Applying a Human-Centered Innovation Biodesign Framework in the Development and Piloting of a Program to Mitigate Cognitive Decline Among Historically Underrepresented Patients

Rebecca Lassell, Adamantia Metaxas, Katherine Wang, Sara Hantgan, Prabhat Gottipati, Sarah Zwerling, Triana Pena, Chava Pollak, Sunit Jariwala

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Rebecca Lassell[1, 2] PhD, OTR; Adamantia Metaxas[3]; Katherine Wang[4]; Sara Hantgan[5]; Prabhat Gottipati[6]; Sarah Zwerling[7]; Triana Pena[1] BSN; Chava Pollak[8]; Sunit Jariwala[9] MD

[1]Department of Health and Wellness Design, School of Public Health, Indiana University Bloomington US
[2]Regenstrief Institute, Indiana University Center for Aging Research Indianapolis US
[3]Department of Chemistry, Princeton University Princeton US
[4]Albert Einstein College of Medicine Bronx US
[5]University of Michigan School of Information, University of Michigan School of Literature Science and the Arts, Michigan Medicine Department of Computational Medicine and Bioinformatics Ann Arbor US
[6]Department of Politics, Princeton University and Department of Neuroscience, Princeton University Princeton US
[7]Roslyn High School Roslyn Heights US
[8]Department of Medicine, Albert Einstein College of Medicine Bronx US
[9]Division of Allergy/Immunology, Albert Einstein College of Medicine Bronx US

Corresponding Author:
Chava Pollak
Department of Medicine, Albert Einstein College of Medicine
1225 Morris Park Ave, Van Etten 308a
Bronx
US

Abstract

Background: Roughly 40% of Alzheimer's disease (AD) and AD related dementias (ADRD) and up to 20% of AD/ADRD deaths are preventable by addressing modifiable risk factors like physical inactivity. Past programs and technologies to promote and measure physical activity often overlook the voices of the end-user in minoritized groups living with AD/ADRD, or memory challenges.

Objective: We apply a human-centered design framework as a call to action to address these gaps and provide a use case.

Methods: We applied a human-centered design based on our published Innovation Biodesign framework, to identify clinical needs and map solutions, including gaps in the design and usability testing of technology to measure and monitor physical activity in dementia care. We illustrated the implementation of the framework utilizing a needs assessment and secondary data from the co-design process of a Green Activity Program that tailors nature or "green" activities to improve well-being measuring sleep, activity, and heart rate using the ActiGraph LEAP activity tracker. The program was designed in collaboration with multiple partners, including Hispanic/Latino individuals living with memory challenges in the Bronx, New York.

Results: The framework involved problem and solution spaces with an iterative refinement process and highlighted a need to utilize human-centered approaches to select, monitor, and assess desired outcomes of well-being, activity, and sleep for Hispanic/Latino people living with memory challenges. The framework enabled us to conduct a needs assessment and an iterative co-design process to design the program and a future pilot study utilizing the ActiGraph LEAP.

Conclusions: The framework empowered us to identify and characterize a clinical problem and gaps in the use of technology to measure and monitor physical activity and advance towards a solution space when designing the Green Activity Program to address the unique social needs of older Hispanic/Latino people living with memory challenges. Application of the framework serves as a call to action to apply human-centered approaches to address the clinical needs of minoritized groups with memory challenges. Clinical Trial: ClinicalTrials.gov NCT06403345.

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Rebecca KF Lassell,[1,2] Adamantia Metaxas[3], Katherine Wang,[4] Sara Hantgan,[5] Prabhat Gottipati,[6] Sarah Zwerling,[7] Triana Pena,[1] Chava Pollak[7], Sunit Jariwala[8]

[1]Department of Health and Wellness Design, School of Public Health, Indiana University, Bloomington, IN, United States
[2]Regenstrief Institute, Indiana University Center for Aging Research, Indianapolis, IN, United States
[3]Department of Chemistry, Princeton University, Princeton, New Jersey, United States
[4]Albert Einstein College of Medicine, Bronx, NY, USA
[5]University of Michigan School of Information, University of Michigan School of Literature Science and the Arts, Michigan Medicine Department of Computational Medicine and Bioinformatics [5]
[6]Department of Politics, Princeton University and Department of Neuroscience, Princeton University.
[7]Roslyn High School, Roslyn Heights, NY.
[8]Department of Medicine, Albert Einstein College of Medicine, Bronx, NY, United States
[9]Division of Allergy/Immunology, Albert Einstein College of Medicine, Bronx, New York, United States

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Trial Registration: ClinicalTrials.gov NCT06403345.

Keywords: user-centered design; medical innovation; Alzheimer's disease; dementia; lifestyle intervention; nature-based

Introduction

Approximately 40% of Alzheimer's disease (AD) and AD related dementias (ADRD)[1] and an estimated 20% of AD deaths as the primary cause of death[2] can be prevented by addressing modifiable risk factors like physical activity. Among the most vulnerable for developing AD/ADRD, are individuals who experience distinct social determinants of health, or external structural and social factors that can increase health risk. Living with lower resources, having lower levels of education, and membership of racial and ethnic groups that have been minoritized in the United States can increase stress and collectively contribute to heightened risk of AD/ADRD and cognitive decline.[3,4] Individuals who identify as Hispanic/Latino residing in the Bronx, New York face multiple risk factors for cognitive decline and are amongst the most vulnerable for developing AD/ADRD.[5] While there are many terms to describe individuals of Hispanic origin and AD/ADRD, we will use the terms "Hispanic/Latino" and "memory challenges," herein, based on participant preferences.

Engaging in an active lifestyle is a key modifiable risk factor for cognitive decline and memory challenges later in life.[1] Yet, Hispanic/Latino individuals are scarcely included in research to design interventions and programs to mitigate risk factors for cognitive decline.[6,7] Researchers, healthcare professionals, public health policy makers, and those living with AD/ADRD are well positioned for developing and implementing collaborative interventions to reduce risk for cognitive decline by applying technology and health programming to address modifiable risk factors and support health equity.

Technology to Address Risk Factors for Memory Challenges

The rapidly evolving digital landscape in healthcare presents promising solutions to address modifiable risk factors, such as physical inactivity, sleep, and stress associated with cognitive decline. A recent review found 19 systematic reviews and meta-analyses on technology to prevent cognitive decline for healthy individuals and those with memory challenges published in the past 12 years.[8] Previous technologies developed for memory challenges include computerized cognitive training programs, virtual reality (VR) interventions, robot-assisted interventions, and wearable technologies such as sensors and activity trackers. Computerized cognitive training includes game-based cognitive exercises,[9] such as Luminosity, Brainer1, and Nintendo Wii Big Brain Academy, require adults to remember to perform a particular task as a specific time, which can translate to real-life memory applications, such as remembering to take medications at breakfast. VR interventions, such as those developed by Nintendo and

Xbox involve physical and cognitive engagement that closely resemble reality.[8] Robot-assisted interventions such as humanoid robots like the Sil-bot, provide users with the feeling of interacting with a "real person." These types of technologies require the simulation of–and have potential to improve–cognition, memory, attention, processing speed, and visual spatial ability. Previous technologies have also largely focused on addressing the training of caregivers, improving medication management via pill bottle sensors, pill organizers, and in-home dispensers.[10] Limitations of these technologies include confusion between interacting with the technology and the "real" world for individuals with cognitive impairments, low quality studies that are reflective of early-stage research, and limited understanding of the long-term effects. [8] Another limitation across these technologies is end-user acceptance by people living with memory challenges and their care partners.

Prior research has applied activity tracking technology to people living with memory challenges as an outcome measure physical activity. Xu et al.[11] utilized activity or fitness trackers and machine learning to predict mild cognitive impairment. Additionally, physical activity is currently being assessed as a digital biomarker for AD.[12,13] Though varying definitions exist,[14] a digital biomarker is an objective, physiological, or behavioral measure collected from a digital device[15]used to predict or explain a health outcome.[15] [12,13] The ActiGraph, a research grade activity tracker, has been used to measure activity and agitation in individuals living in the later stages of memory challenges in nursing homes,[16] and assess sleep,[17] and sedentary behavior for individuals dwelling in the community.[18] Few activity tracker studies include usability testing or perceptions from people living with memory challenges.[19,20] This is important as applying human-centered design approaches to incorporate people living with memory challenges can increase activity tracker adherence and time wearing the device,[20] which is essential for assessing and monitoring the effectiveness of physical activity programs in populations who are at heightened risk for cognitive decline. Ensuring robust usability testing processes and tools is essential for developing effective and accessible technologies for lifestyle interventions to stave off or lessen declines related to memory challenges.

Usability Testing of Activity Trackers for People Living with AD/ADRD

Usability is commonly defined as effectiveness (work completion), efficiency (resources spent), and satisfaction (user reactions),[21] however, this definition does not consider the perceived usability by the end user. The Systems Usability Scale was developed to include this critical dimension for evaluating usability of a system or technology. [22] Still, currently available tools to assess usability, including the SUS have not been geared towards individuals with memory challenges. Recently, tools have been developed to measure the users experience in individuals experiencing cognitive impairment, such as Holden's Simplified Systems Usability Scale (SSUS).[23] As a result, usability is beginning to be explored for people living with Mild Cognitive Impairment (MCI) and memory challenges[20] but is not widely assessed and reported.

There has also been growing interest in human-centered design approaches like co-design methods for individuals that include the end-user's perspective to develop technologies, products, and health interventions.[24] Co-design has grown in popularity for individuals experiencing memory challenges. However, many of these studies have been conducted with non-Hispanic White populations of European descent,[25] or have been caregiver focused,[10,26,27] and have not included diverse perspectives of people living with memory challenges from minoritized groups who are disproportionately impacted by AD/ADRD, such as individuals who identify as Hispanic/Latino.[28]

One way to address these gaps is by including individuals from minoritized groups in the design

process by applying human-centered design approaches. The purpose of the current study was to describe the application of an Innovation Biodesign framework.[29] for the co-design of a human-centered intervention to improve physical activity, sleep, and well-being and assess usability of an ActiGraph LEAP activity tracker to assess outcomes in Hispanic/Latino individuals with memory challenges.

Utilizing Human-Centered Design Approaches: The Innovation Biodesign Framework

Human-centered design is an umbrella term for a flexible and replicable approach to innovation that prioritizes human values and experiences when creating and implementing complex systems, services, or products.[30] While there is disagreement about what "human" means, key design principles include placing the human experience at the center of the design, understanding the demands on users, tasks, and the environment; involving the end-user in every step of the process; and applying user-centered evaluation to iteratively refine the design.[30,31] Human-centered design principles are applied across disciplines and sectors from developing technology, products, services, and mobile health (mHealth), to healthcare programing to promote behavior change. One critique of human-centered design is that it utilizes broad methods of engagement and can lack systematic processes to ensure rigor and quality. Particularly, end-user engagement can occur through observations, or more structured co-design with the end user's input through participatory design sessions, town halls, focus groups, or individual interviews.[24] Utilizing a human-centered design framework can help mitigate this with a systematic process to map the application of human-centered design principles across the development and testing of an intervention or program. One human-centered design framework specifically designed to identify and solve unmet clinical needs of populations experiencing health disparities is the published Innovation Biodesign (IB) framework.

The human-centered IB framework has been designed to include the voices of underrepresented populations in the design process and can be helpful for mapping the development and piloting of healthcare innovations, technologies, and programs.[29] The framework enables researchers to identify unmet healthcare needs through clinical observation and patient feedback and develop, pilot, and iteratively refine user-centered solutions.[32] The IB framework is a helpful approach for clinicians and researchers seeking to solve problems identified by their patients, community, and healthcare partners. In this article, we apply the IB Framework to a use case involving a nature or "Green" Activity Program to address the unmet need of physical inactivity to move from the "problem space" to the "solution space" in a specific at-risk population.

The Green Activity Program

The Green Activity Program (GAP) was co-designed with individuals who identified as Hispanic/Latino with mild memory challenges (MCI and AD/ADRD), to promote an active lifestyle and prevent cognitive decline.[33] As part of the co-design process, participants identified preferred terms of "Hispanic/Latino" and "memory challenges" to describe MCI and AD/ADRD. The program promotes an active lifestyle in a social context through the skillful tailoring of local nature activities a person enjoys and is delivered by occupational therapists. The GAP involves an assessment, goal-setting, a tailored Green Activity Plan, in-person visits, and phone check-ins for 12 weeks. The GAP and key aspects of the pilot study were co-designed to meet the preferences and needs of Hispanic/Latino community members with memory challenges.[33] Furthermore, the program was designed with input from multiple partners, including local healthcare and nature organizations to avoid previous challenges with buy-in[34] that have occurred in green prescribing programs in other countries.

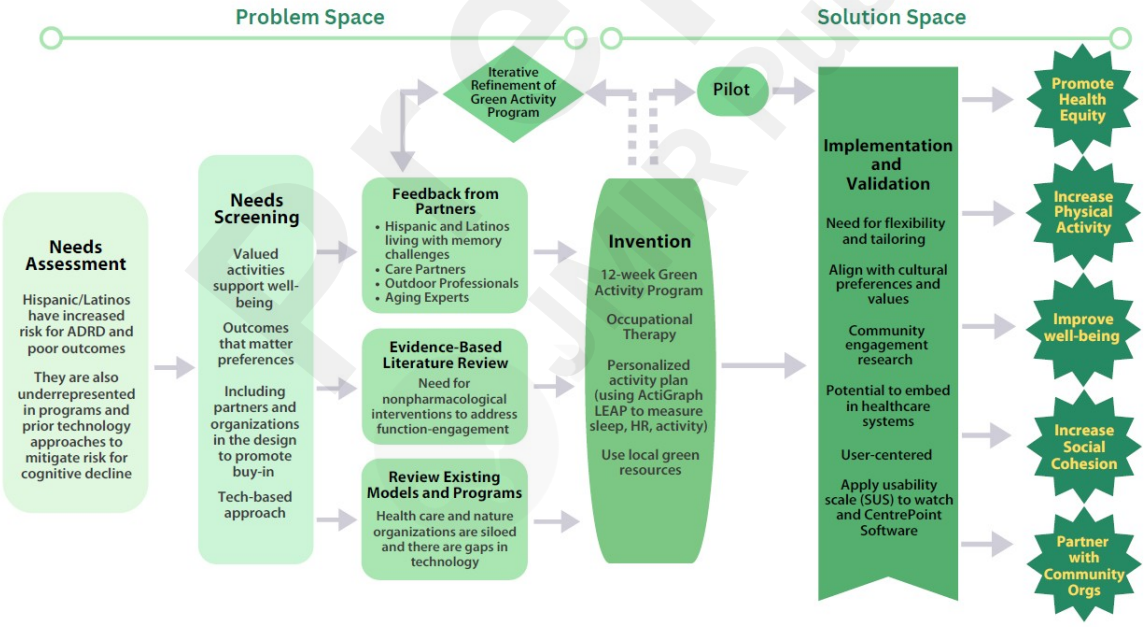
Applying the human-centered IB framework enables the depiction of user involvement from development through the dissemination phases of an intervention or program. Particularly, the framework helped depict piloting the GAP using the ActiGraph LEAP and the mobile CentrePoint® Connect application to measure participant requested outcomes of sleep and well-being (Heart rate, and activity) and assess usability in Hispanic/Latino individuals living with memory challenges. Accordingly, the purpose of this formative paper is to apply the IB framework to map end-user input in the development and piloting of the GAP for Hispanic/Latino people living with memory challenges. This paper serves as a call to action for researchers in the AD/ADRD lifestyle intervention landscape to incorporate the voices of individuals from historically underrepresented groups who are disproportionately impacted by memory challenges via human-centered approaches like the IB framework.

Methods & Results

The Green Activity Program Use Case

To apply the BI framework to the Green Activity Program, we utilized primary data from a needs assessment, and secondary data from co-design sessions that occurred between March 2023 – August 2023 in a previous study for the needs screening "problem space" and "invention" to map an ongoing pilot study (ClinicalTrials.gov NCT06403345), July 2024 - present in the "solution space." See Figure 1.

Figure 1. Applying the Innovation Biodesign Framework to map the development and piloting of a Green Activity Program for patients with memory challenges



Problem Space

Needs Assessment. We identified needs in relation to activity tracker and monitoring technologies for individuals with memory challenges and prior green prescribing programs (Table 1). [27,2825]

Table 1. Needs assessment and summary of prior activity tracker and remote monitoring technology

approaches for people living with memory challenges

Authors	Technology	Population	Outcomes	Gaps
Omberg[35]	Remote-smartphone monitoring involving 5 active assessments	Parkinson's Disease	Task performance was predictive of self-reported PD status and correlated with in-clinic evaluation	Challenges with retention, engagement, and measurement of confounding effects that might impact remote assessments
Muurling[20]	Remote monitoring technologies: Axivity, Fitbit), a wearable camera (Autographer), and an active smartphone app (Mezurio)	Alzheimer's Disease (AD)	RADAR-AD shows that age and impairment are not fundamental barriers to successful remote monitoring, given that wear time of the activity trackers and wearable camera was high (>86%).	The commitment and compliance rates might be inflated due to the consistent rapport between researchers, participants, and caregivers developed by bi-weekly semi-structured phone interviews.
Muurling[36]	Augmented reality (AR) apps that recreate instrumental activities of daily living	AD	The digital score from the AR app could significantly distinguish healthy controls from preclinical AD (preAD) and prodromal AD (proAD), and preAD from proAD, both in the outpatient setting and at home, providing a useful cognition measure.	Did not measure attrition rates without consistent researcher engagement with participants or caregiver involvement.
Stavropoulos[37]	User-centered design, public involvement, activity tracker selection	AD	The patient advisory board of the RADAR-AD project chose comfort, convenience, and affordability as the most important aspects of activity devices. The metrics most valued were activity levels and heart rate. Concerns regarding complexity were raised.	Did not include the perspectives of historically underrepresented populations in the United States.
Finnager Garshol[18]	Utilized ActiGraphs to	AD/ADRD	ActiGraphs were used to measure physical	Did not assess usability of the ActiGraph watch.

	measure physical activity and sedentary behavior	activity during a Green Care Farm intervention.

As the GAP is the first comprehensive green prescribing program to include people living with memory challenges, we included studies of nature programming for this population that measured activity with activity trackers. The needs assessment identified a need to include the perspectives of historically underrepresented groups in the United States, particularly Hispanic/Latino individuals living with memory challenges in assessing the useability of activity trackers as part of a green activity programming.

Needs Screening. Needs screening involved end-user engagement through iterative co-design as described in Lassell et. al[33] to inform key elements of the program and research design of the ongoing pilot study. Co-design occurred with Hispanic/Latino individuals living with memory challenges, care partners, outdoor professionals, and interdisciplinary healthcare providers.

Iterative Refinement

Co-design enabled key elements of the program to align with participant preferences and needs. End-users of Hispanic/Latino people living with memory challenges identified a range of nature activities they enjoyed and preferences for program frequency, duration, and delivery based on prior evidence-based programs.[27,29] They underscored the need to offer a range of options for flexible participation that could be tailored according to individual needs and preferences (e.g., 4-8 sessions between 30-90 minutes long). Outdoor professionals provided input on local nature activities and how they would like to be supported by the occupational therapist to participate in the program. Healthcare providers advised on clinical referral pathways including primary care and community-based organizations.

Co-designed elements of the research design were recruitment strategies, including preferences for terminology and language from the end-users, (e.g., people living with memory challenges vs. AD/ADRD and Hispanic/Latino vs. Latinx). All participants identified outcomes that mattered to them (e.g., well-being, connecting with others, sleep). Accordingly, the ActiGraph LEAP is being used to measure sleep and metrics related to well-being (heart rate, activity). We are also piloting the CentrePoint® Connect mobile app to sync participant data in real-time and assess useability for Hispanic/Latino individuals living with memory challenges utilizing the SSUS. If participants find the CentrePoint® Connect mobile app usable, it has the capability to be integrated with electronic health records and could provide real-time monitoring of program adherence and response to healthcare providers to inform clinical care.

Solution Space

Invention: Green Activity Program. Co-design resulted in the creation of a 12-week Green Activity Program that incorporated the preferences and needs of Hispanic/Latino and care partners, local outdoor professionals, and interdisciplinary healthcare providers.[33] The program was designed to meet outcomes that mattered to Hispanic/Latino individuals living with memory challenges. The program involved an occupational therapy assessment, goal-setting, and a tailored green activity plan. The program was designed to align with the preferences and needs of the end-user, Hispanic/Latino individuals living with memory challenges. The program emphasizes using local

community resources to increase access for homebound participants and to promote sustainability.

Implementation & Validation. To be responsive to the end-user's needs, the GAP involves flexible tailoring to accommodate each participants' daily situation and was designed to align with cultural preferences and values of the Hispanic/Latino community (e.g., personalismo [personal relationships], familismo [family identify and responsibility]).[33] The pilot study is being implemented through continued community engagement with local aging organizations that provide services in the Bronx. Participant feedback regarding program feasibility (retention, feasibility of outcome measures, fidelity) and acceptability (questionnaires and interviews) are being gathered. If determined effective, the GAP has significant potential to be embedded into current healthcare systems, with potential reimbursement covered under Medicare plans.[38]

Anticipated Outcomes and Sustainability. Anticipated outcomes of the program include promoting health equity and an active lifestyle, mitigating risk factors for cognitive decline related to physical inactivity and social isolation, and improving patient health outcomes (sleep, well-being) within the Hispanic/Latino community.[33]

The GAP is designed to be sustainable through its use of local resources that are accessible by participants (e.g., ongoing nature activities in their community) with tailored strategies to adapt and integrate green activities into the person's daily routine. Utilizing local green resources may also contribute to social cohesion for participants and their communities. This can be achieved through continued partnerships with local non-profit outdoor organizations who continue to disseminate nature activities within the local community.

Usability data from the ActiGraph LEAP and the CentrePoint® Connect mobile app will also be collected from Hispanic/Latino individuals living with memory challenges utilizing the SSUS. Additionally, qualitative data will be gathered to learn about their experience during the program and using the ActiGraph as a measurement tool to continue to iterative and refine the program prior to efficacy testing.

Discussion

The application of the IB framework[29] use-case of the GAP[39] highlights the utility in mapping the inclusion of the end-user, of an at-risk Hispanic/Latino patient population, in each step of the design process. Utilizing this framework enabled us to map the GAP's progression from development to piloting and identify gaps in activity-tracker usability and monitoring for this population. The framework will continue to guide human-centered refinements through efficacy testing and dissemination as the program develops. Application of this framework serves as a call to action for other researchers to utilize human-centered design frameworks[29,30] to guide research with populations experiencing health disparities.

Principal Results

The IB framework[29] enabled us to map end-user engagement through the application of co-design in

creating the GAP[39] to be responsive to older Hispanic/Latino's preferences and needs. It also provided a map to guide piloting the ActiGraph LEAP and CentrePoint® Connect mobile app as means to measure sleep and outcomes related to well-being (heart rate, and activity) and assess the useability of these technologies. Additionally, the framework enabled the identification of gaps in activity-tracker technology and usability in Hispanic/Latino groups living with memory challenges. Use of the IB framework and other human design frameworks can advance health equity by prioritizing diverse patients' needs and experiences.[29,30]

The current study underscores the benefits of using the IB framework to develop and test interventions and programs with input from multiple partners as well as the end-user. This aligns with the human-centered design principle of involving the user and multiple partners in every step of the design process and understanding the context in which the intervention or program will occur.[31,40] The IB framework provided guiding principles for moving the challenge of addressing physical inactivity in Hispanic/Latino older adults with memory challenges from a "problem space" to a "solution space" informed by the needs and preferences of partners and participants.[29] The inclusion of multi-partner perspectives is an inclusive innovation process that values input from all involved, including older adults living with memory challenges.

Rapid-cycle iterations within the IB framework enable researchers to map human-centered involvement and adapt a program or innovation based on participants' dynamic needs.[29] For example, the rapid-cycle iterations that occurred during co-design of the GAP enabled researchers to update the program in response to participant feedback and insights. Rapid-cycle iterations can help GAP and other health innovations successfully evolve based on the end-users' dynamic preferences and needs, enhancing the program or products accessibility, impact, and reach. This aligns with human-centered design principles of rapid-cycle iterations and refinements based on the end-user's evaluation.[31,40] Next steps for the GAP are to finish piloting the program and receive input from the end-users (participants and partners) on refinements. Once proof of concept and feasibility have been established, next steps include effectiveness testing and maximizing outreach of the program.

Limitations

A limitation of applying the IB framework in the GAP use case is the framework spans development through the dissemination phases of an intervention or program. Our use case is focused on a program that is in the early piloting phase of development and does not provide the full range of the framework through efficacy testing and dissemination. Yet, a strength of our use case is that it shows the utility of using the framework in the early stages of intervention development, which can guide feasibility and piloting through efficacy testing and dissemination.

Comparison with Prior Work

Benefits of utilizing the IB framework from prior research include improved health and digital health literacy for patients.[29] Through its collaborative approach, this framework has improved clinical outcomes but also enabled healthcare providers to offer more personalized care plans, which is especially crucial for patients at-risk for experiencing health disparities. Patients can be better equipped to understand and manage their health conditions. The framework fosters stronger patient-provider relationships, bolstering trust, and communication. For individuals with memory challenges, active involvement in this framework could enhance their grasp of health issues, treatment choices, and self-care strategies. This empowerment may lead to better adherence to treatment and overall well-being, emphasizing a patient's proactive role in health management and aligns with human-centered design principles of prioritizing the human experience.[31] Empowering patients as the end-user can be critical when designing health interventions and innovations that seek to promote health

equity.[40] Other benefits of the framework include patients developing a deeper understanding of their health conditions, treatment options, and self-management strategies which can lead to more informed decisions about their care.[29]

The IB framework can also be helpful for healthcare providers as it fosters the development of cutting-edge medical technologies and solutions tailored to address unmet clinical needs.[29] By integrating engineering, business, and medical disciplines, the framework equips providers with the tools to innovate and improve patient care outcomes effectively. This aligns with human-centered design principle of utilizing a multi-disciplinary team.[31] The IB framework is also highly relevant to multidisciplinary medical and clinical informatics professionals because it focuses on collaborative and inclusive healthcare innovation with a systematic process to map human-centered design. Public health professionals may also find this framework helpful to develop policies and public health initiatives by using human-centered design principles, such as the end-users' evaluation to iteratively refine a policy for better uptake.[40] This process can guide the development of programs, interventions, and innovations that are specifically designed to meet the needs of diverse populations, which can increase their effectiveness and acceptance.

Conclusions

We applied the Innovation Biodesign Framework in the design and development of the Green Activity Program for Hispanic/Latino older adults with memory challenges. The framework provided a structure for identifying and addressing research gaps in activity-tracker technology in interventions that target modifiable risk factors for cognitive decline such as physical activity and social isolation. Participatory co-design of the Green Activity Program allowed for tailoring of the intervention to the unique needs of Hispanic/Latino older adults with memory challenges and their care partners with the goal of improving buy-in and effectiveness. The framework utilized in the current study can be applied to the development and implementation of other interventions and programs in varied populations to produce innovations that serve the end-user and ensure historically under-represented voices are heard.

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RL conceptualization, data collection, data analysis, writing, and revision of manuscript. AM conceptualization, preparation of tables, writing, and revision of manuscript. KW conceptualization, figure preparation, and writing of manuscript. SH conceptualization, writing, and revision of manuscript. PG conceptualization, writing, and revision of manuscript. SZ figure preparation and writing of manuscript. TP data collection and writing of manuscript. CP writing and revision of manuscript. SJ conceptualization and revision of manuscript.

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Conflicts of Interest

None Declared.

Abbreviations

AD: Alzheimer's disease

AD/ADRD: Alzheimer's disease and Alzheimer's disease related dementias
AR: Augmented Reality
IB: Innovation Biodesign
GAP: Green Activity Program
MCI: Mild Cognitive Impairment

References

1. Livingston G, Huntley J, Sommerlad A, et al. Dementia prevention, intervention, and care: 2020 report of the Lancet Commission. *Lancet*. 2020;396(10248):413-446. doi.org/10.1016/S0140-6736(20)30367-6

2. Sun Y, Chen C, Yu Y, et al. Replacement of leisure-time sedentary behavior with various physical activities and the risk of dementia incidence and mortality: A prospective cohort study. *J Sport Health Sci*. 2023;12(3):287-294. doi.org/10.1016/j.jshs.2022.11.005

3. Pohl DJ, Seblova D, Avila JF, et al. Relationship between Residential Segregation, Later-Life Cognition, and Incident Dementia across Race/Ethnicity. *Public Health*. 2021;18:11233. doi:10.3390/ijerph182111233

4. Babulal GM, Quiroz YT, Albensi BC, et al. Perspectives on ethnic and racial disparities in Alzheimer's disease and related dementias: Update and areas of immediate need. Alzheimers Dement. 2019;15:292. doi:10.1016/j.jalz.2018.09.009

5. Alzheimer's Association. *Researchers Reveal First-Ever U.S. County-Level Alzheimer's Prevalence Estimates.*; 2023.

6. Shaw AR, Perales-Puchalt J, Johnson E, et al. Representation of Racial and Ethnic Minority Populations in Dementia Prevention Trials: A Systematic Review. *J Prev Alzheimers Dis*. 2022;9(1):113-118. doi:10.14283/jpad.2021.49

7. Quiroz YT, Solis M, Aranda MP, et al. Addressing the disparities in dementia risk, early detection and care in Latino populations: Highlights from the second Latinos & Alzheimer's Symposium. 2022. doi:10.100.2/alz.12589

8. Leung C, Kai, Wong C, et al. The application of technology to improve cognition in older adults: A review and suggestions for future directions. *PsyCh J*. 2022. doi:10.1002/pchj.565

9. De Giorgio A, Khurana H, Bhagwat P, et al. Advancing Computerized Cognitive Training for MCI and Alzheimer's Disease in a Pandemic and Post-pandemic World. 2020;11:557571. doi:10.3389/fpsyt.2020.557571

10. Werner NE, Campbell NL, Boustani M, Ganci A, Holden RJ. Helping the Helpers – A research protocol for user-centered technology to aid caregiver management of medications for people with Alzheimer's disease and related dementias. *Res Social Adm Pharm*. 2022;18(9):3680-3686. doi:10.1016/j.sapharm.2022.03.014

11. Xu Q, Kim Y, Chung K, Schulz P, Gottlieb A. Prediction of Mild Cognitive Impairment Status: Pilot

Study of Machine Learning Models Based on Longitudinal Data From Fitness Trackers. *JMIR Form Res*. 2024;8:e55575. doi:10.2196/55575

12. Buegler M, Harms RL, Balasa M, et al. Digital biomarker-based individualized prognosis for people at risk of dementia. *Alzheimer's Dement.* 2020; 12:e12073. doi.org/10.1002/dad2.12073

13. Kourtis, L.C., Regele, O.B., Wright, J.M. *et al.* Digital biomarkers for Alzheimer's disease: the mobile/wearable devices opportunity. *npj Digital Med*. 2019;2:9. doi.org/10.1038/s41746-019-0084-2

14. Alonso M. Definitions of digital biomarkers: a systematic mapping of the biomedical literature. *BMJ Health Care Inform*. 2024;31:100914. doi:10.1136/bmjhci-2023-100914

15. Motahari-Nezhad H, Péntek M, Gulácsi L, Zrubka Z. Outcomes of Digital Biomarker–Based Interventions: Protocol for a Systematic Review of Systematic Reviews. *JMIR Res Protoc*. 2021;10(11):e28204. doi:10.2196/28204

16. Ishimaru D, Tanaka H, Nagata Y, Takabatake S, Nishikawa T. Physical Activity in Severe Dementia Is Associated With Agitation Rather Than Cognitive Function. *Am J Alzheimers Dis Other Demen*. 2019;35:1533317519871397. doi:10.1177/1533317519871397

17. Lysen TS, Luik AI, Kamran M, Tiemeier H, Arfan M, Arfan Ikram CM. Actigraphy-estimated sleep and 24-hour activity rhythms and the risk of dementia. *Alzheimer's Dement.* 2020; 16:9. doi:10.1002/alz.12122

18. Finnanger Garshol B, Ellingsen-Dalskau LH, Pedersen I. Physical activity in people with dementia attending farm-based dementia day care – a comparative actigraphy study. *BMC Geriatr*. 2020;20(1):219. doi:10.1186/s12877-020-01618-4

19. Muurling M, de Boer C, Kozak R, et al. Remote monitoring technologies in Alzheimer's disease: design of the RADAR-AD study. *Alzheimers Res Ther*. 2021;13(1). doi:10.1186/s13195-021-00825-4

20. Muurling M, Hinds C, Wu Y, et al. User Experience and Compliance Rates of Remote Monitoring Technologies in Alzheimer's Disease: Preliminary Results of the RADAR-AD Study. *Alzheimer's Dement.* 2022;18(S5):e064507. doi.org/10.1002/alz.064507

21. International Organization for Standardization. *Ergonomic Requirements for Office Work with Visual Display Terminals (VDTs): Part 11: Guidance on Usability.*1998.

22. Brooke J. SUS-A quick and dirty usability scale. *Usability evaluation in industry*. 1st edition. London: CRC 1996;189(194):4-7. ISBN: 9780429157011

23. Holden RJ. A Simplified System Usability Scale (SUS) for Cognitively Impaired and Older Adults. Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care. 2020;9(1). doi:10.1177/2327857920091021

24. Slattery P, Saeri AK, Bragge P. Research co-design in health: A rapid overview of reviews. *Health Res Policy Syst*. 2020;18(1):1-13. doi:10.1186/S12961-020-0528-9/TABLES/2

25. Fox S, Brown LJE, Antrobus S, et al. Co-design of a Smartphone App for People Living With Dementia by Applying Agile, Iterative Co-design Principles: Development and Usability Study. *JMIR Mhealth Uhealth*. 2022;10(1):e24483. doi:10.2196/24483

26. Rodriguez MJ. Cultural adaptation of a mobile caregiver intervention application for Hispanic caregivers of persons with dementia (PWD). *Alzheimer's Dement*. 2023;19:e072690. doi:10.1002/alz.072690

27. Rathnayake S, Moyle W, Jones C, Calleja P. Co-design of an mHealth application for family caregivers of people with dementia to address functional disability care needs. *Inform Health Soc Care*. 2021;46(1):1-17. doi:10.1080/17538157.2020.1793347

28. Alzheimer's Association. 2023 Alzheimer's disease facts and figures. *Alzheimer's & Dementia*. Published online April 14, 2023. doi:10.1002/alz.13016

29. Metaxas A, Hantgan S, Wang KW, Desai J, Zwerling S, Jariwala SP. A Framework for Social Needs-Based Medical Biodesign Innovation. *Appl Clin Inform*. 2024;15(03):456-459.

30. Holeman I, Kane D. Human-centered design for global health equity. 2019; *Infor Technol Dev*. 2019;*26*(3), 477–505. doi:10.1080/02681102.2019.1667289

31. ISO. *ISO 9241-210: Human-Centered Design for Interactive Systems*.; 2010:1-40.

32. Luff MK, Zarrin DA, Zhou L, et al. Clinical Needs Discovery in Pediatric Urology: Utilizing the Biodesign Process. *Front Urol*. 2022;30:2. doi.org/10.3389/fruro.2022.895057

33. Lassell RK, Tamayo V, Pena TA, et al. "When She Goes out, She Feels Better:" Co-Designing a Green Activity Program with Hispanic/Latino People Living with Memory Challenges and Care Partners. *Front Aging Neurosci*. 2024; 16. doi:10.3389/fnagi.2024.1401255

34. Bergstad CJ, Sörqvist P, Van Den Berg AE. From Green Space to Green Prescriptions: Challenges and Opportunities for Research and Practice. *Front Psychol.* 2017;8:268. doi:10.3389/fpsyg.2017.00268

35. Omberg L, Chaibub Neto E, Perumal TM, et al. Remote smartphone monitoring of Parkinson's disease and individual response to therapy. *Nat Biotechnol*. 2022;40(4). doi:10.1038/s41587-021-00974-9

36. Muurling M, de Boer C, Vairavan S, et al. Augmented reality versus standard tests to assess cognition and function in early Alzheimer's disease. *NPJ Digit Med*. 2023;6(1):234. doi:10.1038/s41746-023-00978-6

37. Stavropoulos TG, Lazarou I, Diaz A, et al. Wearable Devices for Assessing Function in Alzheimer's Disease: A European Public Involvement Activity About the Features and Preferences of Patients and Caregivers. *Front Aging Neurosci*. 2021;13. doi:10.3389/fnagi.2021.643135

38. Centers for Medicare & Medicaid Services. *Medicare & Home Health Care*.; 2023.

39. Holeman I, Kane D. Human-centered design for global health equity. *Inf Technol Devel*. 2019;26:3, 477-505, doi:10.1080/02681102.2019.1667289