Published in final edited form as:

J Am Geriatr Soc. 2011 December ; 59(12): 2332–2336. doi:10.1111/j.1532-5415.2011.03697.x.

Predicting Nursing Home Adherence to a Clinical Trial Intervention: Lessons for the Conduct of Cluster Randomized Trials

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Abstract

Background/Objectives—Lack of adherence to a clinical trial intervention threatens the ability of a study to yield meaningful results. Since developing methods to predict intervention adherence in cluster randomized trials (CRT) will facilitate the successful conduct of studies in the nursing home (NH) setting, we sought to describe factors predictive of NH adherence to a clinical trial intervention.

Research Design, Subjects, Measures—Post-hoc analysis of a CRT evaluating a structured communication intervention to improve nurse-physician telephone communication in 26 NHs. Adherence was defined as active participation for at least 3 months of the 12 month trial. *A priori*, we measured NH characteristics hypothesized to affect trial outcomes (profit-status, bedsize, nursing staff time, NH quality, and leadership turnover). We examined the association between intervention adherence, NH characteristics and pre-intervention questionnaire response rate.

Results—Of 13 intervention homes, 7 were adherent to the intervention. Three factors differentiated adherent from non-adherent NHs: director of nursing turnover (non-adherent NHs [50%] vs adherent NHs [0%], $p < 0.03$); Centers for Medicare and Medicaid Services' (CMS) nurse staffing rating (range 1-5) (non-adherent NHs [mean 3.7, standard deviation (SD) 0.5] vs adherent NHs [mean 4.3, SD 0.5]), $p < 0.05$; and questionnaire response rate (non-adherent NH [15.6%, SD 10.0] vs adherent NH [34.2%, SD 12.1], $p = 0.02$). Profit status, bedsize, and number of NH deficiencies on state surveys were not significantly associated with intervention adherence.

Conclusion—CMS nurse staffing rating, leadership turnover, and questionnaire response rate are associated with adherence to a CRT intervention. Pre-trial evaluation of NH staffing rating by

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Author Contributions: Indicate authors' role in study concept and design, acquisition of subjects and/or data, analysis and interpretation of data, and preparation of manuscript. (Jennifer Tjia, Kathleen Mazor, Terry Field, Jerry Gurwitz were responsible for the study concept and design, analysis and interpretation of the data, and preparation of the manuscript. Peter Doherty and Ann Spenard were participated in the acquisition of subjects and data, interpretation of the data, and preparation of the manuscript.

CMS and of response to a questionnaire can help investigators improve trial efficiency by screening for NHs likely to be adherent to a CRT intervention.

Keywords

cluster randomized trials; methodology; adherence; run-in period; intervention trials

Introduction

The underrepresentation of frail, older adults in clinical trials limits the evidence base from which clinicians can optimize the quality of geriatric care.^{1,2} To address this issue, the American Geriatrics Society recently convened the “Integrating Geriatrics into Comparative Effectiveness Research Conference” which highlighted the need for shared methodologic experience among investigators to facilitate the efficient and successful conduct of studies, including clinical trials, in this understudied population.³ One method that is increasingly being used to evaluate interventions aimed at improving health care delivery for geriatric populations is the cluster randomized trial (CRT).⁴

CRTs are a research design in which organizational, social, or geographically-defined units rather than individuals are randomized between comparator interventions. This research design is typically used to evaluate complex interventions, often comprising a collection of causally-related components, in settings such as such as medical groups, hospitals, or nursing homes (NH). The design is well suited to the controlled evaluation of complex interventions employed in disease prevention, health promotion, and quality improvement initiatives.⁴

As with individual-level randomized controlled trials, one threat to a CRT's ability to detect a treatment effect is nonadherence to the intervention.⁵ In trials with randomization at the level of the patient, investigators may begin with a *run-in phase* in an effort to keep the effect of nonadherence to a minimum. The *run-in* allows investigators to determine adherence of all potential subjects to a placebo or control therapy. The goal is to identify and eliminate, before the start of the study, patients who have a high likelihood of not adhering to the regimen offered, because nonadherence can greatly complicate proper analysis and interpretation of a randomized trial.

Unfortunately, there are several challenges to adapting the *run-in* strategy to system-level interventions at the level of a NH facility. Most notably, it is infeasible to conduct a *run-in* that requires staff time and training for an intervention that may ultimately not occur because of nonadherence in the *run-in* period. Given their demanding workloads, tight fiscal constraints, and increasing public scrutiny, some facilities feel themselves unable to consider engaging in activities like research that impose costs without providing specific, tangible benefits.⁶

Previously, investigators have shown that multiple organizational characteristics such as stable administration and local facility control predicted higher response rates to a survey of nurses and willingness to engage in clinical research.⁶ However, we are unaware of studies demonstrating factors that predict adherence to clinical trial interventions in the NH setting.

This paper describes NH adherence to a clinical trial intervention and examines its relationship with factors hypothesized to be associated with intervention adherence including structural NH characteristics, NH quality of care, and participation in a study survey.

Methods

Study Setting

The current study was conducted in the context of a cluster randomized trial of a standardized, interdisciplinary clinical communication tool to improve the quality and safe management of warfarin therapy in the NH setting.⁷ The clinical trial required a sample of 26 nursing homes in Connecticut matched by bed size. The facilities were recruited by the Connecticut quality improvement organization (QIO) with the goal of achieving an equal distribution of key structural characteristics including profit-status. (Table 1) Agreement from the NH administrator and medical director were obtained from participating facilities. Nursing homes were randomized to intervention or control status within blocks according to bed size (less than 150, 150 to 249, 250 or more). For the intervention homes, trial participation consisted of 4 elements: 1. a pre-intervention nursing staff questionnaire assessing warfarin knowledge, patient safety culture, and challenges to interdisciplinary communication; 2. training of nursing staff in the intervention (a structured communication form and telephone communication protocol) conducted by local nursing leadership within the facility; 3. monthly telephone assessments with facility nursing leadership to assess staff and leadership turnover, and challenges to the intervention; and 4. monthly submission of 'used' structured communication forms to assess adherence to the intervention. The control homes only participated in the pre-intervention questionnaire. All homes underwent quarterly medical record abstractions to assess patient outcomes.

Pre-Intervention Questionnaire Administration

Prior to the beginning of the intervention, we sent questionnaires and instructions to all eligible licensed nursing staff in all participating facilities (control and intervention) via the staff development nurse or nursing supervisor at each facility. The goal of the questionnaire was to assess the baseline perception of the quality of communication between nurses and physicians in each facility. Respondents were asked to complete and return the anonymous questionnaires directly to the central research office. Each questionnaire included a coffee gift certificate as an incentive. In order to maintain confidentiality, no identifying information was included. We were therefore unable to contact non-respondents. To increase our response rate, we requested that a second batch of questionnaires be distributed within each facility to nurses who self-reported non-response to the first request. The results of the survey have been published previously.⁸

Nurse Staff Training, Intervention Implementation, and Assessment of Adherence

The training intervention was disseminated via a train-the-trainer model in which each intervention facility sent their staff development nurse or nursing supervisor to the QIO for training about the intervention that was to be delivered by the trainer within their facility. Each trainer was asked to deliver two 20-minute trainings at their facility targeting all

licensed nursing staff. The content of the training included information about the use and safety of warfarin in NH patients, the use of an interdisciplinary communication tool in the healthcare setting, and strategies for challenging interdisciplinary communication between physicians and nurses.

During the intervention phase, nurses were asked to complete a communication checklist prior to initiating a telephone call to physicians about a clinical management issue for residents using warfarin. The form outlined key elements of the structured communication intervention to be covered during the clinical communication encounter with the physician, and was to be used as a template for the telephone encounter. Each form had a de-identified tab that could be removed after completion to help enumerate form use. We asked the facilities to submit these tabs monthly to the central research office. In addition, the nurse leader responsible for the intervention at each facility received a phone call from the central research office to evaluate progress with the intervention, elicit challenges to participation, and to offer solutions to implementation challenges.

Each month, we calculated adherence to the intervention by determining the ratio of actual-to-expected communication checklist tabs received from each intervention facility. Since safe warfarin management requires at least monthly INR testing,⁹ we defined the expected checklist tabs per facility to be equal to the number of residents prescribed warfarin in that facility for the month. We defined a NH as fully adherent for the month if the ratio of actual-to-expected checklist tabs received for a month was at least 1.0. The ratio of actual-to-expected adherence could exceed 1.0 if a NH tended toward more frequent INR monitoring (e.g. every 2 weeks), in which case the ratio would be closer to 2 in a given month.

Assessment of NH Facility Structural Characteristics

A priori, we measured NH characteristics hypothesized to affect trial outcomes, including profit-status, bed size, nurse staffing time, NH quality, and leadership turnover.¹⁰⁻¹³ Facility characteristics were assessed from the Center for Medicare and Medicaid Services (CMS) Nursing Home Compare Website (www.Medicare.gov/NHCompare/home.asp) which reports ratings in three broad domains including deficiencies on federally mandated health inspections, staffing levels, and quality of care measures. We collected evaluations from the most recent state survey for each participating nursing home. We also collected total number of certified beds, type of ownership, staff-to-resident ratio, number of deficiencies on the most recent state survey, certified nurse assistant hours per resident day, nursing staff hours per resident day. We assessed leadership turnover (director of nursing and nursing home administrator) during monthly intervention follow-up calls.

Data Analysis

For the purpose of this analysis, we defined a NH to be adherent to the clinical trial intervention if there were at least 3 months of full intervention adherence during the 12 month intervention. To assess for differences between adherent and non-adherent homes, we used t-test for continuous measures and Pearson Chi-square for categorical measures. One facility was recruited for participation after the pre-intervention survey was completed to replace a facility that had dropped out; this replacement facility did not complete the survey

and is not included in analysis evaluating the relationship between survey response rates and clinical trial intervention adherence. All other analyses were conducted on the 13 NHs randomized to the clinical trial intervention. All analyses were conducted in STATA 10.0 (StataCorp, College Station, Tx) This study protocol was reviewed and approved by the institutional review board of the University of Massachusetts Medical School.

Results

Nursing Home Characteristics

Participating homes (intervention and control homes) had greater licensed nursing staff hours per resident day, nurse assistant staff hours per resident day, and a greater number of deficiencies than comparable state and national facilities. (Table 1) A lower proportion of intervention nursing homes were for-profit and chain-affiliated than control homes.

Questionnaire Response Rate

The overall response rate to the pre-intervention survey of nursing staff was 25.7% (range 4.4%- 53.9%). The response rate to pre-intervention survey was comparable between the intervention and control homes (mean response rate $26.4\% \pm 14.4\%$ and $24.9\% \pm 13.1\%$, respectively; $p=0.78$).

Factors associated with adherence to clinical trial intervention

Of 13 intervention homes, 7 were adherent to the intervention. (Table 2) Three factors were significantly different between the adherent and non-adherent NHs: 1. turnover of the director of nursing (non-adherent NHs [50%] vs adherent NHs [0%], $p<0.03$); 2. NH staffing rating (range 1-5) by the CMS staffing scale (non-adherent NHs [mean rating 3.7, standard deviation (SD) 0.5] vs adherent NHs [mean rating 4.3, SD 0.5]), $p<0.05$); and 3) pre-intervention questionnaire response rate (non-adherent NHs [15.6%, SD 10.0] vs adherent NHs [34.2%, SD 12.1], $p=0.02$). Profit status, bed size, and number of deficiencies on state surveys were not significantly associated with adherence to the intervention.

Discussion

Our study describes practical strategies analogous to a *run-in* period for a classical randomized controlled trial to predict the adherence to an intervention in a CRT. As with randomized controlled trials, CRTs are labor-intensive and generally entail a high cost per facility. This relatively high cost, in addition to the difficulties that can occur in encouraging participants to actively participate in a study, prevents many randomized trials from enrolling a large number of subjects. For this reason, investigators planning a randomized trial often endeavor to incorporate one or more design features that will increase the trial's sensitivity (ability to detect a treatment effect). Such an increase may be possible by careful attention to the selection of subjects.⁵ We found three factors to be associated with intervention adherence that can analogously guide the selection of participating facilities in CRTs: leadership turnover, measurement of NH staff rating by CMS, and response rate to a pre-intervention questionnaire.

Of the three factors we found to be associated with intervention adherence, two are measurable before the delivery of an intervention: measurement of NH staff rating by CMS, and response rate to a pre-intervention questionnaire. By far, the most economical and easily measured factor is the NH staff rating, which can be obtained from the NH compare website. While this might be advisable for studies that do not have a budget or need for a pre-intervention questionnaire, the measurement rating will pre-date the intervention by at least 6-12 months and may not reflect staffing levels at the time of an intervention is being conducted. Further, targeting homes with higher staffing levels reduces generalizability and may introduce unintended confounding since staffing levels are known to correlate with other NH quality characteristics like better patient outcomes.¹⁴⁻¹⁷

While administering a staff-level questionnaire can be costly and time-intensive, there are several advantages related to enhancing the overall likelihood of study success related to this strategy. First, research study personnel become engaged with staff at each facility and learn best methods for maintaining contact with each facility. Second, investigators can develop rapport with each facility that can help facilitate the roll-out of implementation of the intervention. And third, the questionnaire can be used to solicit valuable information about each facility to help inform the content and delivery of the intervention.

While leadership/Director of Nursing turnover was strongly associated with poor NH intervention adherence, this occurred during the study and could not have been predicted *a priori*. Other literature suggests that staff and leadership turnover are associated with less resident-centered cultures,¹⁸ and with poorer patient outcomes.^{10, 15, 19-21} It is possible that asking about prior or recent staff and leadership turnover may also be associated with poor NH intervention adherence, but we did not evaluate this in our study. It is also important to note that while we solicited NH administration and medical director agreement from each NH to participate in the study, we did not specifically secure buy-in from each Director of Nursing; lack of Director of Nursing buy-in may also explain the low nursing staff response rate on the pre-intervention questionnaire.

A limitation of our study is that we were geographically limited to a single state, possibly reducing generalizability. Further, our clinical trial intervention sought to improve the quality of nurse-physician communication using a structured communication tool, an intervention that presented a moderate additional time burden to nursing staff. Our findings may not be generalizable to interventions that present a less burden to staff. Finally, we selected a relatively low level of intervention participation (i.e. 3 out of 12 months) as the definition of intervention adherence. Further work is necessary to identify NHs with higher levels of adherence.

While CRTs of interventions at the facility level, including nursing homes, have the potential to improve care delivery to a wide range of patients, the notable lack of a body of literature to guide the conduct of clinical trial research in older adults, particularly in the nursing home population, hampers successful execution of future studies.³ Our findings provide evidence for strategies to identify facilities likely to be adherent to a CRT intervention and contribute study design features likely to improve the conduct of future

studies. Further research is necessary to understand how to improve adherence of a facility to organizational interventions.

Acknowledgments

Dr. Tjia was supported by a Mentored Clinical Scientist Career Development Award from the National Institute on Aging (K08 AG021527).

This study was supported by a grant from the Agency for Healthcare Research and Quality (R01 HS016463).

Sponsor's Role: The sponsor had no role in the design, methods, subject recruitment, data collections, analysis and preparation of paper.

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Table 1
Comparison of Study Nursing Homes with Facilities in Connecticut and the United States

Characteristic	Study Homes (N=26)	Connecticut Nursing Homes (N=245)	United States Nursing Homes (N=16,121)
No. Beds			
Mean $\pm$ SD	148.8 $\pm$ 50.7	113.7	95.1
% Female residents			
Mean $\pm$ SD	72.6 $\pm$ 13.4	67.3	66.5
Ownership			
For profit (%)	65.4	77.6	66.3
Nonprofit	27.0		
Government	7.6		
Affiliation			
Chain	42.3		
Independent	50.0		
Government	7.6		
Licensed nursing staff hours per resident per day, Mean $\pm$ SD	1 h 26 m $\pm$ 19 m	1 h 24 m	1 h 18 m
Nursing assistant staff hours per resident per day, Mean $\pm$ SD	2 h 29 m $\pm$ 29 m	2 h 18 m	2 h 18 m
Nursing Home Quality,	9.6 (5.4)	8.5 ²²	6.9 ²²
Total # deficiencies, mean $\pm$ SD			
Pre-Intervention Staff Survey Response Rate (%), Mean (SD)	25.7 (13.5)	-	-
Director of Nursing turnover (%)	38.5	-	-

Abbreviations: SD, Standard Deviation

Table 2
Factors Associated with NH Intervention to Adherence

Predictor	Non-Adherent NH n=6 Mean (SD)	Adherent NH* n=7 Mean (SD)	p-value [†]
For Profit (%)	66.7	28.6	0.17 [‡]
Certified Beds, Mean (SD)	183.2 (79.5)	142 (29.7)	0.22
% Occupancy, Mean (SD)	86.0 (18.0)	99.7 (10.7)	0.12
Director of Nursing turnover (%)	50.0	0.0	0.03[‡]
Nurse staff time (min), Mean (SD)	86.2 (14.4)	84.3 (11.1)	0.79
CMS quality (range 1-5), , Mean (SD)	3.3 (1.2)	4.1 (0.9)	0.19
Total Deficiencies, , Mean (SD)	11.7 (5.5)	7.1 (5.1)	0.15
# Quality of Care Deficiencies, Mean (SD)	3.8 (3.7)	2.1 (1.7)	0.29
# Administration Deficiencies, Mean (SD)	0.6 (0.8)	0.4 (0.5)	0.54
# Pharmacy Deficiencies, Mean (SD)	0.83 (0.75)	1 (1)	0.74
CMS Health Inspection Rating (range 1-5), Mean (SD)	2.7 (1.4)	3.6 (1.3)	0.24
CMS Nursing Home Staffing Rating (range 1-5), Mean (SD)	3.7 (0.5)	4.3 (0.5)	<0.05
CMS Quality Measure Rating (range 1-5), Mean (SD)	3.7 (1.0)	3.0 (1.7)	0.43
Pre-Intervention Nursing Staff Survey Response Rate[§] (%), Mean (SD)	15.6 (10.0)	34.2 (12.1)	0.02

Abbreviations: SD, Standard Deviation; CMS, Centers for Medicare and Medicaid Services

* Adherence defined as active participation (defined as ratio of actual/expected SBAR formed completed > 1) for at least 3 months of intervention period

[†] t-test unless otherwise specified

[‡] Pearson Chi square test

[§] One NH missing survey response rate due to late recruitment to trial