



Utilising the Network to boost recruitment

DeNDRoN LRN (local research network) supported and helped to deliver a UK wide, multicentre, randomized clinical trial involving care home residents within their local regions. One network wanted to pass on some of the valuable lessons learned along the way when conducting research within care homes. The approach they took to supporting the delivery and recruitment of MAIN-AD was through a designated team, who implemented a broad range of strategies.

To successfully deliver the study in the Thames Valley region, they drew on existing links with clinical teams and those made with care homes in previous studies to identify eligible participants, gain consent, and collect data at baseline and various follow up points for 93% of their targeted participants. As it was one of many sites recruiting to the MAIN-AD study, this case study discusses specific challenges faced in the Thames Valley region, however the lessons might well be relevant to care homes elsewhere. One major challenge was in the recruitment of participants, as the number of eligible residents within the region was significantly lower than had been originally anticipated. Only a small percentage of residents with dementia were found to be prescribed neuroleptics (sedative drugs) compared to 40 percent as evidence had suggested might be the case.

The overall target of 300 participants proved difficult across all sites and so this was revised downwards to 184. As a result, the team developed creative options and routes to successfully identifying 39 residents, of

which 28 were eligible and consented to participate in the study.

The study opened in 2009, it did not recruit the numbers of participants it anticipated to then provide the necessary evidence to inform NICE guidelines in the use of memantine as a person, family and practitioners. Neuroleptics (sedative drugs) have often been used to manage these symptoms and recent research suggests that this type of medication can be detrimental for some as it may cause unpleasant side effects, increase cognitive decline and increase the risk of mortality. Evidence from small-scale studies has suggested that memantine might be a safer and effective alternative to neuroleptic treatment. The MAIN-AD study was set up to evaluate the efficacy, safety and tolerability of 24 weeks' treatment with memantine in comparison to neuroleptics in care home residents with Alzheimer's disease.

The local network was involved in the set up of local sites, recruitment of participants and delivery of the study (identified below in blue): potentially safer alternative to neuroleptics. It is hoped that the results of this study will support this argument. However as a result of supporting this piece of research, the Network itself has benefited by building good relationships with a large number of local care home staff who have expressed an interest in taking part in future research and has subsequently developed a database they can draw on to support future studies in the region.

Background

Alzheimer's disease (AD) is a devastating illness which leads to a progressive decline in cognitive and functional ability and often causes distress to individuals affected, their carers and families. People may experience behavioural and psychological symptoms, such as anxiety and agitation, and these symptoms present challenges for the Initial contact was made to the resident's informal carer by a member of care home staff or CMHT team member responsible for their care to provide verbal information about the trial. This was then followed up with a phone call from a research worker (provided the carer gave agreement that they could be contacted) or the staff sent copies of the patient information leaflets out to the carer (either by post or by hand when they visited). NRES did not feel that patients could give their own consent to participate in the trial and so legal representative consent was always sought, although this did include a capacity assessment of the resident – who as per guidance would need to be willing to participate in study procedures to their level of understanding.

Potential participants and their family carers were given information about the study, provided with an information leaflet and opportunity to talk to a Network team member. Those where written informed consent to participate was given were randomised to either carry on taking their sedative medicine (neuroleptics), or to take memantine (as a potential safer and more effective treatment option) for 24 weeks.

Challenges

- Delay to the study getting necessary approvals from Clinical Trials Unit and NHS research and development (R&D) approval meant some time elapsed between researchers initiating the idea, writing the protocol and getting the study started.
- The population of people being prescribed neuroleptics in the Thames Valley region was lower than anticipated, as doctors were no longer prescribing sedative drugs due to the associated side effects and recommendations outlined in the NICE guidelines and National Dementia Strategy. Therefore the Network found it challenging to find eligible residents and recruit the sample size it had agreed.

- The study was fairly resource intensive for the network – in order to get close to target, the Network contacted every care home in 3 counties to recruit residents (almost 240 care homes).
- One Primary Care Trust R&D Department had a different Interpretation of local regulatory guidance, in relation to the approval processes. This meant that access to residents was limited to those under the care of secondary NHS clinical teams in one site (a County), restricting the pool of potentially eligible participants.
- Some care home groups or chains denied access to their homes for this research – reducing the pool of homes.

The approach taken

The network compiled a list of care homes in the county from the local care homes booklet published by the county council social services department. Every care home for older people was identified, as it is not just specialist care homes which care for people with dementia.

To increase the success rate of care homes willing to support the MAIN-AD, study the network approached care homes through the community mental health team (CMHT) who held an existing relationship with the staff, rather than 'cold calling' each home. This approach built on the existing relationships with those within the home, and was intended to give the message that the research was trustworthy, and to help care home managers feel more comfortable about the study. A member of the Network would then get in touch with the care home to give more information about the study.

A designated research team was set up to carry out the study. The team included nurses, research assistant psychologists, study doctors, and administrative team. They worked together to develop and implement the following recruitment strategies and to keep these under review and revise where necessary:

1. Identified potential participants through members of the Community Mental Health Trust (CMHT).

The network targeted secondary care referrals; as care home residents are often referred to secondary care services to help with problems. The team drew on existing links with community mental health

teams, sent emails to clinicians, posted information on boards and intranet sites, provided training sessions for CMHT members on research relevant topics, and liaised with inpatient staff to alert the research team to people about to be discharged to care homes.

2. Identified potential participants through pre-screening activity – CMHTs and care home notes & drug charts.

The team looked at residents' notes to identify any potential participants. The network have set up a system whereby each CMHT was assigned a designated member of the network research team, to act as named contact. The link research worker for that team, attended meetings, and liaised closely with the CMHT team to actively promote research, including this study.

3. Encouraged care home staff and GPs to make direct referrals to the study.

A GP (member of the network team) directly liaised with other GPs to raise awareness of the study and potentially recruit more people. Additionally the network promoted the study through posters and circulated leaflets to care home staff as well as including regular updates to staff on its progress.

4. Opened new sites to expand the pool of potentially eligible participants.

Initially recruitment activity took place in just one site (county); recruitment was subsequently extended to all three sites within the region.

As a result of the study the Network now holds a list of care homes that are interested in being involved in future research and can be easily identified through the Network database.

At present the network does not have on its portfolio to offer this group of care any specific care homes studies homes, however to maintain this relationship the network invites care home managers to continuing professional development events, keeps them up to date by sending copies of the network newsletter, and endeavours to develop good links with homes that are visited when following up residents taking part in other non-care home specific portfolio studies.

Lessons Learned

From conducting the MAIN-AD study the team has learned valuable lessons along the way that it will endeavour to use and influence in all future studies within a care home setting. These include:

During the study design phase the network recommends researchers to:

- Ensure recruitment strategy is as broad as possible; optimising as many different routes as possible (i.e. do not restrict recruitment strategies). research for care home staff to set the study in the research context: many care home staff will not have been exposed to research and may have little understanding of why we need research and what benefits exist. Help organisations understand what research is and why it is necessary.
- Better scoping of local populations to help set more realistic targets
- Target all services who support people with dementia and their carers (residents can be recruited through various mechanisms: GPs, CMHTs, Age UK, Dementia UK, etc).

When carrying out the study, the network recommends others to:

- Build in some education about research for care home staff to set the study in the research context: many care home staff will not have been exposed to research and may have little understanding of why we need research and what benefits exist. Help organisations understand what research is and why it is necessary.
- Build on and utilise existing links and explore ways to maintain these.
- Involve and inform a wide range of care home staff and continue to provide feedback to their staff.



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