

Worldwide Global Multicenter Audit nutritionDay in Nursing Homes

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1. Background

Malnutrition associated with illness or aging is a widely spread problem in hospitals and nursing homes. Malnutrition is defined as an imbalance between nutrition intake and requirement, that leads to change in the metabolism, restriction in mobility (e.g. muscle strength) and loss of body mass ¹. In 1988, Windsor et al. already indicated that an unintentional loss of weight loss is a sure indication for a bad prognosis ². In Austria, as in other industrial nations, lots of patients have normal weight or are even overweight; a reason why not enough attention is paid to unintentional loss of weight loss or appetite and inadequate nutrition intake. Malnutrition is associated with a higher morbidity rate, limited quality of life and an increased mortality rate ^{3,4}, thus causing immense costs for the health care system. In England, for the first time the economical consequences have been estimated. The costs of malnutrition and its consequences were calculated at more than 7 billion pounds per year in 2006, 10.5 billion US dollars. This problem was also taken on by the European Council and resulted in the publication of the resolution on "Food and Nutritional Care in Hospitals" (English Edition): http://www.ake-nutrition.at/uploads/media/Resolution_of_the_Council_of_Europe_english.pdf

Age and Health

Life expectancy has distinctly increased in previous decades in industrial states nations and also in some of the so-called third world countries, with a current average of 79 years in the European Union. On average, women live six years longer ⁵. Due to this longer life expectancy, age-related changes and problems become more significant. Illnesses such as diabetes mellitus type II, cardiovascular diseases and dementia increase with age. The aging process is associated with loss of function and reduced performance. Age-related physiological changes in the regulation of nutrition intake and in the gastro-intestinal tract lead to deterioration of the nutritional status. Deterioration of the health status and of nutritional intake is further associated with chronic malnutrition, impaired quality of life, increased morbidity, mortality and long-term care ⁶.

Malnutrition in elderly people requiring care

The Survey in Europe on Nutrition and the Elderly, a Concerted Action (SENECA) study, a longitudinal study investigation of nutritional status and health behaviour of 70-75 year olds and people living at home or in nursing homes in nine towns across Europe, found a high malnutrition risk despite low prevalence ⁷. In healthy, elderly people living independently, one assumes a prevalence of malnutrition of up to 10%. In hospitals, 40-60% of elderly patients are affected by malnutrition, in nursing homes, the situation is dramatic, up to 85% ^{8, 9,10,11} of the residents may be affected by malnutrition. For German-speaking countries the United States, there is little specific prevalence data. Tannen et al. reported a prevalence of malnutrition – defined by the body mass index (BMI) <20 kg/m² of 15.1% in German nursing homes ¹². Bucher et al. found in 2004 a BMI of <18.5 kg/m² in 19.5% of residents with tube-feeding living in nursing homes in Germany ¹³. In Austria, Kulnik and Elmadfa, using the Nestlé Nutrition Institute's Full-Mini Nutritional Assessment (MNA, a validated method for the evaluation of malnutrition) found a prevalence of malnutrition of nursing home residents of 37.8% ¹⁴. In a Medicare-approved nursing home, Shaver et al. assessed nutritional status using a variety of parameters and found malnutrition prevalence of 85% among residents ¹⁵. After measuring visceral and somatic protein stores, Pinchcofsky-Devin and Kaminski reported 52% of residents in two metropolitan nursing homes to have a poor nutritional status ¹⁶. Silver et al. found 46% of residents over the age of 65 were < 90% average body weight (ABW) and 23% were ≤ 80% ABW in an academic nursing home in California ¹⁷. Malnutrition or unintentional weight loss and loss of independence when eating is associated with an up to 4.6-fold increased risk of mortality in nursing home residents ^{15,16,17,18,19,20}. It not only affects physical and psychosocial functions, and thus leads to a reduction in quality of life, but also burdens the expenditure of the health system increases the costs of health care ^{13, 18,19,20,21,22,23,24,25}.

There are many causes for the high prevalence of malnutrition of the sick and people not living independently. The physiological changes of feeling hungry and thirsty with age are often intensified by swallowing disorders, dysphagia, and dementia, and thus contribute to deterioration in health. A lack of knowledge or awareness in those

affected, their families and the health care team often prevent a risk of malnutrition in residents/patients being detected early enough and nutritional therapy being initiated. In addition to information and training, structural physical factors such as quality of the offered food, eating environment, the amount of time capacity of the nursing staff has to for assistance with eating, feeding, also have an influence on food intake and the nutritional status. Therefore, particularly in nursing homes, the amount of food consumed can be rather a challenge due to the care situation, the old age of the residents and the often limited staff resources.

So far, only a small selection of nursing home residents have been examined in the United States and Europe (except in the Netherlands) ²⁶. The question of the nutritional status situation and food consumption, or a risk of malnutrition in United States, Austrian, and European nursing homes, especially in the context of the outcome (morbidity, mortality), is therefore inevitable.

In order to address this problem with more attention among those affected and their relatives, as well as the practitioners/health workers, the Austrian Association for Clinical Nutrition, together with the European umbrella organization (ESPEN, European Society for Clinical Nutrition and Metabolism) launched the "nutritionDay in Europe" (Currently known as nutritionDay Worldwide) in 2006. nutritionDay in the U.S. was launched in 2009 with the support of the American Society of Parenteral and Enteral Nutrition and in 2010 the support of the American Dietetic Association.

The project is based on the assumption that in order to effectively implement changes at the level of structures dealing with direct care of residents, it is necessary to know the relevant facts and to use them to obtain support of the facility, as well as resident organization advocacy groups in order to effectively implement changes at the level of operations which deal directly with resident care. Overall, 47,382 hospital patients have been under examination through nutritionDay Worldwide since the year 2006. In regard to geriatric institutions, it was requested to adjust that the questionnaires be modified to meet the specific needs and situations of the nursing homes.

2. Rationale of the Study

In order to ensure optimal nutritional care of nursing home residents and therefore have a lasting positive affect on their quality of life, morbidity and mortality, it is necessary:

- to collect data on the quality of nutritional care in nursing homes by means of a simple method that requires no specialization in data acquisition,
- to acquire knowledge on the prevalence of risk factors of malnutrition in nursing home residents in general and on individual nursing units, also in conjunction with the outcome after six months, and to forward the same to the individual nursing units,
- to allow comparison with other facilities (with similar profile) with the help of a benchmarking system,
- to assess the effectiveness of introduced changes in terms of quality management and quality improvement.

3. Target Parameters

The primary outcome measured is the dependence of the outcome of nursing home residents' on their nutrient intake, their current nutritional status and risk factors (state of health, level of care).

Secondary outcomes measured: structural parameters (number and type of unit staff, implementation of regular nutrition screening, see first bullet under "Questionnaire" below).

4. Study design

The study is a population-based, observational cross-section examination carried out on one day, and an outcome evaluation six months later. The examination should be repeated annually.

4.1. Study population

The study evaluates nursing homes units and their residents who must be 50 years of age or older.

4.2. Research methods

This project is an extension of the "nutritionDay in hospitals" (EC No 407/2005) to

nursing homes. The questionnaires (based on those of the nutritionDay survey in hospitals) were modified to meet the special needs of nursing homes, examined and approved of by ten experts.

Questionnaires

The survey is divided into four parts:

- Questionnaire regarding the organization and structure of the nursing unit, especially in relation to dietary management: 1 sheet/nursing unit.
- Questionnaire regarding all residents of the nursing unit on "nutritionDay": Basic characteristic of residents on an anonymous basis including nutrition therapy and nursing diagnoses found in the chart, 1 line/resident.
No additional information is required beyond that available and documented in the routine data.
- Questionnaire for individual residents: weight history, eating habits and social contacts as well as current estimated food and fluid intake, 1 sheet/resident.
- Outcome Questionnaire regarding all residents on the participating nursing unit after six months: including weight and number of hospital admissions, 1 line/resident.

All questionnaires were translated by national contact persons in their national language. The accuracy of the translation was checked by back translation into the "master" languages German or English in the coordinating center.

The questionnaires can be downloaded free of charge on the website: <http://www.nutritionday.org/index.php?id=84>.

Instructions as well as explanations and definitions of the questionnaires are available.

4.3. Recruitment plan

The planned number of residents per year of 5,000-10,000 residents per year in nutritionDay Worldwide should be achieved by 5-50 nursing units (with 20-30 beds per unit) per participating country. The nursing units will be invited by the national societies of clinical nutrition, as well as through national and international conferences for voluntary and free participation. Registration is via the website, and

each nursing unit is automatically assigned with an explicit facility and nursing unit code. The target is to record a whole range of different nursing homes of varying in sizes.

Schedule:

- Two months prior to nutritionDay: online registration of one responsible project leader person per nursing unit, who will present the project to the supervisor and the nursing unit. Requests a center and unit codes from www.nutritionday.org, granted to ensure anonymous use of data.
- One month prior to nutritionDay: display announcements of nutritionDay on the nursing units to inform relatives of those residents unable to give consent themselves for the survey.
- Two weeks prior to nutritionDay: complete forms 1 and 2, and the list of residents.
- One day prior to nutritionDay: meet with residents and families, if needed, to complete consent forms
- On nutritionDay: interview residents with the help of staff and/or relatives.
- Thereafter: online data entry or transmission of anonymous data to the audit center in Vienna, www.nutritionDay.org.
- Six months after nutritionDay: survey of the outcome of the residents and further transmission of the data to the audit center. www.nutritionday.org
- 7-8 months after nutritionDay: the nursing homes receive nursing unit reports with their own results compared to the results of the whole study.

5. Ethical and Legal Aspects

5.1. Information on the residents or their relatives, trustees and consent

The nutritionDay in nursing homes is a population-based, observational study in terms of health care research and due to the anonymous feedback to the nursing unit, is a quality control measure (audit). Intervention does not take place.

To ensure reliable nursing unit feedback, it is very important for the nutritionDay forms to be completed accurately and all of the questions need to be answered for

the participating nursing units, and their residents.

Data collection is carried out via questionnaires. Invasive measures such as taking blood are not used.

The audit is implemented by the facility staff in charge of the respective institutions. External personnel is not required.

The target group is approx. 60% cognitively affected. Since the target institutions usually have no experience with studies, written permission would significantly influence the feasibility and quality of results, and a tendency in favor of the cognitively better-off residents would be expected.

Therefore, the residents are questioned verbally, if possible, for their consent. Alternatively, if unable to give consent themselves, relatives of residents who are unable to give consent themselves are informed in advance via a unit notice board. This provides the family an opportunity to object to their family members' participation (see attachment).

By objecting to participate, the respective resident only receives a serial number as a placeholder on the questionnaire with no reference to the person; no further data is taken.

5.2. Anonymity of residents

Data collection is carried out indirectly via a personal numerical code for residents:

- To ensure anonymity of residents the collection of data is split up between different survey questionnaires, which are only linked by a numerical code. Therefore, no direct link between risk factors and outcomes within the nursing unit can be evaluated, and a person-related analysis is not possible.
- Neither the name nor the date of birth of residents are recorded or transmitted, so that their identity is protected.

5.3. Anonymity of nursing units

The purpose of this project is not to publicize possible weaknesses of the individual

nursing units, but to transparently report the situation locally to the facility personnel in charge of medical and nutrition care.

Therefore, a main focus of the organization is to preserve the anonymity of the participating ward nursing unit. The study team expects that under these conditions the willingness of staff to truthfully complete the questionnaires is greater and decreases the likelihood of socially influenced answers.

In order to strictly maintain the anonymity of the nursing unit, facility reports are only compiled if at least five nursing units in the facility participate. This is to prevent individual nursing units being identified via a facility report without their knowledge.

6. Risk/Benefit

The study implies no risk whatsoever for the residents. On some levels participation can even be expected to be beneficial:

- Direct benefit for residents through increased attention to nutritional problems.
- Raising awareness of decision-makers brought about by the decision-making process taking place prior to participating in the study and receiving the quality report of the nursing unit or facility.
- Increase awareness of the staff of nursing homes by participating in the study and the quality report. Pilot results suggest that in terms of the Hawthorne effect, just participation alone has a positive influence on nutrition management on nursing units.
- Since the project is planned for at least two years, it is possible to repeat the study after one year, to be able to monitor changes which were introduced as a result of the first report.
- Due to prior announcement on the nursing units, residents and their trustees are made aware of the issue of malnutrition and proper diet management. The nutritionDay in hospitals has shown that in many cases for the first time discussions between staff, patients and relatives on this subject were set in motion.

7. Documentation of the results of the study, data management and data security

All the necessary data for documentation of the study are entered on the questionnaires. On the study forms the nursing unit is identified by a numerical code, which is allocated after application from the audit facility. The questionnaires only include information on year of birth of the residents and their initials. If requested by the nursing units, to facilitate the evaluation of outcomes. the evaluation can be completed without the initials.

The data are entered online into the database from the facility. The coordination center does not have access at any time to documents that would influence the anonymity of the residents.

The data in the coordination center is checked for credibility prior to further evaluation. In the case of unclear or incomplete data, feedback to the responsible person on the nursing unit takes place and a possible correction of data is made.

All data are analyzed anonymously, and the results are made available to each nursing unit so that the identity of the nursing unit, as well as the anonymity of the individual residents is assured.

8. Communication of Results

Following data input of the resident's outcome, each nursing unit (the nutritionDay Project Leader person on the ward nursing unit responsible for organizing the nutritionDay and should be who is clearly identifiable by an e-mail address) receives the results compared to the whole project in the form of a quality report on nutritional intake and influencing factors.

The results of the study are published by the head of the study in a scientific journal and presented at scientific conferences.

9. Amendments to Protocol

If modifications to the protocol are required, e.g. inclusion of other test parameters, this will be reported to the Ethics Commission and their consent obtained.

10. Statistical Methods

An analysis on survival with the target variable "death in nursing homes within six months" will be carried out. Existing risk factors are to be taken into account as covariant causes. Information on the time of admission to the nursing home and the time of death of the residents will be available.

In addition, the trend of weight development of the surviving residents between the nutritionDay and a half year thereafter will be recorded. The connection between nutritional status and weight on the nutritionDay and the course of weight thereafter of the surviving residents will be analyzed.

11. The Project Team

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12. Literature

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