

How Pragmatic are Trials in Nursing Home Settings?

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Background & Objective

At the 2019 AMDA-The Society for Post-acute and Longterm Care Medicine symposium, researchers discussed the implementation of pragmatic trials in nursing homes.

We reviewed the extent to which the trials presented at the AMDA symposium were pragmatic to identify how to improve pragmatic nursing home research.

Description of Trials

The six trials were conducted in North America and Europe, had sample sizes ranging from 12-175 nursing homes, and used cluster randomized controlled trial (RCT), RCT, and quasi-experimental study designs.

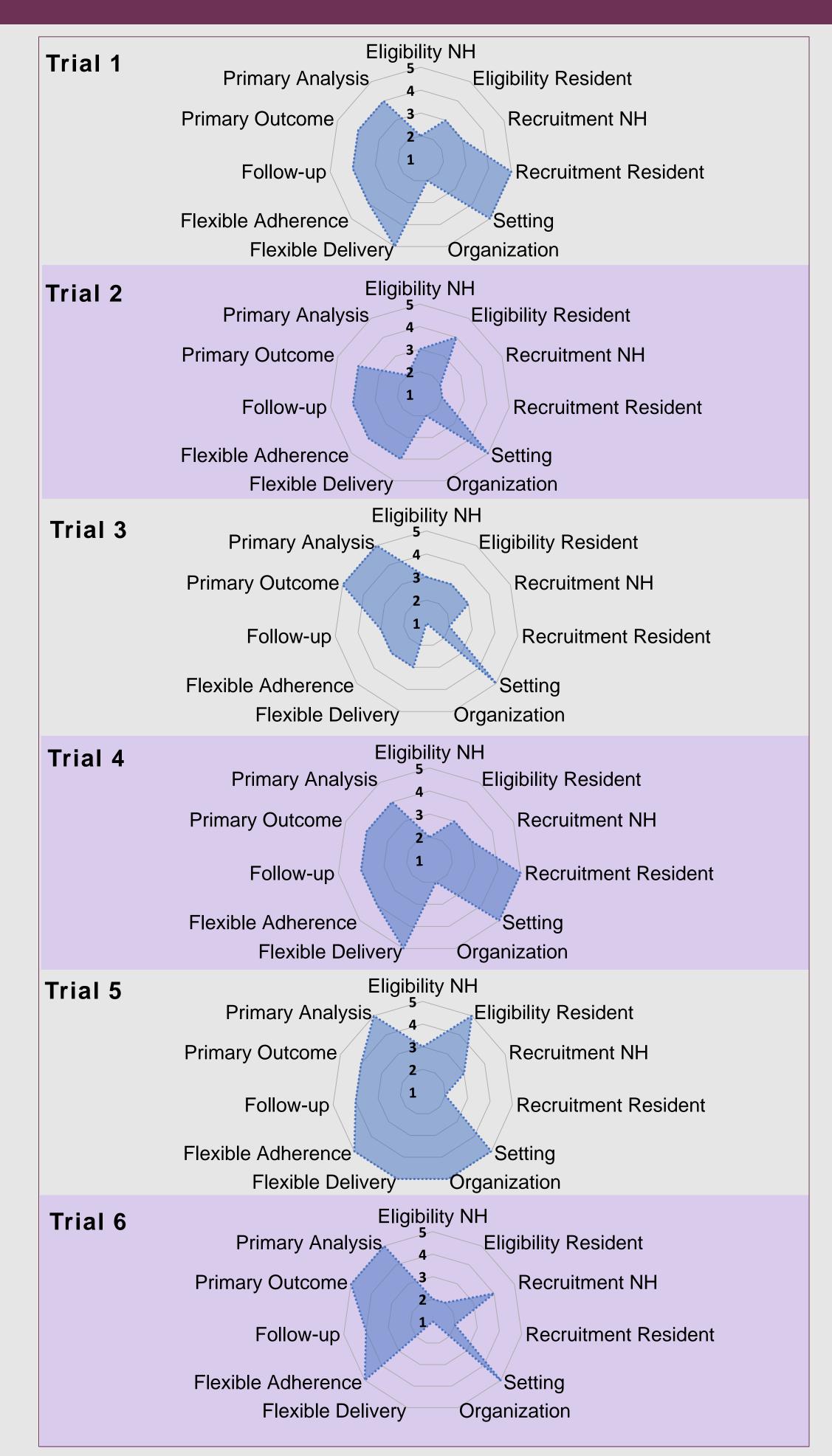
Trial interventions included:

- Audit with feedback on provider antipsychotic prescribing rates
- Oral health training for nursing home staff
- Group music intervention for nursing home residents with dementia and depression
- Audit with feedback on nursing home quality
- Small-scale living facilities as an alternative to nursing home care
- Foam mattress with microclimate-controlling sheet system to reduce pressure ulcer development

Methods

We used Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) criteria to rate the pragmatic nature of the trials and create PRECIS-2 wheels.

Given that the trials were conducted at the level of the nursing home, we rated recruitment and eligibility for nursing homes and residents separately.



Results

Setting, primary outcome, and primary analysis were the most pragmatic domains.

 Trials were conducted in nursing homes that resembled usual care, collected primary outcomes relevant to participants, and mostly did intention-totreat analyses

Organization, nursing home recruitment, and nursing home eligibility were the least pragmatic domains.

- Trials hired additional staff and provided resources beyond what is available in usual care
- Nursing homes were excluded based on resident census, location, and existing interventions
- Nursing homes were recruited through advertisements or direct mailings
- Four trials required residents or their legal guardian to provide informed consent

Implications and Future

Pragmatic trials in nursing homes have pragmatic and explanatory components.

Researchers should create a PRECIS-2 wheel for the cluster level and the individual level.

Investigators should consider using administrative data, such as the Minimum Data Set, to increase the pragmatic nature of data collection.

Researchers should obtain a waiver of consent for nursing home interventions that pose minimal risk to make recruitment more pragmatic.

Please contact kate.magid@va.gov with questions

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