Effect of Continued Nutritional support at Hospital Discharge on Mortality, Frailty, Functional Outcomes and Recovery Trial: The EFFORT II Project

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Description of the initiative

Malnutrition is a strong and independent long-term risk factor for mortality, rehospitalisation and functional decline, particularly in the elderly, polymorbid medical patient population. Current evidence from the EFFORT trial (Lancet 2019) showed that inhospital nutritional support reduces the risk for complications and mortality. Yet, long-term follow-up data of patients included in the EFFORT trial showed a lack of sustained effect of the initial nutritional support strategy, which is possibly explained by the short duration of the nutritional intervention focusing only on the initial hospital stay but not after discharge.
Within the EFFORT II trial, we thus hypothesize that continued post-discharge nutritional support to reach individual energy and protein goals compared to usual care home nutrition in medical patients at nutritional risk is a cost-effective strategy to reduce mortality and prevent complications and a decline in functional capacity (https://clinicaltrials.gov/ct2/show/NCT04926597).

Planned activities & deliverables

We started a step-wise recruiting of patients into EFFORT II in nine participating Swiss hospitals in August 2021. We designed the study as an event-driven trial with a target of 247 mortality events and a total sample size of at least 802 participants assigned equally to the nutritional support and the usual home nutrition groups, on the basis of a hypothesized yearly mortality incidence of 20% in the usual home nutrition group.
This large high-quality trial can provide evidence how and why continued nutritional support after discharge will affect clinical outcomes among the understudied population of polymorbid, frail, elderly patients with complex combinations of medical diagnoses. The results may close an important gap and change clinical guidelines and the gained knowledge will help specifying treatment algorithm and personalize nutritional support.
We plan to finish recruitment within the next 24-36 months and will then analyze the primary and secondary endpoints.

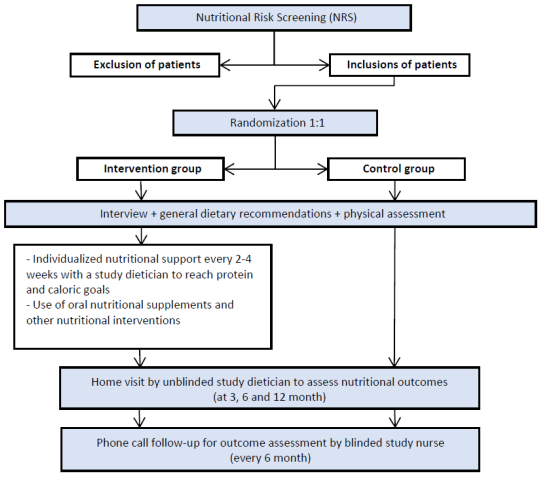

Fig. 1: EFFORT II Study Flow Chart

Resources & enablers

A multidisciplinary team of physicians, dieticians, researcher and study nurses at nine centres run this study. Further funding will be spend on dedicated researcher time to help with data management, extraction and analysis. The existing interprofessional team of experts which succesfully accomplished EFFORT I, the large sample size and generalizable findings make this trial highly important.

Results/outcomes & expected impact

- **How will the findings be implemented? Will the project be likely to influence national nutrition policy?** Providing high-quality evidence regarding the effects of nutritional support for the outpatient setting gathered within EFFORT II has high potential to influence recommendations and guidelines from dedicated societies and to change clinical practise worldwide.
- **How will this project advance patient care / contribute to optimal nutritional care?** There is an obvious pathophysiological rational to correct the risk factor malnutrition in the outpatient setting, but the lack of evidence leads to only weak recommendations and little implementation of continued nutritional support after discharge in many health care systems.
- **What makes the project innovative?** Having such a large patient's sample with diversity in medical diagnosis and comorbidities and a long monitored follow up (incl. home visits), is a unique opportunity to provide strong evidence for optimal outpatient malnutrition management. Additionally there will be possibilities to study predefined sub-analyses, which in turn can inform further about the concept of "personalized nutrition" and understanding of underlying pathophysiological mechanisms.
- **Is the project transferable to other settings / countries?** The multicenter design with few exclusion criteria as well as the high study quality make the findings generalizable. We thus expect our results will have a strong impact on nutritional patient care at both, national and international levels.