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Critical Evaluation of the Methodology and Applicability of Digital ACT for Fibromyalgia Management --Manuscript Draft--

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Author Comments:	<p>Dear Editor,</p> <p>I am writing to submit our manuscript entitled "Critical Evaluation of the Methodology and Applicability of Digital ACT for Fibromyalgia Management" for consideration for publication in The Lancet. Our study provides a detailed analysis of the efficacy of digital Acceptance and Commitment Therapy (ACT) in managing fibromyalgia, a topic that aligns well with the interests of your readership.</p> <p>In our manuscript, we critically assess a recent publication by Gendreau et al., which claims significant efficacy of digital ACT for fibromyalgia management. While acknowledging the innovative approach of the study, we highlight several areas where methodological enhancements could amplify the robustness of the findings. Notably, we propose the integration of more objective measures alongside subjective self-reports to decrease potential bias and provide a more comprehensive evaluation of treatment outcomes.</p> <p>Our critique extends to the analysis methods employed in the study, emphasizing the need for a clearer presentation of effect sizes and their confidence intervals to better understand the variability and reliability of the results. Additionally, we discuss the implications of the treatment modalities' disparity in therapeutic intensity and how this might influence the study's conclusions.</p> <p>This manuscript not only scrutinizes the presented data but also suggests potential pathways for future research, particularly concerning the implementation and scalability of digital health interventions across diverse patient populations. By doing so, it contributes to the ongoing dialogue on how digital health solutions can be optimized to</p>

manage chronic conditions more effectively.

Given the relevance and timeliness of this topic to global health discussions and its potential impact on future research and clinical practice, we believe that our manuscript would be of interest to the readership of The Lancet.

Thank you for considering our work. We look forward to the possibility of contributing to your esteemed journal.

Best,
Dan

Critical Evaluation of the Methodology and Applicability of Digital ACT for Fibromyalgia Management

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Dear Editor,

Gendreau et al. present significant findings on the efficacy of digital acceptance and commitment therapy for managing fibromyalgia(1). However, several aspects warrant further discussion.

Firstly, the reliance on the Patient Global Impression of Change as the primary endpoint, while validated, is subjective and highly susceptible to placebo effects. Given the psychological nature of ACT, participants' expectations and their relationship with the treatment modality could significantly impact their self-reported outcomes. This subjectivity could be mitigated by incorporating more objective measures of improvement, such as biomarkers of stress or pain, alongside self-reported questionnaires(2). Integrating a combination of qualitative and quantitative data could offer deeper insights into patient experiences and outcomes.

Secondly, the authors report a significant improvement in the digital ACT group compared to the active control group, with a 71% improvement rate on PGIC at 12 weeks. However, the presentation of effect sizes, specifically Cohen's d, could benefit from more context. For instance, reporting the confidence intervals for these effect sizes would provide a clearer picture of the variability and reliability of the observed effects. Moreover, the mixed model for repeated measures approach used for continuous outcomes is appropriate,

but assumptions of this model, such as normality of residuals and homoscedasticity, should be explicitly addressed and validated.

The authors assert that digital ACT showed superiority in managing fibromyalgia symptoms, including pain, fatigue, and depression. However, these conclusions might overstate the findings due to the inherent limitations of the study design. For example, the active control group received symptom tracking and educational materials, which, while beneficial, do not equate to the therapeutic intensity of a structured ACT program. This disparity in treatment modalities might contribute to the observed differences in outcomes, rather than the efficacy of digital ACT alone(3). Furthermore, the potential influence of participants' expectations should be considered, as those in the ACT group might have had higher expectations of improvement due to the perceived novelty and structured nature of the intervention compared to the control group's more passive approach.

Additionally, the discussion section briefly mentions the potential for increased accessibility of digital ACT. However, the study does not thoroughly address the feasibility and acceptance of such a digital intervention across diverse patient populations, especially those less tech-savvy or with limited access to digital tools. Future studies should focus on the implementation challenges and real-world applicability of digital ACT to ensure it is a viable option for all patients with fibromyalgia(4). Addressing these issues is crucial for translating clinical trial results into practice. Studies should explore factors such as user engagement, digital literacy, and socioeconomic barriers to understand better how these interventions can be effectively disseminated and implemented in broader, more diverse populations.

Contributors

Dan Shan: Study design & Manuscript Writing and Revision.

Declaration of Interests

I declare no competing interests.

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None

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