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## Dissemination and Implementation of Evidence-Based Dementia Care Using Embedded Pragmatic Trials

Laura N. Gitlin, PhD<sup>\*</sup>, Rosa R. Baier, MPH<sup>†</sup>, Eric Jutkowitz, PhD<sup>†</sup>, Zachary G. Baker, PhD<sup>‡</sup>, Allison M. Gustavson, DPT, PhD<sup>§</sup>, Justine S. Sefcik, PhD, RN<sup>\*</sup>, Nancy A. Hodgson, PhD, RN<sup>¶</sup>, Sokha Koeuth, MPH<sup>\*</sup>, Joseph E. Gaugler, PhD<sup>‡</sup>

<sup>\*</sup>College of Nursing and Health Professions, Drexel University, Philadelphia, Pennsylvania; <sup>†</sup>School of Public Health, Brown University, Providence, Rhode Island; <sup>‡</sup>School of Public Health, University of Minnesota, Minneapolis, Minnesota; <sup>§</sup>Center for Care Delivery and Outcomes Research, Minneapolis Veterans Administration Healthcare System, Minneapolis, Minnesota; <sup>¶</sup>Biobehavioral Health Sciences Department, University of Pennsylvania, Philadelphia, Pennsylvania.

### Abstract

There are many nonpharmacologic interventions tested in randomized clinical trials that demonstrate significant benefits for people living with Alzheimer’s disease (AD) and AD-related dementia, their care partners, or professional care providers. Nevertheless, with few exceptions, proven interventions have not been translated for delivery in real-world settings, such as home care, primary care, hospitals, community-based services, adult day services, assisted living, nursing homes, or other healthcare systems (HCSs). Using embedded pragmatic clinical trial (ePCT) methods is one approach that can facilitate dissemination and implementation (D&I) of dementia care interventions. The science of D&I can inform the integration of evidence-based dementia care in HCSs by offering theoretical frameworks that capture field complexities and guiding evaluation of implementation processes. Also, D&I science can suggest evidence-based strategies for implementing dementia care in HCSs. Although D&I considerations can inform each stage of dementia care intervention development, it is particularly critical when designing ePCTs. This article examines fundamental considerations for implementing dementia-specific interventions in HCSs and how best to prepare for successful dissemination upstream in the context of ePCTs, thereby illustrating the critical role of the D&I Core of the National Institute on Aging Imbedded Pragmatic Alzheimer’s Disease and AD-Related Dementias Clinical Trials Collaboratory. The scientific premise of the D&I Core is that having the “end” in mind, upfront in the design and testing of dementia care programs, can lead to decision-making that optimizes the ultimate goal of wide-scale D&I of evidence-based dementia care programs in HCSs.

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Address correspondence to Laura N. Gitlin, PhD, College of Nursing and Health Professions, Drexel University, 1601 Cherry St, Room 1092, Philadelphia, PA 19102., lng45@drexel.edu; Twitter: @DeanDrexelCNHP.

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## Keywords

dissemination; implementation; dementia care; healthcare systems; caregivers

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## INTRODUCTION

Over the past five decades, a host of nonpharmacologic interventions tested in randomized trials (National Institute on Aging (NIA) stage I, discovery; II, pure efficacy; III, real-world efficacy)<sup>1</sup> have demonstrated significant benefits for people living with Alzheimer's disease (AD) and AD-related dementia, their care partners, or professional care providers.<sup>2-7</sup> Interventions for people living with dementia (PLWD) address various clinical symptoms, including behavioral and psychological symptoms, daily function, and quality of life.<sup>8-14</sup> Numerous interventions enhance care partners' well-being and reduce burden, with interventions for care providers resulting in improved staff knowledge, skills, and on-the-job stress. Nevertheless, with few exceptions,<sup>15-19</sup> proven interventions have not been adapted for delivery in real-world settings, such as home care, primary care, hospitals, community-based services, adult day services, assisted living, nursing homes, or other health and community-based care systems (HCSs).<sup>20</sup> Of the few evidence-based programs evaluated in HCSs, none has been widely disseminated thereafter nor sustained.<sup>21</sup> Consequently, we do not know how interventions function or how outcomes are impacted when implementation occurs in "real-world," complex organizational and payment structures. Nor do we know which strategies are most effective for implementing proven dementia care programs that result in wide-scale dissemination and sustained usage.<sup>22</sup> It takes 17 years or more, on average, for adoption of any evidence to occur,<sup>23</sup> with only 14% of interventions tested in efficacy trials (NIA stages II and III) implemented in HCSs. Moreover, it can take an estimated 9 years for evidence-based practices to be adopted into clinical guidelines for widespread dissemination and sustainability.<sup>22,24</sup>

One strategy to reduce the prolonged time line for dissemination and implementation (D&I) is the use of embedded pragmatic clinical trial (ePCT) designs.<sup>25</sup> Although ePCTs represent only one method for D&I of evidence-based dementia care, such designs afford the opportunity to systematically and simultaneously examine outcomes and implementation processes.<sup>26</sup>

The lack of pragmatic testing has impeded adoption of interventions in HCSs, with families and health providers continuing to have limited knowledge of and access to evidence-based dementia care.<sup>20,27</sup> Another limiting factor has been the lack of attention to D&I concerns throughout an intervention's developmental life cycle.<sup>28</sup>

To address these gaps, the D&I Core of the NIA Imbedded Pragmatic Alzheimer's Disease and AD-Related Dementias Clinical Trials Collaboratory is assisting investigators and stakeholders (HCSs, PLWD, care partners, providers, and payers) in the implementation and dissemination of dementia care interventions in the context of ePCTs.<sup>25</sup> Programs tested under experimental conditions and found to have some level of evidence typically require modifications and additional testing (hence, ePCTs) before widespread real-world adoption is possible. The scientific premise of this core is that D&I must be considered throughout an

intervention's developmental life cycle, and particularly when conducting an ePCT to optimize its potentiality for integration into HCSs. Having the "end" in mind by considering D&I goals at the outset of a pilot test and within a large-scale practical trial is critical for achieving the ultimate goal of bringing evidence-based dementia care to scale and in HCSs. The D&I Core addresses a significant and persistent knowledge-practice gap by applying the evolving science of D&I to: (1) optimize embedding and testing of dementia-related interventions within HCSs; (2) assure that interventions are poised for "scaling up" and dissemination; and (3) provide frameworks for identifying barriers and facilitators to D&I in HCSs and interpreting positive or suboptimal intervention and implementation outcomes. This article examines fundamental considerations for implementing dementia-specific interventions in HCSs being tested in ePCTs and how best to prepare for successful dissemination upstream.

## WHAT IS DISSEMINATION AND IMPLEMENTATION?

D&I is an evolving science that is only recently being applied to dementia care. The field has its roots in various methodological branches, disciplinary traditions, and countries, producing a plethora of terms with similar and/or overlapping meanings.<sup>29–32</sup> The conceptual and theoretical progress of D&I research is hindered due to a lack of standard terminology. As we apply D&I to ePCTs for dementia care, deriving consistency in nomenclature when reporting implementation and dissemination processes and understanding what works and why are important goals of our core that will advance the field.

We use as our working definitions those provided by the National Institutes of Health, which defines *dissemination research* as "the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience."<sup>33</sup> The goal of dissemination research is to identify processes and delivery methods associated with the spread (or lack thereof) of evidence to key audiences, including communities, direct care workers, or care settings.

*Implementation science* refers to the "scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve individual outcomes and benefit population health." Implementation science can inform ways to integrate evidence-based dementia care programs in care settings. An emphasis of implementation science is understanding how PLWD, caregivers, and HCSs behave and interact *in context* and the adoption, implementation, and sustainability of evidence-based interventions. An important methodological element of implementation science is use of frameworks and stakeholder-engaged research strategies<sup>34,35</sup> that incorporate the needs and resources of PLWD, caregivers, and HCSs during implementation. Other select terms pertinent to D&I research for dementia care are listed in Table 1 along with their application to ePCTs.

## IMPLEMENTATION OF EVIDENCE-BASED DEMENTIA CARE IN ePCTs

Implementation of evidence-based programs in a pilot or full ePCT occurs in three recursive phases,<sup>40</sup> with each informing and overlapping with the next. The first phase, “preimplementation,” is preparatory, in which investigators and stakeholders assess the readiness of an intervention and care context to identify a path for implementation. Additionally, identifying value propositions or what matters most to stakeholders (e.g., staff implementing the intervention, administrators, caregivers, and PLWD) is critical to inform outreach, marketing, referral structures, and outcomes to be measured.

The second phase, “implementation,” refers to the actual enactment of evidence-based programs in HCSs and use of strategies to support implementation, such as integrating staff training and coaching within workflows, monitoring fidelity, and evaluating adherence and outcomes. “Sustainability,” the third phase, refers to maintaining evidence-based programs beyond the finiteness of a study. Specifically, at an individual level, sustainability refers to whether a person receives, enacts, and sustains newly imparted knowledge and skills. At an organizational level, sustainability refers to whether staff and administrators fully integrate a program into daily operations such that it becomes routinized in workflows. At the policy level, the focus is on payment mechanisms and external requirements (local, state, and federal) that support continued implementation (or not).

### Preimplementation

At the preimplementation phase, we recommend the use of a novel, dynamic tool, the Readiness Assessment for Pragmatic Trials (RAPT), to guide planning. RAPT is structurally fashioned after Pragmatic–Explanatory Continuum Indicator Summary (PRECIS)-2; the latter determines the relative “pragmatism” of a study design.<sup>41</sup> The RAPT contains nine domains that assist researchers and stakeholders in decision-making as to the readiness to deploy pragmatic methods and move an intervention from efficacy (NIA stages II and III) to effectiveness (NIA stage IV) and eventual D&I (NIA stage V).<sup>1</sup> RAPT is designed to enable researchers and stakeholders to jointly consider the needed elements for a successful pilot and transition to a full ePCT and visually summarize their assessments. Assessments of each domain’s readiness are rated from low to high on a graphical summary wheel to identify domains or elements within that may require consideration when conducting the study. Using RAPT, challenges can be identified and methodological solutions derived to enhance readiness and optimize pragmatism of a study.

RAPT is a working tool for decision-making; there is no cutoff score for readiness, nor should RAPT be used as a quality measure. Nevertheless, low readiness in one or more domains may require the investigative team to address the issue(s) in concert with an HCS partner before and/or when engaging in a pilot or full ePCT. At the minimum, a pilot leading to a full ePCT should start with an intervention previously tested in a randomized clinical trial (NIA stage II or III) demonstrating its efficacy, have a strong level of acceptability among HCS stakeholders and align with their priorities, and have known and low risks. Table 2 lists RAPT domains and their definitions along with exemplars of common challenges and potential solutions when implementing a pilot/ePCT study.<sup>42</sup>

## Implementation

As the central focus of many pilot studies is to identify and evaluate implementation strategies to prepare for large ePCTs, “there is nothing so practical as a good theory,”<sup>43</sup> or a conceptual framework to inform implementation processes and understand what works, what does not, and why. There are 87 implementation theories or conceptual frameworks to choose from that have been developed in other fields but that are applicable to ePCTs for dementia care. Theories can be used to: describe and/or guide the process of translating an evidence-based program for delivery into an HCS (process models); understand and explain what influences implementation outcomes (determinant frameworks, classic theories, or implementation theories); and/or evaluate each aspect of the implementation process (broad evaluation framework).<sup>44,45</sup> For example, Normalization Process Theory (e.g., process theory) articulates four criteria to understand staff acceptability and adoption of an intervention.<sup>46</sup> The Consolidated Framework for Implementation Research (CFIR) synthesizes 19 implementation theories and condenses them into five domains (intervention characteristics, outer setting, inner setting, individual characteristics, and implementation process) and 39 determinants. As a broad framework, CFIR provides guidance concerning which elements of implementation to evaluate.<sup>47</sup> These and others can be applied to examine the unique and nuanced complexities of embedding and testing dementia care in HCSs.

Also, implementing an evidence-based intervention in HCSs requires deployment of a host of strategies. As with theories, there are many to choose from that have evidence for effectively supporting implementation.<sup>48,49</sup> Although implementation strategies have evolved from other fields, they can be used in pilot or full ePCT dementia care studies. Most frequently cited strategies for implementing evidence-based programs are derived from the Expert Recommendations for Implementing Change (ERIC) project.<sup>50</sup> ERIC reflects a compilation of 73 discrete strategies, derived from reviews of health and mental health literature and refined by a consensus panel of clinical and implementation experts.<sup>50,51</sup> This compilation of strategies was created to promote common nomenclature and to help investigative teams build tailored, evidence-informed strategies for implementation. Strategies are clustered into nine themes: (1) use evaluative and iterative strategies, (2) provide interactive assistance, (3) adapt and tailor to context, (4) develop stakeholder interrelationships, (5) train and educate stakeholders, (6) support clinicians, (7) engage consumers, (8) utilize financial strategies, and (9) change infrastructure.<sup>50,52</sup> Clusters can further be classified by stage of implementation. For example, clusters 3 (adapt and tailor) and 4 (develop stakeholder interrelationships) include strategies for a study’s preimplementation phase, whereas clusters 2 (interactive assistance), 5 (train and educate), and 6 (support clinicians) provide strategies for the actual implementation of a program; and clusters 8 (financial) and 9 (change infrastructure) may be more useful when considering sustainability.

Additionally, the Cochrane Effective Practice and Organization of Care group provides a taxonomy for health system interventions targeted at changing organizational culture.<sup>53</sup> Based on literature reviews, 19 implementation strategy subcategories are identified (e.g., audit and feedback; educational games; reminders) and defined.

## Sustainability

Little research on sustainability has been conducted nor have ERIC strategies relevant to sustainability been widely used.<sup>21</sup> Pilot or ePCT studies are not typically designed to address sustainability-type research questions. However, considering sustainability upfront at the pilot/ePCT stage can inform decision-making about implementation processes that may ultimately impact the future dissemination and wide-scale implementation of interventions in HCSs. Of importance to sustainability is determining early on how a program can be fully embedded in HCS care routines, mechanisms for ongoing staff training and support, payment structures, and outcome measures. Consideration of these factors can contribute to successful dissemination, wide-scale implementation, and sustainability. Exemplars from cancer care<sup>54</sup> and hospital-to-home transition care models<sup>55–57</sup> may be informative and help to identify sustainability considerations for dementia care.<sup>58,59</sup> Specific to dementia care, a few efforts have demonstrated that a caregiver support program, Skills<sub>2</sub>Care, can be embedded and reimbursed in home care, whereas the Tailored Activity Program that addresses behavioral symptoms and functional decline can be embedded and reimbursed in hospital care.<sup>55–57</sup> Other payment models will be critical to identify and test when considering sustainability strategies for dementia care.

One way to understand sustainability potential at a pilot study stage is through the application of Lewin's "field theory."<sup>43</sup> Field theory and its associated force field graphic suggest that for organizational change (e.g., implementing evidence-based dementia care programs in HCSs), there are positive forces supporting change and constraining forces against such change. There is some empirical evidence showing that when driving forces are stronger than constraining forces, the status quo will change in favor of the desired change. Identifying positive and negative forces is fundamental when planning and implementing a pilot study and understanding their dynamic nature may be an outcome of a pilot study. Identifying factors that drive or constrain implementation can inform the selection of strategies that improve uptake of the evidence-based intervention in a full ePCT.<sup>60</sup> For example, two key driving (positive) forces found to be successful in an analysis of 28 studies translating dementia care programs for delivery in HCSs included assessing the stakeholder's readiness for implementation and tailoring and adapting the intervention to the practice setting.<sup>21</sup> Two constraining forces identified in these studies included the lack of engagement of caregivers during implementation and the lack of attention to payment approaches to support eventual sustainability.<sup>21</sup> Lewin (1951)<sup>43</sup> advised that attention to constraining forces is essential to propel change (implementation of evidence-based program and its maintenance). For instance, despite attention to driving forces, such as having well-developed training plans or providing technical assistance and coaching for dementia care staff, insufficient attention to payment mechanisms may diminish or negate these positive driving forces, leading to ineffective efforts at dissemination and wide-scale implementation.

## WHAT ABOUT DISSEMINATION?

Although implementation science has evolved from and is often linked with the evidence-based medicine movement, dissemination research has emerged from various branches of social science, such as rural sociology (most prominently, via Rogers' *Diffusion of*



*Innovations*<sup>61</sup>) and policy analysis, among others.<sup>62</sup> Although several implementation frameworks consider dissemination, agreed on measures of dissemination success are lacking.<sup>63</sup> Similarly, dissemination methods have not been considered in dementia care.

The emphasis of ePCT studies should be on implementation processes and outcomes, and considering dissemination and sustainability as the end goal is critical. The D&I core provides technical assistance to investigative teams to consider how to operationalize these goals and evolve a dissemination plan. Although researchers are mostly familiar with passive dissemination modalities, such as professional presentations and scientific publications, the evidence clearly shows that these approaches rarely result in wide-scale uptake. At the pilot testing stage, there are actions that can be taken to help prepare for active dissemination. For example, identifying key stakeholders and what matters most to each are key data points central to formulating value propositions, marketing and outreach materials, and other dissemination activities following pilot/ePCT testing.<sup>64</sup>

## **BARRIERS AND SOLUTIONS TO IMPLEMENTING EVIDENCE-BASED DEMENTIA CARE PROGRAMS**

Numerous barriers are apparent when implementing dementia care in HCSs. These barriers are similar to those found in other fields and contexts and include: uneven implementation of evidence; need for deimplementation or elimination of existing practice(s); premature implementation (e.g., evidence not strong enough); staffing shortages; workforce preparation needs; implementation without use of best practices; site not ready or resistant to adopt new practices (e.g., the context does not support a new practice sufficiently); and poor characterization of an intervention, preventing adaptation and replication. In addition to these general barriers, implementation challenges unique to dementia are also apparent, such as the fragmentation within medical care systems and with community-based programs supporting dementia care (particularly in the United States).

Similarly, barriers limiting dissemination and scaling efforts include but are not limited to: labor-intensive training and fidelity approaches; overreliance on original developers; need for highly trained health professionals to implement the evidence, thus precluding dissemination to regions with workforce limitations; high-dose and high-intensity interventions that are costly; and lack of adequate payment mechanisms to support training, implementation, and sustainability. Table 3 defines barriers at different levels of impact (organizational, recipient) and lists potential solutions of relevance when planning pilots and full ePCTs specific to the dementia care context.

## **FUTURE DIRECTIONS**

In summary, the science of D&I can inform implementation of evidence-based dementia care tested in ePCTs by offering theoretical frameworks that capture field complexities and guide evaluations as well as evidence-based strategies supporting implementation. D&I considerations are critical at each stage of an intervention's development and particularly when designing pilots for pragmatic trials. Designing ePCTs (pilots or full ePCTs) in which implementation processes are considered will facilitate the ultimate goal of dissemination,

wide-scale implementation and sustainability. For example, if the goal is to implement an intervention in all hospital systems in the United States, then at the pilot testing stage actions might include, but not be limited to, engaging with hospital systems and national organizations to determine HCS acceptability of the intervention; determining existing data sources to evaluate outcomes; training embedded staff to deliver the intervention; adapting the intervention to workflows; and determining how to monitor intervention fidelity. The scientific premise is that having the “end” in mind, upfront when designing an intervention and at the pilot/ePCT stages, can lead to decision-making that optimizes the ultimate goal of wide-scale D&I of evidence-based dementia care programs.

Regarding the NIA Collaboratory, the D&I Core has an important role in assisting investigators. The core is generating summations of interventions for PLWD, care partners, and care providers that have demonstrated efficacy, low risk, and acceptability and that are ready for pilot testing, leading to full-scale ePCTs. These summations will also identify gaps in evidence and point to the areas where future intervention development is warranted. Furthermore, using RAPT, we will evaluate readiness levels of studies and the relationship of readiness to the successful enactment of ePCTs. Evaluating the level of pragmatism achieved in pilots and subsequent ePCTs and their outcomes will enable an understanding of whether pragmatic testing in dementia care can shorten the 17-year or more journey from intervention development to full implementation in HCSs. Finally, a future focus includes identifying and cataloguing implementation strategies that result in effectively embedding dementia care interventions in settings and whether strategies differ by setting, intervention complexity, or heterogeneity of PLWD, care partners, and care providers.

Although our focus is necessarily on ePCTs, it represents one method in dementia care for D&I, and several limitations should be noted. It is unclear as to the level of evidence needed to move forward with ePCTs, and not all forms of evidence are amenable to testing using this approach. Due to operational constraints, ethical concerns, or time, organizational partners may be less willing to consider ePCT designs in favor of other methodological approaches, such as comparative case studies, network analysis, or agent-based modeling, to inform implementation and dissemination of dementia care interventions. Furthermore, ePCTs focus on embedding interventions into existing systems of care, versus changing the system itself (which may necessitate more systems science approaches). An ePCT seeks to integrate evidence into existing workflows and examine outcomes using electronic health records (EHRs). Nevertheless, dementia care programs may require deimplementation of existing practices, workflow changes involving interprofessional team care strategies, and consideration of outcomes that are more important and relevant to PLWD and care partners than those captured in standard EHRs. Finally, ePCTs cannot address the fragmentation of HCSs and fissures between medical, social, and aged care systems. Ultimately, comprehensive dementia care requires a seamless, comprehensive, and interprofessional care system. Such system realities may preclude ePCT methods in favor of more formative evaluation approaches to facilitate organizational/system readiness for successful ePCT evaluation and, eventually, successful D&I of dementia care innovations.



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**Table 1.**

**Key Dissemination and Implementation Terms and Relevance to Pilots and ePCTs<sup>36</sup>**

<b>Term</b>	<b>Definition</b>	<b>Relevance to pilots/ePCTs</b>
Adoption	Organizational or community commitment to, and initiation of, an evidence-based intervention.	Involve key stakeholders to obtain buy-in for utilizing an intervention.
Cultural adaptation	Changing or modifying an intervention to fit needs and preferences of a cultural group. <sup>37</sup>	Decide with stakeholders what adaptations to an intervention are needed while maintaining the principles by which the intervention is effective.
Cultural attunement	Modifying interventions to increase reach, engagement, and retention of groups without changing principles of an intervention. <sup>38</sup>	Use preferred language, integrate familial traditions, have staff from culture delivery intervention.
Deimplementation	Stopping, replacing, or abandoning practices that may cause harm or be ineffective, often to improve outcomes or save costs.	Determine if intervention is added value or replaces a practice. If replaced, examine if better outcomes occur.
Diffusion	Spread of interventions passively and without target, planning, or control.	Identify messaging, value propositions to inform future diffusion of the intervention.
Evidence-based intervention	Programs, practices, interventions, with proven efficacy.	Pilot ePCT should start with a tested and manualized intervention.
Fidelity	Determine whether an intervention is delivered as intended and if study design is followed.	Consider adherence to protocol and intervention principles and ways to monitor fidelity within workflows.
Knowledge transfer	The process of transferring knowledge from researchers to stakeholders.	Identify key messaging, what matters to stakeholders; develop strategies for informing different stakeholders about the evidence.
Sustainability/sustainment	Extent to which an intervention continues to be delivered after external support has ended.	Identify workflow and ways to integrate an intervention in organization's flow.
Translational research	Developing and testing treatment and prevention approaches from fundamental laboratory and/or preclinical discoveries (i.e., "bench to bedside to practice"; research).	Modify an intervention for delivery within an HCS. Modify procedures for implementation to facilitate rapid transition through testing stages of an intervention.
Value proposition	Costs, value, and benefits experienced by healthcare suppliers, physicians, managers, purchasers, and/or policymakers. <sup>39</sup>	Articulate clear messaging, reflecting what matters to different stakeholders as it concerns an intervention.

Abbreviations: ePCT, embedded pragmatic clinical trial; HCS, healthcare system.

**Table 2.**

Possible Challenges and Solutions for Pilots for ePCT, by RAPT Domain

RAPT domain and definition	Possible challenge	Possible focus of a pilot for an ePCT
1. Implementation protocol: Is the protocol sufficiently detailed to be replicated?	Investigators may be uncertain as to how to implement an existing protocol using an embedded approach and how to measure fidelity.	Partner with HCS provider sites to test the feasibility of staff incorporating the protocol into their workflow; have supervisors review routinely captured clinical notes to ascertain fidelity to the protocol and implementation.
2. Evidence: To what extent does the evidence base support intervention's efficacy?	At a minimum, a pilot must start with an intervention previously tested in a randomized clinical trial and be efficacious. Investigators may want to test the intervention in a new setting.	Evaluate the feasibility of conducting an ePCT by consulting with leadership and staff methods of randomization, sample size, and other design considerations.
3. Risk: Is it known how safe the intervention is?	At a minimum, an intervention's risks must be known and low and plan to monitor risks.	Develop a plan to record and address any adverse event (e.g., if a patient falls).
4. Feasibility: To what extent can the intervention be implemented under existing conditions?	Investigators may be engaging with new partners or sites or using embedded methods for the first time.	Evaluate feasibility of the intervention when implemented by provider staff at partner sites, if and how changes in policy or practice impact implementation.
5. Measurement: To what extent can the intervention's outcome be captured?	Administrative and clinical data may not capture outcomes of interest or be readily accessible to researchers.	Identify measures used by HCSs; examine how new measures can be integrated into routine workflow. Use mixed methods to overcome measurement limitations.
6. Cost: How likely is the intervention to be economically viable?	Prior studies may have limited data on cost-effectiveness or policies and practices that impact cost-effectiveness may have changed.	Consult with stakeholders to identify potential resource issues, including staff time for training and implementation, and derive business case for intervention.
7. Acceptability: How willing are providers to adopt the intervention?	At a minimum, an intervention must be acceptable to HCS partners. However, often acceptability is ascertained by engaging HCS leaders and not the frontline staff responsible for implementation.	Conduct qualitative interviews with provider staff responsible for implementing the intervention, supervisors, and leadership.
8. Alignment: To what extent does the intervention align with external stakeholders' priorities?	Stakeholders may have previously stated that an intervention aligns with priorities, but priorities can change over time as new policies and practices are enacted.	Incorporate stakeholder-engaged methods to obtain ongoing input as to how intervention processes align with stakeholder values, goals, and mission.
9. Impact: How useful will the intervention's results be to different stakeholders?	Questions about how results of the pilot study can inform care or policy.	Incorporate stakeholder-engaged methods to develop active dissemination strategies for key audiences.

Abbreviations: ePCT, embedded pragmatic clinical trial; HCS, healthcare system; RAPT, Readiness Assessment for Pragmatic Trials.



**Table 3.**

**Barriers to Implementation and Possible Solutions in Pilot and Full ePCTs**

Level and type of barriers	Key modifiable barriers	Possible solutions in pilot and full ePCTs
Innovation level	<ul style="list-style-type: none"> <li>Premature implementation of dementia care practices</li> </ul>	<ul style="list-style-type: none"> <li>Use Readiness Assessment for Pragmatic Trials tool</li> </ul>
Context level	<ul style="list-style-type: none"> <li>High turnover rates impact facilities' ability to implement and sustain dementia care programs</li> </ul>	<ul style="list-style-type: none"> <li>Embed training into new staff orientation to integrate in workflow for sustainability</li> <li>Embed intervention monitoring in ongoing supervision, provide case presentations at staff meetings</li> </ul>
External healthcare system level	<ul style="list-style-type: none"> <li>Healthcare system policies do not support interdisciplinary care planning and communication</li> <li>Productivity and reimbursement constraints</li> <li>Complexity of dementia care not recognized in reimbursement policies</li> </ul>	<ul style="list-style-type: none"> <li>Assess organizational readiness for change and/or adoption of new practices when selecting sites for implementation of dementia care programs</li> <li>Advocate for policy change</li> <li>Identify payment models to support staff training and ongoing use of dementia care program</li> </ul>
Recipient level	<ul style="list-style-type: none"> <li>Limited availability of trained clinicians in dementia care</li> </ul>	<ul style="list-style-type: none"> <li>Advocate for dementia care in health professional curricula</li> </ul>
Provider level	<ul style="list-style-type: none"> <li>Implementation takes time and resources, which are limited in busy clinical settings with full caseloads</li> </ul>	<ul style="list-style-type: none"> <li>Appoint clinical champions to facilitate on-site problem solving in dementia care</li> <li>Provide dementia care training for medical licensure or continuing education credit</li> </ul>
Person living with dementia/ caregiver level	<ul style="list-style-type: none"> <li>Families have autonomy to refuse treatments or may not see value in an intervention or how it addresses what matters most to them</li> </ul>	<ul style="list-style-type: none"> <li>Use online training to facilitate learning and shorten staff training time</li> <li>Consult with a person-led advisory board to inform implementation</li> <li>Include person living with dementia and care partner in identifying implementation processes</li> </ul>
Researcher level	<ul style="list-style-type: none"> <li>Researchers studying the implementation of evidence-based dementia care practice may lack the networks of potential partners interested in adopting or changing care practices</li> </ul>	<ul style="list-style-type: none"> <li>Provide education, empowerment, and shared decision-making</li> <li>Establish networks of healthcare and community partners</li> <li>Develop an infrastructure to collaborate across healthcare and community partners</li> <li>Market implementation research of innovative care as way to solve a facility/system problem</li> </ul>

Abbreviation: ePCT, embedded pragmatic clinical trial.