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ORIGINAL ARTICLE

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Using a theoretically informed process evaluation alongside a trial to improve oral health for care home residents

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Background: Poor oral health is common among older adults residing in care homes impacting their diet, quality of life, self-esteem, general health and well-being. The care home setting is complex and many factors may affect the successful implementation of oral care interventions. Exploring these factors and their embedded context is key to understanding how and why interventions may or may not be successfully implemented within their intended setting.

Objectives: This methodology paper describes the approach to a theoretically informed process evaluation alongside a pragmatic randomised controlled trial, so as to understand contextual factors, how the intervention was implemented and important elements that may influence the pathways to impact.

Materials and methods: SENIOR is a pragmatic randomised controlled trial designed to improve the oral health of care home residents in the United Kingdom. The trial uses a complex intervention to promote and provide oral care for residents, including education and training for staff.

Results: An embedded, theoretically informed process evaluation, drawing on the PAHRIS framework and utilising a qualitative approach, will help to understand the important contextual factors within the care home that influence both the trial processes and the implementation of the intervention.

Conclusion: Utilising an implementation framework as the basis for a theoretically informed process evaluation provides an approach that specifically focuses on the contextual factors that may influence and shape the pathways to impact a given complex intervention a priori, while also providing an understanding of how and why an intervention may be effective. This contrasts with the more common post hoc approach that only focuses on implementation after the empirical results have emerged.

KEYWORDS
care home residents, complex interventions, implementation, oral health, process evaluation, randomised controlled trials

1 | INTRODUCTION

When evaluating complex interventions using experimental designs, care should be taken to understand contextual factors that may affect the implementation of any given intervention.[1] This is particularly relevant for randomised controlled trials (RCT) in order to understand trial processes, explain how and why the active arm may be effective or not and understand any factors that influence the potential pathways to impact.[1] This methodology paper describes the approach to a theoretically informed process evaluation alongside a pragmatic RCT in a care home setting, in order to understand contextual factors, how the intervention was implemented and important elements that may influence the pathways to impact. The care home setting can be challenging due to the availability, turnover and training of staff, time constraints and issues arising due to the cognitive decline of residents. The "uSing rolE-substitutioN In care hOmes to improve oRal health" (SENIOR) pragmatic RCT is an empirical study to determine if a complex intervention using Dental Therapists (DTs) and Dental Nurses (DNs) can reduce plaque levels (improve oral cleanliness) of dentate older adults in care homes over a 6-month period, compared to "treatment as usual". In the United Kingdom, DTs can undertake simple restorations. Both DTs and DNs have a preventive focus, and are able to apply fluoride varnish and advise on the use of high-strength fluoride toothpaste, when prescribed by a dentist.

A well-planned process evaluation enables researchers to account for the importance of context and provides helpful information on any subsequent adaptation of the interventions, and in turn, facilitates implementation.[1] The use of qualitative methods, can provide insight into the contexts, mechanisms and outcomes associated with any given intervention and the perspectives of different stakeholders involved.[1,2] In this sense, process evaluations "show how and why interventions work or not, as opposed to merely evaluating whether they work or not".[3] However, all too often, they are framed as supplementary processes and are assumed to be simple and secondary, with primacy being placed on the quantitative and more empirical aspects of trial design and conduct.[4] Process evaluations should be rigorous and theoretically informed, such that they complement and triangulate findings from the quantitative trial phase that they run parallel to.[4] Qualitative approaches should be embedded from the outset and used to further inform the design and conduct of the trial, the interpretation of the findings and understanding of potential factors that influence pathways to impact.[4] RCTs in oral health will specifically benefit from the inclusion of theoretically informed process evaluations involving qualitative methods. This is especially relevant as the interventions and contexts become more complex such as those designed to improve oral health in non-clinical environments. Engagement from key stakeholders, including healthcare professionals, commissioners, but also other professionals central to oral health interventions in the population group of interest, and service users, should be encouraged so that they adopt active roles in the co-design of interventions and services for those who are intended to use them.[5] Interventions are often likely to require adaptation in some way to ensure they are "fit for purpose" in the system in which they are to be implemented. As such, it makes sense to include stakeholder representation in all aspects of the trial from the initial design, to delivery, to implementation.[6] To understand the complexity of interventions in context, we need to understand different stakeholders' perspectives, so that research designs also focus on how different stakeholders and systems work together.[6]

The UK Medical Research Council (MRC) has replaced previous guidance regarding the development and evaluation of complex interventions with a new framework.[7] While previous guidelines were focussed only on the effectiveness of the intervention, the most recent MRC Framework highlights the need to concomitantly focus on the importance of context and an understanding of the circumstances that influence intervention delivery, so as to successfully drive implementation and change.[7] The new guidance recognises the need to engage with key stakeholders when designing interventions so that they are acceptable and implementable in the appropriate context.[7] Research that does not adopt this approach may not provide policymakers with enough information on how a given intervention may be delivered in a real-world setting.[7]

To successfully implement interventions, and for the findings of health research to have an influence on practice, outcomes need to be relevant to those who provide services and service users within the context in which they will be delivered.[4] While there are excellent examples of studies that do account for context through the engagement of stakeholder groups and parallel qualitative work, they are often the exception. Information regarding context is lacking in many primary studies and systematic reviews and Health Technology Assessments often do not report contextual factors, presenting a potential barrier to the transferability of findings.[8,9] A previous analysis has shown that only 13% of trials exploring health interventions used parallel qualitative methods as part of the trial design and rarely did protocols report how the trial findings would be informed by the qualitative work.[4] Commonly used reporting guidelines, while acknowledging context, only require the reporting of the setting, rather than a detailed description of contextual factors.[8] This omission of the contextual elements of primary studies can be a considerable limitation when study findings are implemented in the "real-world".[8]

1.1 | Methodological aspects

Process evaluation may use a range of complementary methods, including parallel qualitative work such as interviews and focus groups, self-administered questionnaires, checklists or assessments and observational methods in addition to Patient and Public Involvement (PPI).[2,10–12] PPI entails the involvement of lay contributors who represent the interests of patients and the public within research activity. Robust PPI-informed process

evaluations can be further strengthened by broadening the composition of the team and including researchers from a broad range of health service research backgrounds and clinical expertise. As mentioned above, context is key to robust process evaluation and the research protocol should be designed with the intended setting in mind. Furthermore, preliminary researcher visits to the proposed research sites are essential to understanding the context and may improve intervention design.[2,12] A process evaluation is designed to inform intervention delivery. The data collected in a process evaluation should assess recruitment, retention, intervention fidelity, acceptability, reach and dose.[10] A process evaluation should also identify any adaptations to the intervention and unintended effects.[10] A well-designed process evaluation will also identify any barriers or facilitators to intervention delivery, assess the comprehension of any intervention resources such as training materials and gauge participants' understanding of the aims of the intervention.[12] Process evaluations should also be designed using appropriate theoretical frameworks to guide them.

Previous research has shown that the use of process evaluation in oral health studies provides valuable insight into the context in which interventions will be delivered.[4] The Northern Ireland Caries Prevention In Practice (NIC-PIP) trial, an RCT aiming to measure the effects and costs of an oral health intervention for young children is a good example of how effective PPI and parallel qualitative methods can inform trial design, delivery and intervention, management and findings.[4,13] A trial PPI group comprising parents with young children was formed and had regular meetings with the research team at key stages of the study in order to gain perspectives and context regarding intervention delivery. This PPI group performed a crucial role in trial design, management and interpretation of findings.[13]

A further example of the effective use of parallel qualitative work within dental studies, prior to undertaking empirical research, is provided in the "Development of a core outcomes set for oral health services involving dependent older adults (DECADE)" study.[14] Semi-structured qualitative interviews were conducted with key stakeholders to identify which outcomes they considered to be most salient and allow for prioritisation of outcomes for a systematic review.[14] Stakeholders included dental professionals, care home staff and older adults and outcomes were then reviewed by an established PPI group.[14] By taking care to incorporate stakeholder perspectives, the DECADE study has ensured that the outcome set developed is both clinically and patient-centred.[14]

The development and refinement of a Stroke friendly Oral health Promoting (STOP) toolkit to improve oral care practices after discharge from hospital stroke services, also shows how an inclusive approach to design can facilitate the creation of interventions that better meet patient needs.[5,15] This study employed qualitative interviews, focus groups and workshop methods to capture context and perspectives from key stakeholders.[15] The research team invited stroke survivors to become part of the research team and provide vital PPI to inform the development of the toolkit.[15] Perspectives from carers and health care professionals experienced with stroke patients were also utilised.[15] Workshops with stroke survivors were then used to identify areas where the toolkit could be improved prior to evaluation.[15]

The BRIGHT trial involved a classroom-based education session and subsequent short text message reminders for UK school children to encourage tooth brushing and embedded mixed-methods process evaluation.[10] Self-administered questionnaires and qualitative interviews and focus groups were used to assess the ways in which the intervention was delivered, intervention fidelity, reach and dose.[10] The process evaluation also identified mechanisms of impact such as how participants' interactions and intervention processes drive change in behaviour and practice and any unintended effects. These examples show how the utilisation of well-designed qualitative approaches and process evaluations can benefit research by informing study design, providing guidance for study management and facilitating the interpretation of findings.

2 | METHODS

The feasibility, productivity and effectiveness of using DTs and DNs had been tested in primary care, but not in a care home environment.[16] It was argued that their use within SENIOR would improve the provision of care, improve access to services and preventive advice. This was considered important in care homes as poor oral health, including dry mouth, excessive tooth loss, dental caries and periodontal disease, is common and increasingly becoming a public health problem.[17,18] The oral health of care home residents is much worse than their community living peers. With increasing dependency, the ability for self-care deteriorates, polypharmacy leads to dry mouth and diets become rich in sugars. All these factors significantly increase residents' disease burden and the risk of future problems. Oral conditions impact their quality of life, self-esteem, general health and diet, exacerbating underlying medical conditions.[17–20] The National Institute for Health and Care Excellence (NICE) guideline NG48 has identified oral health as a priority area given many residents have complex needs that are difficult to identify and meet.[21] Despite their high level of need, dental service provision in residential care is poor, with little emphasis on prevention. DTs and DNs offer an alternative to dentists to address these challenges and have the potential to improve preventive advice, the provision of care and access to services.[17–20,22]

SENIOR was designed as a two-arm cluster RCT. It involves the use of DNs and DTs visiting care homes to provide oral care for residents and oral education for staff. In the intervention arm, DTs will first assess and then treat eligible dentate residents. This is likely to include basic debridement (for periodontal problems) and the placement of fillings, where appropriate. DNs will also form part of the programme and will visit the care homes to promulgate advice

to improve the day-to-day prevention offered to residents by formal and informal carers. The DTs will visit care homes in their locality every 6 months and the DNs will visit every month for the first 3 months and then 3-monthly. The SENIOR intervention drew on the on-going Gwên am Byth (A Lasting Smile) programme and will be contrasted with current practice (which is likely to be heterogeneous).[23] The Gwên am Byth programme was launched across Wales in 2015 and draws on the services of DNs and DTs to deliver care, with a key aim to improve oral health for older adults living in care homes.[23] The SENIOR study was granted full ethical approval on 05/05/2021 (21/WA/0116).

The visits from the DNs will form an important function in terms of championing oral health among care home managers and staff. This element of the complex intervention is just as important as the 6-monthly clinical management of dental needs by the DTs. As highlighted by Brocklehurst et al.[4] "there is growing support for the use of change agents in implementation processes".[24] Change agents are individuals with specialist knowledge who are able to act as intermediaries or facilitators of new ideas or interventions.[24] Intermediaries have been shown to prompt behaviour modification and implementation via frontline staff.[24] The SENIOR study aims to see DNs and DTs become agents of change, facilitating implementation by

TABLE 1 PAHRIS Framework.

Elements	Sub-elements	Criteria
Evidence	Research	Well-conceived, designed and executed research Seen as one part of a decision Valued as evidence Lack of certainty and social construction acknowledged Judged as relevant, importance weighted and conclusions drawn
	Clinical experience	Clinical experience and expertise reflected upon, tested by individuals and groups Consensus within similar groups Valued as evidence Seen as one part of a decision and judged as relevant Importance weighted and conclusions drawn
	Patient experience	Valued as evidence Multiple biographies used Partnerships with health care professionals Seen as one part of a decision Judged as relevant, importance weighted and conclusions drawn
	Information from the local context	Valued as evidence Collected and analysed systematically and rigorously Evaluated and reflected upon Conclusions drawn
Context	Receptive context	Clearly acknowledged boundaries (eg physical, social, cultural and system) Appropriate and transparent decision-making processes Power and authority processes Resources allocated and feedback provided Initiative fits with strategic goals and is a key practice/patient issue Receptiveness to change
	Culture	Able to define culture(s) in terms of prevailing values/beliefs Values individual staff and clients Promotes learning organisation Consistency of individuals role/experience to value relationships with others and teamwork
	Leadership	Transformational leadership Role clarity Effective teamwork and organisational structures Democratic inclusive decision-making processes Enabling/empowering approach to teaching/learning/managing
	Evaluation	Feedback on individual, team and system performance Use of multiple sources of information on performance Use of multiple methods for evaluation
Facilitation	Role	Doing for others Enabling others
	Skills and attributes	Doing for others and/or task Enabling others and/or holistic

TABLE 2 Interview matrix for the process evaluation.

PARIHS elements/ sub-elements	PARIHS criteria	Residents	Care home staff	Care home managers	DTs and DNs	Directors of community dental services	Commissioners
Context: receptive context	Clearly acknowledged boundaries (eg, physical, social, cultural and system)	When was the last time that you saw a dentist? Does a dentist ever come to see you here at the home?		What is currently in place at your home to look after your residents' teeth? Who usually looks after residents' teeth in (workplace)? How does that process work? Who do you think is the best person to help residents look after their teeth?	What is currently in place in (area/practice) to provide oral care for care home residents? Who is responsible for providing oral care for care home residents? Who do you think this should be? What are the challenges to providing oral health care for care home residents? Do you work to any particular guidelines or policy to promote oral health in care homes (country/ region)?	Why have you decided to take part in SENIOR? How challenging is it delivering an intervention in care homes? What are the limitations/ opportunities? Do these challenges shape how future interventions should be developed and implemented? Do you work to any particular guidelines or policy to promote oral health in care homes (country/ region)?	What is currently in place in (country/ region) to provide oral care for older people living in care homes? Who is responsible in (country/ region) for ensuring oral health is provided to people living in care homes? What are the challenges to providing oral health care to care home residents? Do you work to any particular guidelines or policy to promote oral health in care homes (country/ region)?
	Appropriate and transparent decision-making processes	What happens if you had a painful tooth, what would you do?			How do you think you will manage working with DTs/DNs?		
	Power and authority processes				Any problems with Direct Access or legal restrictions on your ability to care for residents of care homes?		
	Resources allocated and feedback provided	Do you have all that you need to keep your mouth and teeth clean?		What are the barriers to looking after resident's teeth? Is there anything that would make it easier of more difficult to manage?	What will you need to care for residents' oral health?		
	Initiative fits with strategic goals and is a key practice/ patient issue	How important is keeping your mouth and teeth clean? What could be the problem if you do not?	Can you tell me about your own experiences of helping with looking after residents' teeth (toothbrushing and/ or denture care)?	Why have you decided to take part in SENIOR? Could SENIOR produce any unintended effects? How would you design a service to promote the oral health of residents in care homes?	How important are interventions like SENIOR? Why have you decided to take part in SENIOR?	Could SENIOR produce any unintended effects? How would you design a service to promote the oral health of residents in care homes?	Does SENIOR align with your strategic priorities? Do you think the use of skill-mix is helpful in this setting? Why? Is there any way that SENIOR could be improved?

(Continues)

TABLE 2 (Continued)

PARIHS elements/ sub-elements	PARIHS criteria	Residents	Care home staff	Care home managers	DTs and DNs	Directors of community dental services	Commissioners
	Receptiveness to change	What do you normally do to keep your mouth and teeth clean? How often would you like to see someone about your mouth and teeth? How important is prevention for you?	How do you feel about looking after your residents' teeth?	How do you think your residents feel about the health of their teeth? Is this important for you at your home?	Do you agree with using "skill-mix" to care for residents' oral health? Why? Or why not? Is there anything you would change that could make the implementation of SENIOR more possible?		Do you think that interventions like SENIOR could be easily implemented? Why or why not? Are there any barriers to the implementation of interventions like SENIOR? How could an intervention like SENIOR be facilitated at a strategic level? How do you think the SENIOR intervention would work in the long term? Suggestions for improvement
Context: culture	Able to define culture(s) in terms of prevailing values/beliefs Values individual staff and clients Promotes learning organisation Consistency of individuals role/ experience to value relationships with others and teamwork	Would you be prepared to see someone who is not a dentist to look after your teeth?			Can you tell me about your own experiences of providing oral care for care home residents?		
Context: leadership	Transformational leadership				How confident do you think you would be in delivering the SENIOR intervention?		
	Role clarity				Why is your role important in the delivery of SENIOR? Any barriers/enablers? Any overlap or gaps between the DTs and DNs that are used in SENIOR?	Thinking about using "skill-mix" to promote oral-health in care homes: how important are issues such as direct access; legal constraints (eg prescribing)? Could clinical leadership be a factor (eg the influence of the service lead or the ability of DCPs to develop leadership roles)?	

TABLE 2 (Continued)

PARIHS elements/ sub-elements	PARIHS criteria	Residents	Care home staff	Care home managers	DTs and DNs	Directors of community dental services	Commissioners
	Effective teamwork and organisational structures			Do you think the SENIOR intervention is manageable for your staff? Any barriers/enablers? Are regular visits from DTs and DNs possible? Any impact on staff workload?	What is your view about the confidence of DCPs in performing clinical tasks in care homes?	What is your view about the confidence of DCPs in performing clinical tasks in care homes?	
	Democratic inclusive decision-making processes			How do you think your staff feel about looking after your residents' teeth?			
	Enabling/empowering approach to teaching/learning/ managing						
Context: evaluation	Feedback on individual, team and system performance						
	Use of multiple sources of information on performance						
	Use of multiple methods for evaluation						
Facilitation: role	Doing for others Enabling others			What do you think the main advantages of having regular visits from DNs/ DTs are? Any disadvantages?	How do you plan linking with care home staff to promote the oral health of residents? Anything key here re-facilitating the implementation of SENIOR?		
Facilitation: skills and attributes	Doing for others and/ or task Enabling others and/or holistic			How do you think DNs/ DTs should liaise with yourself and your staff?	Any additional skills or training that you think you'll need?		

providing education and support for care home staff. The role of human agency, where clinical or non-clinical staff act as change agents to facilitate the enactment of complex interventions, is increasingly recognised.[25-27] This is in line with the recent publication of the updated "Framework for the development and evaluation of complex interventions". The Framework emphasises "the importance of context and the value of understanding interventions as events in systems" that produce effects through interactions with features of the contexts in which they are implemented.[7] The parallel qualitative component of SENIOR will comprise semi-structured interviews with residents, staff, managers, DTs, DNs and informal carers to assess the intervention's acceptability. Managers and residents who decline participation in the intervention will also be offered an interview, alongside informal carers, to explore their narratives. The sampling frame for care home-based participants will account for geographic differences, care home size, staffing ratios and proportion of residents with severe cognitive impairment. Chief Dental Officers, dental commissioners, Directors of the community dental services and "high-street" dentists will also be interviewed. Interview data will be anonymised, fully transcribed and analysed thematically.

To inform the methods used and the information gathered in the process evaluation, the research team drew on the "Promoting Action on Research Implementation in Health Services" (PARIHS) framework (Table 1). PARHIS comprises three elements (Evidence, Context, Facilitation), which are considered critical to any implementation process.[28]

3 | RESULTS

The PARHIS framework was used to create a matrix (Table 2) mapping the different stakeholder groups within a care home environment across the PAHRIS criteria. The matrix created from the PAHRIS framework, in collaboration with the study PPI representatives, was used in the development of a set of bespoke semi-structured interview guides for all the different stakeholder groups.[28] The research team also adopted an approach where the interview guides could be further adapted to suit individual roles within each stakeholder group and the emerging themes from the interviews while ensuring the critical elements of PARHIS were not lost. This was done to identify the relevant stakeholders and to ensure that all elements of the PAHRIS criteria were considered so that the actions of the different trial processes were fully understood and to identify the factors that could influence the pathway to impact the study. The mapping process allowed for an in-depth understanding of the framework and enabled the formation of interview questions in order to gather as much contextual information as possible.

To explore and identify the factors that underlie the successful and sustainable implementation of the intervention as fully as possible, factors that influence the Context, Evidence, Facilitation (PARIHS) of the intervention will be explored in-depth.[28] Particular attention will be paid to acceptability for care homes and residents, treatment fidelity, contextual factors that shape the intervention; contextual factors that shape implementation; mechanisms that sustain or potentiate effects; and unexpected pathways and consequences. This is an approach that was used in a previous pilot trial, where a realist approach was adopted as the theoretical basis of the parallel process evaluation.[16] There will also be a focus on pragmatic issues, including day-to-day life for residents (personal hygiene, cleanliness and comfort; personal appearance; dining experience; care home environment and social participation); health and well-being of residents (prevention and oral hygiene practices; access to services; and diet and nutrition); staff and leadership in the home (care staff; nursing staff; care home managers); the dental workforce (DTs, DNs and dental commissioners). This will be informed by research already undertaken in a care home environment (eg Goodman et al (2017) and Spillsbury et al (2011)).[29,30] Equally, the role of the DTs and DNs in relation to their role as human intermediaries and the facilitation domain within PAHRIS will be further explored.

4 | CONCLUSION

The inclusion of a well-conducted process evaluation as part of trial design is likely to be key to understanding contextual factors and facilitating the successful implementation of complex interventions in their "real world" settings. SENIOR has been designed to simultaneously include a rigorous and theoretically informed process evaluation, that involves parallel qualitative methods and stakeholder engagement. SENIOR will likely benefit from strong PPI representation being embedded within the trial from the outset. Semi-structured qualitative interviews with stakeholders including commissioners, policy makers, care home staff and residents, will be carried out at key stages of the trial and the data generated will be used to establish the role of relevant contextual factors and facilitate the successful implementation in the intended real-world setting. Owing to the focus on the use of PAHRIS, and in light of the guidance in the latest MRC Framework, the study may inform the design of future trials of complex interventions in oral health studies and the wider health services research context.

AUTHOR CONTRIBUTIONS

Annie Hendry, Alison Jenkins, Saif Sayeed Said, Michelle Harvey and Afshan Mirza have made substantial contribution to acquisition of data, drafting the work and critically revising it. Sarah R. Baker, Georgios Tsakos, Gerald McKenna, Lorraine Morgan and Paul R. Brocklehurst made substantial contribution to the design of the work, acquisition of funding and critically revising the work. All authors gave final approval of the work to be published.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analysed in this study.

ETHICAL STATEMENT

This study has been reviewed and granted full ethical approval by the Bangor University School of Health Sciences Ethics Committee and was granted LREC approval in 2021 (297182; 21/WA/0116).

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