Official Title of the study:
Interventions focusing on nutrition and physical activities for overweight and obese older adults in nursing homes "IFEBO"

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STUDY Protocol Sub-study 2: Interventions focusing on nutrition and physical activities for overweight and obese older adults in nursing homes "IFEBO" (A feasibility study)

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1. **Title for the project:** Interventions focusing on nutrition and physical activities for overweight and obese older adults in nursing homes "IFEBO"

2. **Purpose:** The overall purpose is to investigate how muscle function and care-related quality of life can be maintained or improved through nutrition and physical activity interventions in older adults in nursing homes. Older adults with the combination of both overweight and T2D have a special focus in the sub-study, as the two conditions together increased the demands on the nutritional intervention.

    a. **Specific objectives:**

- What components of existing practice should be included in interventions focusing on nutrition and physical activities?
- What interventions are feasible in practice?
- Does the screening model identify the older adults in need of a nutrition and physical activity intervention?

The project's hypothesis is that the older adults with Ow/O may be malnourished and may benefit from interventions that combine nutrition and physical activities.

b. Short literature review and bibliography

The aging population is increasing both globally (1) and nationally (2). Concurrent with the generally rapidly increasing incidence of overweight (3), a large number of older people risk facing a number of health problems associated with overweight and obesity (Ow/O) (1). Ageing related to malnutrition or undernutrition have received a lot of attention. However, overnutrition described as Ow/O is also classified as a nutritional disorder or a nutrition related condition, in the same term as malnutrition (18).
Today, all older adults in Danish nursing homes are offered a enriched diet type for malnourished older adults, focused on energy dense snacks and a high fat percentage (4).
This is not necessarily an appropriate diet, but it is unknown which nutritional interventions that are effective in maintaining/ improving physical functioning, independency and quality of life.
One of the concerns is that many older adults with Ow/O may have loss of muscle mass, which can worsen with weight loss (5–9), if this is not taken into account in the nutritional intervention.
There is therefore a clear need to develop targeted interventions for older adults with Ow/O that can maintain or improve physical functioning and quality of life under Danish conditions with the Danish dietary tradition.

However, a literature review of interventions within the last 10 years shows that none of the interventions are aimed at healthy older adults ≥ 65 years with a BMI≥ 25kg/m^2 and good physical functioning. Instead, interventions targeted older adults with Ow/O with either low physical functioning or chronic diseases. These interventions show that older adults can lose weight, but without significant positive effects on functioning and quality of life (10–16).
However, interventions aimed at the target group for this project, which has both reduced muscle function and chronic disease, that nutrition and physical activity interventions have a positive effect on physical functioning (17–22) and quality of life (18,21,22). The interventions in the studies contain complex nutrition and exercise interventions, and the differences in the

intervention descriptions and target groups make it difficult to compare and point to safe and effective interventions.

In addition, the studies show that there is no difference between whether the nutrition intervention applies weight loss or weight maintenance interventions (10–20,22,23), but that the intervention itself has an effect, even when the weight is maintained.
However, the above literature review has confirmed that there are older people with Ow/O, especially those with both low physical function and chronic disease, who may benefit from a nutritional intervention, which has led to a proposed screening model (24). The characterization according to the screening model will be performed in sub-study 1, and furthermore adapted to be easy-to-use in a community health care setting.

In sub study 2, on the basis of the screening model (sub study 1), the project, in co-creation with the older adults, the care staff and the project participants, develop and test nutritional interventions that can improve muscle function and quality of life of the target group.

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3. Methods

a. Study design and methods

This pragmatic feasibility cluster randomized controlled intervention study will be performed at six nursing homes in Odsherred City. Participants and care staff from nursing homes in Odsherred City will contribute to the design of this study protocol.
The research group include participants experience from sub study 1. Moreover, the participant's experiences are central during the feasibility state.

Sample size calculation:
Initially the power calculation is performed by the individual randomization, calculated on the basis of the 30 secound chair stand test. The starting point is six nursing homes is involved in the study. Approximately 40-50 residents are living in each location and assumable half of them are Ow/O and wants to participate in the project. (n=20). A desired detectable change of 1.3 (39), a P-value <0.05 and a power of 80%. The study has two arms (control and intervention) and the standardized difference in the nursing center incl. intra cluster correlation, SD diff, nursing center = 0.42.
SD (diff., nursing center) =(SD (diff.,person))/√n, SD diff, person ≈1.87
If SD is 1.87 or less, the power will be at least 80% or greater. If there are more than 20 people per. care center power will increase and if there are fewer than 20 people power will decrease. After sub study 1 a more accurate number can be provide, also knowing what is feasible in sub study 2.

Approximately 100 participants will be included and cluster randomized to either 6 month of nutritional and physical intervention or 6 month of usual care (control). A simple random sample without replacement will be selected by a non-project group member using the lottery method. Effects from the intervention will be examined by mixed methods that include both quantitative and qualitative data, as well as action research that focuses on creating development and change in collaboration with participants and care staff at the nursing homes.

b. The practical implementation, intervention and scope

Six nursing homes in Odsherred City, Region Zealand, Denmark, participate in the project, and estimated 100 older adults is expected to be enrolled in the project. There will be ongoing inclusion.

Intervention
The intervention is developed with a focus on nutritional needs and physical activities.
In follow-up, the PDSA model (25,26) is used to redefine issues and relevant actions together with care staff, the nursing home management and participants. The intervention will be developed on

the basis of new knowledge from sub-study 1, previous studies, practical experiences, the participant`s experiences and wishes as well as the staff's experiences and wishes. Together they will be form an implementation catalog, from here, the nursing homes can select a relevant number of components, which will be tested and implemented in practice. An example could be that the general offer of diet type at the nursing home is changed to the diet type "normal" diet for older adult with a high protein content instead of enriched diet type for malnourished older adults (4). Whether the participants are at nutritional risk is assessed by Ernæringsvurderingsskemaet (EVS), and the participants who need a enriched diet or special diet forms such dysphagia diet (4), is of course offered / continues these diets . However, it may be that some participants can achieve / maintain a better physical function with a normal diet.

The implementation duration is 6 months and the PDSA model (25,26) repeated at two-month intervals to strengthen and qualify the intervention. The PDSA model is known to the city's staff in advance, and is additionally used in connection to continuing education. In addition, every day physical activities that contributes to maintaining / improving physical functional is included, based on the potentials that are uncovered in sub-study 1.

Primary outcome

Primary outcome is sustained or improved muscle function (30 - second chair stand test (30 s CST), gait speed (10 meters) and hand grip strength (HGS))

Secondary Outcome

Secondary outcome is weight development and "Adult Social Care Outcomes Toolkit" (ASCOT) questionnaire (27).

All outcome measures

Data are collected at baseline and 6 months (m). The starting point is the same measurements as described in sub-study 1, combined with feasibility in practice.
The data analysis takes into account that not all participants are included in all measurements.

Tabel 1: Data collection in sub study 2

Variable	**Method**	**Baseline**	**6 m**
Age and sex	Journal data	x	
Weight	Calibrated standard weight as part of routinely weighing, Journal data	x	x
Weight, fat%, fat mass (kg), muscle mass (kg), bone mass (kg), BMI, total body water (TBW), TBW%, intracellular water and extracellular water	BIA	x	x
Calf circumference	Measured by non-elastic plastic tape		
Height	Journal data	x	
Height measured	Measured standing or lying	x	
Chronic disease, diagnosis and number	Journal data	x	
Muscle function	30 s CST , gait speed and HGS	x	x
Nutritional risk	EVS	x	x
Quality of Life	ASCOT questionnaire	x	x

c. Deviations from standard care

Control group include three nursing homes and participant will follow standard care. The interventions group including three nursing homes will implement the intervention developed on

the basis of new knowledge from sub-study 1, previous studies, practical experiences, the participant`s experiences and wishes as well as the staff's experiences and wishes.

4. Statistical analysis

The analysis follow the intention-to-treat principle and thereby including all data after randomization, regardless of non-compliance or lack of results.
The effect of measures and intervention is assessed using covariance analysis (ANCOVA) adjusted for baseline and potential confounders. Kaplan-Meier analysis and parametric or non-parametric regression and correlation analyzes are used to assess data in a timeline perspective with multiple measurements of physical functioning, weight, muscle mass, and care-related quality of life.
Data on recruitment and participants' feasibility and compliance in relation to intervention will be assessed by descriptive and comparative analyzes.
A statistical software program for scientific research e.g. SPSS or R will be used for statistical analyzes.

5. Study population

Participants are recruited from nursing homes in Odsherred City in Region Zealand, Denmark.

a. Inclusion criteria:

- Living at the nursing homes in Odsherred City
- Informed consent form signed after receiving oral and written information
- Read, speak and understand Danish

b. Exclusion criteria:

- Terminal ill

6. Risks, side effects and disadvantages in the short and long term

In the study, no serious adverse events or risks are expected. All participants participate voluntarily and can withdraw from the study at any time. The research group can withdraw a participant at any time if there is a concern for the participant’s well-being. A nurse at each of the nursing homes is included in the project and will be present during all data collection periods. The nurses will be involved immediately if any health issues or concerns about health issues should arise. Data on participants who withdraw will be documented.
This project meets the guidelines of the Declaration of Helsinki II, as well as the guidelines of the Regional Ethics Committee.
The research project has been submitted to the Science Ethics Committees for Region Zealand j.nr .: EMN-2021-07672 and is exempt from the obligation to notify.

7. No biological material are collected.

8. Information from patient records

a. It must be stated which information is needed and what the information is to be used for. There shall distinguish between information to be used before the subjects have given their consent to participate, eg in connection with identification / recruitment, and the information to be used for the project after consent to participation is given.

b. It must be stated that the information to be used in the project before consent has been given from the subjects, are passed on to the researcher.

c. It must be stated that the consent gives the person responsible for the experiment, the sponsor and the sponsor's representatives as well any control authority direct access to obtain information in the patient's medical record, etc., including electronic medical records, in order to view information on the subject's health status, which are necessary as part of the implementation of the research project as well as for control purposes, including self-monitoring, quality control and monitoring, which they are obliged to perform.

See appendix 1: Participant information

9. Processing of personal data in the project:

a. **Data Protection Regulation and the Data Protection Act are complied with**.

In sub-study 2, data collection is performed by the principal investigator and trained students. The students will practice data collection prior to the study. It is principal investigator who are the responsible data manager and collect data from the journaling system (CURA). Only data on the above mentioned information will be transferred by the principal investigator into Absalon secured drive (R-drive), when written consent is received. All data will be reviewed by the principal investigator.
A data manage agreement with Odsherred City and the University of Copenhagen, has been signed. Data managers in the project are University College Absalon, Sdr. Stationsvej 30, 4200 Slagelse. ernaeringogsundhed@pha.dk. Data Protection Advisor (DPO): dpo@pha.dk.

The information is collected and processed in accordance with legal authority in Article 6 (1) of the Data Protection Regulation. 1, letter a and Article 9, para. 2, letter al:

The information is processed in accordance with the University College Absalon's privacy policy, including requirements for technical and organizational security - read more here: https://www2.phabsalon.dk/studienet/studiehjaelp/informationssikkerhed/politikker-og-vejledninger/privatlivspolitik/
A data management plan has been prepared in accordance with the guidelines from Good Clinical Practice (GCP) standards, the general data protection regulation with guidance from the University of Copenhagen's faculty's data management and GDPR special consultants.

A data management plan is prepared following the guidelines from Good Clinical Practice standards (28), the Data Protection Regulation and Data Protection Law (29). All data retrieved during the study will be encrypted after collection and will be handled according to Good Clinical Practice standards.
The principal investigator and the students will continuously document all data on each participants. All participant information will be processed according to Data Protection Regulation and Data Protection Law (29). All data is treated pseudonymised, ie. that all participants have an anonymous ID number, which appears when data is processed.
When the project is completed, data is stored on a specially secured research drive with the data controller, ie. Absalon University College for 5 years after the publication of scientific articles. Relevant anonymized data can only be shared on reasonable request following Data Protection Regulation and Data Protection Law (29).

No personal information are sent abroad the country.

10. Economy

The project is financed by public foundations Innovation Fund Denmark (1.072.000 Dkr) and Steno Diabetes Center Zealand (590.548,00 Dkr), and without sponsorship from private companies. The support is given directly to the University College Absalon's research account and will be used for employee salaries and other costs in the project. No staff have financial or personal relationships with any of the supporting parties, while these parties have no influence on the results or their interpretation. There is therefore no conflict of interest in this project.

11. Fee and / or other benefits to the participants

No fee or other benefits to the participants

12. Recruitment of subjects and informed consent

Recruitment of project participants takes place from Odsherred city's 6 nursing homes. The first step in recruitment takes place by principal investigator orally and in writing informing the nursing homes, care staff, relatives, nursing home councils and the residents of the nursing homes about the project's purpose, content and course. Posters are posted telling about the project. In the next step, (oral information) the principal investigator, the care staff and relatives talk to the residents. Participant information (written information) is provided for both sub-studies as well as the leaflets "Subjects' rights in a health science research project", and "Before you decide - to be in health science experiments". The written information contains a description of the project, its purpose, method and possible consequences associated with the participants' participation. Participation in the project is voluntary, and the participants have the opportunity, without further justification, to interrupt the collaboration and their participation in the project. In the third step, the residents then have 24 hours to decide whether they want to participate in the project and sign a declaration of consent. During the project period, the participants can obtain further information about the project from the principal investigator. Collection, storage and processing of empirical data is done with the Danish Data Protection Agency's instructions for handling confidential information in research work of an empirical nature.

Participants have the opportunity to withdraw consent at any time during the project. If there are measurements, eg performance tests, which the participants do not want to participate in, available data is collected from the journaling system (CURA) without participation in all measurements.

13. Publication of results

Based on the project's results, an implementation catalog and best practice guidelines in the area will be prepared. The implementation catalog intends to anchor the tested intervention in practice both in Odsherred city, but also in other cities in Denmark. The results of the tested measures result in strategies for how Ow/O can be dealt with in older adults. The implementation catalog describes these strategies and how the strategic focus areas are implemented, measured and reported. The strategies will be implemented via existing action and sector plans and also describe responsibilities and roles.

Furthermore, one scientific publications will be submitted.

Tabel 2: Expected publications

Title proposal and expected date of publication	Scientific journals proposal
The effects of combined nutritional and physical activity interventions on physical function and social care related quality of life – an enable study (nov 2024)	Clinical Interventions in Aging

The results will be presented as they are generated at national and international scientific meetings e.g. ESPEN Congress on Clinical Nutrition and Metabolism.

The results obtained will be published in anonymous form in international scientific journals, and presented at conferences. If, contrary to expectations, the results are not published in a scientific journal, they will be published on www.clinicaltrials.gov and www.clinicaltrialsregister.eu

14. Ethics

a. Why risks, neither in themselves nor in relation to the benefits of the trial, are unjustifiable

Participation in the project is not associated with minor risk. This project meets the guidelines of the Declaration of Helsinki II, as well as the guidelines of the Regional Ethics Committee. The research project has been submitted to the Science Ethics Committees for Region Zealand j.nr .: EMN-2021-07672 and is exempt from the obligation to notify.

b. Why the therapeutic benefit for the subjects or future patients justifies the studies

Older adults with Ow/O in nursing homes are a heterogeneous group. The project will be able to identify which older adults with Ow/O, that are in need of a nutrition and physical activity intervention, and also what intervention, that can maintain or improve the physical function and quality of life in older adults with Ow/O in nursing homes.

This is a valuable next step in conceptualizing a strategic framework for taking public-health action.

15. Information regarding compensation

No compensation is made.