

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

Study Protocol

March 19, 2026

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Title: Biophysical Detection of Skin Changes to Cue Pressure Injury Prevention in Nursing Homes

Brief Summary

Pressure injuries, local areas of damage to the skin and underlying soft tissue that are costly and painful, are often preventable with timely use of prevention strategies. Identifying early pressure induced tissue damage among nursing home residents by nursing staff during routine skin assessment is critical for this process. Finding early damage can prompt nursing home staff to start prevention actions and may allow viable tissue rescue, reducing other health problems or death. We propose use of sub-epidermal moisture (SEM) measures as the cue for nursing home staff to start prevention care. SEM provides early detection of skin damage by as much as 5 to 10 days prior to other methods, eliminates the inherent structural bias in visual skin assessment for residents with dark skin tones, and demonstrates a model of care using technology innovation in poorly-resourced healthcare settings to provide bedside, real-time, point-of-care feedback that is can be used immediately by nursing staff. In this study, nursing staff will use a device (the Provizio SEM Scanner) as part of standard skin assessments. The staff will use the values from the Provizio SEM Scanner during these assessments to decide if residents need preventive care for their skin. The study will look at these decisions and residents' subsequent health outcomes. The study will also use information about residents' skin health and prevention actions during the 52 weeks before the study as a comparison.

Brief Background and Rationale

Pressure injuries are localized damage to skin and underlying tissue caused by pressure and shear, most commonly occurring over bony prominences such as the sacrum and heels. Despite standardized prevention protocols, nursing home facility-acquired pressure injury rates remain high and exceed hospital rates. Visual skin assessment is the customary trigger for prevention; however, erythema and discoloration appear after tissue damage has already occurred. Visual assessment is also less reliable in individuals with dark skin tones, contributing to disparities in pressure injury outcomes.

Biophysical assessment of subepidermal moisture using electrical capacitance technology can detect early inflammatory changes associated with pressure damage prior to visible skin changes. The SEM Scanner is an FDA-cleared handheld device that provides numeric values reflecting subepidermal moisture differences and has demonstrated effectiveness in acute care settings for reducing pressure injury

incidence. Its effectiveness has not been tested in nursing homes, where resources are limited and pressure injury rates remain high.

This study will test whether SEM assessment used during routine skin inspection can serve as a cue for earlier initiation of prevention interventions and reduce pressure injury occurrence in nursing homes.

Specific Aims

- 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 PrI prevention.
- 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.
- Aim 3. Explore if SEM usability, NH, and nursing staff characteristics influence the adoption and assimilation of early PrI detection and subsequent PrI prevention practices.

Study Design

This study is an embedded pragmatic stepped wedge clinical trial with a mixed-methods approach to examine use of SEM Scanner assessment results as a cue for initiation of pressure injury prevention for 8 months (35 weeks) in 6 nursing homes with all residents. After nursing home preparation and staff training, nursing home staff will use the SEM Scanner (Bruin Biometrics, Los Angeles, CA) in standard-of-care pressure injury prevention for sacrum and heels. Electronic health record (EHR) data about pressure injury prevention and pressure injury occurrence for the 8-month (35 weeks) intervention will be compared to a 52-week look back period (usual care). We will examine intervention success, differential patterns associated with resident characteristics (e.g., age, gender, Braden Scale risk, skin tone, race/ethnicity, cognitive status, body-mass index (BMI)), and nursing home characteristics related to adoption.

- **Design Type:** Embedded pragmatic stepped-wedge cluster clinical trial
- **Allocation:** non-randomized by facility
- **Intervention Model:** Stepped wedge, with incomplete open cohort
- **Masking:** None (open-label)
- **Primary Purpose:** Prevention

- **Estimated Duration:** 8-month (35 week) intervention per site with usual care 52-week look back period
- **Number of Sites:** 6 nursing homes within one healthcare company

Each nursing home will transition from usual care (52-week look back period with standard care) to intervention (35-week intervention period with SEM-guided assessment) according to a non-randomized rollout schedule with one nursing home per step. All residents in each facility will receive the intervention once the facility crosses over.

Study Setting

Six Medicare-certified nursing homes within a single corporate healthcare system with standardized electronic health records and prevention protocols.

Intervention

Experimental Condition: SEM-Guided Skin Assessment

Following a one-week launch period for nursing home preparation and staff training, nursing staff will perform weekly SEM Scanner assessments of sacrum and heels during routine skin inspection.

If SEM delta ≥ 0.6 units, staff will initiate standard pressure injury prevention according to facility protocol.

No changes will be made to existing prevention protocols; the intervention only changes the cue for initiation.

Standard Care (Usual care 52-week Look back Comparison)

Visual skin assessment and risk assessment used to trigger pressure injury prevention according to facility protocol.

Intervention Procedures

The Implementation Protocol for SEM Scanning for Prolonged Pressure Injury Prevention (Figure below) will be used at each nursing home. Research staff will be onsite for the first week of intervention. During that week, several important tasks will be done: 1) skin tone measures for all residents will be obtained; 2) all SEM Scanner equipment (cradles, devices, protocol reminder cards) will be placed and/or distributed as appropriate; 3)

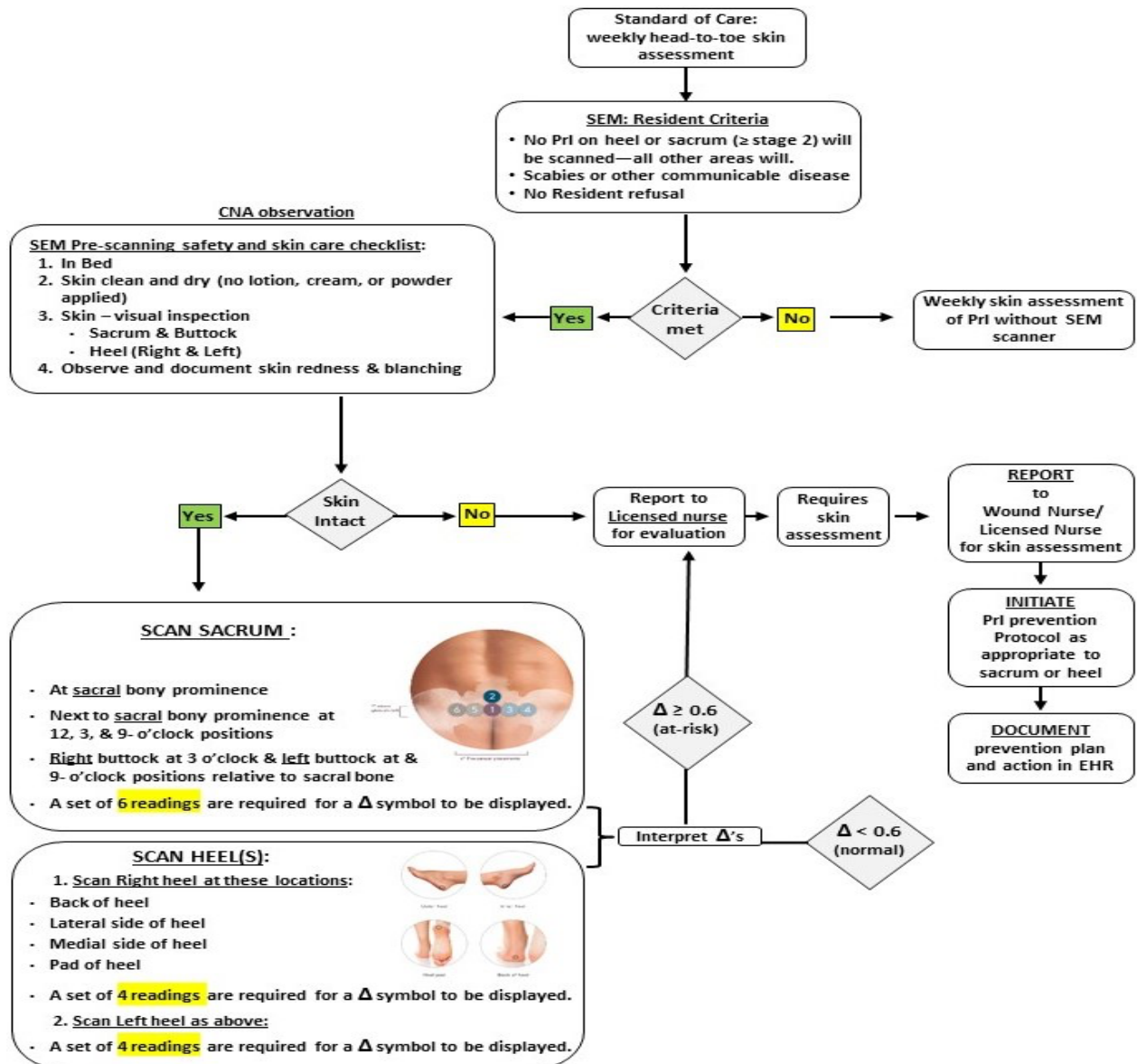
conduct SEM Scanner and dashboard training with nursing home staff across all shifts; 4) nursing home staff trained to use implementation feedback reports; 5) resident barcodes identified and assigned to residents present at intervention start.

During each resident's routine skin assessments (at least weekly), nursing home staff will complete a specific protocol (see Figure below). The SEM Scanner guides staff through the series of readings to be collected. In addition, staff will be provided a protocol reminder card as a memory aid.

Once all SEM assessments for a day are completed, staff will place the SEM Scanner in charging cradle which triggers automatic synchronization of new SEM data with the SEM database. Staff will report any residents with SEM delta values ≥ 0.6 indicating early pressure damage. The licensed nurse will subsequently initiate pressure injury prevention per nursing home standard-of-care. The intervention does not include any changes to pressure injury prevention practices.

On-site training of nursing staff immediately prior to intervention start will be followed by a week of facilitated implementation with on-site coaching by the research team. Important for nursing home staff turnover, just-in-time refreshers and additional training will be available to any staff during new staff orientation hired throughout the intervention period. During the first month, the research team will talk weekly with the on-site designated point of contact and other leadership as needed to address questions and troubleshoot any difficulties with SEM Scanner use. Such calls will then continue monthly through the study period.

Figure 5. Implementation protocol for SEM scanning for pressure injury (PrI) prevention



Outcome Measures

Primary Outcome

Initiation of pressure injury prevention

- Defined as ≥ 1 new prevention action documented in the electronic health record within one week of assessment
- Includes repositioning, support surfaces, nutrition support, incontinence care, pressure redistribution devices, lift devices, or prophylactic dressings

Secondary Outcomes

1. **Time to prevention initiation**
 - Days from visual or SEM Scanner skin assessment to documentation of pressure injury prevention action
 2. **Pressure injury occurrence**
 - Presence of sacral or heel pressure injury
 - Stage 1–4, unstageable, or deep tissue injury
 3. **Time to pressure injury occurrence**
 - Days without pressure injury
 4. **Pressure injury severity**
 - Stage 1–4, unstageable, or deep tissue injury
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Sample Size

- ~6 nursing homes
- ~100 residents per facility per week assessed
- ~31,200 SEM assessments per site over intervention
- ~1,568 unique residents during intervention
- ~2,720 total residents including usual care period

Power calculations were based on clustered repeated-measures mixed-effects models.

Eligibility Criteria

Facility Inclusion

- ≥ 100 beds
- $\geq 2\%$ pressure injury incidence
- Willing to implement SEM Scanner

Resident Inclusion

- Nursing home residents during 8-month (35 weeks) Intervention period: Must reside in nursing home during 8-month (35 weeks) study period and be at least 18 years old at study start
- Nursing home residents during the 52-week Look back usual care period with retrospective EMR records: Must reside in nursing home during 52-week look back usual care period and be at least 18 years old at study start
- All residents present during Look back usual care or Intervention study period
- New admissions included

Resident Exclusion

- Nursing home residents during 8-month (35 weeks) Intervention period: Did not reside in nursing home during 8-month (35 weeks) study period, or younger than 18 years old
- Nursing home residents during the 52-week Look back usual care period with retrospective EMR records: Did not reside in nursing home during 52-week look back usual care period or younger than 18 years old

Data Collection

Data sources:

- Electronic health record
- SEM Scanner database
- Nursing Home Compare CMS website for facility characteristics

Variables:

- Resident demographics
- Braden Scale subscale and total score
- Skin tone: Monk skin tone scale, Munsell color chart, Delfin Colorimeter
- Body Mass Index
- Cognitive status
- Pressure injury prevention actions
- Pressure injury outcomes
- SEM values

All data de-identified before analysis.

Statistical Analysis

Mixed-effects regression models will be used to account for clustering by facility, resident, week, and anatomical site.

Primary analysis:

- Logistic mixed model for initiation of prevention
- Cox proportional hazards for time to prevention and pressure injury
- Ordinal models for pressure injury severity

Covariates:

- Resident characteristics
 - Facility characteristics
 - Time period (usual care vs intervention)
 - Cue type (visual vs SEM)
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Implementation and Fidelity Monitoring

- Staff training before rollout
 - Weekly monitoring of SEM use
 - Monthly calls with facility leadership
 - On-site support during first week of intervention
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Ethical Considerations

- SEM Scanner incorporated into standard care
 - Residents may refuse assessment
 - No change to pressure injury prevention actions
 - De-identified data used for analysis
 - Approved by Institutional Review Board
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Keywords

Pressure injury
Nursing home
Subepidermal moisture
technology implementation