

# Study Protocol: Nutritional Support in a Cross-sector Model for the Rehabilitation of Geriatric Patients: A Randomized Controlled Trial

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## Abstract

**Background:** Hospital stays are generally getting shorter which leaves limited time to improve a poor nutritional status for geriatric patients. Therefore, it seems necessary to integrate nutritional support also in the period after discharge. Furthermore, improving cross-sector cooperation in the transition of geriatric patients between hospital and home-care institutions is essential to ensure follow-up and completion of hospital (nutritional) treatment and rehabilitation of patients. In spite of many issues, i.e. the multi-morbidity, the reduced level of functioning and the excessive use of medication, which have a negative impact of appetite and food intake, little research, has been done to address these problems by investigating the effect of a more comprehensive systematic nutritional approach.

**Method:** A twelve-week randomised controlled trial comparing discharge standard Follow-home Team vs. discharge Follow-home Team in cooperation with a Registered Dietician. Patients are eligible for this study when they are 70+ years old and at nutritional risk. The registered Dietician will perform three home visits. The first visit will take place at the day of discharge together with the Follow-home Team, while the remaining visits will take place approximately three and eight weeks after discharge and will be performed by the RD alone. The information gathered by the Follow-home Team i.e. regarding the medical treatment, the patient's functional abilities and ability to cope with activities of daily living, and the need for change in social services, will be taken into consideration. The primary outcome parameter will be muscle strength measured as hand-grip strength. Secondary outcomes will be nutritional status, dietary intake, physical performance, mobility, Activities of Daily Living, quality of life, use of social services, re-admissions and mortality.

**Discussion:** This project is the first to combine individualized nutritional intervention with intervention from an established Follow-home Team. The results will hopefully help to ensure the cross-sector quality of nutritional support to geriatric patients. This may ultimately lead to reduced health care costs, and improvement in mobility, independence and quality of life for geriatric patients at nutritional risk.

**Trial registration:** Clinical Trials.gov NCT01776762.

**Keywords:** Undernutrition; Registered dietician; Comprehensive nutritional support; Follow-home team

## Background

Under nutrition is common in old people admitted to the hospital, and nutritional state often deteriorates further during hospital stay mainly due to lack of recognition of the problem [1]. Therefore, at discharge a high amount of old patients will still be undernourished or at nutritional risk resulting in an increased risk of re-admissions [2,3].

Hospital stays are generally getting shorter which leaves limited time to improve a poor nutritional status. Furthermore; even a short hospital stay increases the risk of loss of muscle strength, functional capacity and ability to cope with Activities of Daily Living (ADL) [4]. For older medical patients it is shown that only one in three have regained their habitual physical function one year after discharge [5]. Furthermore, any older people continue to lose weight during the first six months after discharge [6].

Therefore, it seems necessary to integrate nutritional support also in the period after discharge. Furthermore; improving cross-sector cooperation in the transition of patients between hospital and home-care institutions is essential to ensure follow-up and completion of hospital (nutritional) treatment and rehabilitation of patients. According to the Resolution of the Council of Europe, patients in need of nutritional support should receive such treatment at the earliest opportunity during hospital stay and after discharge [7]. Following this statement, nutritional risk should be re-assessed for nutritional risk patients when planning discharge from hospital, in order to arrange cross-sector nutritional support for the period of recovery and rehabilitation.

Until now, there are relatively few studies on the effect of cross-sector nutritional support. Recently a systematic review and meta-analysis of six randomized controlled intervention studies of oral nutritional support of older (65 years+) medical and surgical patients after discharge from hospital were performed. The authors concluded that most results showed a positive effect on the energy and nutrient intake, the nutritional status and in some also the functional status. In contrast, there was no effect on the rehabilitation capacity and the survival [8]. One explanation for the limited effect, according to the authors of the review, could be the relatively low level of compliance with the commercial Oral Nutritional Supplements (ONS) reported in some of the earlier studies [8]. None of these studies have included individual goal setting, use of energy dense menus, and systematic counseling focusing on nutritional risk factors, i.e. the expertise from a Registered Dietician (RD).

In addition, none of the studies identified in the systematic review

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have used a more comprehensive systematic nutritional approach involving relevant health care professionals and have not sought to address the many other issues, i.e. the multi-morbidity, the reduced level of functioning and the excessive use of medication, which may have a negative impact on appetite and food intake.

As an example; inappropriate medical treatment often has inadvertent effects, and a considerable number of admissions are attributable to inappropriate medical treatment that could be avoided [9]. In order to address these other issues a recent Danish Randomized Controlled Trial (RCT) comparing discharge follow-up in patients' home by General Practitioners (GPs) vs. discharge follow-up in patients' homes by GPs and Registered Dieticians was performed. In order to secure a more comprehensive approach to nutrition support, it was planned that at least one dietetic counseling should be conducted together with the participant's GP, either in the home or at the GPs clinic to increase co-operation about the nutritional and medical treatment [10]. The results showed a positive effect of the nutritional status and functional abilities but no effect on re-admission. An unexpected finding was that approximately 20% of the participants did not want the visit from their GP, approximately 15% of the GPs did not want to participate, only half of those GPs who actually did participate completed all three contacts with the patients as planned. Furthermore, only 16 (9%) of the visits completed by the Registered Dietician succeeded in implementing co-operation with the GP [10]. Thus, the comprehensive approach to nutritional support was not achieved as planned.

An established model to increasing cross-sector cooperation in Denmark is the Follow-home Team (FHT) based in the hospital, including our hospital. The purpose of the FHT is to facilitate the cross-sector transition of the old patient between hospital and private home; hence to follow-up on the medical treatment, the patient's functional abilities and ability to cope with ADL, and the need for change in use of social services (e.g. home care, home nursing and meals-on-wheels) necessary to the completion of hospital treatment and the rehabilitation of the patient. This takes place at the day of discharge in the patient's own home and is done by means of close cooperation with the GP, the home-nurse and other relevant persons. The model is based on a RCT which have proven a decreased risk of re-admission after such an intervention but no effect on functional abilities [11]. A possible explanation to this lack of finding might be that the FHT programme does not include any particular or systematic nutritional intervention.

Based on the well-established FHT model at Herlev University Hospital one aim of this RCT is to test a model of how a more comprehensive nutritional support can be systematized in order to ensure the cross-sector quality of nutritional support to geriatric patients. Another aim is to assess the possible benefits in relation to muscle strength, nutritional status, dietary intake, physical performance, mobility, ADL, quality of life, use of social services, re-admissions and mortality.

## Method

### Design

This study is designed as a twelve-week randomised controlled trial comparing discharge standard FHT vs. discharge FHT in cooperation with a RD. Patients are eligible for this study when they are 70+ years old and at nutritional risk according to the level 2 screening in NRS2002 [12]. The primary outcome parameter will be muscle strength measured as hand-grip strength in the intervention and control group.

Secondary outcomes will be nutritional status, dietary intake, physical performance, mobility, ADL, quality of life, use of social services, re-admissions and mortality.

### Feasibility of recruitment and sample size

An earlier study has shown that almost 70% of the old Danish hospital population is at nutritional risk according to the level 2 screening in NRS2002 [13]. Therefore a high prevalence of those who are discharged with the FHT will probably also be categorized as at nutritional risk. For a clinical relevant difference of 2 kg in hand-grip strength and an expected drop-out rate of 5% (based on Beck et al. [10]), a statistical significant level of 0.05 and a power of 80%, 40 patients in each group is required to detect a significant difference.

### Randomization

Patients will be randomised the day before discharge and the baseline assessment. Participants, the RDs (AV, LLJ, KM), and the Research Assistants (KØR, EL) are not blinded for the intervention.

### Population, inclusion and exclusion criteria

All old (70+ years of age) patients' hospitalized at the ward of Geriatric Medicine at Herlev University Hospital.

#### The inclusion criteria are

- Nutritional risk according to the level 2 screening in NRS2002 [12], which is the mandatory tool in Danish hospital
- Nutritional support by means of small volume commercial ONS with a high energy- and protein content 2-3 times per day for at least three days at the ward of Geriatric Medicine
- Follow-home Team at discharge

#### The exclusion criteria are

- Senile dementia or terminal disease
- Impaired renal function (eGFR <30 mL/min/1.73 m<sup>2</sup>)
- Unable to understand the Danish language
- Residing in nursing homes
- Not capable of performing hand-grip test
- Planning a weight reducing diet
- Not able to or willing to give informed consent

### Intervention

#### Discharge FHT

At the University Hospital of Herlev the discharge FHT consists of a nurse, an occupational therapist and a physiotherapist. One of these will accommodate the patient to own home at the day of discharge.

The discharge FHT visit is guided by an agenda:

- Testing and eventual installation of different aids (e.g. handles, bed pads, raised toilet seats, emergency calls).
- Reviewing of the discharge letter, medication list, recipes and medical cabinet together with the patient.
- Contacting, if relevant, the discharging ward, the home care, the home-nursing and the GP.
- Writing a FHT note in the Electronic Patient Journal and

forwarding this to the home care, the home-nursing and the GP.

e) If relevant, additional follow-up visits or contacts by telephone.

### Patients randomized to nutritional support

The RDs will be a part of the FHT when the patient is discharged from the hospital. In the home of the participant the RD will perform an individual nutritional assessment focusing on dietary intake, activity level and weight of each participant, as a basis for developing a nutrition care plan consistent with estimated nutritional requirements and nutritional rehabilitation goals. Specific focus will be on optimizing the intake of protein and the distribution of protein during the day [14]. The information gathered by the FHT i.e. regarding the medical treatment, the patient's functional abilities and ability to cope with ADL, and a need for change in social services will be taken into consideration. Basal Metabolic Rate (BMR) will be assessed by means of Schoefield and a factorial method, including adjustments for weight loss, if present. This will be used to estimate the total energy- and protein requirement for each patient [15].

To assess dietary intake, the RD will perform a standardized dietary interview at each visit in order to determine total energy and protein intake of the participant. Strategies for achieving energy and protein requirements and achieving compliance will include dietary counseling with attention to nutritional risk factors, timing, size and frequency of meals, recommendations for nutrient dense foods and drinks, and provision of educational material. Supplementation with energy- and protein dense menus from providers of meals-on-wheels, subscription of commercial small volume ONS with high energy- and protein content as well as vitamin D, calcium and other vitamins-minerals will also be considered to achieve optimal nutritional status.

All in all, the RDs will perform three home visits. The first visit will take place at the day of discharge together with the FHT, while the remaining visits will take place approximately three and eight weeks after discharge and will be performed by the RD alone. The aim of visit 2 and 3 is to reinforce individual dietetic advice and optimize participants' nutritional status by way of reviewing the nutrition care plan, dietary counselling, motivation and education, monitoring participant weight, and ensuring that energy and protein requirements are achieved. If it is considered relevant the participants will receive a short follow-up consultation by telephone by the RDs in order to give advice and to stimulate compliance to the proposed nutritional intake in-between the home visits. If possible, the home care and home-nursing staff will be invited to participate in all three visits. After all three visits the dietary intervention will be documented in FHT notes and forwarded to the home care, the home-nursing and the GP.

### Procedure

After obtaining the patients informed consent an inventory will be made of possible confounders. This includes the following characteristics:

- a) Socio-demographic data (age, gender).
- b) Data on difficulties with chewing, swallowing, and eating.
- c) Medical diagnosis.

d) Cumulated Ambulation Score (CAS) - In geriatric wards, CAS is a feasible tool for evaluating all patients' basic mobility. CAS describes the patient's independence with regard to three activities (getting in and out of bed, sit-to-stand-to-sit from a chair, and walking). Each activity is assessed on a three-point ordinal scale from 0-2 (0=not able

to, despite human assistance and verbal cueing, 1=able to, with human assistance and/or verbal cueing from one or more persons, 2=able to safely, without human assistance or verbal cueing, use of a walking aid allowed) resulting in a total daily CAS score ranging from 0 to 6 where 6 is independent mobility [16].

- e) Prescription/use of commercial ONSs.
- f) Prescription of rehabilitation in the form of physiotherapy.

### Outcome parameters

Outcome parameters will be measured just before discharge (t=0) and at +12 weeks in the home of the participants (t=1). A register-based evaluation of re-admissions will be done after 6 (t=2) and 12 months (t=3). Primary outcome is the muscle strength of the participants measured by means of hand-grip strength. All outcome parameters measured are listed below. If nothing else is stated the data is collected by the Research Assistants.

#### Muscle strength by means of hand-grip strength (t=0 and t=1)

Hand-grip strength (in kg) will be measured with a Jamar 5030J1 Hydraulic Hand Dynamometer. Participants will be seated with forearms rested on the arms of the chair. They are asked to perform three maximum force trials with their dominant hand and using the second handle position. The maximal hand-grip score from the three values will be used.

#### Nutritional status by means of weight, height, and BMI (t=0 and t=1)

Weight is measured with patients wearing light indoor clothes and no shoes. Information about weight will also be obtained by the RDs during the visits to the intervention group. BMI is calculated as actual weight in kilograms divided by the square of height in meters. As measurement of height is often not feasible in this chronically diseased, old and frail population, data on height will be retrieved from self-reported height.

#### Dietary intake by means of a 4-day dietary record (t=0 and t=1)

Participants will receive instructions from the Research Assistants on how to fill in the dietary record. At the hospital the staff and the Research Assistants will aid the participants with the recording. At home the participants will receive the dietary record in advance of the visit t=1. At the visit the finalised record will be inspected and ambiguous entries clarified. If the participants have not been able to perform the dietary registration a dietary interview will be performed. The intake of energy and nutrients will be calculated by means of a computer based Danish food composition table.

Schoefield equations will be used to calculate the BMR by means of information about age and body weight [15]. Underreporting of dietary intake will be considered when calculated energy intake/BMR is below 1.1.

Information about intake of vitamin D, vitamins-minerals, and commercial ONS are gathered at t=0 and t=1 and of the RD at the visit in the intervention group.

#### Physical performance by means of 30 seconds chair stand (t=0 and t=1)

To test the physical performance, the participants are asked to fold their arms across their chest and to stand up and sit down on a chair

without pushing off with arms, as many times as possible during 30 seconds. The arms may be used for assistance or for safety if needed [17]. The mode of chair stand will be registered.

### **Cognitive performance by means of the Mini Mental State Examination (t=0 and t=1)**

The Mini Mental State Examination (MMSE) will be administered to assess cognitive status of the participants. The MMSE is a widely used and easily administered test of cognitive status. It consists of 11 tasks and is graded to assign old people a score in the range of 0 to 30.

Participants, who have difficulties with seeing, hearing or writing, will not be asked to complete the MMSE-test.

### **Mobility by means of de Morton Mobility Index (t=0 and t=1)**

The mobility will be assessed using the validated de Morton Mobility Index (DEMMI) [18]. The DEMMI is a 15-item one-dimensional instrument that measures mobility across the spectrum from bed bound to independent mobility. The raw score total (0-19) must be converted to a DEMMI SCORE (0-100 where 100 is independent mobility).

### **Activities of daily living by means of Barthel-Index-100 (t=0 and t=1)**

The Barthel-Index-100 is a valid measure of disability [19]. The Index includes basic chores of the patient such as personal hygiene, mobility, and the ability to eat, as well as other activities at home. This assessment of functional capacity is used to set targets for rehabilitation, ongoing monitoring and subsequent evaluation of interventions [20]. The Barthel-Index-100 has five response categories, with 0-20 points in each category. A point score 20 indicates that the patient is independent in the activity.

### **Quality of Life by means of EuroQol-5D-3L (t=0 and t=1)**

Euro Qol-5D-3L (EQ-5D-3L) is a standardised instrument for use as a measure of health outcome. 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. The raw score must be converted to an EQ-5D-3L score ranging from 1.000 to -0.624 [21].

### **Social services by means of interview (t=0 and t=1)**

Information about use of social services, i.e. meals-on-wheels, home nursing care, private care, and rehabilitation plans, will be gathered from the participants or their relatives.

### **Re-admissions by means of the Hospital Patient Register (t=1, t=2, t=3)**

A register-based evaluation of re-admissions will be done after 12 weeks, 6 and 12 months. Data on admission to the hospital will be based on the Hospital Patient Register. Information about the number of days spent in the hospital will also be collected from the Register.

### **Mortality by means of the Hospital Patient Register (t=1, t=2, t=3)**

Mortality will be evaluated after 12 weeks, 6 and 12 months after discharge by means of the Hospital Patient Register.

## **Organization**

The Primary Investigator (AB) is overall responsible for the study.

The Primary Investigator will be assisted by two Research Assistants (EL, KØR) who are responsible for the informed consent procedure, the selection of the final participants', the data collection measurements and reports. The Primary Investigator will also be assisted by three RDs (AV, KM, and LL). The RDs are responsible for the nutritional screening of the patients before baseline, as well as the nutritional intervention, where the Research Assistants are responsible for data collection at baseline and at the end of the intervention. Data flow will be controlled by the Primary Investigator. Data-entry and control will be conducted by the Research Assistants under supervision of the Primary Investigator. The Primary Investigator is responsible for the data cleaning and analysis.

## **Statistical Analysis**

All statistical analysis will be performed using SPSS for Windows. Data will be entered in EXCEL and will subsequently be exported into SPSS software for analysis. Data will be analysed by the Primary Investigator who is blinded for the results of randomisation, and data will be implemented in the intention-to-treat, i.e. all participants will be included in the analysis, regardless of whether they have completed the study or not. Depending on the data type and distribution t-test, Mann-Whitney U test and Chi-2 test will be used to compare (changes within and between) the groups.

## **Ethics**

The protocol has been send to the Danish Ethical Board which has concluded that approval is not needed and that the project can be carried on as described. Still, informed consent will be obtained from all participants. They will also be informed about their right to withdraw their consent at any time.

## **Discussion**

This project is the first to combine individualised nutritional intervention with intervention from an established FHT.

We have chosen not to use strict exclusion criteria, but to include all eligible patients even though they are suffering from a variety of diseases including chronic diseases. Their homogeneity is due to their age (70+ years old), nutritional risk and background of disease. If the results of a broad study like this one are positive, it justifies wide implementation, because the included group is representative for a mixed elderly population; in contrast, selection of a more specific group would make the intervention less applicable to other patient groups.

Even though it seems important to integrate nutritional support also to the period after discharge, there are until now relatively few studies on the effect of cross-sector nutritional support and the majority of these have used commercial ONS [8].

We have instead decided to use a comprehensive approach to nutritional therapy combining individual education, motivation and counseling, dietary modification and supplementation offered by a RD. This method is based on the experience from our former study [10] where we showed a very high compliance among the participants to such an approach. Furthermore, in spite of the comprehensive approach the intervention was not very time consuming, averaging two hours per visit [10].

Even a short hospital stay enhances the risk of loss of functional capacity and ability to cope with ADL [4]. Many of the former discharge studies may not have had sufficient statistical power and length of follow-up to be able to detect any beneficial effects in relation

to functional abilities and muscle strength [22]. In the present study we therefore choose muscle strength measured as hand grip strength as our primary outcome when performing the power calculation.

## Weaknesses

In this study there are possibilities of contamination between intervention and control groups since the FHT will be involved in both groups. Since the aim of the study cannot be blinded to the FHT, the chosen method may raise the FHT's attention in relation to nutritional aspects in both intervention and control participants. To try to prevent this contamination it will mainly be the same FHT member who will follow participants in the intervention group to their home.

Another weakness is the in-hospital procedure regarding the FHT. Often the FHT only know one day in advance if a patient is going to be discharged with the team. This could make it difficult to achieve the inclusion procedure and baseline data collection, and hence some relevant patients may not be included.

A third weakness is that we do not have funding for taking and analyzing laboratory parameters before and after the intervention. For example it would have been relevant to look at vitamin D status in the blood in relation to the measures of functional abilities. It could also have been relevant to assess the patients' level of stress metabolism, by looking at, among others, alterations in the white blood cell count. Finally, the condition of included patients may change; hence they may not be followed home by the FHT, as otherwise scheduled.

## Conclusion

It is important to provide adequate nutritional support after hospitalization to rehabilitate geriatric patients as close to pre-morbid function as possible so that physical decline, hospital re-admission and even nursing home admission are minimized. The result of this project will hopefully help to ensure the cross-sector quality of nutritional support to geriatric patients. This may ultimately lead to reduced health care costs, and improvement in mobility, independence and quality of life for geriatric patients at nutritional risk.

## Conflict of Interests

The author(s) declare that they have no competing interests.

## Authors' Contributions

All authors contributed to the design of the study. AB prepared the grant application, AB and KØR drafted the manuscript, while LLJ, EL, KM, and AV contributed to drafts of the manuscript. All authors have read and approve the publication of the final manuscript.

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