Author response to Liebergall

We thank Michal Liebergall for his comments on our systematic review.[1] As Liebergall indicates in his letter, there has already been a similar debate on the same topic.[2–4] We will repeat some of the arguments here and also respond to new issues raised in the letter.

Liebergall argues that we have unfairly criticised his 2009 trial by claiming that he did not conduct an intention-to-treat analysis and by overstating the loss to follow-up. We stand by both claims. The trial report[5] includes a specific statement about post-randomisation exclusions (page 380) and describes a secondary analysis, which was intended to 'approximate an intention to treat analysis'. Leibergall suggests loss to follow-up was 27% instead of 28% because he calculated follow-up incorrectly by not including in the denominator those subjects excluded after randomisation. Either way – 27% or 28% – there is a very high rate of loss to follow-up, which potentially threatens the validity of the trial's conclusions. We note that the trial was independently rated by three trained raters for the PEDro web site and those raters also concluded that the trial did not satisfy either the intention to treat or adequate follow-up criterion.

Liebergall states that 'the Paula method is based on the theory that all sphincters in the body work together, and involves rehabilitation of damaged muscles by contraction and relaxation of specific ring muscles in other areas of the body'. This is a theory with no data to support it.[6,7] Two independent research groups, one from Norway and one from Brazil, with no knowledge of each other's studies and using different measurement methods (transperineal ultrasound and vaginal surface electromyography), have independently tested this hypothesis. Co-contraction of the pelvic floor muscles (PFM) was not detected in either study.[6,7] The theory is therefore inconsistent with data from experimental studies. Theories that cannot be reconciled with sound data should be rejected.

Liebergall argues that the researchers who conducted the experimental studies were not properly trained. If there were to be an *automatic* contraction of the PFM through contraction of ring muscles, as Liebergall claims, neither the physiotherapists nor patients would need training. If, on the other hand, patients must be trained to achieve a co-contraction of the PFM, then the PFM must be trained explicitly (in addition to training of the ring muscles). This makes it impossible to separate whether any effect of ring muscle training is due to contraction of the ring muscles or training of the PFM. Resende and colleagues compared the strength of PFM contractions with and without addition of ring muscle contraction and found that ring muscle contraction made no difference.[7] Experienced physiotherapists, who followed the description given in Liebergall's articles, conducted both experimental studies.

The 2009 trial report[5] states 'The primary outcome was change in the quantity of urinary leakage' (page 378). That is why we chose this variable, not self-reported cure, as the reported outcome measure. Pad testing is a more reliable and valid measurement than subjective report. We would argue that since an effect of the Paula method on the secondary subjective outcome cannot be explained by its theory, there are other more-likely explanations for these results. For example, the apparent effect could be due to differences in the training dosage between the two comparison groups. In both the randomised trials by Liebergall,[5,8] the Paula group had 45 minutes of training per week plus 15 to 45 minutes of individual daily home training for 12 weeks, while the PFM training group had 30 minutes per week of group training and 15 minutes of daily home training for four weeks (plus calls from the physiotherapist every second week). This clearly favours the Paula group (nine hours of individual training and 63 hours of home training compared with three hours of group training and 21 hours of home training). Furthermore, participants in the Paula group also received training for the PFM. It is not possible to make any conclusion about the effectiveness of the Paula method compared to PFM training based on such a design and content of the intervention. The main question remains: is the Paula method more or less effective than PFM training? The primary outcome implies that the Paula method is less effective. Whether Paula therapy adds anything to PFM training is another question that cannot be answered by these two randomised trials.

We wrote that the PFM training program implemented in Liebergall's trials was far from optimal. The most problematic aspect of the PFM training was that the PFM training group received just 30 minutes of group training per week for four weeks. This is substantially less than the doses used in programs that have been shown to be effective in rigorous trials (eg, the trial by Bø and colleagues[9]). In the trial by Bø and colleagues,[9] which Liebergall cites as an effective PFM training program, the women had weekly group exercise classes of 45 minutes for six months, with individual follow-up and clinical assessment of improvement of PFM function once a month. Liebergall compared Paula therapy with a program of PFM training that clearly used a lower dosage of training than what he refers to as effective PFM training.

Our view, based on evidence from high-quality randomised trials and systematic reviews,[10] is that PFM training should be first-line treatment for women with stress urinary incontinence. The design of such exercise programs should be based on the modes of exercise and exercise dosages that have shown to be effective in high-quality randomised trials. There is not yet evidence to suggest that the Paula method is as effective as PFM training. Until such evidence is available, PFM training should be the preferred therapy.

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References

1. Bø K, et al. *J Physiother.* 2013;59:159–168.
2. Bø K, et al. *Int Urogynecol J.* 2011;22:683–684.
3. Liebergall-Wischnitzer M, et al. *Int Urogynecol J.* 2011;22:681.
4. Resende APM, et al. *Int Urogynecol J.* 2011;22:685–686.
5. Liebergall-Wischnitzer M, et al. *J Womens Health.* 2009;18:377–385.
6. Bø K, et al. *Int Urogynecol J.* 2011;22:671–676.
7. Resende AP, et al. *Int Urogynecol J.* 2011;22:677–680.
8. Liebergall-Wischnitzer M, et al. *Int Urogynecol J.* 2005;16:345–351.
9. Bø K, et al. *BMJ.* 1999;318:487–493.
10. Moore K, et al. Adult conservative management. In: Abrams P, Cardozo L, Khouy S, Wein A, eds. In: *Incontinence* 5th edn 2013; 1101–1227.

Websites

www.pedro.org.au

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