Methodology and outcome of trials involving older adults in UK care homes: A rapid review

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Abstract
Background: The United Kingdom (UK) has a well-developed health and social care system, and strong research governance. However, there is limited evidence to guide best research practice among vulnerable older people in care homes and there is no consensus on clinical trial methodology that is deliverable in this setting.

Objectives: To review the literature on trials conducted among older adults residing in care homes within the UK and collate evidence on their methodological characteristics and outcomes.

Methods: A systematic rapid review methodology was employed. MEDLINE, EMBASE and CENTRAL were searched in two incremental stages: stage 1 searched for oral health-related trials conducted within the UK care homes up to July 2021, whereas stage 2 sought for general health-related trials in the same setting from 2011 to 2021. The quality of included studies was assessed using Cochrane’s RoB 2 and ROBINS-I tools. Findings were summarised descriptively.

Results: Five oral health and 33 general health-related trials involving care home residents were included for analysis. The most common trial design was parallel group with two arms (n = 25) involving individual randomisation (n = 21). Consent was mainly obtained from residents and/or their proxies (n = 24), followed by residents only (n = 13) and care homes only (n = 1). Based on available data, the number needed to screen to recruit one participant ranged from 2 to 40 (median: 3; Q1-Q3: 2-9). Attrition rates ranged from 0% to 73% (median: 21%; Q1-Q3: 13%-32%) for follow-up periods between 1 and 52 weeks. The studies were of mixed methodological quality.

Conclusion: This rapid review outlines the methodological characteristics and outcomes of trials conducted among older adults in UK care homes. The findings of this review provide valuable information to assist in navigating and designing future research in this complex setting.

Keywords
aged, care homes, dental care for aged, homes for the aged, nursing homes, older adults, oral health, randomised controlled trials as topic/methods, rapid review, research methodology
1 | INTRODUCTION

The global population is ageing. In the United Kingdom (UK), the number of older adults, defined as people aged 65 and above, is expanding at a significant rate and estimated to reach one in every four people by 2038. In 2016, approximately 410 000 older adults were residing in care homes, a figure expected to rise in the coming years as the need for care from this population increases. Compared to community dwellers, older adults admitted to care homes have a higher disease burden and more complex healthcare needs. However, robust evidence to support quality care in this phase of their lives is lacking. Thus, more research in this setting is urgently needed, particularly in relation to trials, which, when well designed, are considered higher forms of evidence.

Care homes differ from other research settings in that they pose many unique methodological and ethical challenges, which contribute to the disparate inclusion of residents in research and subsequently lead to questions about the generalisability of study findings to this vulnerable group. Complex health profiles of residents mean that often they are unable to meet the stringent eligibility criteria of most studies. Additionally, there are ethical concerns about their capacity to provide informed consent owing to cognitive decline. Thus, recruiting care home residents is time-consuming as it necessitates the involvement of different “gatekeepers,” from care home administrators to family members and the residents’ clinicians. Besides, rigorous methodologies such as randomisation, blinding or the use of inactive control may be infeasible, or deemed unethical, in this setting.

Despite the establishment of the “Enabling Research in Care Homes” network by the National Institute for Health Research, little work has been conducted to explore the methodological attributes of trials in care homes. In light of COVID-19, undertaking care home research has become increasingly difficult and so there is a need to revisit research methodologies that are deliverable in this setting.

Having reviewed the literature, four systematic reviews were identified. Three focused specifically on cluster-randomised trials, while one included all types of randomised trials up to mid-2009. Aspects of study design, intervention type, consent and reporting quality were addressed, but not recruitment and attrition which are important considerations in care home research.

Building on previous reviews, this study aimed to collate evidence on the methodological characteristics of trials conducted among older adults residing in UK care homes by reviewing the literature.

Given that each country’s social care system, and research governance structure and processes, shape the nature and conduct of feasible research, it was decided to limit the search to one jurisdiction and thus only include research that was subjected to UK research governance processes, that is ethical approval, research governance and regulatory approvals.

The term “care home(s)” will herein refer to any establishments which provide living arrangement with personal care (residential home) or nursing care (nursing home) to those with such needs. Some care homes also offer a mix of both services.

2 | METHODS

A rapid review methodology was employed. It is a modification of traditional systematic review, where the process is accelerated through streamlining methods, such as limiting the number of databases searched, setting language restrictions and assigning a single reviewer for certain step(s) while other reviewer(s) verify the results. A systematically conducted rapid review allows the synthesis of evidence in a timely manner while maintaining a rigorous approach.

2.1 | Eligibility criteria

This review included only interventional studies as they provide more robust evidence. Participants were care home residents aged 65 and above. Any oral or general health interventions were included. Outcomes were measures which assess residents’ oral or general health status. Only studies conducted within the UK were included.

Interventions directed at care home management, staff or facilities, such as staff training programme, changes in organisational practice or care home physical environment, were excluded. Studies were also excluded where full texts were not available or not published in English. For general health-related studies, only those published since 2011 were included to focus on recent research.

2.2 | Search strategies

Search strategies were developed based on previous reviews and subject knowledge. The first reviewer (EC) performed the electronic search in two stages using prespecified search strategies which included the UK geographic search filters (Figure 1 and Appendix S1).

2.3 | Study selection

Stage 1 search results from three databases were exported to EndNote X9 and all duplicates were removed. EC screened the citations against predefined eligibility criteria, following training and calibration. The second reviewer (RP) cross-checked a random 10%. Potentially eligible publications were retrieved and examined in full text by EC. Authors were contacted where more information was required. Articles with unclear eligibility were discussed with RP.
and any unresolved issues were referred to the third reviewer (JEG). Multiple publications from the same study were identified and considered as one. Reasons for exclusion of articles reviewed in full text were listed (Appendix S2). These steps were then repeated for the yield from stage 2 search.

2.4 | Data extraction and quality assessment

EC extracted the data into an Excel spreadsheet, which was piloted and then refined using three included oral health trials. The following details were extracted: first author’s name, title, aim, study design, consent, flow of participants, details of interventions and outcome measures. Authors were contacted where clarifications were required. Where a study recruited participants from various settings, only data relating to care home residents were extracted.

Methodological quality of included studies was assessed by EC, using the Cochrane “Risk of Bias 2” (RoB 2) tool for randomised studies and “Risk Of Bias In Non-randomised Studies of Interventions tool” (ROBINS-I), which comprehensively cover different aspects of trial design, conduct and reporting.

For study with multiple publications, the main article reporting detailed trial methodology was selected for data extraction and quality assessment, whereas other publications were examined for additional information. Cross-checking was conducted by RP, and any disagreements were solved through discussion, by the research team, to achieve consensus.

2.5 | Evidence synthesis

The findings of the review were summarised descriptively, as meta-analysis was not feasible due to the heterogeneity of included studies.

3 | RESULTS

The study selection processes are presented in Figure 2. Only five oral health trials were eligible for inclusion (corresponding to references [A1-A5], Appendix S3). Subsequently, the search proceeded to stage 2, where 33 general health-related trials [A6-A38] were identified and included in the analysis.

3.1 | Characteristics of included studies

The characteristics of included studies are presented in Appendix S4. Table 1 summarises the findings of both searches.

3.1.1 | Oral health trials (N = 5)

Most trials were based in care homes within England (n = 4). The majority (n = 3) were double-blind, randomised controlled trials with parallel-group design, wherein randomisation into two groups was the most common. The interventions evaluated were medicated chewing gum (n = 2), dental varnishes alone (n = 2) or in combination with high dose fluoride toothpaste (n = 1).

In terms of recruitment, residents lacking capacity to provide informed consent were excluded in all but one study [A3]. Table 2 presents the recruitment and attrition data of included studies. The number of participants recruited ranged from 49 to 407, and the “number needed to screen to recruit one participant” (NNTS) was in the range of 2:1 and 6:1, based on studies which reported this information [A2, A4, A5]. Attrition rates (range: 10%-73%) rose with increasing follow-up periods from 4 to 52 weeks (Figure 3). Dropout was primarily attributed to death or ill health, but in studies which reported high attrition rates [A2, A4], large numbers of participants were also lost through closure or withdrawal of care homes for multiple reasons, including staff unwillingness to participate and administrator turnover. Study interventions were mainly delivered by trained dentists or hygienists (n = 3), and care staff (n = 2), while outcomes were assessed by dentists through clinical examinations (n = 5).

3.1.2 | General health-related trials (N = 33)

For general health-related trials, the majority of studies (n = 23) were conducted in England. Just under half (n = 14) reported recruiting participants from a mix of residential and nursing homes,
while about one-quarter \( n = 8 \) did not provide details of the type of home. Only four studies [A6, A9, A19, A30], evaluated pharmaceutical interventions, all of which related to Alzheimer’s disease, while the remainder involved non-pharmaceutical interventions including psychosocial [A7, A8, A10, A14, A16, A17, A18, A20, A23, A24, A27, A31, A33, A36], nutritional [A13, A15, A22, A25, A35], occupational therapy [A21, A28, A29, A34, A37], neurological therapy [A12, A38], diabetic education [A11], skin health [A26] and hydration [A32].

With regard to trial design, 85% of the studies employed randomisation \( n = 19 \) individually randomised, \( n = 9 \) cluster-randomised. All had a parallel-group design, with two-arm being more common \( n = 23 \), than three-arm \( n = 4 \) or four-arm \( n = 1 \). Of these 28 studies with more than one arm, all had a control group and they received either usual care \( n = 18 \), placebo \( n = 8 \) or active comparator \( n = 2 \). Only six studies reported using double-blinding, whereas many \( n = 13 \) did not implement any blinding. Some studies \( n = 14 \) also detailed using a mixed-methods approach, instead of being purely quantitative.

In most studies \( n = 21 \), residents and/or their proxies provided consent, but in 11 studies, only residents were approached and those lacking capacity to consent were excluded. Many studies \( n = 13 \) also reported conducting capacity assessments prior to gaining consent.

Out of 33 studies, 22 reported the required sample size, either based on formal calculation or estimation, and it was not met in 15 studies. Of these, one [A26] resorted to community recruitment to reach the planned target. Some studies also reported revising the sample size during the study using interim data to adjust for the unmet target [A9, A35, A38]. Contrarily, one study [A21] with such successful recruitment reported completing the trial earlier than expected despite having the largest planned sample size (1042 subjects) of all studies.

The NNTS varied widely from 2:1 to 40:1 based on studies which reported adequate information (Table 2). The number recruited ranged from 11 to 1042 with attrition rates of 0% to 47%. No attrition was reported by the study with a short follow-up period of one week. Similar to oral health trials, ill health and death were the main causes of attrition, except for study A33 which lost almost half of its participants (47%) over 24 weeks, primarily due to care home staff being unavailable to complete the outcome measures. However, a large proportion of studies \( n = 21 \) did not describe whether dropout was accounted for during sample size calculation.

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**FIGURE 2** Flow diagram of the selection of studies for both Stage 1 and 2. *Multiple publications from the same study were counted as one.*
In terms of intervention delivery, most trials (n = 23) reported obtaining assistance from care staff. Primary outcome assessments were conducted largely through questionnaires only, which includes different types of scales or inventories (n = 20), or questionnaires in combination with other forms of assessment (n = 5). Of these, about half (n = 12) relied on care home staff as proxy informants. Other methods of outcome assessment were care home or medical record checking (n = 6), food intake diary (n = 3), anthropometric measurement (n = 1), blood sampling (n = 1), ultrasound imaging (n = 1) and absorbent pad weight test (n = 1).

3.2 Quality of included studies

The RoB summaries are presented in Appendix S5.

All three randomised oral health trials had high overall RoB ratings. For general health-related trials, 14 out of 28 randomised studies had high RoB. Only four randomised studies [A6, A9, A35 and A38] had overall low RoB, while the remaining ten were rated as having "some concerns." The RoB mainly arose from the domains of outcome assessment, randomisation process (allocation concealment) and selective reporting.

For non-randomised studies assessed using ROBINS-I, both oral health trials that were published in 2021 had serious RoB, whereas for general health trials, two had critical and three had serious RoB. Most of the studies did not control for confounding nor report on selection of participants. All studies also did not provide descriptions about blinded outcome assessments.

4 DISCUSSION

By outlining the types of trials conducted among older adults in UK care homes, and detailing their methodological characteristics, this review supports the findings of Gordon et al., which suggested a paucity of research in UK care home settings, especially in relation to oral health.

First, only two oral health trials among care home residents were identified in the literature after 2002; this may be explained by the introduction of regulations in 2004, whereby many important oral health products were classified as "Investigational..."
### Table 2: Recruitment and attrition data of included studies

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>OHT (N = 5)</th>
<th>GHT (N = 33)</th>
<th>All (N = 38)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of studies (n)</td>
<td>Range</td>
<td>Number of studies (n)</td>
</tr>
<tr>
<td>Sample size needed</td>
<td>1</td>
<td>102</td>
<td>22</td>
</tr>
<tr>
<td><strong>Approached</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of care homes</td>
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<td>–</td>
<td>15</td>
</tr>
<tr>
<td>Number of residents</td>
<td>0</td>
<td>–</td>
<td>0</td>
</tr>
<tr>
<td><strong>Screened for eligibility</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of residents</td>
<td>3</td>
<td>84-1041</td>
<td>20</td>
</tr>
<tr>
<td>From number of care homes</td>
<td>3</td>
<td>2-48</td>
<td>20</td>
</tr>
<tr>
<td><strong>Recruited into study</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Number of residents</td>
<td>5</td>
<td>49-407</td>
<td>33</td>
</tr>
<tr>
<td>From number of care homes</td>
<td>4</td>
<td>2-21</td>
<td>27</td>
</tr>
<tr>
<td><strong>NNTS</strong></td>
<td>3</td>
<td>2-6</td>
<td>20</td>
</tr>
<tr>
<td><strong>Followed up</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of residents</td>
<td>5</td>
<td>13-232</td>
<td>33</td>
</tr>
<tr>
<td>Follow-up period (wk)</td>
<td>5</td>
<td>4-52</td>
<td>33</td>
</tr>
<tr>
<td><strong>Attrition rate (%)</strong></td>
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<td>10-73</td>
<td>32</td>
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<td><strong>Attrition rate by follow-up period</strong></td>
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<td>1-13 wk</td>
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<td>10</td>
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<tr>
<td>40-52 wk</td>
<td>4</td>
<td>24-73</td>
<td>3</td>
</tr>
</tbody>
</table>

Abbreviations: GHT, stage 2 search (general health-related trials); n, number of studies which reported the required information; N, total number of included studies; NNTS, number needed to screen to recruit one participant; OHT, stage 1 search (oral health trials); Q1, first quartile; Q3, third quartile.

*Median was not presented due to the small number of studies involved.*


Study A7 did not provide information on attrition.

### Figure 3: Graphical representation of the relationship between attrition rate and follow-up period
Medicinal Products” (IMPs), thus, requiring complex approvals. It is likely that these stringent requirements, especially involving vulnerable participants, deterred trials of any IMPs in this setting.

Another explanation may arise from the nature of interventions and outcome assessments that entail oral examinations, requiring a higher level of cooperation. In this largely dependent population, even basic daily oral care can often prove challenging because of residents’ resistance. Many studies [A13, A22, A25, A28] stated that outcome measures requiring any cognitive skills or physical cooperation from residents will be difficult to collect due to their fluctuating capabilities and willingness to participate, which may be why most general health-related trials relied on proxy informants. However, the accuracy and representativeness of proxy data should be considered.

Second, engaging with care homes throughout the study was vital to the recruitment and retention of participants, as they were often required to assist in study-related activities. Research causing significant burden or disruption to normal workflow would result in care home or staff withdrawal and subsequent loss of participants. Thus, the leadership and organisational structure and support have significant impact on care homes’ willingness and ability to participate in research. This has been reflected in the focus on patient–public involvement in research in the UK, and it is important in this complex setting. This review demonstrates that care home research is co-delivered and therefore should ideally be co-developed to maximise impact.

Third, most studies involved individual randomisation, despite the premise that cluster randomisation would reduce contamination. This may be due to recruitment issues. The wide range of NNTS (2:1 to 40:1) reported in this review depicts not only the varying levels of difficulty associated with recruitment in this setting but also that it is surmountable. The range could not be explained by the nature of interventions, as NNTS varied greatly between trials investigating the same intervention. Studies that were unable to meet their recruitment target or had high NNTS ratios commonly excluded residents lacking capacity to consent [A10-11, A24-26, A29], or had strict eligibility in terms of pre-existing health conditions [A13, A19, A30], whereas studies with successful recruitment often sampled from large number of sites and reported good rapport with care home administrators [A21-22]. These factors may play an important role in recruitment.

Fourth, given the high prevalence of cognitive impairment among care home populations, it is unsurprising to find that majority of studies obtained consent from residents and/or their proxies. Nevertheless, consistent with the findings of a systematic review, there remained a significant proportion of studies that excluded residents lacking capacity, probably due to complexities involved in the decision-making process. Potentially poorer adherence to intervention could be another plausible reason. However, there are ethical challenges in excluding those who have greater needs and are likely to benefit from research.

The UK research data suggest that upon admission, older adults (on average) spend only 2.5 years (median: 1.5 years) in care homes, before reaching the end of life. This may partly explain the higher attrition rates observed in studies with longer follow-up periods, and it also has implications for the power of a study. Our findings on attrition rates are comparable to that reported by McMurdo et al (13.4% to 37% for care home setting). Owing to residents’ advanced age and compromised health, these losses were anticipated and may have impacted the nature of trials undertaken in care homes, as well as the follow-up period set. The results of studies may also be influenced as survivors are possibly those who are healthier and better able to practise self-care, or receive it compliantly.

This review also highlighted the fluctuating quality of trial reporting. Most studies were not explicit about the methodologies employed nor report sufficient information on recruitment, such as the number of homes and residents approached, declined and screened, and whether dropout was accounted for in sample size calculation. Analyses on consent rates and the consistency between estimated and observed dropout rates were therefore not possible. Transparent and detailed trial reporting, including challenges faced and study limitations, will contribute valuable information to the evidence base, thus enabling other researchers to learn and adopt best practice. Authors may consider reporting this information in an appendix, where manuscript word count is a constraint.

4.1 Study implications

To the authors’ knowledge, no previous studies have investigated the characteristics of trials targeting at care home residents within the UK, providing useful insights for future care home research. Our initial intent was to review the methodological characteristics of oral health trials in care home settings; however, with the limited number of studies identified, the scope of the review was expanded to draw on findings from other health-related trials.

This review identified five areas of consideration when planning care home research, namely care home involvement, legal frameworks, inclusion criteria, study design and sample size. First, the inclusion of care home residents in future studies should be considered to improve clinical applicability of study findings. Strategies to establish rapport, co-developing research project and integrating it into the usual workflow of care staff to minimise disruptions could be investigated to possibly improve recruitment and retention. Second, there is a need for a clear, simplified framework to guide research, including ethics and consent for research in care homes. Researchers may consider engaging individuals with legal and ethical expertise to improve understanding of, and ensure compliance with, the legislative requirements for different types of interventions and in different countries, especially when it involves residents with diminished capacity. Third, researchers may consider broadening the inclusion criteria to improve recruitment in this setting. The exclusion of residents lacking capacity should be reconsidered, where possible, linking strongly to point two above. Fourth, while
all included studies employed a parallel design, there are other research designs which are worth considering in this setting, such as stepped wedge cluster randomisation, where all clusters will eventually receive the intervention. Fifth, wide variations in the NNTS and attrition rate need to be taken into account in planning as they may possibly affect the power of the study.

Future systematic reviews could examine the potential factors affecting the rates of refusal, recruitment and attrition to gain more insights, provided sufficient studies have reported adequate information to allow such analyses. In addition, qualitative research may explore the motivations for, and barriers/facilitators to, conducting trials in care homes to facilitate mitigation of these challenges.

4.2 Limitations

There are some limitations to this rapid review. First, the electronic searches were restricted in terms of language and publication date (notably in stage 2), increasing the risk of selection bias. The use of geographic filter may have missed some relevant studies conducted in the UK; however, reference lists of included studies were hand-searched to reduce the number of missed studies. It is also possible that some studies with unfavourable findings were missed due to reporting bias. Second, study selection and data extraction by a single reviewer may have introduced bias and random error such as non-detection of relevant studies and missed information. To minimise these, cross-checking was performed by the second reviewer. Third, as the nature and level of aged care, and legislation governing care homes and research vary between countries, the decision to include only studies in the UK, where interventions were prescribed directly to residents, means that the global evidence base for trials in care home settings has not been collated in this review. However, the findings from this UK review may be of value and applicability to other countries with similar research and health and social care systems. Results should be interpreted with caution as they were derived from small number of studies, but this in itself highlights the importance of further research in the field. While the numerical data may have limited applicability to research outside the UK, the overall information is relevant to the research community, highlighting areas for due considerations in research planning to enhance quality. Finally, despite the limitations of a rapid review, Watt et al suggest that the overall conclusions of rapid and systematic reviews on the same topic were comparable and must be weighed against the extensive resources required to produce a systematic review; thus, these limitations arising from methodological streamlining are inevitable compromises.

5 Conclusion

This rapid review outlines the methodological characteristics of trials conducted among older adults in UK care homes. The findings of this review provide valuable information to assist in navigating and designing future research in this complex setting.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

AUTHORS’ CONTRIBUTIONS

EKMC contributed to the literature search, study selection, quality assessment, data extraction, data analysis and preparation of the first draft of the manuscript. JEG contributed to the conception and design of the study, study selection, data interpretation and critical revision of the manuscript. RP contributed to the study selection, quality assessment, data extraction, data analysis and critical revision of the manuscript. All authors read and approved the final manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available in the supplementary material of this article.

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