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Care home resident and staff perceptions of the acceptability of nutrition intervention trial procedures: a qualitative study embedded within a cluster randomised feasibility trial

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Abstract

Objectives To examine care home resident and staff perceptions of the acceptability of participating in a feasibility trial evaluating nutritional interventions in the treatment of malnutrition.

Design Phenomenological methodology was used to gather descriptions of resident and staff perceptions of trial procedures, using semi-structured interviews with residents and focus groups with staff. The interviews were used to explore individual perceptions of the acceptability of the assigned intervention and the outcomes measured. Focus groups were used to explore staff experiences of trial participation, and perspectives of nutritional support interventions.

Setting The study was embedded within a cluster randomised feasibility trial, which randomised six care homes to provide standard care (SC), food-based intervention (FB), or oral nutritional supplement intervention (ONS) to residents with, or at risk of, malnutrition.

Participants Residents in the trial with capacity to consent (n=7) formed the sampling frame for inclusion. Four agreed to be approached by the researcher and to take part in the individual interviews. All were women, representing two arms of the trial (ONS and SC). Twelve staff participated in six focus groups, one at each care home. All participants were women, representing all three arms of the trial.

Results Major themes that emerged from both interviews and focus groups included: the perceived acceptability of trial involvement, the value of residents completing Participant Reported Outcome Measures (PROMs) and the challenges associated with outcomes measurement in this setting. Themes that emerged from the focus groups alone, included: the importance of individualising an intervention, and the perceived value of FB and ONS interventions and dietetic input.

Conclusions Residents and staff perceived involvement in a trial evaluating nutritional interventions to be acceptable, although the challenges associated with research in this setting were acknowledged. Resident preferences were highlighted by staff as an important consideration when implementing a nutrition support plan.

Trial registration number: Current Controlled Trials ISRCTN38047922 , Date assigned: 22 April 2014

Strengths and Limitations of this study:

- This is the first study to inform understanding of the feasibility and acceptability of conducting a clinical trial evaluating nutritional interventions in the care home setting from the perspectives of staff and residents.
- Use of individual interviews allowed for the discussion of personal feelings with residents and gave each the chance to freely voice their views.
- The dynamic interaction of the staff focus groups were perceived by the researcher as open and positive, and provided insight into shared viewpoints within and between care home sites.
- The study was limited by small sample size, particularly with regards the number of residents interviewed, but a staff focus group was conducted at each care home site, providing representativeness from each arm of the trial, and capturing the views of both nursing and care staff.
- Exploration of staff experiences of feasibility and acceptability was carried out in engaged and motivated care homes, which may limit transferability to the national care home population.

Funding This study was undertaken as a student project (RS was the MRes student), as part of the National Institute for Health Research (NIHR) Clinical Academic Training Programme for AHP's (Masters in Research). The study was self-funded and involved no research costs for the NHS trust sponsoring the research (The Heart of England NHS Foundation Trust).

Competing Interests None declared.

Authors' contributions RS designed the study, performed the interviews and focus groups and drafted the article. RS analysed the data following peer debriefing and agreement of the final themes with AR. AR and CS have made substantial contributions to the conception and design of the study. All authors have read and approved the final manuscript.

Introduction

Care home residents in the UK are a distinct group of approximately 416,000 people (including 16% of those aged over 85)[1] with different mortality[2], health status, and health and care needs[3] compared to individuals of the same age residing in their own homes. Research outcomes established for older adults living within their own homes cannot be considered valid for care home residents and cannot therefore be used to guide best practice.[4]

The public health and social care expenditure associated with malnutrition in England from 2011-2012, was estimated using the Malnutrition Universal Screening Tool (MUST) as £19.6 billion; 15% of the total expenditure on health and social care[5]. Approximately 30-42% of care home residents are estimated to be at risk of malnutrition,[6-8] placing them at increased risk of infection and pressure ulcers, clinical complications and depression and reducing their overall quality of life.[9-10] There is a need therefore to improve the evidence based nutritional care provided to this population. However, research in care homes presents challenges, and consequently many studies exclude care home residents on the basis that their inclusion would present the team with ethical and practical dilemmas.[11] Recruitment difficulties due to physical and cognitive impairments[12] have been highlighted as a particular challenge, along with the consent process,[12-13] responding to family and carer concerns[12] and high attrition.[12,14] Additional issues for the researcher can include data collection within a busy care home schedule and difficulties for staff in adhering to assigned interventions and methodological protocols.[12] These challenges have led to nutrition intervention trials often excluding those at highest risk of malnutrition, including residents with advanced dementia and immobility.[15-18]

Existing studies of nutrition interventions for malnutrition within this setting have also tended to use a quantitative approach, which whilst useful for determining quantitative outcomes such as nutrient intake and weight change, have provided limited information on resident and staff perspectives of nutritional care and the reasons why the care home environment poses challenges for the researcher. During the last 20 years, researchers have identified the need for employing a range of methodologies to enhance understanding of healthcare complexities and to ensure that disempowered groups are heard.[19] Exploring feasibility outcomes with trial participants is a way to ensure that resident and staff perspectives can be used to inform the design and conduct for future definitive trials in this complex research setting.

The aim of this study therefore, was to seek an in depth understanding of the experience of participating in a cluster randomised feasibility trial which evaluated nutritional interventions in the treatment of malnutrition.[8] The study had two objectives:

1. To examine perceptions of the acceptability of trial procedures (including the intervention protocol, outcome measures and data collection methods) with care home staff and residents.
2. To examine care home staff perspectives of nutritional interventions and dietetic care in the treatment of malnutrition.

Methods

Theoretical Framework:

Phenomenology was selected as the methodological approach for this study, because it aimed to gather descriptions of resident and staff perceptions of the trial procedures in order to understand the reality of their lived experiences from their own individual perspectives. The Phenomenological research method is considered particularly suitable for researchers aiming to investigate and describe people's perceptions, perspectives and understandings of a particular 'real world' experience.[20-21] The study is reported in line with the Consolidated Criteria for Reporting Qualitative Research (COREQ).[22]

Design and setting:

A pragmatic approach to qualitative research, using semi structured interviews with residents and focus groups with staff was embedded within a cluster randomised feasibility trial (ISRCTN38047922)[8] to understand the experience of participating in a trial investigating nutritional interventions in the treatment of malnutrition. Individual perceptions of the acceptability of the trial procedures and the nutritional intervention and care, were explored and collected with residents and staff.

The feasibility trial was conducted within the West Midlands, in England where 17 care homes providing accommodation for older adults (over 65 years), were receiving regular dietetic input. This was being provided by the community nutrition support dietetic service where the lead researcher (female) (RS) was working as a dietitian at the time of the study. Purposive sampling was used to select and invite six, privately owned care homes with a diverse sample based on type of care provided (residential or nursing/nursing and residential) to take part in the trial. All care home sites were made aware that the trial was being conducted as part of a student MRes project by the Lead Researcher (RS). Residents with or at risk of malnutrition were identified across the six sites over 4 months and homes were cluster randomised to receive standard care (SC) (n=2), food-based intervention (FB) (n=2) or oral nutritional supplement intervention (ONS) (n=2), for 6 months. Outcomes were trial feasibility and the acceptability of the design, the nutritional interventions and the outcomes being assessed at 3 and 6-months. These included anthropometry, dietary intake, healthcare resource usage and participant reported outcome measures (PROMs).

Semi-structured interviews:

The dietitian researcher (RS) conducted individual semi-structured interviews lasting 30 to 60 minutes with care home residents to enable exploration of reality from narratives related to their own experiences of trial participation.[23] The interviews were organised around topic guides (Table 1), developed using the trial feasibility objectives and discussions with care home staff. The basic research question explored was the experience and acceptability of participation in the trial. Themes and core questions were refined following the 6-month dietary intervention and the collection of PROMs.

Interviews allowed for greater exploration of individual perceptions of the acceptability of the assigned intervention and understanding and perception of the anthropometric assessments and the PROMs questionnaires than would have been possible with the use of focus groups.[24-26] RS is an experienced nutrition support dietitian with an interest in malnutrition in the older adult population, and who had worked for several years with the care home population. This relevant background allowed for the effective exploration of individual dietary satisfaction whilst on the allocated nutritional intervention plan. Use of the interview technique enabled residents to ask for questions to be further explained, which allowed for the identification of any problems with comprehension and for

questions to be rephrased as appropriate. This was felt to be important with the care home population and may have been less feasible within a group setting.[27] RS was responsible for audio taping the interviews, and transcribing the audio recordings verbatim.

Focus Groups:

The dietitian researcher (RS,) led and audio-taped focus group discussions lasting 45-60 minutes in each of the 6 care homes with between 2 and 3 care home staff in each. The topic guide (Table 1) was developed using the feasibility objectives from the trial alongside discussions with care home staff and was later refined following delivery of the 6-month nutritional intervention and collection of outcomes data. Focus groups were used to enable the views of more people to be included,[23] to highlight any variations in perspectives between the staff within each home and between care home types[28] and to collect information from those staff that were reluctant to be interviewed on their own or who felt they had less to contribute.[29-30] As the staff within a care home work closely together, holding a focus group within each individual home was found to stimulate engagement and discussion[29,31] and it was possible to explore knowledge, experiences and perceptions of participating in a trial, with a focus on the assigned intervention and protocol for delivery, the data collection process, the data collection tools and the outcomes from the trial. With a strong background in nutrition support within the care home setting and a working relationship with the care home staff as a dietetic practitioner, RS was able to appreciate the significance of the aspects discussed and to effectively follow up on the relevant points.[32] RS was responsible for transcribing the focus group audio recordings verbatim.

Table 1: Topic Guides for semi-structured interviews and Focus Groups

SEMI-STRUCTURED INTERVIEWS	
Stage	**Content**
Discussion on involvement in the trial	- The clarity and acceptability of explanations and instructions before and during the trial- *Prompted for any examples where information was not clear, scope for improvement*
Discussion on the dietary plan received	- The acceptability of the dietary plan- *Prompted on appetite, satisfaction with diet, compliance and whether intervention was always received* - Positive and negative outcomes of the interventions- *Personal experiences*
Discussion on the anthropometry assessments	- Acceptability of the assessments undertaken- *Prompted for: understanding of instructions, personal experiences, suggestions to make the process more acceptable*
Discussion on the PROMS questionnaires and scales	- The ease/burden of completing questionnaires and scales- *Prompted for time commitments, changes to routine, ways to make the process more acceptable* - Understanding of the questionnaires/scales- *Prompted for any particular challenges, whether other residents could have completed* - Thoughts on the importance of residents being able to provide feedback through PROMs
FOCUS GROUPS	
Stage	**Content**

Discussion of care home involvement in the trial	- The ease/burden of participation in the trial: *prompted for time commitments, knowledge and competency* - The confidence of the staff in completing malnutrition screening- *prompted for areas of concern/adequacy of training prior to commencement* - Experiences of completing healthcare resource usage questionnaires- *prompted for time commitment/specific challenges/any other items which could have been included*
Discussion of allocated dietary intervention	- The acceptability of the dietary plan for residents - The ease/burden of delivering the dietary intervention - Positive and negative outcomes of interventions- *according to study data, and own perceptions* - Possible reasons for poor compliance
Discussion of PROMs outcome measures	- The ability of residents to complete the questionnaires and scales- *prompted for their thoughts on whether others could have completed, ways to make it easier, completion by proxy*

Participants

Sampling and recruitment

Those residents with capacity to consent who had indicated on the trial consent form that they would like to be considered for individual interviews and had completed the 6-month intervention (n=7), formed the sampling frame for potential inclusion. The care home staff made the initial approach to the 7 potential participants to discuss their involvement. Those that remained interested in participation (n=4) were introduced to the dietitian researcher (RS), to provide further verbal and written information. The 3 residents that declined to take part, did not give specific reasons to the care home staff.

A focus group of staff (2-3) took place within each of the care home sites that had participated in the trial. Care Home staff were selected on the basis that they had participated in the trial.[33] Six focus groups, covering all 3 arms of the trial were conducted.

Nutritional interventions and outcome measures

All six care homes had received training and support to provide a standard care intervention to residents with or at risk of malnutrition. The food-based intervention choices and recipes were based on local nutrition support guidelines, national guidance and best practice resources[34-35] and were intended to increase the participating resident's daily nutritional intake by approximately 600 kcal and 20-25g of protein. The Oral Nutritional Supplement (ONS) intervention consisted of 2 daily liquid ONS containing 600kcal and 24g protein.

The outcomes measured or collected in the trial by the care home staff included height, weight, Body Mass Index (BMI), healthcare resource usage, compliance with the assigned intervention and completion of the standardised mini-mental state examination (sMMSE). Participant-reported outcome measures (PROMs) data was collected from those residents that had capacity and had consented to completing quality of life and health state questionnaires and a Visual Analogue Scale (VAS) related to dietary satisfaction.

Ethical approval

The trial was approved by the West Midlands NHS Local Research Ethics Committee (Ref: 13/WM/0390) and the Research and Development Department of the Heart of England NHS Foundation Trust prior to commencement. The Research Ethics Committee felt that the inclusion of residents lacking capacity in the collection of PROMs and in the qualitative study could not be justified in accordance with the Mental Capacity Act.[36] Written consent was sought on an individual basis from eligible residents assessed as having functional capacity. Residents were provided with a full explanation of their required participation alongside a Participant Information Sheet. They were given one week to ask questions and decide whether they would like to provide information on quality of life, health state and dietary satisfaction. Each resident was asked to sign a consent form for PROMs and to indicate whether they would like to be considered for the individual interviews in the qualitative study. Separate Information sheets and consent forms for the qualitative phase were presented to eligible residents and staff prior to their inclusion and any questions were answered. Participants provided written informed consent.

Data Analysis

Interview and focus group discussions continued until data saturation was felt to be complete. The qualitative data were analysed using the Krueger (1994)[37], and Ritchie and Spencer (1994)[38] framework analyses. The process of data analysis began during data collection, through the effective facilitation and audiotaping of the interview and focus group discussions. As RS undertook all of the interviews and focus groups, this reduced the time taken to become fully familiar with the data.[23] RS transcribed the audiotapes and then cross referenced the transcripts against the recordings for accuracy and to identify the major themes. Concepts, ideas and short phrases were identified within the text and were used to develop thematic frameworks. The initial frameworks and themes were informed by the study objectives and the structure of the topic guides and were developed through deductive analyses and the identification of subthemes. These were then refined, combined and developed by annotating the themes from the draft frameworks on the transcripts, further immersing RS in the data, and enabling the themes and sub-themes to be adjusted and made clearer.[23,39]

Once the frameworks had been refined, the data was indexed using a process of sorting, highlighting and arranging quotations (Using CH1 to CH6 to indicate the care home source and R1 to R4 to indicate the source of the resident interview quotations). At this stage, RS consulted with AR in a process of peer debriefing, to determine whether the themes and subthemes were appropriately clear and comprehensive and to agree the final frameworks.[40] The last stage of analysis involved mapping and interpreting the data, enabling comparison of themes and sub-themes and cross checking against the original transcripts and audio recordings to ensure appropriate context and enhancing rigour.[41] No further changes were made to the themes or subthemes at this stage.

Data were triangulated across staff focus groups and resident interviews for Objective 1, to identify perceptions about trial acceptability that were common to both sets of participants.

Results

Participants:

Twelve staff participants took part in six focus groups, one at each of the care home sites. All participants were women and all three arms of the trial were represented. The participants were all involved with the trial for the full 6-month intervention. The main reason for care home staff that had participated in the trial being unable to attend the focus groups was the busy care home schedule and staff shift patterns.
Four resident participants took part in the individual interviews. All participants were women and two arms of the trial were represented; the ONS arm and the SC arm. None of the residents approached by the dietitian researcher (RS) refused to participate in the interviews, or dropped out.

Table 2: Identified themes and subthemes from care home staff and residents regarding their experiences of the trial procedures:

CARE HOME STAFF	
Theme	**Subthemes**
Perceived acceptability of involvement in the trial	Not viewed as additional work
	Importance of all staff being made aware
Staff completion of nutritional screening	Confident in the process
	The value of 'MUST' training
The challenge of undertaking physical measurements with care home residents	Fluctuating mood and capacity
	Potential for staff training
The challenge of delivering a nutritional intervention protocol in a care home	
Resident completion of PROMs questionnaires	Feasible for more residents to have completed them
	Value of more residents completing them
RESIDENTS	
Theme	**Subthemes**
Perceived acceptability of taking part in PROMs data collection	
Completion of PROMs questionnaires	Understanding of the tools
	Value of residents completing them
Perceived acceptability of the physical measurements	
Perceived acceptability of the	Disagreement regarding acceptability

nutritional intervention protocol	
	No perceived impact of ONS on appetite

Care home staff and residents perceptions of the acceptability of trial procedures:

The themes and subthemes identified from the care home staff focus group data and resident interview data are shown in Table 2. Major themes that emerged from the data included: the perceived acceptability of being involved in the trial, the value of residents completing PROMs questionnaires and voicing their opinion, and the challenge of undertaking physical measurements and delivering an intervention protocol with some groups of residents. Supporting quotations from care home staff and residents regarding their experiences of being involved in the trial are presented in boxes 1 and 2, respectively.

Care home staff perspectives of nutritional interventions and dietetic care in the treatment of malnutrition:

The themes and subthemes identified from the care home staff focus group data are shown in Table 3. Major themes that emerged from the data included: the importance of considering resident preference and the potential for personalised plans, the perceived value of FB and ONS interventions by staff and families and the perceived value of dietetic input. Supporting quotations from care home staff regarding their perspectives of nutritional interventions and dietetic care in the treatment of malnutrition are illustrated in box 3.

Table 3: Identified themes and subthemes from care home staff regarding their perspectives of nutritional interventions and dietetic care

Theme	Subthemes
The value of nutritional interventions for malnutrition	Resident preference and personalisation
	Perceived improvements with FB and ONS interventions
	Perceived value of interventions from the families of residents
The value of dietetic-led intervention	

Discussion

Care home staff and residents perceptions of the acceptability of trial procedures

This is the first study that examined the perceptions of the acceptability of trial procedures in the care home setting with staff and residents, a topic which has not previously been explored within the literature. Triangulation of data from the focus groups and semi-structured interviews highlighted some common themes for both those that reside in and those that work in the care homes. Both the staff and residents felt their involvement in the trial to be acceptable. It was not viewed as creating additional work for the staff, and the residents perceived it to take up little of their time. The use of PROMs to assess self-perceived quality of life and health state and as a means of enabling residents to voice their opinion of the food and nutritional interventions was viewed as positive and of value to the trial, with the tools and questionnaires perceived as acceptable for residents to complete. Both groups of participants felt that more of the residents that took part in the trial could have completed the PROMs. The restrictions imposed by the approving REC meant that those residents lacking capacity were excluded from the collection of this data on the basis that their involvement would not benefit other people with the same or similar impairing condition.[8,36] The perceived acceptability of the tools by staff and residents in this study supports the future assessment of feasibility and acceptability with a more representative care home population, giving scope to investigate the relationship between nutrition support and PROMs and to further explore resident experience of mealtimes and interventions, both areas that have been highlighted within the literature as requiring further research within this setting.[42-43]

Staff noted the value in finding out what the residents think through the use of PROMs, with one stating that 'sometimes this generation like to agree with everything'. Care home residents have been described previously within the literature as 'silent recipients of care',[44] tending not to highlight concerns or make clear their preferences, either due to cognitive impairment or because of the cultural norms of their generation.[45] The use of tools and questionnaires may provide residents with a non-verbal means of expressing their opinions of care and may assist in the effective delivery of person-centred health and social care, as advocated by the Care Quality Commission.[46]

Despite the perceived acceptability of involvement in the trial, the care home staff highlighted the challenges associated with taking physical measurements with residents and delivering a nutritional intervention protocol in this setting. These barriers included fluctuating mood and capacity of some residents, as well as reference to the high proportion of residents with a primary diagnosis of dementia (75%).[8] Other trials conducted in populations with fluctuating capacity have noted similar challenges when taking measurements such as Tricep Skinfold Thickness[47] and handgrip strength.[42,48] Whilst the residents interviewed felt that the physical measurements were acceptable and not deemed to be time consuming, one resident mentioned that daily mood and individual preferences can sometimes result in a lack of acceptance with an assessment schedule or an intervention.

A theme that emerged only from staff focus groups was the interest in care home staff receiving training to enable them to take anthropometric and functionality measures including Mid Upper Arm Circumference, Tricep Skinfold Thickness and Handgrip strength. Some felt that this might have been useful within the trial, as a means of enabling measurements to be taken when residents were in a better mood, or having a good day. Others felt that it would be helpful for staff to be upskilled in this way outside of the trial setting, to support in their assessment of nutritional status. The emergence of this theme may be related to the perceived value placed on nutritional screening ('MUST') training by the staff, and their subsequent self-perceived confidence and competence in completing resident screening as part of usual care. Improvements in 'MUST' documentation and accuracy following dietetic-led projects are supported within the literature.[49-50] The interest from staff to expand their skill base could provide scope to introduce more comprehensive staff-led assessments of nutritional status within the care home setting. There are however, challenges associated with taking these measurements, including measurement error due to poor technique and substantial differences when measurements are made on the same individual by different observers.[51] If such an approach were to be

implemented in practice, it would require a standardised protocol and regular training updates.

Care home staff perspectives of nutritional interventions and dietetic care in the treatment of malnutrition

A major theme which emerged from the focus group data was the perceived value placed by staff on the nutritional interventions, both food-based (FB) and oral nutritional supplements (ONS), when compared to the standard nutritional care provided by the homes. A common perception amongst the staff was that they would expect the introduction of either intervention to be associated with improved outcomes, particularly weight. They also noted that the families of residents involved in the trial viewed the interventions as valuable and wished the residents to continue beyond the assigned protocol. Good staff knowledge of the nutritional interventions available to address malnutrition, and a positive attitude towards these interventions has been shown previously in the literature,[52-53] demonstrating that this is perhaps an aspect of nutritional care that is familiar to care home staff and is therefore perceived to be of value.

Another theme which emerged from the focus groups was the perceived value of dietetic input, with some staff expressing the opinion that residents requiring nutrition support 'would do better with dietetic intervention' and others mentioning that it was of benefit to have the dietitian visit the home more often. Previous research focusing on the knowledge of care home staff has highlighted the greatest knowledge deficits to be associated with nutrient and food requirements in older adults,[52,54] which perhaps explains the value placed on dietetic expertise by care home staff in this study. As the nutritional interventions used in this trial were delivered by the dietitian, an interesting area for future research, might be to explore the care home staff perceptions of the nutritional interventions (FB or ONS) when delivered without dietetic input.

A prominent sub-theme that emerged in relation to the nutritional interventions was the importance placed by staff on resident preferences and the scope to provide a personalised plan. This sub-theme illustrates a commonality with the feedback provided by residents when discussing the acceptability of the interventions, with some expressing a preference for certain types of oral nutritional supplements and others stating that they would have preferred a homemade drink. The importance of involving residents in decisions about their care, including nutrition and mealtimes has been highlighted by the British Geriatrics Society (2011)[55] and has been shown to be positively associated with quality of life.[56] A recent study by Watkins et al (2017),[57] which used semi-structured interviews to explore resident's experiences of mealtime's concluded that freedom of choice is a key component of their experiences of care. Whilst it may not always be possible for residents to make decisions on all aspects of their care, it is apparent from this study that resident preferences should be considered alongside clinical reasoning when implementing a nutrition support plan. The individualisation of an intervention to suit a client's needs is a core component of the shared decision making underpinning dietetic practice as outlined within the British Dietetic Association's 'Model and Process for Nutrition and Dietetic Practice'.[58] This study highlights the importance of this approach within the care home setting.

Strengths and limitations

A key strength of this study is that it is the first to inform understanding of the feasibility and acceptability of conducting a clinical trial evaluating nutritional interventions in the care home setting, by exploring the opinions and perspectives of the staff and the residents involved in

the trial. The inclusion of care home residents, highlighted as an underrepresented group within the research literature[12] has added to our understanding of their experiences of being involved with research and of nutritional care within this setting. Use of individual interviews allowed for the discussion of personal feelings with residents and gave each the chance to freely voice their views. The dynamic interaction of the staff focus groups were perceived by the researcher as open and positive, and provided insight into shared viewpoints within and between care home sites.

A limitation of this study is the small sample size, particularly with regards the number of residents interviewed. The views held by this small sample of residents, who were all female and had capacity, may not be representative of the other residents that took part in the trial. There was a lack of representation from residents in the FB intervention arm, but a staff focus group was conducted at each care home site, therefore providing representativeness from staff in each arm of the trial, and capturing the views of both nursing and care staff. It is possible that the care homes recruited into this study do not necessarily represent the national care home population. All sites had been in receipt of long-term and regular input from the local dietetic service and were engaged in a programme of staff training. The dietitian researcher (RS) had an established relationship with the managers and staff at the homes, which may have made it easier to recruit to and facilitate the staff focus groups. Exploration of staff experiences of feasibility and acceptability was carried out in engaged and motivated care homes, which may limit transferability. However, the focus groups and interviews have informed our understanding of the experiences of trial involvement and the perceived acceptability and value of nutritional interventions from the perspectives of both care home staff and residents.

Conclusions

From staff focus groups and interviews with residents, involvement in a clinical trial evaluating nutritional interventions for malnutrition in the care home setting was perceived as acceptable, although the challenges associated with research in this setting were acknowledged. Both staff and residents agreed that the use of PROMs within the trial was positive and valuable and that more residents could have completed them. Care home staff demonstrated a positive attitude towards both the nutritional interventions used in the trial, and the value added by dietetic input. Resident preferences were identified as important, because they are likely to affect compliance with an intervention. To ensure that these are accounted for, it is suggested that a nutrition support plan be developed collaboratively between the dietitian and the staff, the resident and their relatives, to meet both the clinical needs and the preferences of the individual.

Box 1: Direct quotations supporting themes and subthemes from care home staff regarding their experiences of the trial procedures (Using CH1 to CH6 to indicate the care home source):

Perceived acceptability of involvement in the trial:
Care home staff did not perceive involvement in the trial to be any additional work, with a lot of the required information already being collected in care plans:

'No different to usual at all' (CH1)
'No additional work (collecting healthcare resource usage data)- all in the notes' (CH1)
'I can't say that it was a hassle, we just treated it as we should do anyway'(CH2)
'All the required information is documented in care plans anyway- not extra information' (CH2)
'No, wasn't really any different….it's (SC) what we are doing anyway' (CH3)
'Carers would be fortifying anyway, and working with the kitchen' (CH4)
''I was happy that you chose us to be involved- it wasn't any extra work' (CH6)
'It didn't seem like extra work- it was very organised' (CH1)

Some care home staff stressed the importance of all staff in the home being made aware of the trial and what was required of them:
'We had a list in the kitchen to make it easy for staff to deliver the intervention' (CH2)
'We put extra copies of the sheets (personalised dietetic FB plans) in the residents rooms to make sure the carers understood and knew what it was all about' (CH4)
'Everyone had a list of the residents that needed the FB intervention, they also had all the recipes to follow, so it was not challenging' (CH6)
'It was straightforward so long as staff knew to sign that they (ONS) had been given' (CH1)

Staff completion of nutritional screening:
The care home staff expressed a confidence in undertaking the 'MUST' nutritional screening:
'Very confident in completing' (CH1)
'We do the MUST (the seniors)- no problem with completing it' (CH2)
'Staff are confident in doing this and knowing what to do next' (CH3)
'I think we have gained more confidence in using MUST' (CH6)

Staff discussed the value of training to support them with this:
'I found it hard to begin with, but it's alright now we've had lots of training' (CH2)
'We have a good knowledge now we've been trained' (CH5)
'Further training on completing MUST is always useful' (CH4)
'The only challenge is we don't always have heights, but now I know how to take the arm measurement (ulna length) if I can't get height' (CH5)

The challenge of undertaking physical measurements with care home residents:
The care home staff spoke about how the fluctuating mood and capacity of residents can make it difficult to undertake physical measurements, especially if restricted to a particular day and time
'The patients were not refusing you because it was a study, they refuse to do things for us as well' (CH1)
'It's dementia and it's really hard- it depends on the day' (CH2)
'It's a challenge of the care home setting' (CH3)
'It's just a challenge of care homes- If they refuse, they refuse' (CH4)
'it depends on the individual, not all of them will be weighed either' (CH5)
'Challenging in a care home- with people that have dementia, it depends on the day' (CH6)
'They behave differently at different times of the day' (CH6)
'Limitation of time- you are committed to come on that day- if the residents are having a bad day, you won't be able to get the measurements properly' (CH6)

They expressed an interest in receiving training on how to undertake some of these physical measurements, to improve their skill base
'Would be good if staff could be shown how to do these other measurements' (CH2)
'It might work better if staff could be trained to do these measurements' (CH4)
'If they can't do the weight, it would be good for staff to have more skills' (CH5)

The challenge of delivering a nutritional intervention protocol in a care home:
The care home staff cited challenges including physical space for supplements, additional work for kitchen staff, and encouraging the residents to take the interventions
'It's quite hard to get the residents (with dementia) to have things every day, whatever it is' (CH2)
'There are a couple of residents that won't comply whatever the intervention' (CH4)
'Only negative we had was all the supplements arriving at the same time- we don't have that much space!' (CH1)
'There was more for the kitchen staff to do, but they didn't see it as extra work' (CH6)

Resident completion of PROMs questionnaires
The care home staff indicated that they felt more residents would have been able to complete the PROM's questionnaires used within the trial
'Some (residents without capacity) would be able to take part, but it depends on the day- are they having a good day?' (CH1)
'More of them could have completed them' (CH2)
'We have a couple on here that could have been able to answer these' (CH3)
'I like these (COOP QoL tool) , I've never seen these before- more residents could have completed them' (CH4)
'Not all of them, but yes 2 or 3 could have done' (CH5)
'Yes, they would have been able to complete these or tell you' (CH6)

They felt that there would have been value to more of the residents getting to have their say
'It would be nice for them to be able to give their thoughts' (CH2)
'Would be useful to know what they think…sometimes this generation like to just agree with everything' (CH3)
''I think it is important for more of the residents to have a say' (CH6)

Box 2: Direct quotations supporting themes and subthemes from residents regarding their experiences of the trial procedures (Using R1 to R4 to indicate the source of the quotation):

Perceived acceptability of taking part in PROMs data collection:
The residents perceived their involvement to be acceptable and did not feel that it took up much time
'Didn't take up much time, it was alright' (R1)
'It was alright- not too much of a burden' (R2)
'It was okay' (R3)
'Don't think it's taken up much time' (R4)

Feasibility of completing PROMs questionnaires:
The residents indicated that the tools were easy to understand and that what was being asked made sense:
'Understood, was not complicated' (R1)
'Fine as it was, no need to change them' (R1)
'Yes, understood what you were asking me' (R2)
'Yes, easy to understand' (R3)
'They made sense' (R4)

They felt that there was value to completing these tools and that more residents might also have been able to voice their opinion:

'Good to have a say, would be good if more residents could have done them' (R1)
'It's nice to give an opinion if I can. Some of the other residents could have done them too' (R3)
'It's very important to be asked about the food and your appetite' (R4)
'Could have asked other residents the questions' (R2)

Perceived acceptability of the physical measurements
The residents felt that the physical measurements were acceptable, although one resident mentioned that mood might have an impact
'It was ok, not a hassle' (R1)
'It was fine to take the measures in the bedrooms' (R1)
'No trouble, but probably depends what mood I'm in!' (R2)
'Yes, it was okay to do' (R3)
'It (handgrip) was quite fun' (R3)
'Yes, it was alright- it didn't hurt' (R4)

Perceived acceptability of the nutritional intervention
Some residents felt that the nutritional interventions were acceptable, and provided positive feedback
'I Liked those' (ONS) (R1)
'I liked the flavour and it was good that they were quite small' (compact supplements) (R1)
'Quite liked them (ONS) when I did have them' (R3)
'Yes it is acceptable (SC), I have extra glasses of milk' (R4)

But one resident indicated that the intervention was not always well tolerated
'I had one (ONS) a day, if I have two, they upset my stomach' (R2)
'I think I prefer the homemade ones' (R2)

The residents in the ONS arm, felt that the supplements did not impact upon their appetite for other meals
'No, they were good for my appetite' (R3)
'No they didn't reduce my appetite' (R2)
'No effect on my appetite for meals' (R1)

Box 3: Direct quotations supporting themes and subthemes from care home staff regarding their perspectives of nutritional interventions and dietetic care in the treatment of malnutrition (Using CH1 to CH6 to indicate the care home source):

The value of nutritional interventions for malnutrition:
The care home staff highlighted the importance of patient/resident preference and where possible, being able to provide a personalised plan
'We had one person who didn't like them (ONS), she just did not like the taste' (CH1)
'The majority of the residents liked them (ONS), there was one lady who just completely would not have it' (CH2)
'Would they do as well with snacks as drinks? I've been thinking about that- as they don't always take the snacks- it would depend on what the person preferred' (CH2)
'I think the extra homemade things is better, not everyone will drink the supplements' (CH6)
'Would be a good idea if the kitchen made their own milky drinks- could be a bit more flexible with that' (CH2)
'Personalised plans are better aren't they' (CH4)

'Glass of milk, with cream and chocolate powder as a smoothie- they enjoy it' (CH6)

Some of the care home staff mentioned that the interventions were perceived as valuable by the residents families, with some, wanting them to continue beyond the trial:
'A lot of the families have asked if residents could continue supplements' (CH1)
'Most of the residents accepted it (the FB intervention) as part of their diet plan- they were pleased to have something extra and the families were as well' (CH6)

The care home staff communicated the belief that the FB and ONS interventions would bring about improvements in outcomes such as weight, wellbeing and mental health:
'Improvement in resident's wellbeing, including mental wellbeing' (ONS) (CH1)
'Yes, expected weight to increase- usual food regime plus supplements' (CH1)
'Yes, would expect the weight to increase' (ONS) (CH2)
'I don't think they needed anything additional to FB intervention' (CH4)
'Yes, I would like to think there would be an increase in weight with FB intervention' (CH4)
'I think they would have benefitted by being in one of the other groups- FB or ONS' (CH5)
'Some of the residents behaviour improved while they were in the trial' (ONS) (CH1)
'I feel it was acceptable for the residents…..a lot of them want to continue' (ONS) (CH1)

The value of dietetic-led intervention:
The care home staff highlighted the usefulness of dietetic visits and discussion:
'It's useful to be told specific things to do by the dietitian- extra things to add into the diet that you might not have thought of' (CH3)
'We could have tried different things on discussion with you (dietitian)' (CH5)
'Would think they would do better with dietetic intervention' (CH5)
'It was a benefit to have the dietitian here more often' (CH6)

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COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	21	What was the duration of the inter views or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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Care home resident and staff perceptions of the acceptability of nutrition intervention trial procedures: a qualitative study embedded within a cluster randomised feasibility trial

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Care home resident and staff perceptions of the acceptability of nutrition intervention trial procedures: a qualitative study embedded within a cluster randomised feasibility trial

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Abstract

Objectives To examine care home resident and staff perceptions of the acceptability of participating in a feasibility trial evaluating nutritional interventions in the treatment of malnutrition.

Design Exploratory qualitative methodology was used to gather descriptions of resident and staff perceptions of trial procedures, using semi-structured interviews with residents and focus groups with staff. The interviews were used to explore individual perceptions of the acceptability of the assigned intervention and the outcomes measured. Focus groups were used to explore staff experiences of trial participation and perspectives of nutritional support interventions.

Setting The study was embedded within a cluster randomised feasibility trial, which randomised six care homes to provide standard care (SC), food-based intervention (FB), or oral nutritional supplement intervention (ONS) to residents with, or at risk of, malnutrition.

Participants Residents in the trial with capacity to consent (n=7) formed the sampling frame for inclusion. Four agreed to be approached by the researcher and to take part in the individual interviews. All were women, representing two arms of the trial (ONS and SC). Twelve staff participated in six focus groups, one at each care home. All participants were women, representing all three arms of the trial.

Results Major themes that emerged from both interviews and focus groups included: the perceived acceptability of trial involvement, the value of residents completing Participant Reported Outcome Measures (PROMs) and the challenges associated with outcomes measurement in this setting. Themes that emerged from the focus groups alone, included: the importance of individualising an intervention, and the perceived value of FB and ONS interventions and dietetic input.

Conclusions Residents and staff perceived involvement in a trial evaluating nutritional interventions to be acceptable, although the challenges associated with research in this setting were acknowledged. Resident preferences were highlighted by staff as an important consideration when implementing a nutrition support plan.

Trial registration number: Current Controlled Trials ISRCTN38047922 , Date assigned: 22 April 2014

Strengths and Limitations of this study:

- This is the first study to inform understanding of the feasibility and acceptability of conducting a clinical trial evaluating nutritional interventions in the care home setting from the perspectives of staff and residents.
- Use of individual interviews gave each resident the chance to freely voice their views.
- The dynamic interaction of the staff focus groups were perceived by the researcher as open and positive, and provided insight into shared viewpoints within and between care home sites.
- The study was limited by small sample size, particularly with regards the number of residents interviewed, but a staff focus group was conducted at each care home site, providing representativeness from each arm of the trial, and capturing the views of both nursing and care staff.
- Exploration of staff experiences of feasibility and acceptability was carried out in engaged and motivated care homes, which may limit transferability to the national care home population.

Acknowledgements The participants in the study for sharing their experiences and views. Susan Boex, a carer, who supported the trial steering groups that provided an overview of the trial and the embedded qualitative study.

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Competing Interests None declared.

Authors' contributions RS designed the study, performed the interviews and focus groups and drafted the article. RS analysed the data following peer debriefing and agreement of the final themes with AR. AR and CS have made substantial contributions to the conception, design, and data interpretation of the study. All authors have read and approved the final manuscript.

Data sharing statement No further unpublished data are available.

Introduction

Care home residents in the UK are a distinct group of approximately 416,000 people (including 16% of those aged over 85)[1] with different mortality[2], health status, and health and care needs[3] compared to individuals of the same age residing in their own homes. Research outcomes established for older adults living within their own homes cannot be considered valid for care home residents and cannot therefore be used to guide best practice.[4]

The public health and social care expenditure associated with malnutrition in England from 2011-2012, was estimated at £19.6 billion; 15% of the total expenditure on health and social care[5]. Approximately 30-42% of care home residents are estimated to be at risk of malnutrition[6-8] placing them at increased risk of infection and pressure ulcers, clinical complications and depression and reducing their overall quality of life.[9-10] There is a need therefore to improve the evidence based nutritional care provided to this population. However, research in care homes presents challenges, and consequently many studies exclude care home residents on the basis that their inclusion would present the team with ethical and practical dilemmas.[11] Recruitment difficulties due to physical and cognitive impairments[12] have been highlighted as a particular challenge, along with the consent process,[12-13] responding to family and carer concerns[12] and high attrition.[12,14] Additional issues for the researcher can include data collection within a busy care home schedule and difficulties for staff in adhering to assigned interventions and methodological protocols.[12] These challenges have led to nutrition intervention trials often excluding those at highest risk of malnutrition, including residents with advanced dementia and immobility.[15-18]

Existing studies of nutrition interventions for malnutrition within this setting have also tended to use a quantitative approach, which whilst useful for determining quantitative outcomes such as nutrient intake and weight change, have provided limited information on resident and staff perspectives of nutritional care and the reasons why the care home environment poses challenges for the researcher. During the last 20 years, researchers have identified the need for employing a range of methodologies to enhance understanding of healthcare complexities and to ensure that disempowered groups are heard.[19] Exploring feasibility outcomes with trial participants is a way to ensure that resident and staff perspectives can be used to inform the design and conduct for future definitive trials in this complex research setting.

The aim of this study therefore, was to seek an in depth understanding of the experience of participating in a cluster randomised feasibility trial which evaluated nutritional interventions in the treatment of malnutrition.[8] The study had two objectives:

1. To examine perceptions of the acceptability of trial procedures (including the intervention protocol, outcome measures and data collection methods) with care home staff and residents.
2. To examine care home staff perspectives of nutritional interventions and dietetic care in the treatment of malnutrition.

Methods

Design and setting:

This study used a pragmatic, exploratory approach to qualitative research, embedded within a cluster randomised feasibility trial (ISRCTN38047922)[8] to understand the experience of participating in a trial investigating nutritional interventions in the treatment of malnutrition. The study used semi structured interviews with residents and focus groups with staff which were consistent with the exploratory aim of the study.[20] Topic guides (Table 1) were used to ensure that core questions were asked, whilst allowing for flexibility to follow up on novel information.[21] Due to the paucity of previous work in this area, a specific theoretical framework was not adopted. The study is reported in line with the Consolidated Criteria for Reporting Qualitative Research (COREQ).[22]

The feasibility trial was conducted within the West Midlands, in England where 17 care homes providing accommodation for older adults (over 65 years), were receiving regular dietetic input. This was being provided by the community nutrition support dietetic service where the lead researcher (female) (RS) was working as a dietitian at the time of the study. Purposive sampling was used to select and invite six, privately owned care homes with a diverse sample based on type of care provided (residential or nursing/nursing and residential) to take part in the trial. All care home sites were made aware that the trial was being conducted as part of a student MRes project by the Lead Researcher (RS). The care home sites were cluster randomised to provide standard care (SC) (n=2), food-based intervention (FB) (n=2) or oral nutritional supplement intervention (ONS) (n=2) for 6 months to residents identified with, or at risk of malnutrition Outcomes were trial feasibility and the acceptability of the design, the nutritional interventions and the outcomes being assessed at 3 and 6-months. These included anthropometry, dietary intake, healthcare resource usage and participant reported outcome measures (PROMs).

Ethical approval

The trial was approved by the West Midlands NHS Local Research Ethics Committee (Ref: 13/WM/0390) and the Research and Development Department of the Heart of England NHS Foundation Trust prior to commencement. The Research Ethics Committee felt that the inclusion of residents lacking capacity in the collection of PROMs and in the qualitative study could not be justified in accordance with the Mental Capacity Act (MCA).[23].Within the care home setting, capacity is assessed by trained care home staff or the GP. Written consent for PROMS data collection and for the qualitative study was sought on an individual basis from eligible residents that had been assessed as having capacity. Residents were provided with a full explanation of their required participation alongside a Participant Information Sheet. They were given one week to ask questions and decide whether they would like to provide information on quality of life, health state and dietary satisfaction. Each resident was asked to sign a consent form for PROMs and to indicate whether they would like to be considered for the individual interviews in the qualitative study.

Participants

Sampling and recruitment

Those residents with capacity to consent who had indicated on the trial consent form that they would like to be considered for individual interviews and had completed the 6-month

trial intervention (n=7), formed the sampling frame for potential inclusion. The care home staff made the initial approach to the 7 potential participants to discuss their involvement. Those that remained interested in participation (n=4) were introduced to the dietitian researcher (RS) to provide further verbal information and a written information sheet and consent form. The 3 residents that declined to take part did not give specific reasons to the care home staff.

A focus group of staff (2-3) took place within each of the care home sites that had participated in the trial. Care home staff were selected on the basis that they had participated in the trial[24] and were provided with information sheets and consent forms. Six focus groups, covering all 3 arms of the trial were conducted.

Semi-structured interviews:

The dietitian researcher (RS) conducted individual semi-structured interviews lasting 30 to 60 minutes with care home residents to enable exploration of reality from narratives related to their own experiences of trial participation.[25] The interviews were organised around topic guides (Table 1), developed using the trial feasibility objectives and discussions with care home staff. The basic research question explored was the experience and acceptability of participation in the trial. Themes and core questions were refined following the 6-month dietary intervention and the collection of PROMs.

Interviews allowed for greater exploration of individual perceptions of the acceptability of the assigned intervention and understanding and perception of the anthropometric assessments and the PROMs questionnaires than would have been possible with the use of focus groups.[26-28] RS is an experienced nutrition support dietitian with an interest in malnutrition in the older adult population, and who had worked for several years with the care home population. This relevant background allowed for the effective exploration of individual dietary satisfaction whilst on the allocated nutritional intervention plan. Use of the interview technique enabled residents to ask for questions to be further explained, which allowed for the identification of any problems with comprehension and for questions to be rephrased as appropriate. This was felt to be important with the care home population and may have been less feasible within a group setting.[29] RS was responsible for audio taping the interviews, and transcribing the audio recordings verbatim.

Focus Groups:

The dietitian researcher (RS,) led and audio-taped focus group discussions lasting 45-60 minutes in each of the 6 care homes with between 2 and 3 care home staff in each. The topic guide (Table 1) was developed using the feasibility objectives from the trial alongside discussions with care home staff and was later refined following delivery of the 6-month nutritional intervention and collection of outcomes data. Focus groups were used to enable the views of more people to be included,[25] to highlight any variations in perspectives between the staff within each home and between care home types[30] and to collect information from those staff that were reluctant to be interviewed on their own or who felt they had less to contribute.[31-32] As the staff within a care home work closely together, holding a focus group within each individual home was found to stimulate engagement and discussion[31,33] and it was possible to explore knowledge, experiences and perceptions of participating in a trial, with a focus on the assigned intervention and protocol for delivery, the data collection process, the data collection tools and the outcomes from the trial. With a strong background in nutrition support within the care home setting and a working relationship with the care home staff as a dietetic practitioner, RS was able to appreciate the significance of the aspects discussed and to effectively follow up on the relevant points.[34] RS was responsible for transcribing the focus group audio recordings verbatim.

Table 1: Topic Guides for semi-structured interviews and Focus Groups

SEMI-STRUCTURED INTERVIEWS	
Stage	**Content**
Discussion on involvement in the trial	- The clarity and acceptability of explanations and instructions before and during the trial- *Prompted for any examples where information was not clear, scope for improvement*
Discussion on the dietary plan received	- The acceptability of the dietary plan- *Prompted on appetite, satisfaction with diet, compliance and whether intervention was always received* - Positive and negative outcomes of the interventions- *Personal experiences*
Discussion on the anthropometry assessments	- Acceptability of the assessments undertaken- *Prompted for: understanding of instructions, personal experiences, suggestions to make the process more acceptable*
Discussion on the PROMS questionnaires and scales	- The ease/burden of completing questionnaires and scales- *Prompted for time commitments, changes to routine, ways to make the process more acceptable* - Understanding of the questionnaires/scales- *Prompted for any particular challenges, whether other residents could have completed* - Thoughts on the importance of residents being able to provide feedback through PROMs
FOCUS GROUPS	
Stage	**Content**
Discussion of care home involvement in the trial	- The ease/burden of participation in the trial: *prompted for time commitments, knowledge and competency* - The confidence of the staff in completing malnutrition screening- *prompted for areas of concern/adequacy of training prior to commencement* - Experiences of completing healthcare resource usage questionnaires- *prompted for time commitment/specific challenges/any other items which could have been included*
Discussion of allocated dietary intervention	- The acceptability of the dietary plan for residents - The ease/burden of delivering the dietary intervention - Positive and negative outcomes of interventions- *according to study data, and own perceptions* - Possible reasons for poor compliance
Discussion of PROMs outcome measures	- The ability of residents to complete the questionnaires and scales- *prompted for their thoughts on whether others could have completed, ways to make it easier, completion by proxy*

Nutritional interventions and outcome measures

All six care homes had received training and support to provide a standard care intervention to residents with or at risk of malnutrition. The food-based intervention choices and recipes were based on local nutrition support guidelines, national guidance and best practice resources[35-36] and were intended to increase the participating resident's daily nutritional intake by approximately 600 kcal and 20-25g of protein. The Oral Nutritional Supplement (ONS) intervention consisted of 2 daily liquid ONS containing 600kcal and 24g protein.

The outcomes measured or collected in the trial by the care home staff included height, weight, Body Mass Index (BMI), healthcare resource usage, compliance with the assigned intervention and completion of the standardised mini-mental state examination (sMMSE). Participant-reported outcome measures (PROMs) data was collected from those residents that had capacity and had consented to completing quality of life and health state questionnaires and a Visual Analogue Scale (VAS) related to dietary satisfaction.

Patient and Public Involvement

The care home residents involved in this study were not involved in the development of the research question, the outcome measures or the study design. However, the focus of the study and the development of the topic guides was informed via care home staff discussions and the insight of a carer, who supported the trial steering groups. Participants were recruited through the care homes that participated in the trial as described above. There are no plans to disseminate the qualitative study results to participants directly; however, results will be published in open-access peer review publications.

Data Analysis

Interview and focus group discussions continued until no new emerging ideas were being obtained and it was felt that thematic data saturation had been reached with the study participants.[37]The qualitative data were analysed using the Krueger (1994)[38], and Ritchie and Spencer (1994)[39] framework analyses. The process of data analysis began during data collection, through the effective facilitation and audiotaping of the interview and focus group discussions. As RS undertook all of the interviews and focus groups, this reduced the time taken to become fully familiar with the data.[23] RS transcribed the audiotapes and then cross referenced the transcripts against the recordings for accuracy and to identify the major themes. Concepts, ideas and short phrases were identified within the text and were used to develop thematic frameworks. The initial frameworks and themes were informed by the study objectives and the structure of the topic guides and were developed through deductive analyses and the identification of subthemes. These were then refined, combined and developed by annotating the themes from the draft frameworks on the transcripts, further immersing RS in the data, and enabling the themes and sub-themes to be adjusted and made clearer.[23,40]

Once the frameworks had been refined, the data was indexed using a process of sorting, highlighting and arranging quotations (Using CH1 to CH6 to indicate the care home source and R1 to R4 to indicate the source of the resident interview quotations). At this stage, RS consulted with AR in a process of peer debriefing, to determine whether the themes and subthemes were appropriately clear and comprehensive and to agree the final frameworks.[41] The last stage of analysis involved mapping and interpreting the data, enabling comparison of themes and sub-themes and cross checking against the original transcripts and audio recordings to ensure appropriate context and enhancing rigour.[42] No further changes were made to the themes or subthemes at this stage.

Data collected from the staff focus groups and resident interviews for objective 1 were considered alongside each other, to identify perceptions about trial acceptability that were common to both sets of participants.

Results

Participants:

Twelve staff participants took part in six focus groups, one at each of the care home sites. All participants were women and all three arms of the trial were represented. The participants were all involved with the trial for the full 6-month intervention. The main reason for care home staff that had participated in the trial being unable to attend the focus groups was the busy care home schedule and staff shift patterns.
Four resident participants took part in the individual interviews. All participants were women and two arms of the trial were represented; the ONS arm and the SC arm. None of the residents approached by the dietitian researcher (RS) refused to participate in the interviews, or dropped out.

Care home staff and residents perceptions of the acceptability of trial procedures:

The themes and subthemes identified from the care home staff focus group data and resident interview data are shown in Table 2, along with supporting quotations. Major themes that emerged from the data included: the perceived acceptability of being involved in the trial, the value of residents completing PROMs questionnaires and voicing their opinion, and the challenge of undertaking physical measurements and delivering an intervention protocol with some groups of residents.
8 staff participants commented that involvement in the trial did not pose an additional workload, although some participants stressed the importance of ensuring that all staff in the home were aware of the trial and what was required of them. The 4 resident participants did not consider taking part in the PROMs data collection to be a 'burden' with 2 of them commenting that it did not take up too much of their time. 6 staff participants indicated that they believed more of the residents could have completed the PROMs questionnaires within the trial, with one specifically making a positive reference to the COOP Quality of Life tool. 3 staff participants and all 4 resident participants commented on the usefulness of residents voicing their opinion through completion of these types of questionnaires.
8 staff participants commented on the challenge of undertaking physical measurements such as anthropometry, with care home residents and 4 commented on the challenges associated with delivering a nutritional intervention in this setting. Particular reference was made to the challenges posed by the fluctuating mood and capacity of many of the residents. The 4 resident participants commented on the acceptability of the physical measurements and the nutritional interventions, although it must be noted that these 4 residents all had capacity. 1 resident mentioned that mood might determine the acceptability of the measurements.

Table 2: Identified themes and subthemes from care home staff and residents regarding their experiences of the trial procedures:

CARE HOME STAFF		
Theme	**Subthemes**	**Direct Quotations**
Perceived acceptability of involvement in the trial	Not viewed as additional work	'No different to usual at all' (CH1) 'No additional work (collecting healthcare resource usage data)- all in the notes' (CH1) 'I can't say that it was a hassle, we just treated it as we should do anyway'(CH2) 'All the required information is documented in care plans anyway- not extra information' (CH2) 'No, wasn't really any different….it's (SC) what we are doing anyway' (CH3) 'Carers would be fortifying anyway, and working with the kitchen' (CH4) ''I was happy that you chose us to be involved- it wasn't any extra work' (CH6) 'It didn't seem like extra work- it was very organised' (CH1)
	Importance of all staff being made aware	'We had a list in the kitchen to make it easy for staff to deliver the intervention' (CH2) 'We put extra copies of the sheets (personalised dietetic FB plans) in the residents rooms to make sure the carers understood and knew what it was all about' (CH4) 'Everyone had a list of the residents that needed the FB intervention, they also had all the recipes to follow, so it was not challenging' (CH6) 'It was straightforward so long as staff knew to sign that they (ONS) had been given' (CH1)
Staff completion of nutritional screening	Confident in the process	'Very confident in completing' (CH1) 'We do the MUST (the seniors)- no problem with completing it' (CH2) 'Staff are confident in doing this and knowing what to do next' (CH3) 'I think we have gained more confidence in using MUST' (CH6)
	The value of 'MUST' training	'I found it hard to begin with, but it's alright now we've had lots of training' (CH2) 'We have a good knowledge now we've been trained' (CH5) 'Further training on completing MUST is always useful' (CH4) 'The only challenge is we don't always have heights, but now I know how to take the arm measurement (ulna length) if I can't get height' (CH5)
The challenge of undertaking physical measurements with care	Fluctuating mood and capacity	'The patients were not refusing you because it was a study, they refuse to do things for us as well' (CH1) 'It's dementia and it's really hard- it depends on the day' (CH2)

home residents		'It's a challenge of the care home setting' (CH3) 'It's just a challenge of care homes- If they refuse, they refuse' (CH4) 'it depends on the individual, not all of them will be weighed either' (CH5) 'Challenging in a care home- with people that have dementia, it depends on the day' (CH6) 'They behave differently at different times of the day' (CH6) 'Limitation of time- you are committed to come on that day- if the residents are having a bad day, you won't be able to get the measurements properly' (CH6)
	Potential for staff training	'Would be good if staff could be shown how to do these other measurements' (CH2) 'It might work better if staff could be trained to do these measurements' (CH4) 'If they can't do the weight, it would be good for staff to have more skills' (CH5) The challenge of delivering a nutritional intervention protocol in a care home: The care home staff cited challenges including physical space for supplements, additional work for kitchen staff, and encouraging the residents to take the interventions 'It's quite hard to get the residents (with dementia) to have things every day, whatever it is' (CH2) 'There are a couple of residents that won't comply whatever the intervention' (CH4) 'Only negative we had was all the supplements arriving at the same time- we don't have that much space!' (CH1) 'There was more for the kitchen staff to do, but they didn't see it as extra work' (CH6)
Resident completion of PROMs questionnaires	Feasible for more residents to have completed them	'Some (residents without capacity) would be able to take part, but it depends on the day- are they having a good day?' (CH1) 'More of them could have completed them' (CH2) 'We have a couple on here that could have been able to answer these' (CH3) 'I like these (COOP QoL tool) , I've never seen these before- more residents could have completed them' (CH4) 'Not all of them, but yes 2 or 3 could have done' (CH5) 'Yes, they would have been able to complete these or tell you' (CH6)
	Value of more residents completing them	'It would be nice for them to be able to give their thoughts' (CH2) 'Would be useful to know what they think…sometimes this generation like to just agree with everything' (CH3) ''I think it is important for more of the residents to have a say' (CH6)

RESIDENTS		
Theme	**Subthemes**	**Direct Quotations**
Perceived acceptability of taking part in PROMs data collection		'Didn't take up much time, it was alright' (R1) 'It was alright- not too much of a burden' (R2) 'It was okay' (R3) 'Don't think it's taken up much time' (R4)
Completion of PROMs questionnaires	Understanding of the tools	'Understood, was not complicated' (R1) 'Fine as it was, no need to change them' (R1) 'Yes, understood what you were asking me' (R2) 'Yes, easy to understand' (R3) 'They made sense' (R4)
	Value of residents completing them	'Good to have a say, would be good if more residents could have done them' (R1) 'It's nice to give an opinion if I can. Some of the other residents could have done them too' (R3) 'It's very important to be asked about the food and your appetite' (R4) 'Could have asked other residents the questions' (R2)
Perceived acceptability of the physical measurements		'It was ok, not a hassle' (R1) 'It was fine to take the measures in the bedrooms' (R1) 'No trouble, but probably depends what mood I'm in!' (R2) 'Yes, it was okay to do' (R3) 'It (handgrip) was quite fun' (R3) 'Yes, it was alright- it didn't hurt' (R4)
Perceived acceptability of the nutritional intervention protocol	Disagreement regarding acceptability	'I Liked those' (ONS) (R1) 'I liked the flavour and it was good that they were quite small' (compact supplements) (R1) 'Quite liked them (ONS) when I did have them' (R3) 'Yes it is acceptable (SC), I have extra glasses of milk' (R4) 'I had one (ONS) a day, if I have two, they upset my stomach' (R2) 'I think I prefer the homemade ones' (R2)
	No perceived impact of ONS on appetite	'No, they were good for my appetite' (R3) 'No they didn't reduce my appetite' (R2) 'No effect on my appetite for meals' (R1)

Care home staff perspectives of nutritional interventions and dietetic care in the treatment of malnutrition:

The themes and subthemes identified from the care home staff focus group data are shown in Table 3, along with supporting quotations. Major themes that emerged from the data included: the importance of considering resident preference and the potential for personalised plans, the perceived value of FB and ONS interventions by staff and families and the perceived value of dietetic input.
7 staff participants commented on how resident preference influenced adherence to the intervention schedule, with 2 participants making reference to the importance of flexible and personalised approaches. 8 staff participants commented on the value of FB and ONS interventions, making reference to improvements in wellbeing, weight and behaviour. 2 of the participants also mentioned that the families of some of the residents viewed the FB and ONS interventions positively and would have liked them to continue beyond trial completion. 4 of the staff participants made reference to the value and usefulness of dietetic visits to the care home with 1 participant commenting that residents would do better with dietetic intervention.

Table 3: Identified themes and subthemes from care home staff regarding their perspectives of nutritional interventions and dietetic care

Theme	Subthemes	Direct Quotations
The value of nutritional interventions for malnutrition	Resident preference and personalisation	'We had one person who didn't like them (ONS), she just did not like the taste' (CH1) 'The majority of the residents liked them (ONS), there was one lady who just completely would not have it' (CH2) 'Would they do as well with snacks as drinks? I've been thinking about that- as they don't always take the snacks- it would depend on what the person preferred' (CH2) 'I think the extra homemade things is better, not everyone will drink the supplements' (CH6) 'Would be a good idea if the kitchen made their own milky drinks- could be a bit more flexible with that' (CH2) 'Personalised plans are better aren't they' (CH4) 'Glass of milk, with cream and chocolate powder as a smoothie- they enjoy it' (CH6)
	Perceived improvements with FB and ONS interventions	'Improvement in resident's wellbeing, including mental wellbeing' (ONS) (CH1) 'Yes, expected weight to increase- usual food regime plus supplements' (CH1) 'Yes, would expect the weight to increase' (ONS) (CH2) 'I don't think they needed anything additional to FB intervention' (CH4)

		'Yes, I would like to think there would be an increase in weight with FB intervention' (CH4) 'I think they would have benefitted by being in one of the other groups- FB or ONS' (CH5) 'Some of the residents behaviour improved while they were in the trial' (ONS) (CH1) 'I feel it was acceptable for the residents…..a lot of them want to continue' (ONS) (CH1)
	Perceived value of interventions from the families of residents	'A lot of the families have asked if residents could continue supplements' (CH1) 'Most of the residents accepted it (the FB intervention) as part of their diet plan- they were pleased to have something extra and the families were as well' (CH6)
The value of dietetic-led intervention		'It's useful to be told specific things to do by the dietitian- extra things to add into the diet that you might not have thought of' (CH3) 'We could have tried different things on discussion with you (dietitian)' (CH5) 'Would think they would do better with dietetic intervention' (CH5) 'It was a benefit to have the dietitian here more often' (CH6)

Discussion

Care home staff and residents perceptions of the acceptability of trial procedures

This is the first study that has examined the perceptions of the acceptability of trial procedures in the care home setting with staff and residents, a topic which has not previously been explored within the literature. Consideration of the data gathered from the focus groups and semi-structured interviews for objective one highlighted some common themes for both those that reside in and those that work in the care homes. Both the staff and residents felt their involvement in the trial to be acceptable. It was not viewed as creating additional work for the staff, and the residents perceived it to take up little of their time. The use of PROMs to assess self-perceived quality of life and health state and as a means of enabling residents to voice their opinion of the food and nutritional interventions was viewed as positive and of value to the trial, with the tools and questionnaires perceived as acceptable for residents to complete. Both groups of participants felt that more of the residents that took part in the trial could have completed the PROMs. The restrictions imposed by the approving REC meant that those residents lacking capacity were excluded from the collection of this data on the basis that their involvement would not benefit other people with the same or similar impairing condition.[8,36] The perceived acceptability of the tools by staff and residents in this study supports the future assessment of feasibility and acceptability with a more representative care home population, giving scope to investigate the relationship between nutrition support and PROMs and to further explore resident experience of mealtimes and interventions, both areas that have been highlighted within the literature as requiring further research within this setting.[43-44]

Staff noted the value in finding out what the residents think through the use of PROMs, with one stating that 'sometimes this generation like to agree with everything'. Care home residents have been described previously within the literature as 'silent recipients of care',[45] tending not to highlight concerns or make clear their preferences, either due to cognitive impairment or because of the cultural norms of their generation.[46] The use of tools and questionnaires within the care home setting may provide residents with a non-verbal means of expressing their opinions of care and may assist in the effective delivery of person-centred health and social care, as advocated by the Care Quality Commission.[47] The tendency 'to agree' may also explain the 'directness' of the quotes obtained from the resident participants during interviews, even following probing for expansion on particular points. It is possible that the residents may have been reticent to raise concerns or negative points about their involvement in the trial, perhaps introducing an element of response bias and limiting the depth of understanding of resident experiences that could be achieved in this study.

Despite the perceived acceptability of involvement in the trial, the care home staff highlighted the challenges associated with taking physical measurements with residents and delivering a nutritional intervention protocol in this setting. These barriers included fluctuating mood and capacity of some residents, as well as reference to the high proportion of residents with a primary diagnosis of dementia (75%).[8] Other trials conducted in populations with fluctuating capacity have noted similar challenges when taking measurements such as Tricep Skinfold Thickness[48] and handgrip strength.[43,49] Whilst the residents interviewed felt that the physical measurements were acceptable and not deemed to be time consuming, one resident mentioned that daily mood and individual preferences can sometimes result in a lack of acceptance with an assessment schedule or an intervention.

A theme that emerged only from staff focus groups was the interest in care home staff receiving training to enable them to take anthropometric and functionality measures including Mid Upper Arm Circumference, Tricep Skinfold Thickness and Handgrip strength.

Some felt that this might have been useful within the trial, as a means of enabling measurements to be taken when residents were in a better mood, or having a good day. Others felt that it would be helpful for staff to be upskilled in this way outside of the trial setting, to support in their assessment of nutritional status. The emergence of this theme may be related to the perceived value placed on nutritional screening ('MUST') training by the staff, and their subsequent self-perceived confidence and competence in completing resident screening as part of usual care. Improvements in 'MUST' documentation and accuracy following dietetic-led projects are supported within the literature.[50-51] The interest from staff to expand their skill base could provide scope to introduce more comprehensive staff-led assessments of nutritional status within the care home setting. There are however, challenges associated with taking these measurements, including measurement error due to poor technique and substantial differences when measurements are made on the same individual by different observers.[52] If such an approach were to be implemented in practice, it would require a standardised protocol and regular training updates.

Care home staff perspectives of nutritional interventions and dietetic care in the treatment of malnutrition

A major theme which emerged from the focus group data was the perceived value placed by staff on the nutritional interventions, both food-based (FB) and oral nutritional supplements (ONS), when compared to the standard nutritional care provided by the homes. A common perception amongst the staff was that they would expect the introduction of either intervention to be associated with improved outcomes, particularly weight. They also noted that the families of residents involved in the trial viewed the interventions as valuable and wished the residents to continue beyond the assigned protocol. Good staff knowledge of the nutritional interventions available to address malnutrition, and a positive attitude towards these interventions has been shown previously in the literature,[53-54] demonstrating that this is perhaps an aspect of nutritional care that is familiar to care home staff and is therefore perceived to be of value.

Another theme which emerged from the focus groups was the perceived value of dietetic input, with some staff expressing the opinion that residents requiring nutrition support 'would do better with dietetic intervention' and others mentioning that it was of benefit to have the dietitian visit the home more often. Previous research focusing on the knowledge of care home staff has highlighted the greatest knowledge deficits to be associated with nutrient and food requirements in older adults,[53,55] which perhaps explains the value placed on dietetic expertise by care home staff in this study. As the nutritional interventions used in this trial were delivered by the dietitian, an interesting area for future research, might be to explore the care home staff perceptions of the nutritional interventions (FB or ONS) when delivered without dietetic input.

A prominent sub-theme that emerged in relation to the nutritional interventions was the importance placed by staff on resident preferences and the scope to provide a personalised plan. This sub-theme illustrates a commonality with the feedback provided by residents when discussing the acceptability of the interventions, with some expressing a preference for certain types of oral nutritional supplements and others stating that they would have preferred a homemade drink. The importance of involving residents in decisions about their care, including nutrition and mealtimes has been highlighted by the British Geriatrics Society (2011)[56] and has been shown to be positively associated with quality of life.[57] A recent study by Watkins et al (2017),[58] which used semi-structured interviews to explore resident's experiences of mealtime's concluded that freedom of choice is a key component of their experiences of care. Whilst it may not always be possible for residents to make decisions on all aspects of their care, it is apparent from this study that resident preferences should be considered alongside clinical reasoning when implementing a nutrition support plan. The individualisation of an intervention to suit a client's needs is a core component of

the shared decision making underpinning dietetic practice as outlined within the British Dietetic Association's 'Model and Process for Nutrition and Dietetic Practice'.[59] This study highlights the importance of this approach within the care home setting.

Strengths and limitations

A key strength of this study is that it is the first to inform understanding of the feasibility and acceptability of conducting a clinical trial evaluating nutritional interventions in the care home setting, by exploring the opinions and perspectives of the staff and the residents involved in the trial. The inclusion of care home residents, highlighted as an underrepresented group within the research literature[12] has added to our understanding of their experiences of being involved with research and of nutritional care within this setting. Use of individual interviews gave each resident the chance to freely voice their views. The dynamic interaction of the staff focus groups were perceived by the researcher as open and positive, and provided insight into shared viewpoints within and between care home sites.

A limitation of this study is the small sample size, particularly with regards the number of residents interviewed. The views held by this small sample of residents, who were all female and had capacity, may not be representative of the other residents that took part in the trial and may limit the depth of understanding of resident experiences that can be gained from this study. There was a lack of representation from residents in the FB intervention arm, but a staff focus group was conducted at each care home site, therefore providing representativeness from staff in each arm of the trial, and capturing the views of both nursing and care staff. The directness of quotes obtained from the resident participants has already been commented on, but this was also found to be a feature of the staff focus groups, despite the perceived positive engagement of the participants. The lack of extensive discussion may have been a consequence of the focus groups being held at the care home sites, necessitating the balance of research activities alongside extremely busy care roles[60] The experience of trial involvement also appeared to have been largely acceptable to the care home staff. It is possible that they may have had more to say had they been dissatisfied with the experience or felt that it had increased their workload.

It is possible that the care homes recruited into this study do not necessarily represent the national care home population. All sites had been in receipt of long-term and regular input from the local dietetic service and were engaged in a programme of staff training. The dietitian researcher (RS) had an established relationship with the managers and staff at the homes, which may have made it easier to recruit to and facilitate the staff focus groups. This relationship may also have influenced the participants in giving what would be perceived as more desirable responses. However, with the focus on the exploration of feasibility outcomes to ensure that resident and staff perspectives can be used to inform the design and conduct of future definitive trials, there was not felt to be a desired outcome of this study and the participants were encouraged to say how they really felt. The exploration of staff experiences of feasibility and acceptability was carried out in engaged and motivated care homes, which may limit transferability. However, the focus groups and interviews have informed our understanding of the experiences of trial involvement and the perceived acceptability and value of nutritional interventions from the perspectives of both care home staff and residents.

Conclusions

From staff focus groups and interviews with residents, involvement in a clinical trial evaluating nutritional interventions for malnutrition in the care home setting was perceived as acceptable, although the challenges associated with research in this setting were acknowledged. Both staff and residents agreed that the use of PROMs within the trial was

positive and valuable and that more residents could have completed them. Care home staff demonstrated a positive attitude towards both the nutritional interventions used in the trial, and the value added by dietetic input. Resident preferences were identified as important, because they are likely to affect compliance with an intervention. To ensure that these are accounted for, it is suggested that a nutrition support plan be developed collaboratively between the dietitian and the staff, the resident and their relatives, to meet both the clinical needs and the preferences of the individual.

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COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	21	What was the duration of the inter views or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

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