PROTOCOL VERSION 2.0

NUTRITIONDAY IN PRIMARY CARE

ABSTRACT

Introduction

Malnutrition can be defined as “a state resulting from a lack of intake or uptake of nutrition that leads to altered body composition (decreased fat free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease”(1). It is the result of unintentional weight loss, low food intake and inflammation. Malnutrition manifests as a loss of muscle mass, frailty and functional impairment (2-4).

Several studies from the nutritionDay project showed that the prevalence of malnutrition related risk factors is high in hospital patients and it varies in different unit specialties (5) (6) (7) Malnutrition in hospital settings is estimated to be around 37% (8). In Primary Health Care, this prevalence is not clear, and probably largely underdiagnosed, due not only to the lack of organized screening as well as to the lack of awareness by healthcare professionals about this condition.

This investigation aims to understand the nutritional status and related risk factors for malnutrition of adult patients who come for a visit at a Primary Care Health Center or at the primary care doctor office or who meet the doctor during home visits scheduled by the primary care doctor.

Methods

This investigation is an observational study with a convenience sample composed by 18 years or older patients who will attend a medical appointment at a Primary Health Care Center or praxis or on a specific day in November (day internationally defined as “nutritionDay” or “nDay”). The data will be collected in all Health Care Centers that adhere to this study as well during home visits scheduled by the Primary Care doctor. Family doctors or general practitioners will be recruited to collaborate with this research project by the coordinator of the nDay primary care project in each country. Each health care practitioner/physician who agrees to collaborate will present and explain the project to patients who are seeking medical consultation during the study period and collect their free, informed consent. This study will be carried out in several European and worldwide countries, in partnership with nutritionDay worldwide, with national Clinical Nutrition Societies and with the overall support from the members of the European Society for Clinical Nutrition and Metabolism (ESPEN).

The data that will be collected in this project are: sex, age, weight, height, eating habits, amount of food intake, mobility, weight loss in recent months, reasons for visiting the doctor, self-perception of

health, symptoms associated with lower appetite (if applied), number of pills taken per day, recent hospitalization or recent surgery, comorbidities, nutrition care prescribed (if any), date of doctor visit, follow-up needs and outcome after six months.

The questionnaire will have two parts: the first part is to be filled out by the patients themselves in the waiting room and the second part to be filled out by the collaborating “Primary Care” physician or health care practitioner or associated staff. The data collected on paper sheets will be transferred into the international nutritionDay database created for this purpose. No patients can be identified from the database. Each patient will be assigned a code, so that only the doctor that performed the medical appointment can identify to which patient each answer belongs to. The information collected will be held by the physicians who collaborate with the study and will only be kept for the time necessary for data processing. The data will be entered into the international nutritionDay database and used for further analysis.

INTRODUCTION

Problem identification

Malnutrition can be defined as “a state resulting from lack of nutrition intake or uptake that leads to an altered body composition (decreased fat free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease”, according to the most recent definition by ESPEN (European Society for Clinical Nutrition and Metabolism).(1) The prevalence of malnutrition in hospital settings has been described as a challenge for the healthcare system by the Council of Europe in 2003 and it has been estimated by several studies to be between 27% and 37%(8) (9). Malnutrition has been shown to lead to poor outcome (5, 7), and increased healthcare resources utilization (10) (11).

Malnutrition is typically the result of unintentional weight loss, low food intake and inflammation (1). Malnutrition manifests as a loss of muscle mass, frailty and functional impairment, reduced muscle strength and sarcopenia, fatigue, impaired healing of chronic wounds, a higher risk of infections, loss of patient’s autonomy and independence (2-4).

Since 2006, the nutritionDay project has investigated the prevalence of the nutrition related risk factors in hospitalized patients worldwide. NutritionDay has demonstrated that each of the nutrition related risk factors is associated with an increase mortality within 30 days in hospital (7).

Weight loss and reduced nutrient intake are found in nearly half of the hospitalized patients participating in the nutritionDay audit whereas apparent malnutrition with body mass index BMI<18.5 is only present in less than 10% of the patients. The nutrition related risk factors have been found by the nutritionDay study to be similarly prevalent worldwide.

Most of the malnutrition risk factors are already present at hospital admission and thus are developing in the community before hospitalization. Whereas in hospital, malnutrition screening and assessment are recommended by guidelines and are mandatory at admission in certain countries, no such recommendations exist for the primary care setting. In the context of Primary Healthcare, prevalence of malnutrition and its related factors is not clear, but it is supposed to be largely underestimated, both due to the lack of organized screening and the lack of awareness of health professionals regarding this problem.

Malnutrition is a multifactorial condition that affects all age groups, with special prevalence in the elderly and is independent of Body Mass Index (BMI). It can thus be present in patients with a BMI of underweight, eutrophy, overweight or obesity (2).

By identifying patients at nutritional risk, the multidisciplinary healthcare team will then be able to institute a nutritional care plan according to the severity of the malnutrition risk.

NutritionDay

NutritionDay (or “nDay”) is a worldwide initiative that aims to tackle malnutrition in health institutions. Due to the high prevalence of malnutrition in hospital settings, this initiative aims to improve the knowledge and perception of health professionals about this condition, also aiming to improve the quality of nutritional care for overall patients.

“NutritionDay” is a one-day cross-sectional audit with outcome evaluation.
On a specific day in November of each year (“nDay”), hospital wards and nursing homes that agree to participate, collect data from participants through a simple data collection (questionnaires available in multiple languages) for nutritional risk factors. This data is collected anonymously and stored in an nDay international database at the Medical University of Vienna (MUW).

In 2023, for the first time, this audit will also be carried out in Primary Health Care Centers and individual primary care offices, with the possibility to collect data of non-hospitalized patients. The questionnaire to be applied will be the same in all adherent countries (translated into the language of the country).

PROBLEM PRESENTATION

Overview

Malnutrition has been reported to be in association with hospitalization and diseases-related malnutrition. Many analyses of risk factors suggest that malnutrition develops progressively before hospitalization. Malnutrition in Primary Health Care has been not been systematically studied and it is thought to be largely underdiagnosed thus early treatment may not be given. This study aims to evaluate the nutritional status and nutrition care of patients who resort to Primary Health Care on the day of the study. In this study data collected in the primary care setting will be used to estimate the prevalence of nutrition related signs and symptoms, history of poor eating and weight loss, nutritional risk factors, nutrition care and in addition relevant outcomes will be obtained.

In addition, this study also intends to raise awareness for the problem of malnutrition among primary health professionals and increase their knowledge for this condition.

Research question(s) / Research hypothesis

The aim is to determine the prevalence of individual malnutrition related risk factors and of the use of nutrition therapy in the Primary care context and their association with patient outcome after six months.
In addition to it, the data will be analyzed for diagnostic categories, presence of comorbidities and demographic characteristics. Moreover, the subsequent use of medical resources (return visits, referral to a specialist, and need for hospitalization) and the association of nutritional risk factors to outcomes after six months from nDay will be analyzed.

OBJECTIVES

Main objective

The aim is to determine the prevalence of individual malnutrition related risk factors and the use of nutritional therapy in the Primary care context and their association with patient outcome after six months.

Specific objectives

Data will be analyzed for diagnostic categories, presence of comorbidities and demographic characteristics. Moreover, the subsequent use of medical resources (return visits, referral to a specialist, and need for hospitalization) will be analyzed.

STUDY DESIGN AND METHODS

Type of study

Prospective observational cohort study.

Population and study sample

Population: patients aged 18 or above who seek a medical appointment at the Primary Health Care Center or Primary Care doctor office or during home visits scheduled from the Primary Care doctor participating in the study. A convenience sample will be used.

Sample size and process of selection and recruiting of sample

Inclusion:
Consecutive patients aged 18 or above who seek a medical appointment on predefined days at and around nutritionDay until a sample of minimum 50 patients will be reached by each Primary Health Care Center or primary care doctor office or during home visits scheduled from the primary care doctor participating in the study. All users who, after free and informed consent, agree to participate in the study will be selected to participate in the study.
Exclusion:
Patients not seeing the primary care doctor during the visit at the Primary healthcare centers (e.g. patients who need only a certificate or prescription renewal)
Patients who do not understand the language of the provided questionnaire.
Patients who are not able to give a free informed consent.

Information sources

Patients and the health care practitioner/physician (including dieticians, nurses and healthcare staff members) that performed the medical appointment

Process of information gathering

Two parts questionnaire. The first part will be filled in by the patient in the waiting room and will be composed by 10 simple multiple-choice questions. The second part will be filled by the health care practitioner/doctor who carried out the medical appointment with the patient, completing data on diagnosis, comorbidities, nutritional therapy instituted and current follow-up needs. In addition outcome is collected six months after nDay if possible.

Exposure evaluation

Exposure is derived from questionnaires. No specific additional diagnostic or therapeutic interventions are necessary.

Information management

Information management involves two steps:

Step 1: at the participating Primary Health Care Center/Office

All information is collected with the help of questionnaires. During the participation period patients fill the patient part of the questionnaire while in the waiting room and the doctor/nurse/ dietician fill the diagnosis and treatment part. The questionnaire has a randomly attributed “primary care center” and “primary care Healthcare practitioner/doctor” code and a number for each patient (see nutritionDay questionnaire, nutritionDay patient list). The patient questionnaire does not allow identification of an individual patient because only age, sex and the participant number are recorded. The patient list contains all participating patients and their participant number and is used to document outcome after 6 months. Only outcome available in the Primary Health Care Center local documentation will be used. The questionnaires and the patient list remain exclusively in the Primary Health Care Center until outcome has been collected and documented after 6 months. After completing outcome on the HCP/doctor sheet, the patient list with the local identifier is not used anymore. The storage of the patient’s list is only with the participating Primary Health Care Center/Office for the 6 months until outcome recording.

Only the data recorded on the patient questionnaire that is “pseudonymized” is transferred into the nutritionDay database.

Step 2: Data entry into the nutritionDay database

The nutritionDay database is located on a dedicated server at the Center for Medical Data Science of the Medical University Vienna. Only one system administrator of Medical University Vienna has access to the dataserver in compliance with the security rules of Medical University Vienna.

Data entry of the pseudonymized data by the participating Primary Care Center/Office is done on dedicated web interface where only registered user with a random access code for the Center and the HCP/Doctor is necessary. The access codes allow also generation and download of a summary

report of the entered data of one Primary Health Care Center in comparison with average data from all participating Centers/Offices.
For statistical analysis data are exported into a secure data server of the Department for Medical Statistics only accessed by the nutritionDay statistician. All procedures are following the security rules of Medical University Vienna and follow the Data Protection Directive.
The registration procedure of users is independent of the nutritionDay database and registration information is stored on a separate server.

Statistical analysis

Descriptive statistics: median proportions with **interquartile** range. The level of aggregation will be the individual healthcare center.

WEAKNESSES AND STRENGTHS OF THE STUDY

WEAKNESSES - sample size depending on patients' recruitment and number of participating Primary healthcare centers/HCP/doctors; precision prevalence estimates of the risk factors for malnutrition is depending on the number of participants and on the prevalence itself; estimates might be imprecise if the prevalence registered is very low.

STRENGTHS - multicentric study; pioneer in its extension to Primary Health Care Settings, multi-language audit, data harmonization between countries (same data collected in each country), no need for special knowledge to complete the questionnaires. Participation to the audit is free of costs for the participating healthcare centers/ primary care doctors and for the patients.

ETHICAL CONSIDERATIONS

Anonymity of participating patients as well as of participating centers and primary care doctor offices in the nutritionDay database will be preserved by assigning them random numerical codes at registration to the study. No data that can identify a patient will be stored in the nutritionDay database.

All questions in the nDay audit are formulated in a way that no suggestions on any type of intervention is implied.

Center accounts for data entry and reports download can only be accessed by means of center/HCP/doctor codes received upon center/doctor registration.

PUBLIC HEALTH IMPLICATIONS

By determining the prevalence of individual malnutrition related risk factors and the use of nutrition therapy in the Primary Care context as well as their association with patient's outcome after six months, it is intended to audit patients' nutrition needs; to make healthcare professionals aware of malnutrition and of the need for screening and diagnosing this condition, and to implement strategies to treat and prevent malnutrition in the community.

The study can be used as well to estimate utilization of medical resources (return visits, referral to a specialist, need for hospitalization), and related costs.

This study will allow the development of a simple screening of nutrition risk factors in primary care setting that is related to patient outcome.

Furthermore, the development of a strategy to reinforce continuity of care after hospital discharge may be supported.

PERSONS RESPONSIBLE FOR THE CLINICAL STUDY (AT YOUR TRIAL SITE)

Prof. Dr. Michael Hiesmayr, Dr. Sci. Med. Silvia Tarantino Msc and Alexander Knötzl Bsc from the

Institute for Medical Statistic (CEMSIIS/MUW) and Dr. Karin Schindler from the Internal Medicine department at Vienna General Hospital (AKH) are the persons responsible for the study at the Medical University of Vienna..

BUDGET

Training of primary healthcare professionals, travels, consumables, screening interview time and application of the questionnaire, database data entry, will be supported by the each participating primary healthcare professionals/ center themselves.

Participation to the audit is free. No reimbursements to doctors or patients is foreseen.

The costs related to the development of the dedicated nDay primary care database, to the management and development of the new nDay branch as well as related website interface costs will be additionally included in the 2022-23 nDay Budget (ESPEN sponsoring).

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