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Designing and Disseminating the Next Generation of Interventions for Persons with Dementia

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Purpose

- Summarize Evidence on the Effectiveness of non-pharmacologic interventions to ameliorate disturbed behavior among persons with Advanced Dementia
- Identify gaps in readiness to broadly disseminate “evidence based” interventions
- Present a framework to evaluate the readiness of an intervention for dissemination into health systems
- Provide Examples of intervention readiness
- Consider Implications for disseminating “evidence based” interventions in the “real world” of functioning health systems

Forward

- Many interventions implemented by researchers show positive effects on outcomes
- They are done as proof of concept
- BUT, rarely consider whether and how they would be adopted in functioning health systems
- Why are some interventions adopted and others are not?
- Implementing interventions in the real world requires understanding this process

Summary of Evidence Synthesis

Care-Delivery Interventions to Manage Agitation and Aggression in Dementia Nursing Home and Assisted Living Residents: A Systematic Review and Meta-analysis

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ADRD Interventions

Target	Outcomes	Method of Delivery	Example
Person with ADRD	Quality of life, behaviors, specific behaviors, function, physical activity	Directly to the person with ADRD	Physical exercise
		Through the care staff	Dementia care mapping
		Through family member	Case conferences /decision aids
		Through the environment	Functional modifications
		Through the care delivery system	De-prescribing interventions



Challenges

- Interventions for person with ADRD, care staff, family caregivers often done by researchers & highly trained professionals
- Multiple outcomes and measures
- Establishing criteria to determine what is ready to be tested
- Who cares? Why does it matter?

Challenges

- Settings poorly described
- Heterogeneous interventions hard to summarize with evidence-synthesis tools
- Inconsistent terminology
- Many One-off studies (little replication)

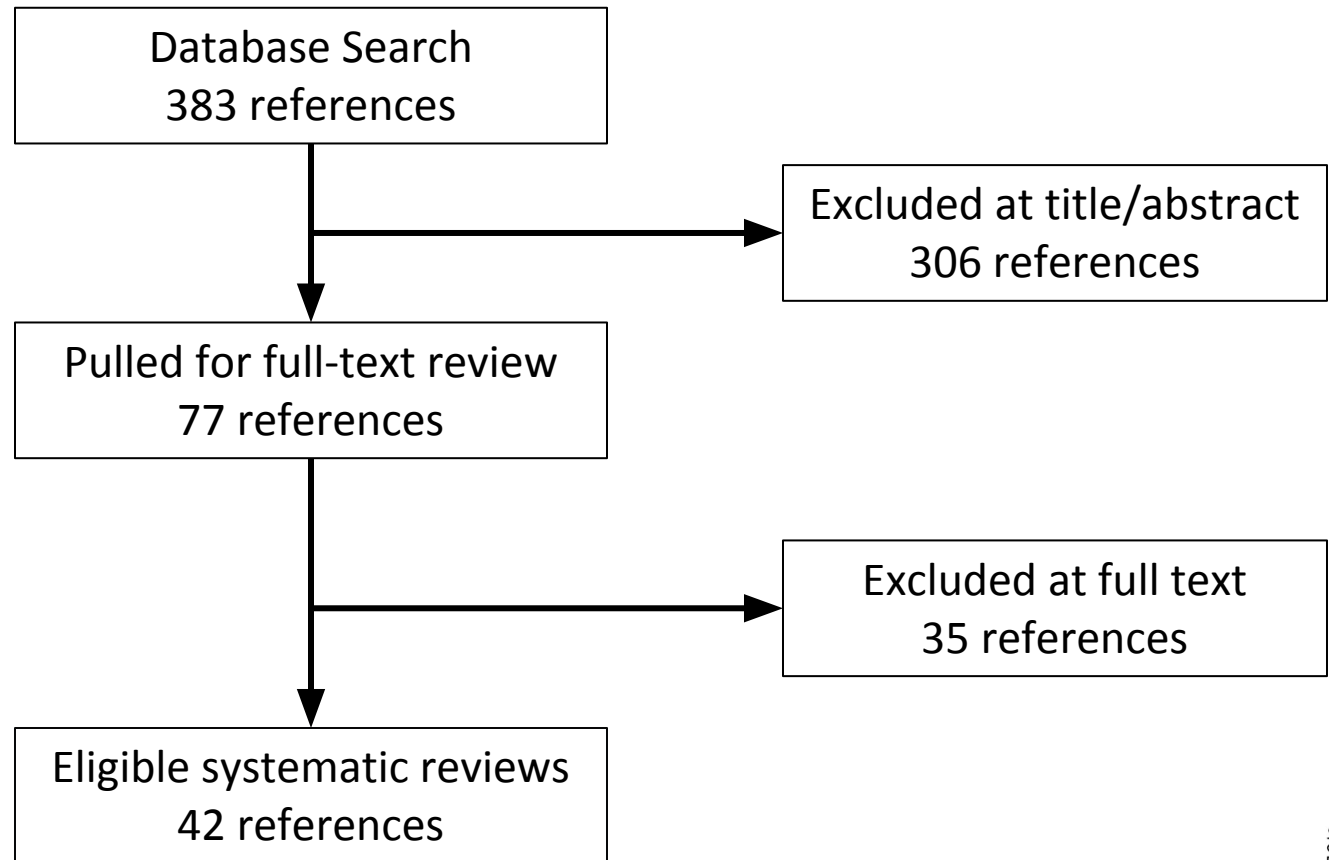
Methods

- Search of systematic reviews
- Find signals in the meta-analysis
 - What interventions
 - What outcomes
 - What results

Methods

- Data sources: Medline, Cochrane, hand searches
- Population: **individuals with dementia** in facilities (nursing home, assisted living, other)
- Interventions: nonpharmacologic interventions
- Outcomes: any outcomes in a person with dementia
- Comparators: usual care or no treatment, attention control or placebo, other nonpharm interventions, pharmacologic interventions

Included Studies



Implementation Challenges Described

- Complexity
- Scalability
- Long term fidelity/maintenance
- Cost

Example: Dementia Care Mapping (DCM)

- Staff or trained experts systematically observe a person with dementia. Feedback is then provided to care staff who use the information to develop person centered care plans.
- Expert training, labor intensive, costly
- Scalable?

Dementia Care Mapping (DCM): Researcher vs. Provider Implementation

- Chenoweth 2009
 - Staff training in DCM followed by care mapping sessions **by researchers and trained staff**
 - Researchers implementing DCM “participated in **hundreds of hours** of intervention procedures”
 - Care plans implemented by staff with researcher input
- Van de Ven 2013
 - Two care staff trained in DCM, all staff provided with high-level briefing on DCM, two DCM cycles performed
- Rokstad 2013
 - Staff trained in DCM, **care mapping by researchers and staff** at beginning of study and at 6 months.
 - Care plans implemented by staff without researcher input

Dementia Care Mapping Results

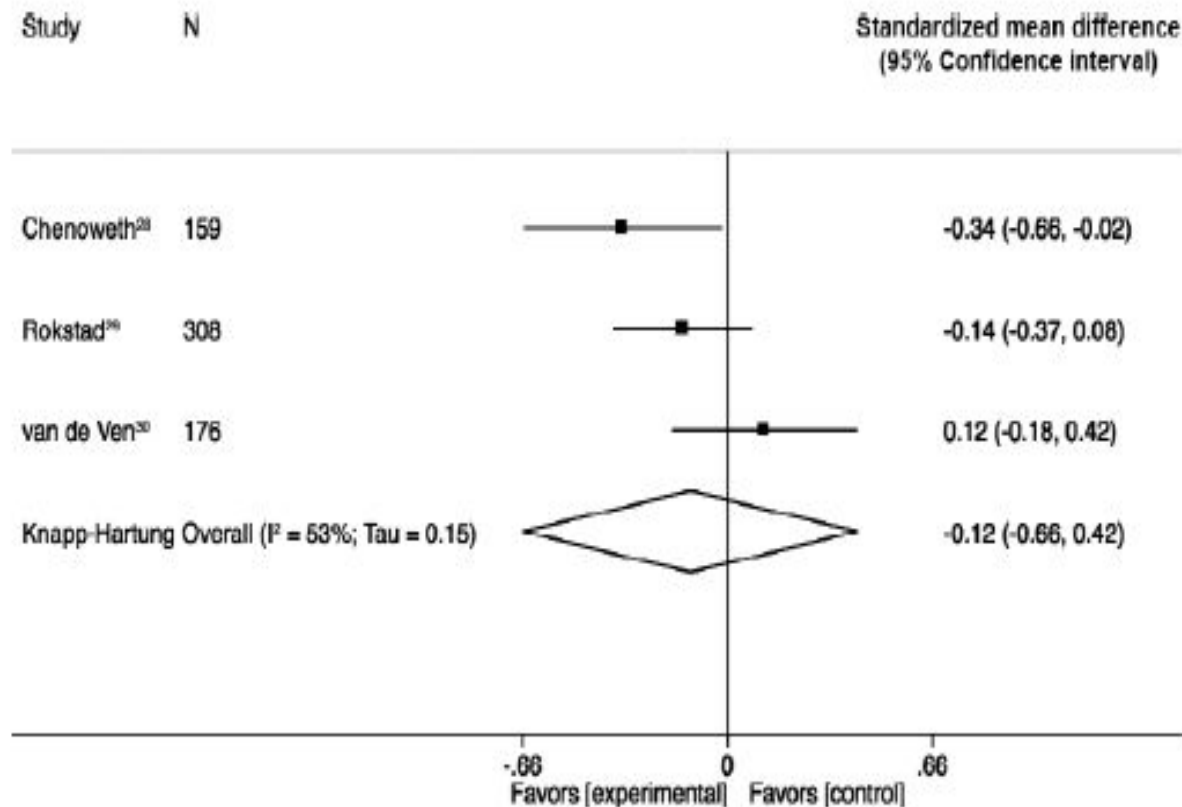


Figure 1. Random-effects meta-analysis for the effect of dementia care mapping on frequency of agitation and aggression. SMD = standardized mean difference; CI = confidence interval.

Translating Researchers' Interventions into Health Systems Programs

- Researcher Directed interventions done in NHs are separate from ongoing care systems
- Even careful training and monitoring of staff implemented interventions are not “usual care”
- Integrating new programs into existing care processes requires re-engineering processes
- To really test whether “evidence based interventions” can be implemented, need Embedded Pragmatic Clinical Trial

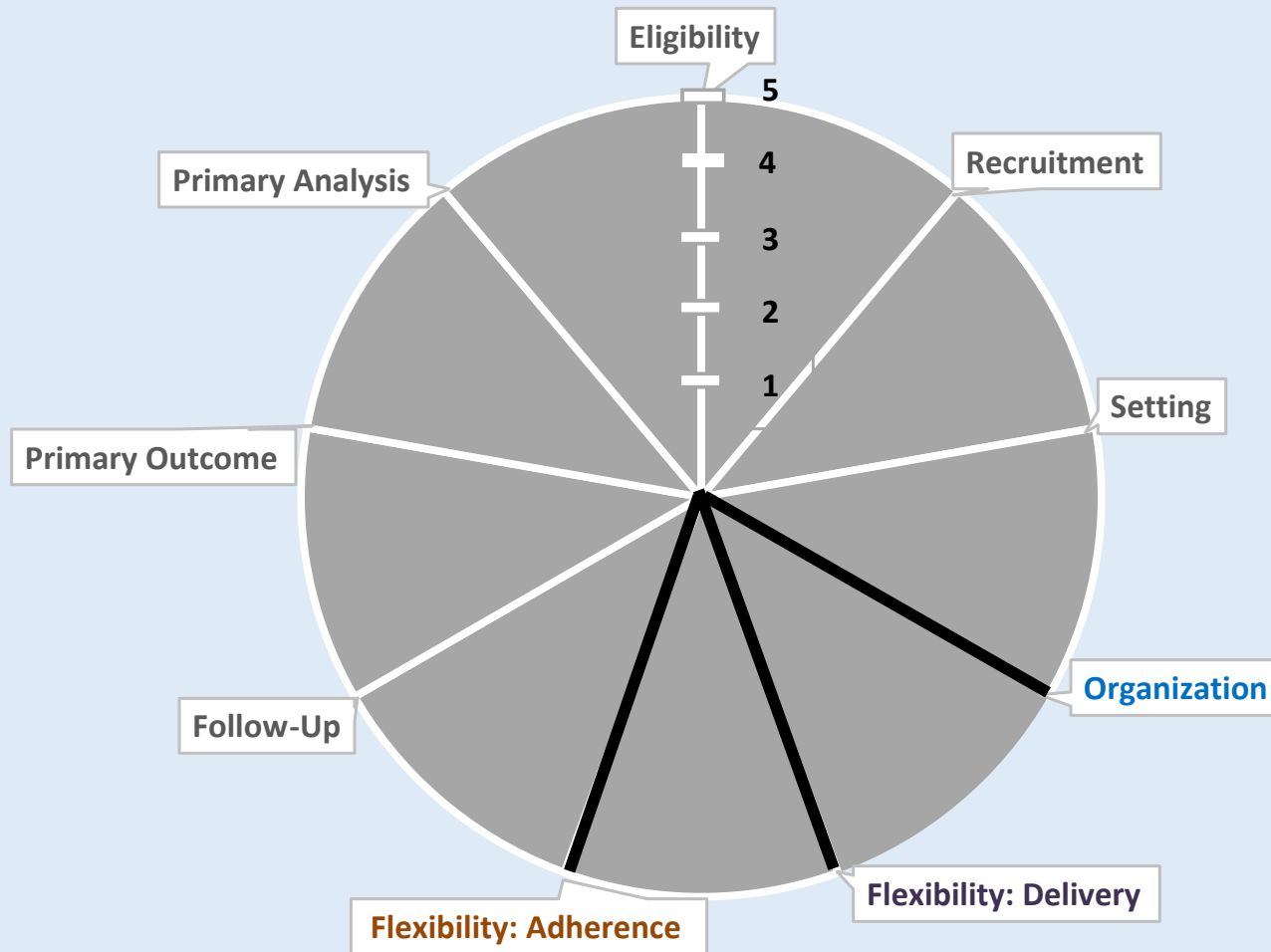
The Simpler the Intervention the Easier to Conduct a Pragmatic Trial

- **Easy:** Substitute one vaccine for another (e.g. high dose influenza vs Standard dose)
- **Surprisingly Complicated:** PROVEN -- Video Assisted Advance Care Planning for ALL in NH
- **Multi-pronged:** Music & Memory
- **Multi-pronged Complexity:** INTERACT, DCM-Dementia Care Mapping, Staff Training

How Pragmatic? How Replicable?

- PRagmatic Explanatory Continuum Indicator Summary (PRECIS)
- Refers to BOTH trial design AND implementation design and flexibility in the organization of the intervention
- PROVEN: Researchers trained Corporate Staff who trained facility staff and monitored intervention adherence
 - Changes required based on monitoring data

PRECIS 2* IMPLEMENTATION DOMAINS



* PRECIS-2 diagram from Loudon et al, BMJ, 2015 with adapted formatting.

Implementation RT vs. HCS: ORGANIZATION

ASPECT	Approach	Challenges
TRAINING	<p>RT: Developed training materials -e.g., printed toolkit, webinars, laminated card</p> <p>HCS: Leveraged existing corporate infrastructures to do trainings</p> <p>RT & HCS: Co-led trainings</p>	<ul style="list-style-type: none"> HCS' had different preferred modalities: HCS1: Centralized, in-person HCS2: Multiple Webinars Turnover of NH champions required multiple re-trainings
PERSONNEL	<p>HCS: Corporate-level leader appointed to oversee project; Site champion(s) at each NH</p>	<ul style="list-style-type: none"> Turnover of both corporate leaders Extensive champion turnover
RESOURCES	<p>RT: Developed intervention; supplied tablets with videos</p> <p>HCS: Provided training venues; embedded video status report into EMR</p>	<ul style="list-style-type: none"> Tablets stolen at one site so RT replaced them

**RT=research team; HCS=health care system*

Implementation: FLEXIBILITY (DELIVERY)

ASPECT	Approach	Challenges
PROTOCOL-DRIVEN	RT: Guidelines for timing of video OFFERING proscribed RT: <u>Flexible</u> guidelines for: -which videos to offer which patient -who shows videos (mostly SW)	<ul style="list-style-type: none"> • Higher adherence for admissions vs. LTC • Competing responsibilities a barrier • LTC-patients hard to find “right time”, family often not at care planning meeting
CO-INTERVENTIONS	HCS: Allowed other ongoing ACP activities to continue in NHs	<ul style="list-style-type: none"> • Other ACP programs highly variable • Many other initiatives to ↓hospitalizations (1^o outcome)
MONITORING	RT: Designed Video Status Report (VSR) HCS: Embeds VSR into EMR at all NHs	<ul style="list-style-type: none"> • Champions interpreted compliance as <u>offering</u> (i.e., VSR completion) vs <u>showing</u> video

Implementation: FLEXIBILITY (ADHERENCE)

ASPECT	Approach	Challenges
PRE-SCREENING	HCS: Excluded sites with major organizational or regulatory difficulties	<ul style="list-style-type: none"> Determination of 'dysfunctional' sites was subjective based on corporate leaders' assessments
SITE WITH-DRAWAL	RT: NHs with low implementation adherence rates were NOT dropped	<ul style="list-style-type: none"> HCS divested several NHs mid-implementation
SITE MONITORING	HCS: Internal monthly reports for VSR completion for <u>admissions only</u> RT: <u>Quarterly reports</u> were completed for admissions and LTC; <u>champion interviews</u> uncovered issues (lack of focus on LTC, champion turnover)	<ul style="list-style-type: none"> HCS internal reports for <u>admissions only</u> and based on <u>offering</u> videos, so missed low compliance among Long Stay Monitored 'show' rate only later

Goal: Disseminating Interventions

- Once FDA approved, Pharmacological treatments promulgated by advertisement
- Pharmacy based treatments are simple; substitute one drug for another OR add new drug; no change in staff routine.
- Non-pharmacologic treatments require BOTH not prescribing AND doing something different
- Passing pills same across NHs; restructuring staff time for other tx may differ across NHs

When is an Intervention Ready for Diffusion in a Health Care System?

- Many non-pharmacologic interventions have been shown to be effective in meeting NH patients' needs
- BUT, generally not replicated
- Rarely replicated under control of Health System
- If Health Systems don't take charge, hard to imagine real diffusion

Readiness Assessment for Pragmatic Trials (RAPT)

Table 1

Criteria to Determine Which Dementia Interventions Are Ready for PCTs

Criterion	Rationale
1. Intervention protocol	The intervention must have a well-articulated protocol in order to be replicated.
2. Evidence	There must be some evidence demonstrating the efficacy that the intervention and/or its components improves the clinical outcomes of interest.
3. Risk	The intervention should be low risk. Adverse events and unintended consequences need to be carefully considered in this vulnerable population.
4. Feasibility	It should be possible to implement the intervention under real-world conditions within health care systems.
5. Measurement	The intervention's impact should be measurable using existing data or with minimal burden by health care partners.
6. Cost	An intervention should be cost-neutral or cost-effective for health care partners and/or incentivized by insurers.
7. Acceptability	Health care partners should believe that the potential impact of the intervention is important and that it can be adopted.
8. Alignment	The intervention should address priorities for health care partners and other stakeholders.
9. Impact	The intervention's outcomes should inform clinical decision making and policy.

PCT, pragmatic randomized, controlled trial.
University of Florida Research Day April, 2019



Implementation protocol
Is the protocol sufficiently detailed to be replicated?

Evidence

To what extent does the evidence base support efficacy?

Risk

Is it known how safe the intervention is?

Feasibility

To what extent can the intervention be implemented under existing conditions?

Measurement

To what extent can outcomes be captured?

Cost

How likely is the intervention to be economically viable?

Acceptability

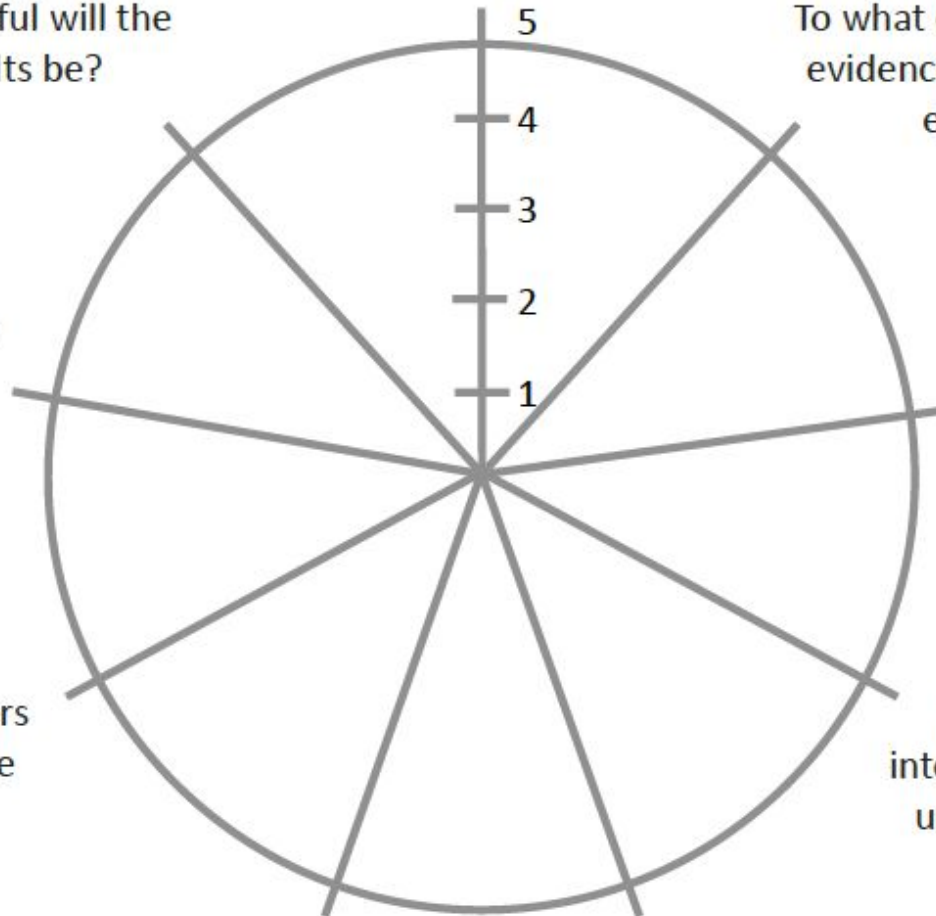
How willing are providers likely to be to adopt the intervention?

Alignment

To what extent does the intervention align with external stakeholders' priorities?

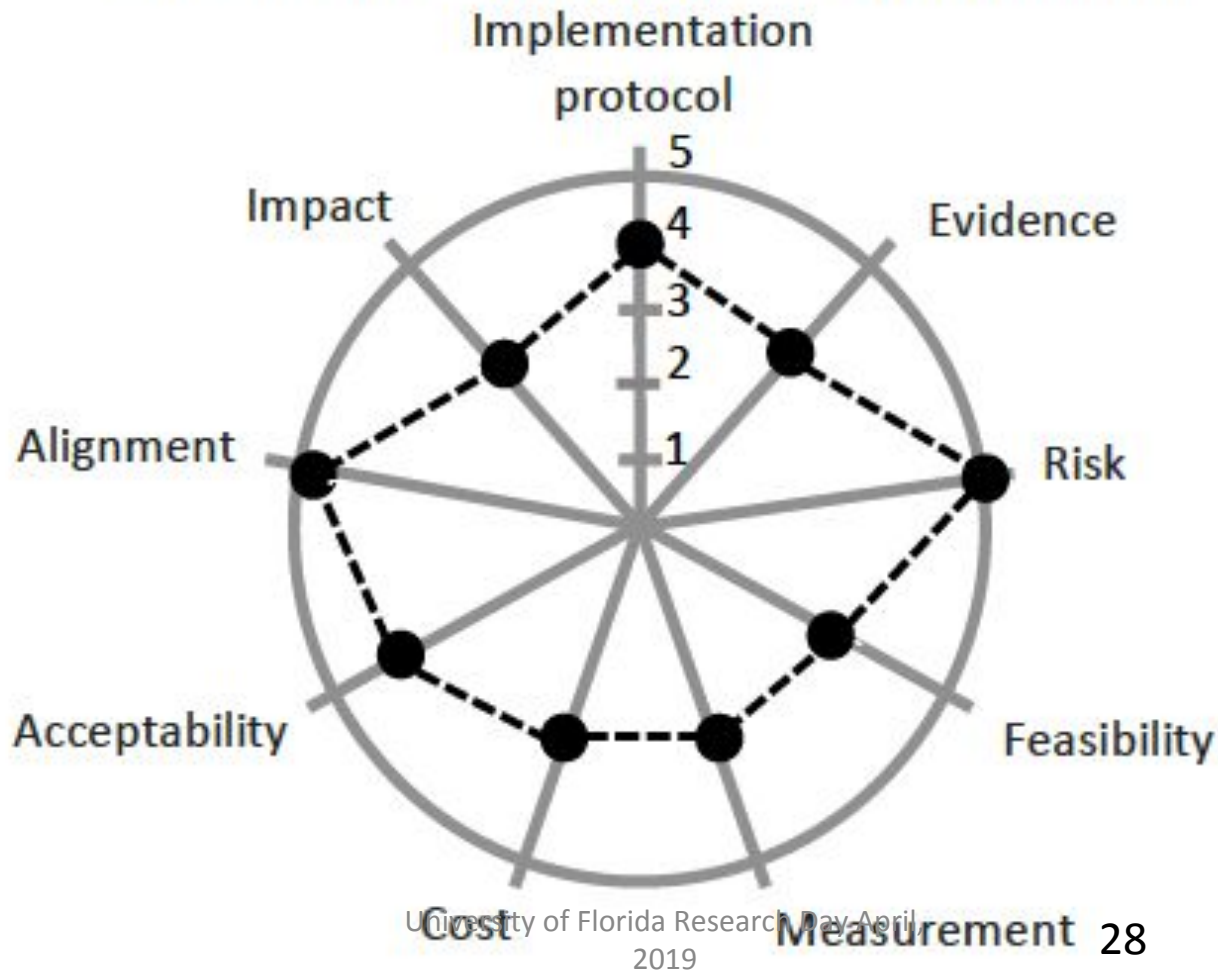
Impact

How useful will the results be?

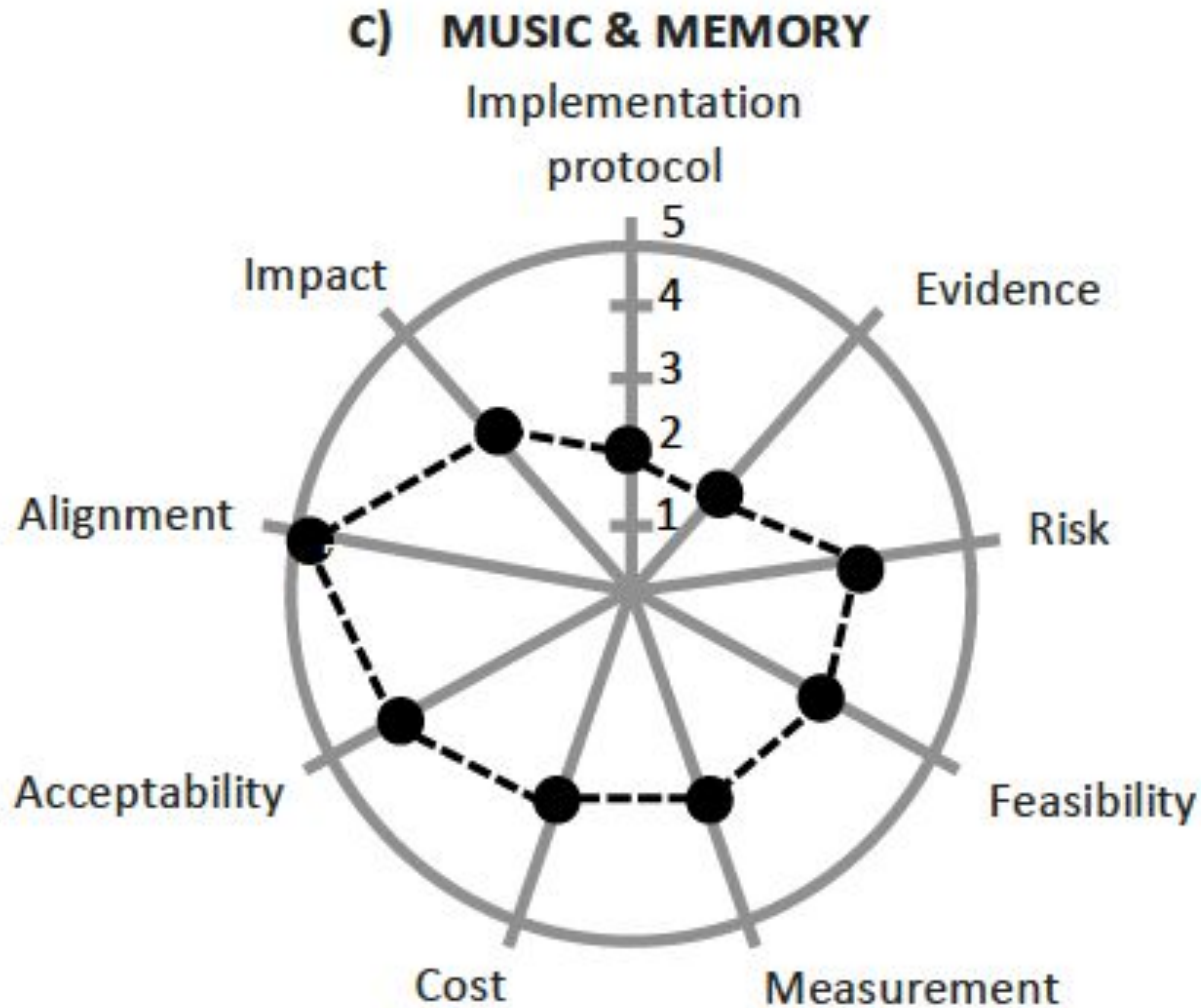


PROVEN: Video Assisted Advance Care Planning RAPT scoring

B) Advance Care Planning Specialist Program



Music & Memory: RAPT Score





What is Music & Memory?

- Music & Memory is a personalized music program
- **Description:** Staff identify music a nursing home resident with dementia preferred when s/he was a young adult and load music on a personal music device (MP3 player)
- **Popularity:** Thousands of nursing homes in the US have become certified in the program, several state initiatives, subject of a powerful documentary “Alive Inside”
- **Potential benefits:** *non-pharmaceutical alternative to managing agitated behaviors*; improve sleep / alertness; decrease resistance to staff assistance with dressing or bathing; appetite stimulation; improve quality of life
- **Limitation:** Rigorous evaluation is necessary to establish efficacy and to characterize factors associated with effective implementation



Music & Memory Pilot (R21)

- 4 nursing homes, 1 per partnering corporation
- 47 residents with moderate or severe dementia received the Music & Memory program during the 6-month pilot (January, 2018 – June, 2018)
- 34 of the 47 residents had data available pre-music and post-music
- Measured agitated behaviors by:
 - Directly observing residents when using and not using music (Agitated Behaviors Mapping Instrument),
 - **Interviewing staff members about resident behaviors (Cohen-Mansfield Agitation Inventory),** and
 - Using available administrative data (MDS 3.0, Section E)



Music & Memory Pilot (R21)

Unpublished Pilot Data: *Within-Person* Changes in Agitated Behaviors Before and After Using Music & Memory, Based on Staff Interviews using the Cohen-Mansfield Agitation Inventory*

	Before Music & Memory	After Music & Memory	Within Person Change	Wilcoxon signed rank test
	Mean (SD)	Mean (SD)	Mean (SD)	p-value
Total Score	61.24(16.32)	51.24(16.05)	-10.00(18.94)	0.002
Physically aggressive behaviors	18.03(7.16)	15.03(5.78)	-3.00(5.98)	0.013
Physically nonaggressive behaviors	15.85(6.51)	13.38(6.84)	-2.47(5.07)	0.002
Verbally agitated behaviors	13.74(6.20)	11.03(6.02)	-2.71(7.47)	0.033
Hiding and hoarding behaviors	2.65(1.23)	2.44(1.69)	-0.21(1.93)	0.303

*Includes 34 of the 47 residents with moderate to severe dementia who received Music & Memory during the pilot and had staff interviews before and after receiving the Music & Memory program. Higher scores = more frequent behaviors



Music & Memory:

Hybrid Parallel/Stepped Wedge Design

- 81 NHs in 4 Health Systems split into 3 waves of 27 facilities; 20 patients each (n~1600)
- First two waves patient outcomes are measured by researchers observing patients and interviewing staff
- Patient outcomes in 2nd & 3rd wave based upon standardized staff rating of behavior
- Primary outcome: disturbed behavior

Summary

- Not enough for researchers to test Non-pharmacologic behavioral interventions for persons with ADRD
- To be used, health systems must be willing to substitute these for drug treatment
- Requires evidence of feasibility AND effectiveness in fully functioning HCS
- Researchers must partner with HCS to implement the most salient features of researchers' interventions