

When non-specific effects matter: methodological considerations in a randomized controlled trial of abdominal massage for pediatric functional constipation

Fei-Yi Zhao^{1,2,3,4}, Li-Ping Yue¹, Qiang-Qiang Fu⁵, Jia-Yi Zhu⁵

¹Department of Nursing, School of Life and Health Sciences, Shanghai Sanda University, Shanghai, People's Republic of China; ²Sydney School of Health Sciences, Faculty of Medicine and Health, The University of Sydney, Camperdown, Australia; ³School of Health and Biomedical Sciences, RMIT University, Bundoora, Australia; ⁴Shanghai Municipal Hospital of Traditional Chinese Medicine, Shanghai University of Traditional Chinese Medicine, Shanghai, People's Republic of China; ⁵Yangpu Hospital, School of Medicine, Tongji University, Shanghai, People's Republic of China.

Dear Editor,

We thank Malekiantaghi et al. for conducting a randomized controlled trial (RCT) evaluating abdominal massage as an adjunctive therapy for functional constipation.¹ While the study offers valuable clinical perspectives on non-pharmacological management, several methodological issues merit further consideration.

First, although food diaries were collected and uniform dietary recommendations were provided, no between-group comparisons of actual dietary fiber or fluid intake were reported. Dietary factors are key modifiable determinants of functional constipation; fiber and fluid intake may influence gastrointestinal transit and stool characteristics.^{2,3} Should dietary composition or consumption patterns differ between groups during the intervention period, the observed differences may partly reflect dietary variation rather than massage effects. Future studies should therefore employ standardized dietary assessment tools, such as three-day dietary records or food-frequency questionnaires⁴, and incorporate dietary intake variables and measures of dietary adherence as covariates in analysis of covariance (ANCOVA)

or multivariate regression models to minimize potential confounding.

Second, both groups received polyethylene glycol at 0.5 g/kg, with doses adjusted according to individual needs. While such flexibility reflects routine clinical practice, it may compromise internal validity and complicate the interpretation of treatment effects in an RCT context. Specifically, laxative dosing in both groups may have varied due to clinical judgment; however, the study did not report actual dosages administered, criteria or frequency of dose adjustments, or between-group comparisons of medication use. This introduces substantial bias risk, as differential dosing patterns—arising from clinician decision-making or varying responses to the intervention—may exist between groups. Consequently, observed outcome differences may partly reflect disparities in medication exposure rather than the effect of abdominal massage itself, with the direction of bias (overestimation or underestimation of the massage effects) remaining difficult to ascertain. A more rigorous approach would involve predefined dosing protocols, such as fixed-dose regimens where clinically appropriate or standardized titration algorithms. Additionally,

✉ Jia-Yi Zhu • 2305119@tongji.edu.cn

Received 23rd Mar 2026, accepted 22nd Apr 2026.

Copyright © 2026 The Author(s). This is an open access article distributed under the [Creative Commons Attribution License \(CC BY\)](#), which permits unrestricted use, distribution, and reproduction in any medium or format, provided the original work is properly cited.

detailed documentation of baseline dosages and subsequent modifications, along with analytical strategies that account for medication exposure (e.g., covariate adjustment or dose-stratified analyses), would improve comparability between groups.

Third, twelve massage sessions involved frequent interaction with therapists, whereas the medication-only control group had limited contact. This imbalance may bias outcomes through the Hawthorne effect⁵, leading to enhanced adherence in the intervention group. Furthermore, children with functional constipation often develop defecation anxiety due to prior painful defecation experiences, resulting in stool-withholding behaviors.⁶ Regular, non-threatening physical contact may foster a trusting clinician-patient relationship and alleviate children's apprehension. Verbal reassurance during massage may also facilitate relaxation of pelvic floor muscles and reduce stool-withholding behaviors. These relational and behavioral mechanisms, prompted by the additional attention and contact provided by therapists, may contribute to symptom improvement independently of the physiological effects of massage. Incorporating attention-matched control conditions (e.g., sham-massage, light touch, or structured interaction) and standardizing therapist-participant interactions in future studies would ensure equivalence in attention, contact intensity, and communication across groups, thereby strengthening causal inference.

Fourth, "time until initiation of bowel movements" was prespecified but not reported; this is selective reporting that limits comprehensive assessment. Per "Consolidated Standards of Reporting Trials" (CONSORT)⁷, all predefined outcomes should be reported or justified, thereby improving transparency.

Author contribution

The authors confirm contribution to the paper as follows: Study conception and design: FYZ, LPY; analysis and interpretation of results: FYZ,

LPY, QQF, JYZ; draft manuscript preparation: FYZ, JYZ; manuscript revision: FYZ, LPY, QQF, JYZ. All authors reviewed the results and approved the final version of the manuscript.

Source of funding

The authors declare the study received no funding.

Conflict of interest

The authors declare that there is no conflict of interest.

REFERENCES

1. Malekiantaghi A, Miladi M, Shabani Mirzaee H, Tolou Ostadan Yazd M, Eftekhari K. Abdominal massage as an adjunctive therapy for pediatric functional constipation: a randomized controlled trial. *Turk J Pediatr* 2025; 67: 669-677. <https://doi.org/10.24953/turkjpediatr.2025.6367>
2. Bliss DZ, Jung HJ, Savik K, et al. Supplementation with dietary fiber improves fecal incontinence. *Nurs Res* 2001; 50: 203-213. <https://doi.org/10.1097/00006199-200107000-00004>
3. Boilesen SN, Tahan S, Dias FC, Melli LCFL, de Morais MB. Water and fluid intake in the prevention and treatment of functional constipation in children and adolescents: is there evidence? *J Pediatr (Rio J)* 2017; 93: 320-327. <https://doi.org/10.1016/j.jped.2017.01.005>
4. Yang YJ, Kim MK, Hwang SH, Ahn Y, Shim JE, Kim DH. Relative validities of 3-day food records and the food frequency questionnaire. *Nutr Res Pract* 2010; 4: 142-148. <https://doi.org/10.4162/nrp.2010.4.2.142>
5. McCambridge J, Witton J, Elbourne DR. Systematic review of the Hawthorne effect: new concepts are needed to study research participation effects. *J Clin Epidemiol* 2014; 67: 267-277. <https://doi.org/10.1016/j.jclinepi.2013.08.015>
6. Vriesman MH, Koppen IJN, Camilleri M, Di Lorenzo C, Benninga MA. Management of functional constipation in children and adults. *Nat Rev Gastroenterol Hepatol* 2020; 17: 21-39. <https://doi.org/10.1038/s41575-019-0222-y>
7. Hopewell S, Chan AW, Collins GS, et al. CONSORT 2025 statement: updated guideline for reporting randomised trials. *Lancet* 2025; 405: 1633-1640. [https://doi.org/10.1016/S0140-6736\(25\)00672-5](https://doi.org/10.1016/S0140-6736(25)00672-5)