ISRCTN01151335 https://doi.org/10.1186/ISRCTN01151335

Pressure RElieving Support SUrfaces: a Randomised Evaluation 2

Submission date	Recruitment status	[X] Prospectively registered
19/04/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/05/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/04/2021	Skin and Connective Tissue Diseases	

Plain English summary of protocol

Background and study aims
The development of pressure ulcers (PUs) in patients staying in hospital is a significant problem in the NHS. Preventive measures include the use of an array of mattress types, cushions and protective clothing. In acute situations the preventative method of choice is the use of an alternating pressure mattress - this mattress type contains many air-filled pockets that inflate and deflate at different times in order to relieve pressure on the body. However, these mattresses are expensive and there is no clear evidence that they are more effective at preventing pressure ulcers than the standard high specification foam mattresses. Also, a previous study indicated that many patients do not like the sensation of lying on an alternating pressure mattress. Therefore, the purpose of this study is to compare the effectiveness of each mattress. The evidence produced in this study will inform more cost effective NHS practice in the future.

Who can participate?
Patients will be eligible at any point during their in-patient stay (and irrespective of Trust provider) if they fulfil the following inclusion criteria:
1. Evidence of acute illness through:
Acute admission to secondary care hospital, community hospital or NHS-funded intermediate care/rehabilitation facility.
Secondary care, community hospital or NHS-funded intermediate care/rehabilitation facility in-patient with onset of acute illness secondary to elective admission.
Recent secondary care hospital discharge to community hospital or NHS-funded intermediate care/rehabilitation facility
2. Aged >= 18 years
3. Have an expected total length of stay of 5 or more days.
4. At high risk of PU development due to one or more of the following:
Bedfast/chair fast AND completely immobile/very limited mobility, Category 1 PU on any pressure area skin site and localised skin pain on a healthy, altered or category 1 pressure area skin site.
5. Consent to participate (written, informed consent/witnessed verbal consent/consultee

agreement)
6. Expected to be able to comply with follow-up schedule.
7. The patient is on an electric profiling bedframe.

What does the study involve?
Patients will be randomly allocated to either High Specification Foam (HSF) or Alternating Pressure Mattress (APM - overlay or replacement) products used by the participating centre. All patients will have an electric profiling bed frame as well as the trial mattress. The treatment phase continues until the patient is discharged from hospital, classed no longer at risk of developing a pressure ulcer, or up to a maximum of 60 days. During the treatment phase, patients will receive skin assessments by a tissue viability specialist research nurse twice weekly for the first 30 days and then weekly thereafter until day 60. During each assessment the nurse may also take photographs of any PUs that have developed. In addition, the research nurse will go through a number of questionnaires - this will be done at baseline, visit 2 and visit 6. The questionnaires will be administered again 30 days post trial completion. 10% of patients will receive an independent assessment by a tissue viability specialist not involved in the routine assessments of the trial - this will include photography of all 'at risk' skin sites, including the lower back area and both left and right buttocks. The purpose of this additional assessment is to ensure that identification of PUs is reported correctly.

What are the possible benefits and risks of participating?
There will be no direct benefits; however, the study will seek to generate robust evidence for the effectiveness of APM or HSF in preventing pressure ulcers, which is a key priority in the NHS.

Where is the study run from?
This study is a multicentre trial and will be coordinated by the Institute of Clinical Trials Research at the University of Leeds (UK).

When is the study starting and how long is it expected to run for?
The study will begin recruitment in September 2013 and will run until June 2016. However, the study has been designed with the possibility of early stopping depending on the results that are observed.

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/36/33, version 4.0

Study information

Scientific Title
Pressure RElieving Support SUrfaces: a Randomised Evaluation 2

Acronym
PRESSURE 2

Study objectives
The aim of this study is to determine the clinical and cost effectiveness of high specification foam (HSF) and alternating pressure mattresses (APM) when both are used in conjunction with an electric profiling bed frame in high-risk acute hospital patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds West NRES committee, 17/04/2013, ref: 13/YH/0066

Study design
Multicentre open randomised double triangular sequential parallel group trial with two planned interim analyses

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Pressure ulcers (PUs)

Interventions
Added 10/02/2017: Participants are randomised using minimisation incorporating a random element via a central 24-hour automated telephone randomisation system.

Patients eligible for the study and providing written informed consent (or consultee/nominated consultee agreement) are randomised to receive either an alternating pressure mattress or a high specification foam mattress. Participants will be defined as 'on treatment' until day 60 post randomisation, or discharge or deemed no longer at risk, whichever is soonest. Participants will be followed up 30 days post trial completion.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 04/07/2014:
To compare time to developing a new Category 2 or above PU, in patients using HSF to those using APM from randomisation to 30 days post treatment phase.

Previous primary outcome measures:
Time to developing a new Category 2 or above PU from randomisation to 30 days post trial completion or withdrawal/death (maximum of 90 days).

Secondary outcome measures
Current secondary outcome measures as of 04/07/2014:
1. To compare time to developing a new Category 3 or above PU, between patients using HSF and those using APM
2. To compare time to developing a new Category 1 or above PU, between patients using HSF and those using APM
3. To compare time to healing of pre-existing Category 2 pressure ulcers between patients using HSF and those using foam
4. To determine the impact of HSF and APM on health-related quality of life using SF-12 and PU-QoL instruments
5. To determine the incremental cost-effectiveness of APM compared to HSF from the perspective of the health and social care sectors using EQ-5D and health and social care resource

utilization questionnaire
6. To compare incidence of mattress change between patients using HSF and those using APM
7. To compare safety between patients using HSF and those using APM

Previous secondary outcome measures:
1. Time to developing a PU of Category 3 or above from randomisation to 30 days post trial completion or withdrawal/death
2. Time to developing a PU of Category 1 or above from randomisation to 30 days post trial completion or withdrawal/death
3. Time to healing of pre-existing Category 2 pressure ulcers from randomisation to 30 days post trial completion or withdrawal/death
4. Health-related quality of life using SF-12 and PU-QoL instruments (assessed weekly until day 30 and then fortnightly until day 60, and then at 30 days post trial completion)
5. Incremental cost-effectiveness of APM compared to HSF from the perspective of the health and social care sectors using EQ-5D and health and social care resource utilization questionnaire

Overall study start date
01/09/2013

Completion date
28/02/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 04/07/2014:
1. Evidence of acute illness through:
1.1. Acute admission to secondary care hospital, community hospital or NHS-funded intermediate care/rehabilitation facility
1.2. Secondary care, community hospital or NHS-funded intermediate care/rehabilitation facility in-patient with onset of acute illness secondary to elective admission
1.3. Recent secondary care hospital discharge to community hospital or NHS-funded intermediate care/ rehabilitation facility
2. Aged 18 years or over, either sex
3. Have an expected total length of stay of 5 or more days
4. At high risk of PU development due to one or more of the following:
4.1. Bedfast/chairfast AND completely immobile/very limited mobility (Braden Activity score 1 or 2 and Mobility score 1 or 2)
4.2. Category 1 PU on any pressure area skin site
4.3. Localised skin pain on any pressure area skin site
5. Consent to participate (written, informed consent/witnessed verbal consent/consultee agreement)
6. Expected to be able to comply with follow-up schedule

Previous inclusion criteria:
1. Acute hospital admission under the care of a vascular, orthopaedic, surgery, medical or care of the elderly hospital consultant; or community hospital admission (i.e., rehabilitation ward/unit) receiving consultant-led care
2. Aged 18 years or over, either sex
3. Have an expected total length of stay of 5 or more days
4. At high risk of PU development due to one or more of the following:

4.1. Bedfast/chairfast AND completely immobile/very limited mobility (Braden Activity score 1 or 2 and Mobility score 1 or 2)
4.2. Category 1 PU on any pressure area skin site
4.3. Localised skin pain on any pressure area skin site
5. Consent to participate (written, informed consent/witnessed verbal consent/consultee agreement)
6. Expected to be able to comply with follow-up schedule.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2030

Total final enrolment
2029

Key exclusion criteria
Current exclusion criteria as of 04/07/2014:
1. Have previously participated in the Pressure 2 trial
2. Have a current or previous Category 3 or greater PU
3. Have planned admission to ICU (where standard care is alternating pressure mattress provision)
4. Unable to receive the intervention (for example, sleep at night in a chair or unable to be transferred to randomised mattress)
5. Patient weight is lower or higher than weight limits for HSF and alternating pressure mattresses (<45 kg/>180 kg)
6. It is ethically inappropriate to approach the patient

Previous exclusion criteria:
1. Acute hospital admission under the care of the General Practitioner
2. Have previously participated in the trial
3. Have a current or previous Category 3 or greater PU
4. Have planned admission to ICU (where standard care is alternating pressure mattress provision)
5. Unable to receive the intervention (for example, sleep at night in a chair or unable to be transferred to randomised mattress)
6. Patient weight is lower or higher than weight limits for HSF and alternating pressure mattresses (<45 kg/>180 kg)

Date of first enrolment
01/09/2013

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
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Sponsor information

Organisation
University of Leeds (UK)

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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of a monograph in NIHR Journals in May 2018 and main trial results and associated papers in high-impact peer-reviewed journals submitted throughout 2018. Conference presentations at Tissue Viability Society Annual Conference April 2018 and European Pressure Ulcer Advisory Panel September 2018.

Intention to publish date
01/05/2018

Individual participant data (IPD) sharing plan
The current data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/12/2016		Yes	No
Protocol article	photographic validation sub-study protocol	20/03/2017		Yes	No
Results article	results	01/09/2019	01/10/2019	Yes	No

Results article	results	03/09/2019	13/11/2019	Yes	No
Basic results		13/12/2019	13/12/2019	No	No
Results article		28/04/2021	30/04/2021	Yes	No
HRA research summary			28/06/2023	No	No