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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 1 and 2

Submission date
23/01/2020

Recruitment status
No longer recruiting

Registration date
07/02/2020

Overall study status
Completed

Last Edited
10/01/2022

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 involves 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. We 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.

We want to find out if:
1. We can develop a manual with people with IAD, their carers & health professionals, with a related training package, to guide the prevention & treatment of IAD in care homes & people's own homes
2. We can work together to design a future research study to establish whether the manual works to prevent and treat IAD and could be tested on a larger group of people

Public & patient involvement was key from the start and we worked with patient groups (Bladder Health UK), people with IAD and their carers to develop our 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
2. Health professionals working with people with urinary and/or faecal incontinence in a care

home, care agency, district nursing team, continence advisory service, tissue viability service, other community and primary care service (such as community pharmacist or GP) or as an NHS registered nurse working in secondary care
3. Informal carers, family members or patient representatives of people with urinary and/or faecal incontinence

What does the study involve?
In phase 1, 10-15 people with IAD and their carers and 10-15 health professionals will be recruited to attend 4 meetings to discuss how they deal with IAD and what they need to improve this care. In these meetings, there will also be discussions around the content of a manual to guide the prevention and treatment of IAD, what might help or stop people using the manual and the training and resources that would be needed so that a manual could be introduced into care homes and the community.

In phase 2 the same participants will attend a meeting to design a future study to test if the manual works and can be successfully introduced into a real-world setting.

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 October 2021

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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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR128865

Study information

Scientific Title
PREVENTion and treatment of Incontinence-Associated Dermatitis (IAD) through optimizing care: development and feasibility of the IAD Manual (PREVENT-IAD), Part 1 and 2

Acronym
PREVENT-IAD

Study objectives
Is it feasible to develop and manualize a 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)
Approved King's College London Psychiatry, Nursing and Midwifery Research Ethics Subcommittee, ref: HR-19/20-17478

Study design
Focus group-based observational qualitative study

Primary study design
Observational

Secondary study design
Qualitative study

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 (IAD)

Interventions
The study has 3 phases. The manualized package of care (IAD Manual) will be developed and designed during phase 1 and tested during phase 3.

In phase 1, 10-15 people with IAD and their carers and 10-15 health professionals will be recruited to attend 4 meetings to discuss how they deal with IAD and what they need to improve this care. In these meetings, there will also be discussions around the content of a manual to guide the prevention and treatment of IAD, what might help or stop people using the manual and the training and resources that would be needed so that a manual could be introduced into care homes and the community.

In phase 2 the same participants will attend a meeting to design a future study to test if the manual works and can be successfully introduced into a real-world setting.

Intervention Type
Behavioural

Primary outcome measure
1. Identification of the content of a manual to guide the prevention and treatment of IAD, what might help or stop people using the manual and the training and resources that would be needed so that a manual could be introduced into care homes and the community, through

focus groups at baseline 3, 6, 9 and 12 months
2. Development of a feasibility study, designed to test the efficacy of the manual and training developed in phase 1 in the prevention and treatment of IAD, through focus groups at baseline 3, 6, 9 and 12 months

Secondary outcome measures
Recruitment rates/attrition will be assessed through investigator notes at 12 months

Overall study start date
09/12/2018

Completion date
21/10/2021

Eligibility

Key inclusion criteria
1. Experience of urinary and/or faecal incontinence with or without IAD
2. Health professional working in a care home, care agency, district nursing team, continence advisory service, tissue viability service, other community and primary care service (such as community pharmacist or GP) or as an NHS registered nurse working in secondary care with older people
3. Informal carer, family member or patient representative of those with experience of urinary and/or faecal incontinence with or without IAD

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
10-15 health professionals and 10-15 residents, informal carers and/or family members

Total final enrolment
23

Key exclusion criteria
None

Date of first enrolment
01/01/2021

Date of final enrolment
14/10/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
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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
1. Updated Cochrane review at approximately 6 to 9 months
2. Submission of a paper detailing the interim findings from workshop one of phase 1 following presentation at a conference at approximately 9 to12 months
3. Registration on the International Standard Randomised Controlled Trial Number Register (ISRCTN) and submission of the trial protocol for the RCT developed in Phase 2

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request

IPD sharing plan summary
Available on request