Reviewer’s report

Title: Effectiveness of oral nutritional supplementation for older women after a fracture: a randomized controlled pilot study

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Reviewer: Angela Vivanti

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Effectiveness of oral nutritional supplementation for older women after a fracture: a randomized controlled pilot study

With an ageing Australian population and the high prevalence of malnutrition amongst those receiving care within our health care services, this is an important issue and area for investigation

Major Compulsory Revisions

The author must respond to these before a decision on publication can be reached. For example, additional necessary experiments or controls, statistical mistakes, errors in interpretation

The study has not been designed in a way that will adequately answer the second objective: “to test the effectiveness of oral supplements on malnourished older people with a fracture”

Several important methodological issues exist,
- The use of albumin alone as an indicator of nutritional status (please see comment to follow)
- The use of self reported weights
- No measure of the proportion of the commercial supplement consumed was incorporated. No assessment of consumption of non-commercial supplements amongst the control group in hospital or at home was provided.
- There appears to be no assessment of the individuals nutritional requirements in order to ascertain that the provided supplements are adequate to meet their nutritional needs, or else the volume of commercial supplement required to meet individuals minimum nutritional needs.

Some of these difficulties were acknowledged by the authors (ie actual compliance, other dietary intake, the standard provision of high protein milk). The authors have recognized the challenges involved with such as study including ensuring consumption, but the implication of this limitation and the means of assessing the volume of supplement consumed is discussed in a limited way (eg a compliance officer). I am of the opinion however, that all the above points need
to be addressed before one can be more confident of the results obtained.

The rationale for the selection of the “dose” of supplementation is also unclear. The energy deficit evident from a weight loss of around 1.5-2.5 kg over the initial few weeks (40 days) indicates that the consumption of at least 2 supplements a day (not one) would be required to prevent the decline in weight and potentially achieve maintenance of nutritional status. The 2 Cal/ml supplement provided certainly has the potential to be very filling which is why particular delivery modes have been trialled and to improve consumption.

Through non-documentation of consumption, the ability to answer the proposed question regarding the effectiveness of commercial supplementation is substantially constrained.

Neither the intervention nor control groups were meeting goal requirements as evidenced by the ongoing weight loss. Consequently, a conclusion of the study appears to be that there is no additional benefit from use of commercial supplements compared with the use of food as supplements.

The step between the act of prescribing a supplement (commercial or food based) and its final consumption is substantially impacted by many systems and organizational issues including, but not limited to, the service delivery models, assistance with consumption, staff encouragement and perceptions of importance. All of these factors seriously impact consumption. Consequently, such systems and organizational issues are also being investigated through the “intention to treat” approach adopted, which is useful to explore once the stated question concerning the actual effectiveness of commercial supplementation has been addressed.

It is often the case that people eat poorly while in hospital. Even with one supplement a day, nutritional requirements are likely not to be met, as evidenced by continued weight loss. Currently, the study has no means of assessing the proportion of goal requirements being attained, even if consuming the supplement. As commented upon in the paper, ways to confirm consumption would strengthen interpretation of the results. It would be valuable to also record the participants overall consumption of either the commercial or food supplement, the energy or protein intake provided and the proportion of nutritional requirement being met. Not just prescribing or receiving supplements but knowing if people are indeed reaching their nutritional goals is the critical factor.

I would suggest the stated aim to “test the effectiveness of oral supplementation” was in fact to “test the effectiveness of oral supplementation compared with the use of regular food as supplements” during a fair portion of the study. Controls received supplementation containing around half the energy and protein of the intervention group. Whether the control group continued additional consumption of food as supplement once home was not ascertained. Both groups were therefore receiving supplementation of energy and protein during their hospital admission, simply different quantities and through different means.
Neither the intervention nor control groups were meeting goal requirements as evidenced by the ongoing weight loss. Consequently, a conclusion from the current study appears to be that there is no additional benefit was evident from use of commercial supplements compared with the use of food as supplements.

Minor Essential Revisions

The author can be trusted to make these. For example, missing labels on figures, the wrong use of a term, spelling mistakes.

Methods

In addition to the overall comments above, some specific comments regarding method are noted below:

The use of self reported weights would not usually be considered acceptable considering it is a key outcome variable. If used, the validity of this approach would need to be assessed and reported with the degree of error factored into the results obtained. Details regarding methods to standardised other weight measurements are not reported.

Could you please elaborate regarding how the consumption of the supplements was confirmed or estimated in hospital.

Could you please report what percentage of participants provided their own consent compared with obtaining consent through next of kin. This other measure would give an indication of cognitive status

Grip strength was performed on dominant hand, but was recorded after i) how many attempts? ii) using average or the best measure.

Could you please include the reference for equation used to estimate height for knee height

The method by which malnutrition is defined is very important. Albumin is sensitive and reduces with acute illness or after surgery and so is not a useful discrete indicator of nutritional status. Plasma proteins are sensitive to the severity of illness rather than indicating nutritional status.


As stated in Watterson et al, 2009 “Single parameters, such as CAMA (corrected arm muscle area), BMI (body mass index) and albumin, have some evidence of
predictive validity however, screening tools with at least two parameters are recommended because there is evidence that they have higher sensitivity and specificity at predicting nutritional status.” The use of MUAC (Mid upper arm circumference) is appropriate as a monitoring and outcome measures to demonstrate improved patient, clinical and cost outcomes as it takes into account both body fat and muscle changes (Watterson et al, 2009). Consequently, it may be worth exploring results of those with low MUAC alone or changes in MUAC alone, as separate from those with low albumin or changes in albumin.


Results
Some specific comments regarding results are noted below:

Weight was declining and continued to decline, so a serious question exists as to whether the participants nutritional requirements were in deed being met.

I would suspect the length of stay is skewed data. If this is the case presentation as median and range rather than means and SD would be more appropriate.

(An Endnote typographical error noted: Miller 17 in the discussion, but listed as 18 in the references)

Discussion -
Considering the albumin is sensitive to disease severity (and not necessarily a sensitive indicator of malnutrition when used on its own) it may not be a surprise that it predicted hospital stay.

The ongoing weight loss suggests there are in fact 2 malnourished groups, who both continue to be malnourished as it could not be confirmed that the supplement provision was adequate to address the intervention groups actual requirements. Unless enough supplement is consumed to slow or cease weight loss (intermediate outcome measures), the impact of supplementation upon other outcome factors including recovery rates, complications, length of stay and need for assistance cannot be confidently ascertained.

Overall comment – this is an important topic implemented in a population deemed to increase with in health service provision.

Key limitations or issues for discussion (as well as for consideration in future study includes -

1) The definition used to assess malnutrition
2) Proportion of goal nutritional requirements met through prescribed supplementation (commercial or high protein milk) (as weight loss continued)
3) Proportion of nutritional requirements met and the compliance with supplement provision (for both groups, for both home and hospital)

Without knowing the consumption and the adherence of intakes, the fundamental question of the value of the supplement provision cannot be answered.

Discretionary revisions:
Were any power calculations completed to estimate the sample size required.
Could I suggest removing the term “only” from the statement regarding one death

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
'I declare that I have no competing interests'