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Preventing pressure ulcers in nursing homes: developing a care bundle using the Behaviour Change Wheel

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Abstract

Objective: To develop, with nurse specialists and nursing home care staff, a theory and evidence-informed pressure ulcer prevention care bundle for use in nursing home settings.

Design: A complex intervention development study.

Methods: We undertook a detailed, multi-staged and theoretically-driven development process. Firstly we identified evidence-informed pressure ulcer prevention practices: these formed an initial set of possible target behaviours to be considered for inclusion in the bundle. During a four-hour workshop and supplemental email consultation with a total of 13 healthcare workers, we agreed the key target behaviours for the care bundle. We explored with staff the barriers and facilitators to prevention activity and defined intervention functions and behaviour change practices using the Behaviour Change Wheel.

Setting: North West England.

Results: The target behaviours consisted of three elements: support surfaces, skin inspection, repositioning. We identified capability, opportunity and reflective motivation as influencing the pressure ulcer prevention behaviours of nursing home care staff. The intervention functions (education, training, modelling) and behaviour change techniques (information about social, environmental and health consequences; feedback on behaviour and the outcome of behaviour; prompts/cues; instruction on how to perform the behaviour; demonstration of behaviour) were incorporated into the care bundle.

Conclusions: This is the first description of a pressure ulcer prevention care bundle for nursing homes developed using the Behaviour Change Wheel. Key stakeholders identified and prioritised the appropriate target behaviours to aid pressure ulcer prevention in a nursing home setting.

Keywords

Pressure ulcer prevention; nursing homes; care bundle; nominal group technique; behaviour change wheel; intervention development; complex intervention.

Article summary

Strengths and limitations of this study

- This study will inform the development of a novel intervention to support nursing home care staff to prevent pressure ulcers in residents.
- Integrating theory, research evidence and expert opinion into the care bundle should maximise the intervention's acceptability, feasibility and potential effectiveness.
- The pressure ulcer prevention care bundle is described in detail along with the intervention's potential mechanisms of action and the specific behaviour change techniques enhancing applicability and reproducibility.
- A number of experienced staff participated in the Nominal Group technique, but there was a limited number of tissue viability nurses who participated face-toface.

Background

Pressure ulcers are areas of localised damage to the skin and underlying tissue [1]. They are caused by prolonged, or short but intense, periods of pressure or pressure and shear. Pressure ulcers can lead to severe pain and distress, poor health-related quality of life and serious complications such as gangrene and mortality [2-4].

Reducing and eliminating pressure ulcers across all healthcare settings in the UK is a priority [5]. People at high risk of pressure ulceration include those who are seriously ill, the elderly and those with impaired mobility [6, 7]. Thus many people living in nursing homes are likely to be at an increased risk of pressure ulcers.

Pressure ulcer prevention processes are shaped by national and international guidelines based on a synthesis of research findings and expert opinion [1, 8].

Current guidelines recommend a range of clinical interventions including: *risk assessment, skin assessment, repositioning, maintaining hydration and nourishment,* the use of *pressure redistributing devices* and *barrier creams, training for care staff* and *accurate monitoring and documentation*. However the implementation of such prevention activities remains challenging, particularly in nursing homes where understaffing, high staff turnover and a lack of monitoring can result in limited staff knowledge and inconsistent clinical care [9, 10].

Care bundles were first introduced by the Institute for Healthcare Improvement to improve the quality and consistency of care [11]. Care bundles comprise three to five evidence-informed clinical interventions (referred to as "elements"), which have the potential to improve patient outcomes when performed collectively and reliably. The Institute for Healthcare Improvement suggests that every eligible patient should receive all of the bundle elements unless medically contraindicated [11].

Care bundles aim to change the behaviour of healthcare workers, therefore the use of behaviour change theory is key [12]. Whilst several care bundles have been developed it is not always clear how they were developed or whether they were underpinned by theory [13]. There are multiple theories and frameworks for behaviour change, many with overlapping constructs [14, 15]. The Behaviour Change Wheel [14, 16] was developed to facilitate the integration of target behaviours, behaviour change theory and intervention development through a series of three key stages that can be subdivided into eight steps (Appendix 1).

The COM-B model [16] forms the centre of the Behaviour Change Wheel [14, 16] and assists with understanding the behaviour in context (Stage 1 of intervention development). The COM-B model hypothesises that capability (C), opportunity (O) and motivation (M) all interact and can explain behaviour (B) and can become the focus for the behaviour change intervention.

Once the targets for change (e.g., physical opportunity) have been identified using the COM-B model, the second and third stages of the Behaviour Change Wheel focus on how intervention developers might facilitate change in these areas using intervention functions, policy categories, behaviour change techniques and modes of delivery. It is recommended that developers consider their intervention design using the APEASE criteria [14].

Currently, there are no published pressure ulcer prevention care bundles designed for, and implemented in, nursing home settings. Most of the published pressure ulcer prevention care bundles focus on acute hospital settings such as intensive care units and critical care units [17-22]. This paper describes the development of the first reported nursing home-specific pressure ulcer prevention care bundle. We aimed, with key stakeholders from nursing homes and the National Health Service (NHS), to co-produce a pressure ulcer prevention care bundle that is relevant to the nursing home context. We describe how the Behaviour Change Wheel was used to support the theory-driven processes in the design of the implementation plan for the care bundle. Figure 1 presents a logic model illustrating our knowledge and understanding at the start of this work and the outcomes we were aiming for. At the end of the work we aimed to design the components of the intervention (the "solution" in Figure 1).

Methods

Study design

We describe a two part care bundle development process. Part 1 used the Nominal Group technique [23] to gain consensus about the elements to include in the care bundle. Part 2 followed the steps outlined in the Behaviour Change Wheel to facilitate the development of the implementation plan for the care bundle.

Participants

The study took place in the North West of England. Purposive sampling was used to recruit participants with relevant clinical and management experience and expertise. Participants were eligible to participate if they were a nursing homebased registered nurse (referred to from now on as a nurse), manager or healthcare assistant or a community-based tissue viability nurse. Written consent was gained from all participants.

Materials and procedures

Figure 2 presents a diagrammatical outline of the processes involved in developing the care bundle and how we applied the Behaviour Change Wheel processes here.

Stage1: Understanding the behaviours

Behaviour Change Wheel Step 1. Define the problem in behavioural terms (pre-workshop)

We reviewed the pressure ulcer prevention literature to gain an understanding of the main barriers to pressure ulcer prevention in nursing homes. We conducted a systematic review that identified and explored existing care bundles and any evidence for particular design features and behaviour change approaches that might be associated with positive clinical outcomes [anonymised for review].

Behaviour Change Wheel Steps 2 and 3. Select and specify the target behaviours (care bundle development workshop)

These two steps involved the identification of care bundle elements (i.e. the specific pressure ulcer prevention clinical interventions) and consideration of who, what, when, where and how often the care bundle elements should be delivered. We held a four hour interactive workshop with key stakeholders to identify the clinical interventions to assist with pressure ulcer prevention in nursing homes. There are several possible methods that can be drawn on for developing a care bundle. We used the Nominal Group technique to gain consensus about the most important pressure ulcer prevention elements to be included in the care bundle. This approach is highly structured; consisting of multiple rounds where items or questions are rated, discussed and re-rated by the expert panellists (e.g., nurses). This method minimises the effects of any dominant participants as all group members are provided with equal opportunities for voting.

We presented participants with an overview of the research-based international and national pressure ulcer prevention guidelines [1, 8]. We then discussed the guideline recommendations, focusing in particular on their applicability in a nursing home setting. All participants had the opportunity to add any clinical interventions they thought were missing from the guidelines before they began voting.

The Nominal Group process was explained and participants were split into two groups for voting purposes (i.e. healthcare assistants or registered nurses). Each participant within these groups was given five votes in the form of coloured stickers which they used to vote individually for their top three to five pressure ulcer prevention clinical interventions. The colour of the sticker indicated whether the voter was a nurse or healthcare assistant. We counted the votes in real time and presented the results to the participants to facilitate discussion prior to the second round of voting. In the case of a tie, we offered the participants one extra vote for one of the two tied clinical interventions. We invited participants to express their opinions on the clinical interventions and whether they believed clarification was required. Again, colour-coded stickers were used to cast votes in the second round. This round was used to finalise the agreement between participants [23]. The care bundle elements were agreed after a final discussion of the clinical interventions that received the highest numbers of votes.

We then asked the workshop participants to specify the detail for each bundle element; the frequency with which they should be delivered, where and by whom and we asked participants to score the components of each element out of 10 (0 = not important, 10 = extremely important). Following the workshop, the care bundle elements and specific components were reviewed in line with existing research evidence and cross-checked for validity by experts in the field such as tissue viability nurses.

Behaviour Change Wheel Step 4. Identifying what needs to change to enable the reliable delivery of pressure ulcer prevention clinical interventions

We collected data from 25 participants using semi-structured interviews where we explored the barriers and facilitators to pressure ulcer prevention using the Theoretical Domains Framework [anonymised for review]. We identified the behavioural and psychological influences on pressure ulcer prevention by mapping the salient barriers and facilitators identified using the Theoretical Domains Framework onto the COM-B model, using the guidance provided by the Behaviour Change Wheel [14].

Stages 2 and 3: Identifying the intervention content and implementation options

Behaviour Change Wheel Steps 5-8. Identifying the intervention functions, policy categories,

behaviour change techniques and modes of delivery

We mapped the components of the COM-B model identified as being relevant to pressure ulcer prevention in nursing homes (Step 4) onto the matrices provided in the Behaviour Change Wheel, and this informed our plan for implementing the care bundle. We applied the APEASE criteria [14] for designing and evaluating interventions to each of the relevant implementation aspects to guide our judgements in selecting the most appropriate intervention functions, policy categories, behaviour change techniques and modes of delivery likely to support the successful implementation of the care bundle.

To ensure the implementation plan was suitable, we held discussions individually with the nursing home care staff, tissue viability nurses and academic researchers before we finalised the care bundle. These discussions were based on the 'modelling' guidance provided by the UK Medical Research Council's guidance for developing and evaluating complex interventions [12] which includes: who should receive the intervention; how changes to practice are usually introduced; what the barriers to change might be and how delivery can be documented.

Patient and public involvement

Patients were not involved in this study.

Results

Behaviour Change Wheel Stage 1: Understanding the behaviours

Behaviour Change Wheel Step 1. Define the problem in behavioural terms (pre-workshop)

We found that the barriers to pressure ulcer prevention commonly reported within the literature included understaffing, high staff turnover and limited staff knowledge [9, 10]; whereas communication and positive attitudes towards pressure ulcer prevention were often described as facilitators [24-26]. Our findings suggested that central to the prevention of pressure ulcers is the belief that the actions of healthcare workers (e.g., repositioning) directly influence the development of pressure ulcers [27]. Consequently, care bundles may be an effective tool to improve the implementation of guidelines and evidence-informed practices [13].

Within our systematic review we were not able to conduct a meta-regression of study features or explore the magnitude of effects as there were insufficient comparisons involving patient outcomes. Consequently, we conducted subgroup analyses. We found that all care bundles (regardless of the number of elements) reduced the risk of the negative patient outcomes and the apparent effect of care bundles appeared to reduce as the number of elements increased. The lowest risk for the negative patient outcomes was in the subgroup with 'eight behaviour change techniques'. However, we considered these data to be of very low quality. Our findings from the systematic review are reported in detail elsewhere [13].

Behaviour Change Wheel Steps 2 and 3. Select and specify the target behaviours (care bundle development workshop)

A total of 10 participants attended the workshop, including one tissue viability nurse and staff from one nursing home (four healthcare assistants and five registered nurses). A further three tissue viability nurses were unable to attend the workshop but participated in email (n = 2) or face-to-face (n = 1) consultations, which followed the processes outlined in the methods section as closely as possible. The participants' ages ranged from 26 to 55 years, one participant was male and one had previously attended wound care training. The median years of experience in working with people at risk of developing pressure ulcers was 11 years (interquartile range: 1.4 years to 13 years).

During the discussion prior to round one, it was agreed that 'pain management' should be added as a clinical intervention, and nutrition and hydration should be separated into two. The clinical interventions voted for in round one by each group differed (Table 1). For example the healthcare assistants did not vote for skin assessment, whereas 80% of the nurses (4/5) and 75% of the tissue viability nurses (3/4) did. Similarly, 75% of the healthcare assistants (3/4) and 50% of the tissue viability nurses (2/4) voted for support surfaces to be included but the nurses did not. During the discussion the nurses explained that they did not select support surfaces as a key clinical intervention as they felt that pressure redistributing devices covered this (although this only received one vote from the nurses' group). Further discussion resulted in reuniting nutrition and hydration as all nursing home participants explained that they offer these together. Consequently, six clinical

interventions went through to the second round of voting (*skin care, continence care, skin assessment, repositioning, nutrition and hydration* and *support surfaces*).

Repositioning, skin assessment, skin care, continence care and nutrition and hydration were voted into the top five in round two (Table 1). Every tissue viability nurse voted for support surfaces; whereas the healthcare assistants considered support surfaces to be important but embedded within repositioning, and this was reflected in their voting. Through discussion the participants agreed that including support surfaces as an element separate to repositioning was important and support surfaces should incorporate pressure redistributing devices too. Whilst the participants deemed nutrition and hydration and continence care to be important, they decided that providing and monitoring such clinical interventions are part of basic care and should not be included in a specific pressure ulcer prevention care bundle. The skin care and skin assessment clinical interventions were merged. Consequently, three elements made up the care bundle: support surfaces, skin inspection and repositioning.

Participants ranked, in order of perceived importance, the components required to ensure the accurate and consistent completion of each of the care bundle elements. All participants agreed that residents should receive a monthly pressure ulcer risk assessment to trigger the activation of the care bundle for those at risk of developing a pressure ulcer. However, more frequent assessments may be warranted for some residents at high risk of pressure ulcer development or if there is a change in a

resident's clinical status. The frequency with which the elements of care are to be delivered will be informed by the risk assessment, although the risk assessment was separate from the care bundle. It was agreed that the nursing home care staff should complete and document every element of the care bundle for all residents deemed to be at risk of developing a pressure ulcer, and where an element cannot be completed a reason must be provided (e.g., where a resident has refused to be repositioned).

Behaviour Change Wheel Step 4. Identifying what needs to change to enable the reliable delivery of pressure ulcer prevention clinical interventions

The semi-structured interview data (reported elsewhere [anonymised for review]), when mapped on to the COM-B model, suggested the following factors as influences on the prevention of pressure ulcers in nursing home settings: psychological and physical capability; physical and social opportunity; and reflective motivation. We found that improvements in pressure ulcer prevention knowledge and skills are required. In particular, the tissue viability nurses could provide information about, and training on, pressure ulcers and how to prevent them within a nursing home context; but the nursing home care staff need to be permitted to attend this training. In addition there appears to be scope to increase the use and documentation of evidence-informed pressure ulcer prevention clinical interventions. Pressure ulcer prevention clinical interventions need to be conducted in line with the resident's risk of developing a pressure ulcer. If it is not possible to complete an aspect of care, this must be documented.

Behaviour Change Wheel Stage 2: Identifying the intervention content and implementation options

We used the Behaviour Change Wheel to define the key intervention functions and policy categories that could be used to improve pressure ulcer prevention in nursing homes using the relevant COM-B components identified in Step 4.

Step 5: Intervention functions

The three most suitable intervention functions were *education, training* and *modelling* (i.e. providing a role model such as a skin champion). Increasing the knowledge of the nursing home care staff and improving their skills through education and training is a crucial aspect to facilitating the prevention of pressure ulcers in nursing home residents. The inclusion of skin champions should assist with accessing training and education as these can be delivered in-house by the skin champion.

Step 6: Policy categories

The policy categories most suitable for achieving the behaviour change included *communication/marketing* (e.g., posters), *guidelines*, *regulation* and *service provision*.

Step 7: Behaviour change techniques

Using the Behaviour Change Technique Taxonomy Version 1 [28] and the findings from our systematic review we selected the seven techniques we believed were most

suitable to facilitate behaviour change and support prevention practices (*information* about social and environmental consequences; information on health consequences; feedback on behaviour; feedback on the outcome of the behaviour; prompts/cues; instruction on how to perform the behaviour; demonstration of behaviour).

Step 8: Mode of delivery

We then formulated a plan regarding how and by whom the care bundle would be implemented in practice and this was based on the discussions held with key stakeholders. The delivery of the care bundle will differ at specific stages and the key modes of delivery are specified in Table 2 (e.g., the tissue viability nurses will deliver the face-to-face group training to address the *capability* of nursing home care staff as identified through the COM-B model in Stage 1).

Discussion

This is the first explicit, behaviour change theory-driven, pressure ulcer prevention care bundle that we have been able to identify. We identified the important elements of the care bundle in collaboration with key stakeholders. Using the COM-B model and with the steps outlined in the Behaviour Change Wheel we developed a pressure ulcer prevention care bundle that focused on the three identified target behaviours (the checking of support surfaces, skin inspection and repositioning). The broad functions of the intervention (education, training, modelling) aim to be achieved using seven theoretically-based behaviour change techniques delivered using a

variety of methods, including face-to-face and written materials. This information can be used to populate the solutions box in Figure 1 in the introduction (Figure 3).

Three main aspects of pressure ulcer prevention that consistently feature in care bundles were included within our nursing home care bundle, albeit operationalised differently: repositioning, skin assessment and the use of support surfaces [17-19, 29]. However, our care home-focused intervention differs from those delivered in hospital settings as we did not incorporate continence care or nutrition and hydration; mainly because they were deemed core aspects of nursing care that should be prioritised irrespective of any tenuous link with pressure ulcer prevention. Whilst our care bundle elements reflect those included in hospital-focused bundles, the process of deciding how to promote the behaviour changes around these target behaviours has not been clear in previous work. We supported this work using a strong theoretical framework for intervention design. Through the transparent reporting of the mechanisms of action, modes of delivery and the theoretical constructs, future evaluations of the effectiveness of this care bundle will be possible.

Strengths and limitations

The theoretical basis and systematic presentation of the development of the care bundle is a strength of our study. The empirical work revealed the target behaviours required (i.e. checking of support surfaces, skin inspection, repositioning) and the Behaviour Change Wheel identified the implementation interventions suitable for

the care bundle. Previous studies detailing pressure ulcer prevention care bundles [17, 19] have not provided such explicit and transparent methods, which may limit the understanding of the mechanisms of action and causal relationships within the interventions [30]. Thus the present study addresses these concerns, facilitating subsequent evaluations and future replications.

The use of Nominal Group technique to develop the care bundle was beneficial for many reasons. The participation of the nursing home care staff and the NHS tissue viability nurses was vital to ensure the integration of specialist knowledge alongside context specific expertise. The Nominal Group technique enabled each participant to express their view (via individual votes) which minimised the effects of any potentially dominant participants. Using the Nominal Group technique during the workshop was advantageous as it yielded extensive and rich data in a relatively short period of time.

A limitation of the current study was the inclusion of only one nursing home and the relatively small number of tissue viability nurse workshop participants. Expert opinion is a fundamental aspect of the Nominal Group technique, and whilst the majority of the participants who did attend had a range of expertise in caring for individuals residing in nursing homes, specialist nurse input was crucial. Initially all of the local tissue viability nurses agreed to attend however, due to unforeseen circumstances, some could not. Consequently, the process was repeated with the

tissue viability nurses via face-to-face meetings or online consultations to ensure their specialist knowledge of the prevention of pressure ulcers could be combined with the results. We believe that taking such a systematic and structured approach to designing the care bundle will result in a more efficacious intervention and will aid subsequent evaluations and improvements.

Future research

The next phase of this research is to test the feasibility of implementing the care bundle in a nursing home context. If the care bundle intervention is feasible and acceptable to nursing home care staff, further evaluation will be necessary to assess the clinical and cost-effectiveness. The explicit theoretical links provided through the use of the Behaviour Change Wheel [14, 16] and Behaviour Change Technique Taxonomy Version 1 [28] will facilitate future replications and data synthesis.

Conclusion

Care bundles have received much attention within inpatient settings over the past decade due to the potentially synergistic effect of incorporating several clinical interventions within one package. The structure of care bundles can be used to facilitate reliable and sustainable changes in the work habits of staff. However, few theory-informed care bundles are reported within the literature. This paper describes how a pressure ulcer prevention care bundle was developed for use in UK nursing homes and how the Behaviour Change Wheel guided the development of

the intervention. Key stakeholders contributed to the design of the care bundle, forging the first step towards standardising pressure ulcer prevention practices within nursing home settings. Whilst preventing pressure ulcers in nursing home residents is complex and multifaceted, this structured and transparent approach has facilitated a thorough process for the development of the intervention. The next step is to assess the feasibility of implementing this care bundle within the nursing home environment to ensure that it is acceptable before wider evaluation ensues. Abbreviations
PU: pressure ulcer
TVN: tissue viability nurse
BCW: Behaviour Change Wheel

Figure legends

Figure 1; Logic model for the pressure ulcer prevention care bundle; an outline of the consequences of pressure ulcers in nursing homes, the potential behavioural causes of pressure ulcers and the pathway to benefit through preventing pressure ulcers. Figure 2; The Behaviour Change Wheel stages; data collection and analysis processes used to develop the care bundle using the steps and stages outlined in the Behaviour Change Wheel.

Figure 3; Solutions box for Figure 1; the content of the pressure ulcer prevention care bundle and the steps required to implement the care bundle in nursing homes.

Additional files

Appendix 1; Behaviour Change Wheel stages and steps [11]; an overview of the Behaviour Change Wheel.

Appendix 2; Pressure ulcer prevention care bundle.

Appendix 3. Care bundle poster (.txt 464KB)

Declarations

Ethics approval and consent to participate

This study was given approval by [anonymised for review] (ref: 15451), together with approval from the Research and Development department at the participating NHS site (ref: 100321).

Consent for publication

Not applicable.

Availability of data and material

All data generated or analysed during this study are included in this published manuscript.

Competing interests

The authors declare that they have no competing interests.

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Author contributions

All of the authors conceived the study and contributed to its design. [anonymised for review] co-ordinated the study, developed the standard operating procedures for the workshop, held the email/face-to-face consultations with the tissue viability nurses and analysed the data. [anonymised for review] facilitated the workshop. All of the authors contributed to the interpretation of the data, assisted with drafting and revising the manuscript and approved the final version before submission.

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References

- 1. Haesler E: National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. *Prevention and treatment of pressure ulcers: quick reference guide[Internet]* 2014.
- 2. Allman RM: Pressure ulcer prevalence, incidence, risk factors, and impact. *Clinics in Geriatric Medicine* 1997, **13**:421-&.
- 3. Keen DC: Should care homes adopt a static-led approach to pressure ulcer prevention? *British journal of nursing (Mark Allen Publishing)* 2009, **18**:S4, S6, S8, passim.
- 4. Essex HN, Clark M, Sims J, Warriner A, Cullum N: Health-related quality of life in hospital inpatients with pressure ulceration: Assessment using generic health-related quality of life measures. Wound Repair and Regeneration 2009, **17**:797-805.
- 5. Harms in the NHS [https://www.gov.uk/government/news/qipp-national-workstreams-updated]
- 6. Coleman S, Gorecki C, Nelson EA, Closs SJ, Defloor T, Halfens R, Farrin A, Brown J, Schoonhoven L, Nixon J: Patient risk factors for pressure ulcer development: Systematic review. *International Journal of Nursing Studies* 2013, **50**:974-1003.
- 7. Moore Z, Cowman S: Pressure ulcer prevalence and prevention practices in care of the older person in the Republic of Ireland. *Journal of clinical nursing* 2012, **21**:362-371.
- 8. Pressure ulcers: prevention and management [cg179] [https://www.nice.org.uk/guidance/cg179]
- 9. Demarré L, Vanderwee K, Defloor T, Verhaeghe S, Schoonhoven L, Beeckman D: Pressure ulcers: knowledge and attitude of nurses and nursing assistants in Belgian nursing homes. *Journal of clinical nursing* 2012, **21**:1425-1434.
- 10. Donoghue C: Nursing home staff turnover and retention: An analysis of national level data. *Journal of Applied Gerontology* 2009.
- 11. Resar R, Griffin F, Haraden C, Nolan T: Using care bundles to improve health care quality. *IHI Innovation Series white paper Cambridge, Massachusetts: Institute for Healthcare Improvement* 2012.
- 12. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M: Developing and evaluating complex interventions: the new Medical Research Council guidance. *Bmj* 2008, **337**:a1655.
- 13. Lavallée JF, Gray TA, Dumville J, Russell W, Cullum N: The effects of care bundles on patient outcomes: a systematic review and meta-analysis. *Implementation Science* 2017, **12**:142.
- 14. Michie S, Atkins L, West R: The behaviour change wheel: a guide to designing interventions. *Needed: physician leaders* 2014:26.
- 15. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A: Making psychological theory useful for implementing evidence based practice: a consensus approach. *Quality and safety in health care* 2005, **14**:26-33.
- 16. Michie S, van Stralen MM, West R: The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implementation science* 2011, **6**:42.
- 17. Anderson M, Finch Guthrie P, Kraft W, Reicks P, Skay C, Beal AL: Universal Pressure Ulcer Prevention Bundle With WOC Nurse Support. *Journal of Wound, Ostomy, & Continence Nursing* 2015, **42**:217-225.
- 18. Baldelli P, Paciella M: Creation and implementation of a pressure ulcer prevention bundle improves patient outcomes. *American Journal of Medical Quality* 2008, 23:136-142.
- 19. Boesch RP, Myers C, Garrett T, Nie A, Thomas N, Chima A, McPhail GL, Ednick M, Rutter MJ, Dressman K: Prevention of tracheostomy-related pressure ulcers in children. *Pediatrics* 2012, 129:e792-797.
- 20. Chaboyer W, Bucknall T, Webster J, McInnes E, Gillespie BM, Banks M, Whitty JA, Thalib L, Roberts S, Tallott M, et al: The effect of a patient centred care bundle intervention on

- pressure ulcer incidence (INTACT): A cluster randomised trial. *International Journal of Nursing Studies* 2016, **64**:63-71.
- 21. Gray-Siracusa K, Schrier L: Use of an Intervention Bundle to Eliminate Pressure Ulcers in Critical Care. *Journal of Nursing Care Quality* 2011, **26**:216-225.
- 22. Schindler CA: More than S.K.I.N. deep: Decreasing pressure ulcer development in the pediatric intensive care unit. Marquette University, 2010.
- 23. Van de Ven AH, Delbecq AL: The nominal group as a research instrument for exploratory health studies. *American Journal of Public Health* 1972, **62**:337-342.
- 24. Dellefield ME, Magnabosco JL: Pressure ulcer prevention in nursing homes: Nurse descriptions of individual and organization level factors. *Geriatric Nursing* 2014, **35**:97-104.
- 25. Hartmann CW, Solomon J, Palmer JA, Lukas CV: Contextual Facilitators of and Barriers to Nursing Home Pressure Ulcer Prevention. *Advances in skin & wound care* 2016, **29**:226.
- 26. Worsley PR, Smith G, Schoonhoven L, Bader DL: Characteristics of patients who are admitted with or acquire Pressure Ulcers in a District General Hospital; a 3 year retrospective analysis. *Nursing Open* 2016, **3**:152-158.
- 27. Black JM, Edsberg LE, Baharestani MM, Langemo D, Goldberg M, McNichol L, Cuddigan J: Pressure ulcers: avoidable or unavoidable? Results of the national pressure ulcer advisory panel consensus conference. *Ostomy-Wound Management* 2011, **57**:24.
- 28. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, Eccles MP, Cane J, Wood CE: The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Annals of behavioral medicine* 2013, **46**:81-95.
- 29. Gibbons W, Shanks HT, Kleinhelter P, Jones P: Eliminating facility-acquired pressure ulcers at Ascension Health. *The joint commission journal on quality and patient safety* 2006, **32**:488-496.
- 30. Soban LM, Hempel S, Munjas BA, Miles J, Rubenstein LV: Preventing pressure ulcers in hospitals: a systematic review of nurse-focused quality improvement interventions. *The Joint Commission Journal on Quality and Patient Safety* 2011, **37**:245-AP216.

Table 1

Votes from rounds one and two from each healthcare staff group

	Healthcare		Tissue	Overall
	assistants	Nurses	viability	percentage of
Clinical intervention	(n = 4)	(n = 5)	nurses $(n = 4)$	votes
Voting round 1				
Nutrition	1	4	4	69%
Hydration	2	4	0	31%
Skin care	2	1	1	38%
Support surfaces	3	0	2	46%
Repositioning	3	5	4	92%
Continence care	4	5	4	100%
Pressure redistributing	1	1	2	31%
devices				
Skin assessment	0	4	3	54%
Pain	0	0	0	0%
Barrier cream	0	0	0	0%
Voting round 2				
Skin care	2	4		45%
Continence care	4	4	4	92%
Skin assessment	0	3	3	46%
Repositioning	4	5	4	100%
Nutrition and	4	5	4	100%
hydration	-	J	-	20070
Support surfaces	0	0	4	31%

Table 2. Implementation plan for pressure ulcer prevention care bundle

What	Why	Who	How/frequency	Where
Training and education: - on risk factors, pressure ulcer prevention, equipment, outcomes, protocols.	Access to training was identified as a barrier to pressure ulcer prevention in nursing homes. To improve pressure ulcer prevention knowledge and skills in nursing home care staff (registered and unregistered). We identified the following two BCTs as important components of the intervention: ;information about social and environmental consequences' and 'information on health consequences'.	Provided by a tissue viability nurse to nursing home care staff (registered and unregistered).	Training will be provided one week prior to the implementation of the care bundle and will be a one-off face-to-face, three hour interactive group session. Presentation using PowerPoint and printed materials will be provided to the staff who attend and also to the nursing home for staff who are unable to attend. Additional training sessions will be offered to the nursing home care staff to maximise attendance.	Due to practical reasons, training will be held off-site. Written training materials will be available in the nursing home.
 on the care bundle and each individual element (support surfaces, skin inspection, repositioning), and how to use the care bundle in practice. 	To increase the uptake of the care bundle, to familiarise staff with the processes involved.	Provided to nursing home care staff (registered and unregistered) by a researcher with expertise in behaviour change.	Face-to-face one hour interactive group session. PowerPoint and printed materials will be provided to staff who attend and also to the nursing home for staff who are unable to attend.	

Table 3

(Cont.)

What	Why	Who	How/frequency	Where
Modelling and	The skin champions will	Nursing home care	This is available face-to-face and is likely	Nursing home.
demonstration of	deliver the care bundle	staff (likely to be a	to be delivered on an individual basis and	
behaviour:	as intended and will be	registered nurse).	will be available as required.	
- skin champions	available during a shift.		The researcher will meet with the skin	
_	Staff can speak with the		champions at least bi-weekly to discuss	
	skin champions if they		any issues or concerns.	
	have any concerns or			
	queries. Skin champions			
	are also able to			
	demonstrate pressure			
	ulcer prevention			
	techniques and provide			
	examples of good record			
	keeping (i.e.			
	documentation).			
Implementation of the care				
bundle:				
- risk assessment	To identify any risk	Registered nurse	Using a validated risk assessment tool, the	Nursing home.
	factors for the	and/or nursing	risk assessment will be completed at least	
	development of a	home manager.	monthly. If there is a change to a	
	pressure ulcer and		resident's clinical status, the risk	
	indicate the frequency		assessment should be conducted again.	
	with which the care			
	bundle needs to be			
	delivered.			

Table 3 (*Cont.*)

What	Why	Who	How/frequency	Where
Implementation of the care				
bundle:				
- complete care bundle for each eligible resident (support surfaces, skin inspection, repositioning).	To improve the reliability of care and to prevent pressure ulcers using elements identified locally as being important within a nursing home context. To improve the documentation of pressure ulcer prevention practices.	Nursing home care staff (registered and unregistered).	Nursing home care staff will complete each element of care included within the care bundle. If it is not possible to conduct all of the elements (<i>support surfaces, skin inspection, repositioning</i>) within the care bundle, this must be documented on the overleaf section of the care bundle documentation sheet. The frequency with which this needs to be conducted will depend on each individual resident. The frequency should be amended in line with a resident's needs and risk. For example, for those at risk of developing a pressure ulcer it should be at least every 6 hours, at least every 4 hours for those at a high risk, and at least every 2 hours for those at a very high risk. Staff are required to ensure the appropriate pressure relieving equipment is being used and is functioning.	Nursing home.

Table 3 (*Cont.*)

What	Why	Who	How/frequency	Where
Prompts and cues	An aide memoire was	The research team	The unit manager will decide the	Nursing home
	reported as a facilitator of	will provide posters	positioning of the posters on the unit (see	(including
	pressure ulcer prevention	and care bundle	Appendix 3). The nursing home staff are	nursing office,
	in nursing homes. Thus,	documentation.	responsible for the completion of the care	residents'
	posters will be placed in		bundle and associated documents. These	bedrooms,
	staff communal areas		will be available daily throughout the	residents' files)
	(e.g., nursing office) to		study period.	
	remind staff of the steps			
	involved within the care			
	bundle. The care bundle			
	itself also acts as a			
	checklist as staff are			
	required to document the			
	provision of care on the			
	care bundle sheets.			

Table 3 (Cont.)

What	Why	Who	How/frequency	Where
Feedback:	To maintain motivation and engagement with			
	the care bundle.			
- on behaviours and	To highlight areas of	Researcher	The research team will provide verbal	Nursing home
outcomes.	pressure ulcer		feedback to the unit manager on a monthly	
	prevention where staff		basis during the study period. This will	
	are maintaining high		include the number of pressure ulcers	
	levels of care and the		acquired and adherence to the care bundle.	
	areas that could be		Feedback will be provided in the form of	
	improved.		percentages on the following:	
			- All-or-none compliance (when all	
			aspects of the care bundle were	
			delivered, including times when it was	
			not possible to complete the care bundle	
			but reasons were documented);	
			- Overall adherence with each individual	
			element: support surfaces, skin	
			inspection, repositioning.	
			Following the completion of the study, the	
			above information will be collated and the	
			findings from the whole study period will be	
			presented verbally to the unit manager and	
_			nursing home care staff.	

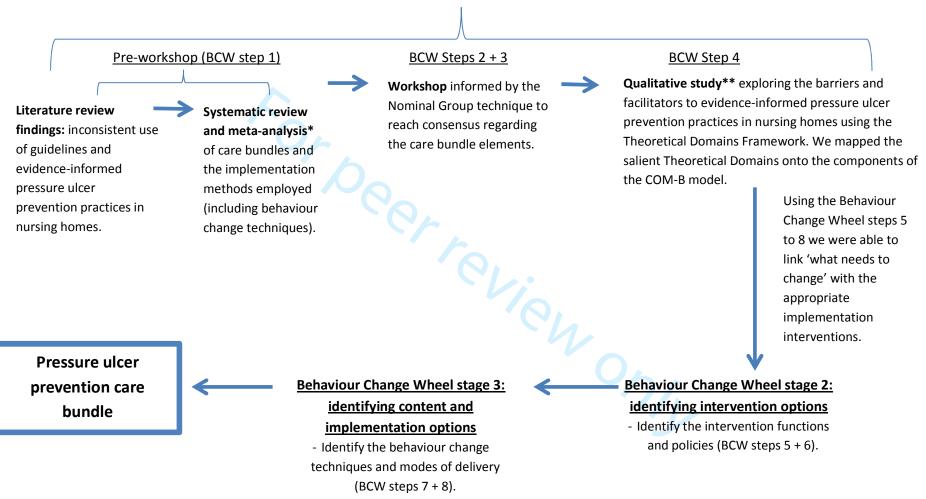
The problem Implementation of PU prevention guidelines High PU incidence Impact on quality of life for resident, carer and family Inappropriate referrals to TVNs

Psychological and behavioural influences Capability Psychological: - Knowledge - Interpersonal skills. Physical: - Physical skills Opportunity Physical: - Environmental context and resources Social: - Social influences Motivation Reflective: - Social/ 4% annual NHS professional role expenditure on and identity treating PUs - Beliefs about capabilities - Beliefs about consequences

Pathway to benefit The solution Key intervention / behaviour change **Process** techniques measures Identified through Adherence to the work presented care bundle in this paper. elements Adherence to behaviour change techniques Feasibility and acceptability

Benefits to residents, nursing homes and NHS **Key behavioural** Long-term outcomes outcomes Reduced PU Adherence to care bundle incidence elements **Improved** Documentation resident (including risk outcomes assessment) Reduction in Adherence to inappropriate behaviour change referrals to techniques **TVNs** PU incidence Reduced cost of treating PUs in NHS

Behaviour Change Wheel stage 1: understand the behaviour



^{*}Methods and findings reported in [anonymised for review]; **methods and findings reported in [anonymised for review].

Care bundle elements:

- Support surfaces
- Skin inspection
- Repositioning

Behaviour change techniques:

- Information about social and environmental consequences
- Information on health consequences
- Feedback on behaviour
- Feedback on the outcome of the behaviour
- Prompts/cues
- Instruction on how to perform the behaviour
- Demonstration of behaviour

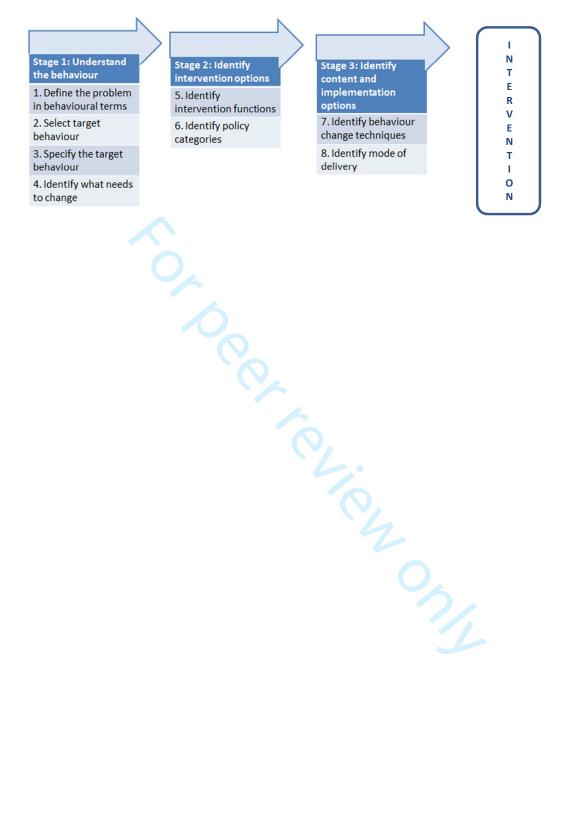


Table 2

The care bundle elements and the specific components

Support surfaces:

Checked for creases, tubing and personal items.

Is all of the equipment working?

Skin inspection:

All pressure areas checked?

Any redness or changes to the skin? (If yes, please document)

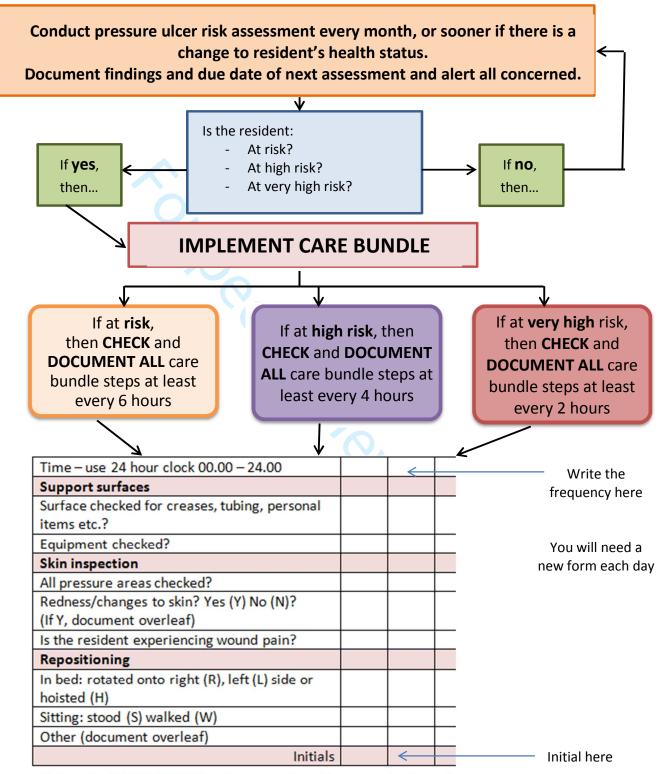
Is the resident experiencing wound pain?

Repositioning:

Document whether the resident has turned/stood/walked/been hoisted to another position.

Additional file 2. Care bundle poster

Pressure Ulcer Prevention Care Bundle



All Care Staff PLEASE READ and ensure all residents 'at risk' have forms in their room. Please ask the nurse in charge to explain if unsure



The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item	Item	Where Id	ocated **
number		Primary paper	Other [†] (details)
		(page or appendix	
		number)	
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.		
	WHY	Abstract, page 2	
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.		
	WHAT	Page 7	
3.	Materials: Describe any physical or informational materials used in the intervention, including those		
	provided to participants or used in intervention delivery or in training of intervention providers.		
	Provide information on where the materials can be accessed (e.g. online appendix, URL).	Pages 9-11	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention,		
	including any enabling or support activities.		
	WHO PROVIDED	Pages 9-11	
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their		
	expertise, background and any specific training given.		
	HOW	Page 8	
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or		
	telephone) of the intervention and whether it was provided individually or in a group.		
	WHERE	Page 18, table 2	
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary		
	infrastructure or relevant features.		

	Abstract, page
WHEN and HOW MUCH	13
Describe the number of times the intervention was delivered and over what period of time including	
the number of sessions, their schedule, and their duration, intensity or dose.	
TAILORING	Page 15, table 2
If the intervention was planned to be personalised, titrated or adapted, then describe what, why,	
when, and how.	
MODIFICATIONS	Page 15
. [‡] If the intervention was modified during the course of the study, describe the changes (what, why,	
when, and how).	
HOW WELL	N/A
. Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any	
strategies were used to maintain or improve fidelity, describe them.	
.* Actual: If intervention adherence or fidelity was assessed, describe the extent to which the	N/A
intervention was delivered as planned.	N/A

^{**} **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

- † If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).
- ‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.
- * We strongly recommend using this checklist in conjunction with the TIDieR guide (see BMJ 2014;348:g1687) which contains an explanation and elaboration for each item.
- * The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a randomised trial is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of ttem 5 of the CONSORT 2010 Statement. When a clinical trial protocol is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of ttem 11 of the SPIRIT 2013
 Statement (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist

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Preventing pressure injury in nursing homes: developing a care bundle using the Behaviour Change Wheel

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Preventing pressure injury in nursing homes: developing a care bundle using the Behaviour Change Wheel

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Abstract

- **Objective:** To develop, with nurse specialists and nursing home care staff, a theory
- 3 and evidence-informed pressure injury prevention care bundle for use in nursing
- 4 home settings.
- **Design:** The development of a care bundle.
- **Methods:** We undertook a detailed, multi-staged and theoretically-driven
- 7 development process. Firstly we identified evidence-informed pressure injury
- 8 prevention practices: these formed an initial set of possible target behaviours to be
- 9 considered for inclusion in the bundle. During a four-hour workshop and
- supplemental email consultation with a total of 13 healthcare workers, we agreed the
- 11 key target behaviours for the care bundle. We explored with staff the barriers and
- facilitators to prevention activity and defined intervention functions and behaviour
- change practices using the Behaviour Change Wheel.
- **Setting:** North West England.
- **Results:** The target behaviours consisted of three elements: support surfaces, skin
- inspection, repositioning. We identified capability, opportunity and reflective
- motivation as influencing the pressure injury prevention behaviours of nursing
- 18 home care staff. The intervention functions (education, training, modelling) and
- 19 behaviour change techniques (information about social and environmental
- 20 consequences; information on health consequences; feedback on behaviour; feedback
- on the outcome of behaviour; prompts/cues; instruction on how to perform the
- behaviour; demonstration of behaviour) were incorporated into the care bundle.

- **Conclusions:** This is the first description of a pressure injury prevention care bundle
- for nursing homes developed using the Behaviour Change Wheel. Key stakeholders
- 25 identified and prioritised the appropriate target behaviours to aid pressure injury
- 26 prevention in a nursing home setting.
- 28 Keywords

- 29 Pressure injury prevention; nursing homes; care bundle; nominal group technique;
- 30 behaviour change wheel; intervention development; complex intervention.

Article summary

32 Strengths and limitations of this study

- This study will inform the development of a novel intervention to support nursing home care staff to prevent pressure injury in residents.
- Integrating theory, research evidence and expert opinion into the care bundle should maximise the intervention's acceptability, feasibility and potential effectiveness.
- The pressure injury prevention care bundle is described in detail along with the intervention's potential mechanisms of action and the specific behaviour change techniques enhancing applicability and reproducibility.
- A number of experienced staff participated in the Nominal Group technique, but
 there was a limited number of tissue viability nurses who participated face-to face.

Background

45 Pressure injuries are areas of localised damage to the skin and underlying tissue [1].

They are caused by prolonged, or short but intense, periods of pressure or pressure

and shear. Pressure injury can lead to severe pain and distress, poor health-related

quality of life and serious complications such as gangrene and mortality [2-4].

Reducing and eliminating pressure injuries across all healthcare settings in the UK is a priority [5]. People at high risk of pressure injury include those who are seriously

ill, the elderly and those with impaired mobility [6, 7]. Thus many people living in

nursing homes are likely to be at an increased risk of pressure injury. Moreover, a

54 point prevalence survey of complex wounds (e.g., pressure ulcers, leg ulcers)

conducted in a northern UK city found 26% of individuals with a pressure ulcer (an

open wound caused by pressure) lived in residential or nursing homes [8].

Pressure injury prevention processes are shaped by national and international guidelines based on a synthesis of research findings and expert opinion [1, 9].

Current guidelines recommend a range of clinical interventions including: risk assessment, skin assessment, repositioning, correction of compromised hydration and nourishment, the use of pressure redistributing devices and barrier creams, training for

pressure injury prevention activities remains challenging, particularly in nursing

care staff and accurate monitoring and documentation. However the implementation of

65 homes where understaffing, high staff turnover and a lack of monitoring can result 66 in limited staff knowledge and inconsistent clinical care [10, 11].

Care bundles were first introduced by the Institute for Healthcare Improvement to improve the quality and consistency of care [12]. Care bundles comprise three to five evidence-informed clinical interventions (referred to as "elements"), which have the potential to improve patient outcomes when performed collectively and reliably. The Institute for Healthcare Improvement suggests that every eligible patient should receive all of the bundle elements unless medically contraindicated [12].

Care bundles aim to change the behaviour of healthcare workers, therefore the use of behaviour change theory is key [13]. Whilst several care bundles have been developed it is not always clear how they were developed or whether they were underpinned by theory [14]. There are multiple theories and frameworks for behaviour change, many with overlapping constructs [15, 16]. The Behaviour Change Wheel [15, 17] is a framework for designing behaviour change interventions and was developed to facilitate the integration of target behaviours, behaviour change theory and intervention development through a series of three key stages that can be subdivided into eight steps (Appendix 1). Thus, the Behaviour Change Wheel outlines a systematic and transparent approach to identify the appropriate

theory-based intervention content which may bring about change in the people who are its target (in this case, nursing home staff).

The COM-B model [17] forms the centre of the Behaviour Change Wheel [15, 17] and assists with understanding the behaviour in context (Stage 1 of intervention development). The COM-B model hypothesises that capability (C), opportunity (O) and motivation (M) all interact and can explain behaviour (B) and can become the focus for the behaviour change intervention. Within the COM-B model *capability* refers to the person's psychological and physical capacity to engage in the target behaviour. *Opportunity* refers to the factors that are external to the individual and influence the potential success of the behaviour (i.e. the physical environment or the social environment). *Motivation* involves the psychological processes that can trigger and direct behaviour, including reflective and automatic motivation.

Once the targets for change (e.g., physical opportunity) have been identified using the COM-B model, the second and third stages of the Behaviour Change Wheel focus on how intervention developers might facilitate change in these areas using intervention functions, policy categories, behaviour change techniques and modes of delivery. It is recommended that developers consider their intervention design using the APEASE criteria [15]. The APEASE criteria are used to guide the decisions on the intervention content and how to implement the intervention within a particular

setting [15, 17]. These criteria involve an assessment of: affordability; practicability; effectiveness and cost-effectiveness; acceptability; side-effects/safety; equity.

We were unable to identify any pre-existing pressure injury prevention care bundles designed for, and implemented in, nursing home settings. All of the published pressure injury prevention care bundles focus on acute hospital settings such as intensive care units and critical care units [18-23]. This paper describes the development of the first reported nursing home-specific pressure injury prevention care bundle. We aimed, with key stakeholders from nursing homes and the National Health Service (NHS), to co-produce a pressure injury prevention care bundle that is relevant to the nursing home context. We describe how the Behaviour Change Wheel was used to support the theory-driven processes in the design of the implementation plan for the care bundle. Figure 1 presents a logic model illustrating our knowledge and understanding at the start of this work and the outcomes we were aiming for. At the end of the work we aimed to design the components of the intervention (the "solution" in Figure 1).

Methods

125 Study design

We describe a two part care bundle development process. Part 1 used the Nominal Group technique [24] to gain consensus about the elements to include in the care

bundle. Part 2 followed the steps outlined in the Behaviour Change Wheel to facilitate the development of the implementation plan for the care bundle.

Participants

The study took place in the North West of England. Purposive sampling was used to recruit participants with relevant clinical and management experience and expertise. Participants were eligible to participate if they were a nursing homebased registered nurse (referred to from now on as a nurse), manager or healthcare assistant or a community-based tissue viability nurse. Written consent was gained from all participants.

Materials and procedures

Figure 2 presents a diagrammatical outline of the processes involved in developing the care bundle and how we applied the Behaviour Change Wheel processes here.

Stage1: Understanding the behaviours

Behaviour Change Wheel Step 1. Defining the problem in behavioural terms (pre-workshop)

We reviewed the pressure injury prevention literature to gain an understanding of
the main barriers to pressure injury prevention in nursing homes. We conducted a
systematic review that identified and explored existing care bundles and any
evidence for particular design features and behaviour change approaches that might
be associated with positive clinical outcomes [14].

Behaviour Change Wheel Steps 2 and 3. Selecting and specifying the target behaviours (care bundle development workshop)

These two steps involved the identification of care bundle elements (i.e. the specific

pressure injury prevention clinical interventions) and consideration of who, what, when, where and how often the care bundle elements should be delivered. We held a four hour interactive workshop with key stakeholders to identify the clinical interventions to assist with pressure injury prevention in nursing homes. There are several possible methods that can be drawn on for developing a care bundle. The Nominal Group technique was developed to facilitate the decision making of groups [24]. In essence we used the Nominal Group technique to gain consensus about the most important pressure injury prevention elements to be included in the care bundle. This approach is highly structured, usually delivered face-to-face; consisting of multiple rounds where items or questions are rated, discussed and re-rated by the expert panellists (e.g., nurses). This method minimises the effects of any dominant participants as all group members are provided with equal opportunities for voting.

We presented participants with an overview of the research-based international and national pressure injury prevention guidelines [1, 9]. We then discussed the guideline recommendations, focusing in particular on their applicability in a nursing home setting. All participants had the opportunity to add any clinical interventions they thought were missing from the guidelines before they began voting.

received the highest numbers of votes.

The Nominal Group process was explained and participants were split into two groups for voting purposes (i.e. healthcare assistants or registered nurses). Each participant within these groups was given five votes in the form of coloured stickers which they used to vote individually for their top three to five pressure injury prevention clinical interventions. The colour of the sticker indicated whether the voter was a nurse or healthcare assistant. We counted the votes in real time and presented the results to the participants to facilitate discussion prior to the second round of voting. In the case of a tie, we offered the participants one extra vote for one of the two tied clinical interventions. We invited participants to express their opinions on the clinical interventions and whether they believed clarification was required. Again, colour-coded stickers were used to cast votes in the second round. This round was used to finalise the agreement between participants [24]. The care bundle elements were agreed after a final discussion of the clinical interventions that

We then asked the workshop participants to specify the detail for each bundle element; the frequency with which they should be delivered, where and by whom and we asked participants to score the components of each element out of 10 (0 = not important, 10 = extremely important). Following the workshop, the care bundle elements and specific components were reviewed in line with existing research

evidence and cross-checked for validity by experts in the field such as tissue viability nurses.

Behaviour Change Wheel Step 4. Identifying what needs to change to enable the reliable delivery of pressure injury prevention clinical interventions We purposively recruited individuals who provide care for those at risk of developing pressure injuries in nursing homes and collected data from 25 participants (healthcare assistants (n = 7), registered nurses (n = 11), nurse managers (n = 3) and community-based tissue viability nurses (n = 4)). Using semi-structured interviews we explored the barriers and facilitators to pressure injury prevention [25] using the Theoretical Domains Framework [26]. The Theoretical Domains Framework comprises 14 domains that can be used to explore the determinants of professional behaviour change and inform intervention design (e.g., knowledge, social influences, beliefs about consequences) [26]. Each of the 14 Theoretical Domains Framework domains can be mapped onto the COM-B model [15, 17] to facilitate understanding of healthcare workers' behaviours within a particular context. We analysed the data deductively, using the Theoretical Domains Framework and identified the behavioural and psychological influences on pressure injury prevention by mapping the salient barriers and facilitators identified onto the

Stages 2 and 3: Identifying the intervention content and implementation options

COM-B model, using the guidance provided by the Behaviour Change Wheel [15].

Behaviour Change Wheel Steps 5-8. Identifying the intervention functions, policy categories,

behaviour change techniques and modes of delivery We mapped those components of the COM-B model identified as being relevant to pressure injury prevention in nursing homes (Step 4) onto the matrices provided in the Behaviour Change Wheel, and this informed our plan for implementing the care bundle. In addition, the Behaviour Change Technique Taxonomy Version 1 [27] informed our choice of behaviour change techniques (step 7). The Behaviour Change Technique Taxonomy Version 1 [27] comprises 93 behaviour change techniques and can be used to identify intervention components, enabling the standardisation of terms as well as the comparison of behaviour change techniques across studies. We applied the APEASE criteria [15] for designing and evaluating interventions to each of the relevant implementation aspects to guide our judgements in selecting the most appropriate intervention functions, policy categories, behaviour change techniques and modes of delivery likely to support the successful implementation of the care bundle.

To ensure the implementation plan was suitable, we held discussions individually with the nursing home care staff, tissue viability nurses and academic researchers before we finalised the care bundle. These discussions were based on the 'modelling' guidance provided by the UK Medical Research Council's guidance for developing and evaluating complex interventions [13] which includes: who should receive the

intervention; how changes to practice are usually introduced; what the barriers to change might be and how delivery can be documented.

Patient and public involvement

Nursing home residents and the public were not involved in the development of the care bundle.

Results

Behaviour Change Wheel Stage 1: Understanding the behaviours

Behaviour Change Wheel Step 1. Defining the problem in behavioural terms (pre-workshop)

Our review of the literature identified that understaffing, high turnover and limited staff knowledge are commonly reported as barriers to pressure injury prevention [10, 11] and that good communication and positive attitudes to pressure injury prevention are described as facilitators [28-30]. In addition, central to the prevention of pressure injuries is the belief that the actions of healthcare workers (e.g., repositioning) directly influence the development of pressure injuries [31].

Consequently, care bundles may be an effective tool to improve the implementation of guidelines and evidence-informed practices [14].

Within our systematic review we were not able to conduct a meta-regression of study features or explore the magnitude of effects as there were insufficient comparisons involving patient outcomes. Consequently, we conducted subgroup

analyses. We found that all care bundles (regardless of the number of elements) reduced the risk of the negative patient outcomes and the apparent effect of care bundles appeared to reduce as the number of elements increased. The lowest risk for the negative patient outcomes was in the subgroup with 'eight behaviour change techniques'. However, we considered these data to be of very low quality. Our findings from the systematic review are reported in detail elsewhere [14].

Behaviour Change Wheel Steps 2 and 3. Selecting and specifying the target behaviours (care

bundle development workshop)

years to 13 years).

Ten participants attended the workshop, including one tissue viability nurse and staff from one nursing home (four healthcare assistants and five registered nurses). A further three tissue viability nurses were unable to attend the workshop but participated in email (n = 2) or face-to-face (n = 1) consultations, which followed the processes outlined in the methods section as closely as possible. The participants' ages ranged from 26 to 55 years, one participant was male and one had previously attended wound care training. The median years of experience in working with people at risk of developing pressure injuries was 11 years (interquartile range: 1.4

During the discussion prior to round one, it was agreed that 'pain management' should be added as a clinical intervention, and nutrition and hydration should be separated into two. The clinical interventions voted for in round one by each group

differed (Table 1). For example the healthcare assistants did not vote for skin assessment, whereas 80% of the nurses (4/5) and 75% of the tissue viability nurses (3/4) did. Similarly, 75% of the healthcare assistants (3/4) and 50% of the tissue viability nurses (2/4) voted for *support surfaces* to be included but the nurses did not. During the discussion the nurses explained that they did not select *support surfaces* as a key clinical intervention as they felt that pressure redistributing devices covered this (although this only received one vote from the nurses' group). Further discussion resulted in reuniting nutrition and hydration as all nursing home participants explained that they offer these together. Consequently, six clinical interventions went through to the second round of voting (skin care, continence care, skin assessment, repositioning, nutrition and hydration and support surfaces). ign.

Table 1Votes from rounds one and two from each healthcare staff group

	Healthcare		Tissue	Overall
	assistants	Nurses	viability	percentage of
Clinical intervention	(n = 4)	(n = 5)	nurses $(n = 4)$	votes
Voting round 1				
Nutrition	1	4	4	69%
Hydration	2	4	0	31%
Skin care	2	1	1	38%
Support surfaces	3	0	2	46%
Repositioning	3	5	4	92%
Continence care	4	5	4	100%
Pressure redistributing	1	1	2	31%
devices				
Skin assessment	0	4	3	54%
Pain	0	0	0	0%
Barrier cream	0	0	0	0%
77 d				
Voting round 2				
Skin care	2	4	1	45%
Continence care	4	4	4	92%
Skin assessment	0	3	3	46%
Repositioning	4	5	4	100%
Nutrition and	4	5	4	100%
hydration				
Support surfaces	0	0	4	31%
-				

Repositioning, skin assessment, skin care, continence care and nutrition and hydration were

voted into the top five in round two (Table 1). Every tissue viability nurse voted for

support surfaces; whereas the healthcare assistants considered support surfaces to be important but embedded within *repositioning*, and this was reflected in their voting. Through discussion the participants agreed that including *support surfaces* as an element separate from repositioning was important and support surfaces should also incorporate *pressure redistributing devices*. Whilst the participants deemed *nutrition* and hydration and continence care important, they agreed that only those residents with inadequate nutrition and hydration require additional nutrition and fluid [9]; therefore, this element would be redundant for some individuals (making the care bundle more of a checklist). Participants believed that continence care was a separate, complex issue; requiring a number of detailed steps to prevent damage to skin integrity and likely to require its own care bundle [32]. Consequently participants decided that providing and monitoring such clinical interventions are part of basic care and should not be included in a specific pressure injury prevention bundle. The skin care and skin assessment clinical interventions were merged and three elements made up the care bundle: support surfaces, skin inspection and repositioning.

Participants ranked, in order of perceived importance, the components required to ensure the accurate and consistent completion of each of the care bundle elements.

All participants agreed that residents should receive a monthly pressure injury risk assessment to trigger the activation of the care bundle for those at risk of developing a pressure injury. However, more frequent assessments may be warranted for some

residents at high risk of pressure injury development or if there is a change in a resident's clinical status. The frequency with which the elements of care are to be delivered will be informed by the risk assessment, although the risk assessment was separate from the care bundle. It was agreed that the nursing home care staff should complete and document every element of the care bundle for all residents deemed to be at risk of developing a pressure injury, and where an element cannot be completed a reason must be provided (e.g., where a resident has refused to be repositioned).

Behaviour Change Wheel Step 4. Identifying what needs to change to enable the reliable delivery of pressure injury prevention clinical interventions

The semi-structured interview data (reported elsewhere [25]), when mapped on to the COM-B model, suggested the following factors as influences on the prevention of pressure injury in nursing home settings: psychological and physical capability; physical and social opportunity; and reflective motivation. We found that improvements in pressure injury prevention knowledge and skills are required. In particular, the tissue viability nurses could provide information about, and training on, pressure injuries and how to prevent them within a nursing home context; but the nursing home care staff need to be permitted to attend this training. In addition there appears to be scope to increase the use and documentation of evidence-informed pressure injury prevention interventions. Pressure injury prevention interventions

need to be conducted in line with the resident's risk of developing a pressure injury. If it is not possible to complete an aspect of care, this must be documented. Behaviour Change Wheel Stage 2: Identifying the intervention content and implementation options We used the Behaviour Change Wheel to define the key intervention functions and policy categories that could be used to improve pressure injury prevention in nursing homes using the relevant COM-B components identified in Step 4. Step 5: Intervention functions The three most suitable intervention functions were education, training and modelling (i.e. providing a role model such as a skin champion). Increasing the knowledge of the nursing home care staff and improving their skills through education and training is a crucial aspect to facilitating the prevention of pressure injury in nursing home residents. The inclusion of skin champions should assist with accessing training and education as these can be delivered in-house by the skin champion. Step 6: Policy categories The policy categories most suitable for achieving the behaviour change included communication/marketing (e.g., posters), guidelines, regulation and service provision.

Step 7: Behaviour change techniques

Using the Behaviour Change Technique Taxonomy Version 1 [27] (which is a taxonomy of 93 behaviour change techniques) together with the findings from our systematic review, we selected the seven techniques we believed were most suitable to facilitate behaviour change and support prevention practices (information about social and environmental consequences; information on health consequences; feedback on behaviour; feedback on the outcome of the behaviour; prompts/cues; instruction on how to perform the behaviour; demonstration of behaviour).

Step 8: Mode of delivery

We then formulated a plan regarding how and by whom the care bundle would be implemented in practice and this was based on the discussions held with key stakeholders. The delivery of the care bundle will differ at specific stages and the key modes of delivery are specified in Table 2 (e.g., the tissue viability nurses will deliver the face-to-face group training to address the *capability* of nursing home care staff as identified through the COM-B model in Stage 1).

Table 2. *Implementation plan for pressure injury prevention care bundle*

What	Why	Who	How/frequency	Where
Fraining and education: on risk factors, pressure injury prevention, equipment, outcomes, protocols.	Access to training was identified as a barrier to pressure injury prevention in nursing homes. To improve pressure injury prevention knowledge and skills in nursing home care staff (registered and unregistered). We identified the following two BCTs as important components of the intervention: information about social and environmental consequences' and 'information on health consequences'.	Provided by a tissue viability nurse to nursing home care staff (registered and unregistered).	Training will be provided one week prior to the implementation of the care bundle and will be a one-off face-to-face, three hour interactive group session. Presentation using PowerPoint and printed materials will be provided to the staff who attend and also to the nursing home for staff who are unable to attend. Additional training sessions will be offered to the nursing home care staff to maximise attendance.	Due to practical reasons, training will be held off-site Written training materials will be available in the nursing home.
 on the care bundle and each individual element (support surfaces, skin inspection, repositioning), and how to use the care bundle in practice. 	To increase the uptake of the care bundle, to familiarise staff with the processes involved.	Provided to nursing home care staff (registered and unregistered) by a researcher with expertise in behaviour change.	Face-to-face one hour interactive group session. PowerPoint and printed materials will be provided to staff who attend and also to the nursing home for staff who are unable to attend.	

381 Table 2

382 (*Cont.*)

What	Why	Who	How/frequency	Where
Modelling and	The skin champions will	Nursing home care	This is available face-to-face and is likely	Nursing home.
demonstration of	deliver the care bundle	staff (likely to be a	to be delivered on an individual basis and	
behaviour:	as intended and will be	registered nurse).	will be available as required.	
- skin champions	available during a shift.		The researcher will meet with the skin	
	Staff can speak with the		champions at least bi-weekly to discuss	
	skin champions if they		any issues or concerns.	
	have any concerns or			
	queries. Skin champions			
	are also able to			
	demonstrate pressure			
	injury prevention			
	techniques and provide			
	examples of good record			
	keeping (i.e.			
	documentation).			
Implementation of the care			Uh ,	
bundle:				
- risk assessment	To identify any risk	Registered nurse	Using a validated risk assessment tool, the	Nursing home.
	factors for the	and/or nursing	risk assessment will be completed at least	
	development of a	home manager.	monthly. If there is a change to a	
	pressure injury and		resident's clinical status, the risk	
	indicate the frequency		assessment should be conducted again.	
	with which the care			
	bundle needs to be			
	delivered.			

384 Table 2

385 (*Cont.*)

What	Why	Who	How/frequency	Where
Implementation of the care				
bundle:				
- complete care bundle for each eligible resident (support surfaces, skin inspection, repositioning).	To improve the reliability of care and to prevent pressure injuries using elements identified locally as being important within a nursing home context. To improve the documentation of pressure injury prevention practices.	Nursing home care staff (registered and unregistered).	Nursing home care staff will complete each element of care included within the care bundle. If it is not possible to conduct all of the elements (<i>support surfaces</i> , <i>skin inspection</i> , <i>repositioning</i>) within the care bundle, this must be documented on the overleaf section of the care bundle documentation sheet. The frequency with which this needs to be conducted will depend on each individual resident. The frequency should be amended in line with a resident's needs and risk. For example, for those at risk of developing a pressure injury it should be at least every 6 hours, at least every 4 hours for those at a high risk, and at least every 2 hours for those at a very high risk. Staff are required to ensure the appropriate pressure relieving equipment is being used and is functioning.	Nursing home.

 388 Table 2

389 (*Cont.*)

What	Why	Who	How/frequency	Where
Prompts and cues	An aide memoire was	The research team	The unit manager will decide the	Nursing home
	reported as a facilitator of	will provide posters	positioning of the posters on the unit (see	(including
	pressure injury	and care bundle	Appendix 2). The nursing home staff are	nursing office,
	prevention in nursing	documentation.	responsible for the completion of the care	residents'
	homes. Thus, posters will		bundle and associated documents. These	bedrooms,
	be placed in staff		will be available daily throughout the	residents' files
	communal areas (e.g.,		study period.	
	nursing office) to remind			
	staff of the steps involved			
	within the care bundle.			
	The care bundle itself			
	also acts as a checklist as			
	staff are required to			
	document the provision			
	of care on the care			
	bundle sheets.			

395 Table 2

396 (*Cont.*)

What	Why	Who	How/frequency	Where
Feedback:	To maintain motivation and engagement with the care bundle.			
- on behaviours and outcomes.	To highlight areas of pressure injury prevention where staff are maintaining high levels of care and the areas that could be improved.	Researcher	The research team will provide verbal feedback to the unit manager on a monthly basis during the study period. This will include the number of pressure injuries acquired and adherence to the care bundle. Feedback will be provided in the form of percentages on the following: - All-or-none compliance (when all aspects of the care bundle were delivered, including times when it was not possible to complete the care bundle but reasons were documented); - Overall adherence with each individual element: support surfaces, skin inspection, repositioning. Following the completion of the study, the above information will be collated and the findings from the whole study period will be presented verbally to the unit manager and nursing home care staff.	Nursing hom

Discussion

This is the first explicit, behaviour change theory-driven, pressure injury prevention care bundle that we have been able to identify. We identified the important elements of the care bundle in collaboration with key stakeholders. Using the COM-B model and with the steps outlined in the Behaviour Change Wheel we developed a pressure injury prevention care bundle that focused on the three identified target behaviours (the checking of support surfaces, skin inspection and repositioning). The broad functions of the intervention (education, training, modelling) aim to be achieved using seven theoretically-based behaviour change techniques delivered using a variety of methods, including face-to-face and written materials. This information can be used to populate the solutions box in Figure 1 in the introduction (Figure 3). Three main aspects of pressure injury prevention that consistently feature in care bundles were included within our nursing home care bundle, albeit operationalised differently: repositioning, skin assessment and the use of support surfaces [18-20,33]. However, our care home-focused intervention differs from those delivered in hospital settings as we did not incorporate continence care or nutrition and hydration; mainly because they were deemed core aspects of nursing care that should be prioritised irrespective of any tenuous link with pressure injury prevention. Whilst our care bundle elements reflect those included in hospitalfocused bundles, the process of deciding how to promote the behaviour changes around these target behaviours has not been clear in previous work. We supported

this work using a strong theoretical framework for intervention design. Through the transparent reporting of the mechanisms of action, modes of delivery and the theoretical constructs, future evaluations of the effectiveness of this care bundle will be possible.

Strengths and limitations

The theoretical basis and systematic presentation of the development of the care bundle is a strength of our study. The empirical work revealed the target behaviours required (i.e. checking of support surfaces, skin inspection, repositioning) and the Behaviour Change Wheel identified the implementation interventions suitable for the care bundle. Previous studies detailing pressure injury prevention care bundles [18,20] have not provided such explicit and transparent methods, which may limit the understanding of the mechanisms of action and causal relationships within the interventions [34]. Thus the present study addresses these concerns, facilitating subsequent evaluations and future replications.

The use of the Nominal Group technique to develop the care bundle was beneficial for many reasons. The participation of the nursing home care staff and the NHS tissue viability nurses was vital to ensure the integration of specialist knowledge alongside context specific expertise. The Nominal Group technique enabled each participant to express their view (via individual votes) which minimised the effects of any potentially dominant participants. Using the Nominal Group technique

during the workshop was advantageous as it yielded extensive and rich data in a relatively short period of time.

A limitation was the exclusion of residents and their families, as well as the wider multidisciplinary team (e.g., podiatrists, dieticians); and the inclusion of only one nursing home and the relatively small number of tissue viability nurse workshop participants. Expert opinion is a fundamental aspect of the Nominal Group technique, and whilst the majority of the participants who did attend had a range of expertise in caring for individuals residing in nursing homes, specialist nurse input was crucial. Initially all of the local tissue viability nurses agreed to attend however, due to unforeseen circumstances, some could not. Consequently, the process was repeated with the tissue viability nurses via face-to-face meetings or online consultations to ensure their specialist knowledge of the prevention of pressure injuries could be combined with the results. We believe that taking such a systematic and structured approach to designing the care bundle will result in a more effective intervention and will aid subsequent evaluations and improvements.

Future research

The next phase of this research is to test the feasibility of implementing the care bundle in a nursing home context. If the care bundle intervention is feasible and acceptable to nursing home care staff, further evaluation will be necessary to assess the clinical and cost-effectiveness. The explicit theoretical links provided through the

use of the Behaviour Change Wheel [15, 17] and Behaviour Change Technique

Taxonomy Version 1 [27] will facilitate future replications and data synthesis. In

addition, exploring the views of residents, their families and the wider

multidisciplinary team will be vital to ensure that a holistic approach is taken to the

prevention of pressure injuries in nursing home residents.

Conclusion

Care bundles have received much attention within inpatient settings over the past decade due to the potentially synergistic effect of incorporating several clinical interventions within one package. The structure of care bundles can be used to facilitate reliable and sustainable changes in the work habits of staff. However, few theory-informed care bundles are reported within the literature. This paper describes how a pressure injury prevention care bundle was developed for use in UK nursing homes and how the Behaviour Change Wheel guided the development of the intervention. Key stakeholders contributed to the design of the care bundle, forging the first step towards standardising pressure injury prevention practices within nursing home settings. Whilst preventing pressure injuries in nursing home residents is complex and multifaceted, this structured and transparent approach has facilitated a thorough process for the development of the intervention. The next step is to assess the feasibility of implementing this care bundle within the nursing home environment to ensure that it is acceptable before wider evaluation ensues.

486	Abbreviations
487	PI: pressure injury
488	TVN: tissue viability nurse
489	BCW: Behaviour Change Wheel
490	
491	Figure legends
492	Figure 1; Logic model for the pressure injury prevention care bundle outlining the
493	consequences of pressure injury in nursing homes, the potential behavioural causes
494	of pressure injury and the pathway to benefit through preventing pressure injury.
495	Figure 2; Data collection and analysis processes used to develop the care bundle
496	using the steps and stages outlined in the Behaviour Change Wheel.
497	Figure 3; Solutions box for Figure 1detailing the content of the pressure injury
498	prevention care bundle and the steps required to implement the care bundle in
499	nursing homes.
500	
501	Additional files
502	Appendix 1; Behaviour Change Wheel stages and steps [11]; an overview of the
503	Behaviour Change Wheel.
504	Appendix 2; Care bundle poster (.txt 464KB)
505	

Ethics approval and consent to participate

This study was given approval by The University of Manchester (ref: 15451),
together with approval from the Research and Development department at the
participating NHS site (ref: 100321).
Consent for publication
Not applicable.
Availability of data and material
All data relevant to the study are included in the article or uploaded as
supplementary information.
Competing interests
The authors declare that they have no competing interests.
The authors declare that they have no competing interests.
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CLAHRC) Greater Manchester.
Author contributions
NC had the original research idea. JL, TG, JD, NC conceived the idea and design for
the overall project. JL developed the standard operating procedures for the
workshop and held the email/face-to-face consultations with the tissue viability

nurses. TG facilitated the workshop. All authors contributed to the interpretation of

study findings, critical revision of the manuscript for important intellectual content and approval of the final manuscript.

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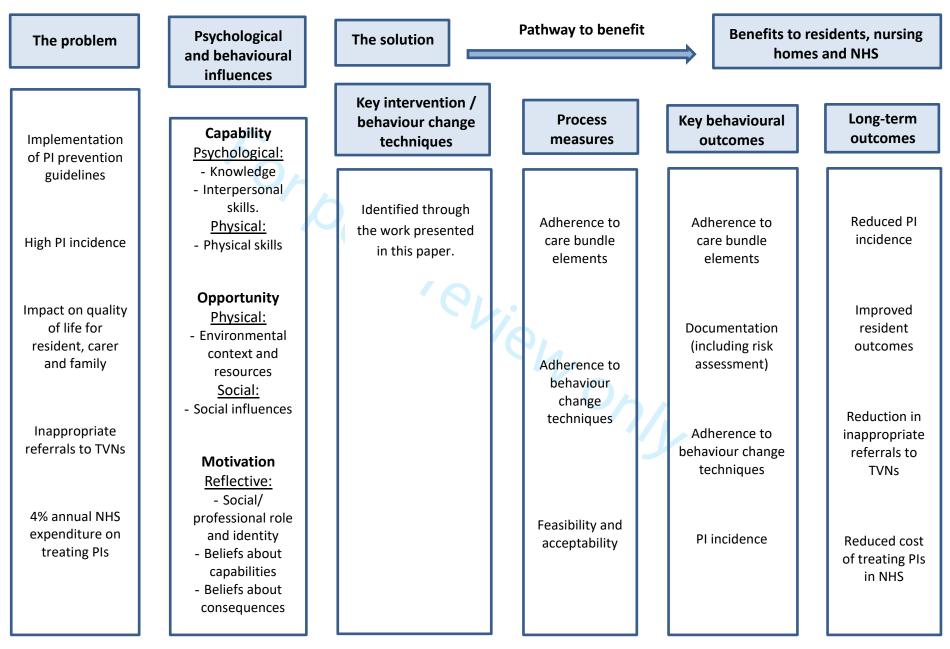
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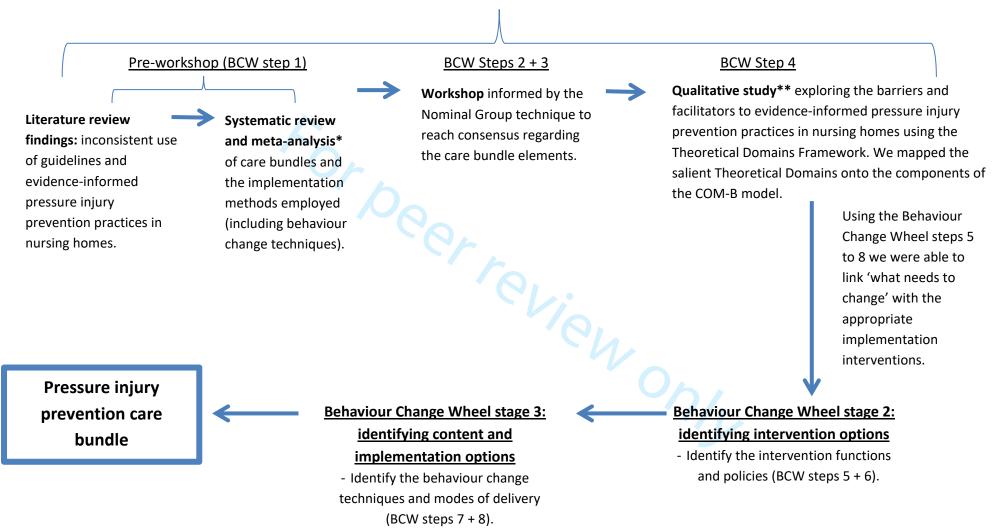
References

- 1. Haesler E: National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. *Prevention and treatment of pressure ulcers: quick reference guide[Internet]* 2014.
- 2. Allman RM: Pressure ulcer prevalence, incidence, risk factors, and impact. *Clinics in Geriatric Medicine* 1997, **13**:421-&.
- 3. Keen DC: Should care homes adopt a static-led approach to pressure ulcer prevention? British journal of nursing (Mark Allen Publishing) 2009, **18**:S4, S6, S8, passim.
- 4. Essex HN, Clark M, Sims J, Warriner A, Cullum N: Health-related quality of life in hospital inpatients with pressure ulceration: Assessment using generic health-related quality of life measures. Wound Repair and Regeneration 2009, **17**:797-805.
- 5. Harms in the NHS [https://www.gov.uk/government/news/qipp-national-workstreams-updated]
- 6. Coleman S, Gorecki C, Nelson EA, Closs SJ, Defloor T, Halfens R, Farrin A, Brown J, Schoonhoven L, Nixon J: Patient risk factors for pressure ulcer development: Systematic review. *International Journal of Nursing Studies* 2013, **50**:974-1003.
- 7. Moore Z, Cowman S: Pressure ulcer prevalence and prevention practices in care of the older person in the Republic of Ireland. *Journal of clinical nursing* 2012, **21**:362-371.
- 8. Hall J, Buckley HL, Lamb KA, Stubbs N, Saramago P, Dumville JC.Cullum N: Point prevalence of complex wounds in a defined United Kingdom population. *Wound Repair and Regeneration* 2014, **22:**694-700.
- 9. Pressure ulcers: prevention and management [cg179] [https://www.nice.org.uk/guidance/cg179]
- 10. Demarré L, Vanderwee K, Defloor T, Verhaeghe S, Schoonhoven L, Beeckman D: Pressure ulcers: knowledge and attitude of nurses and nursing assistants in Belgian nursing homes. *Journal of clinical nursing* 2012, **21**:1425-1434.
- 11. Donoghue C: Nursing home staff turnover and retention: An analysis of national level data. Journal of Applied Gerontology 2009.
- 12. Resar R, Griffin F, Haraden C, Nolan T: Using care bundles to improve health care quality. *IHI Innovation Series white paper Cambridge, Massachusetts: Institute for Healthcare Improvement* 2012.
- 13. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M: Developing and evaluating complex interventions: the new Medical Research Council guidance. *Bmj* 2008, **337**:a1655.
- 14. Lavallée JF, Gray TA, Dumville J, Russell W, Cullum N: The effects of care bundles on patient outcomes: a systematic review and meta-analysis. *Implementation Science* 2017, **12**:142.
- 15. Michie S, Atkins L, West R: The behaviour change wheel: a guide to designing interventions. *Needed: physician leaders* 2014:26.
- 16. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A: Making psychological theory useful for implementing evidence based practice: a consensus approach. *Quality and safety in health care* 2005, **14**:26-33.
- 17. Michie S, van Stralen MM, West R: The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implementation science* 2011, **6**:42.
- 18. Anderson M, Finch Guthrie P, Kraft W, Reicks P, Skay C, Beal AL: Universal Pressure Ulcer Prevention Bundle With WOC Nurse Support. *Journal of Wound, Ostomy, & Continence Nursing* 2015, **42**:217-225.
- 19. Baldelli P, Paciella M: Creation and implementation of a pressure ulcer prevention bundle improves patient outcomes. *American Journal of Medical Quality* 2008, 23:136-142.

- 20. Boesch RP, Myers C, Garrett T, Nie A, Thomas N, Chima A, McPhail GL, Ednick M, Rutter MJ, Dressman K: Prevention of tracheostomy-related pressure ulcers in children. *Pediatrics* 2012, **129**:e792-797.
- 21. Chaboyer W, Bucknall T, Webster J, McInnes E, Gillespie BM, Banks M, Whitty JA, Thalib L, Roberts S, Tallott M, et al: The effect of a patient centred care bundle intervention on pressure ulcer incidence (INTACT): A cluster randomised trial. *International Journal of Nursing Studies* 2016, **64**:63-71.
- 22. Gray-Siracusa K, Schrier L: Use of an Intervention Bundle to Eliminate Pressure Ulcers in Critical Care. *Journal of Nursing Care Quality* 2011, **26**:216-225.
- 23. Schindler CA: More than S.K.I.N. deep: Decreasing pressure ulcer development in the pediatric intensive care unit. Marquette University, 2010.
- 24. Van de Ven AH, Delbecq AL: The nominal group as a research instrument for exploratory health studies. *American Journal of Public Health* 1972, **62**:337-342.
- 25. Lavallée JF, Gray TA, Dumville JC, Cullum N: Barriers and facilitators to preventing pressure ulcers in nursing home residents: a qualitative analysis informed by the Theoretical Domains Framework. *International Journal of Nursing Studies* 2018, **82**:79-89.
- 26. Cane J. O'Connor D, Michie S: Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science* 2012, **7**:37-53.
- 27. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, Eccles MP, Cane J, Wood CE: The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Annals of Behavioral Medicine* 2013, **46**:81-95.
- 28. Dellefield ME, Magnabosco JL: Pressure ulcer prevention in nursing homes: Nurse descriptions of individual and organization level factors. *Geriatric Nursing* 2014, **35**:97-104.
- 29. Hartmann CW, Solomon J, Palmer JA, Lukas CV: Contextual Facilitators of and Barriers to Nursing Home Pressure Ulcer Prevention. *Advances in skin & wound care* 2016, **29**:226.
- 30. Worsley PR, Smith G, Schoonhoven L, Bader DL: Characteristics of patients who are admitted with or acquire Pressure Ulcers in a District General Hospital; a 3 year retrospective analysis. *Nursing Open* 2016, **3**:152-158.
- 31. Black JM, Edsberg LE, Baharestani MM, Langemo D, Goldberg M, McNichol L, Cuddigan J: Pressure ulcers: avoidable or unavoidable? Results of the national pressure ulcer advisory panel consensus conference. *Ostomy-Wound Management* 2011, **57**:24.
- 32. Continence promotion care bundle 2017.
 [https://www.health.org.uk/programmes/innovating-improvement/projects/using-continence-promotion-measures-improve-continence]
- 33. Gibbons W, Shanks HT, Kleinhelter P, Jones P: Eliminating facility-acquired pressure ulcers at Ascension Health. *The joint commission journal on quality and patient safety* 2006, **32**:488-496.
- 34. Soban LM, Hempel S, Munjas BA, Miles J, Rubenstein LV: Preventing pressure ulcers in hospitals: a systematic review of nurse-focused quality improvement interventions. *The Joint Commission Journal on Quality and Patient Safety* 2011, **37**:245-AP216.



Behaviour Change Wheel stage 1: understand the behaviour



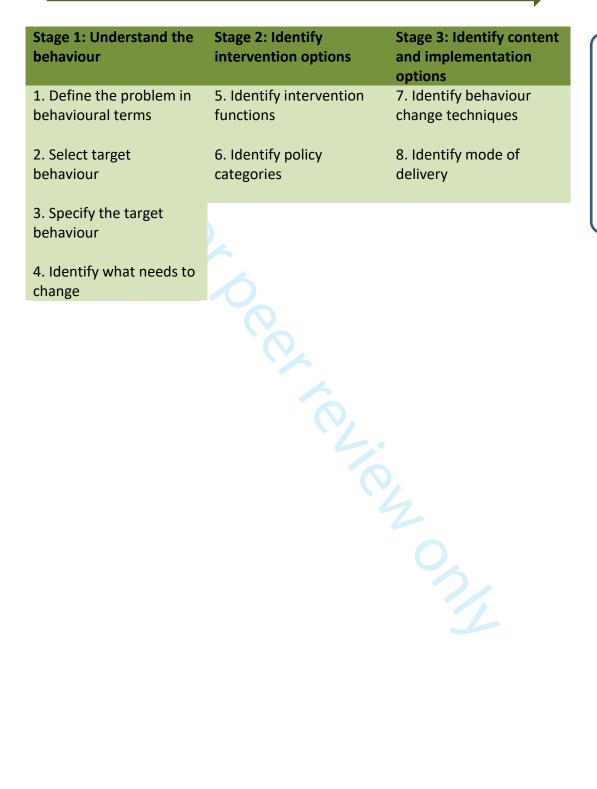
*Methods and findings reported in [14]; **methods and findings reported in [25].

Care bundle elements:

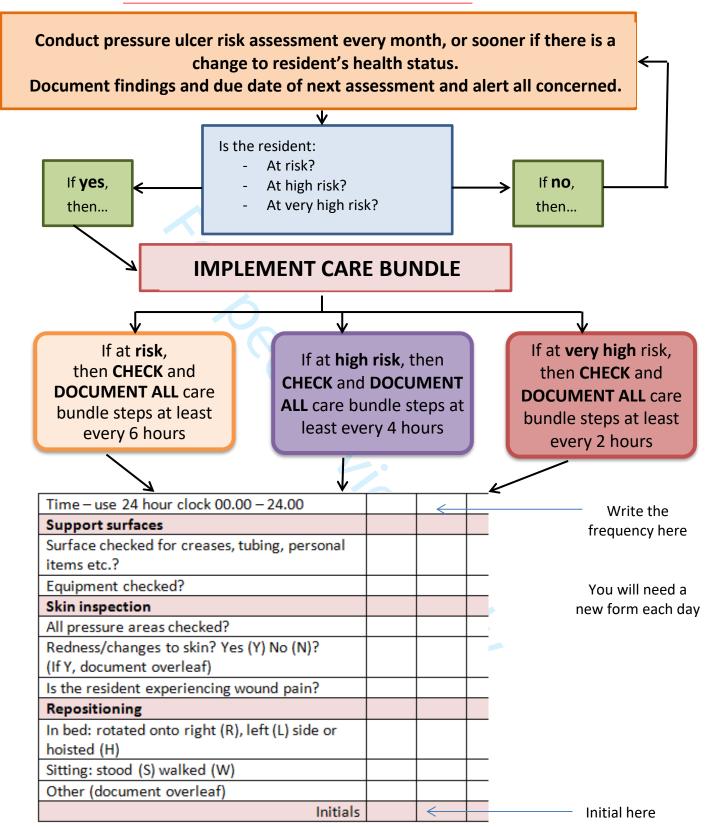
- Support surfaces
- Skin inspection
- Repositioning

Behaviour change techniques:

- Information about social and environmental consequences
- Information on health consequences
- Feedback on behaviour
- Feedback on the outcome of the behaviour
- Prompts/cues
- Instruction on how to perform the behaviour
- Demonstration of behaviour



Pressure Ulcer Prevention Care Bundle



All Care Staff PLEASE READ and ensure all residents 'at risk' have forms in their room. Please ask the nurse in charge to explain if unsure



The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item	Item	Where Id	Where located **	
number		Primary paper	Other [†] (details)	
		(page or appendix		
		number)		
	BRIEF NAME			
1.	Provide the name or a phrase that describes the intervention.			
	WHY	Abstract, page 2		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.			
	WHAT	Page 7		
3.	Materials: Describe any physical or informational materials used in the intervention, including those			
	provided to participants or used in intervention delivery or in training of intervention providers.			
	Provide information on where the materials can be accessed (e.g. online appendix, URL).	Pages 9-11		
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention,			
	including any enabling or support activities.			
	WHO PROVIDED	Pages 9-11		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their			
	expertise, background and any specific training given.			
	HOW	Page 8		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or			
	telephone) of the intervention and whether it was provided individually or in a group.			
	WHERE	Page 18, table 2		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary			
	infrastructure or relevant features.			

	Abstract, page
WHEN and HOW MUCH	13
Describe the number of times the intervention was delivered and over what period of time including	
the number of sessions, their schedule, and their duration, intensity or dose.	
TAILORING	Page 15, table 2
If the intervention was planned to be personalised, titrated or adapted, then describe what, why,	
when, and how.	
MODIFICATIONS	Page 15
. [‡] If the intervention was modified during the course of the study, describe the changes (what, why,	
when, and how).	
HOW WELL	N/A
. Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any	
strategies were used to maintain or improve fidelity, describe them.	
.* Actual: If intervention adherence or fidelity was assessed, describe the extent to which the	N/A
intervention was delivered as planned.	N/A

^{**} **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

TIDieR checklist

[†] If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

[‡] If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

^{*} We strongly recommend using this checklist in conjunction with the TIDieR guide (see BMJ 2014;348:g1687) which contains an explanation and elaboration for each item.

^{*} The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a randomised trial is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of ttem 5 of the CONSORT 2010 Statement. When a clinical trial protocol is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of ttem 11 of the SPIRIT 2013
Statement (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).