the randomisation was done at the individual level. A cluster-randomised design could have masked participants assigned to one intervention from the effects of the other.

Second, the quality control of the instruction of participants on the use of biofeedback was questionable. The maximum anal canal pressure did not change despite anal exercises plus biofeedback, which might have been due to inadequate biofeedback or knowledge of interventions in the control group masking the effect of biofeedback.

Third, we are concerned that change in St Mark's score was used as the primary endpoint. The St Mark's score measures quality of life and faecal incontinence simultaneously, so it cannot accurately reflect faecal incontinence symptoms. We believe a more robust primary endpoint should have been used instead of a multifactorial, subjective endpoint, such as the St Mark's score. For example, other faecal incontinence studies have used the Fecal Incontinence Severity Index.[3,4] Additional findings might still be obtained through a post-hoc analysis of the results using the Fecal Incontinence Severity Index.

Phase 3 trials require substantial resources, considerable effort, and the cooperation of many patients. This large-scale clinical trial without phase 2 trial data might have wasted resources. We believe that additional discussion of these issues could clarify the results in Jelovsek and colleagues' study.

We declare no competing interests.

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We read with interest the high-quality randomised controlled study reported by J Eric Jelovsek and colleagues[1] assessing anal exercises with biofeedback or loperamide to control faecal incontinence in women. The conclusions of this study are as follows: loperamide was equivalent to placebo in controlling faecal incontinence, anal exercises with biofeedback was equivalent to an educational pamphlet, and loperamide and biofeedback were equivalent to oral placebo and biofeedback or loperamide plus an educational pamphlet. However, we are curious as to whether some of the patient's characteristics had an effect on the interpretation of the study results.

Patients in the trial had different surgical histories, including previous surgery for accidental bowel leakage, previous rectal or anal surgery, previous hysterectomy, previous surgery for urinary incontinence, and previous surgery for severe pelvic prolapse. These different surgical histories might have affected the results of the trial. Different approaches to rectal or anal surgery—eg, fistulotomy,[2] stapled hemorrhoidectomy,[3] and botox injection[4]—might also have affected the results. It would be useful if Jelovsek and colleagues could compare the effects of their interventions in subgroups of patients with different surgical histories, or even among subgroups by different surgical methods.

Additionally, how baseline Bristol stool scale score[5] affected the results of each group is unclear, especially for patients with the score of above 4. Individuals with loose faeces at baseline are more likely to develop faecal incontinence. A subgroup analysis to this effect would also be of interest.

In Jelovsek and colleagues' trial, faecal incontinence was defined as any uncontrolled loss of liquid or solid faecal material. However, patients with poor gas control should also be considered. Poor gas control seriously affects the patient's quality of life and ability to work. We recommend that the patients with poor gas control should be included in future studies.

We declare no competing interests.

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Author's reply

We thank Jun Kako and colleagues for their interest in the CAPABLe trial.[1] We acknowledge that the primary manuscript was unable to articulate some important background details. Fortunately, this information is available in two methods manuscripts.[2,3]

We agree that loperamide inhibits intestinal peristalsis and increases oral-caecal transit time. However, lesser known properties of loperamide are that it increases sensitivity of the recto-anal inhibitory reflex, increases rectal

perception and first incontinence volume, and increases anal sphincter squeeze duration.[4,5] These properties might benefit patients with rectal hyposensitivity and faecal incontinence.

We disagree with the suggestion to use cluster randomisation. Site-to-site differences in populations and practices of the interventions under study likely exist, and cluster randomisation by site would have confounded treatment with these site effects. Instead, we controlled for those issues by stratifying the randomisation by site.

We also disagree with the assertion that the biofeedback intervention was questionable and inadequate. The study used excessive quality control for training, certification, and deployment of the intervention.[3] Study interventionists completed online training before attending a centralised, standardised hands-on certification course designed for the trial. For the certification, expert trainers assessed the ability of the interventionists to perform the protocol components using standardised patients. After certification, trainers audited interventionists during trial implementation to improve protocol adherence.[3]

Furthermore, we also disagree with the assertion that the St Mark's score cannot accurately reflect faecal incontinence symptoms. Following recommendations from the National Institutes of Health consensus statement and a Cochrane review, the research team chose a primary outcome that incorporated the patient perspective as well as incontinence frequency, severity, bother, faecal urgency, and patient's desire for treatment. Additionally, at the time of protocol development, the St Mark's score had evidence supporting its reliability, validity, and responsiveness to guide the interpretation and clinical relevance of improvement in scores from the patient perspective.[6]

With regard to Tiancong Du and Qiang Meng's comments, we are currently doing planned secondary analyses of the trial, which will investigate whether specific baseline characteristics, including Bristol stool form types and previous surgeries, are associated with treatment response. Although we agree that incontinence of gas is an important problem, the study findings are limited, because it only included participants who reported leakage of gas and liquid stool and those who reported leakage of gas and solid stool. Women who reported only incontinence of gas were not eligible for the study. Additionally, the St Mark's score includes a single item measuring the frequency of incontinence of gas, so these results are included in the study findings.

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