

Letter-to-Editor

Beyond relaxation: Improving the validity of PMR studies in chronic disease research

Sir,

The article by Arunraj *et al*¹ published in the January 2025 issue of Indian Journal of Medical Research attracted our attention. The research offers meaningful findings about how progressive muscle relaxation (PMR) therapy helps reduce psychological distress and enhances glycaemic control for people with type 2 diabetes mellitus (T2DM). As mental health becomes more acknowledged in chronic disease treatment this research proves to be both timely and relevant.

However, the study contains several limitations that require attention. The authors justify as to why the sample size of this study is adequate, however, there is lack of clarity in context of participant retention due to its assumption of a 20 per cent dropout rate. Providing a thorough explanation about how this estimate was calculated could have strengthened the reasoning behind it. The study lacked blinding procedures, and it remains uncertain whether participants, researchers, or outcome assessors received blinding. Without blinding, there is a risk of performance and detection bias, potentially influencing the study's outcomes².

Furthermore, while the study accounts for diabetes medication, it does not account for other potential confounding variables such as changes in diet, levels of physical activities aside from self-reported walking, or other stress-coping activities used by the participants. This neglect of consideration reduces the accuracy of the isolation of effects for PMR therapy³.

Additionally, the self-reported compliance through WhatsApp, despite being innovative, is prone to reporting bias⁴. More objective data could be collected using methods like digital tracking⁵ or biochemical markers linked with stress relief⁶. Another limitation includes the study duration, as three months is likely insufficient for understanding the long-term effects of PMR on diabetes. Longer follow up could provide more information on the tenability of the intervention's effect⁷.

To summarise, the study appears to be well designed and has all the critical elements required for a thorough investigation. Nonetheless, the study's validity is likely to be increased in the future through enhanced blinding, control of confounding variables, and more objective indicators of compliance. Reducing the reliance on self-reported adherence and increasing the follow up time would also contribute to the improvements in the strength and generalisability of the results.

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Authors' response

Sir,

We thank the author of the letter-to-Editor¹ for reading our article with great interest and providing the insightful comments on our article². The point raised is regarding the sample size calculation and the assumption of a 20 per cent dropout rate. The sample size was calculated based on the prediction of expected variance in the outcome measure using the reported findings of Trimurthula *et al*³, in a similar study conducted in South India. In any intervention study, the expected dropout rate is 20 per cent or less than that, so we also assumed a 20 per cent dropout rate⁴. We conducted a structured pattern of activities like interacting with the participants on a WhatsApp group, calling them once weekly, and weekly online therapy sessions to ensure the participants' retention. In our study, the dropout rate was only 10 per cent, which is half of the assumed dropout rate. The reasons for those dropouts were also mentioned in our article⁴. Perhaps, there was no mention of either the sample size calculation or the dropouts in the study by Trimurthala *et al*³. In their study, the participants were randomly classified into experimental and control groups³.

We agree that providing a clearer rationale by the implementation of a blinding method could enhance the study's validity. Double blindness is needed to avoid the problem of bias, especially in drug trials⁵. Therefore, double blinding is used for clinical trials with new drug interventions⁶. The participants and researcher were not blinded in our study, as the researcher, who is a trained psychologist, had to teach the therapy procedure to each participant individually in the intervention group. The person who knows the therapy details and scales can only do the assessment.

The intervention group participants were instructed not to discuss the therapy procedure with anyone until the completion of the study. The participants were assigned to two study groups based on a randomisation procedure, and the control group was given standard care at baseline and was followed up after three months, whereas intervention group participants were asked to join a WhatsApp group to check the compliance and weekly therapy sessions were conducted to motivate them². There is no cross-contamination between the groups. Hence, there was no risk of performance bias.

Another important comment was on the confounding variables. The potential confounding variables in our study, such as diabetes medication, changes in diet, levels of physical activity, and other stress coping activities used by the participants that could reduce the accuracy of the isolation effect of the PMR therapy were pointed out. In any intervention study, the existence of confounding variables makes it difficult to establish a clear link between treatment and outcome measures. As reported by Skelly *et al*⁷, appropriate methods are to be used to adjust for the effect of the confounders. In our study, we took this into consideration while designing the study to ensure that participants in both the groups received the same treatment procedures, including diabetes medication, diet, and physical activity. The diabetes medication remained unchanged throughout the study. There is no possibility of confounding variable interference in the study because at baseline, the diet pattern, physical activity and treatment regimen were assessed for all the participants, and it remained the same throughout the study period. The study participants were provided with a prescription by the dietician, and they reviewed their diet pattern at follow up. Prior to enrolment, the participants were asked whether they were following any other stress reduction therapies; those who answered 'yes' were excluded from the study.

Additionally, bias on self-reported compliance through WhatsApp in our study and suggested methods like digital tracking were pointed out in the letter-to-editor⁸. Ioannidis and colleagues explained how the selective reporting methods of outcomes can bias clinical trials⁹. We followed the WhatsApp method to assess the compliance. Self-reported WhatsApp messages and weekly phone calls were done with the participants to ensure whether they were consistent in following the therapy, and this WhatsApp message from one participant in the morning gave motivation to the others to undertake the therapy and to share