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Development of a manual to guide care for people with incontinence to prevent or treat incontinence associated dermatitis (sore skin), part 3

Submission date
27/02/2020

Recruitment status
No longer recruiting

Registration date
28/02/2020

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Incontinence-associated dermatitis (IAD) is skin damage caused by repeated contact with urine, faeces or both. It causes pain, discomfort, infections and pressure sores. 14 million UK people have urinary incontinence and 6.5 million have bowel problems, but the number with IAD in the UK has not been reliably established. It may affect as many as 51% of people with incontinence living at home and up to 30% in nursing and residential care. Prevention and treatment involve skin cleansing & use of products to protect the skin, alongside continence promotion & correct use of incontinence pads, but there are no specific guidelines for IAD management. Many people provide this care (e.g. family carers, unregistered care workers, nurses). The risk of developing IAD could be halved using preventative measures. Researchers want to create genuine changes in the way IAD is prevented and treated and will do this by developing and testing a manual (book), that will include a lay version, with training materials.
They want to find out if the PREVENT-IAD manual, and a related training package, can be successfully used to guide the prevention & treatment of IAD in care homes & people's own homes.
Public & patient involvement was key from the start and the researchers worked with patient groups (Bladder Health UK), people with IAD and their carers to develop their plans so that any changes in care will be of real benefit to patients, carers and health professionals.

Who can participate?
1. People who have an experience of urinary and/or faecal incontinence with or without incontinence-associated dermatitis either living in their own homes or in a residential or nursing care home.
2. Health professionals working with people with urinary and/or faecal incontinence in care homes and home care agencies in the sites where the study will take place
3. Informal carers and family members or patient representatives of people with urinary and/or faecal incontinence at the study sites.

What does the study involve?
Four large care homes & two home care agencies will be recruited to test the feasibility of the trial designed in phase 2 (link to the ISRCTN record of phase 1 and 2). The recruited centres will be randomized to one of two groups:
1. Provide training in using the manual to their staff and use the manual to provide care for 6 months. The investigators will assess whether the manual is used as planned by observing its use in practice.
2. Continue to provide usual care for 6 months
In all participating centres, 48 individual patient participants will be recruited per centre and records will be kept of how many stay in the study. At baseline, 3 and 6 months clinical patient participants will be assessed through clinical tools and questionnaires to measure the presence or severity of IAD.
Additionally, of the 48 participants recruited in each centre, a sub-set of 8-10 residents and/or their family members will join 8-10 care home staff who will be recruited to attend qualitative interviews to discuss their experience of being in the study, how the manual worked in practice and what helped or was a barrier to them using the manual.

What are the possible benefits and risks of participating?
There may be a small risk of becoming a little distressed when participants think about the way that bladder and bowel or skin problems affect them. It is unlikely that participants will receive any direct benefit from taking part in this study, but they may value the opportunity to be involved in research which has the potential to improve care for others

Where is the study run from?
King's College London (UK) and University of Southampton (UK)

When is the study starting and how long is it expected to run for?
December 2018 to December 2024

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
296167

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR128865

Study information

Scientific Title
PREVENTion and treatment of Incontinence-Associated Dermatitis (IAD) through optimizing care using the IAD Manual (PREVENT-IAD), part 3

Acronym
PREVENT-IAD

Study objectives
Is it feasible to implement a manualized package of care for the prevention and treatment of IAD that can be delivered by a range of NHS and other relevant caregivers?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Interventional cluster-randomized feasibility study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Incontinence-associated dermatitis

Interventions
The IAD Manual, developed during parts 1 and 2 of the study www.isrctn.com/ISRCTN26169429) will be implemented following the training of care staff and compared with usual care in care homes and home care agencies in a feasibility cluster randomized controlled trial.

In phase 3, four large care homes & two home care agencies will be recruited to test the feasibility of the trial designed in phase 2. The recruited centres will be randomized using stratified computer randomisation by the trial statistician to one of two groups:
1. Provide training in using the manual to their staff and use the manual to provide care for 6 months. The investigators will assess whether the manual is used as planned by observing its use in practice
2. Continue to provide usual care for 6 months

In all participating centres, 48 individual patient participants will be recruited per centre and records will be kept of how many stay in the study. At baseline, 3 and 6 months clinical patient participants will be assessed through clinical tools and questionnaires to measure the presence or severity of IAD.

Additionally, of the 48 participants recruited in each centre, a sub-set of 8-10 residents and/or their family members will join 8-10 care home staff who will be recruited to attend qualitative interviews to discuss their experience of being in the study, how the manual worked in practice and what helped or was a barrier to them using the manual.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 17/10/2024:

Incontinence-Associated Dermatitis presence and severity measured and recorded according to the core outcome set for IAD (erythema, maceration, erosion, pain and satisfaction) using Ghent Global Incontinence-Associated Dermatitis Categorisation Tool (GLOBIAD), Incontinence-Associated Dermatitis Intervention Tool (IADIT), Minimum Data Set (MDS) for IAD, Wong-Baker Faces Scale, Self-Assessment of Psoriasis Symptoms (SAPS), and the Hospital Anxiety and Depression Scale (HADs) at baseline, 3 and 6 months. Care staff from all six study sites will also use the Minimum Data Set (MDS) for IAD to collect weekly data from the recruited adults living in care homes and their own homes.

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Previous primary outcome measure:

Incontinence-Associated Dermatitis presence and severity measured and recorded according to the core outcome set for IAD (erythema, maceration, erosion, pain and satisfaction) using Ghent Global Incontinence-Associated Dermatitis Categorisation Tool (GLOBIAD), Incontinence-Associated Dermatitis Intervention Tool (IADIT), Wong-Baker Faces Scale and Self-Assessment of Psoriasis Symptoms (SAPS) at baseline, 3 and 6 months

Secondary outcome measures
1. Recruitment rates/attrition will be assessed through investigator notes at 6 months
2. Intervention fidelity will be assessed through non-participant observation at 3 and 6 months
3. Acceptability of intervention will be assessed through qualitative interviews of care home staff, patients and carers at 6 months

Overall study start date
09/12/2018

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Urinary and/or faecal incontinence with or without IAD receiving care at home from a home care agency or within a care home providing nursing and/or residential care
2. Capacity to give valid informed consent or declaration by personal or nominated consultee where resident's capacity to give informed consent is lacking as defined under the Mental Capacity Act 2005
3. Relative of an adult with incontinence receiving care at home or as a care home resident
4. Care staff providing incontinence care employed by a care home or home care agency involved in the study

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
6 clusters recruiting 48 individual resident participants per site and a sub-set of 8-10 residents /family members and 8-10 care home staff for qualitative interviews. Total target recruitment - 288

Key exclusion criteria
1. Residents who are continent of both urine and feces
2. Personnel not involved in direct continence care such as work experience, volunteer and short-term agency staff

Date of first enrolment

01/07/2022

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Publication of the trial protocol and a paper detailing the findings of this feasibility RCT in a high-impact peer-reviewed journal and on the HTA website.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/12/2024	17/01/2025	Yes	No