

Letter to the Editor

Posttrial Withdrawal Ethics in the Healthy Ageing Ecosystem for People With Dementia (HAAL) Study

Praisewin Johny, MSW, MBA; Anish KR, PhD

Rajagiri College of Social Sciences (Autonomous), Cochin, Kerala, India

Corresponding Author:

Praisewin Johny, MSW, MBA

Rajagiri College of Social Sciences (Autonomous)

Rajagiri P.O

Kalamassery

Cochin, Kerala, 683104

India

Phone: 91 6238981847

Email: praisewinjohn@gmail.com

Related Articles:

Comment on: <https://www.researchprotocols.org/2025/1/e59860/>

Comment on: <https://www.researchprotocols.org/2026/1/e95516/>

(*JMIR Res Protoc* 2026;15:e93636) doi: [10.2196/93636](https://doi.org/10.2196/93636)

KEYWORDS

older people; dementia; dashboard; technology for older adults; digital health; eHealth; innovation in health care

Letter to the Editor

This letter addresses the protocol by Amabili et al [1] for the Healthy Ageing Ecosystem for People with Dementia (HAAL) study. While the rigorous user-centered design is commendable, an ethical concern about posttrial responsibilities warrants discussion in assistive technology research.

The protocol describes a 3-month deployment of an integrated smart home ecosystem, followed by system removal at the final evaluation [1]. Participants received training, adapted their care routines around the technology, and showed reduced stress in preliminary findings. However, the protocol contains no explicit provisions for posttrial access or management of dependency effects when beneficial interventions are withdrawn.

This raises a critical question: What are researchers' responsibilities to participants who integrate assistive technologies into daily life, particularly vulnerable older adults with progressive cognitive decline and their already-burdened caregivers?

International research ethics frameworks recognize that responsibilities extend beyond intervention periods. The Declaration of Helsinki requires planning for continued access to beneficial interventions [2]. Clinical trial withdrawal studies document that stopping beneficial interventions causes distress for participants and creates tension between beneficence and research constraints [3]. When assistive technologies become

integrated into daily care routines and are then removed, loss of perceived independence or safety constitutes an ethical problem [4].

For people with dementia and their caregivers, this concern carries particular weight. Caregivers may restructure routines around monitoring alerts and experience genuine stress relief. Removing supports after 3 months risks reversing benefits and creating new harms: increased anxiety, perceived safety loss, and care pattern disruption.

Assistive technology feasibility studies should adopt posttrial continuity and transition protocols including (1) explicit disclosure about posttrial plans in consent documents; (2) gradual tapering rather than abrupt removal; (3) transition support periods with counseling and alternative resources; (4) continuation pathways where feasible; and (5) systematic assessment of withdrawal impacts, reported transparently.

This critique does not suggest the HAAL study was unethical; feasibility pilots routinely involve temporary deployment and participants were informed [1]. Rather, as our field matures, frameworks bridging clinical research ethics (emphasizing posttrial access) with technology research (treating devices as temporary interventions) must be developed [5].

The HAAL protocol represents important innovation. Building on this foundation, our community should address the ethical gap between validating assistive technologies and responsibly managing their withdrawal from participants' lives.

Conflicts of Interest

None declared.

References

1. Amabili G, Maranesi E, Barbarossa F, Margaritini A, Bonfigli AR, Su F, et al. A dashboard for managing an ecosystem and people with dementia: protocol for a Healthy Ageing Ecosystem for People With Dementia (HAAL) international feasibility pilot study. *JMIR Res Protoc*. Aug 06, 2025;14:e59860. [FREE Full text] [doi: [10.2196/59860](https://doi.org/10.2196/59860)] [Medline: [40768258](https://pubmed.ncbi.nlm.nih.gov/40768258/)]
2. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA*. Nov 27, 2013;310(20):2191-2194. [doi: [10.1001/jama.2013.281053](https://doi.org/10.1001/jama.2013.281053)] [Medline: [24141714](https://pubmed.ncbi.nlm.nih.gov/24141714/)]
3. Jacobs E, Murphy-Beiner A, Rouiller I, Nutt D, Spriggs MJ. When the trial ends: the case for post-trial provisions in clinical psychedelic research. *Neuroethics*. 2024;17(1):3. [FREE Full text] [doi: [10.1007/s12152-023-09536-z](https://doi.org/10.1007/s12152-023-09536-z)] [Medline: [37942467](https://pubmed.ncbi.nlm.nih.gov/37942467/)]
4. Report of the independent expert on the enjoyment of all human rights by older persons (A/HRC/36/48). United Nations General Assembly. 2017. URL: <https://docs.un.org/en/A/HRC/36/48> [accessed 2026-03-25]
5. Morain SR, O'Rourke PP, Ali J, Rahimzadeh V, Check DK, Bosworth HB, et al. Post-trial responsibilities in pragmatic clinical trials: fulfilling the promise of research to drive real-world change. *Learn Health Syst*. Jul 2024;8(3):e10413. [FREE Full text] [doi: [10.1002/lrh2.10413](https://doi.org/10.1002/lrh2.10413)] [Medline: [39036536](https://pubmed.ncbi.nlm.nih.gov/39036536/)]

Abbreviations

HAAL: Healthy Ageing Ecosystem for People with Dementia

Edited by S Nedunchezhiyan; this is a non-peer-reviewed article. Submitted 17.Feb.2026; accepted 17.Mar.2026; published 08.May.2026.

Please cite as:

Johny P, KR A

Posttrial Withdrawal Ethics in the Healthy Ageing Ecosystem for People With Dementia (HAAL) Study

JMIR Res Protoc 2026;15:e93636

URL: <https://www.researchprotocols.org/2026/1/e93636>

doi: [10.2196/93636](https://doi.org/10.2196/93636)

PMID:

©Praisewin Johny, Anish KR. Originally published in *JMIR Research Protocols* (<https://www.researchprotocols.org>), 08.May.2026. This is an open-access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in *JMIR Research Protocols*, is properly cited. The complete bibliographic information, a link to the original publication on <https://www.researchprotocols.org>, as well as this copyright and license information must be included.