Complexities of trial recruitment in the care home setting: an illustration via the EPIC trial

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Background
• The DCM™ EPIC Trial aims to evaluate the clinical- and cost-effectiveness of Dementia Care Mapping™ in addition to Usual Care vs. Usual Care alone for people with dementia living in care homes in England.
• The trial aims to recruit 50 care homes (750 residents) over a 15 month period (to end of 2015).
• Conducting trials in care homes, however, comes with a number of challenges which are explored below.

Care Home Selection
• There are over 17,000 care homes in England (www.CCC.org.uk) offering a significantly larger pool of ‘services’ than a ‘standard’ NHS-based trial.
• To ensure generalisability of results, the care homes were selected for invitation to participate via a stratified random sample of a known sampling frame.
• This was done by:
  1) Defining ‘catchment areas’ around each of the 3 participating ‘hubs’ (W Yorkshire, London, Oxon)
  2) Screening for initial eligibility using publicly accessible data (CQC)
  3) Randomly ordered listings of all eligible care homes within each area were produced
  4) Batches of care homes were sent trial information and followed up by researchers (who then screened for full eligibility).
• Note: Whilst this is a time consuming and relatively onerous process, it ensured that there was no selection bias over the homes chosen to participate and has allowed the trial team to identify and consent eligible homes from this large pool of possible homes relatively quickly.

Consent in The Context of the Mental Capacity Act
• Given the target population for the trial (care home residents with dementia), a significant proportion of potential participants are deemed to lack capacity at screening, in accordance with the Mental Capacity Act 2005.
• For those eligible residents who are assessed as lacking capacity, a ‘Personal Consultant’ is appointed who can be consulted about what the resident’s wishes would be if they had capacity. Where there is no one able or willing to take on this role, another independent person (a member of the care home staff not involved in the research in any way) who knows the resident well is appointed as a ‘Nominated Consultant’.
• Whilst this process adds substantial time to the consenting process, it ensures all relevant parties have been appropriately consulted prior to obtaining consent.

The trial is recruiting care homes across three ‘hubs’

All 50 care homes have been identified and have agreed to take part. The trial is recruiting slightly behind target, but is still on course to randomise all 50 homes in line with the initial target.

Selection and Involvement of Participants
• Trial participation involves more than just the care home themselves, so as well as ‘consenting’ eligible care homes, the trial is also recruiting:
  1) Care home residents with dementia
  2) A staff proxy informant for each resident
  3) A relative / friend proxy informant for each resident (if available and willing)
  4) Two mappers at each home, to be trained and deliver the DCM™ intervention, if randomised to the DCM™ arm
  5) All care home staff are then given a questionnaire booklet to complete.
• Eligibility must be confirmed for all ‘roles’, and fully informed consent must be obtained. This involves complex, lengthy discussions with all parties and provision of tailored information sheets specific to each ‘role’.
• Whilst identifying staff proxy informants is relatively straightforward, relative / friend proxy informants are, in some cases, a little more difficult. Relative / friends are not always present in the home during the researcher visit, and researchers are therefore reliant on care homes posting the trial materials out directly to the relative / friends, as the researcher has no consent to access their details at this point. This has the potential for delays.
• Appropriate mapper selection is vital to ensure the intervention can be delivered in the homes. Thus selected mappers have to possess certain skills and capabilities to enable them to take on this role. Detailed discussions take place between consented mappers and trial experts to ensure suitability, which can again add to the time needed for recruitment.

Scheduling

Researcher Time
• As with all trials, DCM™ EPIC has only a finite number of researchers and resources. Thus the trial team needed to ensure there was enough manpower to undertake screening, consent, recruitment, baseline and follow-up data collection (at 6- and 18-months post-randomisation).
• A staggered recruitment schedule was devised and ‘slots’ were allocated for each hub - both 1) as already stated, to ensure there is enough manpower to cover all care home visits, and 2) to ensure there were enough places available on DCM™ courses to accommodate recruited mappers (homes are allocated to the DCM™ plus usual care arm of the trial at a ratio of 3:2)
• A schedule, as per the below, was devised for each of the hubs (and overall) to manage this workload. Each home has a ‘planned’ and then actual line, which gives at-a-glance visualisation of slippages occurring as a result of delays at various points in the process.
• This has been an invaluable way of scheduling in workload across the hubs and managing delays in real time - switching care home slots, as required, and ensuring all homes are randomised in time ahead of their allocated DCM™ course.

Discussion
• Carrying out research in the care home environment can have many complex challenges.
• Each stage, from initial selection of services invited to participate, through to recruitment of participants, requires careful thought and planning at the outset to ensure the trial can be successfully implemented within the time constraints of the grant funding.
• Inclusion of participants with diminished capacity brings with it additional challenges, but again careful consideration and anticipation of potential problems early on in the life of the trial mean that any issues encountered are dealt with swiftly.
• Care homes offer a diverse environment in which to carry out research, and growing interest and enthusiasm within care home teams means challenges encountered needn’t be a barrier to successful implementation of trials.
• Care home research is essential to fully understand care needs. The EPIC trial illustrates that it can be done.

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