

“Don’t let the trial kill the intervention”:

How can researchers and care home teams implement complex intervention trials in care homes?

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The profile of care homes has never been higher, and not necessarily for the best reasons[1]. The COVID-19 pandemic has had, and continues to have, a massive impact on care home residents[2], their families, the staff and organisations who care for them, and surrounding local communities[3]. It has also highlighted the lack of good evidence based treatments tailored for this population, and the challenges of rapidly setting up and delivering trials to provide high quality evidence based care for COVID-19 (e.g. the PROTECT-CH trial www.protect-trial.net). The lessons learned from developing care home trials during COVID-19 are also relevant to other trials for conditions that are common in care home residents, such as delirium, dementia, falls, incontinence and pressure damage. Previous trials have often delivered inconclusive results, which is a waste of public funds, particularly as the infrastructure supporting these trials is developed for the specific study and dismantled once it is complete. This has led to the question of whether null results are due to avoidable aspects of trial design, leading to asking: ‘did the trial kill the intervention?’[4]

The qualitative systematic review by [xxxxx \(ref\)](#) provides useful guidance for researchers and care home partners on the implementation of research studies (not the implementation of findings after the study is completed). They performed a systematic literature review of several databases and the grey literature identifying in English, in high income countries, studies that were explicitly termed ‘process evaluations’. Thirty-three studies were identified in the initial search in 2019, and a further 16 in an updated search in 2021 which confirmed the initial findings. We are aware of some studies that were not included e.g. [5], but the findings of these would largely support the conclusions drawn from the systematic review. The methodology used a human factors framework, SEIPS (Systems Engineering Initiative for Patient Safety). This conceptual model for identifying how the processes impact on outcomes places the person at the centre of a work system, acknowledging interactions with the internal environment, the organisation and tools/technology and tasks. Data (quotations) from included papers were coded as barriers or enablers of successful research implementation. By taking this approach, the researchers were able to evidence a broad range of challenges and solutions from different studies, and to synthesise these into a unifying framework providing the basis of recommendations for future research implementation.

The most common domains which affected the implementation of the research interventions related to the compatibility of the task with existing working arrangements, and the time and

resource needed for implementation and continuation of research interventions. Other key factors were engaging staff who may not be open to new ways of working, and supporting change through team-building between researchers and care home staff. Central to this was researchers being aware of care home staff workload, and the impact of staff turnover. The importance of these observations will only have increased through the pandemic due to sustained stressors on care home staff, more employees leaving the sector, staff absence, and those left behind being at increased risk of burn-out.

The researchers provide recommendations for the design phase of care home studies, crucially the role of co-design with care home managers, staff, residents and families. They underline the need to fully understand the context of any planned research, and the current ways of working of staff in the care home. Sensitivities in relationships between health and social care should be carefully considered. Resources need to be allocated to support meaningful co-production and to allow planned interventions to be embedded and sustained.

To an extent, these findings replicate what we know about implementation of interventions more generally in care homes[6], but identifying the ways in which these principles apply to research is timely. There is a real and present need for a context-specific sustainable model for the conduct of, and delivery and implementation of the findings from, high quality research (including randomised controlled trials) in the care home environment. One method for implementing the recommendations from this review would be via initiatives such as the 'Living Labs' or University Care Home network collaborations. In the Netherlands, where Living Labs have been established for over 20 years, there is now flourishing cooperation between research and care home practice[7]. This model has been adapted in other countries[8, 9] including the UK in the NICHE Leeds project[10], the Edinburgh planned ToRCH (Teaching and Research based Care Home)[11]. What all of these approaches have in common is building relationships and trust between researchers and care home providers over time. With investment in appropriate infrastructure, engaged staff, and residents who pre-consent in principle to research, there is the potential to deliver research, including RCTs, with high recruitment rates and at relatively modest cost[12]. The framework identified by this systematic review (ref) provides the basis for such approaches, working across disciplines with care home residents, their families and those who look after them to ensure that everyone can receive high quality, evidence based care, supported by the highest quality research. If not now, when?

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