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Pragmatic Trials for Nonpharmacologic Dementia Interventions

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Introduction

NIA organised the National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers in October 2017. A two-day national research conference, the summit's goal was to accelerate advancements in the care of those with Alzheimer's disease and related dementias (ADRD) and those who provide care for them. An important national goal is to improve ADRD care. Currently, more than 5 million Americans suffer with ADRD; the annual cost of caring for an ADRD patient is more than $226 billion, and the lifetime cost is $321,780,3. In numerous treatment settings, a variety of nonpharmacologic approaches have shown promise in improving outcomes for people with ADRD and their careers.

Description

Observational studies continue to show that care for persons with ADRD and their families is still not provided to the highest standard because many of these interventions have not been broadly adopted. The adoption of evidence-based, nonpharmacologic ADRD therapies into clinical practise may be sped up through pragmatic studies (5e10). The National Institutes of Health (NIH) has invested in a pragmatic trial infrastructure via the NIH Common Fund Collaboratory, but the Collaboratory has not focused on trials of ADRD interventions implemented in the various care settings in which people with ADRD are served. As a follow-up to the National Research Summit, we chaired a workshop at NIA in December 2017 to discuss a national framework for supporting pragmatic trials of nonpharmacologic dementia interventions. Workshop participants included researchers conducting dementia-related pragmatic trials, health care leaders with experience translating interventions into clinical practice, and senior NIA staff. PCTs include evaluating interventions in the actual setting of healthcare delivery and financing structures.

Although PCTs are a relatively new approach to studying health services, NIH has been sponsoring them in order to better understand their distinct operational and methodological characteristics.The present NIH Common Fund Collaboratory seeks, in part by utilising the different experiences of studies on a wide range of themes, to build the national capacity to implement PCTs in collaboration with healthcare professionals. Although funded research do not expressly address nonpharmacologic dementia therapies, the Collaboratory's gathered expertise is influencing our understanding of the characteristics of interventions most suited for PCTs as a whole. Encephalia interventions, which are frequently complicated, may involve a variety of delivery methods and necessitate substantial formal and/or informal caregiver training. A pragmatic trial's design imitates the difficulties of implementation in the actual world. In PCTs, researchers can randomly assign units or locations to carry out an intervention, benefiting everyone who qualifies for it, while other units or locations can act as control sites. Valid administrative and clinical data can be used for review, audit, and feedback.

As is done in quality improvement programmes, the use of novel techniques, such as stepped wedge designs, can enable quick feedback to guide iterative revisions to the intervention's content or implementation. This helps to guarantee that the final intervention reflects a setting's particular needs and is likely to be effective. Although the above approaches may help to accelerate research and dissemination, there are challenges unique to conducting PCTs with people with ADRD, many of whom do not have decisional capacity. Interventions focused on the person with ADRD not only need to give careful consideration to ethical concerns and unintended consequences but may also need to include family caregivers as dyads or target them with supportive interventions.

The criteria relate both to conducting the research and to maximizing the likelihood of adoption by service delivery organizations if the research were to demonstrate effectiveness of the intervention in a real-world setting. For example, researchers and health care providers alike need a minimal level of efficacy data, indicating that the intervention improves outcomes of interest and sufficiently detailed implementation protocols to be able to replicate it. At the same time, for an intervention to be broadly adopted, if effective, health care partners also need to feel that it addresses their priorities, can be adapted to their unique environments, and is possible to implement with existing resources and within current reimbursement models. The infrastructure needed for researchers to conduct pragmatic trials of non-pharmacologic dementia therapies was explored by workshop attendees. They had an idea for a coordination hub akin to the NIH Common Fund Collaboratory [1-5].

Conclusion

Using that example, Participants suggested that an ADRD coordination hub should have working teams, or "cores," dedicated to enhancing the capacity of investigators. The NIA is prepared to apply the lessons learnt from past pragmatic trial projects sponsored by the NIH and apply them to research on dementia. The timing is ideal for conducting PCTs for nonpharmacologic dementia interventions, in part because ADRD research is currently receiving national attention, recent meetings to define the research agenda have gained traction, and a number of interventions have produced encouraging results in efficacy trials.The value of pragmatic research was enthusiastically acknowledged by attendees of this NIA session as a means of ensuring that such treatments are successful in the real world. Researchers can use the established parameters to assess how PCT-ready dementia therapies are. While sharing information about how to establish capacity for such RCTs, recommendations for infrastructure can also inform policy.

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Conflict of Interest

The Author declares there is no conflict of interest associated with this manuscript.

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