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Implementing a Cross-organisational Oral Health Randomised Controlled Trial in Home Care: A Qualitative Study of Organisational Readiness, Coordination and Adaptation

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Abstract

Background: Integrating oral health into home care systems is a global priority, yet little is known about how complex interventions and randomised controlled trials (RCTs) can be implemented in fragmented, cross-sector care settings. Using an oral health intervention as a strategic case, this study aimed to explore the early implementation of a RCT in Swedish home care, focusing on the organisational conditions, stakeholder engagement processes, and stakeholder experiences that shaped trial initiation.

Methods: A qualitative implementation study was conducted using three data sources: (1) stakeholder dialogues including field notes and e-mail responses (n=12 municipalities; 67 participants), (2) individual interviews with the dental hygienists (n=6) who conducted baseline assessments and (3) individual interviews with home care representatives (n=7). Data were analysed using framework informed qualitative content analysis with an abductive approach, drawing iteratively on implementation science concepts related to organisational conditions, implementation processes, and everyday work practices.
Results: Implementation was shaped by four interdependent mechanisms. First, cross-sectoral organisational readiness varied considerably, with municipalities requiring extensive clarification, stakeholder dialogues, and practical support to interpret and operationalise the trial. Second, structural ambiguity and distributed responsibility across healthcare, social care, and dental services created uncertainty regarding roles, documentation, and follow-up procedures. Third, coordination capacity and local tailoring influenced recruitment, logistics, and alignment with existing workflows, resulting in marked variation in participant enrolment. Fourth, frontline adaptive strategies – including iterative problem solving, relational coordination, ethical judgement, and preference-sensitive assessments – were crucial for conducting baseline procedures in complex and unpredictable home environments. Together, these mechanisms made early trial implementation feasible under real-world conditions.
Conclusions: Conducting an RCT in home care across healthcare, social care, and dental care systems is feasible, but requires substantial organisational readiness, cross-sector coordination, and frontline adaptive capacity. The findings demonstrate that implementation feasibility is not a fixed characteristic of study design, but emerges through the interaction between organisational conditions, cross-sectoral coordination and frontline practice. Strengthening organisational readiness, clarifying cross-sector responsibilities, and co-producing implementation routines with care staff and dental services may support implementation of oral health interventions in home care. These findings provide practical guidance for designing feasible, ethical, and context-sensitive trials in decentralised care systems.

Trial registration: ClinicalTrials.gov NCT06310798. Registered on 13 March 2024

Contributions to the literature

- Evidence on how RCTs can be implemented in home care services involving frail older adults remains limited, particularly across healthcare, social care, and dental care services.
- This study identifies four interdependent mechanisms – organisational readiness, structural ambiguity, coordination capacity, and frontline adaptation – that shaped the early implementation of an RCT in home care settings. Together, these findings suggest that implementation feasibility is actively produced through organisational and relational work rather than determined by protocol design and recruitment procedures alone.
- The study provides practical guidance for designing feasible, ethical, and context-sensitive trials in organisations providing home care services with varying levels of research experience and implementation capacity.

Background

Rapid population ageing is reshaping health and care systems globally, with increasing emphasis on delivering care in older adults' ordinary homes (1–4). Throughout this study, these services are referred to as *home care*, consistent with broader international definitions encompassing both healthcare and supportive services (5, 6). The organisational shift to more home care is intended to improve accessibility, continuity, and person-centredness, but also raises important challenges for evaluating care quality and effectiveness in decentralised and organisationally complex settings.

Oral health is a critical component of general health and quality of life among older adults (3), yet it remains insufficiently integrated into general healthcare and social care systems (1). Today, older adults retain more natural teeth than previous

generations, but this change also increases vulnerability to oral diseases that interact with multimorbidity, polypharmacy, cognitive decline, and reduced functional capacity (7–9). Among frail older adults receiving home care – many of whom can no longer access dental clinics – oral health becomes inseparable from broader patterns of dependency, availability, and organisational capacity to provide oral care (10–14).

In this context, oral health in home care can be understood as a strategic case of complex care, where outcomes emerge through interactions between ageing processes, functional decline, and the capacity of care organisations to support daily oral care (2, 11–13). Addressing oral health needs therefore requires not only effective clinical interventions, but also organisational conditions that enable implementation across professional and sectoral boundaries.

Despite these challenges, evidence from trials conducted in home care settings remains limited. Although randomised controlled trials (RCTs) are considered the gold standard for evaluating intervention effectiveness, they remain relatively uncommon in older adults' ordinary homes, particularly when interventions span multiple care providers and must be embedded in routine care practices. Previous research has identified implementation challenges in a range of complex settings, including hospitals, long-term care, dementia care, neurorehabilitation, and resource-constrained environments (15–20). However, little is known about the organisational and frontline processes that shape the implementation of RCTs in home care for older adults.

Existing methodological and implementation frameworks provide only partial guidance for addressing these challenges. Although there is increasing interest in decentralised clinical trials, current approaches rarely capture the organisational and practical realities of conducting research involving frail older adults receiving home care from multiple providers and services (21). Similarly, complex interventions frameworks emphasise that outcomes emerge through interactions between multiple components, actors, and contextual conditions (22), but provide limited empirical insight into how trials are enacted in fragmented care systems. From an implementation science perspective, the implementation of RCTs in such settings can therefore be viewed as complex interventions in its own right, requiring organisational readiness, coordination across actors, and alignment with everyday work practices (23–26).

These challenges are particularly salient in Sweden, where responsibility for home care is distributed between regional healthcare authorities and municipalities (27). Municipalities provide nursing, rehabilitation, and social care in older adults' homes and in nursing homes, whereas physicians and dental services are organised within regional systems (28). As a result, care for older adults often spans multiple organisations, professions, and regulatory frameworks. In daily practice, much of the direct care is delivered by assistant nurses and care assistants, who support daily living but also perform delegated healthcare tasks such as medication administration, insulin injections, and assistance with rehabilitation exercises. However, these staff groups often have limited experience of participating in research activities. In addition, healthcare and social care services operate under different legislation, within separate organisations, and do not always share access to the same patient records (29, 30). Together, these conditions create organisational complexity that may complicate the implementation of research and innovation in home care settings. Oral healthcare for older adults is similarly organised across sectoral boundaries. While regional public dental services are responsible for dental assessments and treatment, daily oral care is largely carried out by municipal care staff within home care services (29). This division of responsibility requires coordination across organisations and relies on non-dental staff to integrate oral care into routine practice. As a result, interventions targeting oral health in home care depend on collaboration across professional, organisational, and regulatory boundaries, further increasing the complexity of implementing and evaluating such interventions.

Against this background, there is a need for empirical studies examining how RCTs can be implemented in home care settings characterised by organisational fragmentation and distributed responsibility, particularly in areas such as oral health where care depends on integration across organisational and professional boundaries. Using oral health as a strategic case, this study aimed to explore the early implementation of a RCT in Swedish home care, focusing on the organisational conditions, stakeholder engagement processes, and stakeholder experiences that shaped the trial initiation.

Methods

Study design

This qualitative study explored the early implementation of a RCT within Swedish municipal home care services for older adults. The RCT, described in detail elsewhere (29), evaluated a practice-based intervention targeting oral healthcare planning for older adults receiving home care.

Multiple sources of empirical material were included in the analysis: stakeholder dialogues documented as field notes (see section ´stakeholder dialogues'), email responses from municipalities that declined participation, individual interviews with municipal representatives, and interviews with dental hygienists involved in baseline assessments.

The present study focused on two interconnected implementation processes: first, how municipal home care units prepared for and decided on participation in the RCT; and second, how dental hygienists planned and experienced conducting baseline assessments with frail older adults in their homes.

The analytical approach was informed by three complementary perspectives. First, trial implementation research was used to conceptualise the RCT itself as a complex intervention requiring organisational readiness, engagement, and adaptation to local work practices (23). Second, implementation outcome constructs proposed by Proctor et al. – particularly acceptability, appropriateness, and feasibility – informed the analysis of trial initiation processes. (25, 26). Third, the Consolidated Framework for Implementation Research (CFIR) was used to identify contextual determinants influencing implementation processes (31). Together, these perspectives supported analysis of how organisational conditions, implementation processes, and everyday work practices shaped the initiation of the trial.

Setting and participants

Six dental hygienists employed by the public dental service participated in the study. All were women and all had more than five years of professional experience. The dental hygienists were responsible for conducting baseline assessments using the Mini-Mental State Examination (MMSE) (32), oral health assessment using the Revised Oral Assessment Guide (ROAG) (33), oral health-related quality of life using the Geriatric Oral Health Assessment Index (GOHAI) (34, 35), and general health status using EQ-5D-5L (36).

All 49 municipalities in western Sweden were invited to participate in the RCT. Invitations were sent by mail to *medicinskt ansvarig sjuksköterska* (MAS) – here translated to Local Authority Senior Medicine Advisors (LASMA) – and to head(s) of healthcare and social care services. Within Swedish municipal healthcare, the LASMA has a statutory responsibility for patient safety, quality of care and compliance with healthcare regulations (37), making LASMAs key actors in the organisational preparation and decision-making processes concerning trial participation. Two reminder emails were sent after three weeks.

Stakeholder dialogues

Sixteen municipalities agreed to participate in stakeholder dialogues conducted on site in each organisation during the preparation phase from September to October 2025. One researcher (JPK) and one dental hygienist (either ES, ABA or ST) participated in all dialogues. In total, 67 municipal employees participated, most commonly LASMAs, heads of social care and social care units (Table 1). The dialogues lasted 45–90 minutes and explored whether and how participants perceived the trial as relevant for their organisation, as well as how it could be implemented within existing structures and work practices.

Table 1
Professional functions of participants in the municipal stakeholder dialogues

Municipality	Participants								
	Head of social services[1]	Head of home care[2]	Head of municipal healthcare[3]	Head of social care unit[4]	Head of nursing homes[5]	Local Authority Senior Medicine Advisors (LASMA)	Quality improvement specialist	Registered nurse	Coordinator home care
1				7					
2				2		1			1
3	1					1			
4			1	2	2				
5	1					1		1	
6	1					1			
7	1					1			
8				15					
9						1	1		
10	1					1			
11	1			10					
12		1				1			
13					1	1			
14	1			1		1			
15		1				1			
16	1					1			
Total	8	2	1	37	3	12	1	1	1

[1]Head of social services = manager of several social care units

[2]Head of home care = manager of both municipal healthcare and social services

[3]Head of municipal healthcare = manager of nurses working in municipal primary healthcare

[4]Head of social care unit = manager responsible for a social care unit, including nursing assistants working within the unit

[5]Head of a nursing home = manager of a nursing home, including nursing assistants and care assistants working there

A semi-structured guide inspired by CFIR (31) and implementation outcomes related to acceptability, appropriateness, and feasibility (25, 26) was used to explore organisational readiness, anticipated barriers, communication structures, available resources, and perceptions of responsibility for oral health in home care (supplementary file). Detailed field notes were taken during and immediately after each dialogue. Following the stakeholder dialogues, four municipalities declined participation in the RCT. Email responses from these municipalities were included in the analysis to capture reasons for non-participation and perceived barriers to participation in the trial. Table 2 presents the participating municipalities and selected demographic characteristics. The participating municipalities reflected considerable variation in terms of rural and urban contexts and included almost all Swedish municipality types according to the Swedish Association of Local Authorities and Regions classification (38). In each municipality, several home care units participated.

Table 2
Participating municipalities and selected demographic characteristics

Municipality	Inhabitants (n = x)	65+ (%)
2	9 076	30.0
3	24 364	26.1
4	5 560	28.5
5	6 376	27.9
6	13 467	27.4
8	40 728	23.2
9	14 381	23.8
10	14 238	29.7
11	35 782	23.9
12	8 934	30.5
14	12 962	25.8
15	15 792	27.6

Interviews with municipal representatives

To further explore organisational decision-making, individual semi-structured interviews were conducted with municipal representatives involved in the trial start-up phase or in decisions to decline participation. Seven out of ten invited participants agreed toparticipate. Participants included five nurses, three of whom where LASMA, and two heads of social care services.

For feasibility reasons, semi-structured telephone interviews were conducted using an interview guide developed by IGL and JPK. Interviews was conducted by IGL and lasted between 2 and 14 minutes. The shorter interviews typically involved participants with limited involvement in the implementation process, those who were not directly engaged in organisational decision-making, or those who reported having no additional information to contribute.

Interviews with dental hygienists

Individual semi-structured interviews were conducted by SPK with all participating dental hygienists at the end of the baseline screening period. The interviews were conducted digitally via Teams, lasted approximately 10 to 15 minutes and explored experiences of logistical challenges, collaboration with home care services, ethical considerations, older adults' engagement, and perceptions of trial feasibility. All interviews were audio-recorded and transcribed verbatim.

Data analysis

A framework-informed qualitative content analysis was conducted (39). The analysis was abductive (40), drawing iteratively on concepts from implementation research, particularly implementation outcomes proposed by Proctor et al. (25) and RCT trial implementation literature (23), as well as CFIR (31), to support interpretation of organisational conditions and trial initiation processes.

The analysis proceeded in three steps:

1. Framework-informed coding:

Meaning units were coded using constructs related to trial implementation (e.g., organisational readiness, logistical capacity), implementation outcomes – particularly acceptability, appropriateness and feasibility (25), as well as organisational conditions and implementation processes reflected in relevant CFIR domains (31). The framework informed, but did not determine, the interpretation of the material. For example, a statement such as "we don't have staff available for this" could be interpreted as reflecting low organisational readiness, limited logistical capacity, and feasibility challenges related to the inner setting in CFIR. Table 3 illustrates the framework-informed coding process.

Table 3
Example of framework-informed coding

Meaning-unit	Code	Framework
E-mail: "Hi, are we going to be a test group in the oral health project? What are we supposed to do? Can you call me?"	Unclear understanding of trial purpose; Low role clarity	CFIR 2.0: Knowledge & Beliefs; Readiness for Implementation (31), Proctor et al (23): lack of clarification of roles and expectations

2. Within-dataset synthesis:

Stakeholder dialogues, email responses, interviews with municipal representatives, and dental hygienist interviews were analysed separately to generate dataset-specific summaries of organisational conditions, decision-making processes, and frontline experiences of trial initiation and early implementation. Table 4illustrates how codes identified in Step 1 were synthesised within each dataset during Step 2.

Table 4
Example of within-dataset synthesis conducted in Step 2

Dataset	Illustrative codes identified in step 1	Dataset-specific synthesis
Email responses	Decision-making structures; role ambiguity; prioritisation processes	Summary of decision-making dynamics and variation in organisational readiness, highlighting how structural ambiguity and competing initiatives influenced decisions about participation

3. Cross-dataset integration:

Findings from the dataset-specific syntheses were subsequently compared and integrated to examine how municipal organisational conditions within municipalities shaped trial initiation and how stakeholders navigated these conditions during early implementation. Table 5 illustrates how evidence across datasets contributed to the interpretation of key organisational and implementation-related patterns.

Table 5
Example of cross-dataset integration analysis

Integrated finding	Evidence across dataset-specific syntheses	Resulting mechanism
Variation in how municipalities interpreted the trial and assessed their readiness	Email responses reflected uncertainty regarding organisational capacity, alignment with core tasks, and expectations related to participation.	Organisational readiness and interpretation of the trial feasibility

Two researchers independently coded a subset of the material and compared coding to discuss interpretation and consistency. The remaining material was coded by the primary analyst (JPK), with regular peer debriefing within the research team. Emerging interpretations and areas of disagreement were discussed iteratively until consensus was reached.

Ethical considerations

All participants received information about the study and provided informed consent. The study was approved by the Swedish Ethical Review Authority (dnr: 2025-03612-01) and was conducted in accordance with the World Medical Association Helsinki ethical guidelines for research (41).

Reporting standards

The underlying cluster randomised trial and intervention are described in detail elsewhere (30). In the present article, only methodological and contextual aspects relevant to the qualitative study of trial initiation and early implementation are reported.

Results

Overall, participants described the trial as a meaningful and relevant initiative that could support the integration of oral health into everyday home care practice for older adults. Analyses of municipal stakeholder dialogues, interviews with municipal representatives, and dental hygienists' experiences during baseline assessments illustrated how structural conditions, coordination processes, and frontline adaptations interacted to enable or constrain trial initiation.

Rather than reflecting a single implementation barrier, trial initiation unfolded through four interdependent mechanisms:

(1) organisational readiness and interpretation of the trial

(2) structural ambiguity and distributed responsibility

(3) coordination capacity and local tailoring

(4) frontline adaptation strategies during baseline assessments.

Together, these mechanisms illustrate how the feasibility of initiating RCTs in home care is shaped by distributed responsibility, cross-organisational coordination, and limited prior experience of research in routine care settings.

1. Organisational readiness and interpretation of the trial

Home care representatives consistently described the trial as relevant and worthwhile, but also complex and unfamiliar. Understanding what participation would entail in practice emerged as a central aspect of organisational readiness. Despite written information and introductory presentations, many participants remained uncertain about what participation would involve in practice and how trial activities would be integrated into everyday work. Core research procedures, such as baseline assessment, follow-up routines, and research documentation were generally viewed positively. However, these procedures were unfamiliar to most participants and required ongoing clarification throughout the start-up phase.

Organisational readiness was not established through written information alone. Rather, it was actively developed through repeated stakeholder dialogues, iterative clarification, and continuous dialogue between municipalities and the research team. This process was particularly important in organisations with limited prior experience of participating in research. The uncertainty surrounding participation is illustrated by the following email from the manager of two social care units (municipality 11):

Hi, are we going to be a test group in the oral health project? What are we supposed to do? Can you call me?

Support needs varied substantially across municipalities. Some units required only limited clarification, whereas others relied heavily on ongoing dialogue with the research team, including digital meetings where participants could seek clarification, ask questions, and discuss practical challenges, as well as newsletters and tailored assistance with recruitment and trial logistics. The extent of external assistance reflected variation in organisational readiness, internal coordination capacity, and prior experience with research participation.

2. Structural ambiguity and distributed responsibility

A persistent challenge concerned the distribution of responsibility for oral health across healthcare, social care, and dental services. Home care representatives described extensive needs among older adults, including needs associated with

multimorbidity, frailty, and limited access to dental services. At the same time, they expressed uncertainty regarding follow-up routines, documentation responsibilities, and coordination of oral health care.

This distributed responsibility created structural ambiguity regarding ownership, accountability, and coordination of oral health activities. As a result, both willingness and organisational capacity to participate in the trial were affected. Competing organisational demands further shaped local decision-making. One head of social care services (municipality 1) described the tension between engaging in research activities and maintaining everyday operations:

As head of social care services, I already have many ongoing implementations … If we enter yet another project, we risk losing focus on our main assignment during an already intensive period.

Several municipalities ultimately declined participation because they lacked personnel able to assume coordinating roles across organisational boundaries, despite in some cases being relatively large organisations. Trial participation therefore depended not only on the perceived relevance of the intervention, but also on the availability of staff capable of coordinating activities, clarifying responsibilities, and bridging organisational and professional boundaries.

3. Coordination capacity and local tailoring

Municipalities differed considerably in their capacity to coordinate trial-related activities. Notably, none of the participating municipalities involved staff with dedicated research and development responsibilities in the stakeholder dialogues. As a result, responsibility for interpreting and coordinating trial activities rested largely with operational managers and clinical staff. The absence of local research or implementation support functions increased reliance on the research team and contributed to variation in implementation capacity across sites. At the same time, municipalities actively adapted aspects of the trial implementation to fit local organisational structures and everyday workflows. For example, one head of municipal healthcare, who also served as LASMA (municipality 9), requested that additional registered nurses be included in the training:

We would also like to include three nurses… as they work in teams with the assistant nurses.

Such adaptations reflected efforts to align trial procedures with existing team structures and care processes, highlighting both organisational engagement and the importance for local tailoring during implementation. However, these adaptations remained compatible with the overall trial protocol.

Differences in recruitment outcomes appeared to mirror broader variation in coordination capacity and organisational conditions across municipalities. Municipalities characterised by stronger internal coordination and clearer communication pathways appeared better able to recruit participants, whereas municipalities with more fragmented organisational conditions reported greater difficulties during recruitment. Across municipalities, the proportion of older adults enrolled relative to initial recruitment targets ranged from 23.3% to 86.7% (Table 6).

Table 6
Differences between the original recruitment target and the number of participants finally enrolled

Municipality	Target - planned number of participants (n = x)	Actually enrolled (n = x)	Difference (n = x)	Percent of target achieved (n=%)
2	30	9	21	30.0
3	45	20	25	44.4
4	30	15	15	50.0
5	45	18	27	40.0
6	30	26	4	86.7
8	45	26	19	57.8
9	45	31	14	68.9
10	45	14	31	31.0
11	60	14	46	23.3
12	30	21	9	70.0
14	45	22	23	48.9
15	30	15	15	50.0
Total	480	237	243	49.4

4. Frontline adaptation during baseline assessments

Dental hygienists confirmed that the baseline assessment phase was logistically demanding and required substantial frontline adaptation. During the initial phase, several dental hygienists described feeling overwhelmed by the number of instruments, procedures and coordination tasks involved, a dental hygienist (A) described:

There was a lot to keep track of during the first days; I was afraid I would forget something.

Calibration sessions were described as essential for enabling assessors to adapt procedures consistently while maintaining fidelity to assessment protocol. Dental hygienists believed that, without these sessions, substantial variation in assessment procedures would likely have occurred.

Fieldwork also exposed gaps between municipal home care routines and dental care systems. For example, some older adults lacked required dental care certificates despite meeting eligibility criteria, requiring dental hygienists to navigate administrative processes that spanned organisational and sectoral boundaries.

At the same time, assessments had to be continuously adapted to the needs and preferences of older adults in highly individualised home settings. A dental hygienist (B) reflected:

Two people with the same oral status could want completely different things – one wanted to do everything; one wanted to do nothing.

Ethical and practical challenges were mentioned as particularly common among older adults with cognitive impairment, sensory impairment, or communication difficulties. Dental hygienists described situations in which participants did not respond to visits because they could not hear the doorbell or were suspicious of unknown visitors. These situations often required repeated visits, coordination with home care staff, and flexible adaptation of procedures in order to complete assessments while maintaining informed consent requirements. Dental hygienists described substantial variation between home care services. In well-prepared units, staff facilitated access, shared relevant information, and supported communication with older adults. In less prepared settings, dental hygienists encountered significant logistical barriers. A dental hygienist (C) reflected on this matter:

It was difficult to even get into the building; no one opened the door and no one knew I was coming.

Such variations affected efficiency, workload, and the practical feasibility of conducting assessments as intended. In several cases, dental hygienists reported spending more time navigating organisational logistics than performing the clinical assessment itself. Despite these challenges, dental hygienists described increasing confidence over time as familiarity with procedures grew. Dental hygienist (D) mentioned:

I was nervous at first, but after a few days everything was second nature.

Conducting baseline assessments across multiple municipalities nevertheless required extensive travel, coordination, and ongoing problem-solving. A dental hygienist (E) recalled:

Working in so many municipalities at the same time was tough; the logistics took a lot of time.

While dental hygienists considered that assessments were ultimately conducted with high fidelity, their experiences demonstrate that protocol fidelity was achieved through ongoing adaptation to local organisational conditions, logistical constraints, and the individual needs of older adults. This highlights the importance of realistic timelines, structured communication pathways, and organisational support during trial initiation in home care settings.

Discussion

This study examined the early implementation of an RCT in home care for frail older adults, a setting where research is rarely conducted and where responsibility is distributed across multiple care providers. The findings show that implementation was shaped by four interdependent mechanisms: 1) cross-sectoral organisational readiness, 2) Structural ambiguity and distributed responsibility, 3) coordination capacity and local tailoring and 4) frontline adaptive strategies during baseline assessments. Together, these mechanisms demonstrate that implementation of complex trials in home care depends on the alignment of organisational, structural, and practice-level conditions rather than on protocol design alone. More specifically, the findings suggest that trial feasibility was not a fixed property of the intervention or study design, but emerged through the work required to create and maintain that alignment.

Across all data sources, implementation emerged as an iterative and adaptive process rather than a linear progression from protocol to practice. Participants frequently worked under conditions characterised by incomplete information, shifting responsibilities, and logistical unpredictability. Rather than waiting for organisational clarity to emerge, municipalities, managers, and frontline staff actively interpreted, negotiated, and adapted trial procedures to fit local conditions. These findings illustrate how implementation in home care settings characterised by organisational fragmentation and distributed responsibility depends on continuous negotiation between organisational conditions and frontline practice.

Contribution to the literature

This study contributes to the limited evidence base concerning the implementation of RCTs in home care for older adults. Previous research has highlighted challenges related to recruitment, decentralised care structures, and limited research participation in non-hospital settings (15–20). Our findings extend this literature by demonstrating how such challenges operate not as isolated barriers, but as interdependent organisational and relational processes that shape trial initiation in practice. More broadly, the findings suggest that feasibility should not be viewed as a fixed property of an intervention or trial design, but as an outcome produced through ongoing organisational and relational work. A central contribution of the study is the finding that organisational readiness for research participation in home care cannot be assumed, even when organisations express positive attitudes toward partaking. Rather, readiness had to be actively constructed through repeated dialogues, iterative clarification, and practical support throughout the implementation process. This finding aligns with CFIR perspectives emphasising the importance of organisational context, readiness, and implementation processes (31) while also challenging implicit assumptions in trial design that implementation can proceed once protocols and recruitment procedures have been established.

The study also highlights the importance of cross-sectoral coordination between municipal home care and regional public dental services. Although collaboration across organisational boundaries is widely discussed in implementation and integrated care

research (10, 42), this interface remains underexplored in empirical studies of trial implementation.

Another contribution concerns the role of distributed responsibility in shaping trial implementation. By focusing on oral health in home care settings, this study makes visible how distributed responsibility, fragmented governance structures, and organisational boundary work shape the feasibility of conducting trials in real-world care environments. The findings instead suggest that implementation capacity is closely linked to broader organisational and infrastructural conditions.

These findings should also be understood in relation to the relatively limited research infrastructure within Swedish municipal care organisations (43). Unlike many hospital healthcare settings, municipal care organisations rarely have embedded research environments or personnel with formal research responsibilities, and research support is often organised through external or inter-municipal research and development structures. These structures vary considerably in size, mandate, resources, and proximity to practice, contributing to uneven organisational capacity for participating in and supporting research activities (44). This broader structural context may help explain why participating municipalities frequently required extensive stakeholder dialogues, clarification, and practical support during trial initiation.

Interpretation through implementation frameworks

The findings can be understood as reflecting the interaction between organisational readiness, contextual conditions, and adaptive implementation processes. Figure 1 illustrates how the identified mechanisms relate to central concepts within the Organisational Readiness for Implementing Change (ORIC) framework, which emphasises change commitment and change efficacy as central preconditions for implementation (45).

Variation in organisational readiness reflected differences in organisational capacity to mobilise staff, coordinate activities, and support implementation work. Municipalities with stronger internal coordination and clearer communication pathways appeared better equipped to interpret trial requirements and integrate implementation activities into everyday operations.

Distributed responsibility for oral health across healthcare, social care, and dental services reflected broader contextual and organisational boundary issues consistent with CFIR perspectives on outer setting conditions and organisational context (31). This distribution of responsibility created structural ambiguity regarding ownership, accountability, and coordination of oral health activities, which in turn influenced local decision-making and affected organisational willingness and capacity to participate in the trial.

Frontline adaptation strategies, particularly among dental hygienists, highlighted the importance of iterative problem-solving, relational coordination, and local tailoring during implementation. These adaptive processes enabled the trial to proceed despite logistical unpredictability, fragmented organisational structures, and variation between municipalities. From an implementation outcomes perspective (25), feasibility therefore emerged not as a fixed characteristic of the intervention itself, but as something continuously produced and maintained through ongoing adaptation and coordination work.

Taken together, these findings suggest that early implementation of RCTs in home care for older adults is best understood as a distributed and negotiated process in which multiple actors continuously interpret, coordinate and adapt the trial activities within existing organisational constraints. In this context, feasibility emerges not as a static property of a trial, but as an outcome of ongoing organisational and relational work.

Implications for future RCTs in home care for older adults

The findings highlight that conducting RCTs in home care requires research designs that explicitly account for organisational fragmentation, limited research participation experience, and the need for cross-sector coordination. First, establishing organisational readiness requires more than the provision of study information. Structured stakeholder engagement processes – including repeated dialogue, iterative clarification, and practical support – appear particularly important in home care services with limited prior experience of research participation.

Second, trial protocols need to explicitly address structural ambiguity, distributed responsibility, and organisational boundaries. Clear definitions of roles, responsibilities, communication pathways, and follow-up procedures are essential when interventions span multiple organisations and professional domains, such as municipal home care and regional dental services. Third, variation

in coordination capacity across organisations should be anticipated and actively managed throughout implementation. Flexible timelines, designated local contact persons, and sustained support from the research team may facilitate recruitment, communication, and coordination during trial initiation.

Fourth, frontline implementers require structured support to carry out trial procedures in complex home environments. Calibration activities, opportunities for peer exchange, and space for professional judgement are essential for managing ethical, relational, and logistical challenges that cannot be fully standardised within trial protocols. Taken together, these findings suggest that RCTs in home care should be understood not only as evaluations of interventions, but as implementation processes requiring continuous alignment between research procedures and the organisational conditions in which they are enacted. Consequently, trial feasibility should be viewed not as a fixed characteristic of study design, but as an outcome of ongoing organisational and relational work.

Strengths and limitations

A key strength of the study is the integration of multiple complementary data sources, including stakeholder dialogues, organisational responses from municipalities that declined participation, as well as interviews with dental hygienists and municipal representatives. This enabled analysis of both organisational conditions and frontline implementation processes and allowed for triangulation across perspectives on early implementation. The study was conducted across multiple home care units in different municipalities, encompassing variation in organisational size, structure, and readiness. This diversity strengthens the transferability of the findings to other home care settings characterised by decentralised organisation and distributed responsibility.

A further strength is the interdisciplinary composition of the research team, which included expertise in gerodontology, oral health, nursing, psychology, organisational learning, and public administration. This enabled analysis of the implementation process from clinical, organisational, and governance perspectives, and supported interpretation across professional and sectoral boundaries.

Several limitations should also be acknowledged. First, the study focused on the early phase of implementation and therefore does not capture longer-term processes related to sustainability, normalisation, or trial outcomes. Second, some interviews with municipal representatives were relatively short, which may have limited the depth of individual accounts (36). However, these interviews were complemented by detailed field notes from stakeholder dialogues and triangulated with other data sources.

Third, the study did not include perspectives from older adults or their family members. Including these perspectives could have provided additional insights into how older adults experienced participation in the trail and the acceptability, and feasibility of research procedures within home care settings. Future studies should therefore explore how older adults experience recruitment, assessment procedures, and participation in home-based trials.

Finally, the study was conducted within the Swedish healthcare and social care context, where responsibilities are institutionally divided between municipalities and regions (28). Although this may limit direct transferability to healthcare systems organised differently, challenges related to fragmentation, coordination, and implementation across organisational boundaries are likely to be relevant in many home care contexts.

Conclusion

Implementing an RCT in home care for older adults requires more than adherence to protocol; it depends on cross-sectoral organisational readiness, coordination capacity, and the ability of frontline staff to adapt procedures within complex and unpredictable home environments.

By identifying the mechanisms that shaped early implementation in this setting, the study demonstrates how trial feasibility emerges through the interaction between organisational conditions, cross-sectoral coordination, and frontline practice. Rather than representing a fixed characteristic of study design, feasibility was continuously produced through the work required to align trial procedures with local organisational realities.

These findings highlight the need to conceptualise RCTs in home care not only as evaluations of interventions, but as implementation processes in their own right. This perspective has important implications for researchers and policymakers

seeking to design rigorous and feasible trials in real-world care systems characterised by fragmentation, distributed responsibility, and organisational complexity.

Declarations

The study was reviewed and approved by the Swedish ethics review authority (dnr. 2025-03612-01). All participants received written and verbal information about the study and provided informed consent prior to participation. All procedures were conducted in accordance with the Declaration of Helsinki and relevant national regulations.

Consent for publication

All authors have agreed on the publication,

Competing interests

The authors declare no conflicts of interests.

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Author Contribution

JPK, HW and SPK conceptualized the study. JPK, ABA and IGL conducted the data analysis. TL contributed theoretical framing. JPK and TL drafted the manuscript, and all authors contributed to critical revisions. All authors read and approved the final manuscript.

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Data Availability

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

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Figures

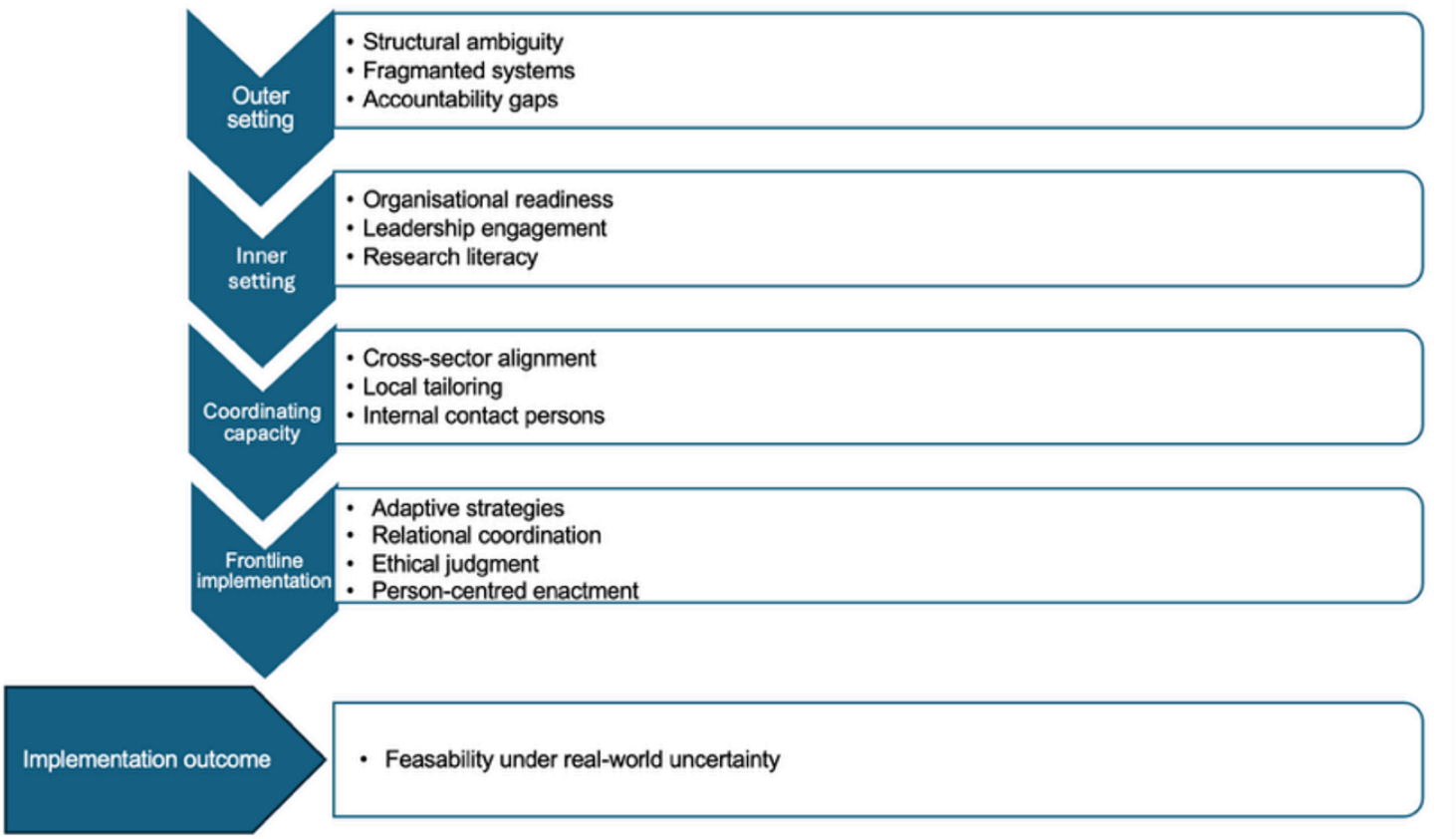


Figure 1

Factors influencing the early implementation of a RCT in home care.