

## Abstract

# The Burden of a Remote Trial in a Care Home Setting: Qualitative Study

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## Abstract

**Background:** Older adults, particularly those with physical and cognitive impairments, are typically under-recruited in clinical trials, despite the fact that they experience the greatest need for healthcare services. Reasons for underrepresentation are disparate but may relate to comorbidities, communication difficulties (e.g. hearing and vision impairments) and physical immobility that constrains transportation to a research site. Remote trials supported by mobile and wearable health technologies have the potential to make clinical research participation more accessible for these groups. In order to determine the feasibility of this model, it is essential to understand the burden remote data collection places on the participants involved.

**Objective:** The REACHES study (Remote Assessment of Older People in a Care Home Setting) explored the burden experienced by participants in a remote trial supported by mobile and wearable technology in a care home setting.

**Methods:** The remote trial focused on implementing a falls prevention programme in a single care home over an eight-week period from March to May 2017. The following technological solutions were selected to support the activities of the trial: QTUG™ (Kinesis Health Technologies, Ireland), a sensor-based medical device that assesses gait, mobility, falls risk and frailty; Aging Research App (ICON Clinical Research, Ireland in partnership with mPROVE Health, US), a tablet version of the Age-Related Muscle Loss Questionnaire that assesses the impact of muscle loss on activities of daily living; and vívosmart® HR (Garmin Ltd., US) a wrist-worn device that tracks daily activity, heart rate and sleep patterns. These devices provided outcome measures for falls risk and mobility in older adults; offer a variety of data collection methods; and are conducive to remote data collection. A participatory design was used to define the study procedures from the outset. A range of qualitative methods were used to capture the “lived experience” of staff and residents participating in the trial. These included semi-structured interviews, ethnographic observations and diaries. Qualitative analytical procedures were employed using thematic analysis supported by NVivo software (QSR International).

**Results:** A total of 6 residents and 8 members of staff participated in the semi-structured interviews (n=14). Results showed that staff experienced extensive burden in fulfilling their roles and responsibilities to support the remote trial, whereas residents reported limited burden. For both groups, the burden of comprehending the research and associated tasks was prominent. Additionally, for staff a lack of time emerged as a substantial burden. Findings suggest that the experience of burden was not mitigated by the perceived value of the trial.

**Conclusions:** These findings provide insight into the experience of burden of a remote clinical trial among staff and residents in a care home setting. Understanding and mitigating the burden created by remote trials is vital to researchers and companies

attempting to scale such a model. Future research could build on the lessons learned from the REACHES study to develop a method to measure the burden remote clinical trial protocols place on patients and other stakeholders involved.

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**KEYWORDS**

mobile technology; older adults; remote trial; burden; wearable technology; participant experience

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**Multimedia Appendix 1**

Full poster.

[\[PDF File \(Adobe PDF File\), 3MB-Multimedia Appendix 1\]](#)

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