CLINICAL INVESTIGATION

A Randomized Clinical Trial of Wheeled Mobility for Pressure Injury Prevention and Better Function

David M Brienza, PhD,[*†‡] *Patricia E Karg, MS,*[*] *Marnie Bertolet, PhD,*[§] *Mark Schmeler, PhD,*[*] *Prerna Poojary-Mazzotta, PhD,*[*] *Helen Vlachos, PhD,*[§] *and Debora Wilkinson, OTR/L*[*]

OBJECTIVES: To evaluate the effectiveness of wheelchair assessment and configuration on pressure injury incidence, mobility, and functioning in a wheelchair.
DESIGN: Randomized controlled trial with participants individually randomized into intervention and control groups.
SETTING: Nursing home.
PARTICIPANTS: Nursing home residents aged 60 and older who used wheelchairs and were at risk for pressure injuries (N=258).
INTERVENTION: Treatment and evaluation, individually configured wheelchair and skin protection cushion; control and evaluation, facility-provided wheelchair and skin protection cushion.
MEASUREMENTS: Pressure injury incidence, Nursing Home Life Space Diameter score, Functioning Every Day in a Wheelchair—Capacity (FEW-C) score, and Wheelchair Skills Test (WST) score.
RESULTS: No differences in pressure injuries (p=.77) were found. Pelvic rotation (odds ratio (OR)=0.15, 95% confidence interval (CI)=0.03–0.70, p=.02) and Day 14 WST skill score (OR=0.74, 95% CI=0.60–0.91, p=.004) were significant predictors of pressure injuries. Significant differences were observed between groups in change in FEW-C independence scores between before randomization and endpoint (p=.03) and before randomization and 14 days (p=.04).
CONCLUSION: Participants with individually configured wheelchairs improved more in the safe and effective use of their wheelchairs than residents with facility-provided wheelchairs. The outcomes indicated that nursing home residents functioned safely at a higher level in their wheelchairs if their devices were individually configured using a comprehensive wheelchair and seating assessment process. There was no difference in the incidence of pressure injuries between the two groups.
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Key words: pressure ulcer; pressure injury; wheelchairs; nursing home

Of 1.4 million U.S. nursing home residents in 2014, 5.1% had Stage 2 or greater pressure injuries[1]. Many pressure injuries are avoidable with available technology and best practices [2]. Immobility and lack of activity increase the risk of pressure injuries[3–9], as does the ability of soft tissue to tolerate pressure [3]. Nursing homes residents with higher peak interface pressures during wheelchair seating were more likely to develop pressure injuries [10,11].

Older adults are more than 4 times as likely as the general population to use wheelchairs[12]. Proper selection and configuration of wheelchairs can enhance mobility, activity, and participation [13]. Poor configuration leads to postures that increase pressure over bony prominences, reducing the ability to propel and reach[14]. Inadequate wheelchair services are common in nursing homes, and may result in poor positioning, discomfort, and pressure injuries.

Our prior randomized controlled trial (RCT) found that the use of a skin protection cushion with an individually configured manual wheelchair reduced the incidence of ischial tuberosity pressure injuries (0.9% vs 6.7%, p=.04) [15]. All participants received individually configured wheelchairs. In practice, most nursing home residents use facility-provided wheelchairs that are not individually configured to meet clinical needs. The results of our previous RCT suggested that wheelchair inactivity could contribute to pressure injury risk. For example, 6.4% of participants

From the *Department of Rehabilitation Science and Technology, University of Pittsburgh; †Department of Bioengineering, University of Pittsburgh; ‡McGowan Institute for Regenerative Medicine, University of Pittsburgh; and the §Department of Epidemiology, University of Pittsburgh, Pittsburgh, Pennsylvania.

Address correspondence to David Brienza, University of Pittsburgh, 6425 Penn Ave, Suite 401, Pittsburgh, PA 15206. E-mail: DBrienza@pitt.edu.

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who could self-propel developed pressure injuries, versus 19.5% of those who could not. Similarly, of participants who could reach and perform tasks at different surface heights, 6.6% developed pressure injuries, versus 19.2% of those without this ability. These results led us to this RCT to assess whether individually configured, lightweight manual wheelchairs used with skin protection cushions would result in less pressure injury risk than facility-provided wheelchairs with skin protection cushions. The secondary aim was to determine the effect of individually configured wheelchairs on functional outcomes.

METHODS

Participants

Participants were at risk of developing pressure injuries and used manual wheelchairs as their primary means of mobility. Inclusion criteria were aged 60 and older, Braden Scale score of 18 or less, combined Braden activity and mobility subscale score of 5 or less, average wheelchair use of 6 or more hours per day, and clinical needs that could be accommodated by using the study wheelchair. Residents were excluded if their weight and body measurements exceeded the wheelchair capacity (weight 113 kg, hip width 508 mm), they used a manual wheelchair that was better than the study wheelchair (Healthcare Common Procedural Coding System (HCPCS) K0005 or better), or they had a current seated surface pressure injury. All research procedures and devices were provided free of charge to participants.

Intervention

Using a parallel design, participants were randomized with a 1:1 allocation using variably sized blocks and site stratification. All participants received a seating and mobility assessment from a research team (SEAT Team) led by an occupational therapist with specialization in wheeled mobility and skin protection cushion assessment. The treatment group received a new individually configured, lightweight manual wheelchair (Sunrise Medical, Fresno, CA, Breezy Ultra 4, HCPCS K0004), and the control group used a wheelchair that the nursing home provided. A cushion (Quadtro, ROHO Group, Belleville, IL; Jay 3, Sunrise Medical, Fresno, CA; or Vicair Vector, Comfort Company, New Berlin, WI) was selected based upon clinical judgment, interface pressure measurement, and participant preference. All participants were coached and assessed in basic wheelchair skills. Participants were followed weekly for 26 weeks or until they experienced a seated surface pressure injury or died.

The intervention for the treatment group included a skin protection cushion and optimization of positioning and functional mobility in the study-issued configurable, lightweight wheelchair. Seating interventions included adjusting seat depth and height; adding an adjustable-tension back to accommodate kyphosis or other musculoskeletal problems; and providing appropriate armrests, backrests, footrests, pelvic belts, brake extensions, anti-tippers, and solid seat inserts, as needed. If the wheelchair needed to be higher or lower than the standard-height Breezy Ultra, the axle height was adjusted, or different-sized wheels were provided.

The intervention for the control group included a skin protection cushion. Minimal adjustments were made to nursing home wheelchairs to accommodate cushions and achieve ethical treatment with respect to posture, comfort, and safety. Adjustments included addition of drop seats to maintain seat-to-floor height, adjustment of leg rest heights to accommodate study cushion height, and adjustment of seat angle to prevent sliding out of the wheelchair, as needed. When minimal adjustments failed to meet perceived ethical treatment, a different nursing home wheelchair was requested. Study staff did not provide pelvic belts, but they were recommended for participants at fall risk.

Positioning and maintenance concerns were assessed during weekly follow-up. Adjustments were made to the cushion (control and treatment) and wheelchair (treatment) to address positioning changes as needed. If wheelchair problems were identified, study staff performed necessary procedures for the treatment group and informed facility staff for the control group. Notes from these encounters were used to monitor concordance with study protocols.

Outcome measures

Pressure injuries on the seated surface, including ischial tuberosities, sacrum, and coccyx, were the primary outcome measure. A masked assessor performed weekly skin assessments. Pressure injuries were staged and characterized. The SEAT team measured secondary outcomes for wheelchair function and mobility (Functioning Everyday with a Wheelchair—Capacity (FEW-C), Nursing Home Life Space Diameter (NHLSD), and Wheelchair Skills Test (WST)); the team was not masked to the intervention.

The FEW is a self-reported tool for users of wheeled mobility technology [16,17]. The FEW-C was developed with the same content of the FEW self-report but was designed for a controlled clinical or laboratory setting. It is a criterion-referenced, performance-based observation system to measure functional abilities (independence and safety) of individuals with regard to wheeled mobility interventions. The FEW-C was administered before intervention initiation, 14 days after the intervention, and at the endpoint.

The NHLSD is a tool used to calculate a nursing home resident's life space, a measure of the extent and frequency of mobility, in the previous 2 weeks [18,19]. The NHLSD was used just before intervention initiation and at the endpoint.

The WST is a tool to evaluate wheelchair skills objectively [20]. The study used a portion of the test to assess basic skill and safety rolling forward 10 m, rolling backward 5 m, turning 90° while moving forward and backward, turning 180° in place, and getting through a hinged door. The WST was administered at intervention initiation, 7 and 14 days after the intervention, and at the endpoint.

Hypotheses

It was hypothesized that at-risk nursing home residents provided with an individually configured, lightweight

Table 1. Baseline Characteristics of Sample

Characteristic	Total, N = 258	Treatment, n = 127	Control, n = 131	P-Value
Age, mean ± SD	89.0 ± 8.9	89.0 ± 8.7	89.1 ± 9.2	.95
Female, n (%)	202 (78.3)	97 (76.4)	105 (80.2)	.46
Caucasian, n (%)	236 (91.8)	117 (92.1)	119 (91.5)	.86
Body mass index, mean ± SD	26.5 ± 5.5	26.0 ± 5.2	26.9 ± 5.8	.20
Incontinent, n (%)	197 (76.7)	102 (80.3)	95 (73.1)	.17
Previous history of injuries, n (%)	44 (19.9)	27 (24.3)	17 (15.5)	.10
Alert and oriented, n (%)	230 (89.5)	114 (89.8)	116 (89.2)	.89
Ambulation distance, feet, n (%)				.29
0	140 (54.5)	63 (49.6)	77 (59.2)	
≤10	50 (19.5)	28 (22.0)	22 (16.9)	
> 10	67 (26.1)	36 (28.3)	31 (23.8)	
Sensation, n (%)				.42
Normal	184 (76.0)	96 (78.0)	88 (73.9)	
Diminished, questionable	57 (23.6)	26 (21.1)	31 (26.1)	
Absent	1 (0.4)	1 (0.8)	0 (0.0)	
Scoliosis, n (%)				.86
Neutral	172 (71.1)	89 (72.4)	83 (69.7)	
Flex deformity	46 (19.0)	23 (18.7)	23 (19.3)	
Fixed deformity	24 (9.9)	11 (8.9)	13 (10.9)	
Kyphosis, n (%)				.96
Neutral	52 (21.5)	26 (21.1)	26 (21.8)	
Flex deformity	129 (53.3)	65 (52.8)	64 (53.8)	
Fixed deformity	61 (25.2)	32 (26.0)	29 (24.4)	
Lordosis neutral, n (%)	242 (100.0)	123 (100.0)	119 (100.0)	
Pelvic tilt, n (%)				.74
Neutral	67 (27.7)	32 (26.0)	35 (29.4)	
Flex deformity	126 (52.1)	64 (52.0)	62 (52.1)	
Fixed deformity	49 (20.2)	27 (22.0)	22 (18.5)	
Pelvic rotation, n (%)				.48
Neutral	184 (76.0)	97 (78.9)	87 (73.1)	
Flex deformity	52 (21.5)	24 (19.5)	28 (23.5)	
Fixed deformity	6 (2.5)	2 (1.6)	4 (3.4)	
Pelvic obliquity, n (%)				.58
Neutral	195 (80.6)	102 (82.9)	93 (78.2)	
Flex deformity	39 (16.1)	18 (14.6)	21 (17.6)	
Fixed deformity	8 (3.3)	3 (2.4)	5 (4.2)	

SD = standard deviation.

manual wheelchair and skin protection cushion would have a lower incidence of pressure injury, and function better in the wheelchair than those using a facility-provided manual wheelchair modified with a skin protection cushion and related adjustments.

Analytical methods

A difference of pressure injury incidence of 20% in the control group and 10% in the treatment group with 80% power would have required 440 participants. One statistical interim monitoring look using the O'Brien Fleming alpha spending function was performed after 131 participants had reached the endpoint. The interim look used α=0.003, leaving α=0.047 for the final analysis. Treatment comparisons were made using an adherers-only analysis for the primary endpoint of incidence of a pressure injury. Data were summarized as means and standard deviations for continuous variables and frequencies and percentages for categorical data. Baseline characteristics were compared using two-sample t-tests for continuous data and chi-square or Fisher exact tests for discrete data. Stepwise logistic regression models were developed to estimate the odds ratios (ORs) and 95% confidence intervals (CIs) of pressure injury for risk and clinical conditions (Tables 2 and 3).

Function and mobility were evaluated using changes in FEW-C, NHLSD, and WST scores between time points (before randomization, 14 days, endpoint) and compared between treatment groups using two-sample t-tests. Participants were included in analyses if measurements were taken. Peak pressure indices [21] were calculated from data collected on Day 14.

RESULTS

Participants (n=258) were randomized to treatment (n=127) and control (n=131) groups. Seventeen facilities participated. Baseline characteristics are presented in Table 1. Participants had a mean age of 89.0±8.9; 78% were female and 92% Caucasian. Twenty percent had a previous history of pressure injuries, 77% were incontinent, 55% could not ambulate any distance, 78% had kyphosis, and 72% had pelvic tilt. There were no significant differences in baseline characteristics between groups. There

Table 2. Regression Analysis of Association Between Clinical Seating Needs Variables and Pressure Injury Incidence

Clinical Seating Needs Characteristic (N = 184)	Odds Ratio (95% Confidence Interval	P-Value
Intermittent or constant pain	1.8 (0.8–4.2)	.19
Flexible or fixed pelvic rotation	0.1 (0.03–0.7)	.02
Incontinent	2.4 (0.7–7.7)	.16
Previous history of pressure injury	2.6 (0.9–7.3)	.07
Day 14 FEW-C safety score	1.1 (0.9–1.3)	.11
Day 14 WST skill score	0.7 (0.6–0.9)	.004

Clinical needs variables: treatment received, participant seating needs (pain, pelvic rotation, propulsion technique, kyphosis, sensation), cushion type (interconnected air cell, individual air cells, foam plus viscous fluid), history of pressure injury, incontinence, Day 14 Functioning Every Day in a Wheelchair—Capacity (FEW-C) safety and independence, Day 14 Wheelchair Skills Test (WST) skill and safety, peak pressure index, and Day 14 Braden scores (combined activity and mobility score, total score). Only participants with an endpoint of 26 weeks, pressure injury or death and had Day 14 follow-up data (N=184) were included. Variables were entered into the model if p≤.20 and stayed in the model as long as p≤.20. Missing values were imputed using the mean of the entire cohort.

Table 3. Results of Regression Analysis for Wheelchair-Related Factors Associated with Pressure Injury Incidence

Wheelchair Characteristic	Estimate	Standard Error	Odds Ratio	Pr>Chi-Square
Intercept	–2.45	0.79		0.002
Treatment	0.04	0.48	1.05	0.93
Wheelchair size (reference 16x16)				
18x16	0.88	0.68	2.40	0.20
20x16	0.47	0.76	1.61	0.53
Other	1.14	0.93	3.14	0.22
Cushion type (reference multi air cell)				
Individual air cells	0.67	0.46	1.96	0.14
Viscous fluid	0.79	0.58	2.21	0.17
Adjustable tension back (ref: standard)	–0.05	0.53	0.95	0.93
Back support (reference middle)				
Low	0.26	0.51	1.29	0.61
High	–0.51	0.69	0.60	0.46
Desk-length armrest (reference full length)	–0.79	0.47	0.45	0.09

The analysis included participants with endpoint of 26 weeks, pressure injury, or death (N = 191).

were no significant differences in dependence in feeding, dressing, hygiene, sitting balance, transfers, ambulation, and wheelchair propulsion (Table 1).

Participant flow and endpoints reached are presented in Figure 1. Endpoints were incidence of a seated-surface pressure injury, 26 weeks of follow-up, or death. Other endpoints included withdrawal (delineated according to some or no active follow-up). Subjects were withdrawn if they did not use study equipment for 3 consecutive weeks or if study equipment no longer met their mobility needs. Reasons included participant not liking chair (n=8), participant medical changes requiring specialized wheelchair (n=14), facility staff changing wheelchair because of medical changes (n=7), participant not using wheelchair for extended period (n=7), wheelchair to be replaced but none available (n=3), and other (n=1). Participants with no days in the study did not undergo an intervention. Reasons included no wheelchair to fit the resident (n=5), resident refused new wheelchair (n=8), pressure injury developed before receiving equipment (n=1), and other (n=8).

Of participants reaching a study endpoint (n=191), 34 (17.8%) developed a pressure injury, 144 (75.4%) reached 26 weeks without a pressure injury, and 13 (6.8%) died; 18.6% of treatment participants and 16.9% of controls had pressure injuries, 73.5% of treatment participants and 77.5% of controls with 26 weeks and no pressure injury, and 7.8% of treatment participants and 5.6% of controls died (p=.77). These pressure injuries were primarily Stage 2 injuries (73%) and occurred most frequently on the sacrum or coccyx (88%) The overall incidence rates for pressure injuries according to site were sacrum or coccyx (15.2%) and ischial tuberosities (2.0%). No significant differences were found between groups in pressure injury site (p=.70), stage (p=.13), or days until pressure injury (p=.50).

Regression analyses were conducted to identify associations between independent variables and pressure injury outcomes. Only pelvic rotation (OR=0.15, 95% CI=0.03–0.70, p=.02) and Day 14 WST skill score (OR=0.74, 95% CI=0.60–0.91, p=.004) were significant factors (Table 2). Propulsion dependence was removed from the model because there was correlation with Day 14 WST skill (p<.001). None of the wheelchair or cushion features were significant predictors of pressure injury (Table 3).

The function and mobility scores before randomization and at 14 days and the endpoint were compared between groups (Table 4). Significant differences were observed between groups for change in FEW-C independence scores between before randomization and endpoint (treatment 1.4, control –0.21, p = .03) and between before randomization and 14 days (treatment 0.87, control –0.27, p=.04). Change in FEW-C safety scores between before randomization and the endpoint was not significant (treatment 0.48, control –0.67, p=.0.057). Mean FEW-C independence and safety scores for the treatment group improved during study follow-up, whereas the control group scores declined. No significant differences in mean FEW-C scores between groups were found at any point (before randomization, 14 days, endpoint). NHLSD scores were not significantly different before randomization (treatment 29.00, control 29.09, p=.97). NHLSD scores increased for the treatment group and decreased for the control group; mean scores were not significantly different between the groups at endpoint (treatment 2.03, control –2.44, p=.07), nor was the change in score between before randomization and endpoint (treatment 31.03, control 26.66, p=.07). WST scores, although not significantly different between groups, were higher for the treatment group at all time points.

Discussion

Our previous RCT demonstrated that individually configured manual wheelchairs with skin protection cushions

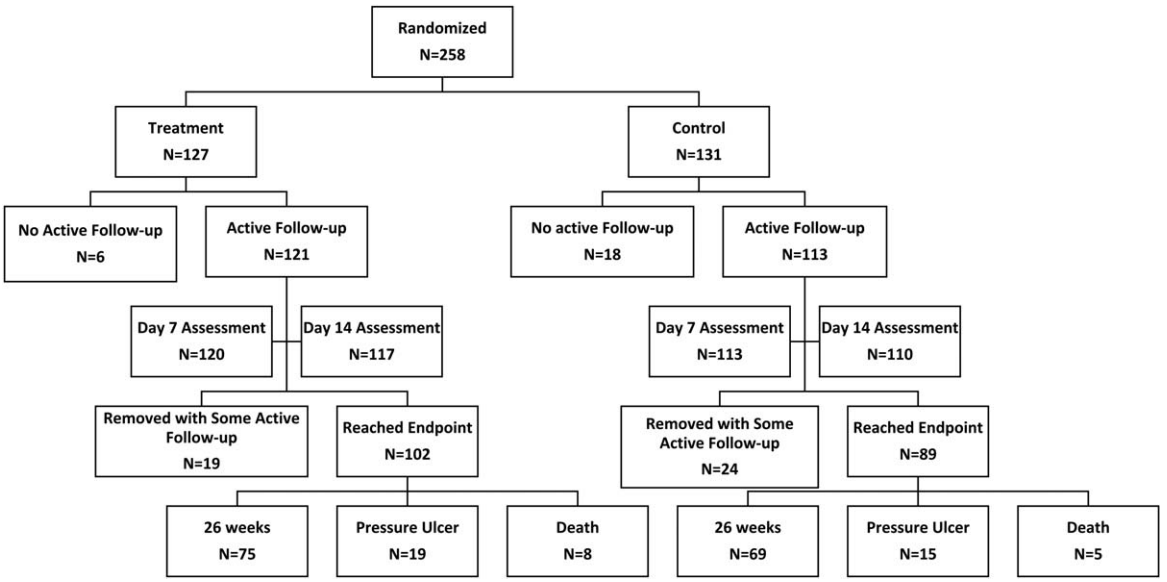

Figure 1. Participant flowchart showing randomization to treatment (n=127) and control groups (n=131). In the treatment group, 121 had active follow-up, and 102 reached an endpoint (75 reached 26 weeks, 19 had a pressure ulcer, 8 died). In the control group, 113 had active follow-up, and 89 reached an endpoint (69 reached 26 weeks, 15 had a pressure ulcer, 5 died).

reduced the incidence of pressure injuries [15]. We expected, in this study, that participants using facility wheelchairs would be at risk of sitting in a way that exposed their sacrum to harmful pressure and shear and would decrease independent reach and propulsion, leading to long periods of tissue deformation and ischemia. In the treatment group, the intervention was expected to provide superior posture and function because of the adjustable features and better fit, but the treatment group did not have a lower incidence of pressure injuries. One possible explanation was that adjustments were made to facility wheelchairs in the control group. Although the intent was not to alter the general positioning of control participants, cushion-related adjustments were needed to maintain seat-to-floor height for foot propellers and provide pelvic positioning to reduce fall risk. It is likely that these interventions had the additional effect of improving pelvic positioning and posture. Use of the study cushion also improved pelvic positioning and posture because of the contour and support provided. Better pelvic positioning and posture in both groups is a reasonable explanation for finding no difference in pressure injury rate between the groups, although achieving the wheelchair and seat adjustments needed to accommodate the study cushion was difficult and limited by the lack of adjustability of facility wheelchairs. Potential participants who could not be safely accommodated with the adjustments needed in a facility wheelchair with the skin protection cushion were not included in the study (n=5 with no active follow-up, n=3 with some active follow-up).

Despite no difference in seating surface pressure injuries between groups, the overall low incidence rate of pressure injuries occurring over the ischial tuberosities, where we would expect pressure injuries attributed to sitting, suggests that the skin protection cushions were effective in preventing sitting-acquired pressure injuries regardless of wheelchair used. Loading when participants were lying in bed or sitting could have caused the pressure injuries occurring over the sacrum and coccyx.

Consistent with the results of the prior RCT on skin protection cushions[15] that found that dependent wheelchair propulsion was a significant risk factor, this RCT found that Day 14 WST skill was a pressure injury risk factor. In addition, participants with pelvic rotation, fixed or flexible, were less likely than those with neutral pelvis to experience a pressure injury. The pelvic rotation result is contrary to what we expected because the presence of pelvic deformities such as obliquities and posterior rotation were assumed to increase risk.

The treatment group improved significantly more than the control group between before randomization and the endpoint in functional independence and safety as measured according to the FEW-C, indicating that treatment group participants were more independent and safer while performing the functional tasks of transferring, applying brakes, reaching side to side and forward, and washing hands. The most improvement was in independent functioning scores for the treatment group, and this was realized by Day 14. The control group had declines in functional independence and safety. This is the first clinical trial to use the FEW-C as an outcome measure in a nursing home population. Results are consistent with the results of a previous study indicating a beneficial effect of individually configured manual wheelchairs on propulsion independence, functional reach, and overall quality of life for nursing home residents[22] in which 30 participants aged 60 and older were followed for 3 months.

The WST was included to measure treatment effect on ability to operate a wheelchair. The results indicated no difference between groups and no change over time for either group, although the treatment group had slight improvement, and the control group had a slight decline

Table 4. Assessment Scores and Differences Between Time Points

	Total		Treatment		Control		
Assessment	**n**	**Mean ± SD**	**n**	**Mean ± SD**	**n**	**Mean ± SD**	**P-Value**
Functioning Every day in a Wheelchair—Capacity Independence score (range 0–20)							
Before randomization	173	11.91 ± 5.03	88	11.55 ± 4.93	85	12.29 ± 5.14	.33
Endpoint		12.52 ± 5.52		12.94 ± 5.33		12.08 ± 5.71	.31
Endpoint minus before randomization		0.61 ± 4.90		1.40 ± 4.41		–0.21 ± 5.26	.03
Endpoint	163	12.53 ± 5.53	83	13.02 ± 5.24	80	12.03 ± 5.81	.25
Day 14		12.59 ± 5.09		12.80 ± 4.78		12.38 ± 5.42	.60
Endpoint minus Day 14		–0.06 ± 4.54		0.23 ± 4.36		–0.35 ± 4.72	.42
Day 14	205	12.13 ± 5.32	106	12.38 ± 5.19	99	11.87 ± 5.46	.49
Before randomization		11.81 ± 5.13		11.51 ± 5.21		12.14 ± 5.03	.38
Day 14 minus before randomization		0.32 ± 4.04		0.87 ± 3.72		–0.27 ± 4.30	.04
Functioning Every day in a Wheelchair- Capacity (FEW-C) Safety Score (range 0– 15)							
Endpoint	173	11.39 ± 4.12	88	11.92 ± 3.76	85	10.85 ± 4.42	.09
Before randomization		11.48 ± 3.98		11.44 ± 4.09		11.52 ± 3.89	.90
Endpoint minus before randomization		–0.09 ± 3.96		0.48 ± 3.85		–0.67 ± 4.02	.05
Endpoint	163	11.39 ± 4.12	83	11.92 ± 3.71	80	10.85 ± 4.46	.10
Day 14		11.96 ± 3.85		12.11 ± 3.66		11.80 ± 4.06	.61
Endpoint–Day 14		–0.56 ± 3.53		–0.19 ± 3.14		–0.95 ± 3.88	.17
Day 14	205	11.61 ± 4.09	106	11.72 ± 4.07	99	11.50 ± 4.12	.70
Before randomization		11.41 ± 4.02		11.24 ± 4.35		11.60 ± 3.64	.52
Day 14 minus before randomization		0.20 ± 3.51		0.48 ± 3.72		–0.10 ± 3.26	.24
Nursing Home Life Space Diameter score (range 0–100)							
Endpoint	174	28.90 ± 15.90	89	31.03 ± 16.17	85	26.66 ± 15.38	.07
Before randomization		29.05 ± 15.61		29.00 ± 16.50		29.09 ± 14.71	.97
Endpoint minus before randomization		–0.15 ± 16.43		2.03 ± 16.95		–2.44 ± 15.63	.07
Wheelchair Skills Test Skill subscore (range 0–6)							
Endpoint	174	3.60 ± 2.59	89	3.93 ± 2.47	85	3.25 ± 2.69	.08
After randomization		3.60 ± 2.51		3.71 ± 2.50		3.48 ± 2.52	.55
Endpoint minus after randomization		0.00 ± 2.33		0.22 ± 2.30		–.24 ± 2.35	.19
Endpoint	164	3.62 ± 2.58	95	4.04 ± 2.43	89	3.19 ± 2.68	.03
Day 14		3.84 ± 2.50		3.96 ± 2.45		3.72 ± 2.57	.53
Endpoint–Day 1		–0.23 ± 2.16		0.07 ± 1.81		–0.53 ± 2.44	.08
Day 14	208	3.73 ± 2.55	108	3.94 ± 2.49	100	3.49 ± 2.60	.20
After randomization		3.55 ± 2.54		3.73 ± 2.53		3.35 ± 2.55	.28
Day 14 minus after randomization		0.18 ± 1.87		0.21 ± 1.85		0.14 ± 1.91	.78
Wheelchair Skills Test (WST) Safety sub-score (range 0–6)							
Endpoint	174	3.05 ± 2.42	89	3.27 ± 2.33	85	2.81 ± 2.50	.21
After randomization		2.99 ± 2.42		3.09 ± 2.45		2.89 ± 2.41	.60
Endpoint minus after randomization		0.05 ± 2.16		0.18 ± 2.21		–0.08 ± 2.12	.43
Endpoint	164	3.08 ± 2.43	95	3.37 ± 2.34	89	2.78 ± 2.50	.12
Day 14		3.39 ± 2.51		3.41 ± 2.42		3.37 ± 2.60	.92
Endpoint–Day 1		–0.31 ± 2.37		–0.04 ± 2.13		–0.59 ± 2.58	.13
Day 14	208	3.25 ± 2.51	108	3.41 ± 2.46	100	3.07 ± 2.57	.33
After randomization		2.99 ± 2.44		3.18 ± 2.48		2.78 ± 2.40	.24
Day 14 minus after randomization		0.26 ± 2.03		0.23 ± 1.99		0.29 ± 2.08	.84

Number of participants varied based upon available data for time points compared.

in propulsion skills. The hypothesis that configuration of the wheelchair would improve skills is supported by a previous study [23] that investigated the effect of axle position and wheelchair type on maneuverability. They found that ultralight wheelchairs required the least amount of space for maneuverability because of the adjustable axles[23].

The NHLSD is a measure of mobility as observed by facility staff. Scores decreased for the control group and increased for the treatment group, indicating better mobility in the treatment group. Another study[24] showed that mobility, along with wheelchair skills, cognition, depression, and perceived environmental barriers, has a significant effect on participation. It also demonstrated a significant negative correlation between wheelchair problems and NHLSD scores. Our results are consistent and confirm a positive relationship between mobility outcomes and designed to reduce wheelchair problems means that the assessment and provision is designed to overcome issues determined in the assessment process.

An RCT[25] examining the effects of a physical training and activity intervention on physical functioning

(including ability to transfer to and from a wheelchair, ability to propel a wheelchair, and functional balance while sitting in a wheelchair) and mobility (measured using the NHLSD) found that the only significant difference between the treatment and control groups was ability to transfer in favor of the treatment group. The sample population in that study was more mobile than the current study population (mean NHLSD 34.4 vs 29.1) and had a higher percentage of participants who could ambulate (75.9% vs 45.5%). That study found a decrease in NHLSD for both groups over a 6-month period. The results of that study, which had no wheelchair assessment or equipment intervention, stands in contrast to the results of this study, in which wheelchair skills did not decrease and mobility increased over a similar follow-up period.

This study had limitations. Twenty-four participants (9.3%) were withdrawn after randomization before receiving their assigned wheelchair. An additional 43 (16.7%) were withdrawn after some follow-up before study endpoint (treatment, n=19; control, n=24). Differences in drop-out rates when the intervention is not blinded to participants is not uncommon. Skin assessments stopped upon withdrawal, not allowing an intention-to-treat analysis. Greater risk of falling secondary to the provision of a wheelchair that improves mobility and activity is a potential concern. Future analysis will explore the relationships between falls and the mobility intervention and functional outcomes presented in this study.

Conclusions

This RCT compared pressure injury and functional outcomes of nursing home residents provided with individually configured manual wheelchairs and skin protection cushions with those of residents provided skin protection cushions in an adjusted, facility-provided manual wheelchair. Participants with individually configured wheelchairs had greater improvement in the safe and effective use of their wheelchairs than those with facility-provided wheelchairs. The outcomes suggest that nursing home residents function safely at a higher level in their wheelchairs if their devices are individually configured using a comprehensive wheelchair and seating assessment process such as the process used in this study. No difference in the incidence of pressure injuries between the groups was found.

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Conflict of Interest: Dr. Brienza was a member of the Permobil Scientific Advisory Board when this study was conducted. Permobil manufactures one of the skin protection cushions provided as an option to participants in the study. No comparisons of outcomes were made between cushions in this study. None of the other authors have any financial or personal conflicts of interest.

Author Contributions: Dr. Brienza had full access to all of the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis. Study concept and design: Brienza, Karg, Schmeler, Bertolet. Acquisition of data: Poojary-Mazzotta, Schmeler, Wilkinson. Analysis and interpretation of data: Brienza, Karg, Bertolet, Schmeler, Vlachos. Drafting of manuscript: Brienza, Karg, Bertolet. Critical revision of manuscript for important intellectual content: Brienza, Karg, Bertolet, Schmeler. Statistical analysis: Bertolet, Vlachos. Obtained funding: Brienza, Karg, Schmeler. Study supervision: Brienza, Karg, Bertolet, Schmeler.

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