PILOT STUDY PRAGMATIC DESIGN WORKSHEET INSTRUCTIONS (Required for Letter of Intent): Use the suggested criteria to score your proposed intervention/design element as either low (L, not ready/pragmatic), medium (M, partially ready/pragmatic), or high (H, mostly ready/pragmatic) and describe the design element and rationale for your score in fewer than 100 words. Your proposed pilot study MUST BE PRAGMATIC. Please read the Readiness Assessment for Pragmatic Trials (RAPT) model and the PRECIS-2 framework for guidance and definitions of these domains.

DOMAIN	PLEASE DESCRIBE AND PROVIDE RATIONALE FOR SCORE (approximately 100 words)
1. IMPLEMENTATION PROTOCOL ***Is the intervention protocol sufficiently detailed to be replicated?*** ☐L There is no protocol. ☐M The protocol provides some documentation, but may be difficult to replicate. ☐H The protocol is well documented and is likely to be replicated.	
2. EVIDENCE ***To what extent does the evidence base support the intervention's efficacy?*** ☐L There are no efficacy studies or the efficacy studies did not use rigorous methods (e.g., a RCT). ☐M A single study using rigorous methods demonstrated efficacy. ☐H Multiple studies using rigorous methods have demonstrated efficacy.	
3. RISK ***Is it known how safe the intervention is?*** ☐L The risks (harms and discomforts) are unknown or are known to be more than minimal (e.g., greater than ordinarily encountered in daily life). ☐M The risks are unknown, but are likely minimal. ☐H The risks are known to be minimal.	

4. FEASIBILITY ***To what extent can the intervention be implemented under existing conditions (i.e., implemented in usual clinical workflow of the health care system)?*** ☐$_L$ Resources necessary for implementation (e.g., staff, infrastructure, payment) are absent or insufficient. ☐$_M$ Minor modifications to existing resources would enable implementation. ☐$_H$ Implementation is possible with existing resources.	
5. MEASUREMENT ***To what extent can the primary clinical outcome be captured using electronic health care system or administrative data (e.g., electronic health records, Medicare data, widely used surveys such as CAHPS)?*** ☐$_L$ Outcomes cannot be captured without major modifications to systems (e.g., clinical assessments, documentation, or electronic health records) or increases in staff time. ☐$_M$ Outcomes can be captured with minor modifications to systems or increases in staff time. ☐$_H$ Outcomes are already routinely captured.	
6. COST ***How likely is the intervention to be economically viable?*** ☐$_L$ Cost-benefit/cost-effectiveness analysis has not been completed (formally or informally) and it is unknown whether benefits outweigh costs. ☐$_M$ Cost-benefit/cost-effectiveness analysis has not been completed, but benefits are likely to outweigh costs. ☐$_H$ Cost-benefit/cost-effectiveness analysis demonstrates benefits outweigh costs.	

7. ACCEPTABILITY ***How willing are providers in the health care system likely to adopt this intervention?*** ☐L Acceptability is unknown or staff are unlikely to believe the intervention is feasible or needed. ☐M Acceptability is unknown, but staff are likely to believe the intervention is feasible or needed. ☐H Acceptability is known and staff believe the intervention is feasible and needed.	
8. ALIGNMENT ***To what extent does the intervention align with key stakeholders' (e.g., health care system, frontline providers, people living with dementia and/or their family caregivers) priorities?*** ☐L Stakeholders do not believe the intervention addresses a current or anticipated priority. ☐M Some stakeholders believe the intervention addresses a priority. ☐H Most or all stakeholders believe the intervention addresses a priority.	
9. IMPACT ***How useful will the results be IF the intervention is found to be effective in positively affecting the primary outcome?*** ☐L Providers and stakeholders (e.g., health care system, frontline providers, people living with dementia and/or their family caregivers) are unlikely to believe that the outcomes are useful (e.g., to inform clinical care or policy). ☐M Some providers or stakeholders are likely to believe the outcomes are useful. ☐H Most or all providers and stakeholders are likely to believe the outcomes are useful.	

10. CONSENT ***Can the pragmatic trial be accomplished with a waiver of individual consent in accordance with Federal regulation 45 CFR §46.116(f)(3)(i.-v.)?*** ☐L The study will require individual informed consent. ☐M The study is designed such that approval for an alteration of consent is anticipated. ☐H The study is designed such that approval for a waiver of consent is anticipated.	
11. SUBJECT IDENTIFICATION ***To what extent can subject identification be accomplished using existing health care system electronic data infrastructures (e.g., electronic health records, administrative/billing data)?*** ☐L Subject identification will require substantial augmentation to existing health care system electronic data infrastructure and/or resources. ☐M Subject identification will require modest augmentation to existing health care system electronic data infrastructure and/or resources. ☐H Subject identification can be completely accomplished using existing health care system electronic data infrastructure and/or resources	
12. IMPLEMENTATION DELIVERY ***To what extent can the intervention be delivered with the usual organization and resources of the health care system?*** ☐L Intervention delivery will require substantial changes to the usual organization and augmentation of existing resources of the health care system. ☐M Intervention delivery will require modest changes to the usual organization and augmentation of existing resources of the health care system. ☐H Intervention delivery will require minimal changes to the usual organization and augmentation of existing resources of the health care system.	