed intervention regimen, and the overall compliance rate was 100%. The number of steps taken by the WE group (M = 6,690.17, SD = 1,020.05) and the AVCWE group (M = 6,939.67, SD = 1,131.51) was similar, but significantly higher than that of the control group (M = 2,090.56, SD = 869.12) ($p < 0.001$). This demonstrates a high level of patient compliance with the intervention. The enrolment and randomisation process for this study is illustrated in Figure 5.1.

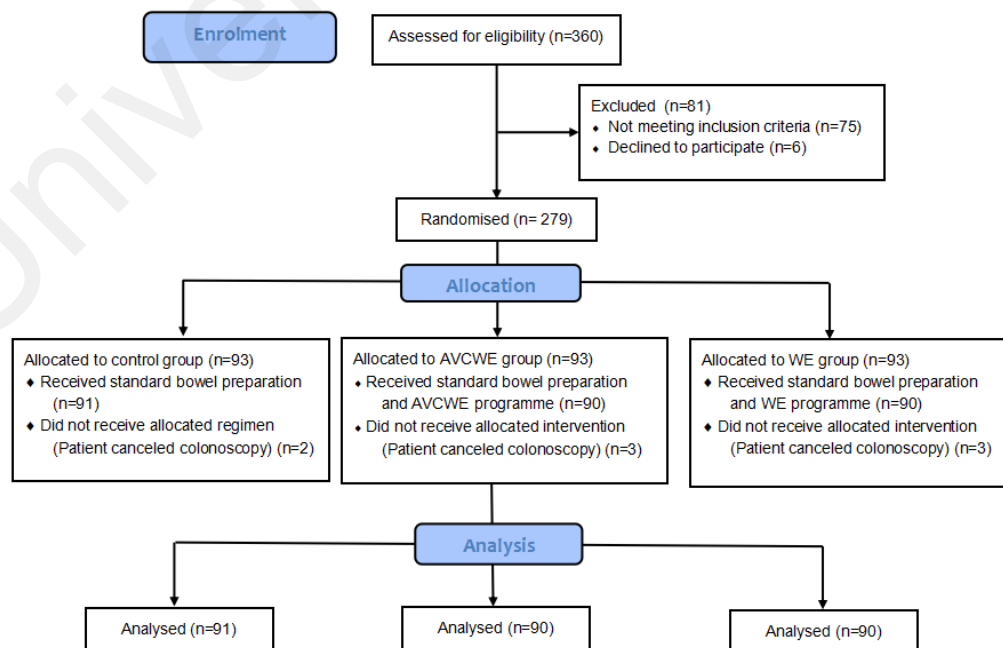


Figure 5.1: Flow diagram of study enrolment and allocation

5.3 Distribution of Data

Table 5.1 shows the results of a normality test conducted on the continuous dependent variables for the three groups. These variables include the Boston Bowel Preparation Scale (BBPS) score, CIT, and satisfaction score. The z-test is commonly used to test the normality of the data by using skewness and kurtosis (Ghasemi & Zahediasl, 2012). A z-score could be obtained by dividing the skewness or kurtosis values by their standard errors (SE). For medium-sized samples ($50 < n < 300$), if the absolute z-score for skewness or kurtosis is less than 3.29, the assumption of normal distribution is supported (Kim, 2013). Therefore, it can be concluded from Table 5.1 that the data of the continuous dependent variables in this study satisfy the normality assumption because the absolute z-scores of all variables are less than 3.29. In addition, the mean and median values of the dependent variables in this study were very close, and the ranges of the confidence intervals (CI) were very narrow, which also illustrates that the data between the groups were normally distributed. Based on the above justification, parametric tests were chosen for all the analyses related to the BBPS score, CIT, and satisfaction score.

Table 5.1: Normality test for continuous dependent variables (N = 271)

| Variables | Mean (SD) | 95% CI | Median | Skewness (SE) | Z_{Skewness} | Kurtosis (SE) | Z_{Kurtosis} |
|------------------------------|-------------|---------------|--------|------------------|-----------------------|------------------|-----------------------|
| BBPS score (Control group) | 5.96(1.14) | (5.72,6.19) | 6.00 | -0.46(0.25) | -1.84 | 0.46(0.50) | 0.92 |
| BBPS score (WE group) | 6.58(1.08) | (6.35,6.80) | 7.00 | -0.45(0.25) | -1.80 | -0.72(0.50) | -1.44 |
| BBPS score (AVCWE group) | 6.99(0.93) | (6.79,7.18) | 7.00 | -0.49(0.25) | -1.96 | -0.35(0.50) | -0.70 |
| CIT (Control group) | 5.45(2.18) | (5.00,5.90) | 5.00 | 0.37(0.25) | 1.48 | -0.59(0.50) | -1.18 |
| CIT (WE group) | 5.17(2.01) | (4.75,5.59) | 5.00 | 0.43(0.25) | 1.72 | -0.64(0.50) | -1.28 |
| CIT (AVCWE group) | 5.41(2.17) | (4.96,5.86) | 5.00 | 0.48(0.25) | 1.92 | -0.63(0.50) | -1.26 |
| Satisfaction (Control group) | 87.37(8.25) | (85.65,89.09) | 90.00 | -0.48(0.25) | -1.92 | -0.58(0.50) | -1.16 |
| Satisfaction (WE group) | 89.39(7.48) | (87.82,90.96) | 90.00 | -0.66(0.25) | -2.64 | -0.34(0.50) | -0.68 |
| Satisfaction (AVCWE group) | 91.98(5.93) | (90.74,93.22) | 90.00 | -0.56(0.25) | -2.24 | -0.37(0.50) | -0.74 |

Note. BBPS, Boston Bowel Preparation Scale; CIT, caecal intubation time; WE, walking exercise; AVCWE, abdominal vibration combined with walking exercise; SD, standard deviation; CI, confidence interval; SE, standard error.

5.4 Baseline Characteristics and Bowel Preparation Compliance

5.4.1 Baseline Characteristics

The baseline characteristics of participants are summarised in Table 5.2. The overall mean age of patients in this study was 66.28 years (SD = 5.30, range = 60–80), and slightly more than half of the patients were male (52.0%). Among the participants, 10 (3.7%) were underweight (BMI < 18.5 kg/m²), 131 (48.3%) had a normal BMI (18.5 ≤ BMI < 24 kg/m²), 107 (39.5%) were overweight (24 ≤ BMI < 28 kg/m²), and 23 (8.5%) were obese (BMI ≥ 28 kg/m²). More than half of the patients (55.7%) had obtained a minimum of secondary school education, only 10% of patients were divorced or widowed, and 15.5% had a monthly income of more than 5,000 RMB (equivalent to USD 691). The proportion of patients with a history of smoking (23.6%) was similar to those with a history of alcohol intake (25.1%). About 71.2% of patients had the habit of exercising more than three times a week. Patients with previous abdominal surgery and colonoscopy accounted for 35.1% and 40.6%, respectively, and only a small proportion (7.0%) of patients had a family history of CRC. Furthermore, hypertension was the most common comorbidity (54.6%), followed by diabetes (15.1%). The median duration of constipation was 4 years (IQR = 5, range = 1–40), and 34.3% of patients used laxatives more than three times per week. Among the constipation-related symptoms, the most common was straining (91.1%), followed by lumpy or hard stools (85.6%) and sensation of incomplete evacuation (72.7%).

The comparative analysis results in Table 5.2 showed no statistically significant differences in the socio-demographic characteristics across the three groups, including age, gender, BMI, education level, marital status, monthly income, smoking history, alcohol consumption history, and exercise habits ($p > 0.05$). Similarly, no significant differences were noted among the three groups in clinical characteristics such as history of abdominal surgery, history of colonoscopy, family history of CRC, comorbidities

(hypertension, diabetes, and stroke), duration of constipation, frequency of laxative use, and constipation-related symptoms ($p > 0.05$). Therefore, it was concluded that the patients in the three groups were homogenous in this study.

Table 5.2: Comparison of baseline characteristics among groups (N = 271)

| Variables | Overall (N = 271) | Control group (n = 91) | WE group (n = 90) | AVCWE group (n = 90) | $F/H/\chi^2$ | p |
|---|----------------------|------------------------------|----------------------|----------------------------|---------------------|-------|
| Age (years), mean (SD) | 66.28 (5.30) | 66.78 (5.22) | 65.37 (4.99) | 66.68 (5.61) | 2.012 ^F | 0.136 |
| BMI, n (%) | | | | | 2.194 ^{χ²} | 0.913 |
| Underweight | 10 (3.7) | 3 (3.3) | 4 (4.4) | 3 (3.3) | | |
| Normal | 131 (48.3) | 42 (46.1) | 44 (48.9) | 45 (50.0) | | |
| Overweight | 107 (39.5) | 39 (42.9) | 32 (35.6) | 36 (40.0) | | |
| Obese | 23 (8.5) | 7 (7.7) | 10 (11.1) | 6 (6.7) | | |
| Gender, n (%) | | | | | 0.677 ^{χ²} | 0.713 |
| Male | 141 (52.0) | 46 (50.5) | 45 (50.0) | 50 (55.6) | | |
| Female | 130 (48.0) | 45 (49.5) | 45 (50.0) | 40 (44.4) | | |
| Education, n (%) | | | | | 2.595 ^{χ²} | 0.640 |
| Illiterate or primary education | 120 (44.3) | 44 (48.4) | 41 (45.6) | 35 (38.9) | | |
| Secondary education | 145 (53.5) | 45 (49.5) | 48 (53.3) | 52 (57.8) | | |
| Tertiary education | 6 (2.2) | 2 (2.1) | 1 (1.1) | 3 (3.3) | | |
| Marital status, n (%) | | | | | 0.690 ^{χ²} | 0.708 |
| Married | 244 (90.0) | 80 (87.9) | 82 (91.1) | 82 (91.1) | | |
| Divorced or widowed | 27 (10.0) | 11 (12.1) | 8 (8.9) | 8 (8.9) | | |
| Monthly income (RMB), n (%) | | | | | 5.268 ^{χ²} | 0.261 |
| < 3,000 | 139 (51.3) | 46 (50.5) | 51 (56.7) | 42 (46.7) | | |
| 3,000–5,000 | 90 (33.2) | 35 (38.5) | 26 (28.9) | 29 (32.2) | | |
| > 5,000 | 42 (15.5) | 10 (11.0) | 13 (14.4) | 19 (21.1) | | |
| History of smoking, n (%) | 64 (23.6) | 22 (24.2) | 19 (21.1) | 23 (25.6) | 0.517 ^{χ²} | 0.772 |
| History of alcohol consumption, n (%) | 68 (25.1) | 24 (26.4) | 24 (26.7) | 20 (22.2) | 0.593 ^{χ²} | 0.744 |
| Exercise, n (%) | | | | | 0.983 ^{χ²} | 0.912 |
| Never | 44 (16.2) | 15 (16.5) | 13 (14.4) | 16 (17.8) | | |
| Seldom (1–2 times/week) | 34 (12.5) | 10 (11.0) | 11 (12.2) | 13 (14.4) | | |
| Often (≥ 3 times/week) | 193 (71.2) | 66 (72.5) | 66 (73.4) | 61 (67.8) | | |
| Previous abdominal surgery, n (%) | 95 (35.1) | 29 (31.9) | 34 (37.8) | 32 (35.6) | 0.709 ^{χ²} | 0.702 |
| First colonoscopy, n (%) | 161 (59.4) | 54 (59.3) | 56 (62.2) | 51 (56.7) | 0.576 ^{χ²} | 0.750 |
| Family history of CRC, n (%) | 19 (7.0) | 6 (6.6) | 4 (4.4) | 9 (10.0) | 2.167 ^{χ²} | 0.338 |

Table 5.2, continued

| Variables | Overall (N = 271) | Control group (n = 91) | WE group (n = 90) | AVCWE group (n = 90) | <i>F/H/χ²</i> | <i>p</i> |
|---|----------------------|------------------------------|-------------------------|----------------------------|--------------------------|----------|
| Comorbidities, n (%) | | | | | | |
| Hypertension | 148 (54.6) | 53 (58.2) | 50 (55.6) | 45 (50.0) | 1.288 ^{z2} | 0.525 |
| Diabetes | 41 (15.1) | 14 (15.4) | 13 (14.4) | 14 (15.6) | 0.050 ^{z2} | 0.975 |
| Stroke | 10 (3.7) | 4 (4.4) | 2 (2.2) | 4 (4.4) | 0.893 ^{z2} | 0.779 |
| Constipation duration (years), median (IQR) | 4 (5) | 4 (6) | 3 (4) | 3.5 (6) | 1.350 ^H | 0.509 |
| Frequency of laxative use, n (%) | | | | | 1.251 ^{z2} | 0.535 |
| ≥ 3 times/week | 93 (34.3) | 32 (35.2) | 27 (30.0) | 34 (37.8) | | |
| < 3 times/week | 178 (65.7) | 59 (64.8) | 63 (70.0) | 56 (62.2) | | |
| Constipation-related symptom, n (%) | | | | | | |
| Straining | 247 (91.1) | 86 (94.5) | 80 (88.9) | 81 (90.0) | 1.987 ^{z2} | 0.370 |
| Lumpy or hard stools | 232 (85.6) | 80 (87.9) | 73 (81.1) | 79 (87.8) | 2.213 ^{z2} | 0.331 |
| Sensation of incomplete evacuation | 197 (72.7) | 62 (68.1) | 68 (75.6) | 67 (74.4) | 1.464 ^{z2} | 0.481 |
| Sensation of anorectal obstruction/ blockage | 130 (48.0) | 46 (50.5) | 40 (44.4) | 44 (48.9) | 0.721 ^{z2} | 0.679 |
| Manual manoeuvres to facilitate defecations | 23 (8.5) | 11 (12.1) | 6 (6.7) | 6 (6.7) | 2.287 ^{z2} | 0.319 |
| ≤ 3 spontaneous bowel movements per week | 73 (26.9) | 26 (28.6) | 24 (26.7) | 23 (25.6) | 0.214 ^{z2} | 0.898 |

Note. *F*, ANOVA test; χ^2 , Chi-square test; *H*, Kruskal-Wallis H test; BMI, body mass index; SD, standard deviation; IQR, interquartile range; CRC, colorectal cancer; WE, walking exercise; AVCWE, abdominal vibration combined with walking exercise.

5.4.2 Bowel Preparation Compliance

As an important covariate, bowel preparation compliance was also analysed in this study (Table 5.3). This study utilised the Chinese version of the Bowel Preparation Compliance Scale (BPCS) to assess patients' compliance with bowel preparation. The maximum score for the BPCS is 8 points, with 3 points allocated for medication compliance and 5 points for dietary compliance. A total BPCS score of 8 points signifies good bowel preparation compliance, whereas a lower score implies poor compliance.

In this study, the mean score for the BPCS was 7.54 (SD = 0.83, range = 4–8), and 72.7% of participants displayed good bowel preparation compliance. Specifically, the average scores for medication compliance and dietary compliance were 2.89 (SD = 0.31)

and 4.65 (SD = 0.70), respectively. Correspondingly, 88.9% of participants exhibited good medication compliance, while 77.5% demonstrated good dietary compliance.

The comparison analysis results in Table 5.3 revealed no significant differences among the three groups in regard to the total BPCS score (Control group vs WE group vs AVCWE group: 7.54 [SD = 0.81] vs 7.59 [SD = 0.72] vs 7.50 [SD = 0.96], $p = 0.774$), medication compliance score (Control group vs WE group vs AVCWE group: 2.88 [SD = 0.33] vs 2.88 [SD = 0.33] vs 2.91 [SD = 0.29], $p = 0.724$), and dietary compliance score (Control group vs WE group vs AVCWE group: 4.66 [SD = 0.65] vs 4.71 [SD = 0.64] vs 4.59 [SD = 0.81], $p = 0.505$). Furthermore, the proportion of good bowel preparation compliance (Control group vs WE group vs AVCWE group: 72.5% vs 71.1% vs 74.4%, $p = 0.881$), the proportion of good medication compliance (Control group vs WE group vs AVCWE group: 87.9% vs 87.8% vs 91.1%, $p = 0.722$), and the proportion of good dietary compliance (Control group vs WE group vs AVCWE group: 75.8% vs 80.0% vs 76.7%, $p = 0.777$) were also similar among the three groups. Therefore, it can be concluded that bowel preparation compliance was comparable among the three groups.

Table 5.3: Comparison of bowel preparation compliance among groups (N = 271)

| Variables | Overall (N = 271) | Control group (n = 91) | WE group (n = 90) | AVCWE group (n = 90) | F/χ^2 | p |
|-------------------------------|----------------------|------------------------------|----------------------|----------------------------|--------------------------------|-------|
| BPCS score, mean (SD) | 7.54 (0.83) | 7.54 (0.81) | 7.59 (0.72) | 7.50 (0.96) | 0.256 ^F | 0.774 |
| Medication compliance | 2.89 (0.31) | 2.88 (0.33) | 2.88 (0.33) | 2.91 (0.29) | 0.323 ^F | 0.724 |
| Dietary compliance | 4.65 (0.70) | 4.66 (0.65) | 4.71 (0.64) | 4.59 (0.81) | 0.684 ^F | 0.505 |
| Good compliance, n (%) | 197 (72.7) | 66 (72.5) | 64 (71.1) | 67 (74.4) | 0.254 ^{χ²} | 0.881 |
| Good medication compliance | 241 (88.9) | 80 (87.9) | 79 (87.8) | 82 (91.1) | 0.652 ^{χ²} | 0.722 |
| Good dietary compliance | 210 (77.5) | 69 (75.8) | 72 (80.0) | 69 (76.7) | 0.505 ^{χ²} | 0.777 |

Note. F , ANOVA test; χ^2 , Chi-square test; BPCS, Bowel Preparation Compliance Scale; SD, standard deviation; WE, walking exercise; AVCWE, abdominal vibration combined with walking exercise.

5.5 Research Question 2:

Are there any differences in colonoscopy quality indicators (bowel preparation quality, ADR, CIR, and CIT) between the intervention (AVCWE group and WE group) and control groups?

5.5.1 Colonoscopy Quality Indicators

Colonoscopy quality indicators include bowel preparation quality, ADR, CIR, and CIT. In this study, bowel preparation quality, as the primary outcome, was assessed using the BBPS and compared among the three groups. According to the BBPS scoring system, the total score is calculated by summing the scores for the left colon, transverse colon, and right colon. The total BBPS score ranges from 0 to 9, with higher scores signifying better-quality bowel preparation. Adequate bowel preparation is defined as a total BBPS score of ≥ 6 , while scores below this threshold are classified as inadequate.

In this study, the total BBPS scores and the BBPS scores for each colon segment of the three groups are shown in Table 5.4 and Figure 5.2. While the rate of adequate bowel preparation (BBPS total score ≥ 6) in the WE group (78.9%) significantly exceeded that in the control group (60.4%), the rate in the AVCWE group (92.2%) surpassed even that of the WE group ($p < 0.001$). Likewise, the total BBPS score of the AVCWE group ($M = 6.99$, $SD = 0.93$) significantly exceeded that of the WE group ($M = 6.58$, $SD = 1.08$), even though the WE group had already demonstrated a significant enhancement over the control group ($M = 5.96$, $SD = 1.14$) ($p < 0.001$). Moreover, although there was no statistical difference in the right colon and transverse colon scores between the AVCWE group and the WE group, they were both significantly higher than those in the control group (right colon score, AVCWE group vs WE group vs Control group: 2.34 [$SD = 0.56$] vs 2.22 [$SD = 0.58$] vs 1.95 [$SD = 0.58$], $p < 0.001$; transverse colon score, AVCWE group vs WE group vs Control group: 2.29 [$SD = 0.48$] vs 2.19 [$SD = 0.42$] vs 1.96 [SD

= 0.47], $p < 0.001$). Furthermore, the left colon score in the AVCWE group ($M = 2.36$, $SD = 0.62$) showed a significant increase compared with both the WE group ($M = 2.16$, $SD = 0.65$) and the control group ($M = 2.05$, $SD = 0.64$) ($p = 0.006$), whereas no significant difference was observed between the latter two groups.

As for other colonoscopy quality indicators, CIR was calculated as the number of patients with successful caecal intubation divided by the total number of patients in the group. Besides, ADR, the proportion of colonoscopies in which at least one colorectal adenoma was detected, was calculated as the number of patients with one or more adenomas divided by the total number of patients in the group. CIT was the time from the insertion of the colonoscope tip into the anal verge until reaching the proximal portion of the ileocecal valve and was recorded by a co-researcher using a calibrated timer.

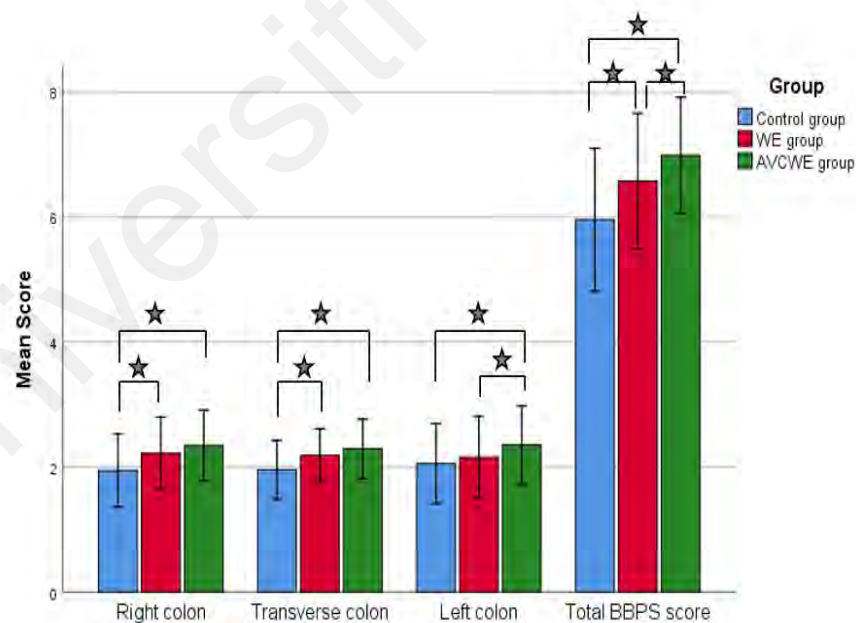
The statistical analysis revealed no significant difference in CIR among the three groups (AVCWE group vs WE group vs Control group: 97.8% vs 98.9% vs 97.8%, $p = 1.000$). In addition, the CIT in the AVCWE group was also similar to that in the WE group and the control group (AVCWE group vs WE group vs Control group: 5.41 min [$SD = 2.17$] vs 5.17 min [$SD = 2.01$] vs 5.45 min [$SD = 2.18$], $p = 0.623$). However, the ADR in the AVCWE group (42.2%) demonstrated a significant increase compared with both the WE group (24.4%) and the control group (20.9%) ($p = 0.003$), with no significant difference observed between the latter two groups (Table 5.4).

Table 5.4: Comparison of colonoscopy quality indicators among groups (N = 271)

| Variables | Control group (n = 91) | WE group (n = 90) | AVCWE group (n = 90) | F/χ^2 | p |
|-----------------------------------|---------------------------|----------------------|-------------------------|-----------------|-----------------------------------|
| Total BBPS score ≥ 6 , n (%) | 55 (60.4) | 71 (78.9) | 83 (92.2) | 26.144 χ^2 | < 0.001^{a,b,c} |
| Total BBPS score, mean (SD) | 5.96 (1.14) | 6.58 (1.08) | 6.99 (0.93) | 21.965 F | < 0.001^{a,b,c} |
| Right colon | 1.95 (0.58) | 2.22 (0.58) | 2.34 (0.56) | 11.477 F | < 0.001^{a,b} |
| Transverse colon | 1.96 (0.47) | 2.19 (0.42) | 2.29 (0.48) | 12.624 F | < 0.001^{a,b} |
| Left colon | 2.05 (0.64) | 2.16 (0.65) | 2.36 (0.62) | 5.195 F | 0.006^{b,c} |
| CIR, n (%) | 89 (97.8) | 89 (98.9) | 88 (97.8) | 0.585 χ^2 | 1.000 |
| CIT (min), mean (SD) | 5.45 (2.18) | 5.17 (2.01) | 5.41 (2.17) | 0.474 F | 0.623 |
| ADR, n (%) | 19 (20.9) | 22 (24.4) | 38 (42.2) | 11.425 χ^2 | 0.003^{b,c} |

Note. F , ANOVA test; χ^2 , Chi-square test; BBPS, Boston Bowel Preparation Scale; CIR, caecal intubation rate; CIT, caecal intubation time; ADR, adenoma detection rate; SD, standard deviation; WE, walking exercise; AVCWE, abdominal vibration combined with walking exercise; Bold values indicate significant differences among the three groups.

^a post-hoc analysis revealed a significant difference between the Control and WE groups; ^b post-hoc analysis revealed a significant difference between the Control and AVCWE groups; ^c post-hoc analysis revealed a significant difference between the WE and AVCWE groups.

**Figure 5.2: Comparison of BBPS scores among the three groups**

★ The data showed that the difference between the two groups was significant ($p < 0.05$).

5.6 Research Question 3:

Are there any differences in adverse events during bowel preparation between the intervention and control groups?

5.6.1 Adverse Events during Bowel Preparation

After completing the bowel preparation, a co-researcher asked the patients if they experienced any adverse events, including nausea, vomiting, abdominal pain, or bloating. As can be seen from Table 5.5 and Figure 5.3, the incidence of nausea (AVCWE group vs WE group vs Control group: 12.2% vs 15.6% vs 11.0%, $p = 0.639$), vomiting (AVCWE group vs WE group vs Control group: 2.2% vs 4.4% vs 2.2%, $p = 0.671$), and abdominal pain (AVCWE group vs WE group vs Control group: 11.1% vs 4.4% vs 9.9%, $p = 0.232$) were similar among the three groups. However, surprisingly, the incidence of bloating in the AVCWE group (22.2%) was significantly lower than that in the WE group (38.9%) and the control group (40.7%) ($p = 0.016$), with no significant difference observed between the latter two groups.

Table 5.5: Comparison of adverse events among groups (N = 271)

| Variables | Control group (n = 91) | WE group (n = 90) | AVCWE group (n = 90) | χ^2 | p |
|-----------------------|---------------------------|----------------------|-------------------------|----------|----------------------------|
| Nausea, n (%) | 10 (11.0) | 14 (15.6) | 11 (12.2) | 0.896 | 0.639 |
| Vomiting, n (%) | 2 (2.2) | 4 (4.4) | 2 (2.2) | 1.004 | 0.671 |
| Abdominal pain, n (%) | 9 (9.9) | 4 (4.4) | 10 (11.1) | 2.922 | 0.232 |
| Bloating, n (%) | 37 (40.7) | 35 (38.9) | 20 (22.2) | 8.326 | 0.016^{b,c} |

Note. χ^2 , Chi-square test; WE, walking exercise; AVCWE, abdominal vibration combined with walking exercise; Bold values indicate significant differences among the three groups.

^b post-hoc analysis revealed a significant difference between the Control and AVCWE groups; ^c post-hoc analysis revealed a significant difference between the WE and AVCWE groups.

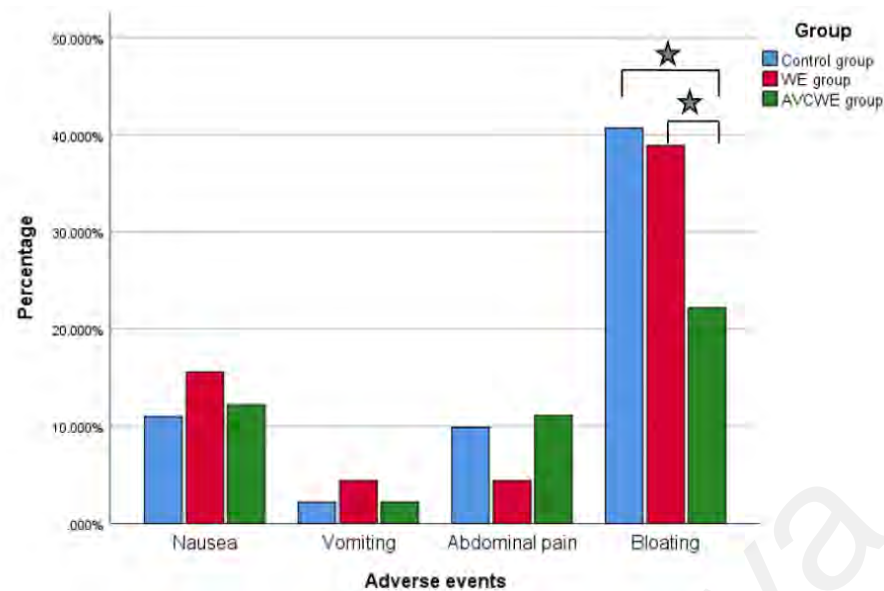


Figure 5.3 Comparison of adverse events among the three groups

★ The data showed that the difference between the two groups was significant ($p < 0.05$).

5.7 Research Questions 4 and 5

Are there any differences in patient satisfaction between the intervention and control groups? Are there any differences in patient willingness to repeat the same bowel preparation between the intervention and control groups?

5.7.1 Satisfaction and Willingness to Repeat the Same Bowel Preparation

In this study, patient satisfaction with bowel preparation was evaluated using a 100-point satisfaction VAS, where higher scores reflect higher levels of satisfaction. Additionally, patients' willingness to undergo the same preparation regimen again was assessed using a three-point Likert scale, where 1 represented unwilling, 2 indicated maybe/uncertain, and 3 denoted willing. As indicated in Table 5.6, although no significant difference was observed in bowel preparation satisfaction scores between the WE group ($M = 89.39$, $SD = 7.48$) and the control group ($M = 87.37$, $SD = 8.25$), the satisfaction score of the AVCWE group ($M = 91.98$, $SD = 5.93$) was significantly higher than that of both groups ($p < 0.001$). However, there were no statistically significant differences between the three groups in willingness to repeat the same bowel preparation ($p = 0.394$).

Table 5.6: Comparison of satisfaction and willingness among groups (N = 271)

| Variables | Control group (n = 91) | WE group (n = 90) | AVCWE group (n = 90) | F/χ^2 | p |
|--|---------------------------|----------------------|-------------------------|---------------------|-------------------------------|
| Satisfaction score, mean (SD) | 87.37 (8.25) | 89.39 (7.48) | 91.98 (5.93) | 9.064 ^F | < 0.001 ^{b,c} |
| Willingness to repeat preparation, n (%) | | | | 4.093 ^{χ²} | 0.394 |
| No | 6 (6.6) | 6 (6.7) | 4 (4.4) | | |
| Maybe/Unclear | 16 (17.6) | 10 (11.1) | 8 (8.9) | | |
| Yes | 69 (75.8) | 74 (82.2) | 78 (86.7) | | |

Note. F , ANOVA test; χ^2 , Chi-square test; SD, standard deviation; WE, walking exercise; AVCWE, abdominal vibration combined with walking exercise; Bold values indicate significant differences among the three groups.

^b post-hoc analysis revealed a significant difference between the Control and AVCWE groups; ^c post-hoc analysis revealed a significant difference between the WE and AVCWE groups.

5.8 Research Question 6:

Are there differences in the primary outcome (bowel preparation quality) among older patients with different background characteristics and bowel preparation compliance?

5.8.1 Univariate Analysis: Factors Associated with Inadequate Preparation

Table 5.7 presents a comparison of characteristic between patients with adequate bowel preparation (BBPS score ≥ 6 , $n = 209$) and those with inadequate bowel preparation (BBPS score < 6 , $n = 62$). In this study, patient background characteristics and bowel preparation compliance acted as the independent variables. Meanwhile, inadequate bowel preparation was the dependent variable in univariate analysis. The results of univariate analysis revealed that the first colonoscopy ($p = 0.035$), frequency of laxative use ($p = 0.003$), medication compliance ($p = 0.018$), and dietary compliance ($p = 0.002$) were significantly associated with the quality of bowel preparation. However, no significant differences were noted between the adequate and inadequate preparation groups in terms of age, BMI, gender, educational level, marital status, family income, history of smoking and drinking, exercise habit, history of abdominal surgery, family history of CRC, comorbidities, duration of constipation, and constipation-related symptoms ($p > 0.05$).

Table 5.7: Univariate analysis of risk factors for inadequate preparation (N = 271)

| Variables | Adequate preparation, BBPS ≥ 6 (n = 209) | Inadequate preparation, BBPS < 6 (n = 62) | <i>p</i> |
|---|---|--|--------------|
| Age (years), mean (SD) | 66.43 (5.40) | 65.77 (4.94) | 0.396 |
| BMI, n (%) | | | |
| Underweight | 8 (3.8) | 2 (3.2) | 0.527 |
| Normal | 96 (45.9) | 35 (56.5) | |
| Overweight | 87 (41.6) | 20 (32.2) | |
| Obese | 18 (8.6) | 5 (8.1) | |
| Gender, n (%) | | | 0.614 |
| Male | 107 (51.2) | 34 (54.8) | |
| Female | 102 (48.8) | 28 (45.2) | |
| Education level, n (%) | | | 0.701 |
| Illiterate or primary education | 94 (45.0) | 26 (41.9) | |
| Secondary education | 111 (53.1) | 34 (54.8) | |
| Tertiary education | 4 (1.9) | 2 (3.3) | |
| Marital status, n (%) | | | 0.379 |
| Married | 190 (90.9) | 54 (87.1) | |
| Divorced or widowed | 19 (9.1) | 8 (12.9) | |
| Monthly income (RMB), n (%) | | | 0.972 |
| < 3,000 | 108 (51.7) | 31 (50.0) | |
| 3,000–5,000 | 69 (33.0) | 21 (33.9) | |
| > 5,000 | 32 (15.3) | 10 (16.1) | |
| History of smoking, n (%) | 48 (23.0) | 16 (25.8) | 0.644 |
| History of alcohol consumption, n (%) | 56 (26.8) | 12 (19.4) | 0.235 |
| Exercise habit, n (%) | | | 0.604 |
| Never | 35 (16.7) | 9 (14.5) | |
| Seldom (1–2 times a week) | 24 (11.5) | 10 (16.1) | |
| Often (≥ 3 times a week) | 150 (71.8) | 43 (69.4) | |
| Previous abdominal surgery, n (%) | 76 (36.4) | 19 (30.6) | 0.407 |
| First colonoscopy, n (%) | 117 (56.0) | 44 (70.9) | 0.035 |
| Family history of CRC, n (%) | 12 (5.7) | 7 (11.3) | 0.156 |
| Comorbidities, n (%) | | | |
| Hypertension | 111 (53.1) | 37 (59.7) | 0.362 |
| Diabetes | 30 (14.4) | 11 (7.7) | 0.513 |
| Stroke | 9 (4.3) | 1 (1.6) | 0.463 |
| Constipation duration (years), median (IQR) | 3 (4) | 5 (8) | 0.143 |
| Frequency of laxative use, n (%) | | | 0.003 |
| ≥ 3 times per week | 62 (29.7) | 31 (50.0) | |
| < 3 times per week | 147 (70.3) | 31 (50.0) | |
| Constipation-related symptom, n (%) | | | |
| Straining | 189 (90.4) | 58 (93.5) | 0.448 |
| Lumpy or hard stools | 177 (84.7) | 55 (88.7) | 0.428 |
| Sensation of incomplete evacuation | 153 (73.2) | 44 (71.0) | 0.728 |
| Sensation of anorectal obstruction | 97 (46.4) | 33 (53.2) | 0.346 |
| Manual manoeuvres facilitate defecations | 18 (8.6) | 5 (8.1) | 0.892 |
| ≤ 3 spontaneous bowel movements/week | 55 (26.3) | 18 (29.0) | 0.672 |
| Medication compliance, n (%) | | | 0.018 |
| Good | 191 (91.4) | 50 (80.6) | |
| Poor | 18 (8.6) | 12 (19.4) | |
| Dietary compliance, n (%) | | | 0.002 |
| Good | 171 (81.8) | 39 (62.9) | |
| Poor | 38 (18.2) | 23 (37.1) | |

Note. BBPS, Boston Bowel Preparation Scale; SD, standard deviation; IQR, interquartile range; BMI, body mass index; CRC, colorectal cancer. Bold values indicate *p*-value < 0.05.

5.8.2 Multivariate Analysis: Factors Associated with Inadequate Preparation

In this study, only variables with a p -value less than 0.10 in the univariate analysis were included in the multivariate logistic regression analysis. Based on the results of univariate analysis, the multivariable logistic regression model included the following four variables: the first colonoscopy, frequency of laxative use, medication compliance, and dietary compliance. Table 5.8 presents the coding of the independent and dependent variables in the logistic regression model. Specifically, the first colonoscopy was coded as 0 (no) or 1 (yes), the frequency of laxative use was coded as 0 (< 3 times/week) or 1 (≥ 3 times/week), medication compliance and dietary compliance were coded as 0 (good) or 1 (poor), and inadequate bowel preparation was coded as 0 (no) or 1 (yes).

According to the results of multivariate analysis, only the first colonoscopy (OR, 2.329; 95% CI, 1.210–4.485; $p = 0.011$), laxative use ≥ 3 times per week (OR, 2.675; 95% CI, 1.452–4.931; $p = 0.002$), and poor dietary compliance (OR, 2.249; 95% CI, 1.142–4.430; $p = 0.019$) were found to be significant predictors of inadequate bowel preparation in older patients with constipation (Table 5.9). However, in this multivariate regression model, medication compliance (OR, 2.252; 95% CI, 0.933–5.432; $p = 0.071$) was not a significant factor in predicting bowel preparation quality in older patients with constipation.

Table 5.8: Coding of variables in the logistic regression model

| Study variable | | Coding |
|------------------------------|------------------------------|---|
| Independent variables | The first colonoscopy | 0 = no, 1 = yes |
| | Frequency of laxative use | 0 = < 3 times/week, 1 = ≥ 3 times/week |
| | Medication compliance | 0 = good, 1 = poor |
| | Dietary compliance | 0 = good, 1 = poor |
| Dependent variable | Inadequate bowel preparation | 0 = no, 1 = yes |

Table 5.9: Multivariate analysis of risk factors for inadequate preparation (N=271)

| Variables | β | SE | Wald χ^2 | OR | 95% CI | <i>p</i> |
|--------------------------------------|---------|-------|---------------|-------|-------------|--------------|
| The first colonoscopy | 0.845 | 0.334 | 6.395 | 2.329 | 1.210-4.485 | 0.011 |
| Laxative use ≥ 3 times per week | 0.984 | 0.312 | 9.951 | 2.675 | 1.452-4.931 | 0.002 |
| Poor dietary compliance | 0.811 | 0.346 | 5.491 | 2.249 | 1.142-4.430 | 0.019 |
| Poor medication compliance | 0.812 | 0.449 | 3.264 | 2.252 | 0.933-5.432 | 0.071 |

Note. β , regression coefficient; SE, standard error; Wald χ^2 , Wald chi-squared test, OR, odds ratio; CI, confidence interval; Bold values indicate statistically significant differences ($p < 0.05$).

5.9 Summary

Overall, the results of Phase 2 revealed that the AVCWE group had significantly higher bowel preparation quality, ADR, and patient satisfaction with bowel preparation, as well as a significantly lower incidence of bloating compared with the WE and control groups. However, CIR, CIT, incidence of nausea, vomiting, abdominal pain, and willingness to repeat the same bowel preparation were similar among the three groups. Furthermore, the first colonoscopy, laxative use ≥ 3 times per week, and poor dietary compliance were identified as significant risk factors for inadequate bowel cleansing in older patients with constipation.

CHAPTER 6: DISCUSSION AND CONCLUSION

6.1 Introduction

This chapter discusses the findings of this study in light of the research questions. The results of the abdominal vibration combined with walking exercise (AVCWE) programme development, validation, and feasibility study are first discussed. Then, the background characteristics and bowel preparation compliance of the patients in this study are discussed by comparison with previous studies. Next, the findings on colonoscopy quality indicators, adverse events during bowel preparation, patient satisfaction, and willingness to repeat the same preparation between the AVCWE, walking exercise (WE), and control groups are discussed. The predictors of inadequate bowel preparation in older patients with constipation are also delved into in this chapter. These are followed by a section on the strengths and limitations of the study. Finally, implications for nursing practice and nursing study, recommendations for future research, and overall conclusions of the study are presented.

6.2 Development, Validation, and Feasibility Study of the AVCWE Programme

Abdominal vibration and walking exercise have been demonstrated to be safe, effective, and economical methods for enhancing the quality of bowel preparation. However, prior research has predominantly concentrated on the general population (Zhang et al., 2024b). This leaves a significant gap in determining whether they are appropriate for patients at high risk of inadequate bowel preparation, such as older patients with constipation (Noh et al., 2020; Zhang et al., 2023b). Furthermore, the previous studies primarily analysed the impact of either abdominal vibration or walking exercise in isolation, without examining their synergistic effects (Gao et al., 2023; Rezamand et al., 2023). A more intensive intervention that incorporates abdominal vibration and walking exercises may be promising for older patients with constipation, as

this demographic experiences greater challenges in achieving optimal bowel cleansing (Zhang et al., 2024b). Based on the extant literature and comprehensive clinical expertise, the researchers of this study initially devised the original AVCWE protocol, which was then validated by a panel of experts with multidisciplinary backgrounds.

Based on expert input, the AVCWE programme was improved to involve two particular procedures during the intake of laxatives: a minimum of 5,500 steps of walking exercise and two cycles of moderate-intensity abdominal vibration (each cycle consisting of 10 minutes of vibration and 10 minutes of rest). Eight professionals from three distinct professions demonstrated strong agreement in their assessments of the programme and recommended only small adjustments. For example, to prioritise patient comfort, the exercise intensity criterion was modified to ensure it did not surpass a moderate level. In addition, abdominal vibration was synchronised with the walking exercise to amplify their collective efficacy. Given the significant agreement among experts in their assessments and recommendations, as shown by a high Kendall's W of 0.416 ($p = 0.002$), it was determined that a second round of evaluation for the modified AVCWE programme was unnecessary.

Regarding feasibility, participants provided a positive evaluation of the revised AVCWE programme, consistently scoring a minimum of 9 out of 10 on each item. All participants (100.0%) said that they did not encounter any challenges in executing the AVCWE programme. Additionally, the feasibility study revealed that the AVCWE programme could positively impact patient tolerability. Specifically, 92.3% of participants who had previously had colonoscopy indicated that their bowel preparation was substantially less unpleasant this time compared with their prior experience. Similarly, a prior meta-analysis showed that walking exercise had significant effects on

reducing adverse events and enhancing patient satisfaction ($p < 0.05$) (Huang & Zhou, 2021).

This study further revealed that the AVCWE programme could have beneficial impacts on increasing the frequency of bowel movements and enhancing the quality of bowel preparation in older patients with constipation. The quality of bowel preparation is strongly correlated with the number of bowel movements that occur after consuming PEG solutions, as evidenced by the available data (Kim et al., 2015; Lee et al., 2017). In other words, more frequent bowel movements indicate better bowel cleansing (Shin et al., 2019). The research conducted by Noh et al. (2020) revealed that abdominal vibration dramatically raised the occurrence of diarrhoea during bowel preparation, thereby greatly improving bowel cleanliness during colonoscopy. In the current study, a notable 84.6% of patients who had undergone colonoscopy in the past reported a substantial rise in bowel movements after participating in the AVCWE programme, compared with their prior experience with a standard bowel preparation regimen. Moreover, prior studies have shown that fewer than 80% of patients are willing to undergo standard bowel cleansing regimens again (Hao et al., 2020; Maeda et al., 2023; Wen et al., 2022). Nevertheless, the current study revealed that a greater percentage of participants (90%) who attended the AVCWE programme expressed a strong willingness to repeat the same regimen. Therefore, this finding underscores that the programme is well-received and recognised by older patients with constipation.

The AVCWE programme, an innovative non-pharmacological method, offers a potentially effective way to enhance bowel preparation in older adults with constipation. Nevertheless, the positive impacts of the AVCWE programme mentioned above are completely reliant on the subjective reports of the participants and have not undergone formal evaluation or validation. Therefore, a randomised controlled trial (RCT) was

conducted in Phase 2 to substantiate the effect of this programme on bowel preparation in older patients with constipation.

6.3 Effects of the AVCWE Programme on Study Variables

The main findings of Phase 2 are comprehensively discussed through comparison with previous studies to offer novel insights for future research.

6.3.1 Patients' Background Characteristics and Bowel Preparation Compliance

6.3.1.1 Patients' Background Characteristics

A total of 271 older patients with constipation participated in the study. These participants were almost equally represented by gender, with 52% male and 48% female, had a mean age of 66.28 years (SD = 5.30). More than half of the older patients in this study had a secondary school education or higher. Additionally, more than one-third of the participants had a history of abdominal surgery or colonoscopy. Hypertension was the most common comorbidity, affecting 54.6% of the participants, followed by diabetes at 15.1%. The median duration of constipation among the participants was four years, with nearly one-third using laxatives more than three times a week. Regarding constipation-related symptoms, straining was the most common (91.1%), while manual defecation was the least common (8.5%). Overall, patient background characteristics were similar between the intervention and control groups.

Several recent local and international studies have reported similar patient background characteristics. For instance, Kwak et al. (2019) found that the average age of older adults undergoing colonoscopy in South Korea was 69.0 years (SD = 2.9), with nearly equal gender representation. Studies on older Chinese adults by Hu et al. (2021), Su et al. (2022), and Xun et al. (2022) also reported similar educational levels, with more than 50% of patients having a secondary education level or higher. Zhang et al. (2018) found that

among older Chinese patients undergoing colonoscopy, 38.8% had a history of abdominal surgery, and 39.6% had a history of colonoscopy, which is similar to this study.

In a cross-sectional study of 110 older Korean patients undergoing colonoscopy, Gwag and Yoo (2022) reported a similar proportion of family history of CRC (9.1%) compared with the current study (7.0%). Furthermore, a prospective cohort study conducted in five Italian endoscopy centres by Maida et al. (2022) showed that 56.0% of older patients undergoing colonoscopy had hypertension and 19.1% had diabetes, reflecting an agreement with comorbidity characteristics observed in the current study. Guo et al. (2020a) conducted a cross-sectional study of 199 patients with functional constipation in four endoscopic centres in China and found that 38.7% of them used laxatives more than three times per week, consistent with the current study's findings. Additionally, recent international studies conducted in Spain, Turkey, and Japan have reported similar findings regarding constipation-related symptoms (Arco et al., 2022; Aydemir et al., 2023; Yamamoto et al., 2022).

In conclusion, the sociodemographic and clinical characteristics of the patients in this study are representative of the broader population of older patients with constipation. This alignment with previous studies underscores the validity and generalisability of the current study's findings. Future research should continue to explore these characteristics in diverse populations to further validate and expand upon these results.

6.3.1.2 Bowel Preparation Compliance

Bowel preparation compliance, as a key covariate, was also compared among the three groups. The results of this study revealed no statistically significant difference in bowel preparation compliance among the three groups ($p > 0.05$), indicating that the covariate was well balanced among the groups.

In this study, the proportion of good medication compliance (88.9%) was higher than good dietary compliance (77.5%). Consistent with current research, a Turkish study of 306 patients undergoing colonoscopy also reported that more patients adhered to medication (87.3%) than to dietary regimen (75.8%) (Arslanca & Aygün, 2022). Similarly, an observational study involving 575 older adults undergoing colonoscopies at five European hospitals showed that patients were less adherent to a dietary regimen (85.5%) compared with a laxative regimen (91.4%) (Maida et al., 2022). The primary reason for this phenomenon may be that, despite current bowel preparation guidelines recommending a low-residue diet the day before colonoscopy, insufficient attention to dietary requirements and the variety of food choices make it difficult for older patients to avoid accidentally consuming fibre-containing foods (Gao et al., 2022; Pan et al., 2023; Zhang et al., 2021b). Therefore, poor dietary compliance is a common problem during bowel preparation in older persons undergoing colonoscopy, suggesting a significant area for improvement (Lee et al., 2019; Walter et al., 2021; Wang et al., 2022d).

A previous study of 275 Chinese patients undergoing colonoscopy also reported a bowel preparation compliance score ($M = 7.51$, $SD = 0.96$) comparable to the current study ($M = 7.54$, $SD = 0.83$) (Kong, 2019). Overall, bowel preparation compliance in both local and international contexts was found to be similar to that in the current study setting. Notably, since the covariates (bowel preparation compliance and background characteristics) were well balanced among the three groups, any differences in outcomes can be assumed to be purely due to the intervention.

The agreement of the current study's findings with those from various international studies substantiates the reliability and generalisability of the results. This consistency across different contexts highlights the global challenge of ensuring adequate dietary adherence to bowel preparation protocols. Future research should focus on developing

strategies to improve dietary adherence, possibly through enhanced patient education and support mechanisms. Improving dietary compliance could lead to better bowel preparation outcomes, ultimately enhancing the effectiveness of colonoscopy procedures.

6.3.2 Impact of AVCWE Programme on Colonoscopy Quality Indicators

Colorectal cancer (CRC) is currently the third most prevalent form of cancer and the second leading contributing cause of cancer-related mortality worldwide, posing a significant threat to people's lives and health (Morgan et al., 2023; Yue et al., 2021). Mounting evidence supports that early detection and treatment of precancerous lesions, such as colorectal adenomas, are critical to reducing the incidence and mortality of CRC (Chan & Liang, 2022; Jung et al., 2022b; Morgan et al., 2023). Colonoscopy is regarded as the gold standard for CRC screening because of its high detection rate and ability to remove precancerous adenomas (Dankner et al., 2023; Rex, 2020; Yang et al., 2023a). However, the effectiveness of colonoscopy relies on the quality of bowel cleansing (Abu Baker et al., 2023b; Keswani et al., 2021; Soeder et al., 2022). Adequate bowel preparation provides the best visualisation for accurately identifying of intestinal lesions and facilitates smooth and quick caecal intubation (Hsu & Chiu, 2023; Rex, 2023). Unfortunately, the current bowel preparation quality among older patients with constipation is notably poor (Abu Baker et al., 2024; Samnani et al., 2023). This can potentially lead to lower caecal intubation rate (CIR), adenoma detection rate (ADR), and prolonged caecal intubation time (CIT), thereby imposing a significant burden on the global healthcare system (Amitay et al., 2021; Fostier et al., 2023; Shi et al., 2023).

This dilemma underscores the challenges of achieving optimal bowel preparation in older patients with constipation using standard protocols (Wang et al., 2022b; Zhang et al., 2024c). In recent years, adjunctive interventions such as abdominal vibration and walking exercise have demonstrated potential in enhancing bowel cleansing (Gao et al.,

2023; Noh et al., 2020). Considering the unique challenges posed by age-related gastrointestinal changes, this study aimed to provide valuable insights into optimising colonoscopy outcomes for older patients with constipation by proposing an intensive regimen that combines walking exercise and abdominal vibration.

The primary outcome of this study was the quality of bowel preparation, assessed using the Boston Bowel Preparation Scale (BBPS), and compared among the AVCWE, WE, and control groups. The findings showed that the total BBPS score and rate of adequate bowel preparation in the AVCWE group were significantly higher than those in the WE group and the control group ($p < 0.001$). Specifically, the BBPS scores of the right colon, transverse colon, and left colon in the AVCWE group were significantly higher than those in the control group ($p < 0.001$). Furthermore, the BBPS score for the left colon was significantly higher in the AVCWE group compared with the WE group ($p < 0.01$). These findings highlight the significant positive impact of the AVCWE programme developed in this study in discernibly improving the quality of bowel cleansing in older patients with constipation, potentially bringing substantial benefits to the prevention and treatment of CRC. This is primarily because by improving bowel preparation, visualisation of the colonic mucosa during colonoscopy can be significantly optimised, thereby increasing the likelihood of detecting intestinal lesions, which is crucial for early intervention and reducing CRC mortality (Dankner et al., 2023; Rex, 2023).

Prior studies have confirmed the importance of walking exercises in improving the quality of bowel preparation. Gao et al. (2023) and Kumar et al. (2016) highlighted the positive impact of physical activity on bowel cleansing for colonoscopy. A meta-analysis of nine cohort and cross-sectional studies ($n = 2,136$) by Zhang et al. (2024a) identified inadequate exercise during preparation as an independent risk factor for poor bowel preparation in older patients undergoing colonoscopy (OR, 3.13; 95% CI, 2.39–4.11; $p <$

0.001). In addition, a prospective observational study of 150 outpatients undergoing colonoscopy at a tertiary hospital in central China found that walking at least 5,270 steps before colonoscopy is required to achieve high-quality bowel preparation (Shi et al., 2021). Additionally, a single-blinded RCT of 300 Chinese patients undergoing colonoscopy found that walking 10,000 steps before colonoscopy significantly improved the quality of bowel preparation (rate of adequate bowel preparation, 10,000-step group vs 5,000-step group vs control group: 89% vs 59% vs 51%; $p < 0.001$) (Gao et al., 2023). However, one apparent shortcoming of the research conducted by Gao et al. (2023) was that all the subjects were less than 65 years old, suggesting that the proposed 10,000-step walking exercise regimen may not be appropriate for those with restricted mobility or older individuals.

Recently, abdominal vibration has demonstrated efficacy in optimising bowel cleanliness for colonoscopy (Noh et al., 2020). Initially used in constipation management, abdominal vibration helped reduce the severity of constipation symptoms without any side effects (Mimidis et al., 2005; Wu et al., 2012). Subsequently, a quasi-experimental study in South Korea applied abdominal vibration to bowel preparation for colonoscopy and found it could achieve high-quality bowel preparation similar to walking exercise (Noh et al., 2020). In their study, the patients in the abdominal vibration group were subjected to a maximum of eight cycles of abdominal vibration stimulation. Each cycle consisted of 10 minutes of stimulation followed by 20 minutes of rest. This stimulation was administered one hour following the intake of the PEG solution. However, their study lacked randomisation, which may have introduced bias into the results. Moreover, the study was conducted in the general population, and the researchers only analysed the impacts of abdominal vibration or walking exercise alone on bowel cleansing. Due to the decreased gastrointestinal motility in older patients with constipation, the positive effect

of either approach alone on the quality of their bowel preparation may be restricted (Zhang et al., 2024b).

To address this, the current study developed an intensive regimen of abdominal vibration combined with walking exercise (AVCWE programme) and conducted an RCT to explore its effectiveness in older patients with constipation. The results indicated that the AVCWE programme was more effective than the WE programme and the standard bowel preparation regimen in improving the quality of bowel preparation in older patients with constipation ($p < 0.001$). Although the specific mechanism responsible for this beneficial effect remains unclear, a possible explanation is that abdominal vibration can have a synergistic effect with walking exercise to increase gastrointestinal motility and reduce colonic transit time, thereby significantly promoting defecation and improving bowel cleansing (Choi et al., 2021; McClurg et al., 2020; Zhang et al., 2024b).

Notably, the current study also found that the AVCWE group had significant advantages over the WE group and the control group in improving ADR (42.2% vs 24.4% vs 20.9%, $p = 0.003$). A prospective RCT conducted in a tertiary hospital in China reported similar findings, showing that ADR in the intensive exercise group (10,000-step group) was significantly higher than that in the 5,000-step group and the control group ($p < 0.001$) (Gao et al., 2023). Optimal visualisation of the colonic mucosa is essential for the accurate detection of adenomas, primarily achieved through adequate bowel preparation (Guo et al., 2019; Moein et al., 2021). In other words, higher ADRs are strongly associated with better bowel preparation quality (Gubbiotti et al., 2022; Sharma et al., 2020). Since the total BBPS score and the rate of adequate bowel preparation (BBPS score ≥ 6) in the AVCWE group were significantly higher than those in the WE group and control group, this may help explain the significant advantage of the AVCWE programme in improving ADR. However, the robustness and generalisability of this

finding need to be confirmed by future RCTs with larger sample sizes and more rigorous designs.

Disappointingly, while the AVCWE programme significantly improved ADR, there were no statistical differences in CIT and CIR among the three groups ($p > 0.05$). This finding aligns with previous studies indicating that CIT and CIR are influenced by factors beyond bowel preparation quality, such as the skill and experience of the endoscopist (Hoff et al., 2017; Matyja et al., 2018). It suggests that while bowel preparation is crucial for mucosal visualisation and lesion detection, technical proficiency in performing colonoscopies is equally important (Jaensch et al., 2024; Karamchandani et al., 2022). The absence of significant differences in CIT and CIR raises questions about the comprehensive benefits of the AVCWE programme. While improvements in bowel preparation quality and ADR are positive outcomes, the lack of impact on other quality indicators suggests that the AVCWE programme may need to be part of a broader strategy that includes endoscopist training and other quality improvement measures.

6.3.3 Impact of AVCWE Programme on Adverse Events

In clinical practice, the ideal bowel preparation should be safe, effective, and well tolerated by the patients (Haydel et al., 2024; Tiankanon & Aniwan, 2024). Better tolerability is closely associated with fewer adverse events (Sun et al., 2023; Zhao et al., 2023). However, a range of gastrointestinal adverse events may occur during bowel preparation, as patients need to take large amounts of poor-tasting laxatives in a short period of time to achieve satisfactory bowel cleansing (Di Leo et al., 2021; Tontini et al., 2021). According to recent statistics, about 20%–40% of patients undergoing colonoscopy experience significant discomfort upon the ingestion of PEG solution, including nausea, vomiting, abdominal pain, and bloating (Tangvoraphonkchai et al., 2023; Zhao et al., 2023). Adverse events experienced during bowel preparation are the

most common reason why patients are reluctant to undergo colonoscopy (Kerrison et al., 2021; Sultan et al., 2017). Therefore, reducing adverse events is critical to improve patient tolerance and compliance rates with CRC screening (Hao et al., 2020; Kamran et al., 2020).

To fully evaluate the effectiveness of the AVCWE programme in bowel preparation, adverse events during preparation were also recorded and compared among the three groups. The results of this study revealed no statistically significant difference in the incidence of nausea, vomiting, and abdominal pain among the three groups ($p > 0.05$). However, while the incidence of bloating was similar in the WE group (38.9%) and the control group (40.7%), it was significantly lower in the AVCWE group (22.2%) than in both groups ($p = 0.016$). This finding is particularly noteworthy because bloating is a common and uncomfortable side effect of bowel preparation that can deter patients from complying with CRC screening protocols. By significantly reducing the incidence of bloating, the AVCWE programme may improve overall patient experience and compliance with future colonoscopies.

The current study revealed no significant benefit of the WE regimen in reducing the incidence of adverse events. This aligns with Gao et al. (2023), who conducted a single-centre RCT on 300 Chinese patients undergoing colonoscopy and observed that walking exercise alone did not reduce the incidence of nausea, vomiting, abdominal pain, and bloating ($p > 0.05$). Similarly, a quasi-experimental study in Korea demonstrated that neither walking exercise nor abdominal vibration alone had any advantage in reducing adverse events during bowel preparation (Noh et al., 2020).

However, more intensive interventions than walking exercise or abdominal stimulation alone appear to have a significant effect on reducing the incidence of bloating. For example, Wei and Liu (2023) conducted a quasi-experimental study of 166 Chinese

children undergoing colonoscopies and found that abdominal massage combined with walking exercise could significantly reduce the incidence of bloating (intervention group vs control group: 22.09% vs 38.75%, $p = 0.019$). Similarly, Meng et al. (2022) found that combining abdominal massage with traditional Chinese exercise (Ba Duan Jin exercise) significantly reduced the incidence of bloating in 246 Chinese adults undergoing colonoscopies (intervention group vs control group: 17.74% vs 30.33%, $p = 0.021$).

Consistent with these findings, the current study confirmed the efficacy of the AVCWE programme in reducing bloating symptoms during bowel preparation in older patients with constipation. The synergy of abdominal vibration and walking exercises may boost blood circulation and glandular secretion in the digestive system (Zhang et al., 2024b). This enhanced physiological response could improve the absorption and elimination of laxatives, potentially easing bloating discomfort to a significant degree (Horner et al., 2015; Song et al., 2021b).

6.3.4 Impact of AVCWE Programme on Patient Satisfaction and Willingness to Repeat the Bowel Preparation

Patient satisfaction, a form of patient-reported outcome, is a critical measure of health care quality because it provides direct evidence of how treatment impact patients' feeling and functions (Davidson et al., 2017; Powers et al., 2016). Recent studies have demonstrated that patients with higher levels of satisfaction are more likely to adhere to prescribed bowel preparation regimens, resulting in higher-quality bowel cleansing (Cash et al., 2021; Waldmann et al., 2019). Therefore, improving patient satisfaction with bowel preparation has become a key issue in gastroenterology research (Farid et al., 2024; Zhao et al., 2019b). However, patients' overall satisfaction with bowel preparation is often low due to intolerable adverse events caused by taking large amounts of laxatives (Hatoum et al., 2016; Wen et al., 2017).

The results of this study demonstrated that the AVCWE programme significantly improved patient satisfaction with bowel preparation compared with the WE programme and the standard bowel preparation regimen ($p < 0.001$). However, there was no significant difference in satisfaction scores between the WE and control groups ($p > 0.05$). This finding is congruent with previous experimental studies reporting that walking exercise alone did not improve patient satisfaction with bowel preparation (Gao et al., 2023; Noh et al., 2020). Interestingly, recent studies have demonstrated that an enhanced strategy combining walking exercises with other interventions holds great promise in improving patient satisfaction with bowel preparation (Chen, 2018a; Zhang et al., 2020c). For instance, Cui and Zhang (2021) conducted a prospective RCT on 90 Chinese patients undergoing colonoscopy and found that patient satisfaction with bowel preparation was significantly higher in the group that combined walking exercise with abdominal massage (95.56%) compared with that in the control group (80.00%) ($p = 0.024$). This finding is also supported by a previous meta-analysis (Chai et al., 2019).

The reduction in adverse events, particularly bloating, is significantly associated with higher patient satisfaction (Kamran et al., 2020; Tian et al., 2021). The AVCWE group in this study reported a significantly lower incidence of bloating than the other two groups, which likely contributed to the improved patient satisfaction with bowel preparation. However, the existing literature often uses simple yes/no questions to measure patient satisfaction rather than validated assessment tools like the 100-point satisfaction Visual Analog Scale (VAS) used in the current study (Gálvez et al., 2017; Hatoum et al., 2016). Given the heterogeneity in measurement tools for bowel preparation satisfaction across studies, future rigorous studies using validated tools are required to further confirm the impact of this intervention on patient satisfaction.

Despite the improved patient satisfaction, the study found no significant differences in the willingness to undergo the same preparation regimen again among the three groups ($p = 0.394$). This finding is consistent with recent Chinese studies by Gao et al. (2023) and Zhang et al. (2023b), which questioned the effectiveness of exercise therapy in improving patient willingness due to non-significant results. This suggests that while the AVCWE programme can enhance immediate satisfaction, it may not be sufficient to influence long-term patient willingness to repeat the same preparation. Future studies with larger sample sizes and diverse geographical areas are needed to verify the real-world effectiveness of this programme on willingness to repeat bowel preparation.

6.3.5 Factors Affecting Bowel Preparation Quality in Older Patients with Constipation

In recent years, a large amount of relevant literature has shown that older patients with constipation are at higher risk of poor bowel preparation, leading to a series of adverse consequences such as missed adenoma detection, failed caecal intubation, prolonged operation time, and increased medical expenses (Amitay et al., 2021; D'Souza et al., 2019; Shahini et al., 2023). Therefore, there is an urgent need to identify potential predictors of inadequate bowel preparation in older patients with constipation, as this may effectively help prevent colonoscopy failure (Fostier et al., 2023; Martel et al., 2018). Currently, several predictors of inadequate bowel preparation have been identified in the general population, including sociodemographic characteristics (older age, male gender, obesity, and lower health literacy), clinical characteristics (constipation, diabetes, stroke, cirrhosis, hospitalisation, and history of abdominal surgery), and the administration of specific medications (tricyclic antidepressants, narcotic, and opioids) (Afecto et al., 2023; Shahini et al., 2023). However, the exact risk factors contributing to inadequate bowel preparation in older patients with constipation are still uncertain.

This study performed a multivariate analysis, where the first colonoscopy, laxative use ≥ 3 times per week, and poor dietary compliance were identified as independent predictive factors for poor bowel cleansing. Similarly, a cross-sectional study of 406 older Chinese individuals undergoing colonoscopy found that the first colonoscopy experience was significantly associated with inadequate bowel preparation (OR, 3.079; 95% CI, 1.724–5.500; $p < 0.001$) (Xu et al., 2022). In clinical practice, the bowel preparation process can be complex and challenging for older patients, especially those undergoing colonoscopy for the first time (AlAmeel, 2018; Gwag & Yoo, 2022). This is mainly ascribable to poor memory in older patients, who tend to ignore or forget a series of complicated bowel preparation instructions, resulting in poor bowel preparation compliance (Chiu et al., 2022; Gimeno-García et al., 2023). Therefore, for older patients undergoing colonoscopy for the first time, in addition to traditional written and verbal instructions, reinforced educational methods such as phone calls, text messages, social media, and online videos should be considered to improve patients' compliance with preparation instructions (Guo et al., 2020c; Patel et al., 2024; Wonggom et al., 2023).

Consistent with the current findings, a prospective observational study involving 1,054 Japanese patients undergoing colonoscopies found that laxative use more than thrice per week was a significant predictor of suboptimal bowel cleansing (OR, 2.57; 95% CI, 1.59–4.17; $p = 0.008$) (Higashimori et al., 2023). According to available evidence, chronic use of laxatives may lead to serious intestinal motility disorders such as intestinal paralysis and irritable bowel syndrome (Bharucha & Lacy, 2020; Milosavljevic et al., 2022). Therefore, current conventional preparation regimens may be less effective at rapidly clearing stool from the colon and providing maximal visualisation of the colonic mucosa in these individuals (Shahini et al., 2023). To address this issue, a targeted intensive bowel preparation regimen should be considered for patients who use laxatives more than three times per week (Jung, 2023; Malkin et al., 2023).

According to current bowel preparation guidelines, dietary restriction is an essential component of the standard preparation regimen (Hassan et al., 2019; National Cancer Center, 2021). Therefore, strict adherence to the prescribed dietary regimen is essential to ensure satisfactory bowel preparation quality (Gausman et al., 2020; Zhang et al., 2021b; Zhang et al., 2024a). The findings of this study demonstrated that poor dietary compliance was significantly associated with inadequate bowel preparation (OR, 2.249; 95% CI, 1.142–4.430; $p = 0.019$). Similar to this study, a survey of 240 older Chinese patients undergoing colonoscopies revealed that non-compliance with the dietary regimen was an independent risk factor for poor bowel preparation (OR, 2.239; 95% CI, 1.122–4.471; $p = 0.022$) (Zhang et al., 2018). Additionally, a retrospective cohort study involving 575 older patients undergoing colonoscopies at five hospitals in Italy found that patients who adhered to dietary restrictions were more likely to obtain satisfactory bowel cleansing (OR, 2.45; 95% CI, 1.42–4.24; $p = 0.001$) (Maida et al., 2022). Likewise, multiple studies in the United States, Korea, and Turkey have reached similar conclusions (Gwag & Yoo, 2022; Kılınç et al., 2023; Ramprasad et al., 2020). This phenomenon reminds healthcare providers to pay more attention to bowel preparation education for older patients and adopt effective strategies to ensure their compliance with dietary restriction regimens (Peng et al., 2022; Zhao et al., 2022a).

In summary, to the best of the researcher's knowledge, this is the first study to explore risk factors for inadequate bowel preparation in older patients with constipation. Three significant risk factors were identified: the first colonoscopy, laxative use ≥ 3 times per week, and poor dietary compliance. These findings provide valuable information for developing targeted interventions to improve bowel preparation quality in this 'difficult-to-prepare' population.

6.4 Strengths and Limitations of this Study

The current study has several strengths worth highlighting. First, this study is an RCT, which is the gold standard for effectiveness research and represents the highest level of evidence. Randomisation balances participant characteristics (observed and unobserved) between groups, allowing any differences in outcomes to be attributed to the study intervention, which is not possible with any other study design. Second, this study adopted an investigator-blind design. Researchers involved in outcome data collection were blinded to patient group assignment, which minimised the risk of detection bias and ensured the credibility of the study conclusions. Third, the AVCWE programme employed in this study was developed using the researchers' extensive clinical experience, input from multidisciplinary experts, and previous literature. In addition, a feasibility study was performed on 30 older patients with constipation to assess the practicality and viability of the AVCWE protocol before the formal study. These details fully guarantee the credibility and acceptability of the AVCWE intervention. Fourth, different groups of patients in this study were scheduled to undergo colonoscopies on different days to avoid possible contamination among the groups. Fifth, the outcome indicators of this study included both objective outcomes (bowel preparation quality, ADR, CIR, and CIT) and subjective indicators (satisfaction, willingness to repeat the same preparation, and adverse events), providing a comprehensive assessment of the true effectiveness of the AVCWE programme for bowel preparation. Lastly, to the researchers' knowledge, this is the first study to evaluate the effectiveness of the AVCWE programme in improving the quality of bowel preparation in older patients with constipation, offering a simple and effective non-pharmacological strategy to optimise bowel preparation for colonoscopy.

Despite those strengths, there are some limitations to consider. First, this was a single-centre study conducted in a tertiary hospital in China, which may limit the generalisability of the findings. However, the characteristics of the participants in this study were similar

to other studies conducted in both local and international contexts. Second, this study could not achieve a double-blind design, as it is generally not possible to blind participants to their treatment during a physical therapy intervention. However, all participants were asked not to disclose their group assignment to any researcher, helping to prevent bias in outcome assessment by ensuring that outcome assessors were blinded to treatment allocation. Third, since ADR is the only recognised colonoscopy quality indicator related to lesion detection in the Chinese guidelines, this study included only ADR and did not consider the number of adenomas per colonoscopy, the post-colonoscopy CRC rate, the advanced adenoma detection rate, or the sessile serrated lesion detection rates as outcome indicators. Therefore, future studies are needed to clarify whether the AVCWE programme also positively impacts the detection of these pathological findings. Fourth, due to the nature of the AVCWE programme, this intervention may only be appropriate for patients undergoing afternoon colonoscopies. Patients scheduled for morning colonoscopies need to take laxatives the night before and 4–6 hours before the procedure, which falls outside the endoscopy centre's operating hours. As a result, it is not feasible to implement the researcher-directed AVCWE intervention during this time. This limitation warrants further investigation and should be addressed in future studies. Lastly, while the AVCWE programme shows promise in improving bowel preparation, it is important to consider the broader applicability and practicality of this intervention. The combination of walking exercise and abdominal vibration requires resources and patient commitment, which may not be feasible for all populations, especially those with mobility limitations or severe comorbidities. Further research is needed to optimise and validate these findings across diverse patient populations and clinical settings. The ultimate goal is to enhance the overall safety, effectiveness, and patient experience of bowel preparation to improve CRC screening rates and outcomes.

6.5 Implications of this Study

In routine gastroenterology practice, bowel preparation quality is recognised as an important quality indicator of colonoscopy and needs to be greatly improved. This is because poor bowel preparation may result in a range of negative consequences, posing significant pressure and challenges to the global medical system. Therefore, endoscopy nurses have an indispensable role in ensuring adequate bowel preparation for patients undergoing colonoscopy. The findings of this study have significant positive implications for nursing practice and nursing research, which are essential for improving the quality of care in health systems.

Older patients with constipation have a significant risk of experiencing inadequate bowel preparation, which may adversely affect the effectiveness and safety of colonoscopy. However, there is a dearth of research evidence on improving the quality of bowel preparation in this high-risk population. Neither Chinese nor international guidelines provide specific bowel preparation recommendations for this demographic. This innovative study found that the AVCWE programme positively impacted patient outcomes, including significantly improved bowel preparation quality, ADR, and satisfaction, and reduced the incidence of bloating. Therefore, this study helps fill an important research gap on optimising bowel preparation in older patients with constipation and provides a valuable reference for developing practical bowel preparation guidelines for this ‘difficult-to-prepare’ population. Based on existing evidence, it is recommended that older patients with constipation undergoing bowel preparation implement the AVCWE programme in addition to the standard bowel preparation regimen to optimise the detection of colorectal diseases and avoid the waste of medical resources caused by repeated colonoscopies due to poor bowel preparation.

Identifying risk factors for inadequate bowel preparation in older patients with constipation can help prevent colonoscopy failure by enabling targeted intensive interventions for high-risk patients before the procedure. This study conducted a logistic regression analysis on the data of older patients with constipation and found that the first colonoscopy, laxative use ≥ 3 times per week, and poor dietary compliance were significantly correlated with inadequate bowel cleansing. This finding offers crucial information for developing predictive models for inadequate bowel cleansing in older patients with constipation, enabling medical professionals to identify high-risk patients accurately and provide targeted interventions before colonoscopy.

Most studies aimed at improving bowel cleansing in high-risk patients focus on exploring the efficacy of various additional laxative regimens. However, these pharmacological treatments may result in a range of undesirable adverse events that reduce patient tolerance and satisfaction with bowel preparation. Considering the limitations of pharmacological therapies, non-pharmacological interventions may be a safe and promising strategy to improve bowel cleanliness. There is currently insufficient research evidence regarding non-pharmacological treatments for bowel preparation. Therefore, the findings of this study may inspire future research on developing non-pharmacological therapies to improve the quality of bowel preparation. In other words, non-pharmacological therapies include abdominal vibration and exercise therapy should be fully valued and considered in bowel preparation practices, as these simple and inexpensive strategies may significantly improve bowel cleansing and patients' subjective experiences.

6.6 Recommendations for Future Research

To build upon the findings of this study, several recommendations for future research are proposed. First, more multi-centre, high-quality RCTs are needed in the future to

confirm the current study's findings, thereby providing reliable and strong evidence for the promotion of AVCWE intervention in clinical practice. Second, the AVCWE programme designed in this study is only suitable for patients who are able to walk independently, and thus, it cannot be generalised to all patients undergoing colonoscopy, such as those with mobility impairments. Future research should focus on developing targeted strategies for patients who are unable or unwilling to engage in exercise. Third, the AVCWE programme in this study was only applicable to patients undergoing afternoon colonoscopies; therefore, it is necessary to develop tailored interventions for patients undergoing morning colonoscopies. Fourth, future research could consider developing more non-pharmacological therapies, such as exercise therapy and the use of probiotics, to improve the quality of bowel preparation in patients with constipation without the burden of adverse effects. Fifth, although previous studies have found that the presence of diverticula is an independent predictor of inadequate bowel preparation in patients undergoing colonoscopy, this variable was not included in the current study. Therefore, further studies are needed to determine the association between colonic diverticulosis and bowel preparation quality in older patients with constipation. Finally, future studies should consider developing predictive models for inadequate bowel preparation in older patients with constipation. These models could help healthcare providers target interventions for specific high-risk patients prior to colonoscopy, thereby improving overall preparation quality and patient outcomes.

6.7 Summary

In conclusion, this study is the first to develop and evaluate the impact of an AVCWE programme on bowel preparation in older patients with constipation. The AVCWE programme, developed in Phase 1 based on the researchers' expertise and input from multidisciplinary experts, includes a minimum of 5,500 steps of walking exercise and two cycles of moderate-intensity abdominal vibration. The feasibility assessment indicated

that older patients with constipation highly appreciated the programme, finding it easy, suitable, safe, and potentially beneficial for their bowel cleansing. The findings from Phase 2 RCT demonstrated that, compared with the WE programme and the standard bowel preparation regimen, the AVCWE programme significantly improved the quality of bowel preparation, ADR, bowel preparation satisfaction, and significantly reduced the incidence of bloating in older patients with constipation. Additionally, the first colonoscopy, laxative use ≥ 3 times per week, and poor dietary compliance were significantly associated with inadequate bowel preparation. Given the substantial benefits of the AVCWE programme, healthcare providers worldwide are recommended to consider this intervention as an important component of bowel preparation for older patients with constipation. The results of this study may provide valuable information for developing bowel preparation guidelines tailored to this population. Future large-scale, multicentre, rigorous RCTs are needed to confirm these findings.

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