

QUALITATIVE PAPER

Contextual factors influencing complex intervention research processes in care homes: a systematic review and framework synthesis

GUY PERYER^{1,2}, SARAH KELLY^{3,4}, JESSICA BLAKE⁵, JENNIFER K. BURTON⁶, LISA IRVINE⁵, ANDY COWAN³, GIZDEM AKDUR⁵, ANNE KILLET^{1,2}, SARAH L. BRAND^{7,8}, MASSIRUFULAY KPEHE MUSA⁵, JULIENNE MEYER⁹, ADAM L. GORDON^{10,11}, CLAIRE GOODMAN^{5,2}

¹School of Health Sciences, University of East Anglia, Norwich Research Park, Norwich NR4 7TJ, UK

²NIHR Applied Research Collaboration, East of England, England, UK

³Cambridge Public Health, University of Cambridge, East Forvie Site, Cambridge CB2 0SZ, UK

⁴THIS Institute (The Healthcare Improvement Studies Institute), University of Cambridge, Cambridge Biomedical Campus, Cambridge CB2 0AH, UK

⁵Centre for Research in Public Health and Community Care, University of Hertfordshire, Hatfield, UK

⁶Institute of Cardiovascular and Medical Sciences, University of Glasgow, New Lister Building, Glasgow Royal Infirmary, Glasgow G31 2ER, UK

⁷St Luke's Campus, Heavitree Road, University of Exeter, Exeter EX1 2LU, UK

⁸NIHR Applied Research Collaboration, South West Peninsula, England, UK

⁹National Care Forum/Care for Older People, School of Health Sciences, Division of Nursing, City, University of London, London, UK

¹⁰School of Medicine, University of Nottingham, Nottingham, UK

¹¹NIHR Applied Research Collaboration East Midlands (ARC-EM), Nottingham, UK

Address correspondence to: Guy Peryer. Email: g.peryer@uea.ac.uk; Claire Goodman. Email: c.goodman@herts.ac.uk

Abstract

Background: Care homes are complex settings to undertake intervention research. Barriers to research implementation processes can threaten studies' validity, reducing the value to residents, staff, researchers and funders. We aimed to (i) identify and categorise contextual factors that may mediate outcomes of complex intervention studies in care homes and (ii) provide recommendations to minimise the risk of expensive research implementation failures.

Methods: We conducted a systematic review using a framework synthesis approach viewed through a complex adaptive systems lens. We searched: MEDLINE, Embase, CINAHL, ASSIA databases and grey literature. We sought process evaluations of care home complex interventions published in English. Narrative data were indexed under 28 context domains. We performed an inductive thematic analysis across the context domains.

Results: We included 33 process evaluations conducted in high-income countries, published between 2005 and 2019. Framework synthesis identified barriers to implementation that were more common at the task and organisational level. Inductive thematic analysis identified (i) avoiding procedural drift and (ii) participatory action and learning as key priorities for research teams. Research team recommendations include advice for protocol design and care home engagement. Care home team recommendations focus on internal resources and team dynamics. Collaborative recommendations apply to care homes' individual context and the importance of maintaining positive working relationships.

Discussion: Researchers planning and undertaking research with care homes need a sensitive appreciation of the complex care home context. Study implementation is most effective where an intervention is co-produced, with agreed purpose and adequate resources to incorporate within existing routines and care practices.

Keywords: nursing home, process evaluation, complexity, context, human factors, qualitative, older people

Key Points

- Care homes are complex social ecosystems; implementing controlled research in these heterogeneous settings is challenging.
- Many expensive, resource-intensive controlled studies in care homes have resulted in neutral findings.
- This review identifies contextual factors that may mediate outcomes of complex intervention research studies in care homes.
- Avoiding procedural drift and engaging in participatory action and learning are key to successful implementation.
- We provide recommendations that researchers and care home teams can use to support complex intervention research implementation.

Background

Care homes (CHs) play a vital role in public health infrastructure, supporting citizens with complex needs [1]. CH is an umbrella term, describing 24-hour care facilities, including those with and without on-site registered nurses, sometimes referred to as nursing and residential homes, respectively. There are marked differences in organisational size, financial support, cultures of care and population between homes [2].

CHs are complex social ecosystems where individuals live. This can pose significant challenges to research paradigms reliant on data [3–6]. Many large CH complex intervention studies have produced neutral findings [7–14]. The combined research award for these cited studies from the UK amounted to over £8.5million. There is uncertainty about whether the neutral findings were attributable to intervention ineffectiveness, or a consequence of study implementation processes or insensitive measurement tools [15]. For clarity, the term implementation in this article refers to how research intervention processes were carried out during the research study and process evaluation period. It does not refer to implementing research findings thereafter. Previous research has queried, ‘did the trial kill the intervention?’ [16] We wanted to explore this question further in a CH context.

A complex adaptive systems approach to research evaluation in CH settings

Research intervention studies need to consider the influence of context to identify factors which might confound the intervention and to maximise translation into practice [3, 17–22]. CHs can be described as a complex adaptive system of interconnected sub-systems where people, tasks, technologies, the physical environment and organisational culture interact [20, 23–29]. Novel interventions in CHs can disrupt and adapt dynamic system relationships. This can lead to the emergence of potentially undesirable outcomes not anticipated in the study design (or by the research team) [17, 18, 22, 30]. These unpredictable dynamic effects can pose complications for the validity of fixed evaluation measures [21, 24, 31]. A complex adaptive systems approach to CH research evaluation may more reliably capture how an intervention is working in context [6, 22].

This systematic review adopted a human factors (HF) perspective [32]. HF accommodates complex systems theory and identifies influences on human behaviour and how

these relate to work performance. The HF perspective is relevant because attempts to modify care practices in CHs involve interactions between people, processes, technologies and organisational systems [25].

Rationale and aim

Process evaluations explore the relationship, similarities and differences between an intervention as planned and implemented [23, 33–37], taking account of contextual factors and their potential influence on study outcomes [20, 22, 23, 38–40]. We aimed to explore the challenges of implementing complex intervention research studies in CHs, identify common and generalizable themes between CH process evaluations, and devise recommendations on how to mitigate against expensive research implementation process failures.

Method

The review protocol was registered online and is reported in accordance with appropriate methodological guidance [41–43].

Search strategy, data sources, inclusion criteria and screening

An experienced medical librarian supported the search. We searched MEDLINE and Embase via OVID from inception to 25 November 2019. Searches of CINAHL via the EBSCO Host platform and ASSIA (Applied Social Sciences Citation Index and Abstracts) via ProQuest followed on 2 December 2019. No date restrictions were applied. We used Medical Subject Headings, keywords and synonyms, entered in grouped stages. (Appendix 1, Table A1.1). We completed a grey literature search (including OpenGrey) on 30 January 2020 (Appendix 1, Table A1.2).

Eligible papers needed to be process evaluations of primary complex intervention research conducted in CHs for older people that used quantitative, qualitative or mixed methods published in the English language. Protocols, secondary data analysis and evidence reviews were excluded. After removing duplicates using Endnote software (Clarivate Analytics, USA) we automated the management of the screening process using Covidence software (Veritas Health Innovation, Australia). Titles and abstracts were screened independently by two reviewers within the team (SK, GP,

AC, JBU, GA LI, JBL, MM). In cases of disagreement, or a need for wider discussion, a third reviewer in the team (SK, GP, JBU) was involved. One reviewer in the team (SK, GP, MM, GA) assessed full text articles for eligibility with support from the team in cases of uncertainty.

Data extraction, and critical appraisal

Extracted summary characteristics included: first author and year of publication, country, intervention topic, sample size, methods and participants.

As there are no formal appraisal tools specific to process evaluations, we engaged with experts at the Cochrane Collaboration Qualitative Methods Group and repurposed an appraisal method devised by Shepherd *et al.* [44, 45]. Two reviewers (JBL, GP, GA, AK, JBU, LI) conducted the appraisals independently for each paper. We focused on the last two questions that appraise reliability and usefulness of findings according to our review question. In the event of a discrepancy in answers to these questions a third reviewer was involved.

We used a 'best-fit' framework synthesis approach: a theory-based method to determine salience and connections in qualitative data [45–49]. This method accommodates reports of complex interventions and adds transparency to data coding [38, 49]:

- i) Familiarisation,
- ii) Identifying and developing a thematic framework,
- iii) Indexing (coding extracted data according to the framework),
- iv) Charting (presenting evidence summaries), and
- v) Interpretation (drawing associations between key themes and concepts identified in the evidence) [46].

Familiarisation and identifying and developing a thematic framework

The first two stages occurred iteratively. To identify a salient conceptual HF framework, we searched Web of Science using the 'Behaviour of interest; Health context; Exclusions; Models or Theories' (BeHEMOTH) template (Appendix 1, Table A1.3) [50]. The Systems Engineering Initiative for Patient Safety (SEIPS 2.0 and SEIPS original) models were chosen as the best conceptual fit [48–52].

SEIPS is a well-known HF model akin to Donabedian's 'Structure-Process-Outcome' approach for measuring quality of care [53]. It targets patient safety and discusses the importance of engaging patients and professionals in collaboration to pursue design-driven improvements. We modified the SEIPS 2.0 graphical representation to apply to CHs (Figure 1) [51]. It places the person at the centre as the focal work system, with interconnected work systems influencing task performance, safety and well-being [51].

The model exemplifies that CHs are a system of sub-systems. It identifies the interactions that take place between CH staff and their environment, and how these interactions and feedback loops may contribute to desirable or undesirable adaptations to, and outcomes from, work

systems and care processes [51, 52]. Outcomes are identified as performance indicators of system behaviour. Poor experiences at a process level that lead to undesirable outcomes suggest a need for system redesign and identifying contributory factors at the work system level [51]. Outcomes from work processes are identified as having an effect over a short or longer term (Figure 1).

Indexing and charting

Work system sub-categories included in the initial coding framework were based on criteria presented in the original SEIPS model [52]. The framework was piloted on two relevant process evaluations prior to performing the systematic search and was developed further following detailed familiarisation [46, 54, 55]. We also included an 'Other' category that comprised additional relevant contextual factors not captured by the SEIPS model [46]. The final synthesis framework had three levels: (i) work system, (ii) work system sub-category and (iii) work system context domain.

We then performed a qualitative content analysis and indexed the data according to the three levels of the synthesis framework. Data were indexed by two reviewers (JBL, GP) using line-by-line coding within NVivo software (QSR International). Extracted data from the results and discussion sections included quotations from research participants (first-order constructs), and quotations and interpretations of process evaluation authors (second-order constructs) [56]. These data were coded and tabulated as barriers or enablers to successful research implementation processes and outcomes.

Interpretation

Themes were generated inductively from the indexed content domain data to identify salient concepts from a complex adaptive systems perspective [34, 56]. Thematic content was refined iteratively between two reviewers (GP, JBL). Recommendations for action that can contribute to successful CH research implementation processes were mapped against three categories: (i) research team responsibilities, (ii) CH staff responsibilities and (iii) collaborative responsibilities (Figure 1).

Stakeholders (including family representatives and CH staff) were involved in: assisting in prioritising the review findings to CH staff and suggesting how to present graphical outputs from the synthesis process.

Results

Characteristics of included process evaluations

We identified 33 process evaluations (32 CH interventions) from 8,097 search results (Appendix 2, Figure A2.1). Summary characteristics of the included papers are presented in Appendix 2, Table A2.1. Included studies were published between 2004 and 2019; most were published after 2016 ($n = 20/33$, 60%). Studies were conducted in high-income countries only: UK-11 [54, 55, 57–66], Netherlands-6 [39, 67–71], Canada-5 [72–76], Germany-3 [77–79], Norway-2 [80, 81], Australia-1 [82], Belgium-1 [83], Portugal-1

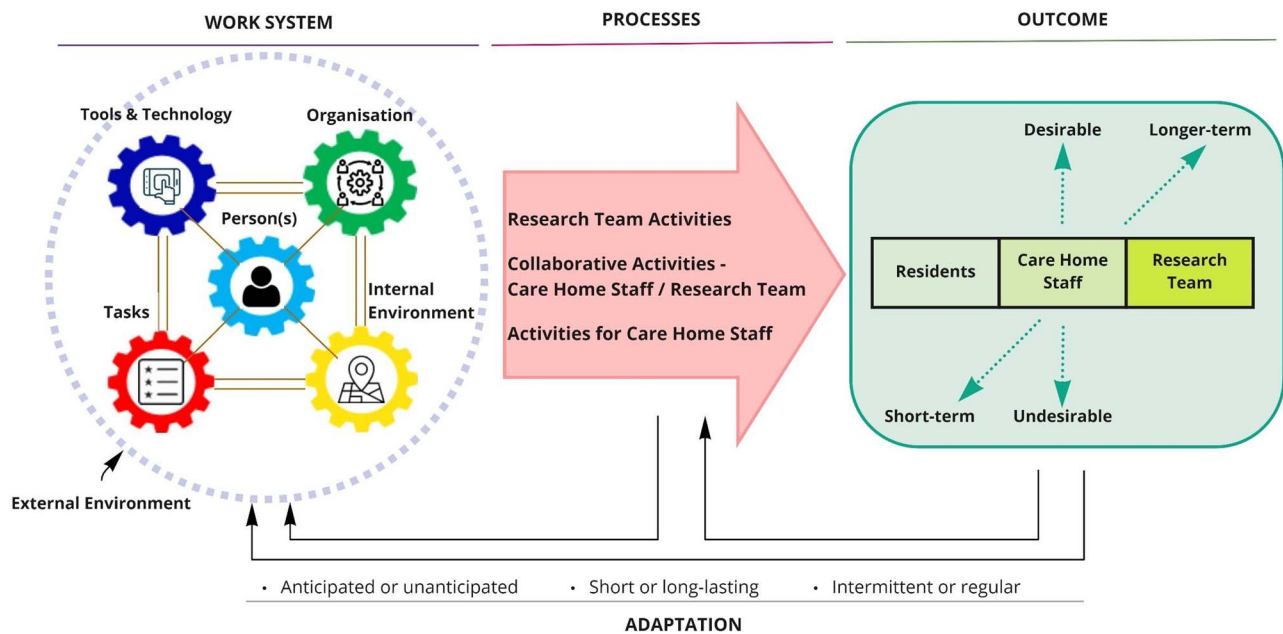


Figure 1. Modified image of the SEIPS 2.0 model [51].

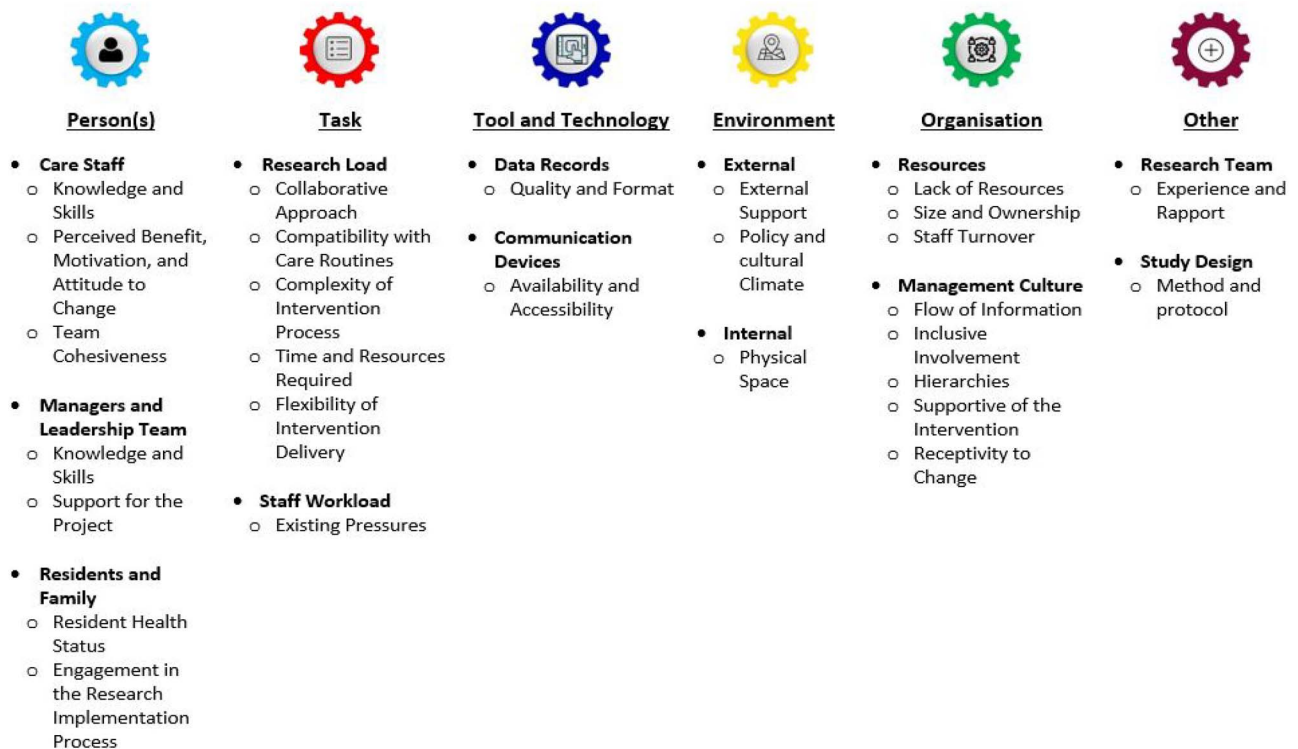


Figure 2. Synthesis framework. Level 1: Work System, Level 2: ● Work System Sub-category (in bold), Level 3: ○ Context Domain (in plain text).

[84], Sweden-1 [85], USA-1 [86] and one multi-national European study [87]. One process evaluation was made available to the review team ahead of publication [65, 66].¹ Critical appraisal details are presented in Appendix 2, Tables

A2.2, A2.3. All eligible reports were rated as having adequate quality to proceed with data synthesis [44].

Indexing

The consolidated three-level framework illustrated in Figure 2 depicts each of the work systems introduced

¹ Data from the PiTSTOP study process evaluation appears with permission from Prof. Najma Siddiqi and Anne Heaven [66].

Contextual factors influencing complex intervention research processes in care homes

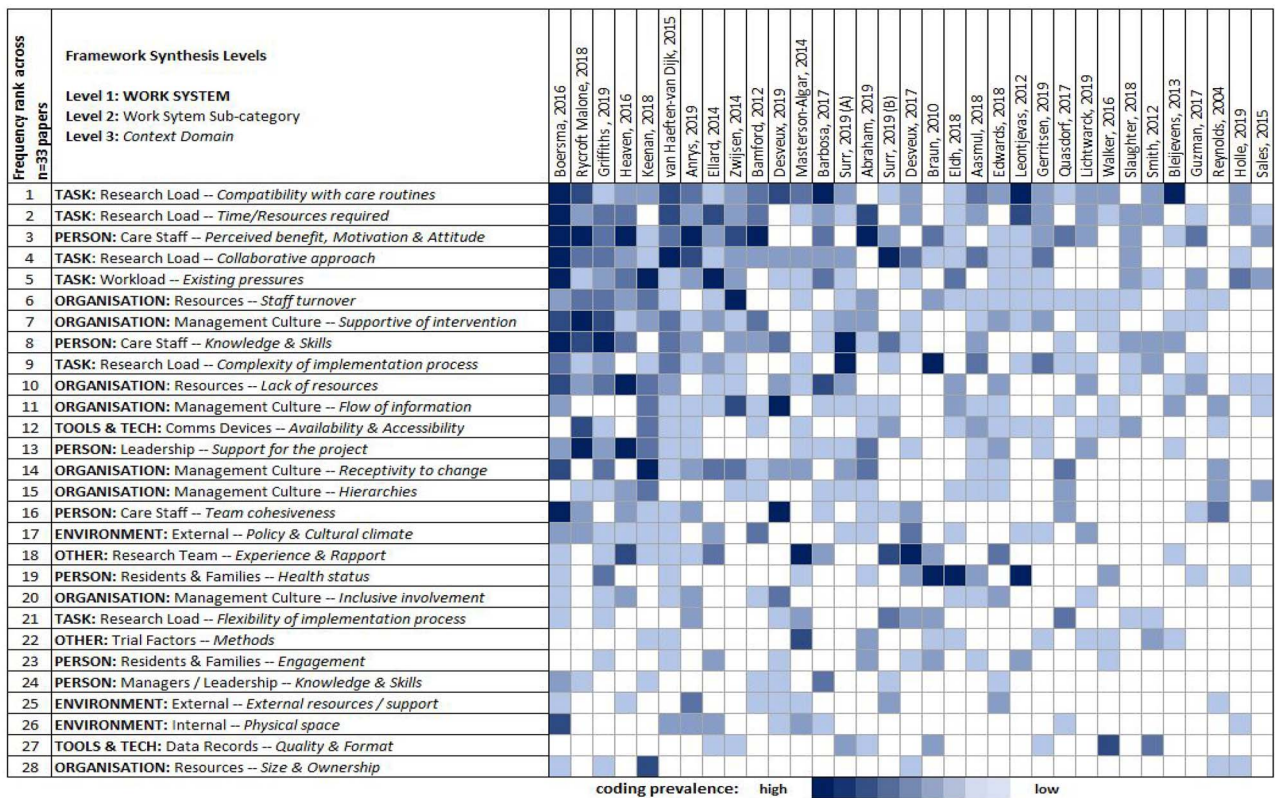


Figure 3. Heatmap matrix displaying the frequency of indexed content across 28 ranked context domains identified from n = 33 process evaluations.

in Figure 1. The indexing process involved assigning data, coded as barriers or enablers to successful research implementation processes and outcomes, to the relevant work system and context domain on the synthesis framework. For example, in reference to Figure 2, if a process evaluation reported that the health status of the residents mitigated their participation in the intervention, extracted narrative data were indexed at the Person(s) work system (level 1), the Residents and Family sub-category (level 2) and the Resident Health Status context domain (level 3).

Charting

A heatmap matrix displaying the distribution of indexed context domains within and across the included studies is presented in Figure 3. Colour coding reflects the frequency of appearance of the context domains on a high to low scale. Context domains were also ranked according to their frequency of appearance across the 33 papers. Appendix 3 (Figure A3.1) presents this context domain frequency hierarchy mapped according to work system. A radar plot and descriptive summary of the indexed data at a work system level is presented in Appendix 3 (Figure A3.2). The radar plot demonstrates that influential contextual factors aligned primarily to Organisation, Task and Person(s) work systems.



A descriptive summary of the most frequent context domains is presented in Table 1. Readers are encouraged to explore the expanded contextual factor dataset in Appendix 4. There are approximately four example quotations for each barrier and enabler to successful trial implementation process in CHs across the 28 context domains.

The six most frequent context domains were indexed in 70–82% of the dataset (Table 1, and Appendix 3, Figure A3.1). Within this group, four context domains originated from the Task work system, one from Organisation and one from the Person(s) work system. Within the Task work system, ‘Research load’ was the most frequent sub-category (framework level two). Novel research activities were often experienced as an extra component to an existing busy work schedule.

Interpretation




The descriptive content analysis summarised in Table 1 and Appendix 4 helps to infer commonality between studies. To derive plausible recommendations on ways to improve quality, efficiency and experience of delivering and participating in CH intervention studies; we performed an inductive thematic analysis on the extracted first-order and second-order narrative data across the 28 framework domains.

Table 1. Summary of the context domain data indexed according to the synthesis framework presented in Figure 2 and ranked according to frequency across the $n = 33$ process evaluations

Framework level 1: Work system 2: Work system sub-category 3: Context domain	Context domain frequency in $n = 33$ papers (%)	Context domain rank (1–28)	Context domain summary
	27 (81.8)	1	The compatibility of the research intervention objectives with the working care routines of the CH mediated successful implementation. Interventions that adopted a clear, practical approach that could be integrated into existing routines helped maintain engagement with staff for longer. Some interventions were also perceived to be incongruent with habitual care routines and others were not deemed significantly different from existing practice to deserve a behavioural change. ‘... you know we already use... the assessments... and the products... if it was going to be a case that you will be introducing new ways of doing things... but that’s not what it was about, so, no, I wouldn’t do that again’ ([Internal Facilitator] IF, type B, 12 month, [England]). In this example, the IF only attended one teleconference and then did not participate further in the programme, [87] p.8.
1. TASK 2. Research Load 3. Compatibility with Routines	25 (75.8)	2	The amount of time and resource investment required for the project impacted the implementation. Some CHs could not meet the demands of the study due to time and resource constraints, whereas others requested further investment in terms of training. Being able to complete project training within work hours was important so staff acknowledged the intervention as part of a working day as opposed to an additional extra. ‘Lack of time emerged as a prominent barrier, particularly time to train and involve colleagues. Furthermore, because few physicians found the time to take part in the two-day seminar, it was difficult to motivate them to participate in the intervention,’ [80] p.7.
	24 (72.7)	3=	Maintaining CH staff engagement was a key driver to successful implementation. Conversely, negative attitudes towards the intervention spread scepticism about its value within the CH. Observing a positive response from residents was a strong motivating factor to continue. ‘One manager argued that as many care assistants had been in their role for considerable periods of time, they had become rigid and developed a closed mind, which made them highly resistant to change and less willingly and able to adjust to new situations,’ [84] p.227.
1. PERSON(S) 2. Care Staff 3. Perceived Benefit, Motivation and Attitude to Change			

Continued

Table 1. Continued

Framework level 1: Work system 2: Work system sub-category 3: Context domain	Context domain frequency in <i>n</i> = 33 papers (%)	Context domain rank (1–28)	Context domain summary
	24 (72.7)	3=	Interventions that stimulated collaboration, rapport-building between team members, and mutual understanding between CH staff and researchers were well received. Clearly defined responsibilities within roles helped CH team dynamics. Insufficient guidance from management and unclear definition of roles reduced individual responsibility and was perceived by staff as poor planning and poor leadership. Enabling opportunities for periodic meetings to discuss resource allocation with care home managers/senior staff were recommended.
1. TASK 2. Research Load 3. Collaborative Approach			[managers] depicted that the workload in care of older people continuously increases; they were frequently requested by their superiors to execute change in their nursing homes (such as implementing new administrative or clinical routines). Yet, they experienced limited opportunities to discuss the relevance of a new routine, why it was proposed, the rationale for change, the time frame for an implementation, and/or how to proceed.' [85] p.90.
	23/33 (69.7)	5=	Existing workload of care staff before a novel intervention was introduced contributed to CH divergence from intended implementation strategies. This contextual factor may pose significant limitations on adopting new practices and sustaining adherence to a protocol that requires specific actions (e.g. timing of data collection or reporting) that are deemed by staff to be of lesser priority.
1. TASK 2. Staff Workload 3. Existing Pressures			... the nursing staff in all [Nursing Homes] took high levels of sick leave over the 3 months prior to baseline, indicating that the remaining nursing staff in the [Nursing Homes] were subjected to a high workload and time pressure. These conditions definitively hinder the application and integration of new innovations.' [78] p.11.
	23 (69.7)	5=	Care home staff, including managers, have a high level of turnover. This impacted on the continuity of projects, as new staff were not familiar with the research intervention processes. Changes in CH managers posed significant challenges to study delivery.
1. ORGANISATION 2. Resources 3. Staff Turnover			'Staff turnover sometimes resulted in situations in which only a part of the team was truly well informed about the care program. Although attempts were made to train new staff members, the situation remained suboptimal. While the turnover of nursing staff had adverse consequences, the change of DSCU [Dementia Specialist Care Units] leader, psychologist or physician was even more detrimental, for they had a leading role in implementing the care program. When these key stakeholders were absent for a period, there was often a drop in attention for implementing the care program.' [63] p.7.

Theme 1: procedural drift

Procedural drift refers to how studies lost momentum over time and deviated from the intended intervention protocol [88]. In most cases protocol deviations and intervention adaptations were normalised over time. Studies often started with adequate engagement and enthusiasm but the impetus and commitment to maintain and prioritise research activities, allocate necessary resources, address time constraints and discuss the intervention internally, dissipated. When staff had been instructed to participate without consultation there tended to be a lack of engagement with the research study from the start.

Negative feedback between staff about the study could spread very quickly throughout the organisation contributing to waning interest. This accentuated any existing fragility in team dynamics at an organisational level. If the purpose and objectives of the research process were not continually reaffirmed and supported the novel activities were often avoided, forgotten or practised less frequently. This led to negative consequences for intervention dose, protocol compliance and fidelity overall.

‘Without one or more key persons taking the lead on implementation and on stimulating the care staff to use the forms, it was very difficult to keep everyone focused on using the care program. Also, support of higher management of the organization (for example, by calculating in extra time) facilitated the implementation, because more time and understanding were available during implementation.’ [p.8] [63].

Contributors to procedural drift were identified in all work systems in the synthesis framework, often attributable to a breakdown in positive working relationships. An insightful comment mentioned that as new work routines were introduced, they were, ‘seldom accompanied by suggestions as to what routines should be replaced,’ [p.90] [85].

Theme 2: participatory action and learning

There was a higher chance of sustained engagement and relevant action if CH staff could enact their training with further guidance and mentoring.

‘Our last training was very informative. Having sessions and then several days of practical assistance was essential. Care assistants don’t (just) need more knowledge, they need to practice, they need to implement what they learnt’. [Maria, manager] ‘It was very important to have the theory coupled with the practice. During individual assistance we were relaxed, we didn’t rush things. We tried to work as we have been taught and this has become routine’ [Andrea, care assistant],’ [p.227] [84].

Clarity of roles and responsibilities in implementing the intervention and shared understanding of the purpose of practice change were important for functional team dynamics. Key drivers for success involved attributes of the individuals involved: enthusiasm, commitment, credibility, team cohesion and a sense of pride in delivering the intervention as a collective. These details influenced positive working

relationships, collective motivation and enhanced the quality of knowledge sharing across the CH. Data examples are presented in Appendices 4.

The importance of appropriate leadership and a supportive and inclusive management culture played a crucial role in promoting a solution-focused ethos when responding to challenges associated with research implementation processes. Poor communication with CH managers, or managers not being actively involved, was frequently reported as a barrier to the research process. CHs with stronger organisational hierarchies generated more negative comments. CHs that supported a culture of staff development, learning and improvement were more receptive to meaningful participation and sustained engagement in the research process.

‘Care assistants recognised their managers as an essential source of ongoing advice and guidance, but considered them to be too far removed from the reality of life and problems “on the floor”. Care assistants felt that their skills and commitment were rarely acknowledged and that their work was largely undervalued. This was seen to impact negatively on their job performance and morale, which may explain why some of the early benefits of the intervention were not sustained over time.’ [p.228] [84].

Recommendations

Table 2 identifies activities that the research team and CH team can undertake individually as well as activities they can engage with collaboratively. The recommendations describe contingencies to reduce the potential for procedural drift and help sustain positive working relationships at a partnership level to encourage a research culture that engenders participatory action and learning.

Discussion

Summary

We identified recommendations from international evidence for researchers involved in designing, implementing and evaluating CH complex intervention studies and for staff considering participating in such studies. Recommendations are divided into activities which researchers and CH teams must consider individually and those which require collaborative and collective efforts to succeed.

Key findings

1. Research teams must not underestimate the effects of restructuring habitual ways of working [89]. CH staff responses to these changes had a mediating effect on successful trial implementation processes. The compatibility of the tested intervention with the CH’s existing work routine was the most prevalent contextual factor discussed within the reviewed process evaluations. Many of the unanticipated behavioural responses of the

Table 2. Anticipatory considerations to promote positive working relationships and reduce the potential for procedural drift interpreted from the indexed dataset

Research team	Collaborative: research team and care home team	Care home team
<p>Protocol</p> <p><i>Design:</i> How well can the intervention be integrated into existing CH organisational routines?</p> <p><i>Study initiation:</i> Has enough time been allocated to assessing suitability, building rapport, and assessing readiness to participate prior to commencing the study?</p> <p><i>Fidelity and Adherence:</i> How much bespoke tailoring of the protocol can be tolerated in the study design?</p> <p><i>Process evaluation:</i> How will the implementation process be evaluated to explore broader system responses?</p> <p><i>Activity:</i> How can monitoring implementation activities detect the emergence of 'procedural drift'?</p> <p><i>Complexity:</i> How can any perceived complexity of data collection or other implementation activities be simplified?</p> <p><i>Learning over time:</i> Are adaptations in the delivery of the intervention across sites and over time anticipated?</p>	<p>Individual context</p> <p><i>Authentic co-production and active collaboration:</i> How can task-oriented dialogue between all stakeholders promote engagement of attitude and action?</p> <p><i>Awareness of opportunity costs of participation:</i> As new tasks are added to CH work routines, what tasks will be reduced or replaced in the same period?</p> <p><i>Participatory action and learning:</i> How can training of CH staff be put into practice early and supported through a coaching approach?</p> <p><i>Commitment:</i> What will help sustain motivation and commitment in working together throughout the study?</p> <p><i>Collective reflection:</i> How stakeholders feedback their experiences consistently throughout the study duration to align and realign shared expectations?</p> <p><i>External support:</i> How can the CH access additional external support in delivering the intervention whilst maintaining care quality and resident safety if needed?</p>	<p>Internal resources</p> <p><i>Resource management:</i> How can necessary resources be released to sustain effective implementation whilst maintaining care quality?</p> <p><i>Participating residents:</i> How can the intervention reach the residents who are most likely to receive a benefit?</p> <p><i>Staff development:</i> Is there sufficient staff capacity to attend intervention implementation training during work hours?</p> <p><i>Resources for key staff:</i> Is there sufficient capacity and commitment for multiple members of staff to help coordinate the study on a day-to-day basis, taking into account sickness and holiday absence?</p> <p><i>Staff turnover:</i> Is there a robust process for informing new staff about the implementation project and their involvement?</p>
<p>Care home engagement</p> <p><i>Motivation:</i> How can the research team gain an understanding of the CH's main interest in participating?</p> <p><i>Study materials:</i> How can study materials be presented in easy-to-use formats to support inclusivity?</p> <p><i>Managerial support:</i> How can support and training opportunities be extended to the managerial team?</p> <p><i>Communication enhancement:</i> How can consistent, reliable and inclusive communication channels be established and maintained?</p>	<p>Positive working relationships</p> <p><i>Relational working:</i> How will the collaboration be nurtured to build rapport, air tensions, identify solutions, and resolve difficulties?</p> <p><i>Inclusivity:</i> How can all staff throughout the care home and residents (if appropriate) be informed about the study?</p> <p><i>Goal setting:</i> How can residents' goals associated with the intervention be shared with staff?</p> <p><i>Language:</i> How can accessible language and 'easy read' formats support effective communication and team dynamics?</p>	<p>Team dynamics</p> <p><i>Managerial involvement:</i> How can regular meetings with the CH manager take place to align shared expectations and discuss ongoing commitment?</p> <p><i>Visibility:</i> How can CH staff responsible for supporting the study be identifiable and accessible across the organisation throughout the implementation process?</p> <p><i>Reflection:</i> How can time be allotted in team meetings to discuss how the study is running in the CH routinely?</p> <p><i>Sharing good news:</i> How can staff share positive stories about their involvement with the intervention?</p>

G. Peryer et al.

CH staff posed significant challenges to the intervention implementation process.

2. Both CH staff and members of the research team made adaptations to and deviations from trial protocols. Further, the complexities of task and person focused factors were compounded by organisational and environment factors such as high staff turnover, inherent variability of CH administration, resource limitations and varying suitability of CH internal environments. The culmination of these effects increased heterogeneity between CH settings [22, 33, 90].

We identified two themes: (i) procedural drift and (ii) participatory action and learning.

Procedural drift

Procedural drift (also referred to as practical drift) has its roots in safety science [88, 91, 92]. It refers to the human tendency to change, or deviate from, or avoid a recommended or required sequence of repeated activities over time. Some deviations from a prescribed protocol may enhance long-term sustainability of an intervention and act as a desirable outcome [88]. Other forms of deviation and adaptation may signify a vulnerability to implementation failure. A significant problem identified in the current data is how task-focused activities and staff engagement with them tended to dwindle over time, often coinciding with when the research team decreased active involvement following the start-up phase [93]. If activities diminished, attention to detail, intervention adherence and commitment to the entire implementation process weakened also. Inconsistencies in data collection caused research teams to question their reliability.

Time constraints

CH resources, staff capacity and workload are strained. If staff could not identify meaning behind implementation activities, sustained engagement was unlikely. When time constraints were experienced by staff, habitual ways of working took priority over novel research activities. Researchers must acknowledge the opportunity costs that arise for CH staff participating in research studies evaluating novel interventions.

Mitigating action

When we consider the concept of procedural drift further, we also need to identify ways to detect it and potentially take corrective action. Two important questions arise: drift with respect to what and to whom [88]. From an implementation perspective it is useful to consider the contextual attributes that may foster resilience to any long-term effects or possible catastrophic failures. Further description of different forms of resilience, a system's capacity to rebound from failure, and system robustness to absorb the effects of failure are discussed elsewhere [88]. Future studies may find benefit in assigning

personnel and resources to detect indications of procedural drift as early as possible.

Participatory action and learning

Prominent contextual factors identified across the process evaluations were indexed within the task and organisational work systems. The interdependent nature of positive working relationships means both the research team and the CH team need to be prepared to alter their behaviour [94]. It is a reciprocal partnership. Despite a high number of neutral findings in the main intervention studies to which the process evaluations belonged, there were examples of promising participatory activities undertaken in partnership with stakeholders (Appendix 4) [14].

Understanding the properties of the intervention, agreeing its purpose, feeling equipped to enact training and drawing on prior experience of caring for residents were crucial in promoting cognitive participation among CH staff [14, 89]. Without a corpus of support within the CH it was difficult to maintain constructive research-focused discussion and engage in effective problem resolution.

Authentic engagement and co-production

Authentic engagement and co-production require awareness of inherent power imbalances, time, and sustained effort to be effective [95]. It helps leverage skills and experiences from all parties involved as opposed to instructing a way of working that may not be compatible with a CH's work routines [96]. This is challenging to achieve [97]. Often it is dependent on personalities, individuals staying in post and other contextual factors specific to the suitability of each individual research project [95, 97, 98]. Intentional stakeholder engagement and co-production methods can also be susceptible to procedural drift [99].

A collective commitment to negotiate, develop mutual understanding, and sustain positive working relationships requires resource allocation from the research team and a receptive infrastructure in the CH to support and maintain co-production and meaningful collaboration [14, 100, 101]. Activities oriented towards developing trust, a sense of collegiality and shared commitment to derive mutual benefit are important precursors [102]. Returning to these principles throughout the process is a suggested means to maintain a shared sense of purpose.

Research study constructs

Staff and health care clinicians involved in implementing the intervention were not passive delivery conduits. There were distinct effects of 'learning over time'. This has implications for experimental design. For example, in a cluster randomised trial a CH that receives the intervention early may not be directly comparable to a CH that receives the intervention at a later stage: there is learning and adaptation in the interim period.

Strengths and weaknesses

There were strengths in using the SEIPS model as a synthesis framework; it produced broad agreement across the dataset [48, 51, 52]. The 28 context domains appeared in 18–82% of the included papers; the top six domains were present in >70% of papers. The theory-based framework synthesis method allowed descriptive content to be indexed in a structured format but also combined inductive thematic analysis to support enhanced interpretation [46, 48, 49, 103].

The searches were updated on 30 September 2021 and a further 16 eligible process evaluations were identified [104–119]. The context domains indexed in the most recent publications mapped well onto the findings of this review which supports the viability of the synthesis framework. Procedural drift, and the need for a participatory action and learning were pervasive: lack of time, resource constraints and heterogeneity between CH settings were described as barriers to successful implementation of complex intervention trials [104, 105, 109–119]. Several papers suggested it may be more appropriate to design research interventions with high staff turnover and a changing context in mind [106, 110]. The importance of purposefully including flexibility within the trial design to tailor the research process to a CH's individual context settings was also discussed as an important enabler to successful implementation processes [107, 108, 112].

There are also limitations from the review to acknowledge. First, all synthesis methods are reductive, and this approach comes with risks. Using this framework meant that the data were considered using a HF work system frame of reference. Alternative approaches may have led to alternative areas of focus, such as Normalisation Process Theory [89], or the Consolidated Framework for Implementation Research [120]. However, both examples are synergistic with our review; they also involve the study of interactions between people, processes, technologies and organisational systems.

The search was limited to the English language, and only identified studies from Western high-income countries. Even within these countries the model of care within CHs is heterogeneous and this will have an impact on the care context and success of complex intervention research processes [121]. Publications from low and middle-income countries more frequently appear in other languages [122].

Moreover, for pragmatic reasons this review identified studies that used the term 'process evaluation' specifically. Broadening the eligibility criteria to include additional studies discussing contextual factors influencing research implementation processes would have increased heterogeneity between study methods.

The SEIPS model does not aim to attribute causality, only plausible contributions to desirable and undesirable outcomes that may occur over short or longer time frames [51, 52]. The work systems to which the data were indexed were coded as discrete elements; however, all intervention activity in this model was inter-related.

Conclusion

This review provides compelling evidence to undertake and report formal process evaluation data alongside intervention effectiveness data in CH complex intervention trials. Exploring contextual data from trial implementation processes and broader system responses to an intervention will maximise the explanatory value of the analysis and provide assurances over a CH trial's internal validity [16, 22, 33, 90].

Our recommendations outline what is needed to trial CH interventions more consistently, and reduce the risk of expensive research implementation failures [123]. The recommendations aim to inform and improve future CH interventional studies more broadly. They are dependent upon operationalising authentic relational approaches within the context of complex adaptive human systems at scale [6, 90, 94]. It is likely that we will learn more about how to do this better as these recommendations are implemented.

Supplementary Data: Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

Acknowledgements: Authors would like to thank Carl May for supportive comments on the manuscript, Isla Kuhn for support with data searches and Andrew Booth for support sourcing the appraisal tool. Acknowledgement of collaborative authors

We would also like to acknowledge the Developing research resources And minimum data set for Care Homes' Adoption (DACHA) research team*: Barbara Hanratty, Liz Jones, Simon Robinson, Karen Spilsbury, Ann-Marie Towers, and Arne Wolters.

Declaration of Conflicts of Interest: None.

Declaration of Sources of Funding: This study/project is funded by the National Institute for Health Research (NIHR) Health Service Research and Delivery programme (HS&DR NIHR127234) and supported by the NIHR Applied Research Collaboration (ARC) East of England. CG is a NIHR Senior Investigator. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Data Availability Statement: Narrative data examples extracted for this systematic review are provided in the appendices.

References

1. Spiers G, Matthews FE, Moffatt S *et al*. Impact of social care supply on healthcare utilisation by older adults: a systematic review and meta-analysis. *Age Ageing* 2018; 48: 57–66.
2. Government Office for Science. Future of an Aging Population https://www.ageing.ox.ac.uk/files/Future_of_Ageing_Report.pdf (12 November 2020, date last accessed).

3. Bonell C, Moore G, Warren E *et al.* Are randomised controlled trials positivist? Reviewing the social science and philosophy literature to assess positivist tendencies of trials of social interventions in public health and health services. *Trials* 2018; 19: 238. <https://doi.org/10.1186/s13063-018-2589-4>.
4. Campbell M, Fitzpatrick R, Haines A *et al.* Framework for design and evaluation of complex interventions to improve health. *BMJ (Clinical research ed)* 2000; 321: 694–6.
5. Long KM, McDermott F, Meadows GN. Being pragmatic about healthcare complexity: our experiences applying complexity theory and pragmatism to health services research. *BMC Med* 2018; 16: 94. <https://doi.org/10.1186/s12916-018-1087-6>.
6. Braithwaite J. Changing how we think about healthcare improvement. *BMJ* 2018; 361: k2014. <https://doi.org/10.1136/bmj.k2014>.
7. Kinderman P, Butchard S, Bruen AJ *et al.* A randomised controlled trial to evaluate the impact of a human rights based approach to dementia care in inpatient ward and care home settings. <https://www.journalslibrary.nihr.ac.uk/hsdr/hsdr06130/#/abstract> (2 November 2020, date last accessed).
8. Underwood M, Lamb S, Eldridge S *et al.* Exercise for depression in care home residents: a randomised controlled trial with cost-effectiveness analysis (OPERA). <https://www.journalslibrary.nihr.ac.uk/hta/hta17180/#/abstract> (2 November 2020, date last accessed).
9. Surr C, Holloway I, Walwyn R *et al.* Dementia Care Mapping to Reduce Agitation in Care Home Residents with Dementia: the EPIC Cluster RCT. <https://www.journalslibrary.nihr.ac.uk/hta/hta24160/#/abstract> (28 November 2020, date last accessed).
10. Moniz-Cook E, Hart C, Woods B *et al.* Challenge Dementia: Management of Challenging Behaviour in Dementia at Home and in Care Homes. <https://www.journalslibrary.nihr.ac.uk/pgfar/pgfar05150/#/abstract> (20 November 2020, date last accessed).
11. Sackley CM, Walker MF, Burton CR *et al.* An occupational therapy intervention for residents with stroke related disabilities in UK care homes (OTCH): cluster randomised controlled trial. *BMJ: British Medical Journal* 2015; 350: h468. <https://doi.org/10.1136/bmj.h468>.
12. Underwood M, Lamb SE, Eldridge S *et al.* Exercise for depression in elderly residents of care homes: a cluster-randomised controlled trial. *The Lancet* 2013; 382: 41–9.
13. Sackley CM, Walker MF, Burton CR *et al.* An Occupational Therapy Intervention for Residents with Stroke-Related Disabilities in UK Care Homes (OTCH): Cluster Randomised Controlled Trial with Economic Evaluation. <https://www.journalslibrary.nihr.ac.uk/hta/hta20150/#/abstract> (13 November 2020, date last accessed).
14. NIHR Dissemination Centre. Advancing Care: Research with Care Homes. <https://evidence.nihr.ac.uk/wp-content/uploads/2020/03/Advancing-Care-Final.pdf> (2 November 2020, date last accessed).
15. Hawe P, Shiell A, Riley T. Theorising interventions as events in systems. *Am J Community Psychol* 2009; 43: 267–76.
16. Bird L, Arthur A, Cox K. “Did the trial kill the intervention?” experiences from the development, implementation and evaluation of a complex intervention. *BMC Med Res Methodol* 2011; 11: 24. <https://doi.org/10.1186/1471-2288-11-24>.
17. Greenhalgh T, Papoutsi C. Studying complexity in health services research: desperately seeking an overdue paradigm shift. *BMC Med* 2018; 16: 95. <https://doi.org/10.1186/s12916-018-1089-4>.
18. Moore GF, Evans RE, Hawkins J *et al.* From complex social interventions to interventions in complex social systems: future directions and unresolved questions for intervention development and evaluation. *Evaluation* 2018; 25: 23–45.
19. Moore L, Hallingberg B, Wight D *et al.* Exploratory studies to inform full-scale evaluations of complex public health interventions: the need for guidance. *J Epidemiol Community Health* 2018; 72: 865. <https://doi.org/10.1136/jech-2017-210414>.
20. Rutter H, Savona N, Glonti K *et al.* The need for a complex systems model of evidence for public health. *The Lancet* 2017; 390: 2602–4.
21. Booth A, Moore G, Flemming K *et al.* Taking account of context in systematic reviews and guidelines considering a complexity perspective. *BMJ Glob Health* 2019; 4: e000840. <https://doi.org/10.1136/bmjgh-2018-000840>.
22. Skivington K, Matthews L, Simpson SA *et al.* A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* 2021; 374: n2061. <https://doi.org/10.1136/bmj.n2061>.
23. Moore GF, Audrey S, Barker M *et al.* Process evaluation of complex interventions: Medical Research Council guidance. *BMJ: British Medical Journal* 2015; 350: h1258. <https://doi.org/10.1136/bmj.h1258>.
24. Pfadenhauer LM, Gerhardus A, Mozygemba K *et al.* Making sense of complexity in context and implementation: the context and implementation of complex interventions (CICI) framework. *Implementation Sci* 2017; 12: 21. <https://doi.org/10.1186/s13012-017-0552-5>.
25. Clarkson P, Bogle D, Dean J *et al.* Engineering Better Care: A Systems Approach to Health and Care Design and Continuous Improvement, 2017.
26. Wilson JR. Fundamentals of systems ergonomics/human factors. *Appl Ergon* 2014; 45: 5–13.
27. Brand SL, Fleming LE, Wyatt KM. Tailoring healthy workplace interventions to local healthcare settings: a complexity theory-informed workplace of well-being framework. *Sci World J* 2015; 2015: 340820. <https://doi.org/10.1155/2015/340820>.
28. The Health Foundation. Complex adaptive systems. <https://www.health.org.uk/publications/complex-adaptive-systems> (2 August 2018, date last accessed).
29. Penney LS, Nahid M, Leykum LK *et al.* Interventions to reduce readmissions: can complex adaptive system theory explain the heterogeneity in effectiveness? A systematic review. *BMC Health Serv Res* 2018; 18: 894. <https://doi.org/10.1186/s12913-018-3712-7>.
30. Clark AM. What are the components of complex interventions in healthcare? Theorizing approaches to parts, powers and the whole intervention. *Soc Sci Med* 2013; 93: 185–93.

31. Bonell C, Oakley A, Hargreaves J *et al.* Assessment of generalisability in trials of health interventions: suggested framework and systematic review. *BMJ* 2006; 333: 346–9.
32. Health and Safety Executive. Reducing Error and Influencing Behaviour. <https://www.hse.gov.uk/pubns/priced/hsg48.pdf> (2 November 2020, date last accessed).
33. Craig P, Ruggiero E, Frohlich KL *et al.*; Taking Account of Context in Population Health Intervention Research: Guidance for Producers, Users and Funders of Research. 2018. doi: <https://doi.org/10.17863/CAM.26129>.
34. Sturgiss EA, Clark AM. Using critical realism in primary care research: an overview of methods. *Fam Pract* 2020; 37: 143–5.
35. Craig P, Matthews L, Moore L *et al.* Updated Guidance: Developing and Evaluating Complex Interventions [DRAFT FOR CONSULTATION]. <https://www.sphsu.gla.ac.uk/stakeholder-survey-2019/Full%20complex%20guidance%20draft%20for%20consultation%20v1.1%2026.03.19.pdf> (2 November 2020, date last accessed).
36. Moore GF, Audrey S, Barker M *et al.* Process Evaluation of Complex Interventions: Medical Research Council guidance. London: MRC Population Health Science Research Network. (2 November 2020, date last accessed).
37. Mills WL, Pimentel CB, Snow AL *et al.* Nursing home staff perceptions of barriers and facilitators to implementing a quality improvement intervention. *J Am Med Dir Assoc* 2019; 20: 810–5.
38. Petticrew M, Knai C, Thomas J *et al.* Implications of a complexity perspective for systematic reviews and guideline development in health decision making. *BMJ Glob Health* 2019; 4: e000899–9.
39. Leontjevas R, Gerritsen DL, Koopmans RTCM *et al.* Process evaluation to explore internal and external validity of the “act in case of depression” care program in nursing homes. *J Am Med Dir Assoc* 2012; 13: 488.e1–8.
40. Proctor E, Silmere H, Raghavan R *et al.* Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health* 2011; 38: 65–76.
41. Kelly S, Peryer G, Cowan A *et al.* A systematic review of process and contextual factors that influence research implementation in care homes and identification of key measures and outcomes in care home research. https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42020155923 (2 November 2020, date last accessed).
42. Moher D, Liberati A, Tetzlaff J *et al.* Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med* 2009; 6: e1000097. <https://doi.org/10.1371/journal.pmed.1000097>.
43. Tong A, Flemming K, McInnes E *et al.* Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ. *BMC Med Res Methodol* 2012; 12: 181. <https://doi.org/10.1186/1471-2288-12-181>.
44. Shepherd J, Harden A, Barnett-Page E *et al.* Using process data to understand outcomes in sexual health promotion: an example from a review of school-based programmes to prevent sexually transmitted infections. *Health Educ Res* 2014; 29: 566–82.
45. Noyes J, Booth A, Cargo M *et al.* Chapter 21: qualitative evidence. In: JPT H, Thomas J, Chandler J *et al.*, eds. *Cochrane Handbook for Systematic Reviews of Interventions* version 6.2 (updated February 2021): Cochrane, 2021.
46. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, RGs B, eds. *Analyzing Qualitative Data*. London, New York: Routledge, 1994; 173–94.
47. Brunton G, Oliver S, Thomas J. Innovations in framework synthesis as a systematic review method. *Res Synth Methods* 2020; 11: 316–30.
48. Carroll C, Booth A, Cooper K. A worked example of “best fit” framework synthesis: a systematic review of views concerning the taking of some potential chemopreventive agents. *BMC Med Res Methodol* 2011; 11: 29. <https://doi.org/10.1186/1471-2288-11-29>.
49. Carroll C, Booth A, Leaviss J *et al.* “Best fit” framework synthesis: refining the method. *BMC Med Res Methodol* 2013; 13: 37. <https://doi.org/10.1186/1471-2288-13-37>.
50. Booth A, Carroll C. Systematic searching for theory to inform systematic reviews: is it feasible? Is it desirable? *Health Info Libr J* 2015; 32: 220–35.
51. Holden RJ, Carayon P, Gurses AP *et al.* SEIPS 2.0: a human factors framework for studying and improving the work of healthcare professionals and patients. *Ergonomics* 2013; 56: 1669–86.
52. Carayon P, Schoofs Hundt A, Karsh BT *et al.* Work system design for patient safety: the SEIPS model. *Qual Saf Health Care* 2006; 15 Suppl 1: i50–8.
53. Berwick D, Fox DM. “Evaluating the quality of medical care”: Donabedian’s classic article 50 years later. *Milbank Q* 2016; 94: 237–41.
54. Ellard DR, Thorogood M, Underwood M *et al.* Whole home exercise intervention for depression in older care home residents (the OPERA study): a process evaluation. *BMC Med* 2014; 12: 1.
55. Masterson-Algar P, Burton CR, Rycroft-Malone J *et al.* Towards a programme theory for fidelity in the evaluation of complex interventions. *J Eval Clin Pract* 2014; 20: 445–52.
56. Toye F, Seers K, Hannink E *et al.* A mega-ethnography of eleven qualitative evidence syntheses exploring the experience of living with chronic non-malignant pain. *BMC Med Res Methodol* 2017; 17. <https://doi.org/10.1186/s12874-017-0392-7>.
57. Bamford C, Heaven B, May C *et al.* Implementing nutrition guidelines for older people in residential care homes: a qualitative study using normalization process theory. *Implementation Sci* 2012; 7: 106–6.
58. Griffiths AW, Kelley R, Garrod L *et al.* Barriers and facilitators to implementing dementia care mapping in care homes: results from the DCM™ EPIC trial process evaluation. *BMC Geriatr* 2019; 19: 1–16. <https://doi.org/10.1186/s12877-019-1045-y>.
59. Guzmán A, Robinson L, Rochester L *et al.* A process evaluation of a psychomotor dance therapy intervention (DANCIN) for behavior change in dementia: attitudes and beliefs of participating residents and staff. *Int Psychogeriatr* 2017; 29: 313–22.
60. Keenan J, Poland F, Manthorpe J *et al.* Implementing e-learning and e-tools for care home staff supporting residents with dementia and challenging behaviour: a process evaluation of the ResCare study using normalisation process theory. *Dementia* 2018; 1471301218803195. <https://doi.org/10.1177/1471301218803195>.
61. Surr CA, Griffiths AW, Kelley R *et al.* The implementation of dementia care mapping in a randomized controlled trial

- in long-term care: results of a process evaluation. *Am J Alzheimers Dis Other Demen* 2019; 34: 390–8.
62. Surr CA, Shoemith E, Griffiths AW *et al.* Exploring the role of external experts in supporting staff to implement psychosocial interventions in care home settings: results from the process evaluation of a randomized controlled trial. *BMC Health Serv Res* 2019; 19: 790.
 63. Zwijsen SA, Smalbrugge M, Eefsting JA *et al.* Grip on challenging behavior: process evaluation of the implementation of a care program. *Trials* 2014; 15: 302.
 64. Walker GM, Armstrong S, Gordon AL *et al.* The falls in care home study: a feasibility randomized controlled trial of the use of a risk assessment and decision support tool to prevent falls in care homes. *Clin Rehabil* 2016; 30: 972–83.
 65. Heaven A, Clegg A, Forster A *et al.* Improving the Quality of Care in Care Homes for Older People: Process Evaluation of a Complex Intervention to Prevent Delirium (data supplied in advance of publication), 2019.
 66. Siddiqi N, Cheater F, Collinson M *et al.* The PiTSTOP study: a feasibility cluster randomized trial of delirium prevention in care homes for older people. *Age Ageing* 2016; 45: 652–61.
 67. Bleijlevens MHC, Gulpers MJM, Capezuti E *et al.* Process evaluation of a multicomponent intervention program (EXBELT) to reduce belt restraints in nursing homes. *J Am Med Dir Assoc* 2013; 14: 599–604.
 68. Boersma P, Weert JCM, Meijel B *et al.* Implementation of the Veder contact method in daily nursing home care for people with dementia: a process analysis according to the RE-AIM framework. *J Clin Nurs (John Wiley & Sons, Inc)* 2017; 26: 436–55.
 69. Braun SM, van Haastregt JC, Beurskens AJ *et al.* Feasibility of a mental practice intervention in stroke patients in nursing homes; a process evaluation. *BMC Neurol* 2010; 10: 74–4.
 70. Gerritsen DL, De Vries E, Smalbrugge M *et al.* Implementing a multidisciplinary psychotropic medication review among nursing home residents with dementia: a process evaluation. *Int Psychogeriatr* 2019.
 71. van Haeften-van Dijk AM, van Weert JCM, Dröes R-M. Implementing living room theatre activities for people with dementia on nursing home wards: a process evaluation study. *Aging Ment Health* 2015; 19: 536–47.
 72. Desveaux L, Halko R, Marani H *et al.* Importance of team functioning as a target of quality improvement initiatives in nursing homes: a qualitative process evaluation. *J Contin Educ Health Prof* 2019; 39: 21–8.
 73. Desveaux L, Saragosa M, Rogers J *et al.* Improving the appropriateness of antipsychotic prescribing in nursing homes: a mixed-methods process evaluation of an academic detailing intervention. *Implementation Sci* 2017; 12: 71.
 74. Edwards NC, Smith Higuchi K. Process evaluation of a participatory, multimodal intervention to improve evidence-based care in long-term care settings. *Worldviews Evid Based Nurs* 2018; 15: 361–7.
 75. Sales AE, Fraser K, Baylon MAB *et al.* Understanding feedback report uptake: process evaluation findings from a 13-month feedback intervention in long-term care settings. *Implementation Sci* 2015; 10: 208–8.
 76. Slaughter SE, Bampton E, Erin DF *et al.* Knowledge translation interventions to sustain direct care provider behaviour change in long-term care: a process evaluation. *J Eval Clin Pract* 2018; 24: 159–65.
 77. Abraham J, Kupfer R, Behncke A *et al.* Implementation of a multicomponent intervention to prevent physical restraints in nursing homes (IMPRINT): a pragmatic cluster randomized controlled trial. *Int J Nurs Stud* 2019; 96: 27–34.
 78. Holle D, Müller-Widmer R, Reuther S *et al.* Process evaluation of the context, reach and recruitment of participants and delivery of dementia-specific case conferences (WELCOME-IdA) in nursing homes (FallDem): a mixed-methods study. *Trials* 2019; 20N.PAG-N.PAG. <https://doi.org/10.1186/s13063-018-3147-9>.
 79. Quasdorf T, Riesner C, Dichter MN *et al.* Implementing dementia care mapping to develop person-centred care: results of a process evaluation within the Leben- QD II trial. *J Clin Nurs (John Wiley & Sons, Inc)* 2017; 26: 751–65.
 80. Aasmul I, Husebo BS, Flo E. Description of an advance care planning intervention in nursing homes: outcomes of the process evaluation. *BMC Geriatr* 2018; 18: 26.
 81. Lichtwarck B, Myhre J, Selbaek G *et al.* TIME to reduce agitation in persons with dementia in nursing homes. A process evaluation of a complex intervention. *BMC Health Serv Res* 2019; 19N.PAG-N.PAG. <https://doi.org/10.1186/s12913-019-4168-0>.
 82. Smith M, Bull AL, Dunt D *et al.* Formative and process evaluation of a healthcare-associated infection surveillance program in residential aged care facilities, Grampians region. *Victoria Healthcare Infect* 2012; 17: 64–9.
 83. Anrys P, Strauven G, Roussel S *et al.* Process evaluation of a complex intervention to optimize quality of prescribing in nursing homes (COME-ON study). *Implementation Sci* 2019; 14: 104. <https://doi.org/10.1186/s13012-019-0945-8>.
 84. Barbosa A, Nolan M, Sousa L *et al.* Implementing a psycho-educational intervention for care assistants working with people with dementia in aged-care facilities: facilitators and barriers. *Scand J Caring Sci* 2017; 31: 222–31.
 85. Eldh AC, Olai L, Jönsson B *et al.* Supporting first-line managers in implementing oral care guidelines in nursing homes. *Nordic J Nurs Res* 2018; 38: 87–95.
 86. Reynolds KS. End-of-life Care in Nursing Home Settings. University of North Carolina at Chapel Hill, 2004; 130 p–130 p.
 87. Rycroft-Malone J, Seers K, Eldh AC *et al.* A realist process evaluation within the facilitating implementation of research evidence (FIRE) cluster randomised controlled international trial: an exemplar. *Implementation Sci* 2018; 13: 138.
 88. Gould K, Schulman P. Drift, adaptation, resilience and reliability: toward an empirical clarification. *Safety Sci* 2016; 117. <https://doi.org/10.1016/j.ssci.2016.03.004>.
 89. Murray E, Treweek S, Pope C *et al.* Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Med* 2010; 8: 63. <https://doi.org/10.1186/1741-7015-8-63>.
 90. Durlak J, Du Pre E. Implementation matters: a review of research on the influence of implementation on program outcomes and the factors affecting implementation. *Am J Community Psychol* 2008; 41: 327–50.
 91. Dekker S. Drift into Failure: From Hunting Broken Components to Understanding Complex Systems. Boca Raton, Florida: CRC Press, Taylor Francis Group, 2011.
 92. Snook S. Friendly Fire. Princeton, New Jersey: Princeton University Press, 2000.

93. McCabe MP, Davison TE, George K. Effectiveness of staff training programs for behavioral problems among older people with dementia. *Aging Ment Health* 2007; 11: 505–19.
94. Nolan M, Davies S, Ryan T *et al.* Relationship-centred care and the ‘senses’ framework. *J Dementia Care* 2008; 16: 26–8.
95. O’Shea A, Boaz AL, Chambers M. A hierarchy of power: the place of patient and public involvement in healthcare service development. *Front Sociol* 2019; 4. <https://doi.org/10.3389/fsoc.2019.00038>.
96. Beckett K, Farr M, Kothari A *et al.* Embracing complexity and uncertainty to create impact: exploring the processes and transformative potential of co-produced research through development of a social impact model. *Health Research Policy and Systems* 2018; 16: 118. <https://doi.org/10.1186/s12961-018-0375-0>.
97. Rycroft-Malone J, Burton CR, Bucknall T *et al.* Collaboration and co-production of knowledge in healthcare: opportunities and challenges. *Int J Health Policy Manag* 2016; 5: 221–3. <https://doi.org/10.15171/ijhpm.2016.08>.
98. Tembo D, Hickey G, Montenegro C *et al.* Effective engagement and involvement with community stakeholders in the co-production of global health research. *BMJ* 2021; 372: n178. <https://doi.org/10.1136/bmj.n178>.
99. Boaz A, Borst R, Kok M *et al.* How far does an emphasis on stakeholder engagement and co-production in research present a threat to academic identity and autonomy? A prospective study across five European countries. *Res Evaluat* 2021. <https://doi.org/10.1093/reseval/rvab013> doi: 10.1093/reseval/rvab013.
100. Devi R, Chadborn NH, Meyer J *et al.* How quality improvement collaboratives work to improve healthcare in care homes: a realist evaluation. *Age Ageing* 2021; 50: 1371–81.
101. Hasche LK, Lenze S, Brown T *et al.* Adapting collaborative depression care for public community long-term care: using research-practice partnerships. *Adm Policy Ment Health* 2014; 41: 687–96.
102. Bunn F, Goodman C, Corazzini K *et al.* Setting priorities to inform assessment of care homes’ readiness to participate in healthcare innovation: a systematic mapping review and consensus process. *Int J Environ Res Public Health* 2020; 17. <https://doi.org/10.3390/ijerph17030987>.
103. Noyes J, Booth A, Moore G *et al.* Synthesising quantitative and qualitative evidence to inform guidelines on complex interventions: clarifying the purposes, designs and outlining some methods. *BMJ Glob Health* 2019; 4: e000893. <https://doi.org/10.1136/bmjgh-2018-000893>.
104. Abraham J, Bake M, Berger-Höger B *et al.* Process evaluation of a multicomponent intervention to prevent physical restraints in nursing homes (IMPRINT): a mixed methods study. *J Adv Nurs* 2021; 77: 1465–77.
105. Allen F, Darby J, Cook M *et al.* Learning from a successful process evaluation in care homes. *Age Ageing* 2021; 50: 1850–3.
106. Bielderman A, Nieuwenhuis A, Hazelhof T *et al.* Effects on staff outcomes and process evaluation of the educating nursing staff effectively (TENSE) program for managing challenging behavior in nursing home residents with dementia: a cluster-randomized controlled trial. *Int J Nurs Stud* 2021; 120: 103982. <https://doi.org/10.1016/j.ijnurstu.2021.103982>.
107. Chambers A, Chen C, Brown KA *et al.* Virtual learning collaboratives to improve urine culturing and antibiotic prescribing in long-term care: controlled before-and-after study. *BMJ Qual Saf* 2021. <https://doi.org/10.1136/bmjqs-2020-012226>.
108. Choi H, Jung YI, Kim H. Implementation fidelity of the Systems for Person-Centered Elder Care (SPEC): a process evaluation study. *Implement Sci* 2021; 16: 52. <https://doi.org/10.1186/s13012-021-01113-3>.
109. Froggatt K, Best A, Bunn F *et al.* A group intervention to improve quality of life for people with advanced dementia living in care homes: the Namaste feasibility cluster RCT. *Health Technol Assess* 2020; 24: 1–140.
110. Groot Kormelinck CM, van Teunenbroek CF, Zuidema SU *et al.* Process evaluation of a tailored intervention to reduce inappropriate psychotropic drug use in nursing home residents with dementia. *BMC Geriatr* 2021; 21: 414. <https://doi.org/10.1186/s12877-021-02357-w>.
111. Hughes C, Ellard D, Campbell A *et al.* Health services and delivery research. In: *A Multifaceted Intervention to Reduce Antimicrobial Prescribing in Care Homes: A Non-Randomised Feasibility Study and Process Evaluation*. Southampton (UK), 2020.
112. Klingshirn H, Müller M, Beutner K *et al.* Implementation of a complex intervention to improve participation in older people with joint contractures living in nursing homes: a process evaluation of a cluster-randomised pilot trial. *BMC Geriatr* 2020; 20: 270. <https://doi.org/10.1186/s12877-020-01655-z>.
113. Oosterveld-Vlug M, Onwuteaka-Philipsen B, Ten Koppel M *et al.* Evaluating the implementation of the PACE steps to success programme in long-term care facilities in seven countries according to the RE-AIM framework. *Implement Sci* 2019; 14: 107. <https://doi.org/10.1186/s13012-019-0953-8>.
114. Potter R, Campbell A, Ellard DR *et al.* Multifaceted intervention to reduce antimicrobial prescribing in care homes: a process evaluation of a UK-based non-randomised feasibility study. *BMJ Open* 2019; 9: e032185. <https://doi.org/10.1136/bmjopen-2019-032185>.
115. Richter C, Berg A, Langner H *et al.* Effect of person-centred care on antipsychotic drug use in nursing homes (EPCentCare): a cluster-randomised controlled trial. *Age Ageing* 2019; 48: 419–25.
116. Sluggert JK, Hughes GA, Ooi CE *et al.* Process evaluation of the Simplification of Medications Prescribed to Long-term care Residents (SIMPLER) cluster randomized controlled trial: a mixed methods study. *Int J Environ Res Public Health* 2021; 18. <https://doi.org/10.3390/ijerph18115778>.
117. Graham L, Ellwood A, Hull K *et al.* A posture and mobility training package for care home staff: results of a cluster randomised controlled feasibility trial (the PATCH trial). *Age Ageing* 2020; 49: 821–8.
118. Ginsburg LR, Hoben M, Easterbrook A *et al.* Examining fidelity in the INFORM trial: a complex team-based behavioral intervention. *Implement Sci* 2020; 15: 78. <https://doi.org/10.1186/s13012-020-01039-2>.
119. Griffiths AW, Robinson OC, Shoosmith E *et al.* Staff experiences of implementing dementia care mapping to improve the quality of dementia care in care homes: a qualitative

- process evaluation. *BMC Health Serv Res* 2021; 21: 138. <https://doi.org/10.1186/s12913-021-06152-6>.
- 120.** Damschroder LJ, Aron DC, Keith RE *et al.* Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Sci* 2009; 4: 50. <https://doi.org/10.1186/1748-5908-4-50>.
- 121.** Sanford AM, Orrell M, Tolson D *et al.* An international definition for “nursing home”. *J Am Med Dir Assoc* 2015; 16: 181–4.
- 122.** Wachholz PA, De Oliveira DC, Hinsliff-Smith K *et al.* Mapping research conducted on long-term care facilities for older people in Brazil: a scoping review. *Int J Environ Res Public Health* 2021; 18: 1522.
- 123.** Hawe P, Shiell A, Riley T. Complex interventions: how “out of control” can a randomised controlled trial be? *BMJ* 2004; 328: 1561. <https://doi.org/10.1136/bmj.328.7455.1561>.

Received 11 July 2021; editorial decision 7 November 2021
