Author’s response to reviews

Title: A cluster randomised feasibility trial evaluating nutritional interventions in the treatment of malnutrition in care home-dwelling adults

Authors:

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Author’s response to reviews: see over
Dear Editor,

Re: A cluster randomised feasibility trial evaluating nutritional interventions in the treatment of malnutrition in care home-dwelling adults

I am re-submitting the revised manuscript and additional files for this cluster randomised feasibility trial that I would like you to consider for publication in Trials.

Please see below a point-by-point description of the changes made in response to the editorial requests and peer reviewer concerns

**Editorial requests:**

<table>
<thead>
<tr>
<th>Request</th>
<th>Change</th>
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<tr>
<td>1. Please include the date of registration with the trial registration number at the end of the Abstract.</td>
<td>The date that the trial registration number was assigned has now been added at the end of the abstract.</td>
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<td>2. Please include a statement in your Methods section explaining that you obtained informed consent from each participant.</td>
<td>As detailed in the ethical considerations section (under Methods, p.5), the ethics committee requested that the consent, randomisation and intervention take place at the care home level. The interventions and the outcomes measured are all used within usual dietetic care and therefore the committee did not wish for individual consent or consultee declaration to be sought from or for individual residents. However, the committee felt that the inclusion of residents lacking capacity in the collection of PROMs could not be justified in accordance with the Mental Capacity Act, as these outcomes are not collected within usual dietetic care. They therefore requested that individual consent was obtained only from those residents that had the capacity to complete PROMs. This is detailed within the Methods section (p.7).</td>
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<td>3. Please state that all authors read and approved the final manuscript in the Authors’ Contributions section.</td>
<td>This statement has now been added into this section (p.18).</td>
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<td>4. For completed randomised controlled trials, Trials requires the submission of a populated CONSORT checklist and flow diagram.</td>
<td>The completed CONSORT checklist has now been completed as an additional file. The CONSORT flow diagram is attached as ‘Figure 1’ on a separate page. This was also the case with the original submission. Please advise if this does not upload correctly.</td>
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Ruth Stow
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Reviewer One
Minor revisions

<table>
<thead>
<tr>
<th>Concerns noted by the reviewer</th>
<th>How the concerns have been addressed</th>
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<tr>
<td><strong>1. Is the question posed by the authors new and well defined?</strong></td>
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<td>Essentially this trial is examining the relative efficacy of food-based and supplement-based approaches in managing malnutrition in nursing homes. The distinction between these two forms of intervention should be clearer.</td>
<td>Further depth has been added to the Background section of the manuscript to further justify why these interventions have been chosen and why they are being tested separately (p.3-4).</td>
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<td>Also more indication of why these interventions and why are they tested separately and not together. There have been some recent systematic reviews of mealtime interventions (Liu Int J Nursing Studies 2014 &amp; Vucea J Nutr Gerontol Geriatrics 2014) and it might be appropriate to consider these in creating the rationale for this study. Indeed more appropriate strategies such as mealtime assistance, use of dining rooms etc might be better ways to improve nutritional status.</td>
<td>This research was conducted with an intended focus on the ‘real world’ care home setting, to enable the findings to be applied to current clinical practice. As explained within the background section, there are a growing number of nutrition support/prescribing projects, which aim to reduce the cost to GP’s of prescribing ONS and to promote a ‘food first’ approach to addressing malnutrition, particularly within the care home setting. Whilst a multicomponent intervention is likely to be more effective than just one individual component, it was considered important to firstly compare the intervention types that are widely used in clinical practice (ONS versus conventional foods) to determine their individual effectiveness when used with this unique population. This could be helpful when providing clinical reasoning to a GP to commence an ONS prescription (many are now quite resistant to do so), or to care home staff when making a recommendation that a sip feed prescription be reduced or stopped. Having explored the recent literature, it still does not seem as though we have a clear idea as to whether ONS is superior to a food-based intervention of equivalent energy and protein content in the treatment of PEM, therefore this remains an area that requires further investigation. The author agrees with the reviewer that mealtime interventions are important strategies to improve nutritional status. All 6 care homes recruited into this trial had been receiving monthly dietetic input, as well as twice yearly training by the dietitian, prior to trial commencement. As a result of care home staff training and regular focus groups to discuss ‘nutritionally at risk’ residents, the staff in these homes (as well as others across the Solihull borough) were providing assistance with feeding, as well as considering aspects such as the layout and environment within the dining setting as part of their ‘standard care’ for residents with, or at risk of malnutrition. This standard care was continued for all 6 care homes throughout the trial with the ONS intervention added for 2 homes and the FB intervention added for another 2 homes. (p.7-8). Both of the stated references are certainly of interest, but they have not been discussed within this paper when generating the rationale for the trial, because of the difference in focus. The SR by Liu et al (2014) investigates a diverse range of interventions across a variety of settings, with a specific focus.</td>
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<td>Reference 23 is 15 years old and therefore may not reflect current priorities.</td>
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on those with dementia, whilst the Vucea et al (2014) study, looks at mealtime service rather than intervention strategies for malnutrition. The latter reference will however, be very useful to consider when the qualitative phase of this trial is being analysed.

The focus of this trial was to determine the feasibility of investigating whether the dietetic-led ONS or food-based interventions that are widely used in care homes with dietetic input, in addition to the standard care provided by the care homes (which would include mealtime assistance etc.), would have an impact on the nutritional status of the residents. The purpose was really to isolate these quite specific aspects of the interventions that are commonly used in practice, in order to give us a clearer idea of how comparable they are. The results of a definitive trial could then hopefully be used to better inform the prescribing projects, medicine management teams and CCG's about the efficacy of these interventions/intervention components.

Reference 23 has been removed from the manuscript.

<table>
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<th>2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?</th>
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<td>There is no indication of how staff compliance was assessed (it was judged to be 100%). There needs to be a robust assessment of this outcome.</td>
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<td>Interesting compliance was defined as &gt;75%. Is there a rationale or precedent for this or is it simply an arbitrary cut-off?</td>
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<td>The food records were completed using simple fractions to describe the amounts eaten. Is this method validated and was there any training of staff to ensure accurate and consistent completion?</td>
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<td>Where the VAS used to assess appetite etc. validated?</td>
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<td>Some aspects of this trial would be better assessed using qualitative methods eg. acceptability of different elements. In the results section there is some indication that this might have been undertaken. If this is only a partial report of the trial then this should be made clear in the methods section.</td>
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<td>The methods section has been revised and the assessment of staff adherence to the intervention schedule is now described after the assessment of resident compliance with the interventions. The same method was used to determine staff adherence, but it is acknowledged that this was not particularly clear within the original manuscript (p.8)</td>
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<td>The categorisation of compliance has been revised within the methods section. Intake of the FB and ONS interventions was actually recorded as: &lt;50% (1 bottle, or 300kcal), 50%-75% or 75% and over (as displayed within the results section). These cut-offs were chosen in order to determine the acceptability of the dosage often recommended within local nutrition support guidelines (2 ONS servings daily) and to determine the acceptability of the dosage that has been shown to be clinically effective within the literature (300kcal-900kcal). This is now described more clearly in the manuscript (p.8) and is also included in Table 3.</td>
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<td>The VAS’s were completed using simple fractions as this was the method used within all of the care homes recruited, to monitor food intake. As described above, it was felt to be important to test the interventions in the ‘real world setting’, rather than an artificial research setting. Using these FRC’s also enabled the researcher to determine whether this method is useful for current clinical practice, or whether other methods could and should be considered for care home staff. Training on FRC completion was provided twice a year to the staff within all 6 care homes. Training was also provided prior to trial commencement. This information has now been added to the Methods section (p.9-10).</td>
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<td>The VAS were developed for this trial and were then piloted with this population. VAS have been used within care home trials (for example in reference 64), but perhaps not for all of</td>
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the same outcomes (i.e. pleasantness of meals). As this was a feasibility trial, the main objectives in relation to the VAS were to determine the acceptability to staff of providing the VAS tools to residents to complete and the acceptability to residents of completing the tool. Some more detail has been added to the manuscript to address this (p.11).

Some information has now been added on p13. Of the methods to explain the broader methodological framework of the trial. There was a second qualitative phase to the trial, which served to explore further, certain aspects of feasibility and acceptability with care home staff and those residents with capacity.

There was not scope within this MRes project to analyse and report on the qualitative data, although the semi structured interviews and focus groups have been completed. There are plans to report on this elsewhere, but it has now been clarified within the methods of this manuscript.

### 3. Are the data sound and well controlled?

The results address all of the objectives apart from the final one, to calculate the intracluster correlation coefficient. Was this done?

The description of change in outcomes uses the phrase ‘...suggests sensitivity to...' which I don’t understand. I would prefer clearer descriptions which indicate simply what the data show. The 95% confidence intervals for many outcomes suggest that the majority of participants did not experience positive benefits.

Information on the ICC has now been added into the Methods (p.13) and results (p.17) sections of the manuscript. The objective was to ‘collect and synthesise data, from which the Intracluster Correlation Coefficient (ICC) and sample size of a definitive cluster RCT (CRCT) could be estimated’, but not to actually carry out the calculation. The data collected for the outcomes that were shown to be feasible and acceptable to measure could be used for this purpose if a definitive trial is taken forwards.

The phrase ‘suggests sensitivity to’ is recommended to describe the results within the context of a feasibility trial. It was important not to describe the data as though the efficacy of the interventions had been investigated, but to use this data to determine which of the outcome measurements was responsive/sensitive to changes in dietary intake during a 6-month intervention duration.

Some changes have been made to the wording of this part of the manuscript to hopefully make it clearer and easier to follow (p.17).

### 4. Do the figures appear to be genuine, i.e. without evidence of manipulation?

I would question whether tables 1&2 are needed.

The data in table 6, also appears at the end of table 5!

Tables 1&2 have been combined to reduce the number if tables. They have not been removed entirely, because they are required in order to address the comments from the second reviewer.

Table 6 has been removed. This duplication of data was an oversight.

### 6. Are the discussion and conclusions well balanced and adequately supported by the data?

It would be helpful to include a summary of the findings in relation to this trial at the start

A summary of the trial findings has now been included at the start of the discussion (p.18).
of the discussion.

It might be useful to consider the value of lack of training in methods (food intake) as a limitation in collection of food intake data.

Reference 64, I think that Turic et al found an overall benefit to energy intake and weight in favour of supplements. It might be good to check this. Did the authors expect a difference in this trial?

As training on the completion of FRCs was provided to the care home staff, this has not been included as a limitation, however, the limitations of the methods used have been discussed (p.23).

Turic et al found increased energy intake with both food-based and ONS intervention, although the increase was greater with ONS (but it was not clear as to whether the nutritional composition of the interventions was comparable). This reference has been used in the manuscript to support an increase in energy intake with both interventions, not specifically food only (p22.).

In this trial, the research was looking primarily at the feasibility and acceptability of conducting the trial, delivering the interventions and measuring the outcomes, rather than considering any differences in the efficacy of the interventions.

### Reviewer Two

#### Major points

<table>
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<td>It may be that the uptake, did the 6 sites all agree straight away?, was of little value as the homes had already been co-operating with the dietetic service? How many did you approach? You have discussed this issue but it really devalues your aim to look at uptake and am not sure the pilot would help you out in this respect. This seems a flaw and I am not sure it gives you any information to use in the design of a full study.</td>
<td>6 care homes were approached and they did all agree to take part in the research, but in the larger homes this was not a quick process and required meetings with management from head office who had not been in contact with the dietetic service. For some of the large care home ‘chains’, decisions could not be made by the local care home manager. Prior cooperation with the dietetic service and an established rapport with the primary researcher (a dietitian) may certainly have made it easier to access the care homes and this has been discussed in the manuscript, but none of the care homes had previously been involved in research (added on p.6). It is felt that receiving input from an NHS dietetic service (which many, although not all care homes will have), in the same way that the home would access a GP practice, District Nurse teams, or hospital departments, is quite distinct from being involved in a research trial where all residents are screened for malnutrition and all of this data is recorded by the researcher. Within usual care, the homes would screen residents for malnutrition and refer to the dietitian when they required input with particular residents. As such, the contact and visitations would be very much on their terms. It is also of note that the dietetic team in this area was so small that assessments for individual residents were only offered to those at high risk of malnutrition who had not responded to the standard care offered by the home. Involvement in a research trial places quite different demands on the homes and it was therefore very interesting to find out if the care homes would be receptive to taking part in a trial, which could potentially identify high levels of malnutrition and expose poor practice. In terms of the information gained- the recruitment of these homes was useful in several ways. As they were homes visited by the primary researcher (dietitian) in a clinical role,</td>
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<td>It may be that the catering provision in the homes was inadequate, was there any assessment of this prior to the intervention? This seems crucial. If not why not?</td>
<td>As mentioned, all of the care homes had existing input from the local dietetic service. Whilst the capacity of the service to see all residents at risk of malnutrition individually was limited, the dietitian did meet with the chef and catering staff once every one to two months (p.6). Training was provided twice yearly to the catering staff and all of the staff in the homes had received training and support to provide standard care for malnutrition, which is described in the manuscript. From the monthly dietetic visits to the homes, all 6 were considered to be providing adequate standard care (p.8). It is also worth noting that all of these homes were subject to quality visits on a regular basis and CQC inspections and no concerns related to nutrition had been identified.</td>
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<td>The estimates of BMI, were recorded by the care staff, as part of their on-going MUST measures. However, what confidence do you have that they recorded weight and height correctly? This is key to identification of those who are under nourished. Many people would be unable to stand up straight or at all to have their height measures made. I see the scales were chair scales and the same ones. Were they calibrated?</td>
<td>As detailed on p.9 of the manuscript, a repeat ‘MUST’ score was calculated for 2 residents per care home at 3- and 6-months by the primary researcher. This involved the measurement of weight and height and the calculation of BMI, along with the other steps of ‘MUST’. The decision was taken for this data to be collected from the records, because this is what happens in usual clinical practice and is how residents are identified as under nourished. In order to ensure that the findings from this feasibility study could be used both the inform a definitive trial, and to evaluate aspects of current practice, it was important to test the measurement of outcomes in the ‘real world setting’ as opposed to artificial research controlled conditions.</td>
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Some detail has been added about the measurement of height on p.9. This was not included in the original manuscript, because of efforts to keep the word count down. Some detail has also been added into the discussion on p.19. It is standard practice for the care home staff to ask for self-reported height from those residents with capacity, or relatives if this is known, or to measure ulna length and estimate height. This is in accordance with ‘MUST’ and with the current literature for this population.

Some residents were weighed with standing scales and some with hoist scales, but the majority were weighed with chair scales (p. 15). More detail about the requirements for the scales have been added on p. 9. The scales used in care homes have to be class III approved and calibrated regularly (as for healthcare professional scales). This was checked with the staff in each of the homes.

As this is a feasibility study it would be very useful if the details of the intervention concerning food could be explained in more detail. How did you decide on it? This is also very important, as the care homes need to be able to deliver this easily.

Was it expensive? Table 1 seems to list quite a labour intensive group of options. How did they fit to the existing menu? Were they costly?

The approximate cost to the care home of making the FB interventions and the approximate cost to the GP practice if they were prescribing the ONS has been added to Table 1. As stated, the FB options were discussed with the care home staff and catering teams and the options agreed were made using ingredients that they already had and used within the home. No new ingredients were purchased by the homes specifically for this trial.

Within usual clinical practice, a dietitian might recommend that a home make, for example, a fortified instant dessert for a resident and provide this twice daily (hence the desire to determine the feasibility of investigating the efficacy of such an intervention). The training provided to the catering teams within usual practice would include demonstrations of how to make simple fortified snacks and drinks. This is also commonplace within the training provided by other dietitians working in a similar field.

According to your table 4 success criteria point 4, how can you state whether or not this was achieved? How was it assessed? Or was it purely a weight outcome? Or did you use the food diaries?

How did you find out whether these were largely filled out correctly? As you state the researcher was unable to be there? Real world settings mean that you are never going to be sure of the intakes. So why use these at all here?

Point 4 in table 4 refers to the intervention acceptability. Further detail about the measurement of resident compliance and staff adherence have been added into methods (p.7 and p.8). It was assessed by review of the information recorded on food record charts or drugs charts as detailed in the methods, alongside discussions with staff. This is how compliance would be assessed in usual clinical practice and again, it was felt to be useful within this trial to determine the usefulness of this method of recording.

Some information on recording change to intervention type is
If a resident did not tolerate an intervention or experienced a significant decline in nutritional status, a change in intervention was considered by the primary researcher during monthly visits to the care home sites. No residents changed interventions without discussion with the primary researcher and any crossover was recorded and reported upon.

Further information about the use of food record charts has been added throughout the manuscript (most notably on p.8). As mentioned in the manuscript, training had been provided to staff on completing FRCs and FC's (p9-10) and this was again re-visited prior to trial commencement. As referred to already, it was felt to be relevant in this trial, to determine the appropriateness and usefulness of the methods currently being used by care home staff to document intake, along with other means of assessment. Real referrals and clinical decisions may currently be made on the basis of the information recorded on charts such as these. The shortfalls with this method highlighted in this trial can be used to inform clinical practice.

As discussed on page 17, weight and BMI did appear to be sensitive to changes in oral dietary intake, on the introduction of nutritional intervention. There was also a noted increase in energy intake, which is understood to be a key component in the causal pathway leading to improved outcomes. The authors have been cautious not to overemphasise the observed trends due to the feasibility nature of the trial and the lack of complete data for all of the outcomes measured. It would not be possible with a trial of this nature to conclude that the changes in weight are due to the intake of the interventions.

The authors have been cautious not to overemphasise the observed trends due to the feasibility nature of the trial and the lack of complete data for all of the outcomes measured. It would not be possible with a trial of this nature to conclude that the changes in weight are due to the intake of the interventions.

A full economic assessment was not conducted as part of this trial, because the primary focus was to pilot the HCRU questionnaire and find out whether care home staff could and would complete the form. In a definitive trial, this data could be used alongside the costs of the interventions and the health outcomes data to enable cost effectiveness of the interventions to be determined.

As stated in Methods, (p5 and p.7), the PROMs tools and questionnaires were only provided to those residents that had been assessed as having the capacity to provide individual informed consent. The feasibility and acceptability is discussed on page 16, although not in any great depth as the number of residents with capacity was very low (again to avoid increasing the word count of this manuscript further). Those that did have capacity were able to complete the tools, although they needed assistance with reading the questionnaires and marking on answers. This has been explored further within the qualitative phase of the trial, as mentioned in the manuscript, but will be analysed and
I hope that you find this original research of interest to Trials and its readers. The trial has not been previously published and is not under simultaneous consideration by another journal. Please direct all correspondence pre-publication to ruth.stow@nottingham.ac.uk. I look forward to hearing from you.

Yours sincerely

Ruth Stow

Registered Dietitian
Assistant Professor in Nutrition and Dietetics

On behalf of all authors