Abstract

Background The evidence base for hydration practice in care homes is underdeveloped. High-quality research is therefore needed to determine what practices support older people with dementia in drinking sufficient fluid. However, methodological developments are needed to be able to do this.

Aim To highlight the methodological issues researchers encountered during a feasibility cluster, randomised controlled trial of ThinkDrink, a hydration care guide for people with dementia living in UK care homes.

Discussion This is a challenging area because of the complexity of recruitment, participation and data collection in care homes. Researchers must pay extra attention to rigour and quality in the design of their studies. There may be multiple challenges, so various strategies may be required.

Conclusion It is important that researchers continue to reflect on rigorous approaches to develop evidence in a crucial area of care, despite these challenges.

Implications for practice Researchers working in complex environments face a variety of challenges to complete methodologically rigorous research. It is important for researchers to be critical of research processes and data, to mitigate and overcome these challenges.

Why you should read this article:

- UK care homes are an important example of a complex environment where research is essential but faces multiple challenges in terms of rigour and methodology
- This paper offers a variety of important methodological strategies to identify and address challenges that could impact findings and the ability to carry out research
- It highlights the importance of taking a critical stance with all elements of the research process and illustrates the need to identify and mitigate challenges when conducting research in complex environments

The methodological challenges faced when conducting hydration research in UK care homes

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Introduction
Considerable attention has been paid to the principles of quality and rigour of methodologies and methods in research. However, there has been far less discussion of the difficulties of maintaining these standards when completing research in challenging environments.

Conducting research in care homes poses multiple challenges, particularly in relation to recruitment, obtaining informed consent and the reliability of quantitative data (Lam et al 2018). This article examines issues that arose during a feasibility cluster randomised controlled trial (RCT) of a hydration intervention for people with dementia living in care homes. The aim is to assist researchers in evaluating their approach to implementing rigorous and appropriate methods.

Background
People with dementia living in care homes face a high risk of dehydration (Bunn et al 2015) because of a range of factors that negatively affect drinking behaviours, including (Masot et al 2018):
- Clinical factors such as health concerns.
- Functional factors impacting the ability to drink.
- Mental factors such as recognising drinks and agitation.

This can create significant challenges for their carers and result in admissions to hospital related to dehydration.

Suboptimal hydration and dehydration result in multiple negative effects for older people, particularly regarding cognition (Pross 2017). A systematic review by Edmonds et al (2021) of the effects on older people of dehydration found evidence that it considerably exacerbated health concerns, such as those related to frailty; the authors stressed the impact of this on mortality, course of illness and admission to hospital. It is therefore important to train care home staff in hydration care (Bunn et al 2019).

A systematic review of hydration interventions in long-term care by Bunn et al (2015) suggested a trend towards increasing patients’ fluid intake via multicomponent interventions – people with dementia often have many coexisting health, sensory and functional problems, so it is unlikely that a single intervention will be effective.

Our study sought to address this issue by developing and assessing the ThinkDrink guide – a multi-component hydration intervention for residents of care homes who have dementia. The guide consists of strategies and approaches to enhance four core elements of hydration practice:
- Hydration support: regular/increased fluid offers and strategies for encouragement.
- Drinking activities: hydration as regular care and hydration as activities.
- Drinking-conducive environments: physical and social.
- Drinking equipment: vessels and aids.

Key points
- UK care homes are complex environments that bring many methodological challenges, though the need for research in this area is vital and such issues should not act as a deterrent
- The issue of hydration in older people is multifaceted and complex, but the associated challenges for research do not mean the topic should not be a key focus of nursing research
- It is important when faced with such challenges that researchers use a variety of strategies to build as much rigour into their studies as possible, as well as remain critical of their whole research process to identify unseen challenges
- Research may produce misleading or less valuable findings unless there is constant reflection on issues related to recruitment, ethics, project management, data collection and data analysis
Researchers may also encounter in general ageing research increased levels of cognitive decline and some of the other challenges (Chowdhary et al 2022), but others are specific to care homes.

General research literature discusses these issues, but the context of the care home highlights the challenges faced in an applied setting. The researchers who conducted the feasibility study discussed in this article were experienced in working in such settings, but nevertheless still had to address many of these problems, which posed questions for future research. This article therefore highlights issues specific to care homes and identifies strategies for critical approaches to research methodology and methods in general.

Methods
A feasibility cluster RCT was conducted in 11 care homes located in north east England to assess the completed ThinkDrink practice guide. The homes – rather than the study participants – were randomly allocated to either the study’s intervention group or its control group. This was to ensure both groups had ranges of capacity and ownership as well as of nursing, residential and dementia care.

The guide was implemented in the six care homes in the intervention group for three months; it was not implemented in the five care homes in the control group. Similar methods of collecting data were used with both groups, with data collected at two time points: baseline and three months after the guide had been implemented in the intervention group homes.

Residents
A total of 87 residents participated in the study: 37 in the control group and 50 in the intervention group. The research team defined and assessed various outcome measures to explore the participants’ levels of hydration at the two time points:

» Change in the proportion of residents who met the recommended daily fluid intake.

» Hospital admissions due to dehydration.

» Number of falls.

» Laxative use.

» Urinary tract infections (UTIs).

» Upper respiratory tract infections.

Staff
The research team interviewed 45 staff from the intervention homes to assess the feasibility of the intervention (see Table 1 for a breakdown of their roles).

The interview topics were:

» The acceptability of the ThinkDrink guide.

» Barriers and facilitators to delivering care.

» The relevance of the ThinkDrink guide to delivering care.

» Observed outcomes on residents.

» Hydration practices adopted because of ThinkDrink.

The interviews were conducted in private areas of the homes to ensure participants’ anonymity and maintain confidentiality. Different types of interview were used, with nine individual and 17 small group interviews conducted. This was for pragmatic reasons, as staff could only attend during breaks or quieter periods in their shifts; however, a benefit was that it enabled some staff to explore their practice individually while others could draw from more shared experiences with colleagues. The research team only interviewed the staff, as it was common for residents to have difficulties communicating and the staff were better placed to address organisational issues such as acceptability.

The interviews were audio recorded, transcribed and thematically analysed (Braun and Clarke 2006) to identify and develop final themes. All identifiable information was removed during the transcribing process.

Methodological challenges

Randomisation
Residents in the intervention group received hydration care from staff who had undergone ThinkDrink education as well as
ongoing support to use diverse hydration practices; those in the control group received their usual hydration care.

Blinded assessments were conducted, but the intervention itself was not blinded – data could have been collected from residents in the control group as the staff in those homes were not overtly focused on hydration; however, staff in the intervention group homes were immediately aware they were taking part in hydration-related training. If participants in a clinical trial are aware there is an intervention, this can affect its outcome significantly (Hróbjartsson et al 2014); however, only limited blinding would have been possible in this study as the differences between the intervention and control groups were too great to go unnoticed.

‘Contamination’ would have been possible if staff in any of the control group homes had learned of the hydration practices implemented in the intervention group homes. The research team therefore asked staff in the control group homes to maintain their standard hydration practices.

**Ethical issues**

Northumbria University and the NHS Health Research Authority provided ethical approval for the study, which was aligned with the ethical concept of beneficence and justified by the need to reduce hospital admissions, improve hydration practice and develop rigorous evidence. This need outweighed concerns that those in the control group would not receive the intervention until after data collection was complete, which is when all ThinkDrink materials and training were made available to them.

Another important consideration was whether certain residents such as those with dementia could provide informed consent to participate. Section 32 of the UK’s Mental Capacity Act 2005 meant the research team could seek consent from those residents who could understand what participation involved. However, many others were unable to recall or understand this information, so their consultees – members of their families or informal carers – were asked to indicate to the best of their knowledge whether the residents would have wanted to consent if they had had the capacity to. Again, the principle that the study would improve the quality of care by generating evidence that would inform interventions justified including participants who lacked the capacity to consent.

**Recruitment**

The identification and recruitment of potential homes and their residents caused delays as well as concerns about whether they were representative. Problems in recruitment remained ongoing concerns throughout the project. Recruitment materials that stressed the importance of the study and the significance of its impacts on care were seen as encouraging for all participants. Nevertheless, future research in this area should dedicate significant time and staffing resources to address these issues.

**Recruitment of homes**

Most homes did not have procedures in place regarding participation in research, but favoured participation, acknowledging they had ongoing concerns about hydration. Nevertheless, it was difficult

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to secure appointments with managers, who were busy and had competing priorities. Multiple phone calls and appointments were necessary to speak to managers, even when they had agreed in principle their homes could participate. If a virus was present in the home or a resident had died, recruitment had to be suspended indefinitely.

Even after recruitment, some homes faced delays in introducing ThinkDrink. This contributed to a situation where it was impossible to finish collecting data at these sites by the end of the six months originally planned.

Recruitment of residents
Recruitment of residents also took considerable time. An overall sample size of 30 is often accepted as appropriate for pilot and feasibility studies (Lancaster et al. 2004). However, some of the residents’ characteristics, such as being later in life, meant the research team felt it was necessary to over-recruit to the study to ensure that a full-scale trial would not be underpowered. This increased the difficulty of and time needed for recruitment.

Participants were recruited from one area or floor of each home where possible, to provide those not wanting to take part in the study the opportunity to decline to do so. This resulted in varying levels of engagement in each participating home, across staff, residents and their consultees. This variation should be seen as inevitable and acknowledged, but made it harder to estimate and maintain levels of recruitment.

It was especially hard to recruit via consultees, who were often family members who lived outside the immediate region and were therefore often absent from the homes during the usual visiting periods. This made it difficult for the research team to meet them face-to-face to discuss participation. Data protection legislation also meant that the team could not contact them directly – staff acted as gatekeepers for the consultees’ contact details and had to first confirm the research team had permission to access them. Subsequent contact was by phone or email, which further complicated consent procedures and recruitment.

Attrition
There was substantial attrition of study sites during the recruitment phase before data collection commenced. For example, one home agreed to participate as an intervention site, but an electronic care planning system was introduced and the manager withdrew the home from the research when the workload associated with the new system became evident. Another home changed manager and their replacement required an induction period. Such situations necessitated recruitment of further sites, which resulted in additional workload. However, one measure of acceptability of ThinkDrink was that no recruited homes withdrew following its implementation.

Discussion with home managers highlighted that requiring participation for six months might be too long because it was likely there would be high levels of attrition. The high levels of frailty experienced by the population meant mortality or functional decline in relation to hydration could be experienced during this period. Therefore, the period chosen in which to collect data was shortened to three months.

Nevertheless, there was still attrition during data collection: seven participants (8%) passed away; one moved to a different home; and another withdrew their consent because they were increasingly declining physically. An additional 10-15% was therefore included as part of the a priori power calculation for the study, to mitigate attrition issues.

High levels of attrition are therefore expected in future studies conducted with this population, particularly if data collection periods are extended.

Quality of data
Hydration care plans in the control and intervention homes were audited. No significant differences in information were
found between the care plans at baseline. However, the audit did reveal interesting trends. Only 12% of care plans contained hydration care plans and where hydration information was found it often related to functional issues such as assessment of capability to drink (72%) and assessment of physical problems in drinking (88%). However, any cognitive or personal issues other than residents’ preferences (75%) were under-reported.

Less than 30% of care plans addressed assessment of daily drinking patterns (8%), cognitive problems in drinking (22%), prompts to encourage drinking (15%) and other issues. Only 3% of care plans included a management plan for when residents reduced or refused drinking. It was therefore apparent that care plans for hydration were focused largely on a functional/physical paradigm and often ignored potential challenges related to cognition and personal support.

**Robustness of data collection**

The robustness of the data collected and included in the study was also a significant challenge. The original protocol set out that the study would rely heavily on data routinely collected in homes, such as fluid balances and the number of falls. However, the team noted variations in the data’s quality. There was evidence – from anecdotal reporting by staff of issues such as falls and UTIs, for example – that this affected all elements of data collection but it was particularly evident in the collection of fluid balance totals.

It was noted during training that many of the staff were concerned about the accurate recording of fluids. For example, the usual practice was to record what had been offered rather than what had been drunk; this notably resulted in frequent use of multiples of 20 on fluid balance charts, such as 200ml being recorded for the offer of every drink. It was stressed during training that accurate recording was important and intervention homes provided more detailed information at follow-up, evidenced by totals such as 115ml or 85ml for partially consumed beverages; one home reported using medicine pots to measure the dregs from drinking vessels to create more accurate records. This resulted in lower totals being collected across the intervention group, while large units remained prevalent in control homes.

These issues could have reduced the accuracy and comparability of data at collection points. Very little change was observed in the intervention care homes at follow-up, yet residents might have been drinking more, with the improved accuracy in recording making it seem like there was no change. This affected the study’s findings and has implications for the development of any subsequent RCTs.

Several concerns remain about the accuracy of the data collected in this study and future work should consider ensuring accuracy by having staff external to the study sites collect data. However, the presence of unfamiliar research staff could be disruptive and distressing for residents with dementia (Fleming et al 2017).

The methodologies adopted in future research should therefore enable researchers to participate in care while collecting data. This would significantly affect the funding required.

**Seasonal impact**

Another variable that influenced outcomes was the timing of data collection. Homes were recruited at baseline during the summer of 2018, with follow-up data collected in the autumn and winter of 2018 and early 2019. This meant there was a strong possibility the data collected naturally varied, particularly as staff reported there was greater emphasis on hydration when temperatures were higher. Only one staff participant attributed changes in fluid consumption to the weather; all other staff participants attributed it to the impact of the intervention. However, the potential for the timing of a study to affect practice means it should be given greater consideration in future work.
One home attributed an increase in chest infections to the winter period – despite a decrease in upper respiratory infections in the intervention homes. This could have occurred after data were collected and so was not represented in the analysis; it could also suggest methodological issues with data collection.

**Qualitative data collection**

It was also challenging to conduct rigorous qualitative interviews in the care homes. The research team emphasised being flexible to ensure interviews were convenient for staff and offered staff participation during breaks on a rolling basis. This facilitated data collection but still resulted in additional demands being placed on participating staff’s limited time. Interviews were therefore often short in duration, with a mean duration of 17 minutes 8 seconds; interviews with managers were often longer as they could prioritise research.

Private spaces were sought for interviews, but these were not always entirely secluded and staff could be distracted by activities going on elsewhere. Staff’s priority was resident care, so these distractions resulted in several interviews beginning but having to be paused and completed later.

These issues reduced the amount and quality of the data that could be collected, as less time was available to build rapport, probe finer points of detail or address issues of reflexivity, such as the power imbalance between the research staff providing the training and the care staff receiving it.

**Discussion**

This article adds to the sparse literature concerning governance (Reed et al 2004) and the methodological challenges involved in studying particular conditions or practices in care homes, such as falls, delirium or incontinence (Eeles and Rockwood 2008, Kehinde et al 2011, Lam et al 2018, Law and Ashworth 2022). It is important in the case of hydration care that the residents of and all staff and professionals working in care homes are engaged in research, to ensure that their perspectives are understood. However, staffing levels and the demands that care places on staff make it harder for them to collect data. Researchers should be cognisant of these issues and explore ways to optimise participation, such as remunerated out-of-hours interviews.

Quality is another important issue when researchers rely on data collected during daily routines such as fluid intake records and care plans. Analysis of the practice data collected in this study revealed flaws in relation to accuracy and completeness that could potentially result in misleading findings. However, it may be impractical and obtrusive for researchers to collect all the data as they cannot be present every time a care home resident is offered a drink – particularly a resident whose primary aim is to enjoy their life in their home.

It may be possible to address some of these issues by using multiple or mixed methods that enable the triangulation and synthesis of findings, or approaches that enable further critical exploration of data and its construction (Moffatt et al 2006). The important point is that researchers need to be highly critical of the quality of data they seek to collect and the feasibility of implementing robust methods of collecting data. It is therefore noticeable here that this study’s design did not use periods of structured reflection so potentially only identified problems as they occurred rather than pre-emptively.

Collingridge Moore et al (2019) argued that the methodological challenges of conducting research in a care home have led to the systemic exclusion of care home residents from research. Law et al (2021) corroborated this view, observing that as few as 7% of care homes in Scotland were involved in research in 2014. Care homes were also inaccessible to researchers during the Covid-19 pandemic and there is little evidence that their engagement in research has improved since.
Older people with dementia are at high risk of suboptimal hydration and dehydration, which can contribute to a poorer quality of life, morbidity and mortality. Hydration care for this group is complex and the lack of strong evidence about what works well in what circumstances means there is little to ensure they are supported to ingest sufficient fluid every day. Hence, there is an ethical imperative to undertake hydration research in care homes, despite the challenges.

Conclusion
This novel article included reflections on collecting research data in care homes. It is useful to researchers looking to ensure levels of quality and rigour when conducting studies in this context.

Researchers must be aware of and challenge approaches to recruitment, ethics, project management, and data collection and analysis in the contexts of their research. Without these reflections, it is possible data can be misinterpreted and future research designed inappropriately for their settings and populations.

However, these difficulties must not deter researchers from working in these areas. It is important to study this topic and work with this population, so it is essential that researchers continue to adapt their practice to develop this vital understanding.

This discussion also reinforces the general need for researchers to constantly challenge and be aware of the strengths and limitations of their methodological approaches. This questioning of research and its design is imperative in ensuring that important questions are answered, regardless of the challenges different approaches can bring.

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