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NIHR128865 – PREVENTion and treatment of Incontinence-Associated Dermatitis (IAD) through optimising care: development and feasibility of the IAD Manual (PREVENT-IAD)

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Version	**Revision Date**	**Author**	**Change Status**
1.1	11/02/2020	S. Woodward	Original Approved Protocol
1.2	11/03/2020	S. Woodward	Ethical approval added

Study Protocol

1. Summary of Research

Background and Rationale

Incontinence-associated dermatitis (IAD) is skin damage caused by repeated contact with urine &/or faeces. 14 million adults in the UK have urinary incontinence and 6.5 million have bowel problems, but the incidence of IAD in the UK has not been established. Prevalence of IAD may be up to 51% of people with incontinence living at home and 30% in nursing and residential care. Prevention and treatment involves skin cleansing & application of skin protectants, alongside continence promotion & correct use of incontinence pads, but there are no specific guidelines for IAD management. Odds of developing IAD could be halved using preventative measures. This study will develop & testing the feasibility of a protocolised manual (including a lay version) with training materials to prevent/treat IAD.

Research Question

Is it feasible to develop, manualise & test a package of care for the prevention & treatment of IAD that can be delivered by a range of NHS & other relevant caregivers?

Aims

1. Develop & manualise an optimal care package for the prevention & treatment of IAD (IAD Manual) within care homes & by care agencies, including a training, implementation & dissemination plan.
2. Design a future trial of the clinical & cost-effectiveness of the IAD Manual
3. Conduct a feasibility cluster randomised controlled trial (RCT) of the IAD Manual.

Methods

This two-year, mixed methods study comprises 3 phases, culminating in a new intervention & design for a definitive cluster randomised controlled trial (RCT) of the IAD Manual.

Phase 1:Evidence synthesis & development of the IAD-Manual, training & implementation plan(0-12m)

We will update our Cochrane review(1) & purposively sample 10-15 health professionals and 10-15 patients/family carers as expert stakeholders in a series of four interactive one-day workshops to co-design the IAD Manual, training & implementation plan. We will develop & test a logic model of the active components within the intervention and causal assumptions. Qualitative data will be analysed using framework analysis.

Phase 2: Design future trial of the IAD Manual(9-12m)

We will work with the same stakeholders from phase 1 to co-design a future definitive cluster RCT to test the clinical & cost-effectiveness of the IAD manual.

Phase 3: Feasibility cluster RCT of IAD Manual & nested process evaluation(12-24m)

4 large care homes & 2 care agencies will be recruited & randomised: 3 to implement the IAD manual, 3 usual care (control). Participants with incontinence will be recruited (48 per site).

Data collection – Feasibility outcomes (recruitment rates/attrition) & core outcomes for IAD (erythema/maceration/erosion/pain/satisfaction) will be recorded using validated outcome measures (GLOBIAD, IADIT, Wong-Baker Faces Scale, SAPS) at baseline, 3m & 6m. Intervention fidelity will be observed at 3m & 6m through non-participant observation.
Up to 20 patients/family members/care staff will be interviewed about acceptability of the IAD Manual & study design
Data analysis - a process evaluation, based on the logic model from Phase 1, will be conducted. Qualitative data will be analysed thematically & prevalence, incidence & standard deviations of quantitative outcome measures of IAD will inform sample size calculations for the definitive RCT

Dissemination

Dissemination will be through 5 professional publications, social media & patient newsletters & at relevant conferences & events

2. Background and Rationale

Incontinence-associated dermatitis (IAD) is an irritant contact dermatitis caused by prolonged and repeated exposure of the skin to urine, faeces or both (1). It is characterised by erythema, maceration and in some cases skin loss, swelling, bullae and/or skin infection may occur (2). Existing prevalence and incidence estimates for IAD among people receiving long-term care are few and variable with no reliable UK estimates available. Halfens and colleagues (3) found an IAD prevalence of 23% on admission with 8% incidence (in those without IAD at admission) over 12 weeks in a long-term care facility in the USA. IAD prevalence amongst those with incontinence could well be higher in the community (41%) (4) although the proportion of people experiencing incontinence is lower (~35%) (5) than in care homes (43-77% - mean 58%) (6). This may be due to different skin care routines or lack of support with personal hygiene at the time it is needed in the community. Amongst community-dwelling adults with faecal incontinence a prevalence of IAD of 51% has been reported (7). A recent study in care homes in Germany estimated the point prevalence of IAD at 5.2% (8), while the incidence of IAD was 5.5% among nursing home residents in the USA (9) and as high as 30% over one month in Belgian nursing homes (10).

Alongside continence promotion and appropriate use of pads and appliances, effective prevention and treatment needs skin cleansing and application of skin protectants (skin

care/barrier products). There are numerous products on the market, including prescribed and 'over the counter' products. Many people are involved in providing this care including informal carers, unregistered care workers and registered nurses. Clear guidance is not easily available and public involvement has told us that use of skin protectants in care homes is "patchy". The odds of developing IAD if preventative measures are used are almost half (46%) the odds if they are not (9) and when skin care regimes are implemented costs can be reduced (11, 12). The products and procedures for both prevention and treatment are similar (1, 13). We therefore propose to develop a manualised package of care that will include treatment as well as prevention of IAD. This will make the most efficient use of research resources and create the most significant impact for patients if successfully translated.

Our Cochrane review (1) and an international consensus statement (13) will underpin the development of the IAD Manual. We found that a structured skin care regime including two key steps i) skin cleansing to remove urine/faeces and ii) application of a skin protectant to avoid or minimise exposure to moisture and irritants, is effective in preventing and treating IAD. No-rinse skin cleansers with a pH similar to normal skin or pre-moistened wipes are recommended (1) and traditional soap should be avoided. A wide range of products are available using different formulations containing petrolatum, dimethicone, zinc oxide, or liquid film-forming acrylate (1, 13). There is little evidence of the comparative effectiveness of products for preventing and treating IAD in adults (1). This may depend on the combination of ingredients, overall formulation and usage (e.g. amount applied) and needs further study, which is beyond the scope of this proposal.

Theories suggest that implementation of a new intervention is more effective when the factors that influence the practical application of the intervention (i.e. barriers/facilitators) are analysed in-depth and taken into consideration (14). Matching implementation to barriers and facilitators will lead to a tailored multifaceted approach that fits the practice context (15).

For the purpose of this study the term 'care homes' will be used to refer to both nursing and residential care homes and 'home care agency' will refer to organisations contracted by local authorities to provide personal and social care to community-dwelling adults in their own homes. Urinary incontinence is defined as a report of any loss of urine (symptom) or observation of involuntary loss of urine on examination (sign) (16) and faecal incontinence is similarly defined as any loss of faeces.

3a. Evidence Explaining why this research is needed now

This research will provide clear protocols guiding how to prevent, treat and care for people with IAD to reduce their pain and distress and reduce unwarranted variation in care provision. As well as causing pain, which patients told us is one of the most important outcomes for them, IAD can affect patients' well-being and social functioning, leading to loss of independence (17). Self-caring patients have told us of a sense of failure in self-managing their continence problems if they develop IAD and have described it as a "stigma within a stigma", resulting in reluctance to seek help to manage this. Dissemination of the output from this study will prompt case finding among health professionals and self-caring patients will have access to clear guidance. Without dissemination of a clear protocol:

- patients may continue to suffer in silence or spend money on products that don't work,
- care may be inappropriate and worsen IAD (e.g. soap and water for cleansing or inappropriate pad use) (13) and
- inappropriate prescribing (e.g. patients have been prescribed steroid cream) and product selection will continue.

One in three people in residential care in England has urinary or faecal incontinence, rising to 2 in 3 in nursing homes (18). The economic impact of IAD in the UK is unknown, but it is likely to contribute to the development of pressure ulcers (1, 19), which cost the NHS over £1.4 billion a year (18). A clinically and cost-effective intervention to prevent and treat IAD could therefore lead to savings. As no clinical guidelines exist for prevention and treatment of IAD currently, development of a manualised package of care offers a potentially scaleable intervention to guide the implementation of evidence-based and best practice care that can be applied across a large and diverse range of settings and professional groups as well as for patients and informal carers.

It is known that transition between care homes/community settings and inpatient hospital settings can be challenging (20, 21). Communication and information sharing are vital to ensure that transition between settings is co-ordinated and all arrangements are in place (20), while ensuring person-centred care. In 2015 a 'Red Bag' scheme was introduced into care homes in Sutton to transfer standardised paperwork, medication and personal belongings. The standardised paperwork ensures that everyone involved in the care of the resident has information about the resident's general health, e.g. an Older Person's Assessment form, which incorporates a section on skin integrity (22). This scheme has proven so successful at improving communication and reducing length of hospital stay that it is being rolled out across England (23, 24). We will explore with stakeholders how this could be adapted to include IAD skin care recommendations and products for handover to and use within hospital to improve continuity of care.

3. Aims and Objectives

This study will take a phased approach to answer the following research question:

Is it feasible to develop, manualise and test a package of care for the prevention and treatment of IAD that can be delivered by a range of NHS and other relevant caregivers?

The aims are to:

• Develop and manualise an optimal care package for the prevention and treatment of IAD (henceforth known as the IAD Manual) within care homes and by home care agencies, including a training and implementation and dissemination plan. To do this we will:

a. Update our Cochrane review to ensure the IAD Manual includes the most recent evidence base

b. Explore current practice and context, i.e. identify the challenges faced in dealing with IAD, current prevention and treatment including products used, and determine the needs, perceptions, preferences and capacities of care providers and recipients

c. Link the barriers and facilitators identified to determinants of behaviour change using the Behaviour Change Wheel (25)

d. Use the findings from steps a-c to develop the IAD Manual

• Design a future trial of the clinical and cost-effectiveness of the IAD Manual

• Conduct a feasibility cluster randomised controlled trial (RCT) of the IAD Manual. Specifically, we will:

a. Determine participant expectations of the IAD Manual

b. Identify any barriers and facilitators to implementation and participation in a future trial (e.g. acceptability of randomisation, recruitment rates, attrition)
c. Consider any potential contextual influences on the intervention implementation and outcomes.
d. Determine if the intervention was delivered as planned (intervention fidelity)
e. Explore participant responses to the intervention both quantitatively and qualitatively
f. Understand stakeholders' views of the intervention and its integration and usability in everyday practice
g. Determine the point prevalence and incidence of IAD in UK care homes/community
h. Confirm whether the trial design is feasible for a definitive study

4. Research Plan / Methods

This two-year, mixed methods study will comprise three phases, culminating in a new intervention and design for a definitive cluster randomised controlled trial (RCT) of the IAD Manual:

- Phase 1: Evidence synthesis and development of the IAD-Manual, training and implementation plan
- Phase 2: Design future trial of the IAD Manual
- Phase 3: Feasibility trial of the IAD Manual with nested process evaluation

User involvement will inform the development of the IAD Manual, training and implementation plan, the acceptability of the intervention, barriers and facilitators to implementation, engagement in research and the design of a future definitive trial.

Health technologies being assessed:

We will be developing and assessing the feasibility of testing a printed manualised package of care, including a lay version, referred to as the IAD Manual, training materials and (following PPI input) a plan to disseminate this via an online decision tree linked to an existing continence product advisory website for patients, public and health professionals developed by our team (www.continenceproductadvisor.org).

Design and theoretical / conceptual framework:

The recommended care, summarised within the IAD Manual, and the context of intervention delivery will contain several interacting components and therefore should be considered a complex intervention (26). We will follow the Medical Research Council (MRC) framework (26) to develop and evaluate complex interventions. This refers to four flexible, iterative stages: 1: development; 2: feasibility; 3: evaluation; and 4: implementation/ dissemination. For this study, the focus is on development and feasibility (stages 1 and 2). Development and evaluation of interventions are often undermined by problems of acceptability and lack of understanding of the barriers to implementation or stakeholders' willingness to participate in research (26). Therefore, we propose to develop the intervention (MRC Stage 1) based on the steps presented by Bleijenberg and colleagues (27) including: 1) problem identification, 2) systematic identification of evidence, 3) identification or development of theory, 4) determination of needs, 5) the examination of current practice and context, 6) modelling the process and expected outcomes leading to final element: intervention design.

We will use a mix of qualitative and quantitative methods to co-design the IAD Manual with stakeholders based on these steps (Phase 1). We will then design a future trial of the IAD Manual (Phase 2) and conduct a feasibility cluster RCT of this trial (MRC Stage 2) (Phase 3)

to see if it can be done. We will nest a process evaluation within the feasibility trial to explore contextual issues and identify barriers or facilitators that have a role in understanding the feasibility of the intervention and optimising its design and evaluation (28). We will assess the feasibility of using core quantitative measures of the outcome of implementation of interventions for IAD (2, 17) alongside qualitative data to provide in-depth understanding of the functioning of the intervention and proposed methods and how they are experienced by recipients and staff. We will apply the Process Evaluation model (28) to underpin the development and assessment of the acceptability and feasibility of the intervention/future trial. These two stages will enable the development of both an intervention and future trial that are likely to be successful.

Evidence synthesis search strategy (phase 1a) (To be registered on PROSPERO)

During the first six months of phase 1 we will update our Cochrane review (1) following the same methods used for the first review, summarised below. Our review included thirteen, mostly small, trials, involving 1316 participants and the review will be almost five years old when this study commences. Scoping searches have identified at least 33 new studies that are likely to be added, which might change conclusions and recommendations. The findings from this review will be available for stakeholder workshops two to four (phase 1b), from 6-12 months, and will inform the development of the IAD Manual during these workshops.

Criteria for considering studies for the review – we will include:

Types of studies - all RCTs and quasi-RCTs of skin care products used to prevent or treat IAD.

Types of participants - Studies involving male or female participants, or both, over 18 years of age, in any healthcare setting, with or without IAD

Types of interventions - trials of topical skin care products such as skin cleansers, moisturisers, and skin protectants of different compositions and skin care procedures aiming to prevent or treat IAD. We will examine the following comparisons:

1. Any topical skin care product versus another topical skin care product.
2. Any skin care procedure (method or frequency of application) versus any unstructured skin care procedure.
3. Any method of application of a topical skin care product versus another method of application of the topical skin care product.
4. Any frequency of application of a topical skin care product versus another frequency of application of the topical skin care product.

Types of outcome measures –

Primary outcomes

1. Number of participants with incontinence-associated dermatitis (IAD) (new or unhealed
2. Number of participants not satisfied with treatment

Secondary outcomes

1. Participants' observations (no. participants with pain due to IAD/skin care product/procedure)
2. Quantification of symptoms (objective measures e.g. size of lesion)
3. Clinicians' observations (no. participants not improved; acceptability/tolerance)
4. Quality of life
5. Economic data (Cost of products; Staff time; Incremental cost-effectiveness)
6. Adverse effects (of the interventions)
7. Other outcomes (e.g. IAD severity; rates of healing/bacterial fungal infection)

Search methods for identification of studies

We will undertake a two-step search strategy to identify relevant literature, searching both electronic databases and other sources, such as conference proceedings. We will impose no restrictions (e.g. language/publication status/dates).

*Electronic searches:*We will search the Cochrane Incontinence Group Specialised Trials Register (see the Group's module in the Cochrane Library for detailed methods), which includes trials from CENTRAL, MEDLINE, CINAHL, ClinicalTrials.gov, WHO ICTRP, and handsearching of journals and conference proceedings. The terms used to search the Cochrane Incontinence Group Specialised Register are given in Appendix 1 of our existing review (1). We will also search the following electronic databases, the search strategies for which are given in appendices two to four of our published review (1): CENTRAL on OvidSP 2015; MEDLINE on OvidSP; MEDLINE In-Process on OvidSP; CINAHL (searched through the EBSCO Interface),Web of Science (WoS) (on Web of Knowledge) will be searched from inception of the constituent databases to the most recent available versions.

Searching other resources:

We will contact authors of trials included in this Cochrane Review and experts in the field to ask them if they know of any other RCTs relevant for this review. We will hand-search the following conference proceedings published since the searches were last conducted (July 2015 to most recent update): European Pressure Ulcer Advisory Panel, European Wound Management Association, and Wound, Ostomy and Continence Nurses Society. We will screen the reference lists of all included trials and other relevant literature reviews to identify additional papers.

Review strategy and strategy for reviewing the literature:

Two reviewers will independently screen and identify studies for inclusion. A third reviewer will be consulted to resolve disagreements and reasons for exclusion of the records read in full will be documented.

Data extraction and management: Two reviewers will independently extract data from the included trials using a standardised form developed for the original review (1). If necessary, we will contact the authors of the included studies to request additional information.

Assessment of risk of bias in included studies: We will evaluate the methodological quality of all included studies using Cochrane's 'Risk of bias' tool *(29)*. Five review authors will independently assess the risk of bias. If necessary, the advice of the lead author will be sought to resolve disagreements.

Measures of treatment effect: We will calculate risk ratios (RRs) with a 95% confidence interval (CI) for binary outcomes and mean differences (MDs) with a 95% CI for continuous data.

Unit of analysis issues: The unit of analysis of RCTs and quasi-RCTs will be individual participants. If appropriate, we will use the first treatment period for cross-over designs and will take the clustering effect into account in Cluster RCTs.

Dealing with missing data: We will contact the authors of studies with missing data to request additional information. We will use the intention-to-treat analysis (defined as analysed in the group to which the participants were randomised whether or not they received the intervention) and available case analysis (that is data as reported by trialists without imputation for missing data).

Assessment of heterogeneity: We plan to combine included studies in a meta-analysis if the clinical and methodological heterogeneity are acceptable. We plan to assess the statistical heterogeneity using the Chi² test at a significance level of 0.10 and calculate the I^2 statistic to quantify the heterogeneity (30) and will explore the source of heterogeneity using subgroup and sensitivity analysis.

Assessment of reporting biases: If possible we will perform a funnel plot to assess reporting bias.

Data synthesis: Data from all included studies will be entered into the software programme Review Manager. We plan to use a fixed-effect model when pooling the data, except for studies with an I^2 equal to or greater than 75%, in which case we will use a random-effects model. If it is not possible to pool data, we will present the results in a narrative way. We will rate the quality of the evidence by using the software programme GRADEpro. GRADE will allow us to assess the quality of the body of evidence by taking into account study limitations, consistency of effect, imprecision, indirectness, and publication bias (31).We have selected the following potentially important participant outcomes.

1. Number of participants with IAD (residual).
2. Number of participants with IAD (new).
3. Number of participants not satisfied with treatment.
4. Number of participants with pain due to IAD.
5. Number of participants with pain due to skin care product or procedure.
6. Adverse reaction due to the skin care product or procedure, e.g. skin irritation, rash, itching, allergic reaction.
7. Incremental cost-effectiveness.

Phase 1b - Development of the IAD-Manual, training and implementation plan (MRC stage 1 – 0-12 months)

Sampling and target population:

Through the professional networks of the research team and patient organisations and representatives we will purposively sample up to 30 expert stakeholders with breadth and diversity of experience at all levels of care provision for community dwelling adults/care home residents with urinary and/or faecal incontinence with or without IAD (the target population at risk of IAD).

We aim to recruit:

• 10-15 health professionals from care homes (nursing and residential), care agencies, district nursing teams, continence advisory services, tissue viability services, other

community and primary care services (e.g. community pharmacists/GPs), NHS registered nurses working in secondary care with older people

• 10-15 patients/residents, informal carers and family members, patient representatives who have experience of urinary and/or faecal incontinence with or without IAD.

We will liaise with care home/home care agency managers to identify potential participants from care homes/community-dwelling adults. Participation in the study will be voluntary and all those willing to take part in the study must give valid informed consent. As this phase mainly involves topic discussion which requires a level of cognitive function, residents/patients identified to have cognitive impairment will not participate in Phase 1. However, a relative of such an individual may be invited to participate to ensure that the resident's/patient's presumed wishes are considered.

Data collection:

We will consult with these stakeholders and invite them to work with us, through a series of four interactive one-day workshops to develop the IAD Manual, training and implementation plan. Rich, contextual data will be obtained from these stakeholders, who will be invited to each workshop, held in London, facilitated by members of the team (SW, CN, RH, JF) and attended by other team members and international consultants (DB, JK).

Workshop 1: will take place during month three of the study and address three steps in Bleijenberg et al's framework (Problem identification; determination of needs; examination of current practice/context) (27). During this workshop we will explore:

- contextual challenges of settings (e.g. non-registered workforce/high turnover of staff/some poor English literacy among staff/high percentage of residents with dementia in care homes; high patient turnover and staff shortages in NHS hospitals; short visit duration in community healthcare and social care);
- desired outcomes for stakeholders to design a manual that "solves" problems;
- recipients and providers' needs, preferences and capacities;
- current practice and context (which products/procedures are used);
- barriers and facilitators to a change in practice, such as use of a manual, among recipients and providers;
- training needs of providers;
- how to develop treatment recommendations that could be understood and handed over during transfers of care to hospital and back and whether the 'Red Bag' Scheme could be a vehicle for this.

We will use these data, with the findings of the updated Cochrane review, to select products and procedures for the manual. Discussions will be noted and digitally audio-recorded throughout.

Workshops 2-4: (Intervention Design) will take place at months 6, 9 and 12 of the study. The same stakeholder participants will be organised into mixed groups of no more than 8 per group to facilitate discussion. The findings of the updated Cochrane review will be discussed during workshop two to ensure the discussion involves best evidence for practice. With the team, stakeholders will:

- develop the IAD Manual content (e.g. how to identify and categorise IAD, advice on product selection and how to perform skin care [underpinned by the findings of the Cochrane review]), including a lay version for self-management/informal carers
- develop a training and implementation plan.

Between workshops the research team will draft and revise the manual, training materials (e.g. technology enhanced learning package, posters) and implementation plan by translating behaviour change methods to practical elements that fit context (Developing theory (27)). These will be sent to stakeholders for review personally and within their own networks of expert patients, carers and health professionals where relevant in advance of the next meeting.

We will develop a logic model of the active components within the intervention and causal assumptions and test this with stakeholders (Modelling process and outcomes). This logic model will be developed by the research team during team meetings, making explicit assumptions about the evidence base and how changes in behaviour driven by the Manual will prevent or treat IAD. This logic model will be tested during the process evaluation (see below). Refinements to the manual, training and implementation plan will be made based on feedback received from our stakeholders before again seeking their views. We are keen to include a breadth of experience and views. Any conflicting views will be explored within the workshops, but the manual will need to address a wide range of clinical presentations and so the content will be developed by the expert research team to ensure its widespread applicability and that it is underpinned by the empirical evidence. Focus group discussions within workshops 2-4 will be digitally audio-recorded and field notes will be taken.

Data analysis:

By month six of the study verbatim transcripts of workshop 1 will be anonymised, coded independently by at least two team members, using framework analysis (32), and themes agreed. This will structure the qualitative analysis to include the key areas identified above with scope to identify new themes. This method is particularly useful where several team members, especially patients, are involved in data analysis (33) and we plan to involve our PPI panel in the analysis. Concurrently we will synthesise the findings of studies included in the updated Cochrane review of existing evidence as described above. Data from workshops 2-4 will not be analysed thematically, but will be analysed to identify the content and approach of the IAD Manual and used by the team in amending the IAD Manual and supporting training materials.

Phase 2 Design future trial of the IAD Manual (6-12 months)

In workshops three and four of phase 1 (above) we will also work with participants to begin to design a definitive future study. We aim to design a two-arm cluster RCT (including an economic health evaluation) with internal pilot and clear stop/proceed rules. These will be similar to the feasibility criteria for this study. For example, we are likely to aim for a four year study with recruitment of 12 clusters per arm and stop rules might include:

- Randomisation of fewer than 30% of clusters within 18 months of commencement
- insufficient data collection by care home/home care agency staff/missing data (>40%);
- High attrition rates of clusters or individual participants (>40%)
- biases within sample of residents/clients (e.g. no participants with IAD would mean progression may need to be purely based on prevention and not treatment)
- Intervention fidelity is achieved in fewer than 75% of observations.

These stop/proceed rules will be the subject of review and refinement with stakeholders during this phase and further refinement based on the outcomes of the feasibility study.

Performing a cluster RCT will prevent contamination within a site if residents or staff move between units in a care home. It would be impossible within a single unit to randomise individuals as there would be inevitable contamination once staff have been trained in using the IAD Manual. Sample size calculations for the cluster RCT will be performed later, based on IAD incidence and prevalence data collected during phase three of this feasibility study, as measured by GLOBIAD (34), clinically meaningful improvement in IAD (50% reduction in incidence) and a range of plausible intra-class correlations. At this stage we don't know how much clustering there might be (within home care agency/care home – intra-class correlation). We might have a better idea after the feasibility study although any estimates will only be based on 2 home care agencies and 4 homes. We will follow the CONSORT guidance for pilot and feasibility trials (35) and for intervention studies and the TIDieR checklist (36). We will aim for the cluster RCT to conduct a two-arm trial comparing usual care with care following protocols set out in the IAD Manual and using the same outcomes from this feasibility study.

Phase 3: Feasibility trial of the IAD Manual with nested process evaluation (12-24 months) (MRC Stage 2)

If it has not been feasible to develop the IAD Manual (i.e. agreement to the content by 80% of workshop attendees), we will be unable to progress to this phase of the study. If successful, however, we will conduct a feasibility two-arm cluster RCT with 1:1 allocation, stratified to include one home care agency and two care homes in each arm, of six month implementation of the IAD Manual vs no intervention/usual care control.

Sampling/setting:

We will situate the study within community settings/contexts most likely to provide care to people with IAD. Two care agencies and four large care homes (each with approx. 100 residential and nursing care beds) from the NIHR Research Ready Care Homes Network will be recruited and randomised (one home care agency and two care homes in London, with equivalents in Southampton), aiming to recruit one that falls below national standards on CQC inspection (i.e. requires improvement on one key area). An IAD baseline rate of IAD of 30% would provide 180 people (from 600) and would be sufficient to estimate recruitment and retention rates (80% recruitment, n=144) with a maximum margin of error of ± 8% and ± 9% respectively (±9% and ±10% if 120 identified). We aim to recruit 48 individual participants with incontinence at least once per week (with or without IAD) per site, anticipating a mean of 58 people with incontinence per 100 beds (6). Standard care will effectively be changed for all residents in care homes in the intervention arm of the study once care staff have been trained in using the IAD Manual. We will ensure that all residents and their representatives are given detailed study information (including using an accessible version of the information sheet for people with mild/moderate cognitive impairment) and we will obtain consent to use of their data, which will be documented.

All residents with capacity to consent and participate and their family members will also be invited to participate in individual (or paired resident and family member if they request this) semi-structured interviews during the qualitative element of this phase of the study described in detail below. Relatives of residents who lack capacity to consent may also be invited to participate to ensure that the resident's presumed wishes are considered. Written informed consent will be obtained from a purposively sampled diverse sub-set of 8-10 patients and/or family members (to include, for example, men/women; people from black, Asian and minority ethnic (BAME) backgrounds (37); patients and family; people with incontinence and with/without IAD) from each study site who are selected. Given the geographical location of the study sites in South London and Southampton, it is likely that we will be able to access

potential participants from BAME backgrounds and purposive sampling will give us an opportunity to include them.

All permanent registered nursing and unregistered care staff from all study sites will also be invited to participate in local focus groups or individual semi-structured interviews (if releasing staff for focus groups is not possible) at the end of the six-month implementation period of the IAD Manual to explore their experience of delivering the intervention and ideas for improvement. Written informed consent will be obtained from a purposively selected diverse sub-set (to include men/women; staff from different ethnic backgrounds; registered/unregistered staff; range of grade and experience) of 8-10 staff from each site who agree to participate in the later qualitative phase of this study.

Target population:

All community dwelling adults with incontinence cared for by the home care agencies, care home residents and care staff meeting inclusion criteria will be eligible for participation.

Inclusion/exclusion criteria

Inclusion criteria:

- Residents with urinary and/or faecal incontinence with or without IAD within the care home (providing nursing and/or residential care) OR:
- Community dwelling adults with urinary/faecal incontinence with or without IAD receiving care at home from a home care agency
- Capable of giving 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 (38)
- Relatives of care home residents or adults with incontinence receiving care at home;
- Care staff employed by the care home/home care agency where the study is taking place and their managers. Care staff is defined herein as those who provide incontinence care for people in care homes or their own home (i.e. registered nurses, care assistants)

Exclusion criteria:

- Residents who are continent of both urine and faeces
- Other personnel employed at the care home who do not meet inclusion criteria (e.g. those undertaking work experience, volunteers or short-term agency staff, other health professionals not involved in direct continence care).

Data collection/outcomes:

We will measure the core outcome set for studies of interventions for IAD (17) (to assess utility for the future trial) comprising: erythema, erosion, maceration, IAD-pain and patient satisfaction. To do this we will use the following outcome measures:

Core Outcome	**Outcome Measure(s)**	**Completed by**
Erythema	Ghent Global IAD Categorization Tool (GLOBIAD) (34) to standardise categorisation of IAD Minimum data set for IAD (incorporates GLOBIAD), piloted and validated in a nursing home population (2), to measure incidence, prevalence and adequacy of IAD	Care home/home care agency staff trained to use these measures or RA employed for the study
Erosion		

Maceration	prevention/treatment (using previously published algorithms constructed from available evidence) (2) Incontinence-Associated Dermatitis Intervention Tool)(IADIT) (39) to score IAD severity	
IAD-pain	Wong-Baker FACES® Pain Rating Scale (40)	Resident/patient
Resident/patient/family member satisfaction	Short Assessment Patient Satisfaction (41)	Resident/patient/family member

We will also collect data for the following other feasibility outcomes:

- Recruitment rates (cluster and individual)
- Acceptability of intervention and study design for patients/residents/family members and staff (qualitative)
- Attrition - attrition is a common issue affecting studies in care homes due to study withdrawal, high mortality, comorbidity, hospitalisation and transfers to another facility (42)
- Intervention fidelity (assessed through observation and review of documentation)

Baseline IAD outcome measures will be collected at each site (care home or home of participants being cared for by home care agency) prior to the introduction of the IAD Manual and again on a single day at each study site at three and six months by the RA attached to the site (registered nurses). The RAs employed for the study will accompany care staff to complete the assessment documentation concurrently, but independently of care staff, to assess point prevalence and severity of IAD in all participating residents/patients with incontinence identified by care home/home care agency staff (inter-rater reliability). Nursing/care staff at all care homes and within both care agencies will be trained in using the MDS-IAD and asked to complete the MDS-IAD weekly for any resident/client with incontinence.

Qualitative data will be collected from at least eight care staff/nurses from each care home/home care agency through focus group/individual interviews to understand their views on the manual and fit with their existing workload. We plan to conduct one focus group interview or individual interviews at each care home and similarly for each home care agency. Qualitative data will also be collected from at least eight participating residents and/or their family members from each study site to understand their views of the care received to prevent and/or treat IAD. From debates in the literature, eight participants from each group at each study site is an average sample size, with a reasonable chance of reaching data saturation in qualitative enquiry (43) and we will conduct up to ten interviews if data saturation has not occurred. The topic guide for these interviews will be developed with our PPI panel, all of whom will be trained to support analysis and interpretation of the data. Focus groups and/or individual interviews will be audio-recorded and transcribed verbatim.

Data analysis:

Process Evaluation:

Our logic model (from phase 1) will be used to monitor intervention fidelity and provide insight into how the intervention did or did not work in practice, identify any unintended consequences and refine the design of the future trial. A list of key assumptions and

uncertainties will be explored by (i) non-participant observation for 15-30 hours per care home/home care agency (at different times from early morning to evening), aiming to observe at least 50 skin care procedures at each site at three and six months to assess adherence to the IAD Manual and (ii) review of a specifically designed patient record linked to the manual in a process evaluation led by Professor Norton. The number of participant observations is based on a pragmatic decision as there is little guidance as to the number of observations required to capture a complex intervention (44)

Prevalence and Incidence:

Prevalence, incidence and standard deviations of quantitative outcome measures of IAD will be estimated to inform sample size calculations for a definitive RCT.

Feasibility:

Feasibility outcomes for progression to the definitive cluster RCT include:

- ≥3 care homes/care agencies (50% of those participating) with ≥10% IAD prevalence before the intervention
- Clusters willing to be randomised
- Recruitment by care home or home care agency staff – 70% of patients/residents are screened against inclusion/exclusion criteria
- 70% completion of outcome measures by care staff
- Attrition – we will examine the reasons for attrition
- IAD Manual and training plan are acceptable to interviewees
- Fidelity is confirmed, i.e. the process specified in the manual is observed in at least 75% of observations

Thematic analysis (45) of qualitative data will be undertaken inductively to explore in-depth understanding of the functioning of the intervention and proposed methods, i.e. how they are experienced by recipients and staff, which may affect feasibility of the intervention and future trial design.

6. Dissemination, output and anticipated impact

Anticipated Output

We aim to produce three main outputs from this study. The first is a manualised package of care incorporating clinical guidelines and an IAD skin care algorithm to guide IAD care. This will be produced as a book, including a lay version, referred to as the IAD Manual, training materials and an online decision tree linked to an existing continence product advisory website for patients, public and health professionals developed by our team (www.continenceproductadvisor.org). The second output will be a protocol for a definitive cluster RCT to test the clinical and cost-effectiveness of the IAD Manual and the third output will be a grant application to submit to the HTA to fund this future study.

The IAD Manual will not be disseminated until after the completion of the definitive RCT. It would be inappropriate to do so as this could prejudice the results of the trial and the present study will not produce definitive evidence that it is effective. We would then plan, in addition, to disseminate this via the Registered Nursing Home Association, Care England and The UK Homecare Association

In addition to presenting interim findings at conferences (for example the International Continence Society, European Pressure Ulcer Advisory Panel, European Wound Management Association, and Wound, Ostomy and Continence Nurses Society), we will produce a monograph/full report to the funder and submit five open access academic papers for publication in peer-reviewed journals of the protocols and findings of this study:

1. An updated Cochrane review at approximately 6-9 months
2. A paper detailing the interim findings from workshop one of phase one to be submitted following presentation at a conference (at approximately 9-12 months)
3. A paper detailing the findings of the feasibility RCT (at approximately 30 months)
4. Two published trial protocols (one for this study and one for the definitive RCT) to be submitted for publication and registered on the International Standard Randomised Controlled Trial Number Register (ISRCTN).

Communicating findings to the wider public

We will produce targeted outputs at each stage above in plain English for consumption by patients and the public. For example, we will develop items for inclusion in patient organisation (e.g. Promocon; Bladder Health UK) newsletters and through their websites and social media platforms. We have engaged with patient organisations throughout the planning of the study and Chris Chatterton (our PPI co-applicant) will take the lead on writing reports for these.

We will engage with the communications teams within both University partner organisations to produce press releases and will publicise these widely, including through our own and university social media platforms.

What are the possible barriers for further research, development, adoption and implementation?

One of the most pressing challenges to the adoption of the findings from this and a future trial of the IAD Manual lies in getting the message to a diverse care home and home care agency sector. Some care home/home care agency staff may have low literacy skills and there is often a high turnover of staff in metropolitan areas. There are pressures in the sector due to restricted budgets and a time-pressured social care environment (46, 47). We will work with stakeholders to understand these issues and how best they may be overcome, such as producing a pictoral “quick guide” synopsis.

IAD is still relatively newly defined and there remain challenges with differentiating this from pressure ulcers. In secondary care there is also a perceived overwhelming volume of documentation that could impact on the implementation of treatment recommendations when handed over from primary care and vice versa. We will work with stakeholders, including NHS nurses from both primary and secondary care, to explore existing pathways and consider whether existing documentation (e.g. for wound management or within the 'Red Bag' scheme) could be adapted to include recommendations for IAD care.

If a simple treatment algorithm is developed as part of the IAD Manual, the implementation may be compromised by availability of products in primary and secondary care. We will ensure we work with stakeholders to identify the most commonly used (and available/affordable) products across care settings and ensure recommendations are simplified so are able to be implemented widely.

What do you think the impact of your research will be and for whom?

Potential patient benefit: patients will receive appropriate care to prevent and treat IAD and inappropriate care that could worsen IAD (e.g. cleansing with traditional soap and water) could be reduced. The incidence of IAD in care homes and other community settings could be reduced. Patient-centred care could be improved through better communication and information sharing between care settings.

Potential healthcare staff benefits: NHS and care staff will have access to a simple and effective manualised package of care, containing clinical guidelines and simple algorithms to guide clinical practice and to be able to select and use appropriate products and regimes for the prevention and treatment of IAD. Communication and information sharing between care homes, community care agencies and hospital settings could be improved.

Potential changes in NHS service (efficiency savings): Improved communication and information sharing between care settings can lead to reduced length of stay in hospital, resulting in efficiency savings. A clinically and cost-effective intervention to prevent and treat IAD could also lead to savings through reduction in the incidence of pressure ulcers and inappropriate prescribing/product selection.

7.Project/research timetable

Pre-study activities and timelines:

Submit IRAS application to seek ethical approval (Dec 2019 – Feb 2020)

Recruit research associates (one each by King's College London and Southampton University) (Dec 2019 - Feb 2020)

	March 2020 – February 2021												March 2021 - February 2022												
	Mar-May			**June-Aug**			**Sept-Nov**			**Dec-Feb**			**Mar-May**			**June-Aug**			**Sept-Nov**			**Dec-Feb**			**July 2022**
Cochrane Review Searches and data extraction																									
Cochrane Review data analysis (a) and write up (w)				**a**	**a**	**a**	**w**	**w**																	
Submit updated Cochrane Review for peer review																									
Recruit stakeholder participants (10-15 healthcare professionals and 10-15 patients and family members)																									
Stakeholder workshop 1																									
Data analysis from workshop 1																									
Stakeholder workshop 2																									
Draft IAD Manual(s)																									
Stakeholder workshop 3																									
Draft Implementation and training plans																									
Stakeholder workshop 4																									
Finalise IAD Manual, logic model and training and implementation plan																									
Submit findings of phase 1b for publication																									
Recruit care homes/agencies for phase 3																									
Baseline data collection – phase 3																									
Implement training and use of IAD Manual																									
Data collection - phase 3																									
Recruit care staff, residents and relatives for focus group/individual interviews																									
Qualitative and Quantitative data analysis – phase 3																									
Refine IAD Manual, training plan and RCT protocol																									
Submit findings of feasibility study and RCT protocol for publication																									

8. Project Management

The study will be registered onto the International Standard Randomised Controlled Trial Number Register (ISRCTN). A Project Management Group for all co-applicants and will be held monthly throughout the study to monitor overall progress, either face to face (coinciding with stakeholder workshops during year one) or online via Skype/WebEx. The lead applicant will also meet independently with two mentors – Professors Christine Norton and Ruth Harris – monthly.

All participating care homes/care agencies in phase three will have an initial set up visit from the lead applicant and another co-applicant (JF for London sites and PW for Southampton sites) to ensure all study processes are in place before recruitment commences. This visit will be combined with the training day for each site.

Monitoring

The purposes of study monitoring are to verify that: (a) the rights and well-being of human subjects are protected. (b) The reported study data are accurate, complete, and verifiable from source documents. (c) The conduct of the researchers is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

The Sponsor, King's College London, through the Chief Investigator (SW) and mentors (CN and RH) will serve as monitors for this study and we will establish an independent study steering group (48) to meet at least annually, comprising six members (Chair, two PPI members, two health professionals with expertise in related fields, statistician) all independent of the research team, study sites and institutions involved (e.g. sponsor). The study team will determine the appropriate extent and nature of monitoring. The determination of the extent and nature of monitoring will be based on considerations such as the objective, purpose, design, complexity, and endpoints of the feasibility study. There will be on-site monitoring, before, during, and after the feasibility study. The sponsor, King's College London, reserves the right to audit this research study.

Audits and inspection by regulatory agencies

For the purpose of ensuring compliance with the protocol, Good Clinical Practice and applicable regulatory requirements, the study team may allow inspection by regulatory authorities. The research team agrees to allow the auditors/inspectors to have direct access to the study records for review, being understood that these personnel are bound by professional secrecy, and as such will not disclose any personal identity or personal medical information of research participants.

9. Ethics

Declaration of Helsinki

In accordance with the principles laid down by the 18th World Medical Assembly (the Declaration of Helsinki), the study will gain ethical approval through the Integrated Research Application System (IRAS). The study will follow all applicable amendments laid down by the World Medical Assemblies, and the International Conference on Harmonisation (ICH) guidelines for good clinical practice (GCP), all applicable laws, rules and regulations. Before the start of the study, a favourable opinion will be sought from a Research Ethics Committee via IRAS.

Consent

We have taken advice from the NIHR Clinical Research Network (CRN) (South London) regarding consent within the care homes, given that standard care will effectively be changed for all residents in the intervention arm of the study once care staff have been trained in using the IAD Manual. As advised by the CRN we will ensure that all residents and their representatives are given detailed study information (including using an accessible

version of the information sheet for people with mild/moderate cognitive impairment) and will be able to consent to or opt-out from participating in data collection, which will be documented. We will instigate robust monitoring and data management procedures to ensure that any data collected inadvertently is destroyed. Written informed consent will be obtained from all participants residing in their own home. In the case of care home residents or community-dwelling adults lacking capacity to consent we will follow the guidance laid out in the Mental Capacity Act(38) and seek an opinion from his/her representative on what they think their relative's wishes would be to participation, which will be documented. All participants will have the right to withdraw from the study at any time without affecting their care.

Confidentiality and data management

The investigators and study site staff must comply with the requirements of the Data Protection Act 1998 (as amended by the Data Protection Act 2018, a statutory instrument that implements UK's General Data Protection Regulation). The PI for each site is responsible for ensuring that participant anonymity is protected and maintained. The CI, through the PIs, will ensure that participants' identities are protected from any unauthorised parties, and she is the 'Custodian' of the data. All information related to study participants will be kept confidential and managed in accordance with General Data Protection Regulation (GDPR), the Research Governance Framework for Health and Social Care, and Research Ethics Committee Approval.

Participant data will be held in a link-anonymised format, with personal identifiable data only accessible to personnel with training in data protection who require this information to perform their study role. Personal data for patient participants to be collected will include, name, date of birth, gender, ethnicity and contact details; for nurses and care staff this will include name, gender, ethnicity, position, nursing/care qualifications and length of care experience. Identifiable information will be stored in a separate but linked database to enable the research team to undertake the study. All electronic data shall be encrypted. Only those members of the research team whose role requires access to personal identifiers will have access.

Each participant will be allocated a unique screening number under which their identifiable information will be held. The screening log will be updated accordingly throughout the study and accessed only by those members of the research team indicated on the study delegation log. Once written informed consent (for community-dwelling adults) or opt-out from consent (for care home residents) or declaration (in case of residents lacking capacity to provide valid informed consent) is obtained a unique Study ID will be allocated, under which all study data will be anonymised. All research data will be stored on a secure password-protected computer under the study ID. All paper copies of study data will be stored under ID number and kept in locked offices within the research facilities; research data will be held separately to identifiable information. No identifiable data will be included in research publications or progress reports.

10. Patient and Public Involvement

Patients and the public have been involved in design and development of this study. We have met with expert patients, family of care home residents and engaged with representatives from Bladder Health UK (PPI panel). PPI has supported the importance of the question, raising concerns about the "patchy" nature of care, with IAD products often not used in care homes, and lack of knowledge/training of care staff. PPI has helped us to identify who the IAD Manual should be aimed towards, suggesting we develop a lay version for self-management by those people who are not seeking health professional advice. Specifically, they have suggested we link dissemination to the Continence Product Advisor website. PPI has identified the most important outcome for them is pain, followed by cost of products. Patient and carer stakeholders will be involved in development and testing of the intervention throughout and Chris Chatterton is a PPI co-applicant. Further detailed

explanation of retrospective and prospective PPI involvement is given in response to the specific questions that form part of the application for this study.

11. Project/Research Expertise

This is a complex project to be delivered to tight deadlines that exploits the pooled expertise and knowledge of the research team in the key areas of interest. We are a multidisciplinary team of UK researchers and people with IAD with expertise in management of urinary/faecal incontinence and IAD, collaborating with 2 international consultants, Prof Dimitri Beeckman and Dr Jan Kottner, representing leaders in the field. Together we have experience and expertise in qualitative methods and the development and evaluation of interventions (SW, CN, RH, JF, PW, LS, MF), research in older people, care homes/agencies and community (CN, RH, JF, LS). The study will be led from King's College London and University of Southampton, both with strong institutional research track records. CN and RH will mentor and hold monthly meetings with SW to develop research leadership capacity.

Co-applicants

Dr Sue Woodward (20%), the lead applicant, along with co-applicants Professor Lisette Schoonhoven and Professor Mandy Fader and international collaborators (DB, JK) were co-authors on the Cochrane review (1) that led to this call. Dr Woodward is a senior lecturer and recognised international expert on IAD and has experience of conducting mixed methods studies, qualitative evaluation and systematic review. She will project manage the study and line manage the research associate employed by King's College London.

Professor Christine Norton (5%) is professor of nursing at KCL, formerly a nurse consultant in bowel control at St Mark's Hospital and a recognised international clinical and research expert on bowel dysfunction including faecal incontinence (FI). She is author of multiple Cochrane reviews and has been an editor of the Cochrane incontinence group. She will provide the expertise and lead on the process evaluation elements of the study.

Professor Mandy Fader (5%) is Professor of Continence Technology and provides expertise on research on continence products and skin care. This includes trials of continence products in care homes and the community and the development of methods for measuring skin health. She has been an editor for the Cochrane incontinence group and has completed three Cochrane reviews as well as other evidence syntheses in the field of continence. She leads the Continence Produce Advisor website project.

Professor Ruth Harris (5%) is Professor of Health Care for Older Adults and provides expertise on care delivery in multiple settings notably acute care and intermediate care. Ruth is a nurse and her research focuses on the impact of the nursing and the multi-professional workforce on processes of care, patient outcomes and patient safety. She has expertise in evaluating complex interventions using a wide range of methodological approaches.

Professor Lisette Schoonhoven (5%) is Professor of Nursing and provides expertise on research on development and testing of complex interventions, skin health and IAD and implementation science. She was co-author of the Cochrane review on IAD and involved in the development of GLOBIAD and the core outcome set for IAD.

Dr Joanne Fitzpatrick (5%) is Reader in Older People's Healthcare and provides expertise on care delivery in care home settings. She leads the Health Education England funded Older Persons Fellowship for specialist nurses and allied health professionals working in older people healthcare, and her research focuses on the organisation and delivery of older people's healthcare in hospital and long-term care settings. She has expertise in conducting mixed methods research. She will lead phase 3 of the study.

Dr Peter Worsley (10%) is an Assistant Professor of Rehabilitative Bioengineering at the University of Southampton. He works in a multidisciplinary Skin Health research group, where he has developed an international reputation in the field. He is currently a trustee of the European Pressure Ulcer Advisory Panel and an editorial board member of the Journal of Tissue Viability. His research expertise focusses on the monitoring of skin health and the adoption of technologies for vulnerable patient groups.

Mr Trevor Murrells (10%) will provide statistical support throughout the study. He has worked in healthcare research for over 35 years, is a statistical associate of the King's Clinical Trials Unit and member of their management group.

Mr Christopher Chatterton (10%) is an expert patient with experience of IAD. He is experienced in being involved as a patient representative in continence research and has previously led PPI for other studies and written reports for patient organisations and newsletters.

International Consultants

Professor Dimitri Beeckman is Professor of Skin Integrity and Clinical Nursing at the University Centre of Nursing and Midwifery at Ghent University in Belgium. He is an internationally recognised expert in skin integrity research, clinical trials and instrument development and validation. In 2015, he authored a global best-practice document about prevention and treatment of incontinence-associated dermatitis (IAD) (13) and in 2018 he developed the Ghent Global IAD categorisation tool (GLOBIAD) (34) to create an internationally agreed description of IAD severity. Prof. Beeckman is President-Elect of the European Pressure Ulcer Advisory Panel (EPUAP) and the International Skin Tear Advisory Panel (ISTAP).

Dr Jan Kottner is Deputy Director of the Clinical Research Center for Hair and Skin Science at the Charité-Universitätsmedizin Berlin, Germany, and Visiting Professor at the University Centre of Nursing and Midwifery at Ghent University in Belgium. He is an expert in clinical skin and tissue integrity research, clinical trial methodology, outcome development and evidence-based skin care. He is the chair of the international group updating the Pressure Ulcer Prevention and Treatment Guidelines (49)

12. Success criteria and barriers to proposed work

We intend to measure success through the achievement of milestones set out in the study timeline (including for example successful recruitment to all phases of the study), adherence to the study protocol, the development of the IAD Manual and production of other study outputs identified above. We have a large team and will recruit contract researchers, so if any unplanned circumstances affect the contribution of a team member, we will be able to mitigate this risk.

There is a risk that care homes and/or care agencies may be too busy to participate. We will mitigate against this by recruiting study sites from the ENRICH list of research-ready care homes, who are more likely to be able to participate. As the phase 3 feasibility study is only planned for 12 months, this will involve recruiting within two to three months to allow time for six month follow-up and analysis. We will mitigate this by beginning recruitment of the care homes/care agencies as soon as it is clear that it has been feasible to develop the IAD Manual in advance of the commencement of the study.