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Divesting from a Scored Hospital Fall Risk Assessment Tool (FRAT): A Cluster Randomized Non-Inferiority Trial

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Abstract

Background/Objectives: We investigated the impact of ceasing routine falls risk assessment tool (FRAT) completion and instead used clinical reasoning to select fall mitigation strategies.

Design: Two-group, multi-site cluster-randomized active-control non-inferiority trial.

Setting: Hospital wards.

Participants: Adult inpatients admitted to participating hospitals ($n = 10$ hospitals, 123,176 bed days).

Intervention: Hospitals were randomly assigned (1:1) to a usual care control group that continued to use a historical FRAT to assign falls risk scores and

We certify that this work is confirmatory of recent novel clinical research by Jellett et al. (2020). Jellett J, Williams C, Clayton D, Plummer V, Haines T. Falls risk score removal does not impact inpatient falls: A stepped-wedge, cluster-randomised trial. J Clin Nurs. 2020;29(23–24):4505–4513.

accompanying mitigation strategies, or an experimental group whereby clinicians did not assign risk scores and instead used clinical reasoning to select fall mitigation strategies using a decision support list.

Measurements: The primary measure was between-group difference in mean fall rates (falls/1000 bed days). Falls were identified from incident reports supplemented by hand searches of medical records over three consecutive months at each hospital. The incidence rate ratio (IRR) of monthly falls rates in control versus experimental hospitals was also estimated.

Results: The experimental clinical reasoning approach was non-inferior to the usual care FRAT that assigned fall risk ratings when compared to a-priori stakeholder derived and sensitivity non-inferiority margins. The mean fall rates were 3.84 falls/1000 bed days for the FRAT continuing sites and 3.11 falls/1000 bed days for experimental sites. After adjusting for historical fall rates at each hospital, the IRR (95%CI) was 0.78 (0.64, 0.95), where IRR < 1.00 indicated fewer falls among the experimental group. There were 4 and 3 serious events in the control and experimental groups, respectively.

Conclusion: Replacing a FRAT scoring system with clinical reasoning did not lead to inferior fall outcomes in the short term and may even reduce fall incidence.

KEYWORDS

disinvestment, education, falls, health care, hospital, injury, non-inferiority, physiotherapy, quality, safety, screening

INTRODUCTION

Inpatient falls are a leading cause of harm in hospitals world-wide and are associated with morbidity, mortality, and increased length of stay.[1-4] In many hospitals, falls risk assessment tools (FRATs) are used to guide allocation of falls prevention interventions. Often this involves scoring risk from 0 (no falls risk) to 10 (high falls risk), or ratings of nil, mild, moderate, or severe falls risk.[1-3] Robust multi-site randomized trials focused on increasing FRAT completion as part of multi-faceted fall-prevention interventions have not reduced fall rates in acute hospital settings.[5,6] FRAT completion is arguably seen by some clinicians as a routine administrative task that limits use of expert clinical judgments.[7-10] Falls screening tools that provide an option for scoring "no risk" or "low risk" can also lead clinicians to inadvertently under-estimate falls risk.[10,11]

The aim of this cluster RCT was to examine the outcomes of disinvestment from completion of a hospital FRAT. The control group continued to use the FRAT. For the experimental group health professionals used clinical reasoning to judge which interventions to implement from a decision support intervention list. It was hypothesized that disinvesting from a traditional FRAT would not lead to inferior hospital falls outcomes in the short term.

Key Points

- Falls risk assessment tools (FRATs) have historically been used to screen hospital falls.
- Ceasing FRAT ratings did not increase fall rates in hospitals.

Why Does this Paper Matter?

Falls risk assessment tools (FRATs) have been used routinely in hospitals world-wide, despite a lack of evidence of benefit. We conducted a cluster randomised non-inferiority disinvestment trial that demonstrated that ceasing routine use of FRATs to assign falls risk ratings did not increase hospital falls.

METHODS

This trial was prospectively registered on the ANZCTR registry (ACTRN12619000103167) and approved by the La Trobe University Human Ethics Committee (HEC18464).

Design

A parallel group cluster randomized controlled trial was used to compare the effects on falls of (i) continuing to use a traditional FRAT, versus (ii) removing the risk scoring elements whilst maintaining a list of potential falls mitigation actions to support clinical decision-making, consistent with the U.K. National Institute for Health and Care Excellence (NICE) guidelines.[4] We used a non-inferiority paradigm, with non-inferiority margins for study outcomes as well as safety stopping rules (monthly falls rates) determined a-priori by our stakeholder advisory board.

Procedure

Ten Australian private hospitals participated (Figure 1). Historically, in all of the hospitals, falls screening was routinely completed at admission for every adult patient, using a fall risk tool that incorporated a 10 point scale, scoring patients no (0), mild (1–3), moderate (4, 5), or high (6–10) risk of falls.[1-3] This was linked to a list of potential falls mitigation strategies (Figure S1).

The participating hospitals had 50–359 beds and at least 8000 clinical staff. Beds per hospital (A–J) were: A 144, B 314, C 148, D 147, E 74, F 46, G 30, H 224, I 141, and J 359. The mean age (SD, years) at each hospital was: A 50.5 (22.4); B 61.1 (21.5); C 62.95 (16.3); D 65.9 (19.7); E 66.95 (16.0); F 70.96 (15.1); G 72.2 (11.2); H 61.2 (17.2); I 72.8 (16.8); J 62.6 (19.7). Pediatric, maternity care, emergency department, and perioperative care were excluded. Sites were randomized (1:1 ratio) to either group by another organization using simple randomized computer number generation that was concealed from the research team.

For the hospitals in the usual care "control" group (F, G, H, I, J), clinical teams continued using the usual care FRAT (Figure S1). The psychometric properties of the historical FRAT had not been tested. Corresponding fall prevention interventions were delivered according to usual care practices at the participating facilities. For "experimental" group hospitals (A, B, C, D, E), falls risk ratings were not required and only a clinical decision support intervention checklist was retained (Figure S2). Clinicians in the experimental group received education regarding the new procedure.[12-14] Hospital staff in the treating clinical teams were blind to the trial aims.

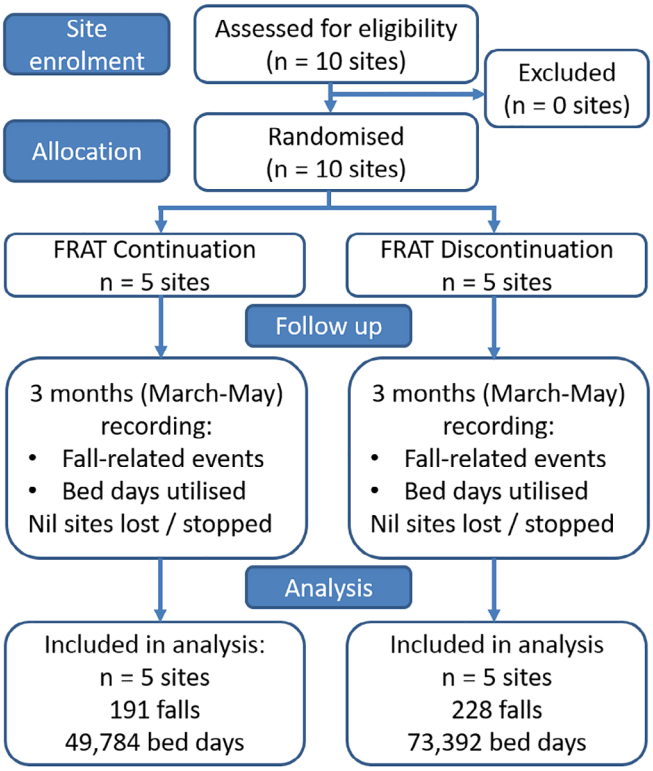

FIGURE 1 Consort diagram outlining the design and site retention in the cluster RCT

Outcomes

The primary outcome was fall rates (per 1000 bed days), derived from the hospital "*Riskman*" electronic incident reporting and management system. We also conducted hand searches of the medical histories of 10% of patients. The secondary outcome was fall injuries (such as lacerations, bruising, fractures, head injuries), including serious events. The age and sex of people who fell during the 3-month observation period was also recorded for each of the sites, as was the fall rate for each hospital in the corresponding 3-month period in the year before the trial.

Safety monitoring

A data management safety committee independent to the team monitored the falls rates at the end of each month of intervention. They also evaluated if there were any serious adverse events that resulted in death, life-threatening injuries, events requiring inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity.

Non-inferiority margin and sample size considerations

The a-priori non-inferiority margin was defined by a stakeholder working party. Consensus was reached to

define the a-priori non-inferiority margin on the basis of absolute falls rate increase of 2 falls per 1000 bed days in the experimental group. With the 10 hospital sites and a 3 month observation period, the study was estimated to have >90% power for this non-inferiority margin (i.e., one-sided, 95% confidence interval limit for mean difference in fall rate not crossing the non-inferiority margin)[15] assuming no true mean difference in fall rates, and a standard deviation of 1.7 falls per 1000 bed days in the observed monthly fall rates, and inflation for the design effect of clustering assuming an intra-cluster correlation of 0.001[6, 15, 16] for falls data. Two additional non-inferiority margins for inclusion in sensitivity analyses were also defined. The first was a 50% reduction in the absolute magnitude of the primary non-inferiority margin (representing an increase in falls rate of 1 fall per 1000 bed days in the experimental group). The second was using a non-inferiority margin based on relative risk, or specifically, an Incidence Rate Ratio (IRR) > 1.25 (in the direction of higher falls rate in the experimental group). The investigators considered it important to apply these sensitivity analyses with more conservative margins on account of lower falls rates being observed at study sites than exemplar falls rates from literature discussed by stakeholders.

Statistical analyses

Descriptive statistics were used to describe the age in years and sex of patients for each fall incident, as well as fall outcome characteristics. Fall rate estimates were derived from individual fall incident data (numerator) and monthly bed day utilization data from relevant wards at the participating facilities (denominator). Various possible approaches to estimating confidence intervals for effect estimates in cluster randomized trials with a relatively small number of clusters have been previously examined.[17,18] A generalized linear mixed model (Gaussian family) was used to estimate between-group differences (and confidence intervals) in monthly fall rates with and without adjustment for historical fall rates (same months as the observation period in prior year) at each hospital (fixed effect) and accounting for dependence of observation within site (random effect). We considered Gaussian family appropriate for this model as the residuals approximated a normal distribution upon visual inspection (standardized normal probability plot and kernel density plot) which was further supported by numerical testing (Shapiro–Wilk test). We also wanted to examine whether study findings were robust to the choice of Gaussian versus Poisson family models (as the fall rate data was based on fall count data and not over dispersed). The above generalized linear mixed model analyses were repeated using Poisson family as a sensitivity analysis and expressed findings as incidence rate ratios. To aid in the interpretation of differences in absolute fall risk, and incidence rate ratio, in comparison to pre-specified non-inferiority margins, visualization of between group differences were prepared using means or incident rate ratio estimates and 95%CI. All analyses were conducted using Stata® version 16 (College Station, Texas).

Deviations from protocol

We had initially planned to complete hand searches for fall incident information for 20% of all medical records in the three-month period of the trial. This was reduced 10% to avoid unjustified use of resources on this time-consuming task after it was observed that fall incident information was widely consistent between these two sources at each site. The medical histories for 100% of falls reported in *Riskman* during the trial period were audited. One of the secondary outcomes to inform a future economic evaluation was an estimation of the difference in time taken to complete the traditional and new forms. We assessed this initially with 25 ratings by five clinicians for each form. We then decided against further completing this timing activity due to concerns about clinician reactivity to being observed and timed (Hawthorne effect).

RESULTS

All sites participated for the full trial period which comprised a total of 123,176 observed bed days (FRAT continuing sites 49,784 bed days, experimental group sites 73,392 bed days). Four hundred and nineteen fall incidents were observed across the 10 sites, representing an overall fall rate of 3.4 falls per 1000 bed days. The mean age at time of fall was 79.0 (13.9) years and 231/419 falls (55%) occurred in females. The absolute rate for the FRAT sites was 3.84 falls per 1000 bed days (191 falls, 49,784 bed days). The absolute falls rate for the experimental group was 3.11 (228 falls, 73,392 bed days). Estimates of between group difference in fall rates from the generalized linear mixed model (Gaussian family) indicated the unadjusted and adjusted (for historical fall rate) differences (95%CI) were −0.84 (95%CI: −2.25, 0.57) and −0.59 (95%CI: −1.61, 0.42) falls per 1000 bed days, respectively, where negative values represent lower falls rates in the experimental group. The incidence rate ratio (IRR) from the Poisson family generalized linear mixed model analyses indicated the unadjusted and adjusted (for

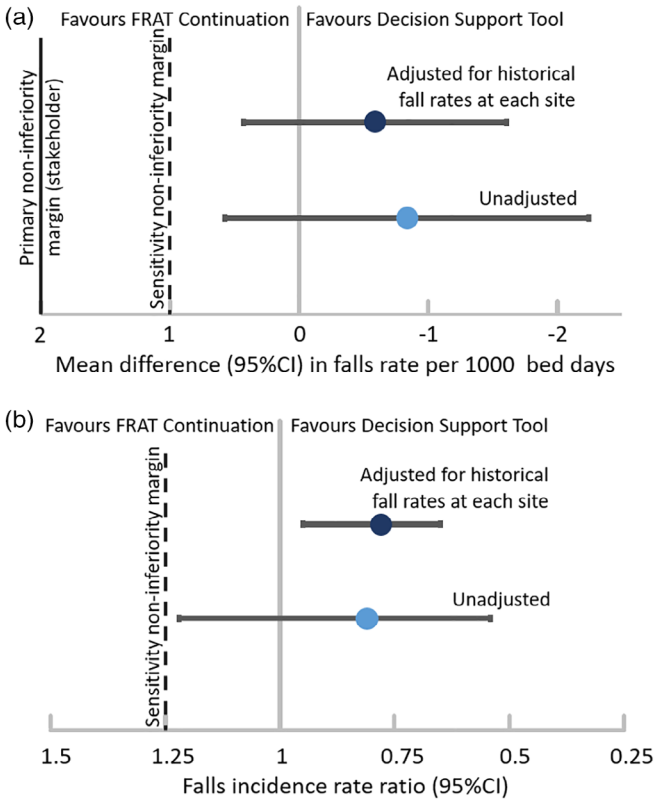

FIGURE 2 Panel A: A visualization of the absolute difference (95%CI) in falls rate (with and without adjustment for historical hospital fall rates) in comparison to the a-priori stakeholder group non-inferiority margin of two falls per 1000 bed days and conservative sensitivity analyses of half that margin. Panel B: A visualization of the incidence rate ratio (95%CI) (with and without adjustment for historical hospital fall rates) in comparison to a second conservative sensitivity non-inferiority margin of incident rate ratio of 1.25

historical fall rate) IRR (95%CI) was 0.81 (0.54, 1.22) and 0.78 (95%CI: 0.64, 0.95), where IRR < 1.00 indicates fewer falls for the experimental group.

Figure 2 shows the mean (95%CI) difference in absolute unadjusted and adjusted falls rate in comparison to the a-priori stakeholder group non-inferiority margin and more conservative sensitivity analysis non-inferiority margin. Figure 2 also shows unadjusted and adjusted IRR (95%CI) in comparison to the second sensitivity analysis non-inferiority margin. The confidence intervals for the difference in falls rate did not cross the non-inferiority margin regardless of the approach used to define non-inferiority, nor whether analyses were adjusted or unadjusted for historical fall rates.

Falls that resulted in injuries were low for the experimental group (0.7 injuries per 1000 bed days) and control group (0.9 falls injuries per 1000 bed days). (Table 1). There were 7 fall incidents classified as serious events (FRAT disinvestment group = 3, FRAT continuing group = 4). There was a comparable number of patients who fell more than once in each group: Control 15; Experimental 13.

TABLE 1 Characteristics of the fall event outcomes in the two groups

Falls outcome, *n* (%)	Control Group (*191 falls, 49,784 bed days*)	Experimental Group (*228 falls, 73,392 bed days*)
Serious event[a]	4 (2.1%)	3 (1.3%)
Injury (moderate)[b]	3 (1.6%)	1 (0.4%)
Injury (minor)[c]	37 (19.4%)	57 (25.0%)
No adverse outcome	146 (76.4%)	165 (72.4%)
Unable to determine	1 (0.5%)	2 (0.9%)

Notes:
[a]Serious event includes falls resulting in major injury with long term consequences including fractures; brain injury or death;
[b]Moderate injury includes falls and near-misses that do not require minor treatment;
[c]Minor injury includes falls and near-misses that do not require treatment.

DISCUSSION

This cluster randomized non-inferiority trial concluded that disinvesting from screening using a historical FRAT was not inferior to replacement with clinician judgment. Fall rates remained comparatively low across both trial groups and did not exceed the stakeholder working party defined primary non-inferiority margin, or more conservative non-inferiority margins applied in sensitivity analyses. Indeed, in one of our analyses, disinvestment from the FRAT appeared to reduce the rate of falls.

Despite significant research and quality improvement efforts over many decades[12,19-27] inpatient falls remain difficult to prevent. Our findings concur with previous clinical trials reporting that assigning risk-of-fall ratings does not reduce the odds of falling or the rate of falls.[5,6] Although there is no evidence of large beneficial effects for FRATs, they are still being implemented in some hospitals along with other interventions with low evidence such as bed alarms and routine use of low-low beds.[23,24]

Our trial had some limitations. It was confined to private hospitals in Australia. Although hospital-level randomization among hospitals from diverse geographical areas protected against the risk of between-group contamination, there was some risk of a chance finding due to between-group differences in hospital characteristics, including historical fall rates. To mitigate this risk, we both adjusted for historical fall rates at each facility and included site as a random effect to account for dependence of observations within sites. Hospital sizes varied and when changing practice, the size of the institution

should be taken into account when designing new procedures. Also, we only had access to de-identified hospital-level falls data and patient level data were not available. This prevented propensity matching of patients, which is common in these types of trials.

A priority for future research is the economic impact of wide-scale adoption of FRAT disinvestment in favor of clinical reasoning to plan and implement patient-centered strategies for preventing falls in hospitals.

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CONFLICT OF INTEREST

Nil.

AUTHOR CONTRIBUTIONS

Meg E. Morris and Steven M. McPhail and all authors were involved in the study conception. Meg E. Morris, Steven M. McPhail, Cathy Jones, and Dana Jazayeri were involved in running of the trial and data collection. Meg E. Morris and Steven M. McPhail conducted the analysis and primary manuscript writing. All authors (Meg E. Morris, Terry Haines, Anne Marie Hill, Ian D. Cameron, Cathy Jones, Dana Jazayeri, Biswadev Mitra, Debra Kiegaldie, Ronald I. Shorr, and Steven M. McPhail) were involved in writing, editing and approving the manuscript.

SPONSOR'S ROLE

There was no sponsor involvement in the design, methods, subject recruitment, data collection, analysis and preparation of the paper.

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REFERENCES

1. Nandy S, Parsons S, Cryer C, et al. Development and preliminary examination of the predictive validity of the falls risk assessment tool (frat) for use in primary care. *J Public Health (Oxf)*. 2004;26(2):138-143.
2. Oliver D, Britton M, Seed P, Martin FC, Hopper AH. Development and evaluation of evidence based risk assessment tool (stratify) to predict which elderly inpatients will fall: case-control and cohort studies. *BMJ*. 1997;315(7115):1049-1053.
3. Morse JM, Morse RM, Tylko SJ. Development of a scale to identify the fall-prone patient. *Can J Aging*. 1989;8(4):366-377.
4. National Institute for Health and Care Excellence. Falls in older people. Quality standard [Q86]. United Kingdom. 2017. https://www.nice.org.uk/guidance/qs86.
5. Cameron ID, Dyer SM, Panagoda CE, et al. Interventions for preventing falls in older people in care facilities and hospitals. *Cochrane Database Syst Rev*. 2018;9:CD005465.
6. Barker AL, Morello RT, Wolfe R, et al. 6-pack programme to decrease fall injuries in acute hospitals: cluster randomised controlled trial. *BMJ*. 2016;352:h6781.
7. Meyer G, Kopke S, Haastert B, Muhlhauser I. Comparison of a fall risk assessment tool with nurses' judgement alone: a cluster-randomised controlled trial. *Age Ageing*. 2009;38(4):417-423.
8. Vassallo M, Poynter L, Sharma JC, Kwan J, Allen SC. Fall risk-assessment tools compared with clinical judgment: an evaluation in a rehabilitation ward. *Age Ageing*. 2008;37(3):277-281.
9. da Costa BR, Rutjes AW, Mendy A, Freund-Heritage R, Vieira ER. Can falls risk prediction tools correctly identify fall-prone elderly rehabilitation inpatients? A systematic review and meta-analysis. *PLoS One*. 2012;7(7):e41061.
10. Haines TP, Hill K, Walsh W, Osborne R. Design-related bias in hospital fall risk screening tool predictive accuracy evaluations: systematic review and meta-analysis. *J Gerontol A Biol Sci Med Sci*. 2007;62(6):664-672.
11. Oliver D, Daly F, Martin FC, McMurdo ME. Risk factors and risk assessment tools for falls in hospital in-patients: a systematic review. *Age Ageing*. 2004;33(2):122-130.
12. Shaw L, Kiegaldie D, Morris ME. Educating health professionals to optimise falls screening in hospitals: protocol for a mixed methods study. *BMC Health Serv Res*. 2020;20(1):54.
13. Shaw LK, Kiegaldie D, Morris ME, Jones C. Improving hospital falls screening and mitigation using a health professional education framework. *Nurse Educ Today*. 2021;98:104695.
14. Jellett J, Williams C, Clayton D, Plummer V, Haines T. Falls risk score removal does not impact inpatient falls: a stepped-wedge, cluster-randomised trial. *J Clin Nurs*. 2020;29(23–24):4505-4513.
15. Julious SA. Sample sizes for clinical trials with normal data. *Stat Med*. 2004;23(12):1921-1986.
16. Killip S, Mahfoud Z, Pearce K. What is an intracluster correlation coefficient? Crucial concepts for primary care researchers. *Ann Fam Med*. 2004;2(3):204-208.
17. Li P, Redden DT. Small sample performance of bias-corrected sandwich estimators for cluster-randomized trials with binary outcomes. *Stat Med*. 2015;34(2):281-296.
18. Li P, Redden DT. Comparing denominator degrees of freedom approximations for the generalized linear mixed model in analyzing binary outcome in small sample cluster-randomized trials. *BMC Med Res Methodol*. 2015;15:38.
19. Heng H, Jazayeri D, Shaw L, Kiegaldie D, Hill AM, Morris ME. Educating hospital patients to prevent falls: protocol for a scoping review. *BMJ Open*. 2019;9(9):e030952.
20. Heng H, Jazayeri D, Shaw L, Kiegaldie D, Hill AM, Morris ME. Hospital falls prevention with patient education: a scoping review. *BMC Geriatr*. 2020;20(1):140.

21. Francis-Coad J, Hang JA, Etherton-Beer C, Ellis A, Hill AM. Evaluation of care staff knowledge, confidence, motivation and opportunity for preventing falls in residential aged care settings: a cross-sectional survey. *Int J Older People Nurs*. 2019;14(2):e12224.
22. Hill AM, McPhail SM, Waldron N, et al. Fall rates in hospital rehabilitation units after individualised patient and staff education programmes: a pragmatic, stepped-wedge, cluster-randomised controlled trial. *Lancet*. 2015;385(9987):2592-2599.
23. Haines TP, Bell RA, Varghese PN. Pragmatic, cluster randomized trial of a policy to introduce low-low beds to hospital wards for the prevention of falls and fall injuries. *J Am Geriatr Soc*. 2010;58(3):435-441.
24. Shorr RI, Chandler AM, Mion LC, et al. Effects of an intervention to increase bed alarm use to prevent falls in hospitalized patients: a cluster randomized trial. *Ann Intern Med*. 2012;157(10):692-699.
25. Haines T, O'Brien L, McDermott F, et al. A novel research design can aid disinvestment from existing health technologies with uncertain effectiveness, cost-effectiveness, and/or safety. *J Clin Epidemiol*. 2014;67(2):144-151.
26. Hill A-M, Hoffmann T, Hill K, et al. Measuring falls events in acute hospitals—a comparison of three reporting methods to identify missing data in the hospital reporting system. *J Am Geriatr Soc*. 2010;58(7):1347-1352.
27. Shorr RI, Mion LC, Chandler AM, Rosenblatt LC, Lynch D, Kessler LA. Improving the capture of fall events in hospitals: combining a service for evaluating inpatient falls with an incident report system. *J Am Geriatr Soc*. 2008;56(4):701-704.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

Figure S1. Control group FRAT tool.
Figure S2. Experimental group tool.

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