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Scientific Research – Falls, Fractures and Trauma

21 ENSURING QUALITY DURING DESIGN AND DELIVERY OF A LARGE CARE HOME STUDY - LEARNINGS FROM THE FALLS IN CARE HOME TRIAL (FinCH)

E. Sims[1], J. Williams[1], V. Bion[1], C. Guillard[1], A. M. Swart[1], J. Horne[2], P. Logan[2], on behalf of the FinCH Study Team
[1]*Norwich Clinical Trials Unit, Norwich Medical School, University of East Anglia, UK*
[2]*University of Nottingham, Nottingham, UK*

Introduction: Research in care homes can be challenging. Clinical data recording infrastructure is not standardised, there is high staff turnover, and knowledge and understanding of research is often limited. To conduct clinical trials in care homes, a risk based, pragmatic approach is required. We report quality management and monitoring (QMM) strategies for delivering the FinCH trial.
Methods: Risks to the trial conduct were evaluated with respect to consent, data availability and site resources and a QMM plan (QMMP) was developed. Findings from the Falls in Care Home feasibility study (FinCH) and blinding to the intervention were taken into consideration.
Results: Table 1 details risks identified, quality strategies and monitoring approaches. For baseline data collection, to date, 13361 individual CRFs have been completed amounting from an expected 14967 (89%). 2766 queries have been raised of which 2261 are closed (82%). Within site communication issues attributed to the largest proportion of queries.

Risk area	Risks identified	Quality strategy	Monitoring strategy
Consent	Residents may not have or lose capacity;	Capacity assessment form developed. Consent requested for continuation in event of losing capacity.	Centralised monitoring of recruitment logs
	Care provided by care home staff;	Researcher responsible for taking consent	Consent forms (consent provided)
		using step wise resident/consultee consent process.	and delegation logs.
Data availability	Large sample size and 6+ research sites	Provide on-site initiation training and virtual RA forum to share best practice including source data availability.	Data monitoring for data consistency and completeness. Statistical monitoring for outliers in key data to inform queries.
	Source data location and format variable	Paper CRF for use in CH – site responsible for entry into REDCAP database.	Random sampling of CRFs to be copied for central monitoring at NCTU
	Frequent archiving of resident records.	Data collection at 3 monthly intervals.	
	Resident may lose capacity	Proxy DEMQol and EQ-5D on all residents irrespective of capacity at baseline	
	Intervention training records held by Falls Leads	Intervention training records sent to NCTU for data entry	
Resources	50% researcher time at site	Simple CRFs. Database designed from researcher perspective.	Site initiation visit Triggered on site monitoring only.

Conclusions: Risk appropriate quality management strategies can be implemented successfully into care home research. Division of data collection/data entry roles should be considered at study design and set-up stages to ensure adequate training and minimise inappropriate queries.