

## **Author's response to reviews**

**Title:**NutOrMed-Optimising nutrition, oral health and medication for older home care clients-study protocol

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**Author's response to reviews:** see over

**Dear** Mr Ian Dominique Trinidad on behalf of Dr Catia Cornacchia

We wish to thank you and all the reviewers for your interest and excellent constructive comments on our manuscript: MS: 2000903579138644 - NutOrMed: Optimising nutrition, oral health and medication for older home care clients

We revised the manuscript in the light of the comments. Our replies to all comments are listed in detail below. Beside this cover letter, we uploaded two files; the marked version showing the changes made on the manuscript and the actual revised version.

On behalf of the author team  
Yours sincerely,

Miia Tiihonen

Editorial comments:

**The TRN included below the abstract section and abstract as the second page in your manuscript file.**

Reviewer(s)' Comments to Author:

Reviewer #1

*Methods*

*Participants and setting*

You should explain about community I, II and III in detail. If community I, II and III are different situations, this study design is not suitable.

**The communities were localized in middle or Eastern Finland in the area of one out of five university hospital district in Finland e.g. district of University Hospital of Kuopio (total population of this area 817 166). Additionally, Finland is ethnically homogenous and municipalities have responsibilities to run social and health care including home care according to the national framework.**

*Dental hygienist interview and clinical examination:*

The questions and oral health examination is explained in detail in manuscript page 9-10:

**Trained dental hygienists interviewed the participants prior to a clinical oral health examination based on written, patterned instructions. The interview included first questions about use of services (treatment place during last visit to dental care, time since last visit to dental care, reason for not having visited dental care) and self-perceived need for care. Next the participant were asked about self-reported oral health (perceived oral health, pain and discomfort related to teeth or dental prosthesis, oral health-related quality of life, eating problems caused by teeth, sense of dry mouth), presence of removable dental prosthesis, oral health-related behaviour (tooth brushing frequency, use of tooth cleaning devices, cleaning**

and overnight storage of removable dental prosthesis, cleaning of oral mucosa), and problems related to cleaning of teeth and mouth.

The clinical examinations were also conducted at participant's home according to WHO instructions (WHO 1997) and with help of a mouth mirror, a WHO's periodontal probe (natural teeth), and a headlamp. Participants were either sitting or lying down. The subjects were first asked about need for antibiotic prophylaxis in dental care and if answered yes, periodontal measurements were excluded. At first type and location (full or partial denture separately in upper and lower jaws), need for repair (yes/no), and hygiene (good if plaque or tartar not shown) of removable dental prosthesis were examined outside the mouth. Possible pain related to use of prosthesis was also asked. Intraoral examination began with examination of oral mucosa using dental mirror and gauze. After this number and location, as well as condition of teeth were recorded as follows: sound, filled with no need for repair, fractured with no caries, carious, root caries, radix without caries, missing, or not able to examine. Tooth mobility was defined with one finger and instrument and registered as none, 1-2 teeth mobility, or 3 or more teeth mobility. Spaces of dental arch were recorded separately in upper and lower jaw by sextants as follows: none, space present but filled by removable prosthesis, fixed prosthesis, or implant, and space present but not filled. Presence of plaque was registered according to modified Silness & Løe (1964) index from each teeth and recorded as none, found at gingival margin only, found also elsewhere, or not able to examine/tooth missing. Presence of gingival bleeding on probing was measured for each teeth except for wisdom teeth and recorded as yes, no, or not able to examine/missing tooth. Depth of periodontal pockets was measured with a ball-ended WHO periodontal probe at four points (distal angle, midpoint of the buccal site, midpoint of the lingual site and mesial angle) and recorded by tooth according to the deepest probing pocket depth (PPD) as no pocket, pocket of  $\geq 4-5$  mm, or not able to examine. The examination was performed according to the asepsis of dental principles and ethical guidelines.

WHO. Oral health surveys. Basics methods. 4. Edition. Geneva: WHO, 1997.

Silness J, Løe H. Periodontal disease in pregnancy. II. Correlation between oral hygiene and periodontal condition. *Acta Odontologica Scandinavica* 1964;22:121-135.

### *Statistical analysis*

*You should explain a regression analyses in detail.*

Regression analysis is a statistical process for estimating the relationships among variables. It includes many techniques for modeling and analyzing several variables, when the focus is on the relationship between a dependent variable and one or more independent variables. Linear models predict a continuous target based on linear relationships between the target and one or more predictors. Logistic regression is useful for situations in which you want to be able to predict the presence or absence of a characteristic or outcome based on values of a set of predictor variables. It is similar to a linear regression model but is suited to models where the dependent variable is dichotomous. Logistic regression coefficients can be used to estimate odds ratios for each of the independent variables in the model. Logistic regression is applicable to a broader range of research situations than discriminant analysis. Multinomial Logistic Regression is useful for situations in which you want to be able to classify subjects based on values of a set of predictor variables. This type of regression is similar to logistic regression, but it is more general because the dependent variable is not restricted to two categories.

**The primary outcome measures in oral health is improvement in oral health status measured by clinical oral health examination and in-home interview (self-reported oral health). The effects of the intervention (the percentage point differences in changes between the intervention and control groups) will estimate using a generalized linear model with binomial distribution and the identity link function. The baseline value will include as a covariate in the model to control for baseline differences.**

Reviewer #2

*1. The title should indicate that this is a protocol.*  
**“study protocol” was added in title**

*Methods*

*2. There should be a better description of the study design than “trial”. It appears to be a non-randomized prospective intervention study of three groups of people.*  
*The study design would be stronger if a cluster randomized design was used.*

**Study design is described as a multidisciplinary intervention study.**

*3. How are each group to be chosen to receive intervention or no intervention and what strategies are to be used to minimize bias.*

**Intervention group was in one city and persons in control group located about mean 100 km away from the intervention location to prevent that intervention effect was nor possible contamination of the control group.**

**To minimize bias: Same investigators (nutritionist, pharmacist, dental hygienist) went through the interviews in each city. Home care nurses were those who who took care of the each home care client on daily basis. However, all nurses were trained by one person from the university. We had no exclusion criteria regarding age except inclusion criteria age of 75 years or older, morbidity or cognition (which are often used as exclusion criteria in previous studies). If the participant had cognitive impairment, data was supplemented by care giver, family member or by home care nurse.**

*4. The first two groups are described as ‘a random sample’ . How was the random sample achieved. The method should be described. The third group is described as a ‘total’ sample. What does this mean? Was this also a random sample and if so how were they chosen?*

**Randomization inside communities I and II to participate to present study was achieved using coded list of home care clients and SPSS random sample tool.**

**Total sample: To maximize the number of participants in city III, all home care clients had possibility to participate. Differences between the demographics in three groups participating in this study were not found at the baseline.**

*5. The purpose of the third group is unclear. Are both groups 2 and 3 control groups and if so why two control groups. This should be justified.*

**Groups 2 and 3 are both control groups. Both groups were included to maximize the number of participants and to make sure that control group presents general home care population in**

**Finland. There were no statistically significant differences between the demographics in three groups participating in this study at the baseline.**

*6. The description of the power calculation is weak and lacks detail. If the study is powered on change in MNA score then there must be a size of change in score that will be both clinically meaningful and also that relates to the numbers needed. The literature that has informed the choice of size of change in score should also be cited.*

**The sample size calculation is estimated based on MNA with the objective to detect an increase in MNA of 0.9 in the intervention group. In our previous study, the standard error of the mean in change in MNA was 0.36 and the standard deviation 3.0 (Nykänen et al. 2014). Former study has a comparable population (risk of malnutrition) to this study, so it was assumed that the standard error and standard deviations are also comparable. Furthermore, a power of 80% and a two-sided alpha of 0.05 was used. Based on these assumptions, 80 people in each group are needed.**

**Nykänen I, Rissanen TH, Sulkava R, Hartikainen S. 2013. Effects of individual dietary counseling as part of a Comprehensive Geriatric Assessment (CGA) on nutritional status: A population-based intervention study. J Nutr Health Aging. 2014;18:54-58.**

*7. Page 7: The biochemical measures relevant to nutritional status should be described to minimize the risk of selective reporting at a future stage.*

**Serum albumin is considered the most accurate indicator of a patient's protein store and so the main indicator of depletion of body protein stores and indicating the protein malnutrition. The half-life of albumin is approximately 20 days, so it represents protein nutritional status from the previous weeks or a month. Although there is no national standard or consensus, a serum albumin level of 3.5 grams/dL is usually considered low. There are also other reasons for low serum albumin levels. These are acute health disasters like septic infections and nephrotic syndrome, that can lower serum protein levels.**

**Covinsky KE, Covinsky MH, Palmer RM, et al. Serum albumin concentration and clinical assessment of nutritional status in hospitalized older people: different sides of different coins? J Am Geriatr Soc. 2002;50(4):631-637.**

**Kyle UG, Unger P, Mensi N, et al. Nutritional status in patients younger or older than 60 y at hospital admission: a controlled population study in 995 subjects. Nutr. 2002;18(6):463-469.**

**Prealbumin has a half-life of 1 to 3 days; therefore, levels respond quickly to protein deprivation and nutritional intervention. It has become a vital objective tool in evaluating acute nutritional changes. Prealbumin is considered a more reliable indicator of the patient's nutritional status. Prealbumin levels respond rapidly to nutritional support and are often used as an indicator of the effectiveness of the feeding intervention.**

**Potter MA, Luxton G. Prealbumin measurement as a screening tool for protein calorie malnutrition in emergency hospital admissions: a pilot study. Clin Invest Med. 1999;22(2):44-53.**

8. Page 8: *The MNA is described as a validated screening tool but in fact also includes elements of assessment. It would be good to revise the description and consider the strengths of this tool.*

**The mini-nutritional assessment (MNA), designed specifically and validated for older people, has a full version of 18 questions. The MNA test fulfills many criteria for screenings instruments and definitive assessment tools. The MNA test was developed and validated on large representative samples of older persons, and has been shown to be clinically useful (Vellas et al. 2006). MNA is the reference instrument, recommended by The European Society for Clinical Nutrition and Metabolism (ESPEN) (Kondrup et al. 2003). With clinical examination as gold standard, the sensitivity and specificity of MNA are respectively 96% and 98%.**

9. Page 9: *The word ‘anamnesis’ would be better as ‘nutritional history’.*

**The word ‘anamnesis’ was changed to ‘nutritional history’.**

10. *It is very unclear who delivered the nutritional intervention and this should be described. The flow diagram implies that it might have been home care nurses, in which case were they trained to do this or were standard protocols used.*

**“The evaluation of nutritional status and eating habits was carried out by a nutritionist. She examined weight, height and daily eating routines with a 24-hour diary. “**

11. *Table 1, appears to describe three different types of intervention given according to the ‘type of malnutrition’. Is the MNA valid to determine these different nutritional situations. Serum albumin is an unreliable marker of nutritional status and yet a lot of weight is being placed on this in guiding the choice of intervention. Although I am supportive of providing nutritional intervention to patients identified as at nutritional risk, the usual process would be to maximize overall nutritional intake from a balanced and mixed diet rather than focusing on either energy or protein. If the strategy of three different interventions is to be pursued then the details of each intervention, corresponding to 1,2 & 3, in terms of actual foods, should be provided.*

**MNA is designed to find the people in nutritional risk before severe visible changes occur (Vellas et al. 1999). The MNA gives professionals who take care of these older persons, a unique opportunity to design specific care plans for prevention and nutritional intervention (Vellas et al. 2006). The complete MNA includes an item for current weight (Kondrup et al. 2003). The MNA scores have been found to be significantly correlated to biological nutritional parameters for albumin (Vellas et al. 2000).**

**Serum protein has been used to assess nutritional status in older persons (Sergi et al. 2006). It is shown that serum albumin decreases when risk of being classified malnourished increases (Cristensson et al. 2002). It is well known that serum albumin is affected by other factors than nutritional status, such as dehydration and inflammation (Govinsky et al. 2002, Hudgens et al. 2004, Langkamp-Henken et al. 2005). Serum albumin level alone is not a good evaluation method, but in home care situations, where the laboratory test is taken, serum albumin gives additional information (Covinsky et al. 2002) and might inform malnutrition risk earlier than changes in anthropometrical measures can be seen (Dormenval et al. 1998). The study of Sergi (2006) et al. that low values still in normal range should be carefully evaluated because they could suggest a poor nutritional status.**

**Noteworthy observation was that many home care clients were normal weight or even over weight; but also malnourished. For health care professionals it is difficult to see protein or micronutrient deficiency behind the overweight (Villareal 2004). When malnutrition, obesity and frailty connected among old people speak “fat frail” (Morley 2001). A study of Sánchez-**

Carsía et al. (2007) reported that overestimation in the number of overweight may lead to the underestimation of malnutrition.

The individualized treatment strategy for each participant was designed by the nutritionist according to the participant's medical and nutritional characteristics. The main aim of the intervention was to help participants improve the wholesomeness of their diet in line with Finnish recommendations by increasing the frequency of meals and/or adding energy (if necessary) and proteins to the meals without nutritional supplements. During the first nutritional treatment meeting, the authorized nutritionist collected important information, such as the client's history of health problems, current dietary intake and specific nutritional problems, food preferences and appetite status. Based on this evaluation, the nutritionist helped the participants draw up their own meal plan with enough energy and proteins. Special leaflets covering, for example, snacking, were handed out.

**1 st intervention Energy-Malnutrition:** To fortify food with energy can be augmented for example vegetable oil also butter margarine and cream, spreads or other, energy sources can be added to soups, porridges and other appropriate foods. Food items with poor energy or nutrient content should be avoided. Meals suitable for older people are often small, and they should be served frequently.

**2 nd intervention Protein-Malnutrition:** To divide protein intake equally among meals using sources of protein for example meat, fish, beans, peas, eggs, nuts, seeds, milk and cheese in diet.

**3 th intervention Protein-Energy-Malnutrition: Breakfast:** For example porridge made with milk plus added cream and sugar, bread with butter or margarine, cheese and bacon. **Main meal:** meat, fish, chicken or eggs and include potato, rice or pasta, vegetables or salad with added butter/margarine and grated cheese, dressings, gravies or sauces. **Snack:** yoghurt and berries and fruit.

*12. Page 9: How will effectiveness of intervention be assessed?*

The participants will categorize into two groups, the intervention and the control group. Statistical comparisons will be made between the groups at baseline using chi-square test or t-test, with  $\leq 0.05$  considered significant. The results were expressed as means or frequencies with standard deviations (SD) or percentile. The different model of linear regression will be used to assess the effects of the nutrition between the baseline and the end of intervention results. The results were reported as adjusted mean differences in MNA scores, body weight, BMI and serum albumin.

**Changed in manuscript:** A regression analysis will be used to measure the effectiveness of intervention over the follow up period.

*13. Page 9: The method used to undertake 24 hour dietary recall should be described. Who did this and what is the method valid to measure in this situation.*

Nutritionist examined daily eating routines with a 24-hour diary. The nutritionist asked a participant to recall all food and drink during previous 24 hours. She administered a 24-hour recall via paper records to estimate energy and macronutrient (protein, carbohydrates and fat) intake.

**For energy and macronutrients (protein, carbohydrates and fat) estimating group means that is to get an average of intake for a group of participants. 24 hours recall is quite adequate and as we noticed in the pilot study, older people have often routine like day-to-day diet. This assessment may have had some inaccuracies such as possible biases caused by cognitive problems, perception and conceptualization of food portion sizes. However, participants with cognitive impairment had a caregiver or a nurse (who were familiar with the eating habits) with them during the interview.**

*14. I would like to see change in weight and BMI as outcomes as these will allow comparison with other similar studies within systematic reviews. At present it would be impossible to compare the nutritional outcomes of this study with others that are similar.*

**MNA include both change in weight and BMI.**