Improving the Oral Health of Older People In Care Homes: the TOPIC randomised feasibility study.

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Synopsis

Improving the Oral Health of Older People In Care Homes: the TOPIC randomised feasibility study

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Abstract

Background: The National Institute for Health and Care Excellence guideline NG48 aims to maintain and improve the oral health of care home residents. However, evidence on oral health interventions among care home residents is weak. A co-design process with residents and care home staff refined National Institute for Health and Care Excellence guidance NG48 aspects to facilitate implementation. This study aimed to assess the feasibility of undertaking a large-scale definitive trial on this intervention. A parallel theoretically informed process evaluation explored factors affecting implementation. The feasibility of collecting data to inform a cost–consequence model was also explored.

Methods: A pragmatic cluster randomised feasibility study with 12-month follow-up was undertaken in 22 care homes across two sites (London, Northern Ireland). Care homes were randomised into an intervention arm (n = 11) that received the National Institute for Health and Care Excellence guidance NG48-based complex oral health intervention, and a control arm (n = 11) that continued with routine practice. The complex intervention included a training package for care home staff in oral health promotion knowledge and skills; using the Oral Health Assessment Tool to assess residents' oral health needs; and a 'support worker assisted' daily toothbrushing regime with 1500 ppm fluoride toothpaste.

Dentate residents aged 65 years or over without severe cognitive impairment were recruited, resulting in a sample of 119 participants. Assessments were undertaken at baseline and 12 months through clinical dental examination and questionnaires. A parallel process evaluation involved semistructured interviews to explore how the intervention could be embedded in standard practice. Rates of recruitment and retention and intervention fidelity were also recorded. Economic evaluation or cost–consequence indicators were collected through interviews with stakeholders, survey and questionnaire data.

This synopsis should be referenced as follows:
Tsakos G, Brocklehurst PR, Syed S, Harvey M, Daniyal S, Watson S, *et al*. Improving the Oral Health of Older People In Care Homes: the TOPIC randomised feasibility study. *Public Health Res* 2026;**14**(5). https://doi.org/10.3310/GJGT0613

Results: Eighty-four per cent of care homes and 88% of residents agreed to participate; 86% of care homes and 69% of residents were retained at 12-month follow-up. Researcher-collected data on clinical and subjective measures had successful completion rates, but completion rates were very low for the weekly symptoms checklist collected by care home staff.
The process evaluation highlighted that most care homes were keen to participate, as accessing oral care provision was challenging. The values and beliefs of managers and staff within each care home were key to intervention adoption. Collecting outcomes relevant for cost–consequence modelling is feasible, therefore, supporting an economic evaluation alongside the definite trial. Residents' quality of life was identified as a key outcome for stakeholders, including care home managers.
Limitations: As ethical approval was granted for care home residents without or with mild cognitive impairment, the inclusion criteria excluded a considerable proportion of residents that had severe cognitive impairment, meaning that the findings are less generalisable to the wider population of care home residents. Attrition rates were high, and recruitment was affected by the coronavirus disease pandemic.
Conclusion: The study documented the feasibility of undertaking a National Institute for Health and Care Excellence guidance NG48-based intervention in care homes. Recruitment and retention were feasible but challenging. A definitive trial should accommodate these challenges.
Future work: A definitive trial should assess the effectiveness of the co-designed intervention, with more inclusive recruitment, improving retention, minimising missing data and outcome selection being important issues to consider.
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The evidence supporting oral health promoting interventions for older adults in care homes was scarce. Therefore, the improving the oral healTh of Older People In Care homes (TOPIC) study was conducted to explore the feasibility of such an intervention. This was a cluster randomised feasibility study across two UK sites, that is London and Northern Ireland. In this synopsis, introduction, rationale for research, objectives, methods and key findings from the different workstreams (WSs), and discussion are presented in sequence. In addition, the research outputs from the study have been listed and cited. Material throughout this synopsis has been adapted from the study publications[1–5] (*Box 1*).

BOX 1 Research papers from the TOPIC study

Tsakos G, Brocklehurst PR, Watson S, Verey A, Goulden N, Jenkins A, *et al.* Improving the oral health of older people in care homes (TOPIC): a protocol for a feasibility study. *Pilot Feasibility Stud* 2021;**7**:138. https://doi.org/10.1186/s40814-021-00872-6[1]

Langley J, Wassall R, Geddis-Regan A, Watson S, Verey A, McKenna G, *et al.* Putting guidelines into practice: using co-design to develop a complex intervention based on NG48 to enable care staff to provide daily oral care to older people living in care homes. *Gerodontology* 2023;**40**:112–26. https://doi.org/10.1111/ger.12629[2]

Tsakos G, Brocklehurst PR, Syed S, Harvey M, Daniyal S, Watson S, *et al.* Improving the oral health of older people in care homes: results from a randomised feasibility study. *Community Dent Oral Epidemiol* 2025;**53**:413–23. https://doi.org/10.1111/cdoe.13043[3]

Brocklehurst P, Langley J, Wassall R, Daniyal S, Syed SS, Harvey M, *et al.* A theoretically informed process evaluation in parallel to a feasibility study of a complex oral health intervention using NICE guidelines in a care home setting. *Community Dent Oral Epidemiol* 2025;**53**:152–9. https://doi.org/10.1111/cdoe.13016[4]

O'Neill C, Brocklehurst PR, Syed S, Syed S, Harvey M, Daniyal S, *et al.* A feasibility study of the costs and consequences of improving the oral health of older people in care homes: findings from the TOPIC study. *BMC Oral Health* 2025;**25**:1062. https://doi.org/10.1186/s12903-025-06322-6[5]

Introduction

Oral health has a considerable impact on general health, diet, and quality of life.[6–9] The Adult Dental Health Survey 2009 has highlighted high levels of oral diseases and unmet dental treatment needs in England, Wales and Northern Ireland. For example, the prevalence of dental caries was 40% in 75- to 84-year-olds and 33% among those aged 85 years or older, while 69% among those 65 years and over had periodontal diseases.[10] Access to oral health services has been a major issue that was further exacerbated since the coronavirus disease discovered in 2019 (COVID-19) pandemic when the services completely ceased and remains a key health services concern currently.[11–13] The overall picture is even starker among older adults as they have further oral health services access barriers because of comorbidities and competing needs.[14,15] As domiciliary services for oral health are challenging in the current context and hospital admissions associated with dental diseases are distressing

and costly, it is essential to prioritise the prevention of oral diseases for older adults.[16,17]

A large number of older adults (around 400,000) now live in care homes, a broad term used to refer to both residential and nursing homes.[18] More than half of these older adults in care homes retain their natural teeth and require care and maintenance.[19] Unfortunately, their oral health has been found to be considerably worse than their peers living in the community.[20] To maintain their oral health, it is essential to have good daily oral hygiene practices, avoid high levels of sugar consumption and ensure good access to preventive care as well as curative services when needed. As age increases, ability to care for oral health decreases. To tackle that, there is a need for long-term care systems that are sustainable, fit for ageing populations, and provide universal care as highlighted by the UN Decade of Healthy Ageing plan of action and WHO.[21,22] However, the evidence for oral health promoting interventions in care home settings is weak.[23]

The National Institute for Health and Care Excellence (NICE) recognised the public health importance of maintaining good oral health among this vulnerable group of older adults and issued, in 2016, the National Institute for Health and Care Excellence guideline #48 (NG48) to maintain and improve oral health of care home residents.[24] This contains a range of suggested actions and interventions and there is also emphasis on prevention, with good oral hygiene seen as a focus on many of these actions. However, there is a clear gap between suggesting a preventive intervention based on the best available evidence and implementing such an intervention in real life, particularly in more challenging contexts such as in a care home.

Moreover, there is very limited evidence to demonstrate the feasibility of such an intervention in that context and there is uncertainty about effect size estimates, recruitment and retention of participants, intervention fidelity and appropriate outcome measures. To undertake a full trial to evaluate such an intervention would be premature and could also be inappropriate in terms of best use of scarce research resources. Therefore, a pragmatic cluster randomised controlled feasibility study was planned and conducted to determine the feasibility of a complex intervention based on the NICE guideline (NG48) for oral health of older people (65 years and over) in care homes. A parallel process evaluation and cost–consequence modelling was undertaken to inform more in-depth understanding of the different aspects of feasibility and implementation of the intervention in that setting and also to help plan a potential subsequent definitive trial. The objectives of the study were described in the published protocol paper.[1] They have since been further elaborated and are presented here:

1. Undertake semistructured interviews and co-design workshops (WS2 – Phase 1) to refine a complex intervention to promote oral health in care home residents in order to:
    a. ensure the intervention is clinically and culturally acceptable
    b. understand the context and mechanisms for delivery; and
    c. work with the patient and public involvement (PPI) group and stakeholder group to determine how the intervention could be optimised.

2. Determine the feasibility of undertaking a definitive trial to evaluate the complex intervention to promote oral health (WS1) to determine the:
    a. proportion of care homes that agree to participate
    b. number of residents that are eligible and able to consent
    c. proportion of eligible residents that agree to participate
    d. proportion of participating residents that receive the intervention per the protocol
    e. proportion of care homes and residents that remain in the study (at least 75% completion rate required)
    f. proportion of completed measures used in the study (at least 75% completion rate required): (1) oral health assessments; (2) quality-of-life questionnaires; (3) clinical measurement records; (4) oral symptoms checklist diaries; and
    g. impact on recruitment of varying the 6-Cognitive Impairment Tool (6-CIT) screening tool[25] threshold.

3. Undertake a parallel process evaluation (WS2 – Phases 2 and 3) using semistructured interviews to explore how the intervention could be embedded in standard practice guided by Pfadenhauer et al.'s framework[26] to maximise pathway to impact, with:
    a. managers and staff to assess the intervention's feasibility and sustainability
    b. residents to explore the intervention's acceptability
    c. managers and residents that refused participation to explore their reasoning

4. Develop a cost–consequence model (WS3) to determine the relevance and relative importance of the different outcome measures in the decision-making context.

The TOPIC study has three different WSs: WS1, WS2 and WS3, respectively, and their connection to each other is demonstrated in *Figure 1*.

As illustrated in *Figure 1*, the study began with the refinement of the complex intervention based on the NG48 guidelines (WS2 – Phase 1) which involved context familiarisation and co-design workshops, and this has already been published.[2] This co-designed intervention was used in a pragmatic cluster randomised feasibility study to promote oral health in care homes (WS1). In parallel to the WS1, a process evaluation (WS2 – Phases 2 and 3) was carried out involving semistructured interviews with key stakeholders. The development of cost–consequence model (WS3) was also carried out which involved questionnaire data, survey and qualitative interviews with stakeholders. The key findings from WS1, the process evaluation (WS2 – Phases 2 and 3), and from WS3 have been published in respective manuscripts that are listed below:

- 'Improving the oral health of older people in care homes: results from a randomised feasibility study'.[3]
- 'A theoretically-informed process evaluation in parallel to a feasibility study of a complex oral health intervention using NICE guidelines in care home setting'.[4]
- 'A feasibility study of the costs and consequences of improving the oral health of older people in care homes: findings from the TOPIC Study'.[5]

The sections below discuss the various WSs and how they address the different objectives of the study.

Workstream 1

This refers to the main work around a pragmatic cluster randomised controlled feasibility study with a 12-month follow-up aimed to determine the feasibility of a complex intervention based on the NG48 guideline. This was undertaken in care homes across two settings (London and Northern Ireland). The eligibility criteria for care homes at cluster level were to have a minimum of 20 residents, later updated to having a capacity for 20 residents thereby acknowledging the dynamic care home environment. At an individual level, care home residents needed to be aged 65 years and over, dentate or partially dentate, full-time resident at the care home, not receiving end of life or palliative care, without severe cognitive impairment (6-CIT score below 10), not taking part in any other oral health study, and have a working level of spoken English.

Initially, the study was planned to be conducted in a total of 12 care homes with an average of 10 residents per care home to meet the required sample size of 120 participants. However, it became obvious that the average number of recruited residents per care home would be lower and

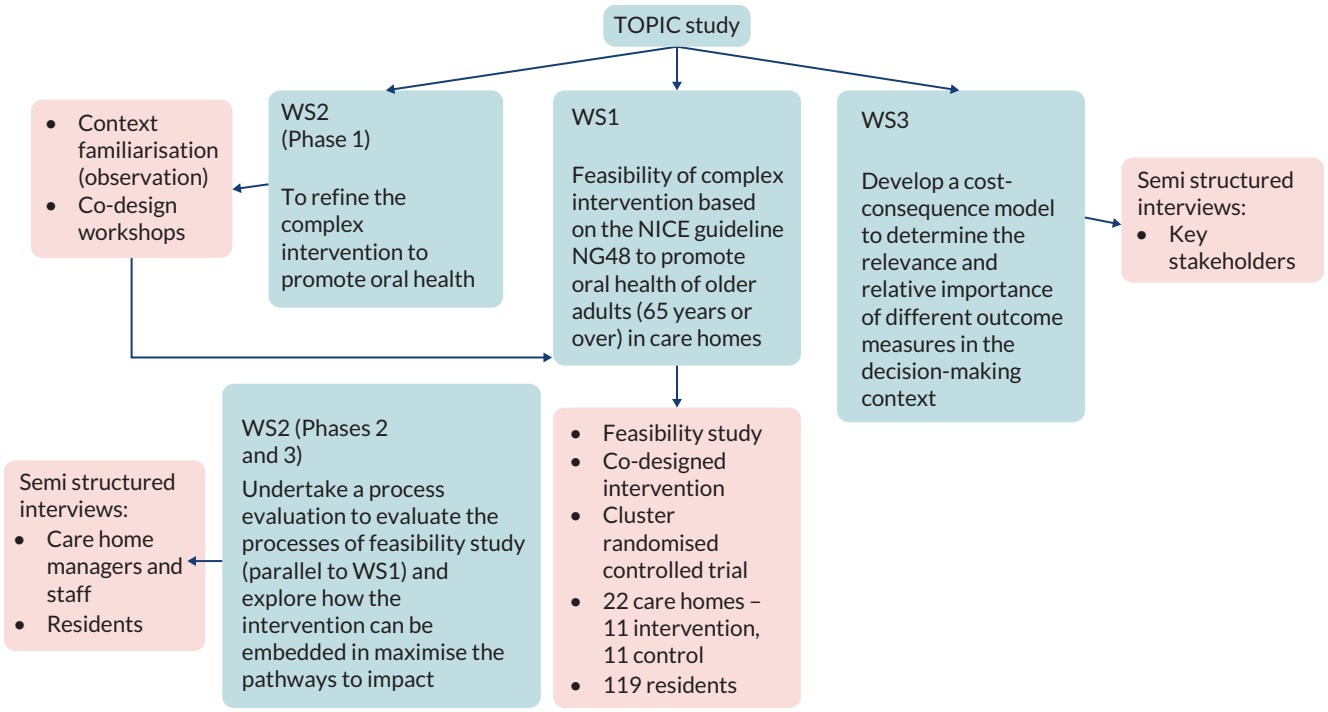

FIGURE 1 Improving the oral healTh of Older People In Care homes study research pathway.

therefore the protocol had to be amended during the study in order to meet the desired sample size. Ultimately, 22 care homes were recruited (11 each from London and Northern Ireland) contributing to a total of 119 participants. The care homes were randomly allocated into the intervention and control groups in equal proportions (1 : 1). Care homes in the intervention group (*n* = 11) received the complex oral health intervention based on the NICE guideline (NG48), while care homes in the control group (*n* = 11) continued with routine practice. The randomisation was completed using a secure, web access randomisation system at North Wales Organisation for Randomised Trials in Health.[27] This system was maintained and monitored independently of the trial statistician or other trial staff. The randomisation was performed by dynamic allocation to ensure that the trial maintained good balance to the allocation ratio of 1 : 1. Randomisation stratified for site (London or Northern Ireland) so that there would be a balanced number of usual care and oral health intervention care homes at both sites. Clinical dental examiners undertaking the assessments were blinded. The trial statistician was also blinded to allocation and was unblinded after the primary analysis. Details of the study methods for WS1 including trial design, inclusion, exclusion criteria, outcomes, sample size and initial statistical plan have been published.[1]

Recruitment began in December 2021 ending in October 2022 with several COVID-19 outbreaks affecting both recruitment of care homes and participants. Data collection was finished by November 2023 and included clinical dental examination by a dentist at baseline and 12-month follow-up, and researcher administered questionnaires at baseline, 6- and 12-month follow-up. In terms of data collection, several measures were recorded:

1. Clinical measures (recorded through the dental examination): number of teeth, number of teeth with coronal and root caries, proportion of teeth with visible plaque, and proportion of teeth with gingival bleeding on probing.
2. Oral health needs (recorded through the dental examination) assessed through the oral health assessment tool (OHAT).[28]
3. Oral symptoms and urgent dental care (recorded by care home staff weekly, and by researchers at baseline, 6-month, and 12-month follow-up): number of reported episodes of dental pain, sepsis, discomfort, and urgent dental care appointments.
4. Health-related quality of life (recorded by researchers) through the EuroQol-5 Dimensions, five-level (EQ-5D-5L) version questionnaire.[29]
5. Oral health-related quality of life (recorded by researchers) through the Oral Impacts on Daily Performances (OIDP)[30] questionnaire.

There were three protocol deviations in total. One referred to allowing the recruitment of care homes that had capacity for 20 residents, even if they did not have 20 residents at the time of recruitment (as stated in the original protocol). This was because the number of residents in a care home can fluctuate over time. The protocol and inclusion criteria were changed to refer to care homes having capacity for 20 residents. Another deviation related to the recruitment of a participant that was aged 62 years, while the eligibility criteria refer to residents aged 65 years or over. The exact age of that specific resident was confirmed after participation and baseline data collection, and it was deemed appropriate to use the data in the analysis. The third protocol deviation referred to the misplacement of weekly symptoms checklists (routinely collected by the care home staff) for one resident. This was identified when the forms were not returned to the research team. The care home staff were subsequently contacted but were not able to retrieve the checklists. All three protocol deviations were discussed with the Data Monitoring and Ethics Committee (DMEC) and the actions suggested by the DMEC were followed.

Statistical analysis

The statistical methods used for each outcome are described below. The number of teeth with coronal caries and number of teeth with root caries were analysed using a multilevel mixed-effects negative binomial regression with the 12-month follow-up rating as the dependent variable, the baseline rating as a covariate, allocated group and site as factors and care home as a random effect. The proportion of teeth that bled on probing and the proportion of teeth with visible plaque were analysed using a fractional response regression with the 12-month follow-up rating as the dependent variable, the baseline rating as a covariate, and allocated group as a factor. Cluster-robust standard errors for site were utilised for this analysis.

The OHAT consists of eight items that are scored as: 0 = healthy, 1 = changes or minor issues, or 2 = unhealthy. The total OHAT score is the sum of the item scores, ranging from 0 to 16 with higher scores indicating worse oral health. The OHAT data were analysed using a multilevel mixed effects linear regression, with the 12-month follow-up OHAT score as the dependent variable, the baseline OHAT score as a covariate, the allocated group and site as factors and the care home as a random effect. Kenward–Roger correction for small degree of freedom was utilised for this analysis.

Oral health-related quality of life was assessed through the OIDP measure.[30] For the OIDP, a frequency score (0 = less often than once a month – 5 = every day or nearly every

day) and a severity score (0 = no effect – 5 = very severe effect) are reported for each of the eight different activities/behaviours. For each activity/behaviour, a performance score is calculated as the frequency score × severity score. The OIDP score is the sum of the performance scores × 100/maximum possible score. The OIDP scores therefore range from 0 to 100 with higher scores indicating worse oral health-related quality of life. The oral health-related quality of life of the residents was analysed using a multilevel mixed-effects negative binomial regression with the 12-month follow-up OIDP ratings (6-month and 12-month follow-ups) as the dependent variable, baseline OIDP ratings as a covariate, visit, allocated group and site as factors, while also considering a visit × group interaction and care home as a random effect. Negative binomial models were chosen in this case due to the high number of zeros in the distribution of this variable, which indicates a large number of participants with no oral impacts (OIDP score = 0). Due to the skewness of the data, a linear model would not be appropriate, and as the data distribution resembles count data a negative binomial model was applied.

Findings (Workstream 1)

Recruitment

The feasibility study showed that recruitment of care homes and residents was feasible. The Consolidated Standards of Reporting Trials (CONSORT) diagram for care homes is illustrated in *Figure 2* and the one for study participants in *Figure 3*. The CONSORT 2010 checklist of information when reporting a pilot or feasibility trial is presented (see *Report Supplementary Material 1*). Care homes were willing to participate; 37 care homes were approached and 6 declined, while 31 (84%) agreed to participate. From those 31 care homes, 9 were ineligible so 22 care homes were recruited to the study. Residents were also willing to participate; 195 residents were approached and 31 declined before screening; therefore, 164 (84%) were willing to participate and were screened for eligibility. A total of 28 were ineligible, most commonly due to having severe cognitive impairment (23 residents, 12% of the 195 initially approached), defined as score of 10 or more on the 6-CIT scale. From the 136 residents who were eligible after the second stage of screening, 119 [88%; 95% confidence interval (CI): 82% to 93%) were recruited to the study, one less than target sample size of 120. The number of recruited residents per care home was most commonly 5, followed by 6 recruited residents per care home. Further details and complete breakdown of recruitment can be found in the respective paper.[3]

From the 22 care homes recruited, 11 were randomised to the control arm and 11 to the intervention arm, maintaining the 1 : 1 allocation ratio between intervention and control arms. Although 22 care homes were recruited and randomised, residents were recruited from 21 of those homes, as the residents from one care home could not be consented before the recruitment period ended. Sixty-four residents were recruited in the control arm, and 55 residents were recruited in the intervention arm.

Retention

Nineteen care homes (of the 22 recruited) completed the 12-month follow-up; therefore, 86% of care homes were retained. As mentioned previously, in one care home residents were unable to be consented prior to the recruitment period ending and therefore did not have any baseline examination. A further two care homes (with nine residents collectively) were withdrawn from the study by their respective managers after baseline data collection. From the 119 recruited residents, 115 had baseline data collected, while 78 completed the 6-month follow-up and 82 residents completed the 12-month follow-up (69% retention; 95% CI: 61% to 77%). There were 11 participants in the control arm and 2 participants in the intervention arm who were not able to complete the 6-month follow-up but completed their 12-month follow-up data collection. The main reasons for non-retention to the study were related to death (12 residents, 32% of the total number of residents withdrawn), withdrawal of care homes which led to loss of residents (9 residents, 24% of the total withdrawals) or moving from the care home (8 residents, 22% of the total withdrawals). *Table 1* summarises the feasibility outcomes in terms of recruitment and retention.

The impact on recruitment of varying the 6-CIT threshold indicated that a considerable number of residents with mild cognitive impairment would have been excluded if a stricter threshold were chosen. Of the 115 residents who completed the baseline visit, only 88 (76.5%) would be eligible (47 control, 41 intervention) if the 6-CIT threshold were lowered to 7, that is they had no cognitive impairment. In contrast, 27 residents would have been excluded as they were classified as having mild cognitive impairment (6-CIT score of 8–9).

Data completion

Data completion rates were generally satisfactory, particularly for data that were collected through the dental clinical examination and questionnaires. At baseline, 107 participants (90% of the 119 recruited) had clinical dental examination data, 1 of them did not undergo denture assessment and 105 participants (88% of the 119 recruited) had their clinical measurement records fully completed. At 12-month follow-up, 75 participants (91% of 82 participants remaining in the study) had their clinical measurement records fully completed, and one participant (1%) had partially completed clinical data.

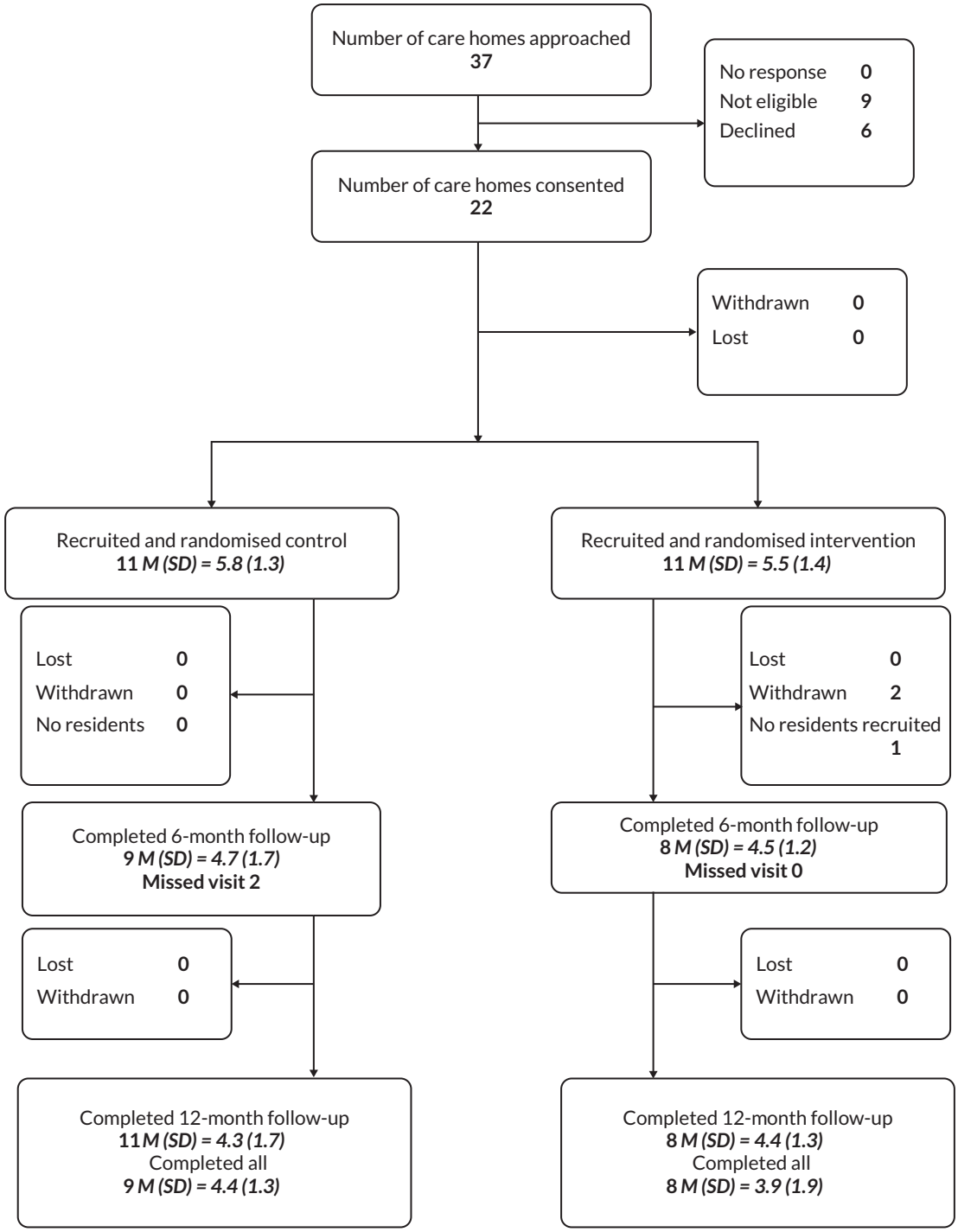

FIGURE 2 Consolidated Standards of Reporting Trials diagram for TOPIC care homes. M (SD), mean number of residents at care home (standard deviation).

There were 105 participants (88% of the 119 participants) who had the OHAT completed at baseline, and 75 participants who had it completed at 12-month follow-up (91% of 82 participants still in the study at that time point). When the OHAT was completed, it was fully completed in all cases.

For the OIDP, there were 115 participants (97% of the total of 119 participants) with fully completed data at baseline, 77 did the same at the 6-month follow-up (99% of the 78 participants that provided data at that time point), and 77 had fully completed OIDP data at the 12-month follow-up (94% of the 82 participants at the 12-month follow-up) while 1 participant (1%) had it partially completed (with missing data for 3 of the 8 items). Sixty-five participants had the OIDP data completed at both the 6- and 12-month follow-up.

There were 115 participants (97% of the 119 recruited) with fully completed EQ-5D-5L data at baseline. At 6-month follow-up, 77 participants (99% of the 78

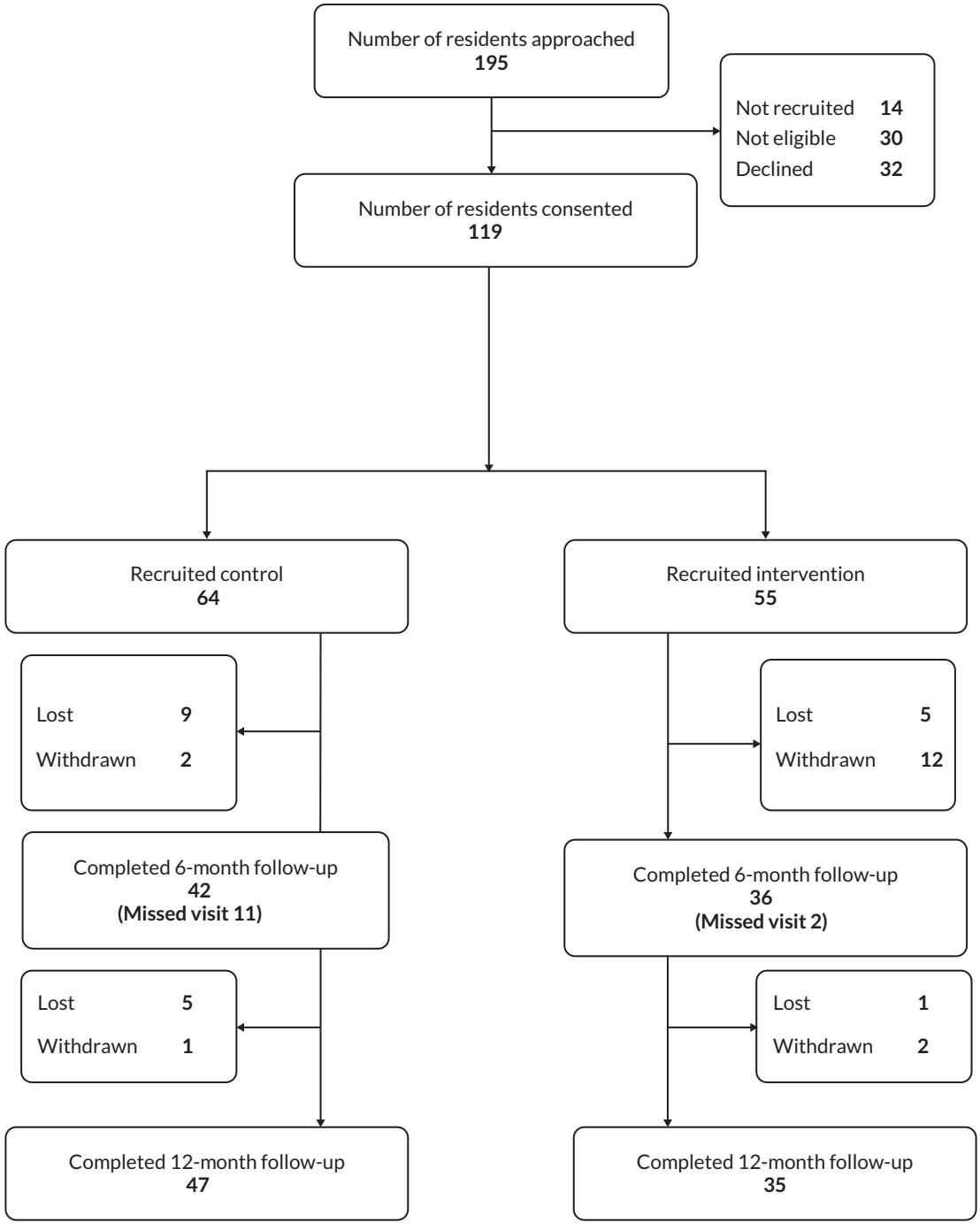

FIGURE 3 Consolidated Standards of Reporting Trials diagram for TOPIC residents.

TABLE 1 Feasibility outcomes for recruitment and retention

Feasibility outcome	Number	Proportion (95% CI)
Care homes who agreed to participate	31/37	84% (72 to 96)
Care homes who remained in the study	19/22	86% (72 to 100)
Eligible residents who agreed to participate	119/136	88% (82 to 93)
Participating residents who remained in the study	82/119	69% (61 to 77)

participants at that point) had fully completed EQ-5D-5L data, while the same was the case for 78 participants at 12-month follow-up (95% of 82 participants that remained in the study at that point).

At baseline, 115 participants (97% of the 119 recruited) had the full completed oral symptoms checklists data collected through questionnaire by the researchers. All 78 participants (100% of those that provided data at that point) had the oral symptoms checklist fully completed at the 6-month follow-up, and 78 (95% of the 82 residents at that point) did so at the 12-month follow-up, while 1 resident (1%) had that data partially completed. A summary of completion rates for the different forms of data collected by the research team is presented in *Table 2*.

The weekly oral symptom checklists (data collected by care home staff throughout the study) were not successfully completed. There were 92 participants (77% of the 119 residents recruited) who had at least 1 weekly checklist completed. However, only two participants had the weekly checklists fully completed for each week over the 12-month period of the study.

Intervention data records

Data were completed for different elements of the intervention, namely the OHAT, the personal oral care plan, and the weekly oral hygiene records. These refer to the observations from the intervention arm only, which consisted of 55 residents residing in 10 care homes, as one care home despite being randomised was not able to recruit participants (as explained above).

For the OHAT, a total of 102 assessments should have been completed for residents. Of them, 44 (43.1% overall, and 71% of those completed) were fully completed, 18 (17.6% overall, and 29% of those completed) were partially completed and 40 (39.2%) were not completed at all. From the 50 personal oral care plans, 2 (4%) were fully completed, 43 (86%) were partially completed and 5 (10%) were not completed at all. For the weekly oral hygiene records (a total of 1708 records), 573 (33.6%) were fully completed, 670 (39.2%) were partially completed and 465 (27.2%) were not completed at all. A summary of completion rates for intervention data records are reported in *Table 3*.

Adverse events and serious adverse events

There were in total 20 adverse events (AEs), 17 of which were serious AEs. Twelve referred to participants' death, and the remaining eight events were cases of participants being admitted to hospital because of illness, such as COVID-19 or swelling of the jaw. None of the events were related to the residents' participation in the study.

Oral health variables

A range of clinical and subjective oral health variables were considered as potentially relevant for a subsequent definitive trial. As this was a feasibility study, the emphasis was on the collection of data in relation to these variables rather than on differences identified between groups as the study was not powered for that. *Table 4* presents the key descriptive results at baseline and follow-up overall and by the two study arms (intervention and control) for these variables, with the exception of those on health-related quality of life (EQ-5D-5L) which are discussed as

TABLE 2 Data completion rates at baseline and 12-month follow-up

	Baseline	12 months	Completion (%)	Feasibility – 75% threshold
Clinical examination data	107/119	79/82	96	Yes
Oral health assessment (OHAT)	105/119	75/82	91	Yes
Health quality-of-life questionnaire (EQ-5D-5L)	115/119	78/82	95	Yes
Oral health-related quality of life (OIDP)	115/119	77/82	94	Yes
Symptoms checklist (researcher)	115/119	78/82	95	Yes

TABLE 3 Intervention records completion rates

Forms	Proportion completed (full)	Proportion completed (partial)
OHAT	44/102 = 43%	18/102 = 18%
Personal oral care plan	2/50 = 4%	43/50 = 86%
Weekly oral hygiene records	573/1708 = 34%	670/1708 = 39%

TABLE 4 Descriptive statistics of the oral health and quality-of-life variables

	Descriptive	Control	Intervention	Total
Coronal caries baseline	*N*	61	46	107
	Median (interquartile range)	0 (0–0)	0 (0–0)	0 (0–0)
Coronal caries 12-month follow-up	*N*	47	32	79
	Median (interquartile range)	0 (0–0)	0 (0–0)	0 (0–0)
Root caries baseline	*N*	61	46	107
	Median (interquartile range)	0 (0–2)	0 (0–4)	0 (0–2)
Root caries 12-month follow-up	*N*	47	32	79
	Median (interquartile range)	0 (0–2)	1 (0–3)	0 (0–2)
Bleeding on probing baseline	*N*	61	44	105
	Proportion (95% CI)	0.40 (0.31 to 0.49)	0.47 (0.34 to 0.60)	0.41 (0.33 to 0.49)
Bleeding on probing 12-month follow-up	*N*	45	32	77
	Proportion (95% CI)	0.55 (0.44 to 0.66)	0.54 (0.40 to 0.68)	0.54 (0.46 to 0.63)
Plaque baseline	*N*	61	44	105
	Proportion (95% CI)	0.57 (0.46 to 0.68)	0.63 (0.51 to 0.76)	0.59 (0.52 to 0.68)
Plaque 12-month follow-up	*N*	45	32	77
	Proportion (95% CI)	0.73 (0.63 to 0.82)	0.71 (0.60 to 0.82)	0.72 (0.65 to 0.79)
OHAT baseline	*N*	61	44	105
	Mean (95% CI)	4.4 (3.7 to 5.2)	5.4 (4.5 to 6.3)	4.8 (4.3 to 5.4)
OHAT 12-month follow-up	*N*	46	29	75
	Mean (95% CI)	5.0 (4.2 to 5.7)	5.5 (4.5 to 6.5)	5.2 (4.6 to 5.8)
OIDP baseline	*N*	63	52	115
	Median (interquartile range)	0 (0–3.5)	0 (0–0)	0 (0–2)
OIDP 6-month follow-up	*N*	31	27	58
	Median (interquartile range)	0 (0–0.5)	0 (0–1.8)	0 (0–1.5)
OIDP 12-month follow-up	*N*	46	31	77
	Median (interquartile range)	0 (0–6)	0 (0–4)	0 (0–5)

part of the WS3 below. Descriptive statistics for those who completed data at all visits are presented in *Table 5*. Overall, the ratings were generally slightly higher in the follow-up, indicating worse oral health; however, direct comparisons between the baseline and follow-up are not methodologically appropriate as they refer to different sample sizes due to some residents withdrawing from the study or being lost to follow-up.

Moreover, *Table 6* presents the results of the linear and fractional response regression analyses and *Table 7* presents the prevalence ratios for the negative binomial analysis models, for the different oral health and quality-of-life variables with the 12-month follow-up rating as the potential dependent variable adjusted for the baseline rating and for several other factors as described in the statistical analysis section above. Overall, the differences between the intervention and the control arms at the 12-month follow-up were very modest for most of the potential outcome variables. Relatively larger differences were observed for: (a) the OIDP prevalence ratio, with better oral health-related quality-of-life ratings (i.e. lower OIDP scores) for the intervention arm, as the intervention OIDP score was 0.8 times the respective score of the control arm, (b) the proportion of teeth with bleeding on probing, with higher proportion for the

TABLE 5 Descriptive statistics of the oral health and quality-of-life variables for those who completed data at all visits

	Descriptive	Control	Intervention	Total
Coronal caries baseline	*N*	46	32	78
	Median (interquartile range)	0 (0–0)	0 (0–0)	0 (0–0)
Coronal caries 12-month follow-up	*N*	46	32	78
	Median (interquartile range)	0 (0–0)	0 (0–0)	0 (0–0)
Root caries baseline	*N*	46	32	78
	Median (interquartile range)	0 (0–2)	0 (0–2.5)	0 (0–2)
Root caries 12-month follow-up	*N*	46	32	78
	Median (interquartile range)	0 (0–2)	1 (0–3)	0.5 (0–2)
Bleeding on probing baseline	*N*	46	32	77
	Proportion (95% CI)	0.41 (0.29 to 0.52)	0.50 (0.37 to 0.64)	0.45 (0.36 to 0.53)
Bleeding on probing 12-month follow-up	*N*	45	32	77
	Proportion (95% CI)	0.55 (0.44 to 0.66)	0.54 (0.40 to 0.68)	0.54 (0.46 to 0.63)
Plaque baseline	*N*	46	32	77
	Proportion (95% CI)	0.59 (0.47 to 0.70)	0.65 (0.53 to 0.76)	0.61 (0.53 to 0.69)
Plaque 12-month follow-up	*N*	45	32	77
	Proportion (95% CI)	0.73 (0.63 to 0.82)	0.71 (0.60 to 0.82)	0.72 (0.65 to 0.79)
OHAT baseline	*N*	45	29	74
	Mean (95% CI)	4.3 (3.5 to 5.2)	5.3 (4.2 to 6.3)	4.7 (4.1 to 5.4)
OHAT 12-month follow-up	*N*	45	29	74
	Mean (95% CI)	4.9 (4.1 to 5.7)	5.5 (4.5 to 6.5)	5.1 (4.6 to 5.7)
OIDP baseline	*N*	35	30	65
	Median (interquartile range)	0 (0–4.5)	0 (0–0)	0 (0–3)
OIDP 6-month follow-up	*N*	35	30	65
	Median (interquartile range)	0 (0–0)	0 (0–0)	0 (0–0)
OIDP 12-month follow-up	*N*	35	30	65
	Median (interquartile range)	0 (0–5)	0 (0–4)	0 (0–4)

TABLE 6 Adjusted results of outcome measures from linear and fractional response regression analysis models

		Control	Intervention	Total	Intervention – Control
Bleeding on probing 12-month follow-up	*N*	45	32	77	79
	Adjusted proportion (95% CI)	0.58 (0.45 to 0.71)	0.49 (0.31 to 0.69)	0.54 (0.39 to 0.70)	−0.09 (−0.14 to 0.04)
Plaque 12-month follow-up	*N*	45	32	77	
	Adjusted proportion (95% CI)	0.74 (0.69 to 0.80)	0.69 (0.67 to 0.70)	0.72 (0.69 to 0.75)	−0.06 (−0.13 to 0.01)
OHAT 12-month follow-up	*N*	46	29	75	75
	Adjusted mean (95% CI)	5.11 (4.51 to 5.71)	5.21 (4.46 to 5.96)	5.15 (4.68 to 5.61)	0.10 (−0.87 to 1.07)

TABLE 7 Prevalence ratios of outcome measures from negative binomial analysis models

Outcome	Factor	Prevalence ratio (95% CI)
Coronal caries	Group (control vs. intervention)	1.44 (0.31 to 6.61)
Root caries	Group (control vs. intervention)	0.94 (0.44 to 2.02)
OIDP	Group (control vs. intervention)	0.80 (0.17 to 3.67)

control arm. The intracluster correlation coefficient (ICC) was: 0.40 for the OIDP; 0.32 for the proportion of teeth that bled on probing; 0.04 for the number of teeth with root caries; 0.02 for the OHAT; ICCs for all other measures were less than 0.01.

Workstream 2

This includes different phases. Phase 1 aimed to refine the intervention based on the NG48 guidelines using a co-design process. Phase 2 referred to the process evaluation and Phase 3 (undertaken together with Phase 2) focused on the embedment of the intervention in standard practice.

Phase 1

Phase 1 (intervention refinement) was led by design researchers to address the gap between ideal guideline and standard practice in care home settings. It involved ensuring that the intervention was practically, clinically and culturally acceptable to care home staff and residents. It also looked at understanding the context and mechanisms for delivery by exploring the challenges of oral care practices in care homes.

This phase involved context familiarisation through observation by researchers, co-design workshops with residents and care home staff, and studio design work before and after the co-design workshops. The context familiarisation through observation was carried out in three care homes that agreed to participate while three to six care home staff participated in the co-design process which involved workshops at those three care homes. A more detailed methodology can be found in the relevant publication.[2]

Phases 2 and 3

These referred to a theoretically informed process evaluation to explore how the intervention could be embedded in standard practice guided by the Pfadenhauer *et al.* framework that maximises pathways to impact.[26] The process evaluation involved semistructured interviews with the managers and staff primarily from the intervention arm to assess the intervention's feasibility and sustainability, and with residents to explore the invention's acceptability. Managers and staff were approached from all participating care homes allocated to the intervention arm and from some care homes allocated to the control arm to identify any further factors relevant to the context of providing care. Care home staff were often busy and, therefore, challenging to recruit, and this also affected the participation of care home residents (a few residents were approached, but most declined to participate in a further interview). Moreover, it was impossible to recruit for interviews managers (and residents) who refused participation in the study, despite repeated efforts of the research team. This was also potentially impacted by the timing of the research study that coincided with the prolonged impact of the COVID-19 pandemic, as recruitment took place immediately after the relative easing of access restrictions in a very challenging period for care homes. In total, interviews were conducted with care home managers (six), care home staff (nine), and a resident (one) in the two study settings (London and Northern Ireland).

Towards the end of the process evaluation, a reflexive workshop was also carried out with the three researchers working on the study to determine whether the framework initially adopted was able to capture and portray the voices of those interviewed. This was not planned in the initial protocol but added value by providing a further perspective from those who frequently came in contact with care homes and residents for the conduct of the study. The workshop also explored the experiences and reflections of researchers working in care home settings.

Findings

Phase 1

Phase 1 led to broad understanding of the care home context. It highlighted the challenging care home environment in terms of time and resource constraints, increasing population with dementia and neurodegenerative disorders, and refusal behaviours of residents, which may also pose as a danger to care home staff. A wide range of coping strategies for these refusal behaviours were co-designed with the care home staff along with the other intervention materials based on NG48 guidance. The co-design process ultimately led to the development of a 'Care Home Oral Care Toolkit', presented in the respective paper.[2]

Phases 2 and 3

The findings from process evaluation (Phases 2 and 3) suggested that a system thinking lens was better than the Pfadenhauer *et al.*[26] framework in describing what the stakeholders were conveying in a more hierarchical structure.[31] It was also able to highlight the idiosyncratic nature of different settings, complexity of the care home environment, and values and beliefs of the key stakeholders. Time poverty, competing needs, staff turnover, differences in shift patterns and differences in response between permanent and agency staff were key factors that affected the intervention.

The system thinking lens acknowledges the knowledge mobilisation through different system structures and is influenced by actors, resources and dynamics of the environment. It further highlights that elements in the system are hierarchical. The beliefs and values of a system (referred as 'paradigm') were deemed to be most important and this further acts on the aim and purpose of system (referred as 'goal'). The 'goal' further acts on regulation and organisation of the system (referred as 'system structure'). This 'system structure' tries to maintain the status quo ('feedback'), and stakeholders and resources ('system elements').[31] The data collected are described under these leverage points (paradigm and goals, system structure, feedback and structural elements).

In terms of the paradigm and goals, there was a strong desire to participate in the study. This was further reinforced through the difficulty care homes faced with access to local dental services, and these values drove interest towards participation.

> *We've struggled to get people the help out there … it is another discriminatory kind of thing.*
>
> *I:1.380 care home manager*

Moreover, the participation of the care homes in the study had a considerable impact on the daily routines for the care home staff.

> *We knew that they weren't really brushing their teeth as often as they said. So now they're really on board and they point out to you after breakfast, I'm away to brush my teeth now.*
>
> *I:8.40 care home manager*

The system structure describes the idiosyncratic nature of care home settings and how the intervention adoption varied between them. The reflexive workshop with researchers further highlighted the variation of organisation and efficiency of processes in different settings.

> *I think I would say every care home is unique. No matter what their organization is, what their ownership is like.*
>
> *W:3, 019 researcher 2*

The position and personality of the person in charge were also a key element in terms of the implementation of the intervention and the study in general.

> *Junior care home staff would struggle to make it happen because they're not high enough in the hierarchy in that particular care home … they don't have the authority, they can't make any changes.*
>
> *W:2, 936 researcher 1*

Time poverty was also an important issue highlighted in both the interviews and the workshop.

> *It takes time to give them [the residents] their personal care and to get them ready*
>
> *W:6.762 care home staff*

> *These people are so over worked. They are very well motivated. They want to do the study. It's just they don't have the time to do that.*
>
> *W:320 researcher 1*

Furthermore, the care home staff had competing needs where they need to prioritise one task over another due to time poverty.

> *So, they are more happy to give someone a shower and give them breakfast and forget about those other bits, yeah.*
>
> *I:1.862 care home manager*

The differences between shift patterns also affected the intervention and routines.

> *The night time staff would be getting the residents ready for bed and so they would have [the oral health routine] at the start and at the end of their shifts [morning routine] … it's one of many other jobs they just had to do.*
>
> *I:9.103 care home manager*

The staff turnover was another important factor to affect the delivery of the oral health intervention.

> *There's a staffing issue, if you don't have enough staff, [it] becomes difficult for them to do it, but they try.*
>
> *I:4.337 care home staff*

And there were differences in how permanent and agency staff responded to the study.

> *Staff wise … it really affected us greatly because when we started most of the team members that we have were agency.*
>
> *I:5.292 care home manager*

Feedback focused primarily on the processes for stability and status quo. A key finding was the excessive paperwork.

> *It's just the paperwork. Because in their mind. The last thing they're thinking of is to fill up to do paperwork.*
>
> *I:6.651 care home staff*

> *When they're actually helping with toothbrushing or helping with maintaining the hygiene, I think they felt like they were doing their job. But when they're doing paperwork they feel like they're doing something extra, it is like an add on.*
>
> *W:1, 687 researcher 2*

Integrating oral health into routine practice within the existing processes of the care home was also seen as key.

> *But if I was doing it today, I would actually make sure the forms were in their bedroom, because that's where everything takes [place].*
>
> *I:9.176 care home manager*

And training was perceived as essential to maintain knowledge levels within the care home and deliver routine oral health care.

> *I've managed services before. It is quite difficult. Because you've got to have the knowledge yourself to share that knowledge.*
>
> *I:1.106 care home manager*

In relation to the structural elements of the system lens approach, the interviews brought forward the role of care home staff as well as the varying cognitive capacity of the residents.

> *It's about getting to know your resident, what works, what doesn't work.*
>
> *I:1.1, 512 care home manager*

> *And it has to be made enjoyable for it, even if it's something silly like singing a wee song or or not. Not to make them out to sound childish. But some of our residents do have dementia and they enjoy things like that. So it's about making it a fun activity.*
>
> *I:8.26 care home manager*

The reflexive workshop also highlighted that cognitive capacity of the residents fluctuated over the course of the study impacting on communication and data collection.

> *They were mild to moderate [in terms of cognitive impairment] when we recruited them, but their ability declined over the course of the study.*
>
> *W:896 researcher 2*

Moreover, staff attitudes seemed to vary and some staff may not have been keen to take part in the intervention though there was always a staff member wanting to take this forward.

> *There are quite a few [staff] that don't wanna take part. I'll be honest with you. I'm the only one*
>
> *I:2.1162 care home staff*

From a practical perspective, the OHAT was deemed to be helpful for raising awareness of oral health among the care home staff. However, it added further burden on them. And the reflexive workshop that considered the perceptions of the researchers on the ground, indicated that the intervention materials (that included the OHAT) were not fully utilised in some care homes.

> *I'm getting a bigger picture … I'm getting to understand who actually brushes their own teeth. Who's having a challenge with it? Who needs much more intervention?*
>
> *1.138 care home manger*

> *The poster might be helpful because it's on their wall … they would be seeing the poster if they are in the room.*
>
> *W:3629 researcher 2*

> *Only some of them are using those 'tips and tricks cards'. They don't have time to? They are like stuck at the back of the file.*
>
> *W:3, 592 researcher 1*

More details about the methodology and findings involved with WS2 Phases 2 and 3 can be found in the respective paper.[4]

Workstream 3

Workstream 3 involved the development of a cost–consequence model to determine the relevance and importance of various outcome measures for decision-making. For this purpose, quantitative and qualitative cost-related data were collected. The quantitative data on

health-related quality of life were collected through the EQ-5D-5L at baseline, 6-month, and 12-month follow-up. Towards the end of the study, an online survey was collected from participating care homes and residents that captured the data related to feasibility of various cost-related outcomes. Qualitative data were also collected through interviews with key stakeholders that complemented the quantitative data to explore perceptions regarding the challenges for conducting a study examining cost–consequences of an oral health intervention in a care home setting. This included an open discussion on oral health in care homes and challenges around the delivery and evaluation of the intervention. These data also allowed an assessment of the overall feasibility of economic evaluation and the potential threats for a definitive study. The quantitative data from EQ-5D-5L were tabulated and summarised using frequencies and percentages for each level and dimension. On the other hand, the qualitative data were analysed thematically. Full details are described in the relevant paper.[5]

Findings (Workstream 3)

Overall, the study demonstrated that it was possible to collect key data on outcomes relevant for an economic evaluation in a subsequent definitive trial, with 95% of participants that remained in the study having EQ-5D-5L questionnaires completed at the 12-month follow-up as described above in *Data completion* and in *Table 2*. There was variation in EQ-5D-5L completion numbers at baseline, 6-month and 12-month follow-up (from 115 residents with complete EQ-5D-5L data at baseline to 78 residents with complete data at 12-month follow-up), and also between the different sites (Northern Ireland and London). Considering the original sample, 50% of responses were missing at the 6-month follow-up in Northern Ireland, while in London 20% were missing at that time point. This was mostly down to sample attrition rather than a specific feature of the WS3-related data.

The EQ-5D-5L scores suggested that the condition of residents deteriorated over time. This deterioration most likely affected mobility, followed by self-care and issues with usual activities. Conditions such as pain/discomfort and anxiety/depression were less prevalent at moderate or higher levels. The details are highlighted in the relevant paper.[5]

The online survey was answered by about a third of the participating care homes (7/22). No care homes in Northern Ireland responded to the online survey and this may be because it was conducted towards the end of the study (October 2023), when all other data collection was completed in most care homes, while some care homes underwent a change in ownership or management. It would be better if this survey is carried out during the active period of study in a potential subsequent definitive trial.

All seven care homes that responded to the survey routinely recorded information about dental care provided to residents, and some (four) were able to provide examples of the type of dental care provided in detail. Five homes also provided information on the type of dental practice that provided care (NHS/private). Two care homes reported that dental care was provided by a private provider, while two other care homes provided dental care exclusively through the NHS. One care home reported getting dental care through NHS, private and community dental services (CDSs). The other findings from survey, explained in detail in the paper,[5] included information on staff training, dentate status of residents, daily oral hygiene provision, and the impact of the intervention.[5]

The interviews with stakeholders helped identify some key themes in relation to oral health, its importance in care homes, focus on prevention and challenges faced in provision of dental treatment. The interviews further highlighted the perceived challenges around the implementation of the intervention and the collection of cost–consequence data that would be crucial to evaluate it. A common theme was the challenging environment for care home staff in delivering and evaluating the intervention. These challenges include low staff-resident ratio, complex resident needs and priorities, and high staff turnover adding to demands on the staff. Apart from care home staff, there was pressure on dentists to provide care to residents in care homes, which was difficult due to transporting equipment and associated opportunity costs at current remuneration levels.

Discussion

The key findings from the different parts of the study are now discussed in sequence, starting with the intervention refinement, and continuing with the main feasibility study, the process evaluation and the cost–consequence exercise that were conducted in parallel.

The NICE guideline NG48 is an evidence-informed resource for improving oral health for people living in care homes. However, the guideline was limited by its practicality. Therefore, the co-design of the intervention with care home staff facilitated the production of intervention materials that were practical to be used in daily practice.

Thus, there is a difference between the findings of research and routine practice.[32] It is because the research findings are general, and application requires the guidance to be specific to context. Often this duty to overcome this gap between general and specific comes down to professional judgement and wisdom.[33] The guidelines should therefore assist the professionals with tools that help with judgement in carrying out practice specific to that context. This context can be passive or dynamic. Gabbay and le May[34] suggest that it is not only the context that is challenging but, overall, the idea of practice-in-context. So, the adoption of guidelines is not affected by one aspect and both practice and context together influence it. It is difficult for co-design to understand this complex interaction. However, it brings together the key stakeholders, who provide insights to practice-in context.[35] It also aligns with the Medical Research Council (MRC) guidance that recognises the need to engage with key stakeholders during the design stage to make the intervention acceptable and implementable in appropriate context.[36] This allows the co-design process to bridge guidance, practice, and context. The same applied to this study where co-design workshops were conducted in the care home environment involving the staff and allowed the exploration of practices-in-context.

The co-design led to development of intervention materials that served as knowledge or information for care home staff. It was important that the intervention accounted for the care home staff needs and preferences. This made the intervention practical, relevant and useful. It also allowed the creation of personal records which helped in sharing and communicating information or knowledge across different settings.[37] The co-design was inclusive as it valued the input from stakeholders from the care homes and considered their feedback equally important as of others involved in the study. This is discussed in detail in the relevant paper.[2]

In terms of the main feasibility study results, it was possible to successfully recruit to the trial care homes and residents. However, there are also lessons to be learned from this feasibility study that would be helpful for a future trial. For this feasibility study, ethical approval was specifically provided only for residents without or with mild cognitive impairment (6-CIT score of nine or lower). If the 6-CIT threshold was decreased to exclude residents with mild cognitive impairment, then it would unjustifiably and severely affect the recruitment by reducing the sample while the intervention and the collection of relevant data was feasible for those residents.[3] Moreover, severe cognitive impairment was common, and it was challenging to complete the recruitment by excluding residents with severe cognitive impairment. In a future trial, it would be prudent to consider favourably adjusting the threshold for the 6-CIT screening tool and broaden the inclusion criteria to recruit also residents who have severe cognitive impairment, so the findings are more generalisable. Such an approach would introduce a level of increased complexity, particularly in terms of recruiting participants (e.g. proxy consent for residents without capacity to consent themselves), as well for the training of staff and intervention delivery so that the materials and techniques are tailored also for the aforementioned residents.[3] It would require cautious selection of outcomes for the trial and also consider data collection more carefully, particularly for self-reported outcomes; however, this is feasible. For example, a current NIHR funded trial in care homes[38] includes proxy reports for the oral health-related quality-of-life measure used also here (OIDP) while a proxy version of the EQ-5D has been used in care homes.[5,39] The relevant literature on using proxy measures of health-related quality of life indicates the challenges around this, with one study showing low levels of missing data and adequate EQ-5D-5L internal consistency[40] while another also showing low levels of agreement between proxy and self-reports.[41] More importantly, the argument for inclusion is solid ethically, considering the increasing proportion, vulnerability, and oral health burden of care home residents that suffer from severe cognitive impairment.[3]

Care homes were retained successfully, though there was some difficulty to retain the residents over the course of the study. The main reasons for withdrawal were death and leaving the care home, which were outside of the control of the trial. Some residents dropped out because their care home management decided to withdraw from the study. This will need attention for a future trial as multiple residents from the site are withdrawn if a care home decides to opt out. A cautious approach is needed during the early engagement stage with care homes to make sure that expectations are realistic. This would mean early engagement with key care home staff that work closely with the research team and serve as an extended research arm of the study in the care home. As recruitment involves several avenues like collaboration with NHS Clinical Research Networks (CRNs) and CDSs, it is important to maintain close contact with them to avoid any gaps in communication or engagement with the interested care homes.

It would also be appropriate to consider a high attrition rate during sample size calculation for a definitive trial. The timing of attrition is also relevant with two homes withdrawing from the study soon after recruitment

and baseline data collection, and after changes in their management, and another one not agreeing arrangements for recruitment of residents within the set time frame. This highlights the importance of care homes' organisational characteristics, management stability and commitment to the study as key success factors for retention in a subsequent definitive trial. Extending the recruitment period may also be helpful, particularly considering the challenging research context. A future definitive trial should also collect information that would allow distinguishing between long-term care home residents and those who became residents in their older years due to age-related reasons.

It was feasible to collect the data for several outcome measures. Clinical outcomes like number of teeth, number of teeth with coronal and root lesions, proportion of teeth with visible plaque, proportion of teeth that bled on probing and oral health needs were feasible to be recorded. Health questionnaires like the EQ-5D-5L and the OIDP were also feasible. The clinical and subjective outcomes were collected separately, and this would require closer coordination between researcher and clinical examiner to avoid any gaps in data collection. Data collection on oral symptoms and urgent dental care was feasible when collected by researchers, but not when collected by the care home staff. This would imply that key study outcomes should be collected by the research team. Since the clinical outcomes and health questionnaires were feasible, they could potentially be included as outcome measures for a definitive trial. The weekly symptom checklists were not successfully completed by care home staff, with low completion rates. The process evaluation indicated that paperwork was a considerable burden particularly considering the time pressures and competing needs they face. A less frequent data collection may facilitate better completion rates, and this can be explored in further research.

The intervention included supervised toothbrushing and intervention materials, such as the oral health assessment, the oral hygiene record and the personal oral care plan, which were completed to some extent. However, the frequency (weekly or monthly) and mode of completion (digital or manual) needs to be reviewed for a definitive trial and feedback from the feasibility study should be incorporated to refine the intervention.

This feasibility study has contributed to the limited empirical evidence-base for interventions to improve oral health among dependent older adults in care homes. A recent systematic review[42] highlighted concerns around study quality, with only a handful of experimental studies having a low risk of bias, while the evidence from better-quality studies was inconclusive, with some studies reporting that interventions led to improved oral health[43–45] while others not.[46,47] Of these, only five studies were based on a cluster design and apart from one study,[43] the remaining definitive studies[44–46,48] recruited a smaller number of care homes than this study. Only one randomised clinical trial tested the effectiveness of an oral health guideline[49] and this was judged to be unclear in terms of risk of bias. More importantly, this is the first research that has assessed whether the NG48 recommended interventions are feasible in a UK setting.

The process evaluation also suggested that care homes are complex environments and there was considerable variation in the organisation and efficiency of the processes, cognitive capacity of the residents, and staff attitudes towards the intervention. Time poverty was a major issue as there were several competing needs that affected staff. There were also different factors like staff turnover, difference in responding to an oral health intervention between permanent and agency staff and the cultural differences between different shift patterns.

The findings align with the complex systems perspective, which is common for public health interventions that capture a snapshot of a system while the real world is not static.[50] Towards the end of the study, the theoretical framework was changed from the Pfadenhauer *et al.*[26] (2017) framework to a system lens approach[31] as this highlighted the hierarchical structure of different systems within the setting and helped portray the findings in a better way. The findings from the study also align with other studies that report oral care as challenging within the care home environment.[51,52] Oral care was considered a personal issue and therefore providing best oral care posed a challenge for care home staff.[53] Through the older adults' transition from independent living to becoming care home residents, there is usually loss of identity[54] and oral health plays an important role in preserving dignity.[53] The cognitive ability of the residents varies and impairment adds to the challenge with difficult behaviours.[2]

The training and opportunity costs for the oral health intervention are important considerations. The various elements like tips and tricks, oral health training, and posters helped with provision and retention of knowledge, which was highlighted as a requirement.[52] There were also challenges, as this practice imposed a burden on the care home staff in terms of workload while the constant flux of agency and permanent staff made it more difficult to manage that burden.[55]

The workshop towards the end of the study served as reflection for the main findings, framework selected and implementation of the intervention. It allowed the team to review whether the undertaken approach was sufficient to explain the findings. The shift towards a systems lens approach made the narrative coherent and highlighted the importance of values and beliefs of those who were 'on the ground' and those who set the paradigm within the care home in the implementation of the TOPIC materials. This means that the intervention must align with the values and beliefs of those that are part of the system[56] and is further discussed in the relevant paper.[4]

The idiosyncratic nature of care homes' structures and practices that were highlighted during the process evaluation suggested that a future definitive trial should be extended to a range of geographical areas within the UK, while also considering including care homes with different organisational characteristics. This would allow the research to capture a wider range of care home types and characteristics, explore potential geographical and other variations, and make the findings more generalisable.

The findings from WS3 showed that it was feasible to collect data for economic evaluation through the EQ-5D-5L and OIDP at different time points. It was also possible to collect key data, such as existing record of dental treatments provided to the residents, arrangements for provision of oral healthcare training to staff, records of needs for residents, and what care home managers perceived to be a key cost outcome from a care home perspective. Quality of life of the residents was identified as a key outcome of concern to stakeholders including care home managers. As such, the study demonstrated the feasibility of collecting such data with face validity in this context, thus making the case for a definitive study to adopt a cost-utility approach of the type favoured by NICE for an evaluation.

Sample attrition may impact on the data completion at follow-up, and mitigation strategies, such as the potential use of proxy reports, need to be considered in this context. There was variation between different care homes but time constraints under which care home staff operates was a common finding. The timing of data collection was also crucial as it was extremely difficult to re-engage with the care homes that completed the study. Collecting relevant data on cost and consequences in the active phase of a future study is recommended, together with monitoring of data completion and quality by the research team. Finally, care assistant time was also identified as a key resource likely to influence the decisions of care home managers when assessing the success of an intervention. More details can be found in the relevant paper.[5]

Limitations and challenges

This was a feasibility study and therefore a cautious interpretation of findings associated with health outcomes is required. The study was not powered to assess and make inferences about the improvement of health outcomes.

The major challenge to the study was COVID-19 pandemic which severely delayed the project timeline. Throughout the data collection, there were again several instances of COVID-19 outbreaks which made the care homes close for 2–3 weeks, and this affected the recruitment of care homes and residents despite allowing for a 10-month recruitment period. Moreover, the recovery from these outbreaks was gradual, meaning that study arrangements were further delayed with consequences on maintaining good retention rates.

Another major challenge was retention of participants because the care home environment is so dynamic and residents keep moving in and out of the care home due to hospitalisation, moving to a different care home, moving back to their home or family, and death. It was also difficult to maintain continued interest in some care homes and a couple of homes withdrew from the study after changes in their management. It meant that all participants from those care homes had to be withdrawn, which made a considerable proportion of withdrawals. The process evaluation exercise documented that care homes also face several other challenges, like staff turnover, management commitment and 'buy-in' and organisational characteristics, and these were seen as major hurdles in engaging and recruiting them to the study.

The care home environment was also challenging for research as the staff trained to perform the oral health intervention kept on changing from time to time or rotating to night shift as the roster changes over time. Sometimes an active member of staff would take the role of an 'oral health champion' and this seemed to work well, making it also a potential suggestion to consider for a definitive trial. However, there were cases when that member of staff was subsequently moved to the night shift and found it difficult to get the paperwork completed from the staff on the other shift. It is therefore crucial that the care home is committed to improving the oral health of the residents and collectively takes responsibility for the delivery of the intervention, an issue that was also highlighted in the findings of the process evaluation in WS2. It is also important from the perspective of collecting data to make sure that key outcomes are collected by the research team and there is less workload for the care home staff. The paperwork was a major burden for the care home staff, as highlighted in detail in the relevant paper.[4] Moreover, data

about the provision of oral care to care home residents within the care home were also challenging to collect, which is highlighted as part of WS3.[5]

Patient and public involvement

The aim of PPI throughout the study was to ensure that the voices of various stakeholders (residents of care homes, their families, care home managers, and care home staff) helped to shape the research. Overall, PPI was included from the start of the study where PPI members were involved in identifying the research topic. Initially, the recommendations from a Priority Setting Partnership on oral health of older adults identified the key concern of oral health of older people residing in care homes. Two PPI representatives were part of the research team throughout the study. One was identified through the Belfast Older Persons' Patient and Public Involvement Group (BELONG)[57] and the other through a long-term involvement with the Centre for Policy on Ageing. They have assisted in preparing the plain language summary, various other documents and have contributed to research outputs including this synopsis.

Stakeholders such as care home staff were involved in the co-design process that led to refinement of the intervention based on the NG48 guideline. The BELONG PPI group constituting older adults at Queen's University Belfast also collaborated to develop and refine the interview schedule for the process evaluation phase of the study. They highlighted some key questions for recruitment, retention, fidelity and participation, which were important for a feasibility study. During the final stages, the PPI group was involved in the production of 'public friendly' versions of the key findings that were communicated to care home managers, staff and residents.

A dissemination event was organised in London on 26 April 2024, with the active participation of a range of stakeholders including care home managers, staff, PPI members, the Chief Dental Officer (Northern Ireland), the Office of the Chief Dental Officer (England), dental professionals, NHS professionals, third-sector organisations, CRNs, academics and consultants. This event allowed an open discussion between the key stakeholders across disciplines, sectors and organisations, which yielded some key recommendations and suggestions to be incorporated as part of a future definitive trial. The summary of the event and a document with the study key findings[58] have been communicated with the participating care homes and with stakeholders more widely.

Furthermore, the plain language summaries, key findings and policy briefs will be disseminated to different stakeholders including care home groups involving managers, care home staff and residents, the Office of Chief Dental Officer (England and Northern Ireland), and third-sector organisations like the Oral Health Foundation and the Alzheimer's Society. These organisations have been identified with the help of PPI members, research team members and the study oversight groups who have all contributed to shaping the engagement and dissemination activities. A podcast to discuss the key findings from the study was also created with the Outstanding Society.[59]

Discussion of patient and public involvement input

The involvement of PPI and other stakeholders including care home staff has proved to be extremely crucial. The contributions from the PPI members and stakeholders during the co-design process helped refine and adapt the intervention for care home settings. It allowed the intervention to be appropriate, acceptable and feasible in a dynamic and fast-paced care home environment.

The active involvement of PPI members allowed the research to be aligned with peoples' expectations and wishes. This evidence to promoting oral health through a co-designed intervention makes it more specific to the context and needs of the care home. This study also allowed the research team to identify and involve networks of a number of care homes which will help in the involvement of care homes, managers, staff and residents in future research, specifically for oral health.

Equality, diversity and inclusion

The care homes that took part in the study were residential care homes (31.8%), nursing care homes (27.3%), mixed (18.2%) and 22.7% were unspecified. Most care homes were privately funded (45.4%) while 18.2% were funded by charity or third-sector organisations, 13.2% by local authorities, while 22.7% did not specify the source of funding. The participating care homes had a mean of 49.5 residents (SD = 27.8), of whom a mean of 11.1 residents (SD = 16.5) were bed-bound.

The participants in the study were mostly female (58.8%) with a mean age of 83.6 years. The vast majority belonged to the English/Welsh/Scottish/Northern Irish/British/Irish ethnic group (85.7%), and 52.1% of participants were widowed. Overall, 31.9% had no educational qualification, 42.9% had O-level/GCSE or A-level education and 21.8% had received degree level education. In terms of previous

employment, the two more prevalent categories were professional or managerial roles (31.1%), and clerical and sales (27.7%).

In terms of cognitive performance, the mean 6-CIT score was 4 (SD = 3). The residents taking part consisted of residents with no or mild cognitive impairment (6-CIT score lower than 10), as those with severe cognitive impairment or dementia (6-CIT score 10 or higher) were excluded. This may have excluded a considerable proportion of residents, depending on the nature of the care home. This selection criterion may make the findings less generalisable to the wider population of care home residents. A more detailed account of the characteristics of the residents at baseline is presented (see *Report Supplementary Material 1*) here and also included in a related publication.[3]

Impact and learning

By its nature, a feasibility study has less potential of an overall real-world impact compared to a definitive trial. Despite that, there has already been considerable impact and learning from the TOPIC study, with many of the relevant points already mentioned in this synopsis, therefore, highlighted here concisely to avoid excessive repetition.

A key impact relates to the co-designed intervention materials for the oral health intervention used in this study. The intervention is directly linked to core recommendations of the NICE guideline NG48 and therefore is essential that the relevant materials can be seen as relevant from the care homes' management and staff that are the ones that are going to use the NG48 to improve the oral health of their older residents. The co-design process followed in WP2 Phase 1 in this study (and also described in more detailed in previous sections and the relevant publication)[2] led to the development of the 'Care Home Oral Care Toolkit', which is a set of resources that can support care home staff in delivering the NG48 based oral health preventive intervention. The resources are readily available[60] and they have been consistently highlighted in all dissemination activities from the study. Moreover, we are currently collaborating with Care England,[61] a charity representing the adult social care sector about a relevant publication on the oral health of older adults in care homes, where the findings and resources from the TOPIC study will feature.

There is considerable potential for a longer-term impact of this work, but this will depend on further research that will aim to assess whether this feasible oral health intervention is also effective and cost-effective. As such, it is premature to consider such a longer-term impact at this feasibility study stage. We are currently preparing an application for funding of that subsequent definitive trial, and this is described in *Research recommendations*.

Several key lessons from this feasibility study will help shape the aforementioned definitive trial and more generally future research in care homes settings. These are described in some more detail in different parts of the synopsis, primarily in the *Discussion* and the *Research recommendations* sections. One important aspect relates to considering non-restrictive inclusion criteria in terms of the cognitive ability of the residents and conducting research in a more generalisable sample of the care home resident population. As mentioned above, a large proportion of care home residents have severe cognitive impairment, and they are the group with worse oral health and higher levels of need for dental care. Therefore, it is important that such a group is eligible to take part in future research on the effectiveness of the intervention.

A second key aspect relates to the wide range of characteristics and idiosyncrasy of the care homes' structure and culture. Our study covered a range of care homes in London and in Northern Ireland, two areas that are different in many sociodemographic and economic aspects, but do not reflect the much richer variability experienced throughout the country. As a starting point, this calls for future research that extends to more diverse geographical regions in the UK in order to be more inclusive of those contextual aspects. In addition, considerations related to successfully delivering an oral health intervention in this challenging context have been discussed, such as a care home staff member nominated as an 'oral health champion', and they constitute another important learning for future relevant research. There are also other lessons learned (described in more detail in the other sections mentioned above) in terms of enhancing retention of care homes and residents in research, achieving high rates of data completion, and also in relation to potential oral health outcomes that are considered relevant by the residents and the key stakeholders.

The study has actively engaged with key stakeholders in a range of dissemination activities. In addition to the scientific peer-reviewed international publications (presented in *Box 1*), the study and key findings have been presented in a range of national and international oral health conferences and also to conferences and events related to research in care homes, with the latter providing opportunities for multidisciplinary interaction and dissemination to social care stakeholders outside of oral health. For example, the podcast with the Outstanding Society, a #CRED Talk

presentation, as well as those in the Care Home Research Forum and in the Enhancing Residential Care event all facilitated this wider multidisciplinary and context specific engagement and dissemination. In addition, the study findings have been disseminated to policy-makers, commissioners, third-sector organisations and other key stakeholders through a dissemination event that was held in London (with details presented in *Patient and public involvement*). A more comprehensive list of dissemination activities is presented in *Award publications* and *Additional outputs*. The dissemination is still ongoing with a good example of current activity being the collaboration with Care England mentioned earlier in this section.

The study has taken on board NIHR's commitments around climate change, health, and sustainability. Assessing the feasibility of a preventive health intervention (the TOPIC intervention is focusing on good oral hygiene of care home residents) is broadly aligned with sustainability of the health and social care system. And there are several more specific features around the methodology and dissemination that considered management of resources, reduction of waste and travel carbon footprint. The intervention materials and the training package were also available online and training of care home staff was done remotely where possible. The NIHR networks and resources, such as the CRNs and NoCLOR, as well as the NHS contributed to the setup of the study and recruitment of care homes, making the whole process more efficient. The recruited care homes were located in specific areas, and this reduced travelling time and resources, as it allowed for planned visits for recruitment, data collection, including monitoring data, to more than one homes on the same day due to their relative proximity. Moreover, all meetings of the core research team and almost all meetings of the wider research team were carried out remotely and the same was the case for the DMEC and the Study Steering Committee that provided crucial oversight throughout the duration of the study. In terms of dissemination, most of the activities, including presentations, were carried out remotely or involved local travel, with the exception of one dissemination event where some members of the research team travelled to London (in 2024), while international travelling was limited to key international conferences attended by one member of the research team.

Implications for decision-makers

The TOPIC study documented the feasibility of carrying out an oral health intervention in care home settings. The co-design process with residents and care home staff helped adapt the intervention based on the NG48 guidance for the care home settings. As this was a feasibility study, the co-designed intervention should be evaluated for its effectiveness and cost-effectiveness in a definitive trial.

Should such a future trial demonstrate the effectiveness of the intervention, implementation and roll out of the intervention would be a key issue with policy implications. This feasibility study has provided some important initial learnings in that direction. It highlighted that it is crucial to engage with care home managers and staff to ensure the implementation of the intervention. The implementation of the intervention seemed to have been facilitated more directly in care homes where a specific staff member was allocated with responsibility to manage the intervention. It is also important for implementation to integrate this intervention with the routine care of the residents.

Research recommendations

The TOPIC study shows that it is feasible to carry out an intervention to improve the oral health of older adults in care homes, which host vulnerable members of the population. Research recommendations are summarised in the following list and explained in more detail in the subsequent text:

1. Undertake a definitive trial to assess the effectiveness and cost-effectiveness of the co-designed intervention.
2. Incorporate key methodological learnings in the design of the aforementioned trial in terms of inclusive recruitment, achieving high retention, selecting an appropriate outcome, and wider geographical coverage.
3. Co-design and evaluate interventions for older adults in care homes based on other aspects of the NICE guideline NG48.

Future research should prioritise a definitive trial to provide evidence of both the effectiveness and cost-effectiveness of this feasible oral health intervention for this population group. The evaluation of the intervention is equally important to understand what works and what does not. Process evaluation alongside the trial will allow us to capture the challenges in real time. This will also inform future policy and decision-making.

This feasibility study has also provided important learnings that can shape and provide direction around important methodological aspects of a subsequent

definitive trial. A more inclusive recruitment that relaxes the inclusion criteria and recruits also residents with severe cognitive impairment in the sample would increase the generalisability of the findings and it is ethically correct. This would also require considerations around recruitment, retention and data collection that may introduce a degree of complexity but with feasible options available (as discussed in previous sections of this report). In terms of selecting a primary outcome, oral health-related quality of life is an important outcome of healthy ageing and particularly in a care home environment,[54,62] collection of the relevant data was feasible and there were relatively larger differences within the context of this feasibility study, while it was also highlighted as a key consideration in the interviews with stakeholders. Finally, it is recommended to consider sampling care homes from different parts of the country and with collectively different organisational characteristics, in order to accommodate as much as possible the idiosyncrasy and heterogeneity of the sector and further contribute to the generalisability of the findings.

There are also some broader recommendations for research in this field. The TOPIC study engaged a number of stakeholders to co-design the intervention allowing it to be acceptable and relevant in the care home context. It suggests that further research should consider using the co-design process to develop interventions that are adapted to specific contexts and will facilitate their implementation. Considering also the wide range of recommendations within the NG48 guideline,[63] it would also be good to evaluate the different interventions recommended, which could further facilitate policy and decision-making.

Conclusion

In conclusion, this study of an oral health intervention in care homes showed that recruitment and retention of both care homes and residents was feasible, while data completion and intervention recording was successful. The parallel process evaluation documented a range of factors that influence the implementation of an oral health intervention in a care home environment, including the idiosyncratic nature and hierarchical structure of influence in these settings. The findings also support the case for the conduct of an economic evaluation in a definitive trial to address a manifest gap in the evidence base on oral hygiene interventions in a care home context. These suggest that a definitive trial could be undertaken to assess the effectiveness of the co-designed intervention, but more inclusive recruitment, high retention, minimising missing data and outcome selection are important issues to consider.

Additional information

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Data-sharing statement

All data requests should be submitted to corresponding author for consideration. Access to anonymised data may be granted following the review.

Ethics statement

The trial was approved by Health Research Authority and Health and Care Research Wales (19/LO/1107) on 5 April 2020.

Information governance statement

University College London is committed to handling all personal information in line with the UK Data Protection Act (2018) and the GDPR (2018). University College London is the data controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and contact details for our Data Protection officer here: www.ucl.ac.uk/data-protection/.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GJGT0613.

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Study registration

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Award publications

This synopsis reports research award *Improving the Oral Health of Older People in Care Homes: a Feasibility Study (TOPIC).*

Other articles published as part of this thread are:

Langley J, Wassall R, Geddis-Regan A, Watson S, Verey A, McKenna G, *et al*. Putting guidelines into practice: using co-design to develop a complex intervention based on NG48 to enable care staff to provide daily oral care to older people living in care homes. *Gerodontology* 2022;**40**:112–26. https://doi.org/10.1111/ger.12629

Tsakos G, Brocklehurst PR, Syed S, Harvey M, Daniyal S, Watson S, *et al*. Improving the oral health of older people in care homes: results from a randomised feasibility study. *Community Dent Oral Epidemiol* 2025;**53**:413–23. https://doi.org/10.1111/cdoe.13043

Brocklehurst P, Langley J, Wassall R, Daniyal S, Syed SS, Harvey M, *et al*. A theoretically informed process evaluation in parallel to a feasibility study of a complex oral health intervention using NICE guidelines in a care home setting. *Community Dent Oral Epidemiol* 2025;**53**:152–9. https://doi.org/10.1111/cdoe.13016

O'Neill C, Brocklehurst PR, Syed S, Syed S, Harvey M, Daniyal S, *et al*. A feasibility study of the costs and consequences of improving the oral health of older people in care homes: findings from the TOPIC study. *BMC Oral Health* 2025;**25**:1062. https://doi.org/10.1186/s12903-025-06322-6

For more information about this research, please view the award page (www.fundingawards.nihr.ac.uk/award/17/03/11).

Additional outputs

Tsakos G, Brocklehurst PR, Watson S, Verey A, Goulden N, Jenkins A, *et al*. Improving the oral health of older people in care homes (TOPIC): a protocol for a feasibility study. *Pilot Feasibility Stud* 2021;**7**:138. https://doi.org/10.1186/s40814-021-00872-6

Presentation - 2019 European College of Gerodontology conference

Presentation - 2021 International Association of Dental Research (virtual) conference

Oral presentation - (April) 2023 British Society of Gerodontology conference (Belfast)

Presentation - TOPIC study in Public Health England meetings on:

Academic dental network

Oral health in care homes network

Presentation - Patient client council (Northern Ireland)

Discussion - TOPIC project with Commissioner for older people in Northern Ireland

Presentation - Oral health in care homes in British Dental Association (Northern Ireland Council)

Presentation - Care home research forum 2022 to a range of care home -level stakeholders

e-Learning resource - TOPIC resources included in Stay Smiling programme website for care staff

Presentation - Care home research forum (London, 2023) to a range of care home level stakeholders

Poster presentation - British Society of Gerodontology Winter Conference 2023

Presentation - (jointly with other NIHR funded care home studies) #CRED Talk (January 2024)

Poster presentation - March 2024 for International Association for Dental Research

Dissemination event - April 2024 (Wellcome Collection, London, UK)

Presentation - Care home research forum (London, 2024) to a range of care home level stakeholders

Podcast - Careology (Outstanding Society): Knowing how to support mouth care and health for older people living in care homes (March 2025)

Presentation (remotely) - Enhancing residential care: how research can make a difference to practice (May 2025)

About this synopsis

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List of supplementary material

Report Supplementary Material 1
Supplementary tables

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/GJGT0613).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

The supplementary materials (which include but are not limited to related publications, patient information leaflets and questionnaires) are provided to support and contextualise the publication. Every effort has been made to obtain the necessary permissions for reproduction, to credit original sources appropriately, and to respect copyright requirements. However, despite our diligence, we acknowledge the possibility of unintentional omissions or errors and we welcome notifications of any concerns regarding copyright or permissions.

List of abbreviations

AE	adverse event
6-CIT	6-Cognitive Impairment Tool
CONSORT	Consolidated Standards of Reporting Trials
COVID-19	coronavirus disease discovered in 2019
CRN	Clinical Research Network
DMEC	Data Monitoring and Ethics Committee
EQ-5D-5L	EuroQol-5 Dimensions, five-level
MRC	Medical Research Council
NG48	National Institute for Health and Care Excellence guidance #48
OHAT	Oral Health Assessment Tool
OIDP	Oral Impacts on Daily Performances
PPI	patient and public involvement
TOPIC	improving the oral healTh of Older People In Care homes
WS	workstream

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