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Randomized control trials

Targeting the underlying causes of undernutrition. Cost-effectiveness of a multifactorial personalized intervention in community-dwelling older adults: A randomized controlled trial

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SUMMARY

Background & aims: Undernutrition in old age is associated with increased morbidity, mortality and health care costs. Treatment by caloric supplementation results in weight gain, but compliance is poor in the long run. Few studies targeted underlying causes of undernutrition in community-dwelling older adults. This study aimed to evaluate the cost-effectiveness of a multifactorial personalized intervention focused on eliminating or managing the underlying causes of undernutrition to prevent and reduce undernutrition in comparison with usual care.

Methods: A randomized controlled trial was performed among 155 community-dwelling older adults receiving home care with or at risk of undernutrition. The intervention included a personalized action plan and 6 months support. The control group received usual care. Body weight, and secondary outcomes were measured in both groups at baseline and 6 months follow-up. Multiple imputation, linear regression and generalized estimating equation analyses were used to analyze intervention effects. In the cost-effectiveness analyses regression models were bootstrapped to estimate statistical uncertainty.

Results: This intervention showed no statistically significant effects on body weight, mid-upper arm circumference, grip strength, gait speed and 12-Item Short-Form Health Survey physical component scale as compared to usual care, but there was an effect on the 12-Item Short-Form Health Survey mental component scale (0–100) ($\beta = 8.940$, $p = 0.001$). Borderline significant intervention effects were found for both objective and subjective physical function measures, Short Physical Performance Battery (0–12) ($\beta = 0.56$, $p = 0.08$) and ADL-Barthel score (0–20) ($\beta = 0.69$, $p = 0.09$). Societal costs in the intervention group were statistically non-significantly lower than in the control group (mean difference −274; 95% CI −1111; 782). Cost-effectiveness acceptability curves showed that the probability of cost-effectiveness was 0.72 at a willingness-to-pay of 1000 €/kg weight gain and 0.80 at a willingness-to-pay of 20,000 €/quality-adjusted life year gained.

Conclusions: This multifactorial personalized intervention showed a statistically non-significant effect and was not cost-effective on body-weight compared to usual care. We observed consistently beneficial treatment effects in the intervention group on all outcomes measures.

Clinical trial registry number and website: NTR5184 (www.trialregister.nl).

1. Introduction

Undernutrition, 'defined as protein-energy malnutrition' in old age is considered an important health problem and is associated with poor physical functioning [1], poor quality of life [2,3], poor health status [4] and increased mortality rates [5–7]. From an

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economic perspective, undernutrition is associated with increased health care costs due to an increased use of health care resources [8,9]. Moreover, undernutrition may result in increased dependence and social isolation [1,10]. The prevalence of undernutrition is reported to be higher in hospitals (18–33%) and nursing homes (18–21%) compared to community-dwelling older adults with home care (12–16%) and without home care (7%) [11]. However, since the majority of older adults in western countries remains living independently at home with or without support from home care organizations, it is important to develop interventions that can be implemented in this setting [12,13].

Previous efforts to treat undernutrition have focused on increasing caloric intake by protein and energy supplementation [14] or treatment by intensive dietetic counseling [15]. Energy supplementation, mostly studied in institutionalized older adults, led to a significant effect on body weight but inconsistent effects on health and functional outcomes [14]. Besides, long term compliance is hampered by the poor palatability of nutritional supplements and adverse events such as nausea or gastro-intestinal discomfort due to highly concentrated and energy dense sip feeds [14,16]. Intensive dietetic counseling aimed at increasing caloric intake showed no statistical significant effect on body weight, caloric intake, or functional outcomes in undernourished community-dwelling older adults [15,17]. Although this lack of effect may be due to inadequate statistical power, the focus on increasing caloric intake alone to treat undernutrition may not be the most effective strategy [15,17].

None of the studies so far focused on the underlying determinants that lead to undernutrition. As it seems difficult to reverse undernutrition and its consequences once present, targeting the underlying causes in an early stage to prevent undernutrition may be a more (cost-)effective strategy. Since the underlying causes of undernutrition in community-dwelling older adults are multifactorial and found in different domains [18–20], a preventive intervention should include a multifactorial approach.

Given the importance of the problem of undernutrition in community-dwelling older adults, its multifactorial causes, and the lack of studies available that intervene on multiple factors besides increasing caloric intake, a paradigm shift to a multifactorial personalized prevention strategy is needed. Therefore, we developed a multifactorial, personalized intervention targeting the underlying causes of undernutrition in older community-dwelling adults. The aim of this study was to evaluate the intervention effect on several nutritional and functional outcome measures. Finally, the cost-effectiveness of the intervention in comparison with usual care was evaluated on body weight and quality-adjusted life years (QALYs).

2. Materials and methods

2.1. Study design

The study was designed as a 6-month, parallel, randomized controlled trial among community-dwelling adults aged 65 years and older [21] with or at risk of undernutrition receiving home care or household support. The trial was executed between December 2013 and April 2015 in two districts: Amsterdam New-West and Hoorn, the Netherlands. The Medical Ethics Committee of the VU University Medical Centre, Amsterdam approved the study. The study was registered at the Dutch Trial Register: NTR5184 (http://www.trialregister.nl/trialreg/index.asp). Written informed consent was obtained from all participants according to the Declaration of Helsinki.

2.1.1. Recruitment and inclusion

Home care workers of two participating home care organizations in the two districts used the Short Nutritional Assessment Questionnaire screening tool (SNAQ^{65+}) [22] to assess the nutritional status of their clients during a home visit or via telephone calls using a standardized protocol (n = 1693). In addition, researchers recruited older adults (n = 27) through flyers, newspaper ads and information meetings in the two districts (see Fig. 1). Older adults were eligible to participate in the study if classified as: 1) undernourished (unintentional weight loss of ≥4 kg in the past 6 months or mid-upper arm circumference (MUAC) < 25 cm) or at risk of undernutrition (poor appetite in the last week in combination with inability to climb up and down stairs of 15 steps); 2) 65 years or older; and 3) living at home and receiving home care or household support. Those eligible and willing to be informed about the study (n = 479) were contacted by telephone by the researchers and screened for additional exclusion criteria (i.e. inability to stand independently, life expectancy of less than 6 months, inability to communicate in Dutch). Those willing to participate received further information by an information letter. A home care visit was scheduled for 161 potential participants of whom another 6 were excluded based on the following exclusion criteria: poor cognitive functioning defined as a Mini-Mental State Examination (MMSE) score <18 (n = 3) [23], inability to stand independently on a weighing scale (n = 1), life expectancy estimated at less than 6 months (n = 1), or inability to communicate in Dutch (n = 1). In total, 155 participants were included in the study and the baseline examination was conducted (see Fig. 1).

2.1.2. Randomization

Randomization was accomplished immediately after performing the baseline examination by opening a sealed envelope with an allocation to either the intervention or control group. Blinding after randomization was not possible due to the nature of the intervention. Block randomization was performed a priori by an independent statistician and stratified by sex, age group (<84 and ≥84 years based upon age at nutritional screening), and SNAQ^{65+} screening outcome (undernourished either based on a low MUAC or unintentional weight loss or at risk of undernutrition). The 155 participants were randomized into the control (n = 76) or intervention group (n = 79) (see Fig. 1).

2.2. Study protocol

2.2.1. Control group

The control group received usual care and did not receive any specific advice. The control group received a standard brochure of the Netherlands Nutrition Centre with general information about a healthy diet after the baseline examination was performed.

2.2.2. Intervention group

In the intervention group a personalized action plan to manage underlying causes of undernutrition was discussed and developed together with the participant, and six months support was provided by the researchers. The intervention group also received the standard brochure of the Netherlands Nutrition Centre. A checklist to assess the potential underlying cause(s) of undernutrition was developed based on previous qualitative [24] and quantitative research [18,25] on the determinants of undernutrition in community-dwelling older adults.

2.2.2.1. Checklist underlying causes of undernutrition. The checklist was administered to all participants (intervention and control group) as part of the baseline examination and served as the basis for the personalized action plan in the intervention group. The checklist consisted of 7 potential causes of undernutrition, each addressed with one or two questions (see Appendix 1). Action was required for both taste and appetite when either one was rated as

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