

A multicentre prospective randomised controlled clinical trial comparing the effectiveness and cost of a static air mattress and alternating air pressure mattress to prevent pressure ulcers in nursing home residents

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ABSTRACT

Background: Pressure ulcers are a global issue and substantial concern for healthcare systems. Various types of support surfaces that prevent pressure ulcer are available. Data about the effectiveness and cost of static air support surfaces and alternating air pressure mattresses is lacking.

Objectives: To compare the effectiveness and cost of static air support surfaces versus alternating air pressure support surfaces in a nursing home population at high risk for pressure ulcers.

Design: Prospective, multicentre, randomised controlled clinical, non-inferiority trial.

Setting: Twenty-six nursing homes in Flanders, Belgium.

Participants: A consecutive sample of 308 participants was selected based on the following eligibility criteria: high risk for pressure ulcer and/or with category 1 pressure ulcer, being bedbound and/or chair bound, aged > 65 years, and use of an alternating air pressure mattress.

Methods: The participants were allocated to the intervention group (n = 154) using static air support surfaces and the control group (n = 154) using alternating air pressure support surfaces. The main outcome measures were cumulative incidence and incidence density of the participants developing a new category II–IV pressure ulcer within a 14-day observation period, time to develop a new pressure ulcer, and purchase costs of the support surfaces.

Results: The intention-to-treat analysis revealed a significantly lower incidence of category II–IV pressure ulcer in the intervention group (n = 8/154, 5.2%) than in the control group (n = 18/154, 11.7%) (p = 0.04). The median time to develop a pressure ulcer was significantly longer in the intervention group (10.5 days, interquartile range [IQR]: 1–14) than in the control group (5.4 days, [IQR]: 1–12; p = 0.05). The probability to remain pressure ulcer free differed significantly between the two study groups (log-rank $\chi^2 = 4.051$, df = 1, p = 0.04). The overall cost of the mattress was lower in the intervention group than in the control group.

Conclusions: A static air mattress was significantly more effective than an alternating air pressure mattress in preventing pressure ulcer in a high-risk nursing home population. Considering multiple lifespans and purchase costs, static air mattresses were more cost-effective than alternating air pressure mattresses.

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What is already known about the topic?

- Various types of support surfaces that prevent the development of pressure ulcer are available.
- There is difference in the mechanism of pressure/shear reduction between an alternating air pressure mattress and static air mattress.
- There is no evidence supporting the notion that alternating air pressure mattresses are more effective than other high-specification support mattresses in preventing pressure ulcer.

What this paper adds

- The use of a static air mattress must be considered in preventing the development of pressure ulcers in a high-risk nursing home population.
- The financial cost for static air mattress that prevents the development of pressure ulcer was lower than that for an alternating air pressure mattress.
- The time to develop a pressure ulcer was significantly longer in the group who used a static air mattress compared to the group who used an alternating pressure air mattress.

1. Introduction

The worldwide population is ageing. Virtually, every country is experiencing growth in the number and proportion of elderly individuals in their population. In 1950, less than 1% of the population in the Organisation for Economic Co-operation and Development (OECD) countries included individuals aged 80 years and older. By 2050, the proportion of individuals aged 80 years and older is expected to reach nearly 10% (OECD/European Commission, 2013). Population ageing is a worldwide concern for health and social care systems. The key characteristics of ageing are increased risk for comorbidities, decreased psychical performance and care dependency (Murphree, 2017). In addition, advanced age, chronic and acute diseases and treatments (e.g. polypharmacy) have been associated with an increased risk of developing skin conditions, such as pressure ulcers (Coleman et al., 2013; Murphree, 2017).

Pressure ulcers are a global issue and substantial concern for healthcare systems. A review of literature between January 2000 and December 2012 has revealed that prevalence rate of pressure ulcers in aged care facilities were between 4.1% and 32.2%, and the incidence rates ranged from 1.9% to 59% (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, P.P.P.I.A., 2014). Similarly, a systematic review by Hahnel et al. (2017) has reported that prevalence of pressure ulcer varied between 0.3% and 46%, and the incidence of pressure ulcer ranged from 0.8% to 34%. Most epidemiological data were obtained from hospitals (38.7%) and institutional long-term care facilities (29.7%) (Hahnel et al., 2017). The nursing home population is at risk of developing pressure ulcer associated with impaired mobility, comorbidities, alterations of skin structure and function and incontinence (Coleman et al., 2013). In the last decade, the development of pressure ulcer became an important indicator of the quality of care and remains a priority associated with patient safety issues (Smith et al., 2016).

The costs associated with pressure ulcer are considerable. According to the Agency for Healthcare Research and Quality (2011), the US healthcare system has allocated approximately \$9.1–\$11.6 billion annually for the health care cost of pressure ulcer. In addition to direct treatment-related costs, the development of pressure ulcer also results in litigation and government

penalties, and it affects hospital performance metrics. A systematic review by Demarré et al. (2015) has reported that cost for treatment of pressure ulcer was higher than its prevention. That is, the cost per patient per day ranged from 1.71 € to 470.49 € (for treatment) and from 2.65 € to 87.57 € (for prevention) across all settings (Demarré et al., 2015). The cost of prevention in long-term care settings (e.g. nursing home) per patient per day ranged from 2.65 € to 19.69 € (Demarré et al., 2015). In addition to financial implications, pressure ulcers have a significant impact on patient morbidity, mortality and quality of life (Essex et al., 2009; Gorecki et al., 2009; Hopkins et al., 2006). To further exacerbate the problem, as the population ages, the risk for developing pressure ulcer is growing, thereby increasing the demand for early-stage prevention.

In 2014, a collaboration between the National Pressure Ulcer Advisory Panel, the European Pressure Ulcer Advisory Panel and the Pan Pacific Pressure Injury Alliance resulted in the development of a clinical practice guideline for the prevention and management of pressure ulcer. According to this international guideline, the key prevention strategies for pressure ulcer include risk assessment, use of support surfaces, systematic patient repositioning, skin care and nutritional care (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, P.P.P.I.A., 2014). In systematic patient repositioning, the frequency should be adjusted to the condition of the individual and the support surface. Patient repositioning (e.g. patient turning every 2 h) is defined as a change in position of the lying or seated individual to relieve or redistribute pressure and to enhance comfort (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, P.P.P.I.A., 2014). The international guidelines recommend that all patients at risk should use pressure-reducing support surfaces (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, P.P.P.I.A., 2014). Unfortunately, there is a lack of evidence regarding the comparative effectiveness between the commercially available support surfaces that prevent the development of pressure ulcer. The selection of the most appropriate support surface for each individual patient involves various factors and is complex. The decision to use pressure reduction support surfaces is determined according to individual characteristics, such as the outcome of risk assessment, patient comfort, general health, training and availability of materials and resources (Beeckman et al., 2013).

There are a variety of commercially available pressure-reducing support surfaces, which include integrated bed systems, mattresses that can be fitted into standard bed frames, overlays that can be placed over existing mattresses, and seat cushions. Support surfaces can be divided into two general categories: high-technology support surfaces (e.g. alternating air pressure mattress) and low-technology support surfaces (e.g. static air mattress overlay) (McInnes et al., 2015; Serraes et al., 2018). Support surfaces decrease pressure damage to tissues by redistributing the mechanical loads imposed on the skin and soft tissues due to patient immobility (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, P.P.P.I.A., 2014; Wounds International, 2010). When an individual lies on a support surface, the pressure acting upon the body is the result of the body weight divided by the area of the body in contact with the support surface (Wounds International, 2010). Pressure-redistributing support surfaces conform to the contours of the body to redistribute the weight of the body over a maximum area (Hampton, 2000; Serraes and Beeckman, 2016). Pressure redistribution is based on the principles of envelopment and immersion to increase surface contact (Wounds International, 2010). Envelopment is the ability of a support surface to conform (fitting or moulding) around body irregularities (National Pressure Ulcer Advisory Panel, 2007). Immersion refers to the depth of

penetration or sinking into a support surface (National Pressure Ulcer Advisory Panel, 2007). Immersion and envelopment are possible with static air support surfaces. Other support surfaces provide pressure reduction via a cyclic interface pressure by actively inflating and deflating air, with or without the body weight of an individual resting on the surface. The intermittent reduction of pressure allows tissues to recover before pressure is reapplied and another area is relieved (National Pressure Ulcer Advisory Panel, 2007).

Several systematic reviews have reported the lack of evidence regarding the relative advantages of higher-specification constant low-pressure mattresses (e.g. static air mattress) versus alternating air pressure mattresses in preventing the development of pressure ulcer (McInnes et al., 2015; Serraes et al., 2018; Shi et al., 2018). Sideranko et al. (1992) have reported a lower incidence of pressure ulcer in the group who used the static air mattress overlay. Other trials have reported a lower incidence of pressure ulcer in the group who used an alternating air mattress (Cobb, 1995; Malbrain et al., 2010; Price et al., 1999).

The present study aimed to compare the effectiveness and cost of a static air support surface versus an alternating air pressure support surface for the prevention of category II–IV pressure ulcer in high-risk nursing home residents. The outcomes were the development of a new category II–IV pressure ulcer, pressure ulcer incidence density, time to develop a new category II–IV pressure ulcer and cost of the support surfaces.

2. Methods

2.1. Study design

A multicentre prospective randomised controlled clinical, non-inferiority trial was designed between April 2017 and May 2018.

2.2. Settings and participants

The study was conducted in Flanders, the Northern region of Belgium. The researchers generated a list of nursing homes. A total of 79 nursing homes with >70 beds were invited to participate in the study by mail and telephone. The nursing homes interested in participating received personal information about the study. In total, a convenience sample of 26 nursing homes, including 94 wards, were included in the sample.

A consecutive sample of nursing home residents was selected based on the following eligibility criteria: (1) high risk of developing pressure ulcer (Braden score ≤ 12 and/or Braden subscale score for mobility ≤ 2) and/or pressure ulcer category 1, (2) being bedbound (> 8 h in bed) and/or chair bound (> 8 h sitting in a chair), (3) aged > 65 years and (4) use of an alternating air pressure mattress. (1) Nursing home residents with a pressure ulcer category II–IV upon admission, (2) those with an expected length of stay < 2 weeks, (3) those who received end-of-life care or (4) those with medical contraindications for the use of static air support devices were excluded. Study completion was defined as follows: (1) 14 days of follow-up, (2) transfer to a non-participating ward, (3) death, or (4) withdrawal from the study.

2.3. Intervention

The participants in the intervention group were provided with the static air support surfaces (Repose®) based on the preference of the participants and the clinical judgement of the researchers. The participants received the following: Repose® mattress overlay, Repose® cushion and Repose® wedge, or Repose® foot protector (Frontier Medical Group, South Wales, the UK). These support surfaces consist of two urethane multidirectional stretch

membranes. The inner membrane is inflated and provides static pressure redistribution throughout the tubular open cells that are oriented along the length of the device. The second membrane is formed from a multidirectional stretch, vapor-permeable material. The combination of the two membranes provides pressure redistribution (Serraes and Beeckman, 2016).

The support surfaces in the control group were not standardised to reflect current clinical practice. Details about the support surfaces used in the control group are provided in Table 1.

2.4. Outcomes

The primary outcomes were the development of a new category II–IV pressure ulcer according to the International Pressure Ulcer Classification system (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, P.P.P.I.A., 2014) and pressure ulcer incidence density. Secondary endpoints were time to develop a new category II–IV pressure ulcer and purchase costs of the support surfaces. Information about purchase costs of the support surfaces was collected during the study to allow cost calculation.

2.5. Sample size calculation

The study was powered based on a pressure ulcer incidence rate of 4.9% on alternating air pressure mattresses (Demarré et al., 2013), 5.1% on static air mattresses (Serraes and Beeckman, 2016) and 16.0% on standard mattresses (McInnes et al., 2015). The significance level (α) was set at $\alpha = 0.05$, and the power ($1-\beta$) was set at 0.80. An inferiority margin of 6% was used, which was half of the difference between the incidence of pressure ulcer on pressure-relieving devices and standard foam mattresses. A sample size of 306 nursing home residents (153 participants in each group) was required.

A pilot study of Serraes and Beeckman (2016) in Belgian nursing homes has estimated that 20% of the participants were at high risk of developing pressure ulcer (Braden score ≤ 12). Moreover, 10% of eligible participants presented with existing pressure ulcer upon admission and had no informed consent, and 20% dropped-out during the study (Serraes and Beeckman, 2016). As a result, 26 nursing homes (with 100 beds on average) were required to meet the required sample size of 306 nursing home residents.

2.6. Randomisation and blinding

The researchers randomised the participants into two study groups on an equal allocation ratio (1:1). The random allocation sequence was based on a computer-generated list of random numbers using an online tool (www.randomization.com). When the participants met the inclusion criteria and an informed consent was obtained, they received an allocation number (first available number on the computer-generated list).

The study was not blinded due to the obvious visible difference between the support surfaces (e.g. external control unit). Both support surface types were presented to ward nurses as pressure reduction support surfaces to prevent pressure ulcer. Statistical analyses were not blinded.

2.7. Procedure

Two weeks before the start of the study, all ward nurses in the participating nursing homes attended an educational program on skin assessment, pressure ulcer classification, difference between pressure ulcer and incontinence-associated dermatitis, risk assessment and risk factor registration. The researchers organised at least two education sessions per nursing home (a total of 55

Table 1

Details of the mattresses, seat cushions and heel protectors used in the control group.

Mattress system	n systems	Type	Cycle time (minutes)	Dimension L × W × H (cm)	Air cells (n)	User weight (kg)
AirMed PLUS GmbH	2	OM	3–30	210 × 90 × 12.5	17	40–160
Air Wave Topper®	2	OM	–	195 × 85 × 12	19	30–160
Alpha Response mattress - Arjo Huntleigh	2	OM	10	209 × 115	17	40–160
Alpha Trancell Deluxe® - Arjo Huntleigh	20	RM	10	204 × 86 × 21	20	<120
Alphaxcell® - Arjo Huntleigh	24	OM	10	204 × 86 × 11.4	20	<140
CuroCell 3® - Care of Sweden	8	OM	10	200 × 90 × 13	17	<160
Duo Care Plus Talley®	4	RM	10	195 × 86 × 16	17	<140
Eazyflow 512ST - DigiluxAgua®	10	OM	–	200 × 83 × 13	17	<150
Eazyflow 623 - Agua®	7	RM	–	200 × 83 × 15	20	<150
ESRI® 200 Air	37	OM	10, 15, 20, 25	200 × 83 × 12.5	17	<200
ESRI® 500 Air	7	RM	10, 15, 20, 25	200 × 83 × 16	20	<250
ESRI® 1000 Air	1	RM	10, 15, 20	200 × 83 × 22	20	<280
NovaCare ASX	3	OM	10	200 × 90 × 14	18	<140
Panacea® Plus Air Alternating	10	OM	–	–	–	–
Permaflow active air mattress	1	OM	–	–	–	–
Supra 5000 Levitas	4	OM	9	200 × 90 × 12.5	17	<140
Not specified	12	–	–	–	–	–

Heel protection	n systems	Type	Dimension L × W × H (cm)	Density (kg/m ³)
Bead-filled	7	Sampli® half-moon pillow	30 × 180	–
Viscoelastic foam	16	Sampli® Viscocam 85	48 × 70 × 4–10	85
		Tempur® wedge	40 × 40 × 1–9	85
Not specified ^a	29	–	–	–
No heel protectors	102	–	–	–
Seat cushions				
Air-filled	20	ESRI® air dynamic	43 × 40 × 10	–
		Repose® cushion	45 × 45	–
		Roho® cushion	40 × 40	–
Fibre-filled	2	–	–	–
Gel-filled	7	Invacare® Matrx® Flo-tech Xtra	44 × 44 × 7.8	–
		JAY® Xtreme Active Gel	34–50 × 34–50 × 5	–
		Behrend® gel seat Ccushion	45 × 43 × 3	–
Viscoelastic foam	102	Sampli® Viscosam 85	40 × 45 × 6	85
		Tempur-Men®	45 × 40 × 5–7.5	85
		ESRI® comfort cushion	45 × 45 × 6	85
		Invacare® Matrx® Contour Visco	40–60 × 43–56 × 9	80
Water-filled	1	–	–	–
Not specified ^a	4	–	–	–
No seat cushion	18	–	–	–

Note: ESRI = European Sleep Research Institute.

RM = Replacement mattress.

OM = Overlay mattress.

– = Not specified.

^a Standard foam, pillow.

training sessions). In relation to this purpose, the Pressure Ulcer Classification (PUCLAS4), which is a validated e-learning tool, was used (Beeckman and European Pressure Ulcer Advisory Panel, 2017). The training aimed to increase the precision and uniformity of data collection. All researchers were registered nurses who worked as a general ward nurse and attended an academic MSC programme in nursing and midwifery.

The head nurses, not the researchers, reviewed the resident lists of the nursing homes to select the participants who meet the inclusion criteria. Permission to contact the nursing home residents for screening and recruitment was obtained from the management and medical staff of the participating nursing home. Then, the head nurses or researchers informed the nursing home residents and/or their representatives when appropriate about study rationale (orally and via writing), and the participants were provided with the consent form. After informed consent was obtained, the researchers collected the following demographic variables and baseline characteristics: gender, age, weight, length, body mass index (BMI), comorbidities, incontinence, pressure ulcer risk assessment score (Braden scale), use of pressure-redistributing support surfaces, frequency of systematic repositioning, pressure area-related pain, body temperature, use of tranquilizers/corticosteroids, functional status (ADL) and nutritional status (Mini-Nutritional Assessment-

Short Form). In addition, the researchers performed a baseline skin assessment. Subsequently, a random allocation of each eligible participant was performed based on a computer-generated list of random numbers. For participants allocated to the intervention group, a researcher removed the support surfaces used during that moment (alternating mattress, heel protectors and seat cushion) and applied the static air devices instead. For participants allocated to the control group, the support surfaces used (alternating mattress, heel protectors and seat cushion) were retained. More details on the support surfaces used in the control group are presented in Table 1.

The following data were collected: skin assessment, body temperature, frequency of repositioning, and pressure area-related pain. Data collection started on the same day (day 0) for all participants on the same ward. The first follow-up data collection was completed on day 1. The transparent disc method was used for skin assessment to differentiate blanchable from non-blanchable erythema. During the follow-up period (days 1–14), the ward nurses collected all data. Skin assessments and technical evaluations (e.g. external control unit, positioning, and inflation of the support surfaces) were performed daily by the ward nurses (qualified nurses and nursing assistants under the supervision of a qualified nurse). Researchers performed independent and unannounced skin assessments and technical controls weekly. The

interrater reliability (Cohen's kappa, κ) for skin assessment (classification of pressure ulcer) indicated a substantial agreement between ward nurses and researchers [$\kappa = 0.61$ (95% confidence interval, CI: 0.38–0.76)] (Landis & Koch, 1977).

2.8. Statistical methods

Categorical variables were presented as frequencies (percentages). The normality of continuous variables was checked using histograms and Q-Q plots and via comparison of mean and median. Normally distributed continuous variables were described using means and SDs. Non-normally distributed continuous variables were reported as medians and interquartile ranges (IQRs). Independent *t*-tests were used in normally distributed continuous variables, and Mann–Whitney U-tests were used in non-normally distributed continuous variables. Categorical variables were analysed using chi-square and Fisher's exact tests.

The incidence of category II–IV pressure ulcer was the primary outcome, which is the percentage of participants in the population at risk who developed a new pressure ulcer. This outcome was compared between the two groups using the chi-square test. The time to develop a pressure ulcer was the secondary outcome. A log-rank analysis and Kaplan–Meier survival plot were used to examine differences in time to the development of pressure ulcer.

The cost was calculated per participant per day considering the multiple lifespans of the support surfaces based on following formula: *Cost per participant per day = Purchase cost (€) of the device / (total lifespan (year) \times 365 days)*. The average lifespan of the support surfaces (reported by industry) was 2 years for a static air mattress and 7 years for an alternating air pressure mattress. The average lifespan was included in the analysis.

Statistical analysis was conducted using the IBM® SPSS® software (version 24, IBM Corporation, New York, NY). An intention-to-treat analysis was performed. A two-sided *p*-value set at $\alpha < 0.05$ was considered statistically significant.

2.9. Ethical approval

All study procedures were conducted in accordance with the ethical principles of the 1975 Declaration of Helsinki. The study was approved by the ethics committee of Ghent University Hospital. All participants or their representatives provided oral and written informed consent in conformity with ethical approval (registration number: EC/2017/0266). The study was registered at ClinicalTrials.gov (under identification no. NCT03597750).

3. Results

3.1. Baseline characteristics of the participants

In total, 308 nursing home residents were included in the study, of which 154 were randomly allocated to each study group. The flowchart for the inclusion and randomisation of the participants is summarised in Fig. 1. In the control group, the standard available pressure-redistributing support surfaces were used when seating and lying in bed: alternating pressure air mattresses (100%), seat cushions (88%), and heel protectors (34%) (Table 1). More information about the support surfaces in the control group is presented in Table 1. In the experimental group, a static air mattress overlay (100%), static air-filled cushion (81%) and static air-filled foot protectors or wedges (100%) were used based on the preference of the participants and the clinical judgement of the researchers. In some participants (19%), the usual seat cushion was used instead of the static air cushion.

The mean age of the included participants was 87 years (SD = 7.6), and 77% ($n = 237/308$) were women. The mean Braden

Score was 13 (SD = 2.2), and the mean BMI was 24 (SD = 5.8). Most participants presented with neurological disorders ($n = 179$) or cardiovascular disorders ($n = 137$). Of all the participants, 72.4% ($n = 223/308$) had dual incontinence. At baseline, 16.6% ($n = 51/308$) of the participants had incontinence-associated dermatitis (IAD), and 10.7% presented with category I pressure ulcer ($n = 33/308$). No statistically significant differences were found in the baseline characteristics of the intervention and control groups, as shown in Table 2.

3.2. Primary outcome

In the intervention and control groups, 5.2% and 11.7% of the participants developed category II–IV pressure ulcer ($\chi^2 = 4.201$; $df = 1$, $p = 0.04$). None of the participants in the intervention group developed category IV pressure ulcer compared, and two (1.3%) participants in the control group had category IV pressure ulcer (Fisher Exact; $df = 1$, $p = 0.50$).

Most of category II–IV pressure ulcers were observed in the sacral area. Moreover, six (3.9%) and 12 (7.8%) participants in the intervention and control groups developed pressure ulcer, respectively (Fisher Exact; $df = 1$, $p = 0.15$). No pressure ulcers were found on the trochanters, scapula, elbows, and occiput. No significant differences were observed in the incidence of pressure ulcer based on body location between the two groups. An overview of the incidence of pressure ulcer per location is described in Table 3.

Pressure ulcer incidence density (category II–IV) in the intervention group was 0.41/100 observed days (8 pressure ulcers/1970 observed days) (95% CI = 0.19–0.77) and 0.89/100 observed days (18 pressure ulcers/2013 observed days) (95% CI = 0.55–1.39) in the control group.

3.3. Secondary outcome

3.3.1. Time to develop a pressure ulcer

The median time to develop a pressure ulcer was significantly longer in the intervention group (10.5 days, IQR: 1–14) than in the control group (5.4 days, IQR: 1–12) (Mann–Whitney U test = 37.00, $p = 0.05$). The probability to remain pressure ulcer free did significantly differ between the two groups (log-rank $X = 4.051$, $df = 1$, $p = 0.04$). The Kaplan–Meier survival plot of time to develop category II–IV pressure ulcer is presented in Fig. 2.

3.3.2. Direct cost of the mattresses

The direct cost of a support surface per participant per day was calculated considering the purchase costs and multiple lifespans (1–9 years). The average lifespan for a static air mattress is 2 years and resulted in a daily cost of 0.20 €. The average lifespan for an alternating air pressure mattress is 7 years and resulted in a daily cost of 0.53 €. A detailed overview of the purchase costs for devices per participant per day is presented in Table 4.

If both support surfaces had a lifespan of 2 years, the daily cost of a static air mattress was 0.20 € per day per participant, and that of an alternating air pressure mattress was 1.87 € per day per participant.

In a lifespan of 9 years, four static air mattresses and two alternating air pressure mattresses were purchased. This resulted in a daily cost of 0.74 € per day for static air mattresses and 2.28 € per day for alternating pressure mattresses. The mattress used by the intervention group had a lower financial cost than that used by the control group.

4. Discussion

This multicentre prospective randomised controlled trial (RCT) aimed to compare the effectiveness and cost of a static air mattress

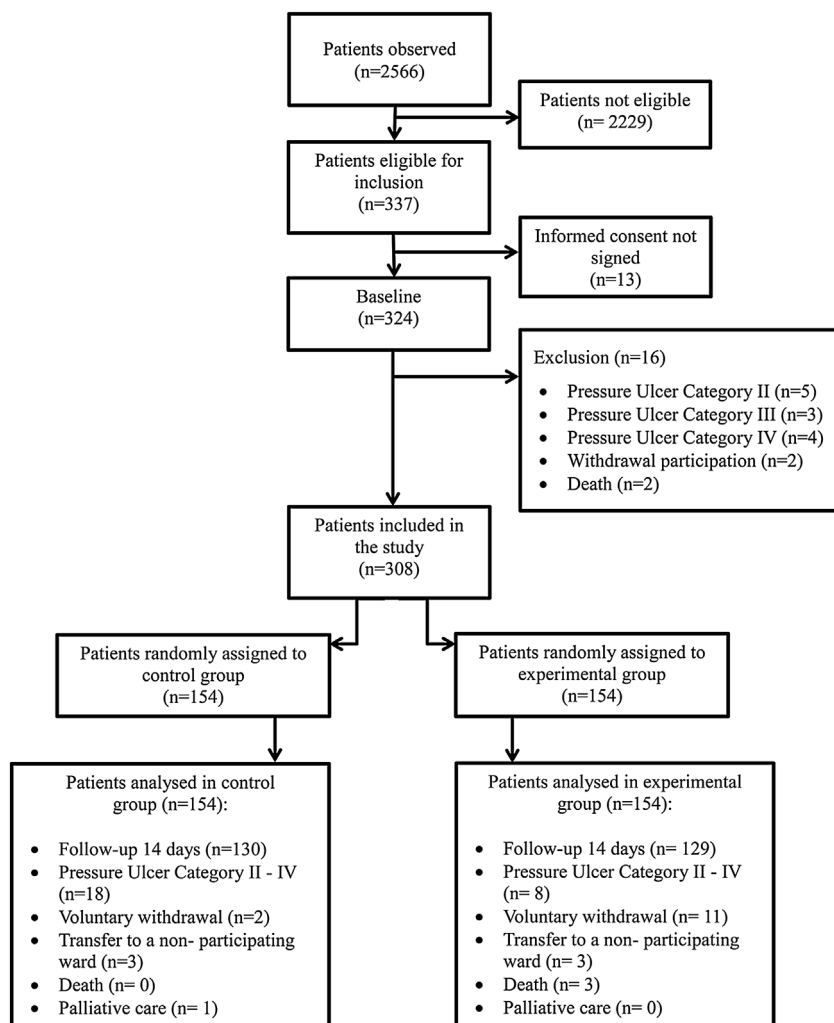


Fig. 1. Flowchart of the participants.

(intervention group) versus an alternating air pressure mattress (control group) to prevent category II–IV pressure ulcer in high-risk nursing home residents. The primary outcome was the cumulative incidence of category II–IV pressure ulcer. A

significantly lower incidence of pressure ulcer was observed in the intervention group than in the control group. The time to develop a pressure ulcer was significantly longer in the intervention group than in the control group. Considering multiple

Table 2
Baseline characteristics of the participants.

	Total (n = 308) Mean (SD)/% (n)	Intervention ^a (n = 154) Mean (SD)/% (n)	Control ^b (n = 154) Mean (SD)/% (n)	p-value
Age (years)	87 (7.6)	86.9 (7.9)	86.8 (7.3)	0.86 ^d
BMI	24 (5.8)	24.1 (5.6)	24.2 (5.9)	0.96 ^d
Gender				0.34 ^c
Male	23.1 (71)	25.3 (39)	20.8 (32)	
Female	76.9 (237)	70.1 (115)	74.4 (122)	
Double incontinence	72.4 (233)	66.5 (109)	69.5 (114)	0.62 ^c
Braden score				0.11 ^c
≤ 12	58.4 (180)	59.1 (97)	50.6 (83)	
> 12	41.6 (128)	40.9 (57)	49.4 (71)	
Cardiovascular disorders ^e	44.5 (137)	43.5 (67)	45.5 (70)	0.73 ^c
Neurological disorders ^f	58.1 (179)	56.5 (87)	59.7 (92)	0.56 ^c
IAD upon admission	16.6 (51)	13.6 (21)	19.5 (30)	0.62 ^c
Cat I PU upon admission	10.7 (33)	9.1 (14)	12.3 (19)	0.47 ^c

^a Intervention: static air support surfaces.

^b Control: alternating air pressure support surfaces.

^c Chi-square test.

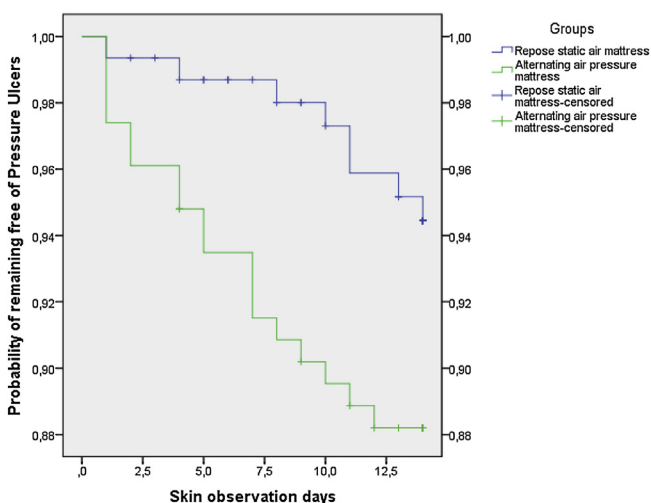
^d Independent sample *t*-test.

^e Cardiovascular diseases included myocardial infarction, chronic heart failure and vascular disease.

^f Neurological disorders included Parkinson's disease, stroke, multiple sclerosis, epilepsy, and dementia.

Table 3
Incidence of pressure ulcer.

	Intervention ^a (n = 154)		Control ^b (n = 154)		p-value
	%	n	%	n	
Category II–IV pressure ulcer	5.2	8	11.7	18	0.04 ^c
Sacral area	3.9	6	7.8	12	0.15 ^c
Heels	1.3	2	2.6	4	0.68 ^d
Spine	0.0	0	1.3	2	0.50 ^d
Category II	3.9	6	9.7	15	0.04 ^c
Sacral area	2.6	4	6.5	10	0.17 ^d
Heels	1.3	2	1.9	3	1.00 ^d
Spine	0.0	0	1.3	2	0.50 ^d
Category III	1.3	2	0.6	1	1.00 ^d
Sacral area	1.3	2	0.6	1	1.00 ^d
Heels	0.0	0	0.0	0	–
Spine	0.0	0	0.0	0	–
Category IV	0.0	0	1.3	2	0.50 ^d
Sacral area	0.0	0	0.6	1	1.00 ^d
Heels	0.0	0	0.6	1	1.00 ^d
Spine	0.0	0	0.0	0	–

^a Intervention: static air support surfaces.^b Control: alternating air pressure support surfaces.^c Chi-square test.^d Fisher's exact test.**Fig. 2.** Kaplan Meier plot of the time to develop pressure ulcers category II–IV.

lifespans and the purchase costs of the mattresses, the mattress used by the intervention group had a lower financial cost than that used by the control group.

Table 4
Purchase costs for devices per participant per day.

	Cost/day					
	Lifespan of 1 year €	Lifespan of 2 years €	Lifespan of 3 years €	Lifespan of 5 years €	Lifespan of 7 years €	Lifespan of 9 years €
Alternating air pressure mattress 1	3.73	1.87	1.24	0.75	0.53	0.41
Alternating air pressure mattress 2	N/A	N/A	N/A	N/A	N/A	1.87
Total alternating air pressure mattress	3.73	1.87	1.24	0.75	0.53	2.28
Static air mattress 1	0.41	0.20	0.14	0.08	0.06	0.05
Static air mattress 2	N/A	N/A	0.41	0.14	0.08	0.06
Static air mattress 3	N/A	N/A	N/A	0.41	0.14	0.08
Static air mattress 4	N/A	N/A	N/A	N/A	0.41	0.14
Static air mattress 5	N/A	N/A	N/A	N/A	N/A	0.41
Total static air mattress	0.41	0.20	0.55	0.63	0.69	0.74

N/A = Not applicable.

*Median value across all alternating air pressure mattress used in the nursing homes.

This RCT first compared the effectiveness of a static air mattress and an alternating air pressure mattress in nursing home residents. In contrast to our study, studies performed in an intensive care unit or an orthopaedic setting did not identify any significant difference in the incidence of pressure ulcer between the same types of support surfaces (Cobb, 1995; Malbrain et al., 2010; Price et al., 1999). This study was powered and found a significant difference between the two types of support surfaces. In the intervention group, the incidence of category II–IV pressure ulcer was 5.2% (n = 8/154). Similar results were found in previous studies about the effectiveness of static air support surfaces conducted in nursing homes. That is, the incidence rates of category II–IV pressure ulcer were 4.8% (van Leen et al., 2011), 5.1% (Serraes and Beekman, 2016) and 5.2% (van Leen et al., 2013). Incidence density is the best indicator of the quality of care based on pressure ulcer prevention programs (Cuddigan, 2012; National Pressure Ulcer Advisory Panel (NPUAP), 2014). The pressure ulcer incidence density (category II–IV) in the intervention group was lower than that in the control group (0.41/100 observed days; 95% CI = 0.19–0.77 vs 0.89/100 observed days; 95% CI = 0.55–1.39) and that of previous clinical studies about the effectiveness of alternating air pressure mattress. The APAM study by Vanderwee et al. (2005) has reported a considerable high incidence rate (15.3%) and incidence density (1.46/100 observation days; 95% CI = 0.98–1.97) (Vanderwee et al., 2005). These findings are supported by the two studies of Demarré et al. about pressure ulcer incidence density (0.54/100 observed days; 95% CI = 0.39–0.75), and approximately 8.9% of participants in the alternating air pressure group presented with pressure ulcer (Demarré et al., 2012a,b, 2013). Based on the differences found in the current and previous studies, the use of a static air support surface should be considered in preventing pressure ulcer in addition to that of an alternating air pressure mattress in a high-risk nursing home population.

How pressure reduction is generated using a static air mattress versus an alternating air pressure mattress must be understood. Various types of support surfaces were designed to manage pressure, shear and microclimate (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, P.P.P.I.A., 2014; Wounds International, 2010). A static air mattress has a constant interface pressure. When an individual rests on the mattress, the weight of the body is spread over a maximum area based on the principles of immersion and envelopment to reduce pressure (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, P.P.P.I.A., 2014; Wounds International, 2010). An alternating air pressure mattress has a cyclical interface pressure and is less reliant on immersion and envelopment. Pressure relief at specific pressure points is typical for alternating air pressure mattresses by active inflation and deflation of air characterized by frequency, duration and amplitude (National Pressure Ulcer Advisory Panel, European

Pressure Ulcer Advisory Panel and, P.P.P.I.A., 2014; National Pressure Ulcer Advisory Panel, 2007; Wounds International, 2010). Additional research must be conducted to determine which principle is effective for the prevention of pressure ulcer (McInnes et al., 2015; Serraes et al., 2018; Shi et al., 2018). Findings in this study indicated that the mechanisms of pressure reduction of static air mattresses are more effective than those of an alternating air pressure mattress.

Support surfaces should be used in conjunction with other preventative strategies, such as risk assessment and repositioning. Repositioning is an integral key element for the prevention of pressure ulcer, and it is widely recommended and used in clinical practice (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, P.P.P.I.A., 2014). However, evidence that supports the use of repositioning is limited in terms of volume and quality. Further research should be carried out to measure the effect of repositioning frequency and positioning on the development of pressure ulcer (Gillespie et al., 2014). Studies have reported a low compliance in daily practice when applying repositioning to prevent pressure ulcer (Gunningberg, 2004; Vanderwee et al., 2011). Barriers to repositioning are sleep disruption, inadequate knowledge of caregivers, high workload and staff shortage (Liesbet Demarré et al., 2012a; Strand and Lindgren, 2010). In this trial, the institution protocols and guidelines were used around systematic repositioning.

The selection of a support surface for each individual involves various factors and is rather complex. International guidelines developed recommendations for the selection of support surfaces. In 2015, an evidence and consensus algorithm for support selection was developed (McNichol et al., 2015). In addition to individual characteristics, the cost must be considered in the selection of support surfaces. Results in this study found a difference in the costs spent for the two groups. The use of static air mattress had a lower financial cost than that of alternating air pressure mattress. Other studies have reported similar results. However, there was a wide variety in the approach of the costs (Cobb, 1995; Price et al., 1999; Vermette et al., 2012). There is a cause for concern about the financial cost to the health care system based on the increasing number of individuals aged 80 years and older between 2010 and 2050, as reported by the OECD (OECD/European Commission, 2013). Along with an increasing need for long-term care facilities, the financial cost among healthcare systems will also increase. A systematic review has reported that the cost for the treatment of pressure ulcer is significantly higher than its prevention (Demarré et al., 2015). Well-designed economic studies must be conducted to confirm the findings of this study.

5. Study strengths and weaknesses

The nursing home residents and ward nurses in the current RCT cannot be blinded to the study. This study was powered, and a large sample size was required, thereby resulting in a longer research process and higher costs. This RCT included a 14-day skin observation period. However, in the study of Serraes and Beeckman (2016), the median time to develop a category II–IV pressure ulcer was 16 days (IQR = 2–26) using a static air mattress in a lower-risk nursing home population. However, a longer observation period is recommended in future studies (Serraes and Beeckman, 2016).

The PULCLAS4 was used for training the ward nurses (Beeckman and European Pressure Ulcer Advisory Panel, 2017). This may have contributed to the substantial interrater reliability (Cohen's kappa, κ) for the classification of pressure ulcer. Education and training of nursing staff is important in improving classification skills between and within skin injuries. A misclassification of skin injuries results in inadequate prevention and treatment strategies.

The presence of non-blanchable erythema (category I pressure ulcer) indicates that the frequency of repositioning and pressure redistribution support surfaces is not effective (Wounds International, 2010). A daily clinical observation of the skin is essential in identifying a resident who is at risk and in providing the best prevention strategy for pressure ulcer. In this study, daily skin assessments were performed based on the transparent disc method to differentiate blanchable erythema (no pressure ulcer) and non-blanchable erythema.

The alternating support surfaces used in the control group were not standardised and do not reflect current clinical practice. Thus, different alternating air pressure mattresses were used (Table 1). We did not analyse for possible differences in the incidence of pressure ulcer between residents using alternating air mattress replacement and those using alternating air mattress overlay because of the low incidence rates and the fact that this trial was not powered to perform such subanalyses. The international guideline revealed that there is no evidence indicating the differences in the effectiveness of alternating air pressure mattress overlays and alternating air mattress replacements for the prevention of pressure ulcers (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, P.P.P.I.A., 2014). Similarly, a multicentre randomised controlled trial has shown no significant difference in the incidence of pressure ulcer when an alternating air pressure overlay or a replacement mattress (10.7% vs 10.3%) was used ($p = 0.75$) (Nixon et al., 2006).

Data about the quality of life (e.g. quality-adjusted life years) and indirect cost were not collected in this study. A cost-effectiveness analysis was not performed due to the lack of these data. In this study, the cost analysis was limited to the purchase costs and multiple lifespans of the mattresses. The options in the participating nursing homes were purchasing or renting mattresses. The maintenance costs were included in a rental contract and excluded when purchasing alternating air pressure mattresses. The maintenance service costs were not included in the cost analysis. Thus, the direct cost difference between the two mattresses might be underestimated. Further research should focus on reporting economic data (direct and indirect cost) and performing a cost-effective analysis to identify which support surfaces are the most effective in preventing pressure ulcers.

6. Conclusion

A static air mattress was significantly more effective than an alternating air pressure mattress in preventing pressure ulcer in a high-risk nursing home population. Considering multiple lifespans and purchase costs, the static air mattress was more cost-effective than the alternating air pressure mattress.

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