

Biophysical detection of skin changes to cue pressure injury prevention in nursing homes

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Study Statistical Analysis Plan

Descriptive statistics, tabular, and graphical displays will summarize resident, staff, and nursing home (NH) characteristics within and across NHs, as well as outcomes and fidelity measures weekly and cumulatively as relevant. Outcome measures aggregated to NH level will be visualized along a calendar timeline. Intraclass correlation coefficient (ICC), cluster autoregulation coefficient (CAC,) and individual autocorrelation coefficient (IAC) indicators will be calculated for outcome measures.

General analytical approach:

Mixed effects regression models for clustered/repeated measures will be used to assess intervention efficacy. This approach allows specialization of models for outcome distributional characteristics (e.g. for proportions or time-to-event outcomes), adjustment for multiple levels of clustering including residents within NH and repeated measures across anatomical sites and weeks within resident. The models will include factors as relevant to the research question including period (baseline vs. intervention), cue (indication of damage by visual or subepidermal moisture (SEM)), and anatomical site. The models will also include week factor to account for NH patterns of intervention efficacy across the weeks within period and allow time-dependent covariates. Covariates (confounders and effect modifiers) will include resident, staff, and NH characteristics (Table 1) and selected interactions among covariates. If effects differ by anatomical site, then contrasts will examine effects for each site separately. Because the models allow incomplete data over time and across anatomical sites, no imputation will be done. Analyses will be done primarily using SAS 9.4.

Table 1: Resident and NH characteristics for use as predictors, mediators, moderators for evaluation

Measure	Description/Definition
Resident Characteristics	
Skin tone	Match skin tone to Munsell color chart at intervention start for all residents & within 1 month for newly admitted residents
Gender	EHR gender documentation
Race/ethnicity	EHR race/ethnicity documentation
Functional status	EHR & Minimum Data Set (Activities of Daily Living section) at intervention start, quarterly as available
Risk status	EHR Braden scores at intervention start, quarterly as available
Braden activity subscale score	EHR Braden activity subscale score (most recent)
Braden mobility subscale score	EHR Braden mobility subscale score (most recent)
Body mass Index	EHR data
Cognitive status	EHR Minimum Data Set (cognitive status) & Braden Scale sensory perception subscale score at intervention start for all residents & within 1 month for newly admitted residents
Diagnoses	EHR Minimum Data Set diagnosis section & Admission form
Nursing Home Characteristics	

% Medicare residents	Centers for Medicare and Medicaid data; NH data
Registered nurse (RN) hours/resident/day	NH Compare publicly available staffing measures as reported for each NH for the quarter immediately preceding intervention start and quarterly timeframes throughout the intervention period
Unlicensed Assistive (CNA) hours/resident/day	
Licensed practical/vocational (LPN) nurse hours/resident/day	
Licensed nurse (RN + LPN) hours/resident/day	
Overall Medicare quality star rating	
% of long stay high-risk residents with PrI	
% of residents with PrI new or worsened	NH Occupancy rate monthly
Occupancy rate	

Aim 1 Determine if early pressure damage detected by SEM assessment at time of visual skin observation of NH resident sacral and heel areas is effective in cueing the initiation of NH standard pressure injury (PrI) prevention. Analysis:

The critical analyses for Aim 1 will address the relationship between detection of pressure injury and the cueing of prevention practices by NH staff.

Primary Hypothesis 1: The odds of initiating PrI prevention when cued by SEM assessments during the intervention will be greater than by visual assessments during the baseline period. A mixed effects logistic model will include initiation of new PrI prevention (no/yes) as the outcome, with period, cue, week, anatomical site, and interactions among these factors as predictors.

Model 1 (mixed effects logistic) for baseline vs. intervention: $\text{PrI Prev Initiated} = b_1(\text{cue (delta, visual)}) + b_2(\text{period (baseline vs intervention)}) + b_3 \dots b_x(\text{nesting: NH, resident, anatomic site, week})$

Further mixed effects logistic models will assess component effects, including: 1) comparison of visual and SEM cues in predicting initiation of PrI prevention specifically during the intervention period; and 2) time trends of PrI prevention cued by SEM during the intervention period. A mixed effects Cox proportional hazards will assess difference in time to initiation of PrI prevention between visual cued assessments during the baseline period and those cued by SEM during the intervention period.

Aim 2 Examine the association between NH standard PrI prevention and SEM assessment and NH residents' characteristics (age, gender, risk, skin tone, race, ethnicity, BMI, Cognitive status) and their interactions on individual NH residents with regard to *initiation* of PrI prevention and PrI occurrence. Analysis:

Analyses for Aim 2 expand on those for Aim 1 by including resident, staff, and NH characteristics as additional predictors of PrI initiation, as well as expanding the outcomes to include PrI occurrence and severity.

Primary Hypothesis 2: The intervention effect on initiation of PrI prevention will differ by

resident and NH characteristics (Table 1).

Model 2 (mixed effects logistic) for intervention vs comparison: $\text{Prl Prev Initiated} = b1(\text{cue (SEM delta, visual)}) + b2(\text{period (baseline vs intervention)}) + b3a\dots b3x$ (resident, staff, NH characteristics) + $b4\dots bx$ (nesting: NH, resident, anatomic site, week)

Additional mixed effects logistic models will assess impact of resident, staff, and NH characteristics on: 1) difference in Prl initiation between visual and SEM-cued assessments specifically during the intervention period, 2) difference in Prl occurrence between baseline and intervention periods, 3) difference in Prl occurrence between visual and SEM-cued assessments specifically during the intervention period. A Cox proportional hazards model will assess differential effects of the intervention in terms of time to Prl initiation and time to Prl occurrence by resident, staff, and NH characteristics. A mixed effects ordinal logistic model will assess effects on Prl severity of time to Prl prevention initiation, Prl prevention actions, and resident, staff, and NH characteristics. Additional analyses will explore possible mediation effects of staff and NH characteristics for characteristics shown as significantly related to outcomes in earlier analyses. Analysis will be done using a structural modeling approach with Mplus-V8 to capture multilevel clustering and mediation structures.