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Original Study

Evaluation of Nursing Facility Resident Safety During Implementation of the INTERACT Quality Improvement Program



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ABSTRACT

Keywords: Nursing facilities nursing facility residents INTERACT quality improvement safety *Background*: Medicare incentivizes the reduction of hospitalizations of nursing facility (NF) residents. The effects of these incentives on resident safety have not been examined.

Objective: Examine safety indicators in NFs participating in a randomized, controlled trial of the INTERACT Quality Improvement Program.

Design: Secondary analysis of a randomized trial in which intervention NFs exhibited a statistically nonsignificant reduction in hospitalizations.

Setting: NFs with adequate on-site medical, radiography, laboratory, and pharmacy services, and capability for online training and data input were eligible.

Participants: 264 NFs randomized into intervention and comparison groups stratified by previous INTERACT use and self-reported hospital readmission rates.

Intervention: NFs randomized to the intervention group received INTERACT materials, access to online training and a series of training webinars, feedback on hospitalization rates and root-cause analysis data, and monthly telephonic support.

Measures: Minimum data set (MDS) data for unintentional weight loss, malnutrition, hip fracture, pneumonia, wound infection, septicemia, urinary tract infection, and falls with injury for the intervention year and the year prior; unintentional weight loss, dehydration, changes in rates of falls, pressure ulcers, severe pain, and unexpected deaths obtained from the NFs participating in the intervention through monthly telephone calls.

Results: No adverse effects on resident safety, and no significant differences in safety indicators between intervention and comparison group NFs were identified, with 1 exception. Intervention NFs with high levels of INTERACT tool use reported significantly lower rates of severe pain.

Conclusions/Implications: Resident safety was not compromised during implementation of a quality improvement program designed to reduce unnecessary hospitalization of NF residents.

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Medicare reimbursement policies are increasingly providing incentives for nursing facilities (NFs) and other post-acute and long-term care organizations to reduce hospitalizations, hospital readmissions,

and emergency department (ED) visits.¹ As care providers in these settings strive to manage acute changes in condition without hospital transfer, the impact of these efforts on patient safety becomes an

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strategies to provide training on INTERACT. No financial conflicts of interest are declared for Drs Tappen, Newman, Huckfeldt, Engstrom, Wolf, or Rojido, or Mr Yang.

Work on this and other projects are subject to terms of Conflicts of Interest Management plans developed and approved by the FAU Division of Research Financial Conflict of Interest Committee.

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important consideration. A report issued by the Office of the Inspector General has raised concerns about patient safety in NFs. This report documented that one-third of Medicare beneficiaries experienced an adverse event or temporary harm during the first 45 days of their NF stays.² Many of these events were attributed to substandard treatment, inadequate monitoring, and failure or delay of necessary care.

Safety during hospital transfers has frequently been identified as a concern, but safety could also be compromised if NF residents are not transferred when they experience an acute change in condition. Thus, incentivizing NFs to manage even sicker patients, that is, those who would have been transferred to acute care prior to the efforts to reduce potentially preventable hospitalizations, could have the unintended consequence of further challenging patient safety and care quality by increasing complications such as falls, septicemia, or wound infection. There could also be an increase in the incidence of conditions considered potential indicators of safety and quality problems, such as pneumonia and urinary tract infection, because these conditions could be both the target of efforts to avoid hospital transfer or complications of treating acute changes in condition without transfer.

Specific safety indicators reported for NF care vary between different organizations. For example, the 2017 National Healthcare Quality and Disparities Report Chartbook on Patient Safety,⁵ which reports on safety and quality in a wide range of settings, includes 3 indicators for long-term care: urinary tract infection, use of restraints, and infections per 1000 resident-days. The Centers for Medicare and Medicaid (CMS) monitors 5 Quality Measures for short-stay NF patients and 13 for long-stay residents. Short-stay measures include moderate to severe pain and new or worsened pressure ulcers; longstay measures include falls with major injury, restraints, and weight loss as well (the complete list may be accessed at https://www.cms. gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ HospitalQualityInits/OutcomeMeasures.html).⁶ Patient safety is one of the 6 priorities of AHRQ's National Quality Strategy. An AHRQ technical report noted that the 4 safety measures (falls with injury, pressure ulcers, medication errors, and infections) identified by AHRQ do not capture the entirety of safety concerns in NF settings.8 Additional domains of concern have been suggested, including unintentional weight loss, dehydration, functional activities of daily living, fecal and urinary incontinence, depressive symptoms, moderate to severe pain, influenza and pneumococcal vaccines, physical restraints, catheter use, antipsychotic medication use, and polypharmacy.⁹

The Interventions to Reduce Acute Care Transfers (INTERACT) quality improvement program focuses on improving the quality of care provided when an acute change in condition occurs, thereby preventing unnecessary hospitalizations. ^{10,11} In our randomized controlled implementation trial of the INTERACT quality improvement program, the intervention group exhibited a statistically nonsignificant reduction in rates of hospitalizations and ED visits that did not result in hospital admission. No significant effect on mortality was found. ¹² Because of the concerns discussed above, the data safety monitoring board of this implementation trial ¹² recommended that we monitor selected patient safety measures in addition to hospitalizations and ED visits. The objective of this article is to describe changes in safety measures during the implementation of the INTERACT program.

Methods

This study was approved by the University IRB as a quality improvement project and was monitored quarterly by a 3-person Data Safety Monitoring Board (DSMB). DSMB members were independent experts in long-term care.

Sample

Participating NFs were recruited nationally through the major NF organizations and large NF corporations. Inclusion criteria were support from the facility's leadership evidenced by their signatures on a participation agreement, medical providers on site at least once per week, adequate x-ray, laboratory and pharmacy services, and technical resources to support online training and data input. Hospital-based facilities and facilities participating in other hospital readmission initiatives or other major quality improvement projects that would divert attention from INTERACT program implementation were excluded.

Altogether, 613 NFs expressed interest in participation; 391 were interviewed by project staff and 264 were enrolled (see Appendix Figure A1). The 264 NFs were randomized to 1 of 3 groups: intervention (INTERACT program training and implementation support) and 2 control groups, 1 that tracked their hospital readmissions and 1 that did not. Randomization to 1 of the 3 groups was stratified by extent of adoption of INTERACT tools and self-reported hospital readmission rates prior to enrollment.

Intervention

The INTERACT Quality Improvement Program involves a set of tools and resources designed to address the primary reasons for potentially avoidable hospital admissions of NF residents. NFs randomized to the intervention group received a start-up package of INTERACT tools, access to an online training program and participated in a series of webinars, an intensive 10 week initial training program, and monthly follow-up webinars. They were asked to select a project champion and co-champion. Monthly calls from members of the project team assessed progress and challenges encountered and any adverse events that may have occurred. Intervention NFs also completed root cause analyses on transfers 13–15 and online reports on residents experiencing acute changes in condition that did not result in hospital transfer. These data were summarized and provided to the intervention NFs quarterly during the intervention period.

Measures

Medicare beneficiary records and MDS data

We used the Minimum Data Set (MDS) to identify residents in each of the 264 NFs enrolled in the intervention and comparison groups and to construct safety measures. We analyzed assessments associated with resident-months in the year prior to the intervention (March 2012— February 2013) and during the intervention (March 2013—February 2014) to obtain these results. Our analysis focused on residents with fee-for-service Medicare coverage (ie, parts A and B), identified using the Master Beneficiary Summary File. We also obtained patient demographic characteristics from the Master Beneficiary Summary File. We constructed health risk scores using the Medicare Provider Analysis and Review files and outpatient claims files. Baseline NF characteristics and quality performance were derived from the CMS Nursing Home Compare website.

We calculated resident-quarter level safety measures using the MDS for the following measures: unintentional weight loss (exclusive of physician-prescribed weight-loss), malnutrition, hip fracture, pneumonia, wound infection, septicemia, urinary tract infection, and falls resulting in injury (minor or major). We identified each outcome as occurring if the condition was recorded on at least 1 assessment during the quarter. We dropped resident-quarter observations when a safety measure was missing for every assessment during that quarter. Resident-level control variables included age (in 5-year increments), gender, race and ethnicity, Medicaid eligibility, hierarchical condition category score, any part A stay and total part A days, MDS-based

measures of activities of daily living (indicator variables for 0-4, 5-8, 9-12, 13-16), and the cognitive performance scale (indicator variables for 0-2, 3-4, 5-6).

Telephone interviews

The champion, co-champion, and/or other NF leadership of the 71 NFs that were randomized to and actively participated in the 12-month intervention took part in monthly phone calls conducted by one of the INTERACT team members. At each telephone call the NFs were asked specifically if unintentional weight loss, dehydration, incidence of falls, new pressure ulcers, severe pain, and unexpected deaths had increased, decreased, or remained the same over the last month.

Data Analyses

MDS-based safety measures

First, we estimated the percentage of resident-quarters with MDS-based adverse outcomes in the year prior to the intervention and during the intervention year for the intervention and control NFs separately. Then we tested for differences in the percentage of each MDS-based safety measure across resident-quarters in intervention versus control NFs in the preintervention year (March 2012—February 2013) and during the intervention (March 2013—February 2014) using linear regression, clustering standard errors at the facility level. We also used linear regression to test for differential changes in the intervention versus control NFs from the preintervention year to the intervention year. In each case, differences were adjusted for the resident characteristics described above.

Telephone interviews

The safety outcome measures obtained from the monthly telephone interviews varied slightly from those reported in the MDS data and included unintentional weight loss, dehydration, falls, new pressure ulcers, severe pain, and unexpected deaths. An unexpected death was defined as one that was not apparently imminent in a resident who had not had acute symptoms such as fever, increased respiratory rate, tachycardia, hypotension, decreased oral intake, and/or was in a semi-comatose state. Because of the low numbers of unexpected deaths, statistical analyses were not possible, and changes in unexpected deaths are only displayed graphically. Employing the Missing Value Analysis function in SPSS, 16 the data were not found to be missing completely at random (MCAR) or even missing at random (MAR) on Little's MCAR test $\chi^2(149) = 200.12$, P = .003, so imputation was not done.

Safety measures by engagement level

Since fidelity to implementation can influence outcomes, generalized linear mixed models were used to assess safety measures across 3 engagement levels. Engagement was defined by the number of INTERACT tools that were used prior to implementing INTERACT and then at the end of the intervention period. The 3 engagement groups included 1 group that maintained a low level of engagement during the study period, a second that increased their engagement from low to moderate or high, and a third that maintained a moderate to high level of engagement during the study period.¹⁷ Generalized linear mixed models (GLMMs) were used to analyze change in the safety measures over time for each NF. An advantage of GLMM is that NFs with missing data can be included in GLMM analyses. NFs missing data for 9 or more of the 11 months were removed from the analyses. Both linear and nonlinear changes over time were examined with parameter estimates calculated for intercept, slope, and curvature to create the best predictive model fit. Because GLMMs show longitudinal changes as a function of time, the time variable was centered at

the baseline. Centering at baseline produces results reflecting no change in safety measures over time as a flat horizontal line, increases in safety measures as a positive slope, and decrease in safety measure as a negative slope.

Results

Characteristics of the Study Sample

Table 1 displays the baseline characteristics of intervention and control NFs for the entire sample of 264 NFs. Intervention and control NFs were similar across all measures, except that intervention NFs exhibited lower survey ratings at baseline.

MDS-Based Results

Figure 1 panels (a) through (h) display the percentage of residentquarters exhibiting each MDS-based safety measure in the 4 quarters prior to and following the INTERACT intervention, separately for intervention and control. The occurrence of these safety indicators was nearly identical in the intervention versus control facilities over the sample period. Table 2 displays the percentage of residentquarters during which each MDS-derived safety indicator occurred at least once during the preintervention and intervention periods for the intervention and control NFs. Table 2 also displays interventioncontrol group differences and P values during the preintervention and intervention year, as well as the estimated differential change from the preintervention to the intervention year for intervention versus control NFs and the associated P values. Across all measures, we found no statistically significant differences in the percentage of resident-quarters exhibiting MDS-derived safety measures between the intervention and control groups in either the preintervention or intervention years. In addition, we found no statistically significant differential change in these measures for intervention versus control NFs from the preintervention year to the intervention year.

Table 1Baseline Nursing Home (NF) Characteristics by Intervention Status

	Intervention NFs ($n = 88$)	Control NFs $(n = 176)$			
Facility Characteristics	Percent or Mean (SD)				
Rural, %	13	14			
For profit, %	58	63			
Nonprofit, %	40	35			
Government, %	2	2			
Certified beds	142 (66)	135 (66)			
Occupancy rate	0.88 (0.16)	0.88 (0.15)			
Proportion of resident days that	0.64 (0.12)	0.64 (0.14)			
are long-stay					
Staff hours per resident day	Mean (SD)				
Certified nursing assistant (CNA)	2.51 (0.53)	2.42 (0.58)			
Licensed practical nurse (LPN)	0.84 (0.34)	0.84 (0.33)			
Registered nurse (RN)	0.77 (0.33)	0.80 (0.34)			
Quality performance*	Percent				
Overall quality of 4 or 5	55	59			
Survey rating of 4 or 5	26	43			
Quality rating of 4 or 5	89	87			
Staffing rating of 4 or 5	52	48			
RN staffing rating of 4 or 5	48	51			

Long-stay defined as the proportion of total 2012 resident days that are more than 100 days into a stay.

*Quality performance measures come from 2012 Nursing Home COMPARE data. In December 2011, the percentage of facilities receiving 4 or 5 stars was 43% for overall quality, 47% for quality, 48% for staffing, and 39.9% for RN staffing. (Source: Abt Associates Inc. Nursing Home Compare Five-Star Quality Rating System: Year Three Report. June 7, 2013).

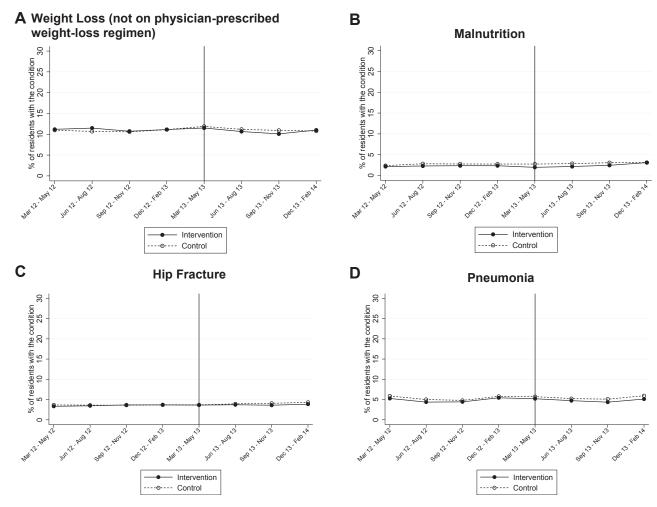


Fig. 1. Percentage of resident-quarters with MDS-derived safety measures, by intervention status for the following changes in condition: (A) weight loss (not on physician-prescribed weight-loss regimen); (B) malnutrition; (C) hip fracture; (D) pneumonia; (E) wound infection; (F) septicemia; (G) urinary tract infection; (H) falls with injury (minor or major). The vertical line indicates the first quarter of the intervention period.

Telephone Interview Results

There were no statistically significant increases in safety indicators over time [fall rates (P = .321), new pressure ulcers (P = .274), severe pain (P = .687), weight loss (P = .946), or dehydration (P = .661)] (see Figure 2).

There were also no statistically significant changes in safety measures by level of engagement across the 12 months of INTERACT implementation for weight loss [F(2, 141.48) = 0.52, P = .471], dehydration [F(2, 127.33) = 2.32, P = .130], fall rates [F(2, 109.21) = 0.28, P = .559], or pressure ulcer [F(2, 109.71) = 0.21, P = .652]. There was insufficient variability in unexpected deaths for analysis. However, there were statistically significant differences by engagement group for severe pain [F(2, 153.31) = 2.90, P = .005] with the highly engaged (engagement group 3) reporting significantly lower incidence of severe pain when compared to the low engagement (group 1)[$\beta = 0.11$, t(201.45) = 1.99, P = .012] and moderate engagement (group 2) [$\beta = 0.12$, t(204.67) = 2.40, P = .002] (Appendix Table A1).

Discussion

In our analysis of MDS assessments, we identified 8 safety-related outcomes in addition to hospitalizations and ED visits that could have been unintentionally impacted by the intervention, including unintentional weight loss, malnutrition, hip fracture, pneumonia, wound

infection, septicemia, UTI, and falls with injury (minor or major). Controlling for residents' demographic characteristics and comorbidities, we found no difference in the percentage of resident-quarters exhibiting these MDS-derived safety measures between the intervention and control NFs in the preintervention year or the intervention year. In addition, we found no differential change in these measures for intervention NFs relative to control NFs from the preintervention year to the intervention year. Given no evidence of adverse effects on resident safety, these findings suggest that the intervention did not adversely impact resident health.

Similarly, there were no significant differences in any of the telephone interview safety measures except severe pain. Even when the INTERACT treatment intervention was disaggregated by engagement level, there were no negative differences across the safety measures of weight loss, dehydration, falls, and pressure ulcers. There were insufficient numbers of unexpected deaths across the engagement groups to investigate differences by engagement levels. Only severe pain differed across engagement level with the NFs, with high engagement levels evidencing a significant decrease in reported incidence of severe pain compared to the other use groups.

To our knowledge, this is the first empirical evaluation of potential risks to the safety of NF residents related to efforts to reduce hospitalizations. This study also reflects the nascent move away from the acute care framework for patient safety that has traditionally been applied to long term care. At present, we do not have an accepted

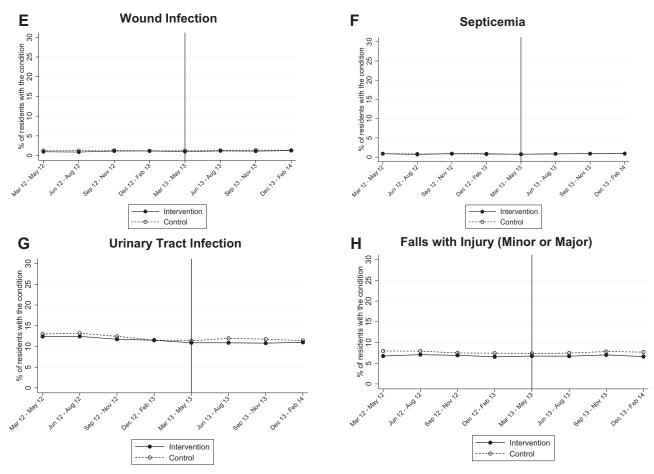


Fig. 1. (Continued).

measure or set of measures of resident safety.¹⁸ Simmons and colleagues⁹ remarked upon the unique features of long term care, suggesting additional measures above and beyond the current 4 identified by AHRQ (falls with injury, pressure ulcers, medication

errors and infections), including unintentional weight loss, dehydration, restraint use, antipsychotic medication and so forth. The factors examined in this study include 3 of the 4 identified by AHRQ (medication errors were not reported) as well as several, but not all of those

Table 2Percentage of Resident-Quarters With MDS-Derived Safety Measures by Intervention Status

	Preintervention (March 12–February 13)			During Intervention (March 13—February 14)			Differential Change,
	Intervention Group Mean (n = 47,660)	Control Group Mean (n = 88,137)	Difference Between Intervention and Control Groups* [P Value]	Intervention Group Mean (n = 46,802)	Control Group Mean (n = 87,327)	Difference Between Intervention and Control Groups* [P Value]	Preintervention to Intervention Period for Intervention vs Control Group [P Value]
Weight loss (not on physician-prescribed weight-loss regimen)	11.14	10.85	0.51 [.463]	10.83	11.20	-0.16 [.825]	-0.68 [.149]
Malnutrition	2.27	2.67	-0.34 [.656]	2.41	2.94	-0.45 [.601]	-0.14 [.753]
Hip fracture	3.53	3.65	-0.17 [.560]	3.70	4.01	-0.35 [.288]	-0.17 [.460]
Pneumonia	4.87	5.36	-0.40 [.323]	4.85	5.51	-0.54 [.118]	-0.14 [.594]
Wound infection	1.05	1.26	-0.23 [.103]	1.15	1.33	-0.17 [.262]	0.06 [.621]
Septicemia	0.85	0.84	0.03 [.833]	0.85	0.88	0.01 [.931]	-0.02 [.860]
UTI	12.03	12.55	-0.40 [.654]	10.90	11.63	-0.59 [.480]	-0.19 [.719]
Falls with minor or major injury	6.82	7.70	-0.97 [.105]	6.76	7.58	-0.98 [.083]	-0.03 [.935]

UTI, urinary tract infection

Table displays the percentage of resident-quarters where an adverse outcome was recorded at least once during a 3-month period. The means are weighted by the total number of resident days during the 3 months. The estimated differences and *P* values are from regressions using the total number of resident days during the 3 months as regression weights and with standard errors clustered at the facility level. Among the 94,462 intervention resident-quarters and 175,464 control resident-quarters, the percentage of observations with missing data ranged from 0% to 1.55% across outcomes.

*Differences were adjusted for resident characteristics, including age in 5-year increments, sex, race and ethnicity, Medicaid eligibility, hierarchical condition category score, any part A stay and total part A days, function reported on the MDS, including activities of daily living (ADL) (indicator variables for 0-4, 5-8, 9-12, 13-16),²⁰ and the cognitive performance scale (indicator variables for 0-2, 3-4, 5-6).

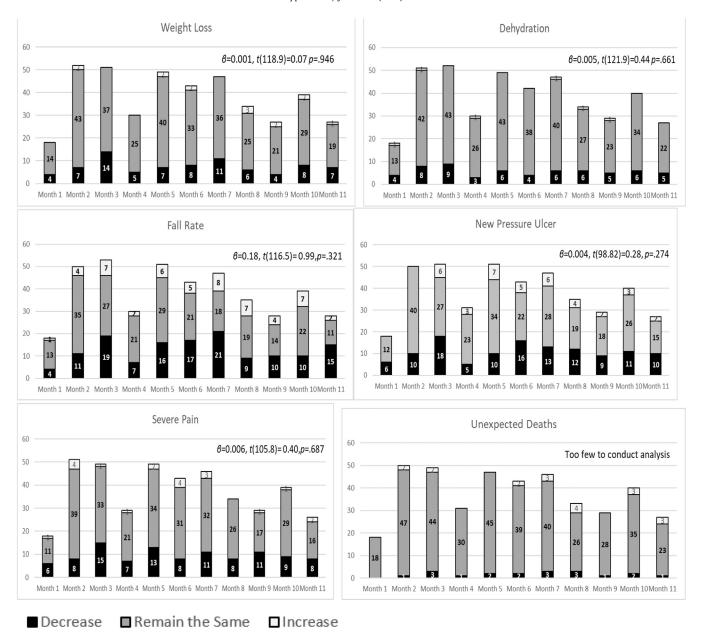


Fig. 2. Change (decrease, increase, or if remained the same) in safety measures across INTERACT implementation through telephone reports for weight loss, dehydration, fall rate, new pressure ulcers, severe pain and unexpected death.

suggested by Simmons et al.⁹ In addition, we found no effect on hospitalizations, ED visits, and mortality.

There are several limitations to this study. The INTERACT program includes more than a dozen separate tools, several of which are adopted more frequently than are others. Further, some are designed to facilitate early identification of changes in condition while others are designed to improve communication between NF staff, medical providers, and other facilities, and still others address implementation of advance directives, thereby reducing the use of acute care when it is clearly futile. The use of tools with different purposes may have had different effects on resident safety. Although we were able to access data on a number of safety measures, there were some differences in measures available from the 2 sources, MDS data and telephone interview. The need for a well-developed conceptual framework for resident safety and for a generally accepted set of measures is evident in these limitations and in some of our team discussions. For example, prior to analysis of the results, there was some debate among the

investigative team as to the meaning of an increase or decrease in expected or unexpected deaths in the context of efforts to reduce transfers to the acute hospital, should either be found. These questions need further study.

Given these issues, we suggest that this study should be considered the first effort to examine the effect on resident safety of initiatives to reduce transfers to acute care. Further work on developing a framework for resident safety and identification of the critical safety indicators is needed. At present, however, the results presented suggest that initiatives to reduce resident hospitalizations, such as the use of the INTERACT program, do not present a significant risk to resident safety.

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Appendix

 Table A1

 NF Report: Type III Tests of Fixed Effects for Differential Results of Safety Outcomes by INTERACT Engagement

Outcomes	Source	df_1	df_2	F	P
Weight loss	Baseline	1	126.51	4.02	.047*
	Engagement grouping	2	126.51	0.13	.715
	Month	1	141.48	0.20	.658
	Engagement grouping × Month	2	141.48	0.52	.471
Dehydration	Baseline	1	150.78	8.18	.005
	Engagement grouping	2	150.78	1.19	.277
	Month	1	127.33	1.69	.196
	Engagement grouping × Month	2	127.33	2.32	.130
Fall Rate	Baseline	1	136.34	3.74	.055
	Engagement grouping	2	136.34	0.07	.791
	Month	1	109.21	0.19	.660
	Engagement grouping × Month	2	109.21	0.28	.599
Pressure ulcer	Baseline	1	137.32	3.40	.067
	Engagement grouping	2	137.32	0.37	.545
	Month	1	109.71	0.06	.807
	Engagement grouping × Month	2	109.71	0.21	.652
Severe pain	Baseline	1	150.57	27.27	.000
	Engagement grouping	2	150.57	5.99	.003
	Month	1	140.88	1.00	.320
	Engagement grouping × Month	2	153.31	2.90	.005 [†]
Unexpected deaths	_	_	_	_	_

^{*}P < .05.

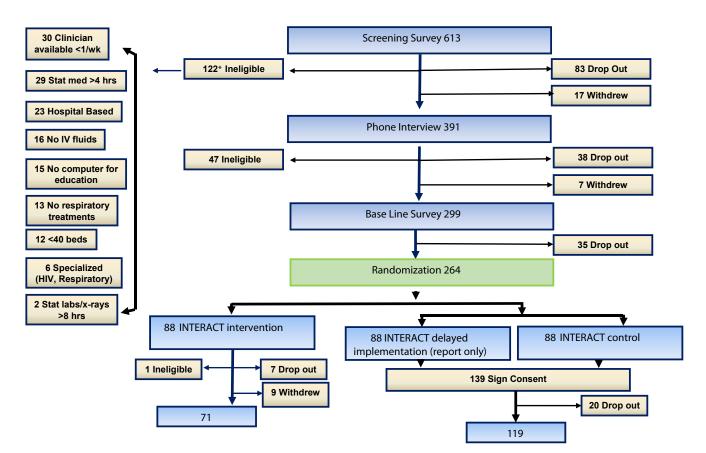


Fig. A1. Consort diagram: nursing home recruitment, enrollment, and retention.

 $^{^{\}dagger}P < .01.$