Multidisciplinary Nutritional Support for Undernutrition in Older Adults in Nursing Home and Home-Care is Cost-Effective

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Abstract

Few intervention studies have evaluated the cost-effectiveness of nutritional support among frail older adults and none of these have been multidisciplinary.

The aim of the study was to assess the cost-effectiveness of multidisciplinary nutritional support for undernutrition in older adults in nursing home and home-care identified with the validated Eating Validation Scheme (EVS).

The design was an 11 week cluster randomized trial with setting (home-care or nursing home) as the unit of randomization. Before the start of the study a train-the-trainer intervention was performed involving educated nutrition coordinators. In addition, the participants assigned to the intervention group strategy received multidisciplinary nutrition support. Focus was on treatment of the potentially modifiable nutritional risk factors identified with EVS, by involving physiotherapist, registered dietician, and occupational therapist, as relevant and independent of the municipality’s ordinary assessment and referral system. Outcome parameters used for the cost-effectiveness analysis were costs and time of the intervention, quality of life (by means of Euroqol-5D-3L); and change in weight. Respectively, 55 (46 from home-care) and 40 (18 from home-care) were identified by EVS and comprised the intervention and control group.

A difference was seen after 11 weeks in quality of life (0.758 ± 0.222) vs. 0.534 ± 0.355, p = 0.001). Even though a small gain in weight was observed in the intervention group there was no difference in change in weight. The effect on quality of life, measured in terms of Quality-Adjusted Life Year (QALY) gain relatively to the control group, gave a cost-effectiveness ratio of DKK 46,000 per QALY gained which compares reasonably well to other interventions found worthwhile in the Danish healthcare sector.

Keywords: Nursing home; Home-care; Quality of life; Weight; Quality-adjusted life year.

Introduction

Older adults in nursing home and home-care are a particularly high-risk population for weight loss or poor nutrition [1]. In Denmark, as many as 50% of older adults in nursing homes suffer from unintended weight loss and, app. 20% of the residents and 12% of the clients have a Body Mass Index (BMI) below 18.5 [2,3].

The negative consequences of undernutrition, i.e. increased risk for morbidity and mortality, impaired cognitive, physical, and social function and hence reduced the quality of life, and increased health care costs, hospital stays, more general practitioner visits, more intensive nursing care, increased requirement of nursing home-care etc [1].

A Dutch study showed the extra cost for managing nursing home residents at risk of undernutrition at 8.000 euro per nursing home resident and 10.000 Euro for undernourished residents [4]. And Danish, Swedish and a Norwegian study have shown that older adults respectively in nursing homes and home-care, who are undernourished, need more assistance with Activities of Daily Living (ADL) than older adults who are in good nutritional status and due to that, may add to the substantial and costly burden of care [3,5,6].

Several potentially modifiable nutritional risk factors increase the likelihood of weight loss or poor nutrition [7,8]. Even though there is an increasing evidence that the use of Oral Nutritional Supplements (ONS) among nursing home residents improves weight and reduces mortality [9], the evidence for a benefit among older adults in home-care is very limited [9]. In addition, a much more structured and multidisciplinary approach, focusing on the significant modifiable nutritional risk factors (e.g. eating dependency, chewing and swallowing problems) and involving e.g. dieticians, occupational therapists, physiotherapist, may achieve additional benefits. Recently, the Danish National Board of Social Services, therefore, developed...
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and validated a nutritional tool, Eating Validation Scheme (EVS), which is designed to use among nursing home residents and home-care clients. In Denmark, home-care services for old people are almost exclusively the responsibility of the local authorities. The basic purpose of home care is to provide assistance with basic housekeeping and personal care. This includes a variety of tasks performed by the helpers, and a wide variation in the amount of help received by different clients.

EVS consist of a combination of formerly validated tools, and is designed to use among nursing home residents and home-care clients [10]. EVS contains information about eating habits, recent unintended weight loss and the presence or absence of nutritional risk factors (eating dependency, chewing and swallowing problems, acute disease or acute change in chronic disease) with the aim of using these information's in a multidisciplinary approach as needed. The information is combined to give a total number of points; 0 point (no risk); 1 point (at risk) and 2 points (intervention) [10]. In contrast to other nutritional tools developed for older people, EVS includes both a screening part and an intervention part. The Danish National Board of Social Services plans to implement EVS all over Denmark. However, the EVS has only been tested in a small unpublished pilot study, including a train-the-trainer intervention and nutrition coordinators. These results need to be confirmed by a proper randomized controlled trial, where the benefits of a multidisciplinary nutritional intervention aimed at residents and clients, who are identified by means of EVS, are assessed.

In addition, up till now a few intervention studies have evaluated the cost-effectiveness among frail older adults. Recently these studies were summarized in a systematic review [11]. The authors concluded that the use of ONS or enteral feeding nutrition in the management of undernutrition could be efficient from a health economic perspective [11]. Only two of the studies included in the review were performed among nursing home residents and home-care clients and the main focus was on reduced cost due to lower prevalence of morbidity and hospital admissions [11]. The costs of e.g. dieticians and other health care staff providing the ONS and enteral nutrition were not included.

Furthermore, none of the studies included in the review focused on the quality of life and none used a multidisciplinary approach. It could be expected that such a multidisciplinary approach would be accompanied by higher health care costs than usual care, due to the additional staff and assistance of physiotherapist, registered dietician, occupational therapist, etc., especially in home-care where these staff groups are not always present. But it could also be expected that these higher costs are negligible compared with increased quality of life and the cost-savings can potentially generate.

The aim of this study was to assess the cost-effectiveness of multidisciplinary nutritional support for undernutrition in older adults in nursing home and home-care.

Methods

Details about the methods used in the study can be found in Beck et al. [12]. A brief description is given below.

The study comprised all three home-care areas in the Municipality of Frederiksberg, with a specific focus on participants receiving assistance with meals. Furthermore, two nursing homes had accepted an invitation to participate. The design was an 11 week cluster randomized trial with setting (home-care or nursing home) as the unit of randomization. The study comprised all three home-care areas in the Municipality of Frederiksberg, with a specific focus on participants receiving assistance with meals. Furthermore, two nursing homes had accepted an invitation to participate in the study. The duration of the study was based on the length of former nutritional intervention studies using ONS where a benefit has been proven on both weight, cost-effect and mortality [9,11]. Before the start of the study a train-the-trainer intervention was performed involving educated nutrition coordinators.

In addition, the participants assigned to the intervention group strategy received multidisciplinary nutrition support. Focus was on treatment of the potentially modifiable nutritional risk factors identified with EVS, by involving physiotherapist, registered dietician, and occupational therapist, as relevant and independent of the municipality’s ordinary assessment and referral system, see figure 1.

In brief the intervention group received nutritional support consisting of;

1. Individual dietary counselling by a dietician including advice on the use of prescribed ONS;

2. 30-45 minutes of resistance type exercise by a physiotherapist two times per week, either in groups in one of the participating nursing homes or alone in the participants own home in combination with the intake of 150 mL ONS (“training” supplement) providing an average of 1010 kJ and 14.4 g of protein per 100 mL and

3. Dysphagia assessment and treatment, including texture modification of food and drinks, by an occupational therapist, as needed.

The intervention contained a formalized multidisciplinary collaboration including a meeting once in a week to discuss, evaluate and adjust the multidisciplinary support of each of the participants.

The physiotherapists documented the consumption of “training” supplement (recorded as 1, ⅔, ⅓ or ¼ portion consumed). After each exercise bout, the physiotherapist recorded each participant’s attendance, training intensity, and potential adverse events. The registered dietician and occupational therapist documented number of visits, reasons for cancelling appointments and possible problems with the suggested intervention strategies.

The primary outcome parameter was the quality of life (by means of Euroquol-5D-3L). Secondary outcomes were physical performance (30-seconds chair stand), nutritional status (weight, and hand-grip strength), oral care, fall incidents, hospital admissions, rehabilitation stay, moving to nursing
The effects of the intervention were measured both in terms of changed body weight and as a change in the quality of life, measured in QALYs on the basis of the Euroqol-5D-3L measurements. Time used for the different tasks was registered and used in the calculations. The cost of the intervention included the cost of screening, the cost of the multidisciplinary nutritional support, including costs of “training” supplement provided during the exercise, the cost of travelling (set to 30 minutes for each home visit), and cost of education of nutrition coordinators for the train-the-trainer intervention. Specifically for the dietician 45 minutes was the time set for the initial counselling and 30 minutes for each follow-up; for the occupational therapist the time set for each counselling was 30 minutes. For both dietician and occupational therapist, the same time set was used, regardless of whether the counselling was by telephone or by a home visit. Hence, the differentiation in these costs was in relation to the time used for travelling.

The results were compared to other interventions in healthcare, and the uncertainties in the assessments were illustrated by suitable sensitivity analyses (Figure 1).

**Statistical Analysis**

Based on a former study of multidisciplinary nutritional support among another frail group of older adults; hip fracture patients; which found a significant difference between intervention and control group in the Euroqol-5D-3L follow-up score of 0.145 ($p = 0.004$) after 3 months it was calculated that two groups of 65 older adults would be sufficient (with a statistical significance level of 0.05 and a power of 80 %) [12].

Based on the results of another former study using another measure of the quality of life among nursing home residents, we estimated that the effect on quality of life of living conditions, i.e. in a nursing home or in the own home were limited [13]. This was confirmed in a post-study one-way ANOVA of the EQ-5D-3L data which resulted in an Intra-Correlation Coefficient (ICC) of 0.2627. Hence the main factor “setting” (home-care or nursing home) contributed with 26% to the variance in the quality of life. Thus, the impact of “setting” was relatively limited.

All statistical analysis was performed using SPSS for Windows. Data was entered in EXCEL and was subsequently exported into SPSS software for analysis. Data was analysed by the Primary Investigator who was re-blinded for the results of randomization. All participants were included in the analysis, regardless of whether they had completed the study or not. Depending on the data type and distribution t-test, Mann-Whitney U test, Kruskal-Wallis test, Pearson’s Chi-square or Fishers exact test was used to compare changes within and between the groups. We estimated that the participants from the nursing homes would have more cognitive and ADL-problems and therefore made the comparisons also according to living conditions.

**Results**

Before the start of the intervention, 389 older adults (221 from home-care) had been screened with the EVS. Of these 143 was excluded, because; they were not able to complete the planned tests according to the staff caregivers (N = 75); they were hospitalized at the start of the study (N = 9); they died before start (N = 14); the result of the EVS was missing (N = 9), no reason...
given \((N = 1)\). A total of 25 declined the invitation to participate. Hence, 246 older people (106 from home-care) were included in the study. The participants differed from the non-participants since there were more women; they were older; had less home nursing and fewer had 2 points in EVS (data not shown).

Details about the participants in the different clusters and a comparison between participants from, respectively, home-care and nursing homes at baseline, and the effect of the intervention in the two settings will be presented in another article. The results presented below are mainly focussing on those which were relevant for the cost-effectiveness analysis.

**Baseline characteristics**

Respectively, 55 (46 from home-care) and 40 (18 from home-care), of these older people were identified with 2 points according to EVS and their baseline characteristics are presented in table 1. Due to the cluster randomization there was a higher prevalence of participants from nursing homes in the control group, and hence also a higher prevalence of ADL problems (56 vs. 73%, \(p = 0.093\)) and cognitive problems (56 vs. 78%, \(p = 0.030\)). Furthermore, the number of modified 30-second chair-stands was lower in the control group (4.9 (± 3.3) vs. 2.5 (± 2.7), \(p = 0.004\)). In spite of that there were no differences between the two groups, in the quality of life measured by Euroqol-5D-3L (0.6856 (± 0.2408) vs. 0.6282 (± 0.3324), \(p = 0.646\) (Table 1).

**The multidisciplinary nutritional support**

The control group received more standard interventions from physiotherapist (25% vs. 5%, \(p = 0.013\)) and occupational therapist (10% vs. 0%, \(p = 0.028\), but not from the registered dietician (5% vs. 2%, \(p = 0.569\)) or care dentistry (4% vs. 2%, \(p = 0.547\)) requested through the municipality’s normal assessment and referral system, than the intervention group.

With regard to the residents in the intervention the most frequent multidisciplinary approaches involved all three groups (26 %) or registered dietician and physiotherapist together (26 %).

A total of 32 (58%) participants received the physiotherapist intervention, 10 (18%) received group exercise and 22 (40%) received individual exercise at home. Participants completed 12 (26 %) or registered dietician and physiotherapist together (26 %) of the offered exercise sessions and after these training bouts drank ¾ or more of the “training” supplement. The primary cause for not participating in the exercise was an acute disease. No one dropped out and no adverse events were registered.

A total of 41 (75%) participants received the dietician intervention and had on average 4.5 home-visits or contacts by telephone with the dietician. Oral nutritional supplements were recommended for 26 (63%). No visits were cancelled.

A total of 21 (38%) received the occupational therapist intervention and had on average 3 home-visits or contacts by telephone with the occupational therapist. No visits were cancelled.

A significant difference after 11 weeks in the final quality of life (0.758 (± 0.222) vs. 0.534 (± 0.355), \(p = 0.001\)), change in quality of life (0.0368 (± 0.187) vs. -0.089 (± 0.346), \(p = 0.017\)), final 30-seconds chair stand (3.9 (± 5.49) vs. 1.6 (± 3.6), \(p = 0.048\)), final modified 30-seconds chair stand (4.9 (± 3.7) vs. 2.3 (± 2.9), \(p = 0.005\)), improved 30-seconds chair-stand (47 vs. 17%, \(p = 0.005\)) and final oral care (1.1 (± 0.3) vs. 1.3 (± 0.5), \(p = 0.021\) was observed between the intervention and control group, see table 2. No other differences were observed, however there was a tendency to a difference in mortality, which appeared lower in the intervention group (2 vs. 13 %, \(p = 0.079\)).

The results from the total group were reflected in the results found for, respectively, the nursing homes, the home-care and the individual clusters (data not shown) (Table 2).

**Economic evaluation**

In the economic assessment, it is investigated whether the program of nutritional support is cost-effective, in the sense that the effects, measured either in body weight increase or in the quality of life, is obtained at a reasonable cost. This assessment pertains to a future implementation of the program, using the results obtained from the trial.

The cost of the program of nutritional support consists of an initial screening of all potential participants and subsequent costs of carrying out the program for the individuals selected. In order to obtain a correct measure of the cost of obtaining additional body weight or additional quality of life, it was necessary to add the screening cost also for individuals not selected for additional nutritional support. These costs, as well as those arising from carrying out activities, were found using the registered data on time spent together with assessments of hourly wages for the relevant categories of staff, see Table 3.

Combining these cost assessments with the effects of the program, cost-effectiveness measures could be obtained, either in the form of cost in DKK per kg gained body weight, or alternatively, using the results on health-related quality of life obtained, as cost in DKK per QALY gained from the program. These results are shown in the first row of Table 4, which also displays the results of the sensitivity analysis, showing how the basic result is modified if some of the underlying assumptions and assessments are modified. In general, the results obtained were rather robust, showing that although the effect in terms of absolute increase in body weight is rather modest, there is a reasonable gain if compared to what would have happened otherwise, and comes at a cost of approximately DKK 8,500 per kg. The effect on health-related quality of life, measured in terms of QALY gain relatively to the control group, gives a cost-effectiveness ratio of DKK 46,000 per QALY gained the present program of nutritional support is cost-effective, in the sense that

**Discussion**

The present study found that a multidisciplinary nutritional support for undernutrition in older adults in nursing home and home-care identified with 2 points according to EVS were
### Table 1: Characteristics of participants at baseline with 2 points according to Eating Validation Scheme.

|                          | Intervention | Control | p-value b) |
|--------------------------|--------------|---------|------------|
| Women, N (%)             | 41 (75)      | 30 (75) | 0.960      |
| Age, year, mean (± SD)   | 86.0 (8.4)   | 87.3 (7.6) | 0.678     |
| Living in a nursing home N (%) | 9 (16)   | 22 (55) | <0.001     |
| Weight, kg, mean (± SD)  | 56.9 (11.5)  | 57.1 (11.1) | 0.762     |
| Height, m, mean (± SD)   | 1.66 (0.08)  | 1.64 (0.1) | 0.181     |
| BMI mean (± SD)          | 20.7 (4.0)   | 21.1 (3.3) | 0.445     |
| BMI < 18.5, N (%)        | 18 (33)      | 10 (26) | 0.494      |
| Hand-grip strength, max kg mean (± SD) | 16.0 (8.6) | 13.5 (6.3) | 0.244     |
| 30-seconds chair-stand mean (± SD) | 3.6 (5.0)  | 2 (3.8) | 0.181     |
| 30-seconds chair-stand modified, mean (± SD) | 4.9 (3.3) | 2.5 (2.7) | 0.004     |
| Quality of life, mean (± SD) | 0.685 (0.2408) | 0.628 (0.3324) | 0.646     |
| Oral care (scale 1-3 (worst)), mean (± SD) | 1.13 (0.40) | 1.21 (0.41) | 0.265     |
| Cognitive problem, N (%) a) | 29 (56) | 31 (78) | 0.030     |
| Activities of daily living problem, N (%) a) | 30 (56) | 29 (73) | 0.093     |
| Number of social services, mean (± SD) | 9.3 (3.1) | 8.9 (3.4) | 0.674     |
| Home help                | 2.4 (2.0)    | 2.9 (2.0) | 0.275     |

a) Based on data from the Resident Assessment Instrument; b) Pearson’s Chi-square/Fisher’s exact test or t-test/Mann-Whitney U-test

### Table 2: Quality of life, physical performance, nutritional status, oral care, fall incidents, hospitalization, and rehabilitation stay, moving to nursing homes, drop outs and mortality at 11 weeks.

|                          | Intervention | Control | p-value b) |
|--------------------------|--------------|---------|------------|
| Quality of life, mean (± SD) | 0.758 (0.222) | 0.534 (0.355) | 0.001     |
| Change in quality of life, mean (± SD) | 0.0638 (0.187) | -0.089 (0.346) | 0.017     |
| 30-seconds chair stand, mean (± SD) | 3.9 (5.4) | 1.6 (3.6) | 0.048     |
| 30-seconds, chair stand, modified, mean (± SD) | 4.9 (3.7) | 2.3 (2.9) | 0.005     |
| Improved chair-stand, N = 53, 34 (%) | 25 (47) | 6 (17) | 0.005     |
| Weight, kg, mean (± SD) | 57.4 (11.4) | 56.9 (11.0) | 0.959     |
| Change in weight, kg, mean (± SD) | 0.12 (1.94) | -0.36 (3.89) | 0.817     |
| Change in weight, percent, mean (± SD) | 0.22 (3.46) | -0.32 (7.2) | 0.820     |
| Hand-grip strength max kg, mean (± SD) | 15.8 (7.9) | 12.9 (6.7) | 0.169     |
| Change in hand-grip strength max kg mean (± SD) | -0.73 (3.00) | -0.64 (3.59) | 0.757     |
| Oral care (scale 1-3 (worst)), mean (± SD) | 1.1 (0.3) | 1.3 (0.5) | 0.021     |
| Change in oral care, mean (± SD) | -0.02 (0.4) | 0.1 (0.5) | 0.257     |
| Number of rehabilitation stay, N (%) a) | 1 (2) | 1 (6) | 0.483     |
| Moving to a nursing home, N (%) a) | 2 (5) | 0 (0) | 1.000     |
| Number of fall incidents, N (%) | 4 (8) | 4 (11) | 0.710     |
| Number of hospitalizations, N (%) | 10 (16) | 10 (28) | 0.323     |
| Drop outs, N (%) | 1 (2) | 0 (0) | 1.000     |
| Died, N (%) | 1 (2) | 5 (13) | 0.079     |

a) For participants in home-care; b) Pearson’s Chi-squared test/Fisher’s exact test/t-test/Mann-Whitney U-test
**Table 3:** Cost items used in the evaluation of the intervention, in DKK per individual.

|                  | Cost   |
|------------------|--------|
| Initial screening | 117.46 |
| Dietician        | 228.75 |
| Occupational therapist | 96.38 |
| Physical training | 2895.93 |
| Education of staff | 743.69 |
| Total cost       | 4082.21 |

**Table 4:** Sensitivity analysis: Cost-effectiveness with changed assumptions on basic variables.

| Basic result                           | Cost in DKK per kg weight increase | Cost in DKK per QALY gained |
|----------------------------------------|-----------------------------------|----------------------------|
| 25 % larger weight increase in the intervention group | 8467                             | 46.388                     |
| 25 % smaller weight increase in the intervention group | 7977                             | -                          |
| 25 % larger QALY gain                   | 905.5                            | -                          |
| 25 % smaller QALY gain                  | -                                | 39.270                     |
| 25 % increase in wage rates for all staff | 10.019                           | 55.057                     |
| Depreciation rate of staff education 50 % | 9262                            | 50.742                     |
| Depreciation rate of staff education 25 % | 8093                            | 44.339                     |
| Physical training in teams only         | 7535                            | 41.283                     |
| Physical training at home only          | 8891                            | 48.709                     |

The study was cost-effective with a cost-effectiveness ratio of DKK 46,000 per QALY, which compares reasonably well to other interventions found worthwhile in the Danish healthcare sector. Furthermore, the compliance was high, which might be due to the formalized multidisciplinary collaboration including a meeting once a week to discuss, evaluate and adjust the multidisciplinary support of each of the participants.

Not all participants identified with 2 points according to EVS were underweight (see table 1) probably because low BMI is not included in the information obtained by the EVS. The reason is that the use of BMI alone is not a sufficient nutritional screening tool to assess whether or not participants may benefit from nutritional intervention [10].

According to our knowledge, this is the first prospective randomized controlled trial evaluating whether multidisciplinary nutritional support is cost-effective in a randomized design. This study is apparently also the first study of multidisciplinary nutritional support among home-care clients.

Recently intervention studies evaluating the cost-effectiveness of ONS among frail older adults’ studies were summarized in a systematic review and it was concluded that the use of ONS could be efficient from a health economic perspective [11]. In another study, an economic model was developed to calculate the budget impact of using ONS in community-dwelling elderly and it was found that the use of ONS may lead to cost savings [14].

Even though our findings support our findings the studies are difficult to compare. The nutritional support in the studies by Freijer and co-workers [11,14] was mainly in the form of ONS, no costs were added for additional staff, e.g. dieticians, which may have been involved in the intervention, and outcomes of interest were e.g. morbidity and prevalence of readmissions.

We had decided to use quality of life as our primary outcome choosing EQ-5D-3L which has apparently not been used in nutritional studies among this population before. However, the decision to use the EQ-5D-3L was based on the possibility of using the results from the EQ-5D-3L to estimate the cost-effectiveness of the intervention.

The EQ-5D-3L descriptive system comprises the following 5 dimensions (5D): mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels (3L): no problems, some problems, extreme problems. Hence, the instrument is considered a preferred approach in the end of life care, where treatment is about caring for the old people, rather than curing disease.

Another relevant outcome measure could have been ADL, especially since former studies have shown that older adults in respectively, nursing homes and home-care, who are undernourished, need more assistance with ADL than older adults who are in good nutritional status and due to that, may add to the substantial and costly burden of care [3,5,6]. Apparently it seems difficult to convey improvement in ADL to cost, since the price is unknown.

Also, it could have been relevant to consider the cost of hospital admissions, falls, visits of general practitioners, or moving to nursing homes as has been done in former cost-effectiveness studies [11,14]. However our sample size lacked power in order to be able to detect a significant difference in these outcomes.

Our power calculation had shown that we needed 65 older adults in each group, to be able to see a difference in the quality of life. Also the Intra-Correlation Coefficient (ICC) of 0.2627, suggested some impact of “setting”, and hence an even higher number of participants should actually have been included. Finally, there were more nursing home residents in the control group, and hence a higher prevalence of e.g. ADL and cognitive problems (see table 1). In spite of that there were no difference in the quality of life at baseline (see table 1) and we were able to prove a significant difference in both final quality of life and change from baseline (see table 2).

Even though our cost-effectiveness ratio of DKK 46,000 per QALY compares reasonably well to other interventions found worthwhile in the Danish healthcare sector, a few adjustments might improve the cost-effectiveness. In the present study all participants were assessed with EVS, also those not selected for the intervention. This took on average 15 minutes for each older-
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adult. An alternative suggestion could be to screen only those with unplanned weight loss. Since weighing is already performed this would result in no extra costs.

The education of staff was also time-consuming since it included three whole-day courses plus train-the-trainer sessions with other staff members. Since education needs to be an ongoing process and hence continues to cost time and hence money, a suggestion could be that some of the education is performed as e-learning.

In conclusion, multidisciplinary nutritional support in older adults in nursing home and home-care identified with EVS is cost-effective since the cost-effectiveness ratio compares reasonably well to other interventions found worthwhile in the Danish healthcare sector.

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Authors’ Contributions

BSH, AGC and HK provided AB support in the conception and design of the study. BSH, AGC, TKSM and SD-S generated, collected and assembled the data. HK performed the cost-effectiveness analysis, AB performed the analysis of the other data and all other authors participated in the interpretation. AB and HK drafted the manuscript and all other authors contributed to the further editing and revision of the research work for the intellectual content. All authors provided consent to the final version of the manuscript to be published and agreed to be accountable for the accuracy of the data.

Ethical Approval

The protocol was send to the Danish Ethical Board which concluded that approval was not needed and that the project could be carried on as described. Still, informed consent was obtained from all participants.

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