Front. Med. 2025, 19(4): 693−695
https://doi.org/10.1007/s11684-025-1153-3

Response to “A critical perspective on patient activation through integrative healthcare counselling in oncology”, based on the “CCC-Integrativ” study

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We appreciate the interest of Ardila and Yadalam in our CCC-Integrativ study evaluating an interprofessional, evidence-based counseling program for complementary and integrative healthcare (CIH) in oncology patients [1]. Their insightful engagement underscores the critical role of patient activation in fostering self-management and enhancing engagement in cancer care. While many of the limitations they note were already addressed in our original publication and study protocol [2], we welcome the opportunity to provide further clarification on specific aspects of our findings and their clinical implications.

Magnitude of the observed effect

Although the adjusted mean difference of 2.22 points on the PAM-13 scale may appear modest and did not reach a 4-point difference in PAM score as assumed in our study protocol, it is important to note that minimal clinically important differences (MCID) for the PAM-13 in oncology have not been firmly established [3,4]. Moreover, evidence suggests that even small improvements in patient activation can be linked to enhanced self-management behaviors and better health outcomes. For example, Hibbard *et al*. have reported that each one-point increase in PAM score is associated with a 2% reduction in hospitalizations, a 2% increase in medication adherence, and fewer emergency department visits [5]. Thus, our findings contribute to the ongoing discussion regarding the threshold for clinical relevance in patient activation

Received May 16, 2025; accepted May 29, 2025

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Maintenance of patient activation at six-month follow-up

It is important to note regarding the loss of significance in patient activation at the six-month follow-up that the effects observed in the intervention group remained nearly stable over time, whereas the control group demonstrated a marked improvement (see Fig. 3 in Ref [1]). We suspect this discrepancy may be attributed to differences in recruitment strategies. Both groups were recruited within six months of initial diagnosis, disease progression, or recurrence. In the intervention group (IG), patients independently and actively sought CIH counseling (a passive recruitment approach), whereas in the control group (CO), patients were actively approached by study staff during waiting times in the day clinic’s CCC. Therefore, CO patients were often recruited at an earlier stage of their disease—frequently during the initial oncological treatments such as surgery, chemotherapy, or radiation. Consequently, after six months—when primary oncological treatments may have concluded—the CO might have experienced a natural improvement in their activation levels. In contrast, patients in the IG could still have been undergoing treatment, resulting in relatively stable scores. Nonetheless, the reduction or lack of change in PAM-13 scores during the follow-up in the intervention group is consistent with findings reported in previous studies [6,7].

Study design and potential biases

Although randomized controlled trials are considered the gold standard for clinical research, particularly in pharmaceutical studies, this approach is not always applicable in health services research [8–10]. Our

naturalistic, non-randomized, implementation design was selected to better reflect real-world clinical conditions and address ethical considerations [2]. Notably, a classical parallel-group design with patient-level randomization was not feasible, as previous studies have demonstrated that patients with a high need for CIH counseling cannot be effectively randomized [11]. While this design carries inherent risks of selection bias and residual confounding, we employed rigorous statistical adjustments to minimize these effects. Nonetheless, as acknowledged in our limitations, the possibility of unmeasured confounding effects—arising from factors such as concurrent psychosocial support or differing patient expectations—cannot be entirely excluded.

Complement to the effectiveness evaluation, an ongoing mixed-method process evaluation was also conducted based on the Consolidated Framework for Implementation Research (CFIR), which examined the perspectives of the patients and the counseling teams [12]. Therefore, patients' perceptions on the counseling sessions as well as integration of the CIH interventions into their daily lives and health care were examined by interviewing patients [13,14]. In addition, interactions between patients and healthcare providers were examined by analyzing focus groups and patient interviews allowing insights into counseling styles [15].

Heterogeneity in counseling delivery

To ensure standardized, evidence-based CIH counseling, all team members completed a mandatory blended-learning training program. Additionally, symptom-specific guidelines (e.g., for chemotherapy-induced nausea and vomiting) were developed through structured literature reviews and expert consensus [2]. While individual counseling styles and patient-provider interactions may have influenced outcomes, this variability also reflects a strength of our approach—allowing for tailored counseling based on patients' PAM levels, resources, and needs, in line with international recommendations [16,17]. A formal evaluation of implementation fidelity would have further enhanced insights, as systematic fidelity assessments are essential for replicating intervention effects across settings [18].

Assessment of post-counseling adherence to CIH interventions

The primary outcome and focus was on measuring patient activation indicator of a patient's knowledge, skills, and self-management [19]. We agree that assessing adherence to CIH recommendations (e.g., exercise, nutritional changes, stress management) as a secondary outcome would provide a more comprehensive evaluation of the intervention's real-world impact. However, given the already extensive assessment of primary and secondary outcomes, we aimed to avoid overburdening and overwhelming patients in their oncological situation (see inclusion criteria).

Broader systemic considerations

Integrating CIH counseling into routine oncology care within a naturalistic implementation trial presents systemic challenges, including provider training, logistical constraints, and resource allocation. As discussed in our paper, these factors can impact the generalizability and scalability of such interventions. While our findings may not be fully transferable to all settings and healthcare systems, they provide valuable insights into the role of CIH in oncology care.

In summary, our study provides new evidence on the potential benefits of interprofessional CIH counseling for patient activation. We further agree with Ardila and Yadalam emphasizing the need for additional research to refine the intervention, assess its long-term sustainability, and explore its broader integration into clinical practice, considering the points discussed above.

Compliance with ethics guidelines

Conflicts of interest Jan Valentini, Daniela Froehlich, Cornelia Mahler, and Stefanie Joos declare no conflicts of interest.

This manuscript is a correspondence and does not involve a research protocol requiring approval by the relevant institutional review board or ethics committee.

References

1. Valentini J, Froehlich D, Roesel I, Stolz R, Mahler C, Martus P, Klafke N, Horneber M, Witte C, Kramer K, Greil C, Gruen B, Tomaschko-Ubelaender K, Joos S. Enhancing patient activation: a controlled implementation study of an interprofessional evidence-based counseling program for complementary and integrative healthcare in cancer patients ('CCC-Integrativ'). Front Med 2024; 18(6): 1013–1025
2. Valentini J, Fröhlich D, Stolz R, Mahler C, Martus P, Klafke N, Horneber M, Frasch J, Kramer K, Bertz H, Grün B, Tomaschko-Ubeländer K, Joos S. Interprofessional evidence-based counselling programme for complementary and integrative healthcare in patients with cancer: study protocol for the controlled implementation study CCC-Integrativ. BMJ Open 2022; 12(2): e055076
3. Wright A, Hannon J, Hegedus EJ, Kavchak AE. Clinimetrics corner: a closer look at the minimal clinically important difference (MCID). J Manual Manip Ther 2012; 20(3): 160–166
4. Ganju J. Why "minimal clinically important difference" for interpreting the magnitude of the treatment effect is not useful.

Pharm Stat 2025; 24(3): e70015
5. Hibbard JH, Greene J. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. Health Aff (Millwood) 2013; 32(2): 207–214
6. Krouse RS, Grant M, McCorkle R, Wendel CS, Cobb MD, Tallman NJ, Ercolano E, Sun V, Hibbard JH, Hornbrook MC. A chronic care ostomy self-management program for cancer survivors. Psychooncology 2016; 25(5): 574–581
7. Lemanska A, Poole K, Manders R, Marshall J, Nazar Z, Noble K, Saxton JM, Turner L, Warner G, Griffin BA, Faithfull S. Patient activation and patient-reported outcomes of men from a community pharmacy lifestyle intervention after prostate cancer treatment. Support Care Cancer 2022; 30(1): 347–358
8. Soumerai SB, Ceccarelli R, Koppel R. False dichotomies and health policy research designs: randomized trials are not always the answer. J Gen Intern Med 2017; 32(2): 204–209
9. Fernainy P, Cohen AA, Murray E, Losina E, Lamontagne F, Sourial N. Rethinking the pros and cons of randomized controlled trials and observational studies in the era of big data and advanced methods: a panel discussion. BMC Proc 2024; 18(Suppl 2): 1
10. Frieden TR. Evidence for health decision making—beyond randomized, controlled trials. N Engl J Med 2017; 377(5): 465–475
11. D'Egidio V, Sestili C, Mancino M, Sciarra I, Cocchiara R, Backhaus I, Mannocci A, De Luca A, Frusone F, Monti M, La Torre G. Counseling interventions delivered in women with breast cancer to improve health-related quality of life: a systematic review. Qual Life Res 2017; 26(10): 2573–2592
12. Bossert J, Mahler C, Boltenhagen U, Kaltenbach A, Froehlich D, Szecsenyi J, Wensing M, Joos S, Klafke N. Protocol for the process evaluation of a counselling intervention designed to educate cancer patients on complementary and integrative health care and promote interprofessional collaboration in this area (the CCC-Integrativ study). PLoS One 2022; 17(5): e0268091
13. Dürsch H, Boltenhagen U, Mahler C, Joos S, Joachim S, Klafke N. A qualitative investigation of factors influencing the integration of complementary and integrative healthcare recommendations in the daily lives of patients with cancer. Integr Cancer Ther 2024; 23: 15347354241252195
14. Dürsch H, Boltenhagen U, Mahler C, Joos S, Szecsenyi J, Klafke N. A qualitative analysis of cancer patients' perceptions of an interprofessional counseling service on complementary and integrative healthcare. Qual Health Res 2024; 34(12): 1132–1146
15. Klafke N, Bossert J, Boltenhagen U, Froehlich D, Mahler C, Joos S, Wensing M. Counseling lifestyle medicine in oncology: a qualitative analysis of interprofessional patient-nurse-physician interactions. Patient Educ Couns 2024; 127: 108352
16. Leitlinienprogramm Onkologie. (Deutsche Krebsgesellschaft, D. K., AWMF) S3-Leitlinie Komplementärmedizin in der Behandlung von onkologischen PatientInnen, Langversion 2.0, 2024, AWMF-Registernummer: 032–055OL. 2024. Available at https://www.leitlinienprogramm-onkologie.de/leitlinien/komplementaermedizin/
17. Harvey L, Fowles JB, Xi M, Terry P. When activation changes, what else changes? The relationship between change in patient activation measure (PAM) and employees' health status and health behaviors. Patient Educ Couns 2012; 88(2): 338–343
18. Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. Implement Sci 2007; 2(1): 40
19. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. Health Serv Res 2005; 40(6 Pt 1): 1918–1930