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Authors

Aranda, María

Baier, Rosa

Hinton, Ladson

et al.

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Preparing for pragmatic trials in dementia care: Health equity considerations for nonpharmacological interventions

María P. Aranda, PhD[1,2], **Rosa Baier, MPH**[3,4], **Ladson Hinton, MD**[5], **Katherine D. Peak, MPH**[6], **Jonathan D. Jackson, PhD**[7], **Peggye Dilworth-Anderson, PhD**[8], **Laura N. Gitlin, PhD**[9,10,11], **Eric Jutkowitz, PhD**[3,4,12], **Ana R. Quiñones, PhD**[6,13]

[1]Suzanne Dworak-Peck School of Social Work, University of Southern California, Los Angeles, Los Angeles, California, USA

[2]Edward R. Roybal Institute on Aging, University of Southern California, Los Angeles, California, USA

[3]Department of Health Services, Policy & Practice, Brown University School of Public Health, Providence, Rhode Island, USA

[4]Center for Long-Term Care Quality & Innovation, Brown University School of Public Health, Providence, Rhode Island, USA

[5]Department of Psychiatry and Behavioral Sciences, University of California Davis, Sacramento, California, USA

[6]Department of Family Medicine, Oregon Health & Science University, Portland, Oregon, USA

[7]Department of Neurology, Massachusetts General Hospital, Boston, Massachusetts, USA

[8]Department of Health Policy and Management, University of North Carolina, Chapel Hill, North Carolina, USA

[9]College of Nursing and Health Professions, Drexel University, Philadelphia, Pennsylvania, USA

[10]School of Nursing, Johns Hopkins University, Baltimore, Maryland, USA

[11]Center of Innovation in Long Term Services and Supports, Providence VA Medical Center, Providence, Rhode Island, USA

[12]Center for Gerontology & Healthcare Research, Brown University School of Public Health, Providence, Rhode Island, USA

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Correspondence: María P. Aranda, USC Suzanne Dworak-Peck School of Social Work, Montgomery Ross Fisher Bldg., 321, Los Angeles, CA 90089-0411, USA. aranda@usc.edu.

AUTHOR CONTRIBUTIONS

All authors contributed to the conceptual development and provided significant review of the manuscript. All authors have approved this final version.

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None.

SUPPORTING INFORMATION

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[13]OHSU-PSU School of Public Health, Oregon Health & Science University, Portland, Oregon, USA

Abstract

Inequities with regard to brain health, economic costs, and the evidence base for dementia care continue. Achieving health equity in dementia care requires rigorous efforts that ensure disproportionately affected populations participate fully in—and benefit from—clinical research. Embedding-proven interventions under real-world conditions and within existing healthcare systems have the potential to examine the effectiveness of an intervention, improve dementia care, and leverage the use of existing resources. Developing embedded pragmatic controlled trials (ePCT) research designs for nonpharmacological dementia care interventions involves a plethora of a priori assumptions and decisions. Although frameworks exist to determine whether interventions are “ready” for ePCT, there is no heuristic to assess health equity-readiness. We discuss health equity considerations, case examples, and research strategies across ePCT study domains of evidence, risk, and alignment. Future discussions regarding health equity considerations across other domains are needed.

Keywords

dementia care; embedded pragmatic controlled trials; health equity; nonpharmacological interventions; underrepresented groups

INTRODUCTION

Major disparities in cognitive health and dementia care exist in the United States. A recent review identifies continuing inequities with regard to population brain health, economic costs, and the evidence base for dementia care and long-term services and supports.[1] Ensuring that dementia care incorporates equal access to assessment, diagnosis, and evidence-based treatments for all segments of the US population is essential for health equity.[1–3] Achieving health equity in dementia care requires rigorous efforts to ensure that disproportionately affected populations fully participate in clinical research. Health equity refers to having access to assessment, diagnosis, evidence-based care, and supports for all people, including populations with documented health care disparities—namely, historically underrepresented racial and ethnic groups, individuals with low socioeconomic status, underserved rural residents, and sexual and gender minorities.[2–4]

Embedded pragmatic clinical trials (ePCTs)[5,6] provide ways to test proven interventions in healthcare systems within routine clinical practices. Embedding-proven interventions under real-world conditions and within existing healthcare systems have the potential to examine an intervention’s effectiveness, improve dementia care, and leverage existing resources.[7] Achieving health equity in dementia care, and ePCTs more specifically, is an ethical, regulatory, and scientific goal[3,8,9] such that all people have a fair and just opportunity to access evidence-based care and be as healthy as possible.[10] Nonpharmacological interventions in dementia care improve outcomes for people and families living with dementia whether offered singularly, in combination with other nonpharmacological

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interventions, or with pharmacological treatments.[11–13] Developing ePCT designs for nonpharmacological care interventions involves a plethora of a priori assumptions and decisions such as identifying which evidence gaps to address, evaluating an intervention's stage of development and the relative risks and benefits, ascertaining the target population, assessing alignment with person-centered outcomes across multiple collaborators and partners, and selecting relevant design and analytic strategies.

While health equity must be considered in all types of study designs, this is particularly the case for ePCTs in which interventions are evaluated for their implementation and performance in real-world clinical settings with the goal of sustainability in routine care.[14] Although frameworks or guides exist to determine whether an intervention is "ready" to be tested in an ePCT, there is no heuristic or tool to assist researchers to determine whether an intervention is health equity-ready for an ePCT or the best approach when evidence may be partial. Our article addresses this gap by discussing health equity, nonpharmacological interventions, as well as practical considerations and case examples to assess whether an intervention is health equity-ready for an ePCT research design.

ROOT CAUSES OF DISPARITIES AND ePCTS' ROLE IN ACHIEVING HEALTH EQUITY

Given that health equity considerations in ePCT research are not well understood, it is important to recognize the root causes of disparities and the potential role that ePCTs can play in achieving health equity. Ample evidence exists that social factors (gender, age, income, race and ethnicity, education, occupation, place/region, racism, and discrimination) account for wide disparities in health across groups or geographic areas, and are evident in differences in health status, health outcomes, as well as access and quality of health care.[15,16] The underlying causes or mechanisms of health inequities are often complex, multifactorial, and arise from systemic causes such as structural inequities and unequal allocation of power and resources arising in poor social, economic, and environmental conditions and social determinants of health.[17–19]

Why does this matter in ePCT research on behalf of persons living with dementia (PLWD), their families, and care partners? By definition, ePCTs are "pragmatic:" They are meant to test an already-efficacious intervention, treatment, or care program in a real-world treatment setting comprised of existing organizational infrastructure and care processes, with typical patients (relaxed exclusion criteria), delivered by qualified providers (with no/minimal research background), and under less controlled conditions than what is applied to explanatory trials.[7] Therefore, ePCT research for PLWD can inform care delivery models and address health inequities by specifically improving the following sources of inequities: (1) access to care: implementing already-efficacious interventions or programs into wider practice, thus increasing access and generalizability to a wider audience including underrepresented populations; (2) workforce competencies: increasing training and skills development of an existing healthcare workforce already trusted and known to the target population, as well as including a more representative workforce reflecting underrepresented groups; (3) communication: relying on existing organizational infrastructures including

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electronic medical records, health portals, etc., to enhance communication between patient–provider, patient–care partner, and provider–provider on behalf of populations with complex needs; and (4) financing/organization of care: operating within real-world clinical workflows, reimbursement processes, and care delivery protocols to provide insights into implementation and feasibility of proposed interventions deemed acceptable by all collaborators or partners.

NONPHARMACOLOGICAL DEMENTIA CARE INTERVENTIONS: EXISTING FRAMEWORKS FOR DESIGNING PRAGMATIC TRIALS

Ample recognition exists that nonpharmacological dementia care interventions need to be tested within routine clinical practice.[5,6] Currently, there are several frameworks or guides for designing ePCTs and assessing readiness to conduct ePCTs in general: (1) Pragmatic Explanatory Continuum Indicator Summary Framework (PRECIS-2)[20] (Supplemental Table S1); (2) Readiness Assessment for Pragmatic Trials Model (RAPT[21]; see Table 1); and (3) NIH Pragmatic Trials Collaboratory Rethinking Clinical Trials Living®: A Living Textbook of Pragmatic Clinical Trials (Living Textbook of PCTs).[22] The Living Textbook of PCTs provides detailed guidance from developing a compelling ePCT grant application to building partnerships to ensure a successful trial. Both PRECIS-2 and RAPT include nine ePCT design domains that overlap, and provide a scoring tool to ask researchers to qualitatively assess an intervention's level of "readiness" from low to high on a five-point scale, across several domains.

Only the RAPT model addresses dementia care, and none discusses health equity readiness explicitly,[20,21] thus elucidating a key research gap.

Nonpharmacological dementia care interventions present challenges because they are often complex, may be difficult to uniformly implement across multiple sites, generally have low-quality or varying levels of evidence, and have minimal representation of disparity populations in prior efficacy trials.[12,23] Thus, ePCTs have a unique role in advancing the science of nonpharmacological interventions through adoption of proven interventions in real-world settings with routine care providers and existing data systems. However, one challenge for the field is determining which interventions are ready for an ePCT design. Prior to conducting any ePCT, an important step is to assess the readiness of the intervention to be embedded and evaluated in a pragmatic trial. If an intervention is not ready, moving forward "can have serious consequences ranging from wasted time to false conclusions",[21] and missed opportunities to align the intervention with collaborators or partners' preferences, needs, and priorities.

In the following sections, we apply a health equity lens to critically evaluate existing ePCTs readiness assessment frameworks. Based on the authors' extensive experience in intervention development and testing[24] among underrepresented groups and NIH-designated health disparity populations (Supplemental Text S2),[25] we integrate health equity considerations when applying ePCT readiness assessment tools to future research. Although not included in the NIH list of health disparity populations, we acknowledge

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additional populations such as people living with disabilities and people with limited English proficiency.

DETERMINING READINESS THROUGH A HEALTH EQUITY LENS: A FOCUS ON EVIDENCE, RISK, AND ACCEPTABILITY

While health equity is important across all aspects of an ePCT design, we focus on the study domains of Evidence, Risk, and Acceptability because in preparing to conduct an ePCT, an investigative team must first prioritize establishing evidence for the intervention, minimizing risk, and establishing adequate acceptability with underrepresented groups.[11]

Readiness assessment tools for ePCTs ask researchers to qualitatively assess a nonpharmacological intervention's "readiness", from low to high on a five-point scale, across several domains. As previously mentioned, we prioritized three of the nine domains: Evidence, Risk, and Acceptability. Second, we provide select questions for each domain intended to generate discussion, inform decision-making, and practical use of resources. Third, we offer real-world case examples to elucidate how health equity considerations are salient to the three domains. Fourth, we categorize an intervention's health equity readiness along a continuum of three categories: "Low," "Medium," or "High" (Table 1). Lastly, we list possible research strategies to address health equity-readiness, which can be considered ahead of a full ePCT trial.

EVIDENCE

The Evidence domain addresses the extent to which the evidence base supports the intervention's efficacy, such that moving to an ePCT would increase external validity of the findings, that is, increase generalizability. A health equity lens highlights the need to consider the evidence base for underrepresented populations and raises several critical questions. To what extent does the extant evidence support the intervention's efficacy for a new target group and/or health disparity populations? Are there multiple studies using rigorous trial methods that have demonstrated the intervention's efficacy ("is it ready")? If not, does a single study exist that used rigorous trial methods, which demonstrated efficacy with the target population ("is it possibly ready")? Is there evidence to support the efficacy of one of more specific intervention components (of the same or another intervention, e.g., case management; telephone reassurance) to warrant going forward with an ePCT? If not, what preparatory steps or research strategies can be taken to address the evidence gap before embarking on an ePCT? Below is a real-world case example of the Evidence Domain, health equity considerations, and possible research strategies to increase ePCT preparedness (also see Table 2).

Case Example: Evidence

Brief narrative: Agitation and aggression are common neuropsychiatric symptoms in PLWD, and highly distressful to patients, caregivers, and nursing home staff. A behavioral treatment intervention based on environmental modifications to mitigate agitation and aggression in persons with dementia has demonstrated effectiveness in nursing home settings with very

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low health disparities population representation. The current study purports to test the same intervention against routine care in a community-based home care setting with higher representation of diverse racial/ethnic patients, that is, English- and Spanish-speaking Latinx and monolingual English-speaking Black Americans.

Health equity issue: The demonstration of effectiveness for the behavioral trial to address agitation and aggression was well-documented, yet not for the new target population, new treatment setting (environmental factors in particular), or across different languages.

There are racial/ethnic inequities in nursing home quality such that nursing homes with greater proportions of Latinx and Black American residents are more likely to be located in urban areas and to have fewer resources such as lower revenue and staffing levels. These limitations could affect challenges to implementing the intervention. If Latinx and Black American residents are not sufficiently represented in prior trials, the results may not be generalizable to them, and to the facilities in which they reside, and provider groups.

Readiness—Low

Preparatory Strategies:

1. Engage in initial needs assessment to elucidate needs, preferences, etc., across collaborator groups (patients, family members, interventionists, providers, manager-level decision-makers).
2. Establish other collaborator input mechanisms to ascertain the same (focus groups, key informant interviews, etc.).
3. Conduct a scoping review to identify whether similar interventions have been conducted on the new target population, paying attention to sociocultural factors, language/linguistic factors, engagement with index condition (neuropsychiatric symptoms), etc.
4. Identify whether certain components of the proposed intervention have higher levels of evidence for the individual components among the new target populations.
5. Engage in culturally appropriate, translation, and transformation procedures to ensure the intervention procedures (and measures) are attuned to language considerations (Latinx Spanish-language/dialects), and available literacy levels for all subgroups.
6. Conduct a small pilot with nursing home settings, representative target sample, and provider group to establish feasibility and acceptability of the study intervention and research procedures.

RISK

Alongside evidence, it is important to ascertain the level of risk, in other words, to ascertain whether there are any known risks related to the intervention to understudied populations. To establish risk, it is necessary to have tested the intervention with a well-

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characterized sample—which includes participation from underrepresented populations—to carefully track and report safety concerns and adverse events. Relevant health equity considerations involve ascertaining whether there were any serious adverse events and safety monitoring issues in previous trials, how these were managed and monitored, and whether they occurred differentially—or more severely—within some subgroups versus others. Is there high evidence from multiple studies that the risks are known to be minimal and easily attended to by provider interventionists ("ready")? Or, if the risks and discomforts are unknown, have similar interventions indicated that there is no greater discomfort than typically encountered in daily life ("maybe ready"). Or is no risk known and no comparable intervention available to compare previously documented risks ("not ready")? To elucidate health equity considerations based on the Risk Domain, we offer an international case below indicating different levels of ePCT readiness depending on the responses to these questions (also see Table 3).

Below is a real-world case example of the Risk Domain, health equity considerations, and possible research strategies to increase ePCT preparedness (also see Table 3).

Case Example: Risk

Brief narrative: This is a cluster-randomized controlled trial of a multicomponent (REACH VA) family caregiver intervention among Vietnamese family caregivers in northern Vietnam. The study was conducted in a community setting—provincial hospital and associated local healthcare centers. All intervention components will be delivered by local staff at the provincial hospital to the family caregiver who provides the most day-to-day hands-on care. The primary outcomes are caregiver burden and psychological distress. The multicomponent intervention was developed in the United States and tested with racially and ethnically diverse populations in the United States but has not been previously tested in Vietnam. In Vietnam, many PLWD have not been previously diagnosed.

Health equity issue: Substantial global inequities exist in the availability of evidence-based family caregiver interventions in low- and middle-income countries such as Vietnam. Rural populations in Vietnam are particularly vulnerable based on under-resourced healthcare systems and the lack of trained local providers and research personnel to conduct multicomponent intervention models.

There are two sides to the Risk Domain in this case study, and thus two possible levels of readiness. Although risks are unknown in Vietnam, they are likely minimal based on research already conducted in the United States, including among underrepresented groups specifically among Asian Americans. Thus, the level of readiness may be "medium."

There are several potential pitfalls in Vietnam. In rural, family-centered communities, social ties are strong and based on local customs of taking care of one another. Second, the human subjects' assurances of privacy, confidentiality, and protection of health-related information do not have the same saliency and prominence in communities where these research concepts are unfamiliar. Thus, sharing of information may not be readily perceived as a violation of human rights in a country where human rights and rights as a study participant may not be viewed the same as in the United States, for example. Although well-meaning,

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information about an individual's diagnosis, prognosis, and treatment may be shared among nonresearch personnel or local community residents. The potential for risk may be high if additional safeguards are not put into place. Thus, the level of readiness may be "low."

Readiness—Low to medium

Preparatory Strategies:

1. Conduct key informant interviews with local staff and other local experts to: (a) assess feasibility and acceptability of the intervention itself and identify any potential adaptations; (b) assess the capacity of the local healthcare system to sustain the intervention and identify any adaptations that are necessary to achieve this goal; and (c) anticipate any potential harms that may arise from participation in the intervention and strategies to mitigate those risks.
2. Use a theoretical framework to adapt the intervention based on local sociocultural context and resource constraints.
3. Develop a culturally tailored training to address privacy and confidentiality, accounting for local values, attitudes, and potential barriers.
4. Plan subject compensation in accordance with local socioeconomic circumstances and norms to ensure that the amount is not coercive.
5. Assess and strengthen the local health system to support persons identified by the project as having dementia.
6. Conduct a single arm pilot feasibility study to further evaluate feasibility, acceptability and potential risks.

ACCEPTABILITY

Acceptability addresses the extent to which healthcare providers (such as practitioners and staff) are likely to adopt the intervention, or the extent to which they believe the intervention is feasible or needed, as well as how participants experience and value the intervention. Existing frameworks or guides focused on providers as collaborators responsible for embedded implementation of the intervention and were silent on other end users, who may have been engaged at earlier stages of intervention development. Our health equity framework extends acceptability to incorporate all end users: not just providers, but PLWD, family members, and other care partners. This reflects the idea that the intervention—and its multiple components—is acceptable and tolerable not only to those responsible for implementation but for those targeted or directly impacted by study.

Has acceptability been established such that end users or target populations have expressed that the distal goals of the intervention are reasonable and good (acceptable), that the study components and procedures are discernable and easy to follow with low to moderate prompting (user-friendly) ("is it ready")? Is there documentation that the intervention components can be implemented with the available provider and organizational resources to execute the trial? If so, then the ePCT is "ready" to go forward.

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Including the end user's acceptance of the intervention is a key goal. Thus, one must consider (1) if most or all collaborators believed the intervention addresses a priority, and (2) was the intervention "accepted" as good, beneficial, and aligned with the group's values, preferences, and selection of outcomes. If there is no evidence of acceptability (not ready), then it behooves the research team to regroup and take preparatory steps to address this gap. We offer a case example below for the Acceptability Domain (also see Table 4).

Case Example: Acceptability

Brief narrative: Caregiver stress, strain, health, and psychological well-being are important and relevant outcomes for many community-based behavioral interventions involving persons living with dementia and their families. Supporting caregiver needs and facilitating caregiver well-being is critical to their ability to provide care to the person living with dementia. An evidence-based behavioral intervention program has been shown to be effective in reducing caregiver strain, self-reported health, and depressive symptoms in studies conducted mostly in urban and suburban settings. The multimodal intervention incorporates caregiver psychoeducation and skill-building, counseling, and case management. The current study purports to test the same intervention with a local Native North American nation in the United States.

Health equity issue: The acceptability of the behavioral trial components and the program's ability to address caregiver mental health outcomes were demonstrated with non-Native North American populations and not yet assessed among the intended Indigenous community. In particular, the barriers and mechanisms of action that the behavioral intervention was designed to address were not assessed within the community and local healthcare system. Native North Americans, and other Indigenous communities, have sacred teachings, stories, and health-preserving practices that are steeped in cultural norms, expectations, and familial traditions, including the roles and activities of caregivers.

No information is available that documents how this Indigenous community is engaged, or how respected adults and leaders are incorporated in the health of caregivers and their loved ones from the onset of establishing the research questions. It is important to determine which outcomes are relevant and important to individuals, community leaders, and the overall community.

Readiness—Low

1. Preparatory Strategies: Identify clear and mutual communication with community leaders before any preparatory research design elements and strategies are conceptualized. Affirm the members' ways of being and knowing as the central guide to any action. If recognized by community leaders as important and significant to their lives, then proceed with the following with clarity and respect.
2. Engage in initial assessment to establish needs, preferences, preferred outcomes, and assess specific barriers and facilitators facing the community, etc., across groups (patients, caregivers, family members, community members as identified by key informants recognized by community leaders)

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3. Conduct community-based participatory research strategies to identify the problem(s), research questions, outcomes, etc.
4. Establish acceptability in assessments with community collaborators, including established community advisory boards, and patient advocacy groups).
5. Engage in culturally appropriate and culturally receptive adaptation of the intervention, including adapting the intervention to cultural norms, targeting specific outcomes of importance to the population group, and attending to any linguistic translation/transformation procedures to ensure the intervention procedures (and measures) are attuned to language considerations, and available literacy levels for all subgroups.
6. Conduct a small feasibility pilot with the community-based home care setting and representative target sample.
7. Establish regular check-ins with leaders and collaborators to eliminate drift in agreed-upon goals, and to ascertain quality of relationships between community members and the research team.

CONCLUDING REMARKS

Achieving health equity in dementia care and supports is an ethical, regulatory, and scientific goal predicated on ensuring that we account for heterogeneity in mechanisms of action, treatment targets, and interventional components or actions,[13] and inclusion of underrepresented groups most vulnerable to cognitive decline. Although frameworks exist to determine whether an intervention is ready to be tested in an ePCT, there is no heuristic to determine whether an intervention is health equity-ready for an ePCT in dementia care. To address this gap, we provided a practical approach to integrating a health equity ePCT framework across three domains: Evidence, Risk, and Acceptability. Through case examples, we elucidated health equity considerations and offered possible research strategies to increase ePCT health equity readiness.

Some remaining points are worth stating. First, some studies may fall short on more than one domain. For example, if much of the preparatory or preliminary work has not been conducted with a particular population group, is there a litmus test or idea of minimum requirements in any domain? Is there a “stake in the ground” we want to consider such as establishing a maximal level of acceptable risk (no or minimal risks, for example), which, if not sufficiently demonstrated, indicates that an intervention is not ready for an ePCT? The counterargument implies that we may be delaying access to potentially beneficial interventions and innovations (benefits) to underrepresented populations. If we decide to “relax” the rules, is relaxing the rules an example of benign beneficence (we know best), or an attempt to bring the best science to the most at-risk of cognitive decline and low access to care? There may be a calculus that the likely benefits outweigh potential or known risks for the populations of interest, in which case the scientific team may consider proceeding to a full-scale ePCT with an intervention that does not score high in a particular domain.

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Second, when considering multicomponent interventions, there may be evidence that an individual component has been tested in previous studies with health disparities populations with good indications that the component is ready for an ePCT. Still, questions remain about the remaining components. How reliant will the study be on components that do not have documented efficacy, yet have clear indications that the intervention is highly utilized in routine care? And, what is the degree of reach of the routine care practices with disparities populations?

Third, the lack of health equity preparation reflects in part the under-resourced environments of the research enterprise related to underrepresented populations. The lack of preparation for ePCT implementation parallels the lack of attention to how social determinants of health impact research resources from funding through sustainability, and by extension, research participation by underrepresented populations. The tension between the allocation of scientific funding and resources on recruitment of health disparities populations is sometimes juxtaposed to the need to fund basic science that will 1 day help us find a cure to Alzheimer's disease and other neurocognitive disorders.[26]

Future work should include exploring how these enhanced domains can be put to the test, and ultimately provide guidance to the scientific community, funders, payers, policymakers, advocates, and community-based collaborators, on the implementation of nonpharmacological interventions in ePCTs with ADRD underrepresented populations. Attending to health equity considerations in the remaining RAPT domains (measurement, cost, alignment, feasibility, impact, and implementation protocol) should be addressed.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Key points

- Health-related inequities in dementia care are well-documented, and thus underscore the need to require rigorous efforts that ensure disproportionately affected populations participate fully in clinical research opportunities.
- Embedding-proven interventions under real-world conditions and within existing healthcare systems have the potential to examine the effectiveness of an intervention, improve dementia care, and leverage use of existing resources —all important health equity considerations.
- Although frameworks exist to determine whether interventions are “ready” for embedded pragmatic controlled trials (ePCT), there is no heuristic to assess and guide decisions on the health equity-readiness of proposed (or active) research designs.

Why does this paper matter?

We discuss health equity considerations, provide case examples, and research strategies across ePCT study domains such as *evidence, risk*, and *alignment*.

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TABLE 1

Health Equity Readiness Assessment for Pragmatic Trials (RAPT) domains and scoring guidance.

		Scoring guidance		
Rapt domain	**Assessment**	**Low**	**Medium**	**High**
Evidence	*To what extent does the evidence base support the intervention's efficacy*	There is no efficacy study or the efficacy study(ies) did not use rigorous methods or scant evidence to indicate efficacy for URGs	One study using rigorous trial methods with URGs.	Very large single trial(s) using rigorous methods with URGs
Risk	*Is it known how safe the intervention is?*	With regards to URGs, the risks (harms and discomforts) are unknown or are known to be more than minimal (e.g., greater than ordinarily encountered in daily life).	The risks are unknown for URGs, but are likely minimal	The risks for URGs are known to be minimal.
Acceptability	*How willing are providers, staff, patients, care partners*, etc., *likely to be to adopt the interventions?***	Acceptability is unknown, and *providers, staff, patients, care partners*, etc., are unlikely to believe the intervention is feasible or needed for URGs.	Acceptability is unknown or very limited, but *providers, staff, patients, care partners*, etc., are likely to believe the intervention is feasible or needed for URGs.	Acceptability is known and *providers, staff, patients, care partners*, etc., believe the intervention is feasible and needed for URGs.

Abbreviation: URGs, underrepresented groups.

** We include both providers and staff/personnel. Providers include physicians, specialists, and other clinical care team members such as nurses, pharmacists, care managers, etc. Staff may include medical assistants, schedulers, community health workers, etc. We also include key collaborators such as patients and their care partners.

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TABLE 2

Evidence domain, health equity considerations, and preparatory strategies.

Evidence domain	
A. Brief study narrative Brief description of the proposed study: • Proposed intervention/procedures • Among which population(s) • In what type of setting(s) • To assess which primary outcomes etc.	Agitation and aggression are common neuropsychiatric symptoms in persons living with dementia, and highly distressful to patients, caregivers, and nursing home staff. A behavioral treatment intervention based on environmental modifications to mitigate agitation and aggression in persons with dementia has demonstrated effectiveness in nursing home settings with very low health disparities population representation. The current study purports to test the same intervention against routine care in a community-based home care setting with higher representation of diverse racial/ethnic patients, that is, English- and Spanish-speaking Latinx and monolingual English-speaking Black Americans.
B. Health equity issue Identification of the primary HE issue: • What makes this a health equity issue? • Is there a particular group that is unduly affected by the health equity issue? • What are some of the research pitfalls that may emerge as a result of going forward with the ePCT and not addressing the health equity issue?	The demonstration of effectiveness for the behavioral trial to address agitation and aggression was well-documented, yet not for the new target population, new treatment setting (environmental factors in particular), or across different languages. There are racial/ethnic inequities in nursing home quality such that nursing homes with greater proportions of Latinx and Black American residents are more likely to be located in urban areas and to have fewer resources such as lower revenue and staffing levels. These limitations could affect challenges to implementing the intervention. If Latinx and Black American residents are not sufficiently represented in prior trials, the results may not be generalizable to them, and to the facilities in which they reside, and provider groups.
C. Readiness[a] • Determination of level of readiness based on RAPT qualitative scoring	Low
D. Preparatory Strategies • Suggested strategies to address limitations and weaknesses	1. Engage in initial needs assessment to elucidate needs, preferences, etc. across collaborator groups (patients, family members, interventionists, providers, manager-level decision-makers) 2. Establish other collaborator input mechanisms to ascertain the same (focus groups, key informant interviews, etc.). 3. Conduct a scoping review to identify if similar interventions have been conducted on the new target population, paying attention to sociocultural factors, language/linguistic factors, engagement with index condition (neuropsychiatric symptoms), etc. 4. Identify if certain components of the proposed intervention have higher levels of evidence for the individual components among the new target populations. 5. Engage in culturally appropriate, translation and transformation procedures to ensure the intervention procedures (and measures) are attuned to language considerations (Latinx Spanish-language/dialects), and available literacy levels for all subgroups. 6. Conduct a small pilot with nursing home settings, representative target sample, and provider group to establish feasibility and acceptability of the study intervention, and research procedures.

Note: The intervention described here is for illustrative purposes only and should not be associated with a particular intervention or program unless otherwise noted.

[a]Readiness categories are based on subjective or qualitative scores: Low, Medium, High (see Table 1 for scoring suggestions).

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TABLE 3

Risk domain, health equity considerations, and preparatory strategies.

Risk domain	
A. Brief study narrative Brief description of the proposed study: • Proposed intervention/procedures • Among which population(s) • In what type of setting(s) • To assess which primary outcomes, etc.	This is a cluster-randomized controlled trial of a multi-component (REACH VA) family caregiver intervention among Vietnamese family caregivers in northern Vietnam. The study was conducted in a community setting—provincial hospital and associated local healthcare centers. All intervention components will be delivered by local staff at the provincial hospital to the family caregiver who provides the most day-to-day hands-on care. The primary outcomes are caregiver burden and psychological distress. The multi-component intervention was developed in the United States and tested with racially and ethnically diverse populations in the United States but has not been previously tested in Vietnam. In Vietnam, many persons living with dementia have not been previously diagnosed.
B. Health equity issue Identification of the primary HE issue: • What makes this a health equity issue? • Is there a particular group that is unduly affected by the health equity issue? • What are some of the research pitfalls that may emerge as a result of going forward with the ePCT and not addressing the health equity issue?	There are substantial global inequities in the availability of evidence-based family caregiver interventions in low and middle-income countries such as Vietnam. Rural populations in Vietnam are particularly vulnerable based on under-resourced healthcare systems and the lack of trained local providers and research personnel to conduct multicomponent intervention models. There are two sides to the Risk Domain, and thus two possible levels of readiness. Although risks are unknown in Vietnam, they are likely minimal based on research already conducted in the United States, including among underrepresented groups specifically among Asian Americans. Thus, the level of readiness may be “medium.” There are several potential pitfalls in Vietnam. In rural, family-centered communities, social ties are strong and based on local customs of taking care for one another. Second, the human subjects’ assurances of privacy, confidentiality, and protection of health-related information do not have the same saliency and prominence in communities where these research concepts are unfamiliar. Thus, sharing of information may not be readily perceived as a violation of human rights in a country where human rights and rights as a study participant may not be viewed the same as in the United States, for example. Although well-meaning, information about an individual’s diagnosis, prognosis, and treatment may be shared among nonresearch personnel or local community residents. The potential for risk may be high if additional safeguards are not put into place. Thus, the level of readiness may be “low.”
C. Readiness[a] • Determination of level of readiness based on RAPT qualitative scoring	Low to Medium
D. Preparatory strategies • Suggested strategies to address limitations and weaknesses	1. Conduct key informant interviews with local staff and other local experts to a) assess feasibility and acceptability of the intervention itself and identify any potential adaptations, b) assess the capacity of the local healthcare system to sustain the intervention and identify any adaptations that are necessary to achieve this goal, and c) anticipate any potential harms that may arise from participation in the intervention and strategies to mitigate those risks. 2. Use a theoretical framework to adapt the intervention based on local sociocultural context and resource constraints. 3. Develop a culturally tailored training to address privacy and confidentiality, accounting for local values, attitudes, and potential barriers. 4. Plan subject compensation in accordance with local socioeconomic circumstances and norms to ensure that the amount is not coercive. 5. Assess and strengthen the local health system to support persons identified by the project as having dementia. 6. Conduct a single-arm pilot feasibility study to further evaluate feasibility, acceptability, and potential risks.

Note: The intervention described here is for illustrative purposes only and should not be associated with a particular intervention or program unless otherwise noted.

[a]Readiness categories are based on subjective or qualitative scores: Low, Medium, High (see Table 1 for scoring suggestions).

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TABLE 4

Acceptability domain, health equity considerations, and preparatory strategies.

Acceptability domain	
A. Brief study narrative Brief description of the proposed study: • Proposed intervention/procedures • Among which population(s) • In what type of setting(s) • To assess which primary outcomes, etc.)	Caregiver stress, strain, health, and psychological well-being are important and relevant outcomes for many community-based behavioral interventions involving persons living with dementia and their families. Supporting caregiver needs and facilitating caregiver well-being is critical to their ability to provide care to the person living with dementia. An evidence-based behavioral intervention program has been shown to be effective in reducing caregiver strain, self-reported health, and depressive symptoms in studies conducted mostly in urban and suburban settings. The multimodal intervention incorporates caregiver psychoeducation and skill-building, counseling, and case management. The current study purports to test the same intervention with a local Native North American community in the United States.
B. Health equity issue Identification of the primary HE issue: • What makes this a health equity issue? • Is there a particular group that is unduly affected by the health equity issue? • What are some of the research pitfalls that may emerge as a result of going forward with the ePCT and not addressing the health equity issue?	The acceptability of the behavioral trial components and the program's ability to address caregiver mental health outcomes were demonstrated with non-Native North American Indian populations and not yet assessed among the intended Indigenous community. In particular, the barriers and mechanisms of action that the behavioral intervention was designed to address were not assessed within the community and local healthcare system. Native North Americans, and other Indigenous communities, have sacred teachings, stories, and health-preserving practices that are steeped in cultural norms, expectations, and familial traditions, including the roles and activities of caregivers. No information is available that documents how this Indigenous community is engaged, or how respected adults and leaders are incorporated in the health of caregivers and their loved ones from the onset of establishing the research questions. It is important to determine which outcomes are relevant and important to individuals, community leaders, and the overall community.
C. Readiness[a] • Determination of level of readiness based on RAPT qualitative scoring	Low
D. Preparatory strategies • Suggested strategies to address limitations and weaknesses	1. Identify clear and mutual communication with community leaders before any preparatory research design elements and strategies are conceptualized. Affirm the members' ways of being and knowing as the central guide to any action. If recognized by community members as important and significant to their lives, then proceed with the following with clarity and respect. 2. Engage in initial assessment to establish needs, preferences, preferred outcomes, and assess specific barriers and facilitators facing the community, etc., across collaborator groups (patients, caregivers, family members, community members as identified by key informants recognized by community leaders) 3. Conduct community-based participatory research strategies to identify the problem(s), research questions, outcomes, etc. 4. Establish acceptability in assessments with community collaborators, including established community advisory boards, and patient advocacy groups). 5. Engage in culturally appropriate and culturally receptive adaptation of the intervention, including adapting the intervention to cultural norms, targeting specific outcomes of importance to the population group, and attending to any linguistic translation/transformation procedures to ensure the intervention procedures (and measures) are attuned to language considerations, and available literacy levels for all subgroups. 6. Conduct a small feasibility pilot with the community-based home care setting and representative target sample. 7. Establish regular check-ins with leaders and collaborators to eliminate drift in agreed-upon goals, and to ascertain quality of relationships between community members and the research team.

Note: The intervention described here is for illustrative purposes only and should not be associated with a particular intervention or program unless otherwise noted.

[a]Readiness categories are based on subjective or qualitative scores: Low, Medium, High (see Table 1 for scoring suggestions).