Pragmatic trials may help to identify effective strategies to reduce nursing home antipsychotic medication use

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Abstract
Despite widespread agreement that nursing homes’ use of antipsychotic medications for residents without specific psychiatric diagnoses is a marker of poor quality of care, prevalence remains high. Additionally, variation suggests continued opportunity to improve care even in countries, like the United States, that have long-standing policies designed to decrease antipsychotic medication use. In a recent Israel Journal of Health Policy Research article, Frankenthal et al. presented results linking increased antipsychotic medication use prevalence in Tel Aviv nursing homes with facility characteristics, including some that “undermine quality of care,” and called for increased national focus on this area. While we agree with the authors that government focus can help to decrease antipsychotic medication use, experience in the United States shows that such efforts may not be sufficient: we present data showing significant variation among United States nursing homes’ antipsychotic medication use prevalence after more than ten years of national warnings and programs. This suggests that United States nursing home clinicians and caregivers continue to need effective non-pharmacologic interventions to substitute for antipsychotic medications. We suggest expanded use of cluster-randomized trials to test strategies to withdraw residents from antipsychotic medications and to implement alternate, non-pharmacological approaches for addressing the behavioral and psychological symptoms of dementia.

Keywords: Antipsychotic medications, Dementia, Nursing homes, Chemical restraints, Quality

Main text
The off-label use of antipsychotic medications to address the behavioral and psychological symptoms of dementia is controversial, because antipsychotic medications may increase older adults’ risk of heart failure, sudden death, and pneumonia [1, 2]. As a result, nursing homes’ use of antipsychotics as chemical restraints for the purpose of behavioral control is widely considered inappropriate, absent a psychiatric diagnosis, and is increasingly considered to be a marker of poor quality of care. Despite general agreement that non-pharmacological approaches are preferable, studies in Europe [3], Canada [4], the United States [5, 6], and elsewhere show that antipsychotic medication use remains highly prevalent in this setting with evidence of substantial variation between facilities [5, 7] and between countries [3, 8].

Understanding this variation can inform programs and policies intended to reduce antipsychotic medication use. The SHELTER study compared treatment of nursing home residents in seven European countries and Israel, and found that 32% of residents with a dementia diagnosis had an antipsychotic prescription; prevalence ranged from 18% in Israel to 60% in the Czech Republic [3]. However, this study only included a relatively small number of volunteer facilities in each country, with considerable intra-country variation. In a recent Israel Journal of Health Policy Research (IJHPR) article, Frankenthal et al. [7] presented results linking increased APM prevalence among Tel Aviv nursing homes with facility characteristics, including some that “undermine quality of care.” These included the presence of medical directors without specialized geriatrics training, shortages of social workers and occupational therapists, and the use of unsafe or non-fitting self-aid equipment [7]. The authors argue that their findings shed light on a problematic care process, making it transparent in a country where antipsychotic medication
use is not regulated or publicly reported, and call for increased national focus on this area.

In the United States, there has been a national spotlight on reducing nursing home antipsychotic medication use since our country's Food and Drug Administration issued a “boxed warning” against the use of these medications for off-label indications among older adults, in 2005 [1]. More recently, the Centers for Medicare & Medicaid Services began publicly reporting nursing home antipsychotic medication rates on its Nursing Home Compare website (in 2011) [9] and implemented a national campaign to lower use (in 2012) [10]. Although national prevalence has decreased over the past 10 years, our analysis of longitudinal data available through Brown University’s LTCFocus.org database [11] illustrates significant, ongoing variation in facility-level antipsychotic medication prevalence (Fig. 1) and suggests continued need for intervention in the United States. While there are many nursing facilities with no residents (or virtually none) taking antipsychotics, even in 2014 there were hundreds of facilities with 40% or more of their residents prescribed these medications.

To reduce nursing home antipsychotic medication use, clinicians must implement strategies to identify and discontinue inappropriate off-label use among residents with existing prescriptions [12] and practices to avoid new prescriptions when the behavioral and psychological symptoms of dementia become manifest [13]. Both approaches require alternative techniques so that clinicians and caregivers have strategies to implement in lieu of antipsychotic medications if dementia behaviors re-emerge or persist. Although there are numerous studies evaluating various non-pharmacological strategies to reduce antipsychotic medications use or address dementia behaviors, much of the evidence for the effectiveness of these interventions is insufficient [14]. Furthermore, complex, labor-intensive interventions that might substitute for antipsychotics can be difficult to implement with existing staff and resources. Indeed, many interventions that reveal a positive effect in small-scale studies implemented by research staff have difficulty showing similar effects in real-world replications. Additionally, some researchers argue that rigorously testing such interventions may be difficult, in part because it is not possible to blind nursing home clinicians to interventions.

Cluster-randomized trial methods are one methodological approach to overcome research limitations for testing strategies to reduce antipsychotic medication use or improve the behavioral and psychological symptoms of dementia using non-pharmacological approaches. By randomizing NHs to implement antipsychotic medication practice guidelines, for example, or to serve as control sites, we can rigorously test such interventions using pragmatic methods. At Brown University, we use cluster-randomized trials to conduct studies on topics such as influenza vaccination [15, 16]; others have used these methods for antipsychotic medication reduction interventions [17–19]. The Brown studies pair cluster-randomized trial methods with the use of existing clinical and administrative data, such as United States Minimum Data Set resident assessment data; this allows us to conduct rigorous nursing home research efficiently. We suggest that others use similar approaches and data sources, e.g., the Minimum Data Set or InterRAI assessment tools [20], to test antipsychotic medication interventions using approaches that mimic real-world conditions. One such trial is currently underway in Ontario, offering a model for others around the developed world [21].

![Fig. 1 Percent of United States nursing home residents on antipsychotic medications without a psychiatric diagnosis, 2000–2010](image)
Conclusions

Despite widespread agreement that nursing homes’ use of antipsychotic medications as chemical restraints is associated with poor clinical outcomes and as such constitutes a marker of poor quality of care, prevalence remains high and variation suggests continued opportunity to improve care even in countries, like the United States, that have long-standing policies designed to decrease APM use. While we agree with Frankenthal et al. [7] that regulation and public reporting can help to decrease prevalence, the United States experience suggests that nursing home clinicians and caregivers also need effective alternative interventions to employ as substitutes for antipsychotics. We suggest expanded use of cluster-randomized trials to test strategies to remove residents from antipsychotics and to implement alternate, non-pharmacological approaches for addressing the behavioral and psychological symptoms of dementia.

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Availability of data and materials

The data supporting the conclusions of this article are available from the Shaping Long-Term Care in America Project at LTCfocUS.org [1] LTCfocUS.org is a Brown University database containing aggregated information from United States nursing home residents’ Minimum Data Set assessments and facilities’ Online Survey, Certification, And Reporting data, collected during the state inspections.

Authors’ contributions

VM analyzed the longitudinal trends regarding antipsychotic medication use in United States nursing homes. RRB and VM interpreted the data. RRB drafted the manuscript and VM provided edits. Both authors read and approved the final manuscript.

Authors’ information

RRB and VM direct the Center for Long-Term Care Quality & Innovation, a Brown University database containing aggregated information from United States nursing homes. RRB and VM interpreted the data. VM analyzed the longitudinal trends regarding antipsychotic medication use in United States nursing homes. RRB and VM provided edits. Both authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

Not applicable.

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