

Best Practices for Integrating Health Equity into Embedded Pragmatic Clinical Trials for Dementia Care



Rationale

The NIH Revitalization Act of 1993 was enacted to compel scientists to design for, and report on, the effectiveness of interventions by gender and racial/ethnic groups, yet the evidence base for underrepresented people living with dementia (PLWD) is sparse. Higher rates of dementia and worse health outcomes have been documented for many minoritized populations relative to PLWD who are non-Hispanic White, yet these populations that experience health disparities are vastly underrepresented in dementia efficacy trials. A concerted effort to integrate health equity into study designs is necessary to ensure researchers are conducting quality science and avoiding harm where evidence gaps exist. However, the efficacy, safety, and tolerability of treatments have not been sufficiently assessed for many groups that experience Alzheimer’s disease (AD) and AD-Related Dementias (AD/ADRD), creating critical knowledge gaps at a time when our aging population is becoming increasingly diverse.

The sparse evidence applicable to health disparity populations derived from AD/ADRD efficacy trials extends to pragmatic clinical trial designs embedded in health care systems (ePCTs, HCS). ePCTs aim to evaluate interventions in real-world settings. ePCTs have unique design features that introduce additional novel challenges with respect to health equity, yet to date there is very little guidance on how to integrate health-equity-relevant considerations into the design of impact ePCTs, including those targeting PLWD and their care partners.

How to Use this Packet

Health-equity-relevant considerations are necessary in all aspects of ePCTs. The key is to consider these issues early in the planning process, as well as systematically and throughout the conduct of the trial. Health-equity-relevant concepts can be nuanced and complex, and the degree to which researchers can incorporate health equity into each ePCT design component depends on the scope and objectives of the trial. These best practices are meant as a starting place for investigators to systematically explore how to integrate health equity into their ePCT design and identify potential pitfalls in their current research processes.

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Additional Resources

This best practices package includes a glossary of terms and key references for additional resources and publications. The community-based participatory research, implementation science, and cultural adaptation literature offer some additional guidance. We encourage investigators to seek more in-depth guidance incorporating health-equity-relevant features into the ePCT from these resources as well as from methodological and content experts and community partners.



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6 Best Practices for Getting Started

Integrating Health Equity into ePCTs for Dementia Care



1 Consider health equity in all domains of ePCT design

There are health equity considerations in all ePCT design domains, as guided by the [PRECIS-2 framework](#). The key is to consider these issues early in the design phase and throughout the trial's conduct.

2 Select a research question that matters to health disparity populations

All trials are ethically required to maximize their social value. One way to achieve this is to prioritize questions that address the needs of health disparity populations including those that are historically disadvantaged, underrepresented, or otherwise underserved.

3 Collaborate with community members to ensure relevant, respectful, and inclusive research

Engage representative partners who are knowledgeable about the community. Keep in mind there are many aspects of diversity (e.g., race/ethnicity, geography, education). Consultation with community members is valuable across the trial lifespan.

4 Allocate sufficient resources to ensure appropriate and inclusive engagement of health disparity populations

Plan for the effort and budget needed to support inclusive participant engagement. Examples include budgeting for: translation or interpretation services, remuneration of research activities for community partners, and project staff diversity training.

5 Build a research team that is diverse and knowledgeable about health equity issues

Your research team should include investigators, consultants, and project staff with the diversity, methodologic expertise, content knowledge, and training to enable rigorous integration of health-equity-relevant issues throughout the ePCT design.

6 Design with health equity monitoring & reporting in mind

When you design an ePCT, keep in mind the health-equity-relevant aspects that need to be monitored and reported. The [Consort Equity Extension](#) and [Progress-Plus frameworks](#) are useful guidelines.

6 Best Practices for **Community Partner Engagement**

Integrating Health Equity into ePCTs for Dementia Care



1 Apply a health equity approach to community engagement throughout the study

Engage community partners throughout the study lifespan, including: choosing research questions and outcomes that matter, tailoring interventions and protocols, developing appropriate and accessible materials, designing enrollment strategies, interpreting data, and planning for dissemination and implementation.

2 Engage community partners who are representative of the ePCT participants

Consider the racial, social, and cultural backgrounds of potential study participants who will receive and deliver the intervention, including people living with dementia (PLWD), care partners (CP), clinicians, non-clinician medical staff, and community members.

3 Engage the community before and during the ePCT

Include a period of “pre-engagement” to get to know the community, understand their priorities, preferences, and needs, and build relationships and trust. Keep the community informed about the ePCT throughout its progress. Support the community through information, education, and other efforts. Use plain rather than scientific language.

4 Use a mix of strategies to identify community partners from health disparity populations

Partner with community leaders and groups. Go to places that community members frequent such as local businesses, recreation or senior centers, and places of worship. Use culturally-relevant media such as flyers, local radio, social media, and television.

5 Evaluate the impact of community partner engagement

Assess the experiences of community partners related to their involvement with the research. Describe how their contributions had an impact on study design and conduct.

6 Disseminate results to community partners

Plan to deliver presentations (i.e., at community gatherings and settings) of results during and/or upon completion of the study.

6 Best Practices for **Design and Analysis**

Integrating Health Equity into ePCTs for Dementia Care



1 Clearly state health-equity-relevant aims & hypotheses

All ePCT designs should employ health equity principles, but not all will formally investigate hypotheses relevant to health equity. If an ePCT has explicit objectives related to health equity, they should be clearly stated in the aims and hypotheses.

2 Pre-specify analyses related to health equity

Analyses related to health equity should be specified during the design phase (e.g., to estimate heterogeneity of treatment effects across participant subgroups).

3 Be explicit in sample size justifications with regard to health equity objectives

Sample size justification should support health equity aims and hypotheses. Comparisons between subgroups may not be powered to demonstrate differences with high probability, but may still be important for reporting results, and should be justified on that basis.

4 Consider stratified randomization on health-equity-relevant parameter

Stratified randomization may help ensure a balance of health-equity important parameters across clusters and trial arms, and can be especially useful if such parameters may directly influence clinical outcomes of the ePCT.

5 Collect data to allow description and reporting of health-equity-relevant participant characteristics

Design data collection to enable construction of tables and/or flow diagrams to describe participants across equity-relevant groups that were included in the trial, received the intervention, and lost to follow up.

6 Be aware of, monitor, and report differential risk-benefit across health-equity-relevant groups

Adequately protecting the interests of diverse populations requires knowing if/how their risk-benefit balance may differ from that of the general population.

6 Best Practices for Intervention Design and Implementation

Integrating Health Equity into ePCTs for Dementia Care



1 Determine who is meant to benefit from the intervention

Consider the racial, social, socioeconomic, linguistic and cultural backgrounds of those who are intended to receive the intervention (providers, people living with dementia (PLWD), care partners (CP) and the healthcare system).

2 Involve community partners and other interested parties in intervention design and implementation

Community partners and other interested parties who represent the backgrounds and interests of the people delivering and receiving the intervention should be involved in its design, content, delivery and adaptations.

3 Adapt interventions for different settings and populations

Most existing interventions for PLWD and their CPs need to be adapted for health disparity populations and implementation in different settings. Take a systematic approach to these adaptations using existing frameworks. Document and report adaptations.

4 Ensure intervention materials are accessible and acceptable to health-equity-relevant populations

Ensure intervention materials are acceptable and accessible with regard to different literacy levels, languages spoken, settings, and cultural practices.

5 Identify and address barriers to equitable implementation

| PLWD and CPs | Providers | Healthcare systems |
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| Computer access, transportation, time and cost, acceptability of intervention | Inequitable training, lack of time, discriminatory attitudes, intervention acceptability, incongruence of background with PLWD & CP | <ul style="list-style-type: none">• Variable resources• Less attention to sites with underrepresented populations• How programs are marketed and referral pipelines |

6 Monitor implementation across health-equity-relevant populations and incorporate corrective adaptations

Plan to monitor implementation (reach, coverage, intensity, uptake) in these groups and take corrective adaptations if inequities occur. Document and report adaptations.

6 Best Practices for Health Care System and Participant Selection

Integrating Health Equity into ePCTs for Dementia Care



1 Select health care systems (HCS) that serve populations with the greatest need for improved care

2 Consider health-equity-relevant features of the HCS

Consider features such as: state, rurality of setting, ownership, care model (accountable care organization, integrated delivery system, etc.). Identify existing disparities in the HCS relevant to intervention implementation.

3 HCS and participant selection should support the health equity objectives of the ePCT

The HCS sampling frame and participant eligibility criteria should allow the health equity goals of the ePCT to be met including pre-specified health equity-specific analysis.

4 Consider health-equity-relevant features of the HCS's population and data available to characterize it

Consider characteristics such as: insurance coverage, race, ethnicity, language, nativity/country of origin, sexual/gender identity, disabilities, diagnoses, type of residence, location of residence (rural/suburban/urban), education, and socioeconomic status.

5 Consider the validity and biases of approaches to identify participants

Methods should identify all eligible participants (e.g., people living with dementia, care partners). Consider who may be "missing" (e.g., undiagnosed) from a health equity standpoint. If using an electronic health record-based algorithm, validate it locally by relevant subgroups. Be aware that while an algorithm may not include race, other system-related factors (e.g., access to services) may introduce bias.

6 Consider threats to health equity in the enrollment and recruitment strategy of eligible participants

Once eligible participants are identified, health-equity-relevant factors may impact how they are enrolled such as mode of outreach (e.g., computer access), or recruitment materials (e.g., health literacy, language). If consent is needed, ensure an equitable approach to obtaining it.

6 Best Practices for **Selecting Outcomes**

Integrating Health Equity into ePCTs for Dementia Care



1 Select outcomes relevant to health disparity populations

Select outcomes with evidence of broad value in health disparity populations.

2 Assess the validity of outcomes for health-equity-relevant groups to ensure applicability in specific populations

Assess existing evidence of outcome validation regarding race, ethnicity, educational attainment and other health-equity-relevant characteristics.

3 Explore how outcomes may be interpreted with respect to norms and expectations of health-equity-relevant groups

Review qualitative and comparative research on cultural differences in the lived experience of people living with dementia (PLWD), and the meaning of potential outcome domains.

4 Consider pilot work to evaluate acceptability and psychometrics of outcomes for health disparity populations

In the absence of evidence of psychometric properties in specific populations, pilot work may be needed to assess an outcome measure's validity, reliability, and cross-cultural differences in these groups.

5 Require linguistic and health literacy accessibility in outcome ascertainment

For clinically embedded patient/care partner relevant outcomes, ensure forward and back-translation required for linguistic and health literacy accessibility.

6 Ensure health equity of outcome data capture

For PLWD and care partners, assess and adapt for limited computer, internet or smart phone access. For health care systems, assess the need for enhanced technical assistance for outcome data in populations at risk for health disparities.



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| Community | Social grouping based on individual characteristics and/or geographic location. |
| Community Engagement | <p>Community engagement is the process of working collaboratively with groups of people who are affiliated by geographic proximity, special interests, or similar situations with respect to issues affecting their well-being and viability.</p> <p>Clinical and Translational Science Awards Consortium, Community Engagement Key Function Committee, Task Force on the Principles of Community Engagement. Principles of Community Engagement, 2nd Edition. 2011. NIH publication. 2011; no. 11-7782. https://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf</p> |
| Community Health | <p>Community health refers to the wellbeing of a defined group of people and the context, actions, and conditions available to promote, protect, and preserve the community's health.</p> <p>The process of improving community health involves multisectoral and multidisciplinary collaborative efforts in evidence-based science, public health, to engage and work with communities, in a culturally appropriate manner, to optimize the health and quality of life of all people who live, work, or are otherwise active in a defined community or communities."</p> <p>Goodman RA, Bunnell R, Posner SF. What is "community health"? Examining the meaning of an evolving field in public health. Prev Med. 2014;67(Suppl 1):S58-S61. PMID: 25069043. doi: https://doi.org/10.1016/j.ypmed.2014.07.028</p> |
| Community Leader | Person who is very knowledgeable about the community and takes responsibility for the growth, development, and improvement of the community in a formal or informal way. |
| Community Members | <p>People who live and interact in any personal or professional way in a specific community.</p> <p>Community Members. County Health Rankings & Roadmaps. https://www.countyhealthrankings.org/take-action-to-improve-health/partner-center/community-members</p> |
| Community Partner | Any local organization (non-profit, for profit, governmental), groups, or people working together with another team to provide input about interventions or initiatives affecting care. This could include people who represent the backgrounds and interests of the people delivering and receiving the intervention. |
| Community-Based Participatory Research (CBPR) | <p>Community-based participatory research is a collaborative research approach that is designed to ensure and establish structures for participation by communities affected by the issue being studied, representatives of organizations, and researchers in all aspects of the research process to improve health and well-being through taking action, including social change.</p> <p>AHRQ Activities Using Community-Based Participatory Research to Address Health Care Disparities. Agency for Healthcare Research and Quality. https://www.ahrq.gov/research/findings/factsheets/minority/cbprbrief/index.html</p> |
| Cultural Adaptation Cultural Tailoring | <p>Cultural adaptation and cultural tailoring is a systematic process of modifying an evidence-based intervention to address language and cultural contexts to make them compatible with practices, meanings, and values of those involved. Cultural adaptations are a key aspect of implementation considerations necessary in ePCTs.</p> <p>Barrera M Jr, Castro FG, Strycker LA, Toobert DJ. Cultural adaptations of behavioral health interventions: a progress report. J Consult Clin Psychol. 2013;81(2):196-205. PMID: 22289132. doi: https://doi.org/10.1037/a0027085</p> <p>Stirman SW, Miller CJ, Toder K, Calloway A. Development of a framework and coding system for modifications and adaptations of evidence-based interventions. Implement Sci. 2013;8:65. PMID: 23758995. doi: https://doi.org/10.1186/1748-5908-8-65</p> <p>National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care. Think Cultural Health. https://thinkculturalhealth.hhs.gov/clas</p> |



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| <p>Cultural Humility</p> | <p>Cultural humility is a position of openness, self-awareness, and incorporation of self-reflection and self-critique when purposefully interacting with diverse communities.</p> <p>Foronda C, Baptiste D-L, Reinholdt MM, Ousman K. Cultural humility: A concept analysis. <i>J Transcult Nurs.</i> 2016;27(3):210-217. PMID: 26122618. doi: https://doi.org/10.1177/1043659615592677</p> <p>Foronda C. A theory of cultural humility. <i>J Transcult Nurs.</i> 2020;31(1):7-12. PMID: 31516091. doi: https://doi.org/10.1177/1043659619875184</p> |
| <p>Culturally Appropriate</p> <p>Culturally Responsive</p> <p>Culturally Receptive</p> <p>Cultural Competence</p> | <p>Work (research, intervention, etc.) that is culturally appropriate, responsive, or receptive deliberately and purposefully integrates the values, beliefs, norms, practices, and linguistic needs of those involved.</p> <p>Cultural competence is used to describe the ability to successfully tailor services and programs to meet the diverse values, beliefs and behaviors, social, cultural, and linguistic needs of those involved. There is concern in the field whether cultural competence is attainable when involving individuals from another culture. As a result, the other terms listed may be more appropriate.</p> <p>Betancourt JR, Green AR, Carrillo JE. Cultural competence in health care: emerging frameworks and practical approaches. <i>The Commonwealth Fund</i>, October 2002.</p> <p>Cultural Respect. National Institutes of Health. https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/cultural-respect</p> <p>Kirmayer LJ. Rethinking cultural competence. <i>Transcult Psych.</i> 2012;49(2):149-164. PMID: 22508634. doi: https://doi.org/10.1177/1363461512444673</p> |
| <p>Culture</p> | <p>Culture is an interpersonal process through which language, customs, values, actions, and institutions influence beliefs, norms, values, and behaviors. Culture is dynamic and shapes individual and/or group behavior.</p> <p>Cultures merge and change in response to population changes. Changes in human diversity assure that different lifestyles and beliefs will persist so that systems of value remain autonomous and distinct. In this sense, culture can be understood as not only habits and beliefs about perceived wellbeing, but also political, economic, legal, ethical, and moral practices and values.</p> <p>Hughes V, Delva S, Nkimbeng M, et al. Not missing the opportunity: strategies to promote cultural humility among future nursing faculty. <i>J Prof Nurs.</i> 2020;36(1):28-33. PMID: 32044049. doi: https://doi.org/10.1016/j.profnurs.2019.06.005</p> <p>Dilworth-Anderson P, Gibson BE. The cultural influence of values, norms, meanings, and perceptions in understanding dementia in ethnic minorities. <i>Alzheimer Dis Assoc Disord.</i> 2002;16 Suppl 2:S56-63. PMID: 12351916. doi: https://doi.org/10.1097/00002093-200200002-00005</p> <p>Napier AD, Ancarno C, Butler B, et al. Culture and health. <i>The Lancet.</i> 2014;384(9954):1607-1639. PMID: 25443490. doi: https://doi.org/10.1016/S0140-6736(14)61603-2</p> |
| <p>Equitable Implementation</p> | <p>Intervention is implemented in such a way as to achieve equal opportunities to engage and access services and resources across health disparities populations.</p> |



Health Disparities

Health disparities refer to unjust health differences with adverse impacts that are closely linked with social, economic, and/or environmental disadvantages.

Health Disparity Populations

Health disparity populations are defined by the National Institutes of Health as underrepresented racial and ethnic populations, less privileged socioeconomic status populations, underserved rural populations, sexual and gender minorities, and any subpopulations that can be characterized by two or more of these descriptions.

US Department of Health and Human Services. Healthy People 2020.

Minority Health and Health Disparities: Definitions and Parameters. National Institute of Minority Health and Health Disparities (NIMHD). <https://www.nimhd.nih.gov/about/strategic-plan/nih-strategic-plan-definitions-and-parameters.html>

Duran DG, Pérez-Stable EJ. Novel approaches to advance minority health and health disparities research. Am J Public Health. 2019;109(S1):S8-S10. PMID: 30699017. doi: <https://doi.org/10.2105/ajph.2018.304931>

Health Equity Health Inequity

Health equity is achieved when every person has the opportunity to “attain his or her full health potential” and no one is “disadvantaged from achieving this potential because of social position or other socially determined circumstances.” Health inequities are reflected in differences in length of life; quality of life; rates of disease, disability, and death; severity of disease; and access to treatment.

Attainment of the highest level of health for all people. Achieving health equity requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health disparities.

Advancing Health Equity in Chronic Disease Prevention and Management. Centers for Disease Control and Prevention National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). <https://www.cdc.gov/chronicdisease/healthequity/index.htm>

US Department of Health and Human Services. Healthy People 2020.

Health Literacy

Personal health literacy is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Organizational health literacy is the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Health Literacy. Centers for Disease Control and Prevention. <https://www.cdc.gov/healthliteracy/index.html>



**Minority
Underserved
Under-
represented
Minoritized**

A minority or minority group is a subgroup of the population with unique social, religious, ethnic, racial, and/or other characteristics that differ from those of a majority group. The term usually refers to any group that is subjected to oppression and discrimination by those in more powerful social positions, whether or not the group is a numerical minority. Examples of groups that have been labeled minorities include African Americans, women, and immigrants, among others.

The general term minorities should be avoided when describing groups or populations; instead, specify with terms such as racial or ethnic minority groups. Other terms such as underserved groups or underrepresented populations may be used provided the categories of individuals included are defined. Marginalized groups can be suitable in certain contexts if the rationale for this designation is provided.

Unlike the term minority, minoritized emphasizes that certain groups are rendered into a minority category rather than basing assignment on features of their identity.

Perkins K, Wiley S. (2014) Minorities. In: Teo T (eds) Encyclopedia of Critical Psychology. Springer, New York, NY.
Flanagin A, Frey T, Christiansen SL, Bauchner H. The reporting of race and ethnicity in medical and science journals: comments invited. JAMA. 2021;325(11):1049-1052. PMID: 33616604. doi: <https://doi.org/10.1001/jama.2021.2104>
Gilmore-Bykovskiy A, Croff R, Glover CM, Jackson JD, Resendez J, Perez A, Zuelsdorff M, Green-Harris G, Manly JJ. Traversing the aging research and health equity divide: toward intersectional frameworks of research justice and participation, The Gerontologist, 2021.
Alvidrez J, Castille D, Laude-Sharp M, Rosario A, and Tabor D, 2019. The National Institute on Minority Health and Health Disparities research framework. American Journal of Public Health 109, S16_S20. PMID: 30699025. doi: <https://doi.org/10.2105/ajph.2018.304883>

**Race and
Ethnicity**

Race categories generally reflect social definitions in the US and are not an attempt to define race biologically, anthropologically, or genetically. Race categories include social constructs generally based on ancestry, national origins, and sociocultural groups. Although race is a social construct and has very limited utility in understanding biological differences, it is important from a sociopolitical perspective to study racism, discrimination, and inequity.

The American Sociological Association defines ethnicity as “shared culture, such as language, ancestry, practices, and beliefs.” The Oxford English Dictionary defines ethnicity as “[t]he fact or state of belonging to a social group that has a common national or cultural tradition.” In the US, ethnicity may refer, for example, to Hispanic or Latino/a/x people.

Ethnicity is also primarily a social construct and some have argued against “arbitrary separation of race and ethnicity, instead of using a mutually exclusive single race/ethnicity variable.” Terms used to define and describe race and ethnicity change over time depending on shifts in policy, social norms, and other sociocultural factors.

Flanagin A, Frey T, Christiansen SL, Bauchner H. The reporting of race and ethnicity in medical and science journals: comments invited. JAMA. 2021;325(11):1049-1052. PMID: 33616604. doi: <https://doi.org/10.1001/jama.2021.2104>
Diez Roux AV. Conceptual approaches to the study of health disparities. Annu Rev Public Health. 2012;33:41-58. PMID: 22224879. doi: <https://doi.org/10.1146/annurev-publhealth-031811-124534>



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| Social Determinants of Health | <p>Social determinants of health are the conditions under which people are born, live, learn, work, play, worship, and age. These conditions affect a wide range of health, functioning, and quality-of-life outcomes.</p> <p>Social Determinants of Health. US Department of Health and Human Services. Healthy People 2030. https://health.gov/healthypeople/objectives-and-data/social-determinants-health</p> |
| Stakeholders* | <p>Stakeholders are individuals or groups who have an interest or concern in a project, activity, or course of action.</p> <p>*Due to a number of negative historical uses of the word “stakeholder”, IMPACT uses alternative terms such as “community partners” or “interested parties” whenever possible.</p> <p>Preferred Terms for Select Population Groups & Communities. Centers for Disease Control and Prevention. Accessed November 3, 2022. https://www.cdc.gov/healthcommunication/Preferred_Terms.html</p> |

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