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A Randomized Clinical Trial on Preventing Pressure Ulcers with Wheelchair Seat Cushions

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Abstract

Objectives—To determine the efficacy of skin protection wheelchair seat cushions in preventing pressure ulcers in the elderly, nursing home population

Design—Clinical trial with participants assigned at random to either a skin protection or segmented foam cushion. Two hundred thirty two participants were recruited between June 2004 and May 2008 and followed for 6 months or until pressure ulcer incidence.

Setting—Twelve nursing homes

Participants—Nursing home residents' age ≥ 65, using wheelchairs ≥6 hours/day, Braden score ≤ 18, and combined Braden activity and mobility score ≤ 5. Participants were recruited from a referred sample.

Intervention—All participants were provided a fitted wheelchair and randomized into skin protection (SPC) or segmented foam (SFC) cushion groups. The SPC group received an air, viscous fluid/foam, or gel/foam cushion. The SFC group received a 7.6 cm crosscut foam cushion.

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Measurements—Pressure ulcer incidence over 6 months for wounds near the ischial tuberosities (IT ulcers) were measured. Secondary analysis was performed on combined IT and sacral/coccyx ulcers.

Results—One hundred eighty participants reached a study endpoint and 42 were lost to follow-up. Ten did not receive the intervention. There were 8/119 (*6.7*%) IT ulcers in the SFC group and 1/113 (*0.9*%) in the SPC group (p<0.04). In the group of combined IT and sacral/coccyx ulcers, there were 21/119 pressure ulcers (*17.6*%) in the SFC group and 12/113 (*10.6*%) in the SPC group (p=0.14).

Conclusion—Skin protection cushions used with fitted wheelchairs lower pressure ulcer incidence for elderly, nursing home residents and should be used to help prevent pressure ulcers.

Keywords

pressure ulcer; elderly; nursing home; seat Cushion; wheelchair

INTRODUCTION

Pressure ulcers in nursing homes occur at rates estimated between 2.2% and 23.9% [1]. They are associated with diminished quality of life, loss of function, increased risk of death and increased healthcare costs.[2] Many pressure ulcers are potentially preventable.[3] Prevention strategies with some evidence of effectiveness include using support surfaces, periodic repositioning, maintaining high nutritional status, and moisturizing the skin.[4]

A variety of wheelchair seating inadequacies that contribute to pressure ulcer development and diminished quality of life have been identified.[5] Shaw quantified the scope of this problem in nursing homes when he found as many as one-third of wheelchair users experienced sitting discomfort and more than half had high sitting interface pressure.[6] His research supports previous investigations demonstrating that many wheelchairs do not fit their elderly users.[7, 8] Shaw also found that 34% had discomfort, poor mobility, or poor posture and up to 80% had one or the other.[9] Individuals who cannot independently reposition tend to be at the greatest risk for ulcer development.[10] Several studies have indicated that the use of pressure-redistributing wheelchair cushions designed to maintain tissue integrity will reduce the incidence of sitting-induced pressure ulcers.[5, 11, 7, 12, 13, 14]

Reddy, et. al.[4] performed a systemic review of the evidence from studies investigating interventions to prevent pressure ulcers. The 59 RCTs selected for review enrolled a total of 13845 patients, 2367 (17.1%) in long-term care (LTC). Fifty-one of these studies targeted mobility (1866 patients in LTC), five targeted nutrition and three targeted skin health. Reddy concluded that many of the randomized controlled trials had important methodological limitations and that well-designed RCTs following standard criteria were needed. Four studies,[5, 12–14] all in LTC, have examined the effects of wheelchair cushions on pressure ulcer incidence. These four studies where either too small to detect a difference or did not control for the wheelchair to isolate the effects of the cushion.

Skin protection cushions (SPC) are designed to maintain tissue integrity by reducing pressures near bony prominences, accommodating orthopedic deformities through immersion, enveloping irregularities at the seating interface to reduce high pressure gradients, and regulating dissipation of heat and moisture.[15] Cushions cannot, however, compensate for violation of basic principles of body mechanics in wheelchair fitting. Therefore, providing a cushion that meets skin protection needs requires a seating evaluation performed by a competent clinician and a properly fitted wheelchair.[16] These services and products are not routinely available to elderly wheelchair users in nursing homes who

routinely receive standard segmented foam cushions (SFC) not designed for skin protection. While such services and products are beneficial to the entire population of wheelchair users, they are crucial to the comfort, function and maintenance of skin integrity in the portion of this population at greatest risk for pressure ulcer development.

METHODS

The trial was conducted to test the hypothesis that the incidence of sitting-acquired pressure ulcers is greater for at-risk elderly wheelchair users using segmented foam seat cushions than for those using appropriate skin protection seat cushions. The University of Pittsburgh IRB approved the protocol. The recruitment, contact and data collection schedule is summarized in Table 1.

Recruitment

Potential participants were elderly nursing home residents who used wheelchairs as their primary means of seating and mobility and were at-risk for developing pressure ulcers. Inclusion and exclusion criteria are:

1. LTC resident 65 years of age or older;
2. Braden Score of ≤ 18 (at risk for developing pressure ulcers);[17]
3. Combined Braden Activity and Mobility Subscale score ≤ 5;
4. Absence of ischial area pressure ulcers;
5. Tolerance for daily wheelchair sitting time ≥ 6 hours; and
6. Ability to accommodate seating and positioning needs with the wheelchair selected for use in this study.

The exclusion criteria are:

1. Body weight exceeding 113 kg (exceeds wheelchair weight capacity);
2. Hip width exceeding 51 cm (exceeds wheelchair width capacity);
3. Wheelchair seating requirements for head support, seat depth > 46 cm, or accommodation of severe orthopedic deformities of the pelvis, lower extremities or back that exceed the capability of the study wheelchairs; and
4. Current use of any cushioning material(s) other than the SFC or equivalent, or a lower quality cushion.

Subjects were recruited from 12 nursing homes in the Greater Pittsburgh Area. Four nursing homes were for profit with 120–180 licensed beds. Four nursing homes were nonprofit with 120–180 licensed beds. Four were county-run, nonprofit nursing homes with 210–360 licensed beds.

A charge nurse or supervisor identified potential participants from each nursing home. Following informed consent, a member of the research team completed an initial screening, consisting of review of medical records and Braden Scale scoring. A final eligibility screening was performed to validate the inclusion criteria with an in-person examination and skin inspection to confirm the absence of ischial area pressure ulcers.

Pilot Study

Prior to this clinical trial a pilot study was conducted to assist in the development of methods and determination of sample size.[14] Estimating the incidence of pressure ulcers

caused by excessive pressure while sitting is difficult due to the uncertainty concerning the loading on the sacrum. The sacrum and coccyx region, the most common anatomical location for pressure ulcers, may be subjected to pressure and shear force both while lying in bed and while seated. The pilot study resulted in pressure ulcer rates of 58% in the control group and 40% in the treatment group. The pilot study used a generic, 7.2 cm thick convoluted foam (egg crate) cushion (Bioclinic Standard #CE3408, Sunrise Medical, Stevens Point, WI) for the control and a broad definition of a sitting induced pressure ulcer comprising the entire pelvic region, including the sacral/coccyx area. Since this study replaced the then standard-of-care convoluted foam cushion with the superior current standard-of-care segmented foam cushion and narrowed the definition of sitting-induced pressure ulcer to only ulcers near the ischial tuberosities, we estimated incidence rates of 20% in the control group and 7% in the treatment group. In order to have 90% power to detect this difference in incidence rates as statistically significant, using a one-tailed test, $\alpha=0.05$, a sample size of 234 was estimated.

Randomization

A 1:1 allocation randomization scheme stratifying by clinical facility was prepared by a research team member independent of those with participant contact. We used randomized blocks of varying length (containing random permutations of the two treatment combinations) for randomization. This approach allowed relative balance of treatment allocations overall and within each clinical center, while effectively keeping clinical center staff masked as to the treatment the next participant was to receive. The trial assigned participants at random to either a skin protection cushion (SPC) or a segmented foam cushion (SFC).

Intervention

Treatment began with a seating assessment performed by the research team's seating specialist, an occupational therapist trained in seating and mobility. Seating needs for the participants were determined according to procedures described by Engstrom[19] and Waugh, [18] and verified through audit by the seating trainer, an occupational therapist, PhD, certified Assistive Technology Practitioner, with more than 20 years of experience in prescribing wheelchairs and cushions. The seating specialist performed a physical motor assessment to evaluate if the study wheelchairs could accommodate a participant. Once wheelchair and cushions were properly fitted and adjusted, functional tasks (reach, wheelchair propulsion, and transfers) were performed.

SFC group participants received a crosscut, 7.6 cm thick, segmented foam cushion (Span-America Medical Systems, Inc., Greenville, SC), fitted incontinence cover, and solid seat insert. This cushion was chosen as the control because it is representative of a large number of cushions currently used in nursing homes.

SPC group participants received a commercially available cushion with an incontinence cover. Cushions were selected from a group of three that were designed to improve tissue tolerance by reducing peak pressures near bony prominences, accommodating orthopedic deformities through immersion, enveloping small irregularities at the seating interface without causing high pressure gradients, and dissipating heat and moisture (Table 2). Solid seat inserts were provided. Multiple SPC group cushions were necessary to allow for cushion selection based upon specific clinical conditions. Clinical judgment and expertise of the team was used to select a particular SPC cushion based on its compatibility with the subject's clinical needs and preferences.

For all participants, interface pressure measurement data was used to monitor the effects of adjustments made to the wheelchair and, in the case of the SPC group, to additionally compare the pressure distributions on specific cushions or modifications to cushions. The benefits of interface pressure have been previously established.[16, 20, 21] Interface pressure measurements were recorded for all participants while on the seat cushions using a Force Sensing Array pressure-mapping device (Vista Medical, Winnipeg, Manitoba, Canada).

Each participant received a new, properly fitted wheelchair. Two models were used, the Guardian Escort or the Breezy Ultra 4 (Sunrise Medical Products, Longmont, Colorado). The Guardian Escort was selected for use in this study because it is a common Medicare K0001-coded wheelchair built to withstand the rigors of long-term usage. The wheelchair's features are standard for the nursing home setting and permit limited adjustment in the length of the legrests and the height of the armrests. The floor-to-seat height is fixed at 51 cm. Adjustments are possible, but not easily accomplished. Subjects needing an alternate seat-to-floor height were provided a Breezy Ultra 4 wheelchair (Sunrise Medical Products, Longmont, Colorado).

Follow-Up

Weekly skin assessments and risk assessments (Braden Score) were performed by the research team's skin assessor (a research nurse trained in detecting and staging pressure ulcers) who was masked to the treatment assignment. Skin assessments commenced at the time of subject enrollment and continued until the first incidence of a pressure ulcer, discharge from the facility, voluntary withdrawal from the study, death, or the study end date 6 months from the initiation of the seating intervention. The main outcome variable for this study was the occurrence of a sitting-acquired pressure ulcer.

Although the intervention was not completely masked due to the readily identifiable differences in configuration and weight between the SPC and the SFC cushions, the research staff members who performed outcome measures were masked to the treatment group assignment. Removing all identifying labels from the cushions and using the same color and style of incontinence covers for all cushions accomplished this objective. Monitoring of pressure ulcer status was performed by the research team's skin assessor while the subject was in bed. If facility staff identified an ischial pressure ulcer between weekly skin monitoring sessions, the skin assessor was contacted and a skin inspection was completed within 24 hours to confirm that the lesion was a pressure ulcer. Identified pressure ulcers were staged and photographed at the time of first observation.

Wheelchairs and cushions were checked weekly by the seating specialist aided by occupational therapy students, and repaired or adjusted as needed. The research staff monitored actual sitting time by periodically sampling the daily use of wheelchairs by participants in a single facility on a single day. All participants were given the opportunity to assume ownership of their wheelchair upon attainment of one of the study endpoints.

Operational definition of sitting-acquired pressure ulcers

The operational definition of a sitting-acquired pressure ulcer for this trial incorporated the National Pressure Ulcer Advisory Panel[1] definition with specific limitations. The NPUAP definition stated "pressure ulcers are usually located over bony prominences and are graded or staged to classify the degree of tissue damage observed."[22] Skin reactions were classified according to the NPUAP staging system current at the time of this study.[23]

Our definition of sitting-acquired pressure ulcers is based on the results of the pilot study[14] and is consistent with the clinical view expressed by Pompeo and Baxter,[24] that sitting-acquired pressure ulcers occur primarily over the ischial tuberosities (IT) while sacral ulcers

primarily result from excessive loading in bed. The definition limits the region of incidence to a defined ischial area. This area was specified, taking into account the effects of pelvic position on the displacement of the ischium and this effect on the possible location of the lesion.[25] The area consisted of a rectangle surrounding the IT with the hip flexed 90 degrees. The medial and lateral borders of the rectangle were located 3.5 cm on either side of the ischium. The anterior border of the rectangle is 6 cm anterior to the ischium with the posterior border being located 5 cm from the ischium. A template (7 cm × 11 cm) was used to inspect the defined area over each ischium.

Statistical Methods

Data are summarized as mean and standard deviation for continuous variables and frequencies for categorical variables. Comparisons of characteristics of participants in the two groups (SFC and SPC) were done using two sample t-tests or Wilcoxon two sample tests for continuous variables and Fisher's Exact and Chi square for discrete data. The rate of pressure ulcers (IT pressure ulcers, sacral/coccyx pressure ulcers and the combined group) in participants using the SPC cushions was compared to the rate of those using the SFC cushions. This primary comparative analysis was done on an intention to treat basis. All tests were two-sided and p values < 0.05 were considered statistically significant. Although statistical power was extremely limited, secondary analysis focused on the Kaplan-Meier method to estimate the cumulative incidence of pressure ulcers, with the log-rank statistic used to assess differences by treatment group. Data were analyzed using SAS version 9.2 (SAS Institute Inc, Cary, North Carolina).

RESULTS

Of the 232 participants who were entered into the trial, 119 were randomly assigned to the Segmented Foam Cushion (SFC) group and 113 were assigned to the Skin Protection Cushion (SPC) group. Participant status is summarized in Figure 1. Reasons for not reaching endpoint included voluntary withdrawal, death and *other*. The *other* reasons for not reaching endpoint typically included instances where participants were removed or advised to be removed from the study by nursing home staff who disagreed with our research staffs' seating intervention or changes in medical status that necessitated seating types other than the wheelchair provided in the study.

Baseline characteristics

Demographics, characteristics and diagnoses are shown in Table 3. None of the characteristics and diagnoses in this table were significantly different between randomization groups, except for ambulation. The mean age of the 232 participants in the study was 86.7 (± 7.6) years, with the majority being white (92.2%) and female (84.9%). The SFC and SPC groups were similar in regard to age and ethnicity. There were slightly fewer males in the SFC group (10.9%) than in the SPC (19.5%). The top four primary diagnostic categories for participants were vascular conditions (89.6%), psychiatric (85%), musculoskeletal/integument (63.2%) and heart conditions (54.6%).

Almost 90% of participants in the study were urine or fecal incontinent with no difference by intervention assignment. In the SFC group, 85.8 % were incontinent, of those 99% were urine incontinent, 86.6% were fecal incontinent, and 86.5 % were both. In the SPC cushion group, 90.7% were incontinent, of that group, all were urine continent, 86.6% were fecal incontinent and 86.6% were both.

In regard to how far participants could walk unassisted, 69.6 % could not walk at all (0 meters). By randomization group: 76.1% of SFC participants could not walk at all vs. 62.6%

of SPC, 4.4% of SFC and 13.1% of SPC could walk 3 meters or less, and 19.5% of SFC and 24.3% of SPC could walk more than 3 meters (p<0.04).

Wheelchairs

Of the 222 patients who received the intervention (Figure 1), 131 (59%) got the Breezy and 91 (41%) got the Escort. Difference between randomization groups was not significant.

Follow up

The SFC and SPC groups received weekly adjustments to wheelchairs and cushion as needed. Wheelchair adjustments included repairing brakes, casters, armrests and footrests. Cushion adjustments included ensuring the proper amount of air and cushion orientation. The types and amounts of adjustments was not recorded and compared between groups.

Pressure ulcers

For those participants who were randomly assigned (n=*232*), there were 8/119 (*6.7*%) participants with IT ulcers in the SFC group and 1/113 (*0.9*%) in the SPC group (p<0.04). The severities of the IT ulcers at the time they were first observed were stage 1 (n=1), stage 2 (n=7), and unstageable (n=1). For combined IT and sacral/coccyx ulcers, there were 21/119 participants with pressure ulcers (*17.6*%) in the SFC group and 12/113 (*10.6*%) participants with pressure ulcers in the SPC group (p=0.14). These 33 participants had 38 IT and sacral/coccyx pressure ulcers that were staged as stage 1 (n=6), stage 2 (n=29), stage 3 (n=2), and unstageable (n=1). Kaplan-Meier methods did not demonstrate statistically significant differences in the cumulative incidence of pressure ulcers by treatment group (SFC vs. SPC for either the IT group by itself or the combined group of IT and sacra/coccyx ulcers.

DISCUSSION

This clinical trial demonstrated significant differences in pressure ulcers occurring over the ischial tuberocities between segmented foam and skin protection wheelchair cushion groups. The study is the first clinical trial to test the effectiveness of wheelchair seat cushions while controlling for the effects of the wheelchair. Controlling for the wheelchair is important because poorly fitting wheelchairs are likely to result in poor posture (e.g., posterior pelvic rotation, pelvic obliquity) that will result in higher pressure and increased pressure ulcer risk. In other words, both poor posture and inadequate immersion and envelopment by the cushion can lead to prolonged ischemia-inducing pressure and shear that is believed to be the primary factor leading to pressure ulcer development. The provision of a properly fitted wheelchair to both control and treatment arms of the study was intended to reduce the chance that poor posture would cause the pressure ulcer and allow for the effect of the cushion properties to be compared.

The incidence rates for pressure ulcers near the ischial tuberosities were lower than we anticipated prior to the trial. Several factors may have contributed to this result. In the control group, the segmented foam cushions may have performed better in preventing pressure ulcers than we had anticipated. In our pilot[14] we used egg crate foam cushions as a control because they represented the standard-of-care cushion at the time. By the time we developed this full-scale trial, the standard-of-care had shifted to the cushions represented by the segmented foam cushion used here. We may have underestimated the improvement that the segmented foam provided. To roughly compare the relative effectiveness of the segmented foam cushion of this trial to the egg crate foam cushion from our pilot study, we can compare the rate of combined IT and sacral/coccyx ulcers in the larger trial, 17.6%, to the rate in the pilot, 58%, to see that there is a large difference.

The intervention protocol used for the participants of this study may not represent the current practice in nursing homes. The protocol was designed to isolate the effect of the cushion while optimizing other pressure ulcer related seating variables. For example, wheelchair fit and function was monitored and adjusted regularly to avoid problems such as missing foot and arm rests, malfunctioning brakes, loose upholstery, etc. that could have contributed to increased pressure ulcer risk had these issues gone unattended for a long period of time. In other words, applying the control necessary for performing the RCT, the effective risk level of the cohort may have been lowered. This is another possible explanation as to why the overall IT pressure ulcer incidence rate was lower than we anticipated. Although the frequency of maintenance issues was not recorded, we performed a large number of wheelchair and cushion adjustments during this study and recommend that more attention be paid to wheelchair and cushion maintenance and fit in nursing homes.

A second, notable difference between our study protocol and current practice in nursing home wheelchair seating services concerns the use of pressure mapping to assist in the selection of skin protection wheelchair cushions. Our protocol specified that the seating assessment use pressure mapping as a tool to help guide the selection of a cushion in the treatment group. All other aspects of the assessment process were the same for both groups. Therefore, our study and its results compare the use of a SFC to the use of a SPC under conditions where the seating assessment incorporated pressure mapping in the skin protection cushion selection process. The assessment protocol, including pressure mapping for cushion selection, represents best practices for this population.

The severities of pressure ulcers observed on the ITs were stage 1 (n=1), stage 2 (n=7) and unstageable (n=1). Since an IT pressure ulcer was an endpoint in the study, we could not follow up to record if and how these wounds progressed after this first observation. The incidence of sacral pressure ulcers was not a defined study endpoint hence the recorded severity of the ulcers in this category reflected the worst condition that these wounds would assume before a study endpoint.

Based on the results of this study and our experience providing seating and wheeled mobility interventions in nursing homes, we recommend that nursing home residents be assessed for their risk of developing pressure ulcers. Those residents that are determined to be at high risk as determined by the Braden Scale score and who use a wheelchair as their primary means of mobility should be provided with a wheeled mobility and seating assessment and properly fitted wheelchair with a skin protection cushion. The economic impact of such interventions still needs to be studied and should follow from this investigation focused on clinical outcomes.

Limitations

Support surface and posture conditions were only controlled for periods of time when the participants were sitting in their wheelchairs. The study did not attempt to control conditions that may have affected pressure ulcer risk while the participants were in bed or on other support surfaces. This may have had an effect on the combined IT and sacral ulcer results since this lack of control introduced uncertainty regarding the loading condition that may have contributed to the sacral pressure ulcers. Pressure and shear could have been applied to the sacrum when a participant was in either the lying or sitting positions. The pressure ulcer incidence rate may have been affected by possible nursing home staff awareness of residents' participation in the study. This effect was likely the same for both randomization groups. Finally, our sample was primarily female and white and may not be representative of the entire nursing home, elderly population.

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References

1. NPUAP NPUAP. Pressure Ulcers in America: Prevalence, Incidence, and Implications for the Future. Reston, VA: National Pressure Ulcer Advisory Panel; 2001.
2. Berlowitz DR, Brandeis GH, Anderson J, et al. Effect of pressure ulcers on the survival of long-term care residents. J Gerontol A-Biol Sci Med Sci. 1997; 52:M106–110. [PubMed: 9060978]
3. Lyder C. Pressure ulcer prevention and management. JAMA. 2003; 289:223. [PubMed: 12517234]
4. Reddy M, Gill SS, Rochon PA. Preventing pressure ulcers: A systematic review. JAMA. 2006; 296:974–984. [PubMed: 16926357]
5. Lim R, Sirett R, Conine TA, et al. Clinical trial of foam cushions in the prevention of decubitis ulcers in elderly patients. J Rehabil Res Dev. 1988; 25:19–26. [PubMed: 3361457]
6. Shaw CG. Seat cushion comparison for nursing home wheelchair users. Assist Technol. 1993; 5:92–105. [PubMed: 10146319]
7. Bardsley G. Wheelchairs and seating. Curr Opinion Orthopedics. 1993; 4:110–116.
8. Brubaker CE, Sprigle S. Seating and wheelchairs. Curr Opinion Orthopedics. 1990; 1:445–449.
9. Shaw G, Taylor SJ. A survey of wheelchair seating problems of the institutionalized elderly. Assist Technol. 1991; 3:5–10. [PubMed: 10149066]
10. Allman RM. Pressure ulcer prevalence, incidence, risk factors, and impact. Clin Geriatr Med. 1997; 13:421–436. [PubMed: 9227937]
11. Shaw I, Shaw G. Demography, nursing and community care: A review of the evidence. J Adv Nurs. 1993; 18:1212–1218. [PubMed: 8376659]
12. Conine TA, Hershler C, Daechsel D, et al. Pressure ulcer prophylaxis in elderly patients using polyurethane foam or Jay wheelchair cushions. Int J Rehabil Res. 1994; 17:123–137. [PubMed: 7960335]
13. Conine TA, Daechsel D, Hershler C. Pressure sore prophylaxis in elderly patients using slab foam or customized contoured foam wheelchair cushions. Occup Ther J Res. 1993; 13:101–116.
14. Geyer MJ, Brienza DM, Karg P, et al. A randomized control trial to evaluate pressure-reducing seat cushions for elderly wheelchair users. Adv Skin Wound Care. 2001; 14:120–132. [PubMed: 11905977]
15. Brienza DM, Geyer MJ. Understanding support surface technologies. Adv Skin Wound Care. 2000; 13:237–244. [PubMed: 11075023]
16. Ferguson-Pell MW. Seat cushion selection. J Rehabil Res Dev Clin. 1990:49–73.
17. Bergstrom N, Braden BJ, Laguzza A, et al. The Braden Scale for Predicting Pressure Sore Risk. Nurs Res. 1987; 36:205–210. [PubMed: 3299278]
18. Waugh, K. Therapeutic Seating I: Principles and Assessment. Paper presented at: RESNA Annual Conference; 1997; Pittsburgh, PA.
19. Enstrom, B. Ergonomic Seating and Propulsion Improves Performance. Stockholm, Sweden: Posturalis Books; 1997. Seating for Independence.
20. Crawford SA, Stinson MD, Walsh DM, et al. Impact of sitting time on seat-interface pressure and on pressure mapping with multiple sclerosis patients. Arch Phys Med Rehabil. 2005; 86:1221–1225. [PubMed: 15954063]

21. Stinson M, Porter A, Eakin P. Measuring interface pressure: A laboratory-based investigation into the effects of repositioning and sitting. Am J Occup Ther. 2002; 56:185–190. [PubMed: 11905303]

22. Agency for Health Care Policy and Research. Vol AHCPR Publication No 92-0047. Washington, DC: US Department of Health and Human Services: Agency for Health Care Policy and Research; 1992. Pressure Ulcers in Adults: Prediction and Prevention.

23. Donnelly J. Should we include deep tissue injury in pressure ulcer staging systems? The NPUAP debate. J Wound Care. 2005; 14:207–210. [PubMed: 15909435]

24. Pompeo M, Baxter C. Sacral and ischial pressure ulcers: Evaluation, treatment, and differentiation. Ostomy Wound Manage. 2000; 46:18–23. [PubMed: 10732632]

25. Hobson DA, Tooms RE. Seated lumbar/pelvic alignment. A comparison between spinal cord-injured and noninjured groups. Spine. 1992; 17:293–298. [PubMed: 1566167]

26. Sprigle S, Press L, Davis K. Development of uniform terminology and procedures to describe wheelchair cushion characteristics. J Rehabil Res Dev. 2001; 38:449–461. [PubMed: 11563498]

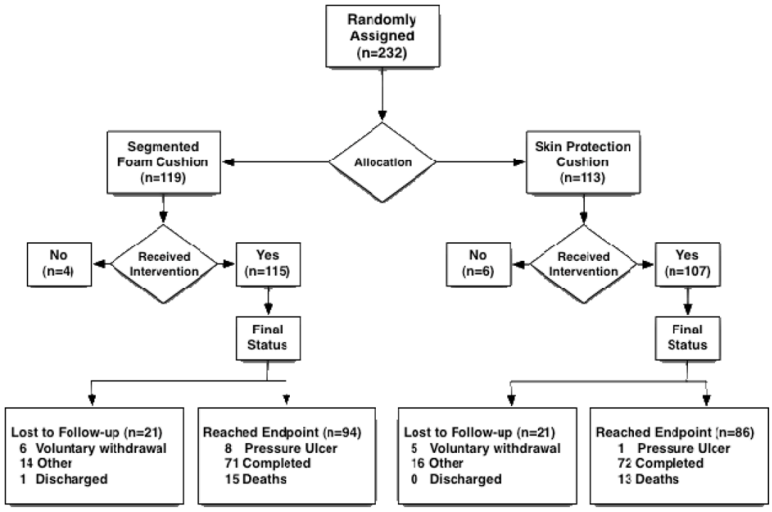

Figure 1.
Participant flowchart

Table 1

Recruitment, contact and data collection summary

Procedure	Initial Screening	Final Screening	Seating Evaluation	Intervention Initiation	1-week Follow-up	Weekly Monitoring (over 6 mo.)	Arbitrarily Sampled (over 6 mo.)	Pressure Ulcer endpoint	6 month endpoint
Chart review (demographics, diagnoses)	X								
Seating assessment			X					X	
Skin inspection		X	X	X	X	X			
Pressure ulcer risk assessment	X	X			X	X			
Wheelchair sitting time							X		
Pressure mapping				X	X			X	X
Seating system adjustment as needed					X	X		X	X

Table 2

List of skin protection cushions

Cushion	Manufacturer	Description [26]
Quadtro	Roho, Inc.	Adjustable multi-chamber segmented air cushion
J2 Deep Contour	Sunrise Medical, Inc.	Separate viscous fluid and urethane foam bladders atop a bonded non-deforming foam base with cut-out
Infinity MC	Invacare Corporation	Viscoelastic foam atop contoured urethane and non-deforming foams, with optional solid gel insert

Table 3

Baseline characteristics by wheelchair seat cushion assignment

Characteristic	Segmented Foam Cushion (SFC) (N=119)	Skin Protection Cushion (SPC) (N=113)
Age (yrs.)(mean/SD)	86.6 +/− 7.8	86.8 +/− 7.4
Females (%)	106 (89.1)	91 (80.5)
White (%)	111 (93.3)	103 (91.2)
Body Mass Index (mean/SD)	25.0 +/− 5.2	24.6 +/− 4.4
Total Braden Score	15.5 +/− 1.5	15.4 +/− 1.4
Incontinent	97 (85.8%)	97 (90.7%)
Diagnosis	(N=113) *	(N=107) *
Heart (%)	59 (52.2)	61 (57.0)
Vascular (%)	101 (89.4)	96 (89.7)
Hematopoietic (%)	34 (30.1)	30 (28.0)
Respiratory (%)	37 (32.7)	27 (25.2)
Eyes, Nose, Throat, Larynx (%)	44 (38.9)	47 (43.9)
Upper Gastrointestinal (%)	48 (42.5)	37 (34.6)
Lower Gastrointestinal (%)	22 (19.5)	21 (19.6)
Liver (%)	1(0.9)	0 (0)
Renal (%)	15 (13.3)	15 (14.0)
Genitourinary (%)	33 (29.2)	32 (29.9)
Musculoskeletal/Integument (%)	76 (67.3)	63 (58.9)
Neurological (%)	24 (21.2)	29 (27.1)
Endocrine/Metabolic/Breast (%)	57 (50.4)	52 (48.6)
Psychiatric (%)	92 (81.4)	95 (88.8)
Other (%)	36 (31.9)	30 (28.0)
Medication		
3–8 meds	36 (31.9%)	28 (26.2%)
9–11 meds	38 (33.6%)	48 (44.9%)
12+ meds	39 (34.5%)	31 (29.0%)
Ambulation **		
0 feet	86 (76.1%)	67 (62.6%)
<= 10 feet	5 (4.4%)	14 (13.1%)
> 10 feet	22 (19.5%)	26 (24.3%)

* Incomplete data due to discharge from the facility or death prior to data collection

** $p<0.04$