

# Development of a manual to guide care for people with incontinence to prevent or treat incontinence associated dermatitis (sore skin), Part 1 and 2

<b>Submission date</b> 23/01/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 10/01/2022	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?

Dr. Sue Woodward  
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## Contact information

**Type(s)**

Public

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

### **Study type(s)**

Prevention

### **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## 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

United Kingdom

England

## Study participating centre

**King's College London**

King's College London

57 Waterloo Road

London

London

United Kingdom  
SE1 8WA

**Study participating centre**  
**University of Southampton**  
University Road  
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SO17 1BJ

## Sponsor information

**Organisation**  
King's College London

**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

**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