

Official title: Effects of Exercise Training on Pelvic Floor Symptoms and Function in Adults with Constipation: A Randomized Controlled Trial

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Study protocol

Constipation is a common problem in adult population¹. Constipation may also lead to pelvic floor muscle dysfunction due to prolonged stress on the pelvic floor. The recommended initial treatment for constipation includes lifestyle modifications (e.g., increasing physical activity, balanced diet) and laxatives². Pelvic floor muscle training (PFMT) with biofeedback has been recognized as an effective therapy for relieving constipation in patients who have failed initial treatment³. Since constipation is a multifactorial disorder, a multimodal intervention program may be more effective than single treatment in solving constipation problem⁴. However, there is no research investigating the effects of a multimodal exercise training on pelvic floor symptoms and pelvic floor muscle function in this population and only few studies have evaluated the pelvic floor muscle function using objective assessment tools among this population. This study aims to evaluate the effectiveness of a multimodal exercise training program on constipation symptoms and pelvic floor muscle function in adults with constipation.

This is a randomized controlled trial. Adults with functional constipation will be recruited and randomly assigned to two groups, the intervention group, or the control group. The intervention group will receive 16 sessions of physical therapist supervised, combined resistance (including PFMT) and aerobic exercise training twice weekly for 8 weeks, and home exercises (PFMT and walking). The control group will receive only one session of usual care after baseline assessment.

Assessments will be performed at baseline and after eight-week program. The primary outcome measure is the severity of patient's self-reported constipation symptoms. The secondary outcome measures include the pelvic floor muscle function, physical activity levels, constipation-related quality of life, and 7-day bowel chart will also be collected. Moreover, adherence will be calculated separately for PFMT and walking

as the days of home exercises completed over 56 days in intervention group.

Statistical analysis plan

Intention-to-treat analysis will be performed to preserve the sample size and original randomization. For participants who have a missing outcome in baseline assessment, the outcome value will be estimated through calculating mean and mode from the existing data. For those who have a missing outcome in post-intervention assessment, the observation from baseline assessment will be carried forward. Shapiro-Wilk test will be used to evaluate the normality of data. Descriptive data will be presented as number, percentage, mean and standard deviation (SD). Mann-Whitney U test and Chi-square test will be used for continuous data and categorical data to compare the baseline characteristics between two groups. Wilcoxon signed rank test and the Mann-Whitney U test will be used for intragroup and intergroup comparison of outcome variables. The p-value of < 0.05 will be considered as statistically significant. All data analyses will be performed using SPSS software version 25.0.

References

1. Andrews CN, Storr M. The pathophysiology of chronic constipation. *Can J Gastroenterol*. 2011;25(Suppl B):16B-21B.
2. Włodarczyk J, Wasniewska A, Fichna J, Dzik A, Dzik L, Włodarczyk M. Current overview on clinical management of chronic constipation. *J Clin Med*. 2021;10(8):1738.
3. Rao SS, Benninga MA, Bharucha AE, Chiarioni G, Di Lorenzo C, Whitehead WE. ANMS-ESNM position paper and consensus guidelines on biofeedback therapy for anorectal disorders. *Neurogastroenterol Motil*. 2015;27(5):594-609.
4. George SE, Borello-France DF. Perspective on physical therapist management of functional constipation. *Phys Ther*. 2017;97(4):478-93.