Pilot and Feasibility Studies

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

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Abstract

Background Incontinence-associated dermatitis (IAD) is prevalent in long-term care (LTC) facilities and homecare settings amongst adults who are incontinent of urine and/or faeces. Strategies to protect skin integrity are needed. This study aimed to co-design and test the feasibility of a training manual and care guidance (IAD-Manual) to prevent and treat IAD in LTC facilities and homecare settings.

Methods This was a three-phase study: (1) developing the intervention, (2) designing the empirical study (a cluster RCT with an embedded process evaluation) to assess its effectiveness (not reported here) and (3) a 3-month feasibility study. The feasibility study recruited three LTC facilities and two homecare providers, randomising them (each as a cluster) to intervention or control. Process evaluation interviews with two care recipients, 11 family carers and 13 care staff implementing the IAD-Manual and their managers were conducted. Observations of 22 episodes of care assessed fidelity to the intervention. Qualitative data were analysed using thematic analysis. Summary feasibility outcome measures using means or proportions together with 95% confidence intervals were reported.

Results Five sites were recruited from 49 approached. All randomised sites were retained. Seventy-six (16% [95% CI: 13–20%]) of the 477 participants approached were randomised, of which 58 (76% [95% CI: 65–85%]) completed the study. Candidate IAD outcomes had complete or almost-complete 3-month outcome data in those participants remaining, whereas other outcome measures had contrastingly poor data completeness largely due to participant cognitive impairment. Process evaluation showed few potential participants had the capacity to consent, and gaining consultee approval was challenging. Care staff at study sites liked the IAD-Manual, describing it as '*helpful*'. Twenty-eight people accessed the IAD-Manual online, and 15 care staff downloaded a certificate of completion of training. Intervention fidelity was not always observed.

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Conclusions It was feasible to develop the IAD-Manual. The RCT as designed was not feasible in its original form, with specific challenges regarding site and participant recruitment, governance and intervention fidelity.

Trial registration This trial was prospectively registered on 07/02/2020 (intervention development) ISRCTN26169429 and 28/02/2024 (feasibility study) ISRCTN70866724.

Keywords Incontinence-associated dermatitis, Social care, Intervention development, Co-design, Training manual, Feasibility cluster RCT, Prevention, Treatment, Long-term care (LTC)

Key messages regarding feasibility

- It was uncertain whether (i) we would be able to achieve stakeholder consensus when developing the intervention, (ii) we would be able to recruit and retain study sites and individual participants for the cluster feasibility randomised controlled trial, (iii) whether intervention fidelity would be observed and (iv) whether the study design and data collection methods could be delivered as planned.
- It was feasible to develop the intervention, but it was not feasible to recruit the planned number of study sites without significant effort, to retain study sites to the point of randomisation and to recruit the required number of individual participants. It was possible to retain study sites after randomisation. Few potential participants had capacity to consent and gaining consultee approval was challenging. Most incontinent participants did not have IAD at either time point (nowhere near the 30% anticipated).
- Care staff liked the IAD-Manual, but did not always engage fully with the intervention as planned and intervention fidelity was not always observed—care staff were more likely to follow the manual for application of skin protectants, which were prescribed, than cleansing. Completion of weekly data collection was variable. The RCT as designed was deemed not feasible in its original format.

Background

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 amongst adults receiving long-term care (LTC) are few and variable, with no current reliable UK data 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. IAD prevalence amongst those with incontinence could well be higher for community-dwelling adults (41–51%) [4, 5], although the proportion of older people experiencing incontinence is lower (~35%) [6] than in care facilities (43–77%) [7]. This may be due to different skin care routines or lack of support with personal hygiene at the time it is needed due to resource constraints.

Alongside continence promotion and appropriate use of pads and appliances, effective IAD prevention and treatment needs skin cleansing and application of skin protectants (also widely known as 'skin barrier or leave-on products'). These include prescribed and 'over the counter' products consisting of various ingredients and product formats [8]. The likelihood of developing IAD is almost halved if preventative measures are used [9]. As a result, when skin care regimens are implemented, costs can be reduced [10, 11]. The products and procedures for both prevention and treatment of IAD are similar [12]. Clear guidance is not easily available and our patient and public involvement and engagement (PPIE) panel have told us that the use of skin protectants in LTC facilities is 'patchy' [13]. This research sought to develop protocols guiding how to prevent, treat and care for adults with incontinence to reduce the incidence of IAD and help manage the pain and distress associated with this skin damage. In addition, the training and manual aimed to reduce unwarranted variation in care provision, confirmed in our early phase work [13]. Plans for implementation were underpinned by behaviour change theories, namely the COM-B model and behaviour change wheel [14].

Theories suggest that the 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 [15]. Matching implementation to barriers and facilitators will lead to a tailored multifaceted approach that fits the practice context [16]. The behaviour change wheel (BCW) is a comprehensive framework to support intervention development, implementation and behaviour change [14]. Behaviour should be analysed in context, and the BCW was endorsed as a key theoretical framework for intervention development [17]. At the core of the BCW is the COM-B model which identifies sources of behaviour as capability, opportunity and motivation. Applying the BCW in combination with the COM-B model during intervention development enables

Table 1 Feasibility research questions and progression criteria

Feasibility research questions	Progression criteria
a. Is it feasible to develop the intervention?	80% of stakeholder participants approve the final version of the intervention
b. Is it feasible to recruit study sites (clusters) and individual participants?	Recruitment of at least 80% of sites and 80% of participants
c. Are study sites willing to be randomised?	Randomisation of at least 70% of sites within 6 months of commencement of recruitment
d. What proportion of study sites and participants are retained to the end of the study?	Retention of at least 60% of clusters and 60% of participants to the end of the study
e. What proportion of data will be collected by care staff?	Collection of at least 60% of data by care staff (missing data less than 40%)
f. Was the intervention delivered as planned?	Intervention fidelity is maintained in 75% of observations
g. What are stakeholders' (residents, family members, care staff, care managers) views of the intervention and its integration and usability in everyday practice?	Qualitative data
h. Is the trial design feasible for a definitive study?	All of the above criteria (a–f) have been met

the identification of components that need to change to facilitate the new desired behaviour.

This study aimed to (1) co-design a manual (the IAD-Manual) with stakeholders that included evidence-based protocols and training materials guiding how to prevent, treat and care for people with IAD, and (2) assess the feasibility of a cluster RCT to evaluate the IAD-Manual with a nested process evaluation.

Methods

This study was prospectively registered on 07/02/2020 (intervention development) ISRCTN26169429 and 28/02/2024 (feasibility study) ISRCTN70866724. Ethical approval for the intervention development phase was obtained from the King's College London Research Ethics Committee (Ref: HR-19/20–17478) and for the feasibility study from the Queen Square Research Ethics Committee (REC Reference: 23/LO/0363).

This three-phase study comprised: (1) evidence synthesis and intervention development, (2) designing the empirical study—a cluster RCT with an embedded process evaluation—to assess its effectiveness and (3) conducting a feasibility study of the planned design to prepare for the designed trial. The planned study flow chart is presented as Additional file 1. This paper reports on phases one (intervention development) and three of the study, neither of which has been reported previously. The CONSORT guidelines for reporting pilot and feasibility studies [18] were followed and a completed checklist submitted with the manuscript.

Research question

Is it feasible to develop and test a package of care (manual) for the prevention and treatment of IAD that can be delivered in LTC and community settings through relevant caregivers?

Feasibility research questions and progression criteria

Feasibility research questions alongside previously published progression criteria [19] are detailed in Table 1.

Phase 1: intervention development

Evidence synthesis was completed through an updated Cochrane review [1] and underpinned the development of the IAD-Manual. We aimed to purposively sample 10–15 health professionals and 10–15 patient representatives/family carers as expert stakeholders in a series of four interactive 1-day workshops to co-design the IAD-Manual, training and implementation plan. Sixteen health professionals and five patient and public stakeholders participated in these workshops (Table 2).

Within our first stakeholder workshop, we explored:

- Contextual factors associated with delivering care for adults living at home/LTC settings
- What outcomes stakeholders think are important for a manual
- Care 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, for recipients of care and care providers
- Training needs of care providers
- How to develop treatment recommendations that could be understood and handed over during transfers of care to hospital and back

A logic model of the active components within the intervention and causal assumptions was developed (Additional file 2), based on these discussions. Verbatim transcripts of workshop 1 were anonymised, coded

Table 2 Stakeholder participant characteristics

Patients and the public (*n* = 5)
• Experts by experience of IAD (*n* = 3, 2 male)
• Family member of LTC facility resident (*n* = 1)
• Carer of family member receiving care at home (*n* = 1)
Nurses (*n* = 11, all female)
• District nurse (*n* = 1)
• Tissue viability nurse (hospital based) (*n* = 3)
• Tissue viability nurse (integrated community and hospital provider *n* = 1)
• Continence nurse specialist (hospital based) (*n* = 1)
• Continence nurse specialist (community based) (*n* = 2)
• Long-term care facility nurse lead (*n* = 1)
• Product advisor/educator (industry) (*n* = 2)
Care staff (*n* = 5, all female)
• Homecare agency manager (*n* = 1)
• Care staff (LTC facility) (*n* = 3)
• Care staff (homecare agency) (*n* = 1)

independently by two team members (SS/SW) and two patient representatives, with themes agreed upon. This exploration of current practice and context has been reported elsewhere [13].

During this workshop, both health professional and patient participants told us that the IAD-Manual should not be a book but should be a more interactive online resource with other formats, such as a poster, available. It should be simple, and a flowchart format was preferred. There should be evidence-based e-learning in '*bite-sized chunks*' that included photos, diagrams and patient experiences. Plain English was important as English is not the first language for many carers. While these views were echoed across all stakeholder groups (Additional file 3), one participant summed this up:

> *It should be like a protocol with steps in as to what happens, when it happens, what we need to do. So, like a diagram that has arrows and points at the end of it … from prevention to identifying to knowledge to treatment. (Homecare agency manager)*

There was consensus between health professional and patient participants as to what was important to include in the e-learning content, focusing on the fundamental aspects of care and included:

- What is IAD; the impact of urine and faeces on the skin
- Differentiating IAD from pressure ulcers
- How to identify IAD on darker skin tones; skin cleansing and appropriate use of pads and barrier products (Additional file 3)

This was described by one participant:

> *Stick with the basics because the basics… the products to use, how to look after your skin, and how you can protect your skin. Those are the three fundamental things. (Female family carer)*

The emotional and psychological impact of incontinence and IAD was also considered important, and participants agreed we should include:

> *person's experience with continence … make it personal, make it a narrative that people are going to be interested in. (Male expert by experience)*

Three subsequent stakeholder workshops took place every 3 months, with participants in mixed groups of no more than eight to facilitate discussion. These followed an iterative process to co-design the IAD-Manual. Revisions were made by the research team between meetings, with the content informed by our updated Cochrane review, and developed into an electronic resource hosted on a non-public website by an instructional designer. Readability was assessed using the Flesch Kincaid readability ease score, and language was revised until a readability level of 9 years old was achieved.

Revisions and feedback were discussed with participants at each workshop until a consensus was reached, with all (*n* = 21 (100%)) participants agreeing on the final content and format (Additional file 4). The IAD-Manual comprised a treatment flowchart with training materials (i.e. technology-enhanced learning package, posters) and an implementation plan.

Barriers and facilitators to the implementation of the e-manual were identified with stakeholders and linked to the behaviour change wheel [14] (Table 3). A training and implementation plan was then developed to address these issues (Additional files 5 and 6), using the BCW as a framework. In the COM-B model [14], capability, opportunity and motivation interact to generate behaviour change. Capability requires an individual to have relevant knowledge and skills, while opportunity refers to external influences that make behaviour possible or promote it. This was considered during intervention development

Table 3 Stakeholders views of barriers and facilitators to implementation of the IAD-Manual (linked to BCW)

Barriers	Facilitators	BCW intervention functions linked to facilitators
• Lack of engagement from leadership • Variation in product availability • Poor communication between primary and secondary care	• Promotion/leadership • Time for learning • Continuous professional development accreditation/certificate • Champions • Empowerment of residents/clients	Persuasion Education/training Incentivisation Enablement/training Persuasion

and planning implementation. Recruitment of project champions who would undergo face-to-face training with the research team was planned on site or via MS TEAMS. These champions would act as a resource for other colleagues using a 'train the trainers' model, which has been shown to enhance knowledge and skills [20]. Funding for training of 10 champions per intervention study site for 2 h was offered.

Phase 3: feasibility cluster RCT of IAD-Manual and nested process evaluation

We conducted a feasibility two-arm cluster RCT with 1:1 allocation (intervention or usual care), stratified to include one homecare provider/agency (HCA) and two LTC facilities from London and the South East of England, UK, in each arm, of 6-month implementation of the IAD-Manual vs no intervention/usual care control. The protocol for this feasibility phase has been published elsewhere [21].

Recruitment of study sites (clusters)

Recruitment of study LTC facility sites with at least 100 residents or HCA with a caseload of 100 clients was conducted using a multifaceted and iterative approach described elsewhere [22]. Potential LTC facilities and HCAs were sent a site information sheet, and visits from the research team further supported participation. Those interested in acting as study sites were required to sign an Organisation Information Document (OID), with key individual(s) identified to lead the site implementation.

Randomisation, allocation and blinding

Randomisation of study sites was conducted after all sites were recruited, Individual participants had consented (or personal consultees had agreed to participation), and baseline data were collected. A computerised random sequence was generated by the study statistician, and allocation was known only to one member of the study team (JF), who was available to reveal treatment allocation to each study site during business hours. Staff at the study sites could not be blinded, as they would know if training and the manual had been provided. Care recipients were kept blinded to the allocation. The study statistician (NB-H) (outcome assessor) remained blind to allocation throughout. Research team members who consented participants and collected data remained blind to allocation until all baseline data were collected. Team members delivering the training and conducting follow-up data collection were unblinded.

Inclusion/exclusion criteria

Inclusion criteria:

- Residents with urinary and/or faecal incontinence with or without IAD within the LTC facility OR:
- Community dwelling adults with urinary/faecal incontinence with or without IAD receiving care at home
- Capable of giving valid informed consent or a declaration by personal or nominated consultee when capacity to give informed consent (assessed by the care team) was lacking as defined under the Mental Capacity Act 2005 [23]
- Family members of LTC facility residents or adults with incontinence receiving care at home
- Care staff employed by the LTC facility/HCA research site and their managers. Care staff were defined as those who provide incontinence care for people in LTC facilities or their own home (i.e. registered nurses, care assistants)

Exclusion criteria:

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

Sample size

We aimed to recruit two HCAs and four large LTC facilities each with approximately 100 residential and nursing care beds and randomised these as clusters (one HCA

Table 4 Core outcome set [24] and associated measures in the PREVENT-IAD feasibility RCT study

Core outcome	Outcome measure(s)	Completed by
Erythema Erosion Maceration	Ghent Global IAD Categorization Tool (GLOBIAD) [25] to standardise categorisation of IAD Minimum data set (MDS) for IAD (incorporates GLOBIAD), piloted and validated in a nursing home population [2], to measure incidence, prevalence and adequacy of IAD prevention/treatment (using previously published algorithms constructed from the available evidence) [2] Incontinence-Associated Dermatitis Intervention Tool (IADIT) [26] to score IAD severity	LTC facility/HCA staff trained to use these measures or research team
IAD-pain	Wong-Baker FACES® Pain Rating Scale [27]	Resident/client
Resident/client satisfaction	Short Assessment Patient Satisfaction [28]	Resident/client

and two LTC facilities in region A, with equivalents in region B). Based on IAD prevalence reports between 23% [3] and 41–51% [4], an IAD prevalence of 30% would provide 180 people with IAD (from 600) and would be sufficient to estimate recruitment and retention rates (80% recruitment, $n=144$) with a maximum margin of error of approximately ±7%. We aimed to recruit 48 individual participants with incontinence (with or without IAD) per site, anticipating a mean of 58 people with incontinence per 100 beds, and 30 with IAD per 100 beds [7].

Intervention/control

Intervention

The IAD-Manual includes an illustrated algorithm (Additional file 4) with six interconnected boxes. Care staff at intervention sites were asked to access the IAD-Manual, hosted by our instructional designer, via a weblink. Clicking on each box within the algorithm reveals evidence-based content and e-learning about experiences of and preventing and managing IAD. Staff were asked to work through each link in turn to complete the e-learning and complete self-test questions based on e-learning content at the end. On successful completion of these questions (i.e. ≥80% correct), staff could download a certificate of completion as evidence of continuous professional development (CPD). Care staff were then expected to provide care to their residents/clients following the flowchart in the IAD-Manual.

Control

At control sites, staff continued to provide care as usual for the prevention and treatment of IAD. Control sites were offered access to the IAD-Manual after the end of the study.

Data collection/outcomes

Data for the following feasibility outcomes were collected:

- Recruitment rates (sites and individuals)
- Attrition rates
- Missing data rates
- Access and use of the IAD-Manual online training materials via Google Analytics
- Intervention fidelity (assessed through structured observations)
- Acceptability of the intervention and study design for clients/residents/family members and staff (qualitative interview data)

The core outcome set for studies of interventions for IAD [24] were assessed (to assess utility for the future trial), comprising erythema, erosion, maceration, IAD-pain and patient satisfaction. To do this, several clinical outcome measures were collected (Table 4).

At the request of our PPIE panel, an additional outcome (Hospital Anxiety and Depression Scale (HADS) [29]) was added.

All outcomes in Table 3 and the HADS were collected at baseline and again at 3 (all sites) and 6 months (one site only, as this site had been recruited and commenced data collection earlier than others). Data were collected concurrently but independently of care staff by a research nurse competent in skin assessment or a member of the research team (SW/PW) to assess point prevalence and severity of IAD in all participants (inter-rater reliability). Nursing/care staff at all study sites were trained in using the MDS-IAD and asked to complete this outcome (only) weekly for all participants via an online survey administered securely through www.onlinesurveys.ac.uk.

Process evaluation

All residents/clients with capacity to consent and family members were invited to participate in individual (or paired participant and family member) semi-structured interviews or focus groups to assess the acceptability of the intervention and study design at the three intervention study sites. Personal consultees of participants who lacked capacity to consent were also invited to participate

in interviews/focus groups so that these participants were included.

Focus groups of a sample (reflecting different genders, care roles and length of experience) of at least eight nursing and care staff from all intervention sites were invited to participate in focus groups held via Microsoft TEAMS following 3 months of implementation of the IAD-Manual and data collection. Due to delayed recruitment of study sites, it was not possible to conduct these focus groups after 6 months as planned. Focus groups explored staff experience of delivering the intervention, adherence to the IAD-Manual, its acceptability and ideas for improvement.

In addition to staff and participant interviews, a list of key assumptions and uncertainties was explored by non-participant observation (documented via field notes using a standardised template) of skin care procedures for a range of participants (Additional file 7) at each intervention site at 3 months to assess adherence to the IAD-Manual. Assessment of intervention fidelity is considered vital when evaluating complex interventions [30]. Observations were undertaken by a research nurse with expertise in skin care for IAD while care was provided to participants in the LTC facility or their own home. Contemporaneous records using the standardised template were made of observations of care and any comments or discussions held with care staff including cleansing procedures, application of leave-on products and whether they accessed/referred to the IAD manual for care provision. Through the process evaluation and observations of care episodes, we sought to assess the fidelity of (i) the delivery of the IAD-Manual (i.e. delivering it consistently and as per the protocol to care staff who were to implement the intervention), (ii) receipt (staff understanding) and (iii) enactment of the intervention (implementation of the IAD-Manual) [30].

Data analysis

Qualitative data analysis

Thematic analysis [31] of qualitative data were undertaken inductively to provide in-depth understanding of both how the intervention worked and study processes, i.e. how they were experienced by participants and staff, which may affect feasibility of the intervention and future trial design. During this iterative process, the six steps identified by Braun and Clarke [31] were followed. These steps included:

- Familiarisation with the data
- Generating initial codes
- Searching for themes
- Reviewing themes
- Defining and naming themes
- Writing the report

Experienced qualitative researchers from the team read and re-read the data (familiarisation), manually generated initial codes and identified themes which were then refined during team discussions. Data analysis software was not used. Candidate themes were reviewed for coherence and distinctiveness. The essence of each theme was also agreed and named during team discussions. Emphasis was placed throughout on the iterative and reflexive nature of the process and team members acknowledged their individual thoughts and perspectives while engaging with the data [32].

Statistical analysis

We described baseline characteristics by treatment arm and overall, using means and standard deviations, or counts and proportions, where appropriate. We estimated the proportions relating to each of the study's main feasibility outcomes with counts and exact Clopper-Pearson (C-P) 95% confidence intervals (CIs).

We report summary outcome measures using means and *t*-distribution-based 95% CIs, or proportions and exact 95% CIs, where appropriate.

For categorical outcomes continence status (bladder and bowel), diarrhoea status, GLOBIAD status, bathing wipe use, leave-on product use status, anti-microbial agent use status, incontinence product use and IAD status, we performed logistic regression adjusted for the corresponding baseline outcome variable, reporting odds ratios and asymptotic 95% CIs. There was no planned estimation of the intra-cluster correlation coefficient (ICC), given the small number of clusters and associated imprecision [33].

Because of the exploratory nature of the study, no significance testing was carried out [34]. The statistical analysis plan, developed a priori, was approved by an independent statistician and can be accessed here: https://osf.io/5wbjt.

Results

Quantitative results/feasibility outcomes

Recruitment of sites

In addition to indirect approaches, 17 LTC facilities were approached directly. Four LTC facilities (one in London and three in Southern England) and two homecare providers (both in London) were recruited. Two LTC facilities withdrew before randomisation due to staff capacity to support the study and were replaced by one further LTC facility in the South of England.

Five of the 49 sites approached were randomised, with all five remaining in the study at 3 months (Fig. 1).

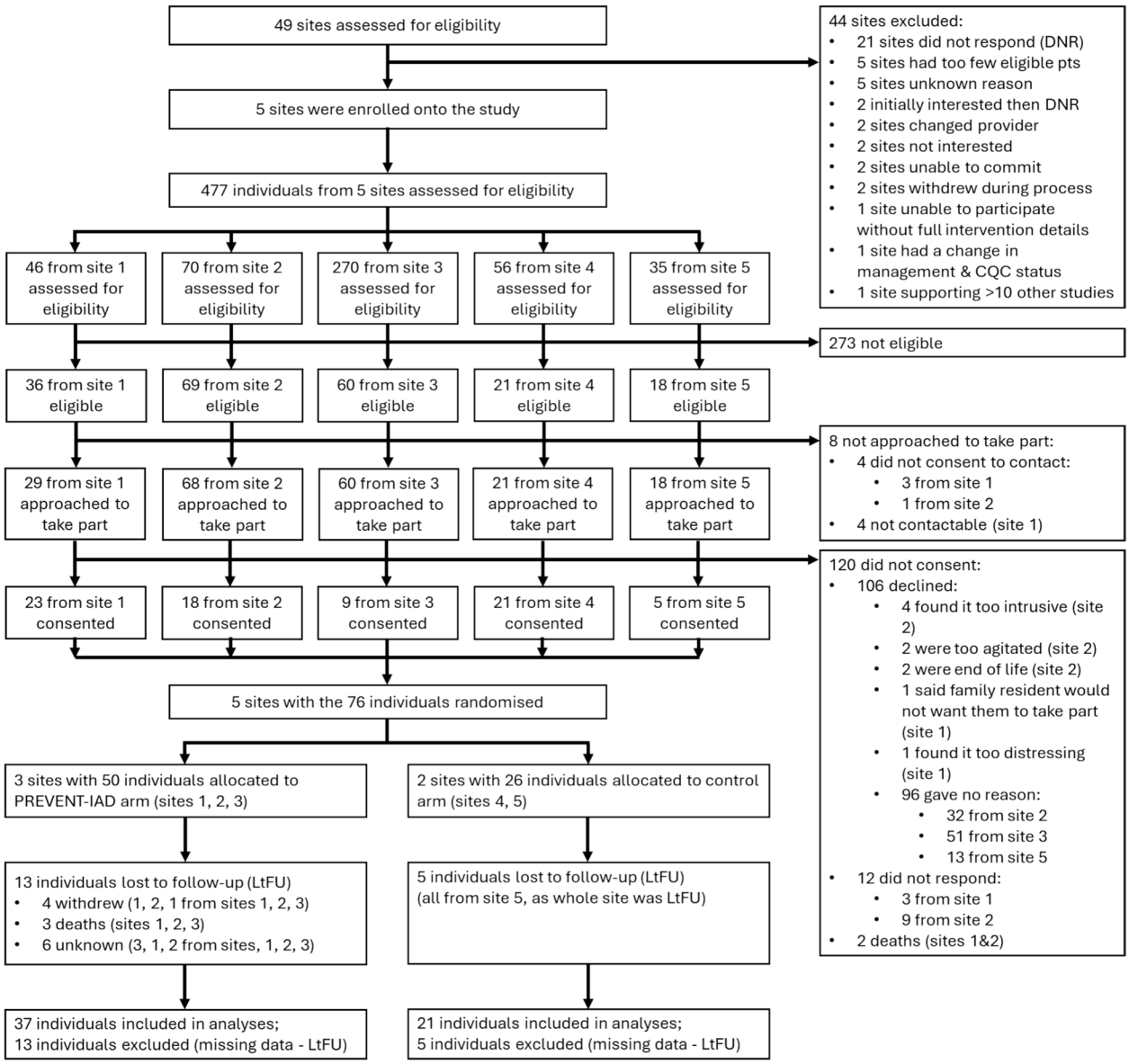

Fig. 1 CONSORT diagram

Recruitment of participants

Recruitment of participants began in January 2024 and was completed by June 2024. Seventy-six (16%) of the 477 eligible residents and clients approached across study sites were recruited before sites were randomised (Fig. 1), with over 80% ($n=62$) of these coming from the three LTC facility sites. Fifty-eight (76%) of these 76 participants completed 3 months of data collection.

Baseline characteristics (Table 5) showed that participants were mostly over 80 (mean age (SD) 82.5 (13.9)) and were nearly twice as likely to be female (62%), with high rates of incontinence, although most (82%) had no IAD. Most participants lacked mental capacity to consent for themselves ($n=67$, 88%).

Randomisation and retention of clusters

All initial study sites ($n=4$ LTC facilities; $n=2$ HCAs) agreed to randomisation, but two LTC facilities withdrew prior to randomisation and one further LTC facility was recruited. The three LTC facilities and two HCAs were retained throughout the study (Table 6).

Table 5 Baseline characteristics by randomised arm and total

Baseline measurement	Intervention group (*n* = 50)	Control group (*n* = 26)	Total (*n* = 76)
Age in years (mean, SD)	84.1 (13.7)	79.5 (14.0)	82.5 (13.9)
Complete	49 (98.0%)	26 (100.0%)	75 (98.7%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Gender, *n* (proportion)			
Male	16 (32.0%)	12 (46.1%)	28 (36.8%)
Female	33 (66.0%)	14 (53.8%)	47 (61.8%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Bladder continence status			
Not incontinent	2* (4.0%)	0 (0.0%)	2 (2.6%)
Occasionally incontinent	6 (12.0%)	5 (19.2%)	11 (14.5%)
Frequently incontinent	8 (16.0%)	7 (26.9%)	15 (19.7%)
Always incontinent	33 (66.0%)	14 (53.8%)	47 (61.8%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Bowel continence status			
Not incontinent	4 (8.0%)	1 (3.8%)	5 (6.6%)
Occasionally incontinent	7 (14.0%)	6 (23.0%)	13 (17.1%)
Frequently incontinent	5 (10.0%)	7 (26.9%)	12 (15.8%)
Always incontinent	33 (66.0%)	12 (46.1%)	45 (59.2%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Diarrhoea			
Yes	2 (4.0%)	2 (7.7%)	4 (5.3%)
No	47 (94.0%)	24 (92.3%)	71 (93.4%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Place of care			
LTC facility	40 (80.0%)	21 (80.8%)	61 (80.3%)
Homecare agency	9 (18.0%)	5 (19.2%)	14 (18.4%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
IAD core outcomes			
GLOBIAD			
No IAD present	39 (78.0%)	23 (88.5%)	62 (81.6%)
Category 1A: persistent redness without clinical signs of infection	9 (18.0%)	3 (11.5%)	12 (15.8%)
Category 1B: persistent redness with clinical signs of infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Category 2A: skin loss without clinical signs of infection	1 (2.0%)	0 (0.0%)	1 (1.3%)
Category 2B: skin loss with clinical signs of infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Minimum data set for IAD			
Skin cleansing regime**			
Toilet paper	6 (12.0%)	1 (3.8%)	7 (9.2%)
Water and cleanser	20 (40.0%)	4 (15.3%)	24 (31.6%)
Water and oil	0 (0.0%)	0 (0.0%)	0 (0.0%)
No-rinse skin cleansers	2 (4.0%)	0 (0.0%)	2 (2.6%)
Cleansing foam	1 (2.0%)	0 (0.0%)	1 (1.3%)
Single-use disposable wipes	43 (86.0%)	22 (84.6%)	65 (85.5%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Leave-on product used			
Yes	42 (84.0%)	13 (50.0%)	55 (72.4%)
No	7 (14.0%)	13 (50.0%)	20 (26.3%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)

Table 5 (continued)

Baseline measurement	Intervention group (*n* = 50)	Control group (*n* = 26)	Total (*n* = 76)
Anti-microbial agent used			
Yes	1 (2.0%)	0 (0.0%)	1 (1.3%)
Yes, on prescription	2 (4.0%)	0 (0.0%)	2 (2.6%)
No	46 (92.0%)	26 (100.0%)	72 (94.7%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Incontinence product used**			
Pads/briefs/liners	42 (84.0%)	21 (80.8%)	63 (82.9%)
Pull-up pants	5 (10.0%)	5 (19.2%)	10 (13.2%)
Under pads	5 (10.0%)	0 (0.0%)	5 (6.6%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Incontinence-Associated Dermatitis Intervention Tool			
No IAD	31 (62.0%)	21 (80.8%)	52 (68.4%)
High risk of IAD	11 (22.0%)	1 (3.8%)	12 (15.8%)
Early IAD	7 (14.0%)	4 (15.4%)	11 (14.5%)
Moderate IAD	0 (0.0%)	0 (0.0%)	0 (0.0%)
Severe IAD	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Wong-Baker FACES Pain Rating Scale			
No hurt	20 (40.0%)	4 (15.4%)	24 (31.6%)
Hurts little bit	2 (4.0%)	1 (3.8%)	3 (3.9%)
Hurts little more	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hurts even more	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hurts whole lot	1 (2.0%)	0 (0.0%)	1 (1.3%)
Hurts worst	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unable to complete	26 (52.0%)	21 (80.8%)	47 (61.8%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Short Assessment Patient Satisfaction	22.9 (3.0)	20.3 (7.6)	22.3 (4.2)
Complete	10 (20.0%)	3 (11.5%)	13 (17.1%)
Unable to complete	39 (66.0%)	23 (88.5%)	62 (81.6%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Hospital Anxiety and Depression Scale—Anxiety subscale	4.0 (3.3)	3.5 (3.5)	3.9 (3.2)
Complete	15 (30.0%)	2 (7.7%)	17 (22.4%)
Unable to complete	34 (68.0%)	24 (92.3%)	58 (76.3%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)
Hospital Anxiety and Depression Scale—Depression subscale	4.0 (3.1)	6.5 (0.7)	4.3 (3.0)
Complete	13 (26.0%)	2 (7.7%)	15 (19.7%)
Unable to complete	36 (72.0%)	24 (92.3%)	60 (78.9%)
Missing	1 (2.0%)	0 (0.0%)	1 (1.3%)

Numbers are presented as mean (SD) or n (%)

*These two participants had faecal incontinence

**Participants for these outcomes could select more than one option

Table 6 Key cluster-level feasibility rates by randomised arm and total

Outcome	Intervention group	Control group	Total
Proportion of clusters recruited (%)	/	/	5/37 (14% [5–29%])
Proportion of clusters retained (%)	3/3 (100% [29–100%])	2/2 (100% [16–100%])	5/5 (100% [48–100%])

Numbers are presented as n/N (% [CI]), where the CI is a 95% Clopper-Pearson exact confidence interval

Table 7 Key participant-level feasibility rates by randomised arm and total

Outcome	Intervention	Control	Total
Proportion of participants recruited (%)	/	/	76/477 (16% [13–20%])
Proportion of participants retained (%)	37/50 (74% [60–85%])	21/26 (81% [61–93%])	58/76 (76% [65–85%])
Completeness of 3-month outcome data (%)			
Global Incontinence-Associated Dermatitis score (Q6,7)	36/37 (97% [86–100%])	21/21 (100% [84–100%])	57/58 (98% [91–100%])
Minimum Data Set for Incontinence-Associated Dermatitis (Q8–26)	37/37 (100% [91–100%])	21/21 (100% [84–100%])	58/58 (100% [94–100%])
Incontinence-Associated Dermatitis Intervention Tool (Q28,29)	37/37 (100% [91–100%])	21/21 (100% [84–100%])	58/58 (100% [94–100%])
Wong-Baker FACES Pain Rating Scale (Q30)*	9/37 (24% [12–41%])	0/21 (0% [0–16%])	9/58 (16% [7–27%])
Short assessment Patient Satisfaction (Q31–37)*	4/37 (11% [3–25%])	0/21 (0% [0–16%])	4/58 (7% [2–17%])
*Hospital Anxiety and Depression Scale (Q38–51)**	3/37 (8% [2–22%])	0/21 (0% [0–16%])	3/58 (5% [1–14%])

Numbers are presented as n/N (% [CI]), where the CI is a 95% Clopper-Pearson exact confidence interval

*Many of these incomplete outcomes are a product of participants lacking capacity and it was not possible to collect these data

Retention of participants

Eighteen participants were lost to the study, mostly due to deaths ($n=3$ within 3 months and a further 3 at the study site that was able to collect data to 6 months), participants moving into a LTC facility from home, from one LTC facility to another or being hospitalised at follow-up timepoints. All other participants were retained (Table 7). No harms were reported for any participant.

Completeness of data

Twenty of the 58 participants included in the analysis (34.5%) had data collected every week for 3 months. GLOBIAD, MDS and IADIT had complete or almost-complete 3-month outcome data in those participants remaining in the study, whereas Wong-Baker, SAPs and HADS had contrastingly poor data completeness; in particular, none of the 21 participants in the control arm remaining in the study at 3 months had data on these outcomes. No large differences were observed between treatment arms for any of the IAD or other core outcome characteristics. Only one of the five sites consistently completed the weekly data collection (site 1 with a mean of 10.6 of the 12 weeks completed), and only one other site achieved over half (site 3 with a mean of 7.1) (Table 8).

Process evaluation

Access to online IAD-Manual

Google Analytics for the online IAD-Manual revealed a mean user engagement time per unique visit of 6 min and 20 s per visit. The primary landing page was 'Prevent-IAD', an index page which garnered 665 views, while other popular pages included 'Incontinence Associated Dermatitis' (128 views) and 'Steps to Prevent Skin Damage - Box 3' (64 views). All users accessed the platform via a computer or tablet, with no data indicating activity from mobile phone or other platforms.

Twenty-eight people took the online self-test at the end of the online training materials. The mean score was 9.8/12 (range 3–12). The questions most likely to be answered incorrectly were:

- 50% wrongly said change a wet pad as soon as possible
- 25% answered the question about assessment of IAD wrongly
- 21% wrongly said IAD is caused by pressure

There were 15 care staff who both completed the test and downloaded a certificate of completion.

Interviews

A summary of the interviews is presented here. Online additional files give verbatim quotes which are numbered next to statements (Q1, Q2, etc.) here to illustrate the points.

Family member and client interviews (quotes in Additional file 8) Eleven family members were interviewed (125 min in total), seven from one LTC facility (three individuals (11, 15 and 20 min), four in a group interview lasting 40 min) and three from the HCA at their own home (6, 15 and 18 min). For one interview, the client was also present (but was non-verbal and could only nod), and one client was interviewed alone. Most clients lacked capacity to be interviewed.

Generally, family members seemed to be satisfied with care (one commenting '*I couldn't fault them*') and most were unaware of what care was given for continence (except at home where they purchased products). Interviewees mostly did not seem aware of any changes since the IAD project started (Q1, Q2, Q3), although one LTC facility resident reported noticing more frequent checking.

Table 8 Categorical outcome measure values and completeness at 3-months follow-up

Outcome	Arm A (*n*=50)	Arm B (*n*=26)	Odds ratio, arm A vs arm B
Bladder continence status			0.90 [0.76, 1.06] ("Always incontinent" vs all other non-missing categories)
Not incontinent	1 (2.0% [0.1, 10.6%])	0 (0.0% [0.0, 13.2%])	
Occasionally incontinent	1 (2.0% [0.1, 10.6%])	2 (7.7% [0.9, 25.1%])	
Frequently incontinent	2 (4.0% [0.5, 13.7%])	3 (11.5% [2.4, 30.2%])	
Always incontinent	33 (66.0% [51.2, 78.8%])	16 (61.5% [40.6, 79.8%])	
Missing	13 (26.0% [14.6, 40.3%])	5 (19.2% [6.6, 39.4%])	
Bowel continence status			0.86 [0.72, 1.03] ("Always incontinent" vs all other non-missing categories)
Not incontinent	2 (4.0% [0.5, 13.7%])	0 (0.0% [0.0, 13.2%])	
Occasionally incontinent	2 (4.0% [0.5, 13.7%])	3 (11.5% [2.4, 30.2%])	
Frequently incontinent	1 (2.0% [0.1, 10.6%])	4 (15.4% [4.4, 34.9%])	
Always incontinent	32 (64.0% [49.2, 77.1%])	14 (53.8% [33.4, 73.4%])	
Missing	13 (26.0% [14.6, 40.3%])	5 (19.2% [6.6, 39.4%])	
Diarrhoea			0.97 [0.86, 1.09] ("Yes" vs "No")
Yes	3 (6.0% [1.3, 16.5%])	1 (3.8% [0.1, 19.6%])	
No	34 (68.0% [53.3, 80.5%])	20 (76.9% [56.4, 91.0%])	
Missing	13 (26.0% [14.6, 40.3%])	5 (19.2% [6.6, 39.4%])	
GLOBIAD			0.98 [0.80, 1.21] ("No GLOBIAD categories present" vs all other non-missing categories)
No GLOBIAD categories present	28 (56.0% [41.3, 70.0%])	17 (65.4% [44.3, 82.8%])	
Category 1A: persistent redness without clinical signs of infection	2 (4.0% [0.5, 13.7%])	3 (11.5% [2.4, 30.2%])	
Category 1B: persistent redness with clinical signs of infection	0 (0.0% [0.0, 7.1%])	0 (0.0% [0.0, 13.2%])	
Category 2A: skin loss without clinical signs of infection	5 (10.0% [3.3, 21.8%])	1 (3.8% [0.1, 19.6%])	
Category 2B: skin loss with clinical signs of infection	1 (2.0% [0.1, 10.6%])	0 (0.0% [0.0, 13.2%])	
Missing	14 (28.0% [16.2, 42.5%])	5 (19.2% [6.6, 39.4%])	
Skin cleansing regime*			
Toilet paper	3 (6.0% [1.3, 16.5%])	0 (0.0% [0.0, 13.2%])	NA
Water and cleanser	6 (12.0% [4.5, 24.3%])	1 (3.8% [0.1, 19.6%])	NA
Water and oil	0 (0.0% [0.0, 7.1%])	0 (0.0% [0.0, 13.2%])	NA
No-rinse skin cleansers	1 (2.0% [0.1, 10.6%])	0 (0.0% [0.0, 13.2%])	NA
Cleansing foam	0 (0.0% [0.0, 7.1%])	0 (0.0% [0.0, 13.2%])	NA
Single-use disposable bathing wipes	33 (66.0% [51.2, 78.8%])	21 (80.8% [60.6, 93.4%])	1.12 [0.98, 1.29] ("Single-use disposable bathing wipes" vs not)
Missing	13 (26.0% [14.6, 40.3%])	5 (19.2% [6.6, 39.4%])	NA
Leave-on product used			0.98 [0.78, 1.23] ("Yes" vs "No")
Yes	30 (60.0% [45.2, 73.6%])	14 (53.8% [33.4, 73.4%])	
No	7 (14.0% [5.8, 26.7%])	7 (26.9% [11.6, 47.8%])	
Missing	13 (26.0% [14.6, 40.3%])	5 (19.2% [6.6, 39.4%])	
Anti-microbial agent used			NA
Yes	0 (0.0% [0.0, 7.1%])	0 (0.0% [0.0, 13.2%])	
Yes, on prescription	0 (0.0% [0.0, 7.1%])	0 (0.0% [0.0, 13.2%])	
No	37 (74.0% [59.7, 85.4%])	21 (80.8% [60.6, 93.4%])	
Missing	13 (26.0% [14.6, 40.3%])	5 (19.2% [6.6, 39.4%])	
Incontinence product used*			
Pads/briefs/liners	32 (64.0% [49.2, 77.1%])	20 (76.9% [56.4, 91.0%])	1.06 [0.92, 1.22] ("Pads/briefs/liners" vs not)
Pull-up pants	6 (12.0% [4.5, 24.3%])	1 (3.8% [0.1, 19.6%])	NA
Under pads	0 (0.0% [0.0, 7.1%])	0 (0.0% [0.0, 13.2%])	NA
Missing	13 (26.0% [14.6, 40.3%])	5 (19.2% [6.6, 39.4%])	NA

Table 8 (continued)

Outcome	Arm A (*n*=50)	Arm B (*n*=26)	Odds ratio, arm A vs arm B
Incontinence-Associated Dermatitis Intervention Tool			1.00 [0.79, 1.26] ("No IAD" vs all other non-missing categories)
No IAD	26 (52.0% [37.4, 66.3%])	16 (61.5% [40.6, 79.8%])	
High risk of IAD	3 (6.0% [1.3, 16.5%])	1 (3.8% [0.1, 19.6%])	
Early IAD	5 (10.0% [3.3, 21.8%])	4 (15.4% [4.4, 34.9%])	
Moderate IAD	2 (4.0% [0.5, 13.7%])	0 (0.0% [0.0, 13.2%])	
Severe IAD	1 (2.0% [0.1, 10.6%])	0 (0.0% [0.0, 13.2%])	
Missing	13 (26.0% [14.6, 40.3%])	5 (19.2% [6.6, 39.4%])	
Wong-Baker FACES Pain Rating Scale			NA
No hurt	8 (16.0% [7.2, 29.1%])	0 (0.0% [0.0, 13.2%])	
Hurts little bit	1 (2.0% [0.1, 10.6%])	0 (0.0% [0.0, 13.2%])	
Hurts little more	0 (0.0% [0.0, 7.1%])	0 (0.0% [0.0, 13.2%])	
Hurts even more	0 (0.0% [0.0, 7.1%])	0 (0.0% [0.0, 13.2%])	
Hurts whole lot	0 (0.0% [0.0, 7.1%])	0 (0.0% [0.0, 13.2%])	
Hurts worst	0 (0.0% [0.0, 7.1%])	0 (0.0% [0.0, 13.2%])	
Unable to complete	28 (56.0% [41.3, 70.0%])	21 (80.8% [60.6, 93.4%])	
Missing	13 (26.0% [14.6, 40.3%])	5 (19.2% [6.6, 39.4%])	

Numbers are either presented as n (% [CI]) where the CI is a 95% Clopper-Pearson exact confidence interval, or as OR [CI] where the CI is a 95% asymptotic confidence interval estimated from a logistic regression model adjusted for the equivalent baseline binary outcome variable (because there was only one site in arm B, site was not included in the models due to overlap with the treatment arm variable)

*Participants for these outcomes could select more than one option

Staff/carer interviews (quotes in Additional file 9) Thirteen care staff participated in three focus groups (31, 40 and 82 min) at the intervention sites: two LTC facilities and one HCA.

Care prior to IAD research In one LTC facility, previously, staff had different views on the best management, with no formal training, just learning on the job, largely through trial and error. Others reported that they had been trained. One manager supported the concept of an evidence-based package to standardise care.

Carers reported all LTC facility residents are incontinent, nearly all doubly so. Continence referrals are made, but just to get pads supplied. The three–four pads supplied per day, as standard care, are not enough; families are asked to supplement this. Everyone had a care plan, developed by a '*senior*' [nurse or senior carer] and reassessed monthly. '*Shower gel*' was the norm for cleansing, with preventative '*derma*' added to water for sensitive skin. Barrier cream was then applied, but carers seemed unsure of the product's name. The GP decides if anything else is needed.

The intervention Many saw the poster as the intervention (Q1). In one LTC facility, staff engaged with the poster, especially the flow chart, which was widely displayed, including on visitor notice boards (Q2, Q3). The images were also appreciated. It was less clear if they had accessed the online tool after initial training. Staff reported they were aware of the content, but this did not necessarily change practice, continuing to use whatever product the GP had prescribed.

Many LTC facility staff were less enthusiastic about e-learning as they were not allowed to do this in work time. They also had 30 other compulsory e-learning packages to complete (Q4), so these were naturally prioritised. Colleagues would see you as not working if you accessed the e-learning in work time. Those who did access it found it easy but felt that e-learning would put people off, saying it was heartsink or stigmatised amongst care staff (Q5).

When accessed, this was on phone (often in a lunch break) or on a laptop (Q6). There was a definite preference for face-to-face training (Q6). With over 100 staff, one site did not have a mechanism for monitoring who had completed the e-learning (Q7).

The main thing reported to have changed at one LTC facility was moving from soap and water to wipes for cleansing (Q8). This, they felt, had made a difference to skin health (Q9), with IAD becoming less frequently reported during handover. However, the two other sites felt that they were already doing everything the correct way, and so nothing really changed.

Staff also reported general awareness about more frequent pad changes (Q10). It empowered care staff to

discuss care with nurses. However, others felt it was overlong (Q11) and could possibly be combined with pressure area care.

Research issues Getting consultee consent was the most onerous aspect. Staff enjoyed participating in the research, but felt that reporting weekly was too repetitive, lengthy and monotonous. This was particularly the case when little had changed in the skin status or care plan for the resident. Consequently, reporting was not always done on time, and it was not possible to stop weekly reports until the end of the study, even if someone died or was in hospital. Overall, the staff reported enjoying the experience of participating in research (Q12).

Manager interviews (quotes in Additional file 10) Four managers and three NHS clinical research nurses (CRNs) were interviewed (38–74 min, 193 min in total), focusing on participant recruitment and suggestions for improvements/changes to research design in future studies.

Most managers appeared to have felt interested to be involved; it was seen as an opportunity. Screening was often a team effort (Q1, Q2), and recruiting participants had been the most onerous and time-consuming aspect (Q3); it was difficult to find time to prioritise the study (Q4), especially where clients lacked the capacity to consent (Q5). CRNs with experience only expected 10–20% to agree (Q6), whereas managers had overestimated recruitment rates. Care staff and CRNs may have had different definitions of capacity to consent (Q7). Where there was not capacity, getting hold of consultees was very onerous, with multiple attempts needed, especially if they did not visit the care facility or home. Families wanted to talk about their family member, not the study (Q8). Sometimes one family member agreed, but others did not, causing conflict between family members. Even once they agreed verbally, obtaining a signed form was difficult (Q9) (and could have been easier if using telephone agreement rather than wet ink signatures (Q10)): there were too many steps to consultee signing. Some consultees refused if they perceived the study was too intrusive and broke taboos or would be too stressful (Q11, Q12), stating that intimate care was stressful enough already (Q13), or they did not want strangers visiting at home (Q14). On-site researcher support helped, as did financial incentives for organisations (Q15) and face-to-face training. Residents with capacity enjoyed the visits. Delays in getting started lost some recruits to death, hospitalisation, nursing home admission or they lost interest (Q16, Q17).

The managers felt that staff liked to be involved (Q18, Q19), they liked the certificate (Q20) and displaying laminated posters worked well (Q21, Q22), as did allocating one person to fill in returns weekly (Q23). The iPads provided for data collection were not helpful (Q24): a laptop for returns with manager support was better. It was tricky to track which staff had completed the e-learning (Q25); it was unclear how many had completed this.

The CRNs emphasised how having a prior relationship with staff was crucial; they were known and supported (Q27). They felt that simpler aims were needed for this group to explain the study (Q28), with simpler and consistent paperwork. Consistent with reports from staff, they felt filling in the weekly returns was too repetitive for staff and could have been simplified if nothing had changed. There was more work involved for staff than they originally thought (Q29).

Some had no suggestions for improvement. Others suggested speeding up the processes, with flexible recruitment to replace those who dropped out and including smaller homes. Where care was already excellent, the study was harder to sell.

Willingness to be randomised

All study sites signed documentation confirming their willingness to be randomised and none dropped out when allocation was revealed, although one control site did become difficult to contact/engage.

Observations of intervention fidelity

We undertook 22 observations of care provided by 18 carers across all intervention sites (LTC facilities $n=18$, homecare $n=4$) (Additional file 11). Intervention fidelity was maintained in 16 (73%) of observations. The IAD-Manual was more likely to be followed for the application of barrier products than for cleansing, largely because these products were prescribed. Cleansing was more hit and miss, with '*shower gel*' seen to be directly applied to the skin in one case and variation in products used. Some staff asked participants about their skin and if this was sore, but not always, and skin assessment was compromised by cognitive impairment.

Discussion

Intervention development, acceptability and fidelity

It was feasible to develop an intervention for the prevention and treatment of IAD in LTC facilities and community settings. Others have previously successfully developed a similar intervention to improve pain assessment and management for people living in LTC facilities [35]. Stakeholders unanimously approved the final flow chart (Additional file 4) and interactive e-learning training package that comprised the IAD-Manual [21]. Care staff liked the poster and training materials, describing these as '*good*'. However, the

implementation and adoption of the IAD-Manual was challenging, with limited evidence that the intervention was delivered as planned.

While some care staff engaged with the e-learning and said they felt it was useful, many others did not complete the training. Some care staff reported having to complete up to 30 h of e-learning for mandatory training in their own time, so they were reluctant to take on more. There are some parallels here between our findings and those of other authors [36]. In other cases, the training was not made available to all care staff by managers as requested; instead, they followed their usual training regimen of face-to-face delivery in a training room. We had adopted a 'train the trainers' approach [37] in the belief that this would be easier to roll out at scale for the different care providers but did not appreciate the rigidity of existing training models in practice. This was not something that was highlighted by our stakeholders during intervention development. It may also be reflective of issues such as private ownership of many LTC facilities and home-care providers, who focus on training that is mandatory because of cost implications. An intervention that fits more closely with existing training options may be more successful, and the suggestion to combine this with training on pressure ulcers as part of mandatory training for skin health was made.

Leadership is also likely to be a key factor in changing practice, and where IAD champions disseminated their learning to peers and more junior staff, they were able to effect change, for example eliminating the use of traditional soap and water cleansing for people in their care. In line with the COM-B model [38], the IAD-Manual was designed to increase the knowledge of care staff. Opportunity had been enhanced with posters to prompt correct skin care and project champions to role model and promote this behaviour. Despite this, it became apparent that two sites in the intervention arm did not change practice. This was in part for operational reasons, and care staff used the cleansers and barrier products available to them or that had been prescribed. They did not cite following the flowchart or training package as a reason for care decisions, many of which were based on a clinical hierarchy. While many cleansing procedures were not followed as set out in the intervention, we generally observed good practice in relation to applying a barrier product at each pad change. Carers reported not always knowing the name of the products they were using. This concurs with the wider literature, with reports that care staff often do not know what they are applying, which is problematic if evidence-based skin care is to be achieved [39, 40].

Study site/participant recruitment and randomisation

It was feasible to recruit and randomise study sites, but it was not feasible to recruit individual participants to target and recruitment of both study sites and participants was challenging, onerous and drawn out. Obtaining requisite approvals and recruitment of study sites took 27 months to complete for a variety of reasons, including COVID-19 delays and governance delays, which have been discussed in detail elsewhere [22].

Our findings are consistent with previous findings that recruitment and retention of LTC facilities is a challenge [41, 42] and a lengthy process [43]. Building relationships with study sites was crucial, with many LTC facilities and HCAs citing workload burden as the primary reason for not participating. Where sites did express an interest, the delays in governance approvals resulted in attrition of some sites prior to starting the study. The study team modified the inclusion criteria to support smaller sites, but this did not result in a significant increase in recruited LTC facilities or HCAs. A commentary of the study team's experiences in recruitment and governance and recommendations for change to advance social care research is reported separately [22]. Study sites that were recruited were willing to undergo randomisation. We were able to recruit five study sites, but the effort involved meant that the process was not feasible for a larger-scale study.

Retention of sites and participants

Following randomisation, all sites remained in the study. Over 76% of participants were retained in the study at 3 months. Had we been able to continue to 6 months it is likely that attrition may have been higher. As anticipated, some participants died during the study ($n=6$) and others were lost to follow-up due to moving into a LTC facility from their own home or moving LTC facilities. Data were missing from others as they were hospitalised for long periods. Attrition rates need to be considered when calculating sample size for any future study [43].

Completeness of data collection and feasibility of trial design

Only 34.5% of participants had weekly data collection returns submitted every week for the duration of the study, falling short of this feasibility progression criterion. Of those that were submitted, many data were missing. There were discrepancies between GLOBIAD and IADIT scores recorded at baseline. These two tools should both be assessing presence/absence and severity of IAD, yet there were differences recorded at baseline for participants with no IAD between the tools, with fewer being recorded using IADIT than GLOBIAD. It is unclear whether this was due to the tools or an issue with data collection.

Outcome measures were selected based on recommendations in the core outcome set for IAD [24]. Several of the outcome measures selected were not found to be suitable for use with a cognitively impaired population. Many participants living with dementia were unable to select options from the Wong-Baker Faces Scale [19], the SAPS [28] or the HADS [29]. The Wong-Baker Faces Scale was developed for use in children and has been advocated for use with people living with dementia, but it is known that only 36% of people with severe dementia, a similar population to this study, can use this tool [44]. These measures are not feasible for use with this population, and any future studies investigating the IAD-Manual will need to evaluate which outcomes, including newer measures [45] would both meet the requirements of the core outcome set for IAD and the needs/abilities of a population with moderate to severe cognitive impairment.

Feasibility studies are intended to reduce waste in research, and one review has concluded that 83% of feasibility studies prove to be feasible [46]. When a feasibility study is unfeasible, as in this case, it is not possible to proceed to a definitive RCT, and further feasibility work will be needed after a re-evaluation of the study design [47].

Limitations

The prevalence and incidence of IAD in the study sites that volunteered was low. This meant that calculating a point prevalence for IAD would be relatively meaningless. This may be due to study sites that knew they had a good track record of preventing and treating IAD volunteering to take part, while those where the prevalence of IAD was higher did not come forward. It may be that a fear of being judged created a reluctance to participate [43].

The recruitment of participants fell well short of the target. Baseline characteristics between intervention and control groups were similar, except that control participants were less likely to have barrier products applied than those in the intervention arm. Due to severe delays in recruiting both study sites and participants, we were unable to complete data collection at 6 months for all except one site.

Only permanently employed care staff were included as participants in this study. While our study sites all had a stable workforce and any temporary staff were regularly employed at these sites, the reality of care delivery has not been adequately reflected in the current feasibility study. If we had included temporary staff in the training, it could have provided valuable insight into whether the feasibility was compromised by the inclusion of these groups. This represents a limitation, particularly considering the objective of designing pragmatic clinical studies that accurately reflect real-world practice. While we sought to assess intervention fidelity through the process evaluation of this complex intervention, we did not use a particular model to structure our approach.

Conclusions

It was feasible to develop the IAD-Manual, but it was not feasible to recruit study sites to target or the required number of individual participants. Few potential participants had the capacity to consent, and gaining consultee approval was a lengthy and challenging process. Once recruited, retention was variable. Most incontinent participants did not have IAD at either time point (<30% anticipated). Data collection by care staff at study sites was variable and most consistent where CRN support was available. Care staff liked the IAD-Manual, but did not always engage fully with the intervention as planned, and intervention fidelity was not always observed. Care staff were more likely to follow the manual for the application of skin protectants, which were prescribed, than cleansing. Care staff preferred face-to-face training rather than e-learning, but this is not a scalable option, and future studies should consider incorporating e-learning as part of mandatory training alongside that for pressure ulcers. The study design failed to meet all the required progression criteria and was deemed not feasible in its original form due either to study design or study resources and the challenging context of support for research in social care.

Abbreviations

CRN	Clinical research nurse
GLOBIAD	Ghent Global IAD Categorization Tool
HADS	Hospital Anxiety and Depression Scale
HCA	Homecare provider/agency
IAD	Incontinence-associated dermatitis
IADIT	Incontinence-Associated Dermatitis Intervention Tool
LTC	Long-term care
MDS	Minimum data set
NHS	National Health Service
SAPS	Short Assessment Patient Satisfaction
UK	United Kingdom
USA	United States of America

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40814-025-01729-y.

Supplementary Material 1. Study Flow chart - phase 3.

Supplementary Material 2. PREVENT-IAD logic model v2.0.

Supplementary Material 3. what is wanted from the IAD-Manual.

Supplementary Material 4. IAD-Manual flowchart.

Supplementary Material 5. Training Plan.

Supplementary Material 6. Implementation Plan.

Supplementary Material 7. Observations-participants.

Supplementary Material 8. Relative and client interview data.

Supplementary Material 9. Staff and carer interview data.

Supplementary Material 10. Manager interview data.

Supplementary Material 11. Observations intervention fidelity.

Supplementary Material 12. CONSORT CHECKLIST v3.

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Authors' contributions
SW, MF, JF, RH, CN and PW proposed the research scope and idea for this study. SW, DB, CC, MF, JF, RH, JK, CN, SS and PW developed the research strategy and methodological process. SW, TG, JF, RH, CN and PW collected data. CN, SW and TG conducted qualitative analysis. NB-H conducted quantitative analysis and provided statistical support. SW drafted the manuscript. All authors critically revised and approved the final manuscript.

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Data availability
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
All participants gave written informed consent to both participate and for their data to be used in publications. Ethical approval for phase one of the study was obtained from the King's College London PNM Research Ethics Subcommittee (KCL Ethics Ref: HR-19/20-17478) and for phase three from the Queen Square Research Ethics Committee (REC Reference: 23/LO/0363).

Competing interests
CN declares the following conflicts of interest: speaker fees from Janssen, WebMD, Medscape, Merck Pharmaceutical, Tillotts Pharma UK and Lilly, and Pfizer advisory board. CC declares the following conflicts: Attends UK Ltd—presentation funding, Clinisupplies UK Ltd—presentation/conference funding, Essity—presentation funding. DB declares the following conflicts: MOLNLYCKE HEALTH CARE US, LLC (independent contractor—consultant); Urgo Medical North America, LLC (independent contractor—consultant); 3M Company (independent contractor—consultant). SW, TG, SS, MF, JF, RH, PW, NB-H and JK have no conflicts.

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