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Randomized control trials

The effects of the administration of oral nutritional supplementation with medication rounds on the achievement of nutritional goals: A randomized controlled trial☆

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SUMMARY

Background & aims: Oral nutritional supplements (ONS) are often considered for hospitalized patients with acute severe malnutrition, however the compliance to the supplements is known to be variable. The aim of our study was to investigate whether providing a lower volume of ONS at a higher frequency during medication rounds would improve the intake of the supplements.
Methods: In this randomized controlled trial, 234 malnourished inpatients (mean age 71.2 years, 55% male, median LOS 10 days) were randomized to receive ONS (300 kcal and 12 g Protein per 125 ml serving) in one of three different schemes. The usual care group ($n = 88$) was offered ONS 125 ml twice per day in between meals. This was compared to two intervention groups that were offered ONS during medication rounds: intervention group 1 ($n = 66$) received 125 ml of ONS twice per day, at 12 and 17 o'clock, and intervention group 2 ($n = 80$) received 62 ml of ONS four times a day, at 8, 12, 17 and 20 o'clock. Follow-up was performed until discharge or until ONS was no longer needed, with a maximum follow-up period of 30 days. The primary outcome measure was the percentage of patients who consumed at least 75% of the prescribed volume of ONS.
Results: No significant differences were observed between the control groups and intervention group 1 (risk difference of −16.0% (95% CI −33.2–1.2). However, the percentage of patients consuming at least 75% of the prescribed ONS was higher in intervention group 2, with a risk difference 23.4% (95% CI 7.8–39.0%) and a mean increased intake of 35 ml (84 kcal) per day, $p < 0.001$). Median time ONS were taken was 5 days (range 1–17).
Conclusion: A higher frequency of a lower volume of ONS during medication rounds increased the compliance of patients needing ONS.
Clinical trial registration number NTR2535; www.trialregister.nl.

1. Introduction

Disease-related malnutrition is a primary risk factor for the poor clinical outcome of hospitalized patients. There is increasing evidence for the beneficial effects of ONS to counteract malnutrition, especially in the acutely ill, older and undernourished patients [1–5]. However, in hospitals patient compliance with ONS varies around 67% [6], due to, for example, taste fatigue, anorexia or diminished appetite resulting from the malnutrition itself [7]. Variable patient compliance to ONS may also result from the psychological and post-absorptive process that regulates satiation and satiety; the short time interval between ONS and the regular hospital meals leads the patient to stop drinking or eating due to rapid satiation [8].

In hospitals, there is an ongoing debate whether the distribution of ONS during medication rounds would increase patient compliance [7]. One belief is that patients will better accept ONS when the

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Abbreviations

ONS	oral nutritional supplementation
SNAQ	Short Nutritional Assessment Questionnaire
BMI	body mass index
CI	confidence interval
NNT	number needed to treat

supplements are presented as a medication for treatment of disease related malnutrition by medical or nursing staff [1,7]. In that case, ONS can be used instead of water to swallow regular oral medication while providing energy and nutrients at the same time [8]. Furthermore, medication rounds give dietitians the opportunity to administer ONS several times a day in a lower dose instead of the larger volumes in between meals, two or three times per day.

In this study, we investigated whether the distribution of ONS during medication rounds, either in 2 higher volumes or in 4 lower volumes, would increase the intake of the supplements. The other objective was to evaluate the effect of lower volumes of ONS at a higher frequency on patient compliance with the consumption of ONS.

2. Methods

2.1. Participants

From April to December 2010, all patients from the Deventer Hospital in the Netherlands who were referred to the internal or surgical wards were eligible for inclusion. The internal medicine wards includes oncology, nephrology, cardiology, pulmonary disease, internal gastroenterology, gynaecology, urology, neurology and geriatrics. The surgical wards include orthopaedics, gastroenterology, and vascular and trauma surgery.

Upon admission to hospital all patients were screened by a nurse with the Short Nutritional Assessment Questionnaire (SNAQ) [9]. All patients screened to be at risk of malnutrition (scoring 3+) were routinely referred to a dietitian for further nutritional assessment and they were provided a protein and energy rich diet and snacks. Patients could also be referred by their physician due to insufficient food intake caused by for example anorexia, drug and treatment-induced side effects or dislike of institutional catering. Patients who were advised to take ONS by the dietitian were approached and invited to participate in the study. For geriatric patients with cognitive disorders their legal representatives were asked to give informed consent. Patients were excluded from the study when they were younger than 18 years of age, had swallowing problems, had end-stage renal disease and/or haemodialysis, received total (par)enteral nutrition or had an expected length of hospital stay of less than 3 days.

As part of nutritional assessment the dietitian calculated the energy requirements with the FAO/WHO/UNU equation with adjustments for metabolic stress and activity factors [10]. Protein requirements were calculated with 1.2–1.5 g protein per kg bodyweight per day, using a body mass index (BMI) of 27 kg/m^2 when BMI $>$ 27 kg/m^2. The deficit between nutritional intake and (calculated) nutrition requirements was the basis for the prescription of the volume of ONS.

2.2. Data collection

This randomized controlled trial was conducted with the approval of the ethical committee of the Isala Clinics Zwolle, registration number NL31647.075.10 on 15 April 2010. After informed consent and tasting the different flavours of the study product (Nutridrink Compact vanilla, coffee, banana and strawberry: 300 kcal and 12 g Protein per 125 ml serving, Nutricia, Zoetermeer, Netherlands). The participants were randomly assigned into one of the three therapy groups by a computerized random numbers system and concealed blinded envelopes. The usual care group was offered 125 ml of ONS by nutrition assistants twice a day in between meals at 10 and 15 o'clock. The intervention groups were offered ONS by the nursing staff on medication rounds. Intervention group I was offered 125 ml ONS twice a day, at 12 and 17 o'clock, an hour before their daily meals, together with their prescribed medication, if any. Intervention group II was offered 63 ml ONS four times a day together with their prescribed medication, if any, at 8, 12, 17 and 20 o'clock (Fig. 1). All patients in the control and intervention groups had one hour to drink their ONS. The nutrition assistants assisted the nursing staff in preparing the ONS before serving. All drinks were served in drinking glasses. All disciplines (dietitians, nutrition assistants and nursing staff) were trained to provide the same information to the patients with regard to the necessity of taking the supplements, presenting it to the patients, or changing flavours, if desired.

The primary outcome measure was the percentage of patients who reached the treatment objective of at least 75% of the prescribed volume of ONS during admission [11]; as a secondary endpoint the mean intake of ONS per day in ml was registered. Patients who were given ONS for less than two days during their hospital stay were not included in the final analyses. Power and sample size considerations assumed that under usual care 50% would reach their treatment objective of energy and protein intake by ONS. Tests of independence considering three proportions demonstrated a power to statistically detect a 15% absolute difference with 70 patients per group (type I error of 0.05; 80% power, variance of proportions 0.01, average proportion 0.62, effect size of 0.047). These assumptions are based on a discussion board with the authors of the manuscript and some (research) dietitians in Teaching Hospital Deventer and other hospitals. We assumed a 15% drop-out rate and aimed to include 250 patients.

ONS was served in drinking glasses with 5 ml (usual care and intervention I) and 1 ml indication (intervention II). Intake was measured by nutrition assistants (usual care) and nurses (intervention I and II), who measured the end volume from the volume provided. The reliability of the ONS intake measurements was assessed by a series of 10 different amounts of ONS doses that were measured independently by nurses and nutrition assistants. Length of hospital stay and time ONS were taken was measured. Adverse events were reported and re-hospitalization was measured during the study period and one month after completing the study.

2.3. Statistical analyses

Statistical analyses were conducted using SPSS version 16.0 for Windows (Chicago, IL, USA). Descriptive statistics were used to assess the patient characteristics in the three therapy groups. Pearson's chi-square tests were used to detect differences in the proportions of patients reaching treatment objectives of energy and protein intake by ONS during admission and one-way ANOVA (Bonferroni corrected) to detect differences in the intake of ONS in ml. The absolute percentages of patients reaching their treatment objectives and the associated 95% confidence intervals (CI) were used to compare the effectiveness of the different ONS administration modes. The numbers needed to treat were computed as the inverse of the risk differences. The calculations were performed according to as treated. Deviations from randomized allocations were stated. Last measured mean intake and loss-to follow-up were