Project Description **Date April 17th 2024**

A 3-month lifestyle change program's impact on body composition, resting metabolic rate, health-related quality of life and food intake and

Project leader: Nima Wesseltoft-Rao

Project members: Anette Skarpaas Ramm, Marita Moe, Benedikte Holsen, Thomas Olsen, Christine Henriksen

Ethical approval: The Regional Committee for Medical and Health Research Ethics: 761798

Introduction

In Norway, a significant proportion of the adult population is currently classified as overweight (~50%) or obese (~23%). Over the past four decades, there has been a significant rise in the prevalence of overweight and obesity in both children and adults. Obesity is associated with a higher risk of chronic diseases such as cardiovascular diseases, type 2 diabetes, respiratory disease, osteoarthritis and specific cancers. Consequently, leading to increased morbidity and reduction in life expectancy (1). A healthy lifestyle including meeting recommendations for diet and physical activity is considered beneficial the prevention of chronic diseases, and for quality of life (2-4). There is limited evidence on weight reduction programs implemented outside specialized healthcare services, however intensive lifestyle modifications have demonstrated promising effects on sustainable weight loss (5, 6).

The Kickstart Program, initiated by Anette Skarpaas Ramm and Martin Johnsrud Sundby in 2022, is a lifestyle program addressing weight reduction, changes in body composition and improved health-related quality of life (HRQoL) by integrating personalized dietary guidance and physical activity (PA) over a three, four or six-month period for registered participants, and can be considered an organized follow-up intervention. The participants receive close monitoring and support from clinical dietitians, physiotherapists and personal trainers (7). Unlike patients in specialized healthcare, Kickstart participants sign up and pay for it themselves, without any support from referrals or financial aid. This financial commitment is thought to make participants more motivated and facilitate compliance with the program. Recognizing the potential of programs like Kickstart to reduce healthcare costs by preventing lifestyle diseases, especially outside of specialized healthcare, shows why it is important to study how well they work.

Earlier studies have focused on the effect on body weight og body mass index (BMI). Because of the limitations with BMI, it is also important to study body composition. Body composition refers to the proportion of fat, muscle, bone, and other tissues that make up a person's body weight. It provides information about the distribution and relative proportions of body tissues, which can be important for evaluating overall health status, and progression of fitness during and after lifestyle change. Measurements of body composition can include body fat percentage (%), visceral fat,

and fat free mass (FFM), including muscle mass that is the primary variable of interest in this study.

Resting metabolic rate (RMR) is the energy the body uses at rest to maintain vital functions (8). RMR is the main contributor to total energy expenditure, contributing up to 60-70 %. Other components of total energy expenditure is energy used from physical activity (20-30%) and lastly from the thermic effect of food (10%) (8). Studies have demonstrated a decrease in RMR following weight loss (12), largely attributed to the loss of FFM, which plays a significant role in metabolic rate (12). It has been speculated that rapid weight loss induce metabolic adaptations resulting in greater than predicted decreases in RMR (13).

The concept of HRQoL is frequently utilized to assess how health status influences overall quality of life (14). Reported low HRQoL is typically found in individuals with multiple chronic conditions and low levels of PA (15).

In The Norwegian Healthy Life Centre Study by Samdal et al. (2018), the objective was to assess the impact of behavioral change interventions at Norwegian Healthy Life Centers (HLC) on participants' physical activity six months after baseline. The study concluded that individuals with high socioeconomic status increased their physical activity more over the course of six months, but simultaneously consumed more unhealthy food. The intervention did not significantly influence dietary habits, but participants who attended the "good-food course" notably increased their consumption of healthy food (16). A follow-up study on HRQoL in 2020 revealed a positive association between physical activity and improved HRQoL. All HRQoL dimensions showed enhancement from baseline to the three-month follow-up, and these improvements were sustained at the 15-month follow-up (15).

By focusing on healthy lifestyle and weight reduction, valuable healthcare resources can be conserved, emphasizing the need for such programs outside specialized healthcare services. This also involves the individual's ability to cope and their overall quality of life. The study's findings can be leveraged to assess the influence of lifestyle programs and enhance the support available to adults with obesity in this area.

The Kickstart program reveals a knowledge gap concerning how an intervention of intensive dietary changes and PA specifically effects weight loss, FFM and HRQoL within a three-month timeframe.

Aim and hypothesis

The overall aim of the study is to investigate the effect of a combined diet and PA intervention for people with a BMI≥25 kg/m² on body weight, body composition, RMR and HRQoL.

Specific aims are:

- Describe the change in weight and body composition (muscle mass, fat percentage, visceral fat) from start to three months after intervention.
- Describe the changes in RMR from start to three months after intervention.
- Explore the association between change in body composition and RMR from start to three months after intervention.
- Describe the changes in dietary habits from start to three months after intervention.
- Describe the association between body composition on HRQoL from start to three months after intervention.
- Investigate the long-term effect on weight, dietary habits and HRQoL one year after intervention.

Research plan

Study design

This master project is a prospective, single-group pre-post intervention study. The participants will follow the intervention for three-months. Assessments will be done at baseline, at three months and one year after interventions. All 40-50 participants will undergo anthropometric measurements of body composition by bioelectrical impedance analysis (BIA). A subgroup of 20-25 participants will undergo additional measurements of body composition by Dual-Energy X-Ray Absorptiometry (DEXA) and measurements of RMR.

Participants and sample size

Adults aged 18 years or older, with a BMI≥25 kg/m^2 will be included. This study will include 40-50 participants and subgroup of 20-25 participants that will be invited to in-depth analyses of body composition and RMR. Based on a previous study with intensive lifestyle intervention, we hypothesize a pre-post difference in fat mass of -2.5 kg with a standard deviation of 3 (17). Accounting for 20 % drop-out, two-sided alpha of 0.05 and beta of 0.9, yielded a sample size of 23.

Method

Intervention

The intervention will consist of three individual one-hour consultations with a clinical nutritionist, an individualized training program with the possibility for grading, joint training sessions both physical and digital, direct dialogue with the Kickstart Team as well as seminars on training, diet and motivation (18).

Outcome measurements

Measurements of body composition and metabolic rate at rest

Anthropometric data (weight, muscle mass, waist circumference) will be collected from the participants, in consultation with a clinical dietitian at Kickstart or by the master student, using waist circumference tape and BIA, and the data will be recorded in Pridok. Pridok EPJ is a web-based and up-to-date patient journal system for primary health care, tailored and optimized for a more efficient clinical everyday life (19).

BIA is a non-invasive, cost-effective, reliable, and widely employed method for measuring and assessing body composition for both epidemiological and clinical purposes. The fundamental principle of BIA technique lies in the fact that the transition time of a low-voltage electric current through the body depends on the characteristics of the body composition (20). Body composition

will also be assessed by DEXA-scans (Lunar iDXA, GE Healthcare), which utilizes low-emission X-rays to measure the attenuation of incident X-ray beams when they pass through different body tissues. DEXA can for example provide estimations of lean body mass and visceral fat using validated prediction algorithms (21) (23).

There are simple, time-efficient and practical ways to calculate RMR, such as the Harris Benedict and the Mifflin St. Jeor equations (9), however these methods do not consider possible conditions of inflammation, metabolic diseases, body temperature, or body composition (8-10). Whole room indirect calorimetry (WRIC) implement state-of-the-art technology and measure actual RMR and will thus be more accurate in terms of including parts that the equations do not take in too account (8). The principle behind indirect calorimetry is to measure the rates of O2 consumption (VO2) and CO2 production (VCO2) to calculate RMR using Weir's equation (8). WRIC has been shown to be more accurate in calculating RMR than other methods such as ventilated hood (11). The duration of the WRIC measurements is 30-60 minutes in the present project (24).

To assess the participants' dietary habits, we will use a digital food frequency questionnaire (FFQ) called Digikost, that is developed by the Department of Nutrition. The FFQ examines, among other things, consumption of red meat and processed foods, snacks and sweets, fruit and vegetables, fish and nuts. It would be interesting to investigate whether the FFQ indicates a shift towards a more "nutritious diet" among the participants of Kickstart.

The assessment of HRQoL will be conducted using the Norwegian-translated and validated version 1.0 of the Medical Outcome Short Form (MOS SF-36), RAND-36, which evaluates quality of life across eight multi-item dimensions using 35 items, with an additional item measuring health transition (perceived health compared to one year ago). The eight dimensions include physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and overall mental health (22).

Data handling and statistics

Statistical analysis will be determined using Stata 17. Outcome measures will be presented with a measure of central tendency (mean or median) and dispersion (standard deviation or range). The analysis will include paired t-tests, and linear regression will be used for adjusted analyses if there is a need to control for variables like age. In the analysis, the significance level is set to a value of 0,05. Simple imputation will be used for any missing values, where missing values will be replaced with the subject's average score for the completed items.

Ethical considerations and approvals

An application will be submitted to the Regional Ethical Committee (REK) and SIKT in April 2024.

Progress plan

The practical work will be conducted by two master students.

Spring 2024	• Submission of project description March 2024 • Literature search and writing introduction/background
Autumn 2024 (August – December)	• 4 weeks of clinical practice • Training in the use of BIA, DXA and WRIC • Data collection (BIA, DXA, WRIC, RAND-36) • Writing methodology
Spring 2025	• Statistical analysis • Interpretation of and writing results and discussion • Submission of the master theses, May 2025
Automn 2025	One-year follow-up

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