

Pressure RELieving Support SURfaces: a Randomised Evaluation 2

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

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 $\geq$ 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?

Professor Jane Nixon PhD, RN
j.e.nixon@leeds.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Jane Nixon

ORCID ID

<https://orcid.org/0000-0003-1705-7698>

Contact details

Institute of Clinical Trials Research
Fairbairn House
71-75 Clarendon Rd
University of Leeds
Leeds
United Kingdom
LS2 9JT
+44 (0)113 343 1477
j.e.nixon@leeds.ac.uk

Additional identifiers**Protocol serial number**

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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

University of Leeds

Leeds

United Kingdom

LS2 9JT

Sponsor information

Organisation

University of Leeds (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, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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?
Results article	results	01/09/2019	01/10/2019	Yes	No

Results article	results	03/09/2019	13/11/2019	Yes	No
Results article		28/04/2021	30/04/2021	Yes	No
Protocol article	protocol	20/12/2016		Yes	No
Protocol article	photographic validation sub-study protocol	20/03/2017		Yes	No
Basic results		13/12/2019	13/12/2019	No	No
HRA research summary			28/06/2023	No	No