Association between Refrigerator Openings and Protein Intake after Hospitalization for Heart Failure Decompensation: Protocol for a Prospective Cohort Study

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Abstract

Background: Sarcopenia with loss of muscle mass, loss of strength and increasing frailty is common in elderly adults and is often the result of underlying diseases such as advanced stages of heart failure (HF). Protein intake is crucial for maintaining muscle mass and strength. However, older adults typically eat less protein compared to younger adults. It has recently shown that the time of the first refrigerator opening in the morning indicated by a door sensor at the refrigerator may correlate with frailty in elderly single living persons.

Objective: The aim of this study is to measure whether the time of the first refrigerator opening in the morning is a potential indicator for protein intake in elderly patients after hospitalization for heart failure decompensation over a period of six month.

Methods: This is a sub study of a prospective interventional cohort study which aims to identify changes in ambient sensors system derived digital biomarkers with a high potential for early detection of HF decompensation. In this sub study frequency and timing of participants opening the refrigerator door at their homes will be measured. To identify associations between protein intake and refrigerator openings, a dietary assessment will be carried out by 24-hour diet recalls at three different time points: at 1, 3 and 6 months after hospital discharge. All 24-h diet recalls will be completed on weekdays by trained dietitians in face-to-face interviews. The primary outcome of this study will be the correlation between protein intake and first refrigerator door openings after midnight in minutes over 1, 3 and 6 months.

Results: The study is in the collection phase. Study recruitment started in February 2024. Data analysis is scheduled to start after all data are collected. As of manuscript submission, 4 patients have been recruited. Results are expected to be published by the end of 2025.

Conclusions: Considering that protein-rich foods are mostly stored in the refrigerator, the relationship between frailty and use of the refrigerator could be an important issue for nutritional assessment in terms of protein intake. Furthermore, sarcopenia / frailty could also be related to protein distribution over meals. The present study will provide insight whether the use of the refrigerator openings would allow easy monitoring as indicators of increased frailty and sarcopenia risk. Interventions could be initiated at an early stage and thus reduce the risk of these diseases. Clinical Trial: ClinicalTrials.gov NCT06126848;

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Trial Registration: ClinicalTrials.gov NCT06126848; https://clinicaltrials.gov/study/NCT06126848
International Registered Report Identifier (IRRID): PRR1-10.2196/55953

Keywords: nutrition assessment; protein intake; muscle mass; muscle strength; elderly; digital health; ambient sensor system

Introduction

The population of older people is increasing significantly around the world including Switzerland [1]. With higher life expectancy and increasing age, the risk of diseases characterized by a decrease in muscle mass is also rising [2,3]. Loss of muscle mass and strength are associated with an increased risk of further mobility impairment, fractures, prolonged hospitalization, hospital readmission, poor quality of life, morbidity and mortality [2,4–6]. These conditions arise due to a combination of reduced food intake, increased nutrient requirements, metabolic changes, sepsis, trauma, ageing as well as physical inactivity [4]. The 'interplay' between malnutrition, sarcopenia and frailty in older people has already been demonstrated in many studies [7–10]. A systematic review and meta-analysis, has shown that about half of hospitalized older adults suffer from 2 or even 3 of these diseases or precursors [3].

Furthermore, sarcopenia and frailty are often the result of other underlying diseases such as chronic heart failure (HF). The prevalence of sarcopenia has been found to be 55% (95% CI: 43-66%) in hospitalized patients with HF and 26% (95% CI: 16-37%) in non-hospitalized patients [11], 79% of HF patients are frail. This in turn may be associated with poorer quality of life and poor prognosis [12]. Overall, diet quality is associated with the risk of frailty and poor intake is adversely related to muscle mass and strength [13,14]. Nutritional status is therefore also a crucial risk factor for the development and prognosis of HF.

Due to the high prevalence of sarcopenia and frailty in HF patients, more attention should be paid to protein intake as an important influencing nutrition factor [14–16]. To achieve this, the protein intake of HF patients in the home environment must first be assessed. Ideally, simple, valid instruments should be used for this purpose. Common screening tools such as the Mini Nutritional Assessment (MNA) are insufficient to recognize people with low energy and protein intakes [17]. Currently, a number of screening and assessment tools are available [18], however, the assessments with these tools are very time-consuming for long-term monitoring at home and therefore not very feasible for application HF patients everyday lives.

Digitalization can offer new possibilities that allow HF patients living at home to be monitored easily and regularly. It has been shown that a sensor system using interaction-free, contactless and inexpensive sensors is suitable for long-term monitoring of physical activity, sleep and door openings including the refrigerator door in the homes of elderly people living alone [19]. Considering that protein-rich foods (such as meat, meat products, fish, milk and dairy products) are mostly stored in the refrigerator, the relationship between frailty and use of the refrigerator door could be an important indicator for nutritional status in terms of protein intake. Furthermore, sarcopenia and resulting frailty could also be related to protein distribution over meals. To date, there are very few studies on this. A study among older women in the Nurses' Health Study, indicates that consuming at least 30 g of protein over two or more meals could be more effective for maintaining muscle mass and physical performance compared with eating a single high-protein meal [20]. In addition, two recent studies in elderly populations indicate that skipping breakfast increases the risk of frailty [21,22]. A Japanese survey (n=2468) showed a correlation between breakfast habits and frailty in older people aged 75 and over. Breakfast skippers generally had lower food intake and poorer nutrient density than daily breakfast consumers. The multivariable-adjusted odds ratio (95% confidence interval) of breakfast skippers for frailty was 1.62 (1.04-2.52; P = 0.032) in one model (adjusted for age, sex, body mass index (BMI), and living alone) [22].

The use of refrigerator openings (e.g., the first door opening of the day or frequency) as indicators for increased risk of sarcopenia and frailty would provide an easy monitoring opportunity. In this context, the study by Schütz et al. has shown that the time of the first refrigerator opening in the morning indicated by a door sensor at the refrigerator may correlate with frailty in elderly single living persons [19]. With such simple assessment tools, interventions could be initiated at an early stage to reduce the risk of these diseases. This in turn would have an impact on quality of life of those affected and may also contribute to a decrease in health care costs.

As a part of prospective interventional cohort study (for details see study protocol of Vögeli et al. 2024) [23]), a sub study will be conducted with the aim to evaluate the sensitivity and specificity of the time of the first refrigerator opening in the morning as a potential indicator for protein intake in elderly patients after hospitalization for HF decompensation over a period of six month.

Methods

Study Design and Participants

In this prospective cohort study, 24 consecutive patients living alone at their homes and with hospitalization for HF decompensation at two Solothurner Spitäler AG secondary care hospitals in Olten and Solothurn (Switzerland) will be included.

The study inclusion criteria are current hospitalization for HF decompensation, age ≥ 70 years, left ventricular ejection fraction < 50% and treatment with diuretics, New York Heart Association class II or III, living alone, willing to participate with informed consent, agreement for follow-up appointment in hospital at 3 and 6 months. Exclusion criteria include major depression (Patient Health Questionnaire – PHQ-9 score >9) or being on hemodialysis. In addition, patients with a left ventricular assist device, or those who had undergone coronary revascularization or cardiac resynchronization therapy implantation within 28 days before the index event of HF decompensation or have been scheduled for such interventions are excluded from the study.

Ethical Considerations and Data Protection

The study will be conducted based on the principles expressed in the Declaration of Helsinki, the Guideline of good clinical practice (ICH-GCP) and the Human Research Act after protocol approval by the regional ethics committee (Ethikkommission Nordwestschweiz). Patients will provide written informed consent for the main and the sub study. Data will be collected by specially trained research staff and entered into a password-protected data environment. Each patient will be attributed a study-specific patient identification number (PID). For statistical analysis, these datasets will be merged using the PID as identifier. At the end of the data acquisition, including follow-up, patient data will be coded using the PID, and the database will be locked. Coding using the PID will be done at the earliest time point after completion of follow-up data collection. Data generation, transmission, storage and analysis of health-related personal data within this study will follow the current Swiss legal requirements for data protection and will be performed according to the Human Research Ordinance Art. 5. Health-related personal data captured during this study is strictly confidential and disclosure to third parties is prohibited. Participants will be compensated for costs resulting from travel expenses due to follow-up visits in the hospital. For study participation, no costs incur for participants.

Assessment

Baseline Assessment

The baseline parameters that will be evaluated at hospital entry have been previously described [23].

Dietary Assessment

For dietary assessment, food intake will be measured using the 24-hour (h) diet recall. The 24-h dietary recall is an open retrospective dietary assessment method. It aims at recording as much detailed information as possible about all foods and drinks consumed by the respondent in the previous 24-h or the day before [24]. In this study, 24-h diet recalls are conducted at three different time points, at 1 (optional), 3 and 6 months after hospital discharge. All 24-h diet recalls will be completed on weekdays by trained dietitians in face-to-face interviews. As the major drawback of this method is the forgetfulness of the participants, the 24-h diet recalls will be conducted by using the Automated Multiple-Pass Method (AMPM) as described elsewhere [25]. The AMPM uses multiple memory cues with standardized wording to elicit recall of all possible foods. Before the start of the 24-h diet recall, it will be recorded whether the day surveyed reflected a normal (average) day in terms of diet or whether it was a special day. The amount of consumed food will be estimated using the photo book of the national nutrition survey in Switzerland (menuCH) [26]. See Multimedia Appendix 1. The conversion of the estimated amounts eaten into weights will be conducted according to the menuCH photo book manuals and commercially available packaging sizes in Switzerland. All the conversions of estimated amounts consumed into weights will be conducted by experienced dietitians. Protein intake in grams (g) and energy intake in kilocalories (kcal) will be calculated using nut.s nutritional software (version 1.33.10 – 2022.08.26) based on the 24-h diet recalls. The nutritional database used in nut.s is adapted for the evaluation of Swiss foods.

Anthropometric measurements

Anthropometric measurements include body height, body weight and Body Mass Index (BMI). Weight is measured using a clinically validated and calibrated scale. Participants have to remove heavy clothing (e.g., jackets, jumpers) and shoes. Weight is recorded to the nearest 0.1kg. Height is measured using a calibrated stadiometer. The measurement is taken in an upright position with the feet on a hard surface. The heels, buttocks, shoulders and the back of the head touch the wall and the arms are placed at the sides. Height is recorded to the nearest 0.1 cm. BMI is calculated by dividing body weight in kilograms by height in meters squared. Measurements will be carried out 1 (optional), 3 and 6 months after hospital discharge, in each case after the 24-h diet recall.

Mini Nutritional Assessment Short Form (MNA-SF)

Screening for malnutrition or risk of malnutrition will be carried out 1 (optional), 3 and 6 months after hospital discharge, using the MNA-SF. The MNA-SF, consisting of 6 questions, is cost-effective, simple, suitable for use in hospitals and therefore fulfills the requirements for a screening instrument, which can be used to identify existing malnutrition or the risk of malnutrition in older people [27]. The MNA-SF includes questions on mobility, psychological stress or acute illness and neuropsychological problems, which increase the risk of malnutrition but do not directly detect malnutrition. The MNA-SF is therefore particularly suitable if the aim of the screening is to detect malnutrition as early as possible [28].

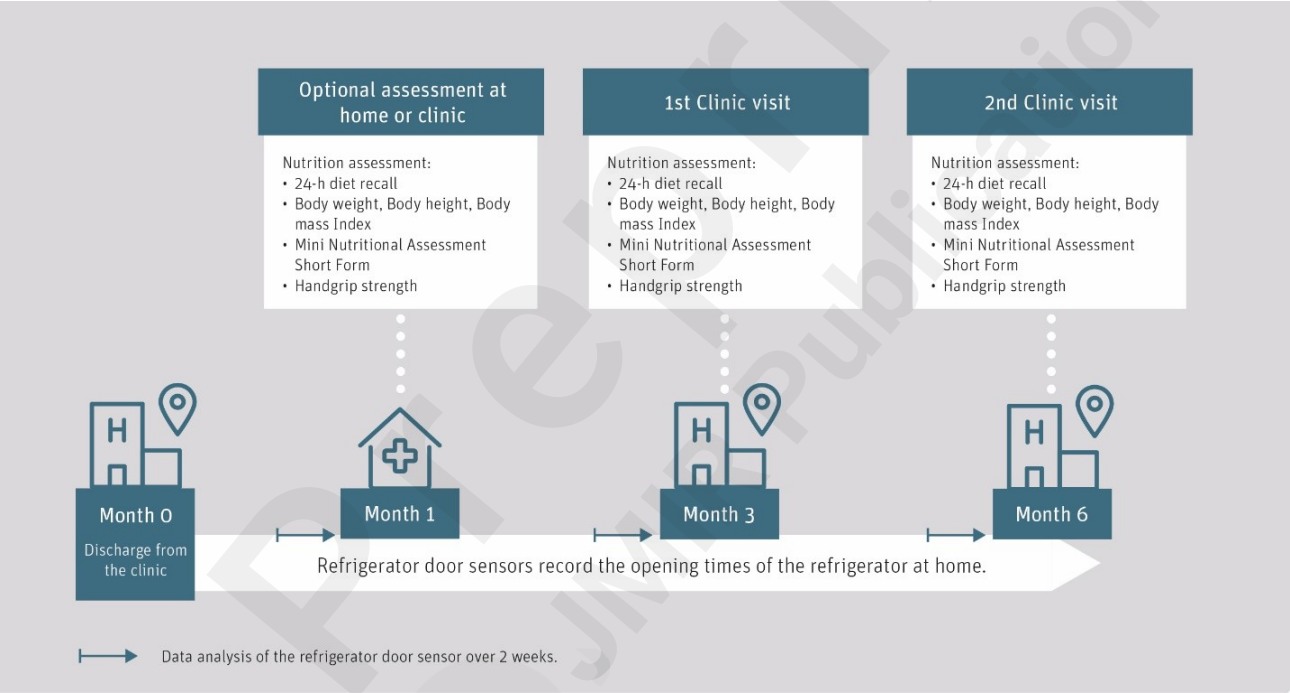
Handgrip strength

There is strong evidence for a correlation between weak handgrip strength (HGS) and reduced nutritional status, increased mortality, complication rates, and hospital length of stay [29–32]. Therefore, HGS will be measured 1 (optional), 3 and 6 months after hospital discharge, using a

dynamometer as follows: the participants, sitting on a chair, the elbow joint bent 90 degrees. On request, the dynamometer is squeezed as tightly as possible. First the non-dominant hand and then the dominant hand will be tested three times each. The best value on the left and right is entered into the database.

Refrigerator door sensors

The refrigerator at the patient's home will be equipped with a door sensor recording the opening and closing of the fridge door. This sensor consists of a small magnet fixed on the door and a sensor with a reed relay attached to the frame. When the door opens or closes, the sensor immediately sends this information over a wireless radio link to a data-collecting base unit in the home. This unit then transmits the data, including the timestamp of the event, to the cloud-based database over a mobile data connection. Open and close events are recorded with a time resolution of one second. Opening durations are calculated as a difference between the two events.
The refrigerator door sensors will be installed at the patient's home within one week after hospital discharge. Frequency and timing of refrigerator openings are collected over a 6-month period after hospital discharge. The assessment during the study is shown in Figure 1.



Statistical Analysis

We will compute the cross-sectional correlations between protein-intake (g) and first refrigerator door opening after midnight in minutes (RDmin) at start (1 month), 3 and 6 months (primary outcome). Further, quantities of interest are the correlation between protein-intake (g) and refrigerator opening frequency per day (RDfreq), between energy intake (kcal) and RDmin / RDfreq, between (risk of) malnutrition (score) and RDmin / RDfreq and between handgrip strength (kg) and RDmin / RDfreq. From the time-series of refrigerator opening time after midnight in minutes over the period of 6 months, we will create 3 time-windows. Each window representing the period of 2 weeks before the nutrition assessment (see figure 1) will be used to compute a mean RDmin measurement within each window, leading to 3 RDmin measurements, 3 RDfreq and 3 measurements of protein (g) and energy intake (kcal) from the 24-h diet recalls, 3 measurements of malnutrition and HGS (after 1, 3 and 6 month). We will estimate the cross-sectional associations

between RDmin / RDfreq and protein intake (g), energy intake (kcal), (risk of) malnutrition (score) and handgrip strength (kg) at 1, 3 and 6 months. This will enable us to quantify the correlation and to assess the stability of this correlation over time. We will compute spearman correlation with corresponding 95% confidence intervals.

Results

The study is in the collection phase. Study recruitment started in February 2024. Data analysis is scheduled to start after all data are collected. As of manuscript submission, 7 patients have been recruited. Results are expected to be published by the end of 2025.

Discussion

What does the study offer?

Because overall diet quality is associated with the risk of frailty and poor protein intake leads to loss of muscle mass and strength [13,14], more attention should be paid to healthy nutrition and adequate protein intake in HF patients. Although results suggest that HF patients may benefit from a high-protein diet, conclusive evidence on the potential benefits of a high-protein diet from prospective controlled clinical trials is scarce, particularly regarding mortality. Individual studies, such as a randomized double-blind pilot study in 29 HF patients, were able to show an improvement in quality of life after 18 weeks on a high-calorie, high-protein diet [33]. However, most studies on protein intake are observational and were conducted in the general population [34], whereas little data are available for HF patients. Simpler and innovative tools to collect information about protein intakes of HF patients would be beneficial to reduce the burden for long-term monitoring at home. Furthermore, a recall bias can also be minimized, which can be caused by retrospective nutritional assessment methods, especially in older people.

Refrigerator openings could be a simple tool for this, both in terms of the first opening of the day and in terms of frequency. For example, late opening the fridge door for the first time after midnight can be related to skipping breakfast. In general, little is known about the nutritional status of older people who skip breakfast and there are contradictory results regarding meal frequency and frailty [35,36].

To the best of our knowledge, this is the first prospective study investigating the use of refrigerator openings as potential indicator of protein intake. The use of the refrigerator openings in relation to frailty and sarcopenia would allow easy monitoring. Interventions could be initiated at an early stage and by this reduce the risk of disease progression.

Limitations

This study has several limitations. First, the patterns of refrigerator openings in regard to daytime and number of openings may be subject to great variations, and the use of single values and combinations of values have to be validated internally and externally. Second, the operating area is limited to patient who live alone. This complicates the generalizability of the results to other HF populations. The small sample size is based on experience from a previous study including similar patient population with hospitalization for HF decompensation. For a regular power calculation, there are no previous data available.

Third to verify the accuracy of the refrigerator openings to assess the protein intake, it must be compared with a standard method. This is done in this study with a 24-h recall. As a retrospective method, it also has weaknesses, in particular recall bias or unusual eating days. For this reason, at least 2 24-h-recalls per person are carried out.

Conclusions

This study aims to provide new insight into the relation of refrigerator openings with nutrition and in particular with protein intake. It is hypothesized that monitoring refrigerator openings in the framework of an ambient sensor system may help to identify patients at risk for malnutrition and with that for loss of muscle mass and muscle strength. Such an identification of poor and in particular protein deficient nutrition would allow easy monitoring and early intervention to prevent or at least delay sarcopenia and frailty and with this to improve quality of life, and this potentially at reduced health care costs. In addition, such a simple way of monitoring could also be interesting for other target groups (e.g. older people living at home in general).

Data Availability

The dataset sets generated and analyzed during this study are available from the corresponding author on reasonable request.

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KH, FS, HS have designed the sub-study. BV, NA, HS are responsible for the overall study. HK and SF are responsible for collecting the data. AM designed the analyses and will conduct them. HK, SF, HS, wrote the first and subsequent versions of the manuscript. All authors have read and approved the final manuscript. HK has final responsibility for the content of this manuscript. Special Thanks to Antonia Kilchmann (Study nurse) for her excellent work.

Conflicts of Interest

PB works for DomoHealth, one of the manufacturers of the sensor system used in the study. The other authors have no conflict of interest.

Abbreviations

BMI: Body Mass Index
HF: heart failure
HGS: hand grip strength
menuCH: National Nutrition Survey Switzerland
MNA: Mini Nutritional Assessment
MNA-SF: Mini Nutritional Assessment Short Form
RDfreq: refrigerator door opening frequencies per day
RDmin: refrigerator door opening after midnight in minutes
24-h diet recall: 24-hour diet recall

Multimedia Appendix 1

Examples from the photo book of the national nutrition survey in Switzerland (menuCH)

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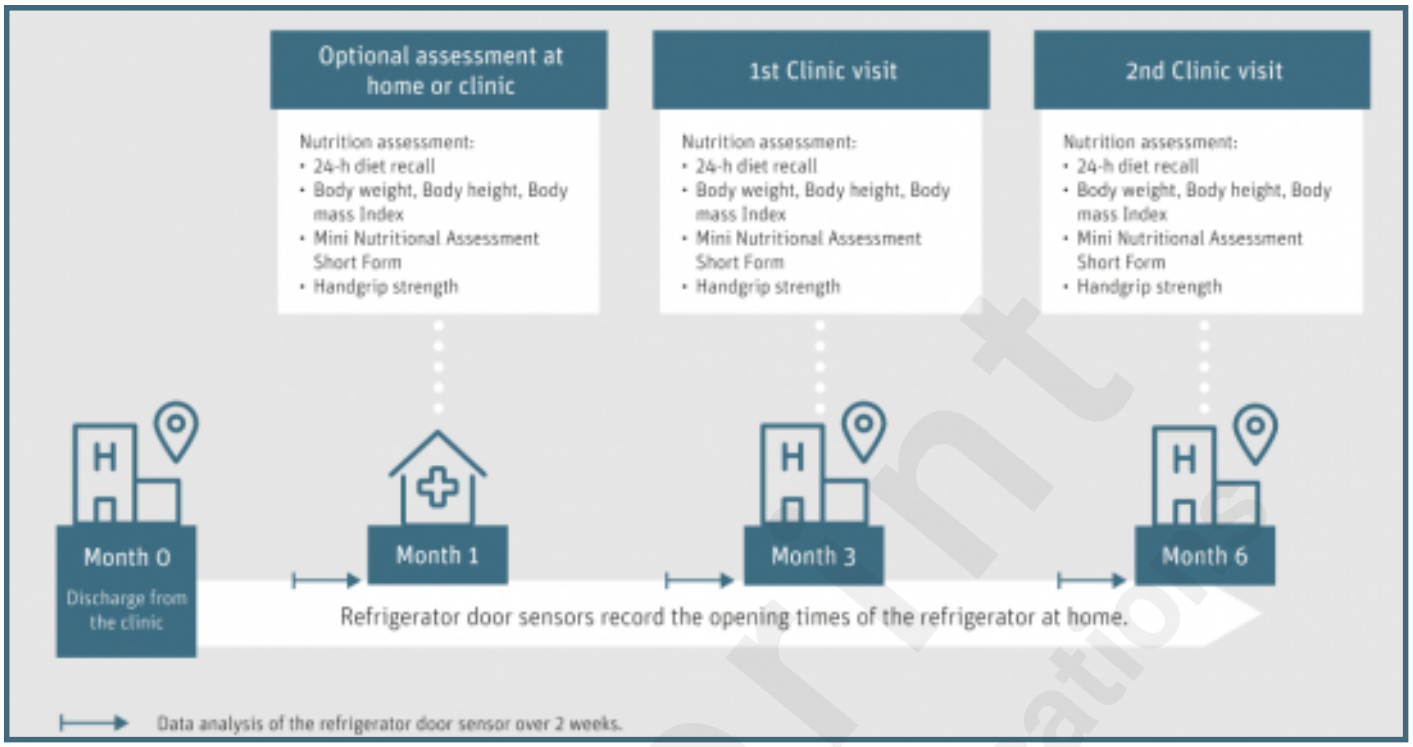
Supplementary Files

Figures

Assessments during the sub study.



Multimedia Appendixes

Examples from the photo book of the national nutrition survey in Switzerland (menuCH).
URL: http://asset.jmir.pub/assets/bde4dbfbb99c37fedf3b38ec61cbea63.pdf