

Development of a Novel Clinical Outcome Assessment: The Digital Instrumental Activities of Daily Living Scale

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Introduction: With the proliferation of digital technology, previously non-digital activities have come to be performed digitally and new inherently digital activities have become essential to daily life [1]. Digital exclusion is now associated with higher functional dependence [2], and people with motor disabilities are at the highest risk of digital exclusion. People with motor impairments report significantly higher satisfaction and quality of life when they are able to use digital devices to support daily functioning compared to those who don't [3], and continuous access to a digital environment should be considered a basic human right for those with severe disability [4]. However, assessment tools that can accommodate digital performance of instrumental activities of daily living (IADLs) for those living with severe quadriplegia are lacking. This gap was emphasized during the joint FDA and NIH workshop on implantable brain-computer interface clinical outcome assessments held in September 2024. To address this need in-part, our aim was to develop a novel Digital IADL Scale for research and clinical practice.

Materials, Methods and Results: This study comprised a multi-stage methodology, aligned with FDA guidance for the development of clinical outcome assessments. The methodology included: (i) deductive item generation (systematic review), (ii) inductive item generation (survey and interview of people with lived experience), (iii) item refinement and rating (key opinion leaders and people with lived experience), and (iv) focus group discussions (by key opinion leaders and people with lived experience).

71 validated IADL scales were retrieved. 935 items were extracted from the scales identified during database searching, and 315 items were added from grey literature (total n=1250 items). Of these items, 224 were excluded on the basis of being purely cognitive and 260 were BADLs and removed. A further 414 items were removed as they were deemed unable to be performed digitally in their entirety. Remaining items were deduplicated, reducing the number of items to 77. The remaining 77 items were presented in the Delphi process and reduced to 42 items during two survey rounds. People with lived experience inductively generated 152 items, which were reduced to 41 through a deduplication process. 83 items (42 deductive, 41 inductive) were evaluated by experts for representativeness within their domain and eight items were removed. In response to focus group feedback, the list was reduced to 37 items.

Conclusion: The aim of this study was to develop a set of domains, items and accompanying scoring scale that would address an important gap in the clinical assessment of functional independence in a world that can be empowered by digital technologies. This process created an initial draft of a scale to assess digital functional independence, which will be submitted to further validation.

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[1] Fessler, E. B., Brown, R. T., & Miller, R. K. (2022). Rebooting instrumental activities of daily living for the 21st century. *Annals of Internal Medicine*, 175(3), 278–279. <https://doi.org/10.7326/M21-3065>. [2] Lu, X., Yao, Y., & Jin, Y. (2022). Digital exclusion and functional dependence in older people: Findings from five longitudinal cohort studies. *EClinicalMedicine*, 54, 101708. <https://doi.org/10.1016/j.eclinm.2022.101708>. [3] Rigby, P., Ryan, S. E., & Campbell, K. A. (2011). Electronic aids to daily living and quality of life for persons with tetraplegia. *Disability and Rehabilitation: Assistive Technology*, 6(3), 260–267. [4] United Nations General Assembly (2016). Human Rights Council thirty-second session, agenda item 3: promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development. Retrieved from https://www.unhcr.org/data/files/Internet_Statement_Adopted.pdf;