Will change in lifestyle have a correlation with ability to work?
Life style factors that affect work participation

Occupational rehabilitation for people with body mass index above 30

Summary

This trial will follow up a group of people with BMI above 30 and who have participated in an occupational rehabilitation program at Muritunet. The aim of this study is to gather information about how life style changes affect the ability to work.

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1 Introduction

Numbers from Statisk Norway indicate that one out of three has overweight (BMI >25) or obesity (BMI >30) in the population in the age of 16 to 74 [1]. Development of overweight and obesity have the latest years dramatically increased. In Norway, the consequences of this development is an epidemic situation with an increase in life style diseases and work absence. Central Norway Regional Health Authority (HMN RHF) has initiated action to reduce work absence and consequence of obesity by introducing a work related rehabilitation program for people with BMI above 30. Combination of weight loss programs and work related intervention is new in Norway. Outcomes of this intervention are so far are not known.

The trial can be used to improve the quality of occupational rehabilitation in Norway in the Specialised Health Care services. Others who work with life style changes and with work related rehabilitation can also use the collected information. This study is a Cohort clinical trial with a Pseudo prospective design.

1.1 Status of knowledge

Development of overweight and obesity is one of the three biggest health challenges in Norway. Overweight and obesity influence the person's life quality, psychiatric and physical health and social life [2]. Overweight and obesity associates with high comorbidity and illnesses such as muscular and skeletal problems, lung diseases, cancer, social isolation, stress, psychiatric diagnoses and early death [3-6]. Higher BMI gives more complications [7]. The reason for obesity is complicated since many factors affect. Individual factors as the personal life style, society, culture, socio-economic status, genetic and biological factors influence the development [8].

High BMI and the consequence of obesity gives challenges for the individual, for the society and the occupational. Studies in the latest years indicate that high BMI is increasing longer periods with work absence [9] and that there is directly context between high BMI and long-term sick leave above seven days [3, 10]. Obesity contributes to independent factor to work absence and indirect thru lifestyle related illnesses.

Long-term sick leave also affects the society with cost cause reduced work productivity and increasing Social Security benefits [10]. A study from Denmark refers to that obesity contribute to yearly 1,8 million extra days of work absence and closely to 1.100 cases of disability pension related to obesity [11]. In a study on Swedish women concludes that overweight and obesity cause ten present of the total cost regarding social security. A rapport from OECD through Statisk Norway shows that persons in the age between 50 to 59 with obesity have three times as much work absence than those that don't have obesity [12]. The reasons for work absence is complexed. Factors that contribute is disease and symptom from the muscular and skeletal system, mental disorders, relation at the workplace, family relationship and socioeconomic issues.

A person with a long-term sick leave in Norway can participate in an institutional work related rehabilitation stay. The aim for such stay is to increase function and work ability to prevent the individuals permanent to fall out of working life [13]. The intervention in occupational rehabilitation builds on physical activity, cognitive therapy, and cooperation with Norwegian Labour and Welfare Administration (NAV), employer and others that can contribute to deal with the health challenge and to increase work ability. The intervention based on the World Health Organisation's classification of health and health-related domains, known as The International Classification of Functioning, Disability, and Health, ICF. ICF is the WHO framework for measuring health and disability at both individual and population levels, known as a bio-physio-social framework [14-16]. Many studies

indicate that occupational rehabilitation can be an effective intervention to reduce sick leave and disability benefit [13].

People with high BMI needs beside work rehabilitation also focus on life style changes to reduce consequences of obesity. The basic treatment of obesity is a focus on cognitive treatment that helps people changing diet and increasing activity.

In Norway, there is entirely 340.000 humans with overweight and obesity in the age between of 20 to 76. Obesity cost yearly for the western countries 2 to 7 present of the national health budget [17]. In Norway, people with obesity can participate in weight loss programs in specialized institutions that focus on life style treatment.

1.2 Knowledge challenge

Occupational rehabilitation with a focus on weight loss program is new in Norway, and just a few institutions offer this kind of intervention. The consequence of this extent is little knowledge, experience, and few studies were done in the crossing fields between occupational rehabilitation and rehabilitation generally [18] and in work related rehabilitation individually [19].

Life style changes take time. The weight loss program needs to focus on changes in diets, physical activity, and cognitive therapy [20]. The primary challenge with weight loss programs is that the body weight gain with a third of the total weight loss within a year. Studies show that about fifty present of those who participate in weight loss programs going back to their original weight after five years [21]. There is a lack of documentation on what kind of life style treatment that gives a good effect, both in and outstay [22]. Therefor life style treatment is often given without proper documentation for what intervention that works or not [23].

Today many unknown factors affect in between obesity and sick leave. The challenge is that traditional occupational rehabilitation does not include weight loss programs, and weight loss programs don`t include the focus on work participation. There is also in the field of work related rehabilitation lack of knowledge about effect full interventions that can reduce sick leave and disability pension in people with nonspecific muscular and skeletal problems, obesity and physiatric disorder [24]. Besides lack of information on the effect of occupational rehabilitation, few studies have focused on the mechanism that can be effect full between obesity and sick leave [10], on individual factors that generate changes in life style [8, 25] and what will make work participation [26].

1.3 Background

In 2015 established HMN RHF an occupational rehabilitation program for people with BMI above 30 who might be or is on sick leave directly or indirect cause obesity. This program combines work participation and life style changes and exists only in two institutions in Norway. The goal of the program is to increase function and work ability and weight loss. The program is new, and few documents exist on the effect and the correlation between life style changes and work ability. There is also need to question whether obesity is the reason for work absence or is there other factors that affect work ability. This study wants to follow up a group of people who have been participating occupational rehabilitation at Muritunet.

1.4 Research fields meaning for patient treatment and disciplines

This trial can contribute to improving the quality of work related rehabilitation in the specialized health care services and for other institutions who work with obesity and occupational rehabilitation. The study can also contribute to:

1. Participants in this trial might get the opportunity to increase their knowledge about their health and function that affect their everyday living.
2. New research-based knowledge and professional development in the crossing field between obesity and work participation.
3. New insights about effective interventions that can contribute to reducing the number of sick leave and long lasting weight loss.
4. Documentation of result over time for the group that has participated in the professional program for people with BMI above 30.
5. Developing the program for people with BMI above 30.
6. Increasing political focus on a fast growing group.
7. Indirect social-economic and individual benefits.

2 The research question and goal

Lifestyle is a field that contains several areas. It tells us about how persons live their life measured in physical activity, diets, inactivity, intoxication, smoking, alcohol, circadian rhythm, sleep behavior and stress. The focus for people in life style changes is weight loss through reducing energy consumption and increasing energy consumption through physical activity [27] with the help of cognitive methods. One of the goals is to reduce the weight with 5 to 10 percent. This reduction will accumulate health benefits as better life quality, reducing life style diseases and better mental and physical health and this health benefits will gain the society. Several studies indicate that there is an association between high BMI and sick leave [3, 10, 28]. The question is what correlation is there between life style changing and work participation. What motivates people to work and what happens with the sick leave when BMI is decreasing?

The purpose of this trial is to get more information about how life style changes affect work participation for people with BMI above 30. The information can contribute to improving the quality of occupational rehabilitation programs in the specialized health care services and for others who work with weight loss programs and work related rehabilitation programs.

The primary goal of this trial: What correlation is there between life style changing and work participation after participating in occupational rehabilitation on Muritunet?

Aims of the trial are:

1. Will changes in physical activity, diets, and life quality correlate with work participation?
2. Will changes in physical activity, diets, and return to work self-efficacy correlate with life quality?
3. Will changes in work participation, life quality, and diets correlate with weight changes?
4. What experience the participants as important factors to achieve lifestyle changes and work participation?

Work participation defined in this study is working full time or partial with an employer, permanent or temporary or as a student. The employee has to work coherently in 28 days without to receive social benefits.

Life quality defines in either in a subjective or an objective perspective [29]. In this study, the subjective perspective emphasizes the individual's positive, negative, cognitive and emotional experience that concern life quality.

Diet in this study is the intake of food and liquid that shall ensure a satisfying amount of calories, nutrient and prevent life style diseases.

Physical activity in this study is action made by musculature in a way that it results in increased energy consumption higher than resting.

3 Implementation

3.1 Design, methods and analyze

This study will follow-up a group of people with BMI above 30 over a period of one to four years. Study with a Pseudo prospective design that includes collecting data through both qualitative and quantitative methods. Both methods will take place at the same time, Parallel mixed Methods. The data is linked to each other in the different stages in the study, and the methods will confirm, cross-validate or confirm findings in one method with another result in another process. Creswell uses the Current concept Triangulation [30]. The purpose of this plan is to make one method stronger with using the strength of another method.

The definition of Mixed Method research in this study is; Approach to gathering data through quantitative and qualitative methods with the use of designs that involve both philosophical and ethical theory [31].

Collecting data through forms, physical test, journal, interviewing, from national register from the Norwegian Labour and Welfare Administration and National

Education Data Base. Using registry data will be useful because there might be a link between different variables that might contribute to clarify the association between health and work participation. It then can be specified whether the participant is on sick leave because of obesity related issues or if there are other reasons for the sick leave. Another example is the connection between education and work participation because the level of education may have importance for choice of profession and sick leave. There are several links in this study that can strengthen the findings in the data collection.

Data collected at four different stages.

1. Baseline (BL). From the beginning of the stay at Muritunet. Data gathered from the journal, from self-reported forms, and from a physical test. The particular data package is; in and out date for the stay, age, sex, diagnosis, education level, health problems, work status, social benefits, changing in work status, work place, expected work time pr. Week and occupation code, work motivation, income, diet, physical capacity and activity, life quality and overeating behaviour.

2. T1, six months after the first stay at Muritunet. Data gathered from the journal, from self-reported forms, and from a physical test. The particular data package is; in and out date for the stay, diagnosis, health problems, work status, social benefits, changing in work status, work place, expected work time pr. Week and occupation code, work motivation, income, diet, physical capacity and activity, life quality and overeating behaviour.

3. T2, 12 months after the first stay at Muritunet. Data gathered from the journal, from self-reported forms, and from a physical test. The particular data package is; in and out date for the stay, diagnosis, health problems, work status, social benefits, changing in work status, work place, expected work time pr. Week and occupation code, work motivation, income, diet, physical capacity and activity, life quality and overeating behaviour.

4. T3, Focus group interview, one to four years after the participants finishing their stay at Muritunet.

5. T4, Data collecting from Norwegian patient register (NPR) and National Education database (NUDB). Will be collected once. Data collected are social benefits as sick leave, work assessment allowance, disability benefits, unemployment benefits, diagnosis for sick leave, changing in work employment, work place and expected work time pr. A week and occupation code.

Some participants will return to their work, but some will not. It will lead to variation for my chose of how to design methods and analyze the data material. Different ways will complete each other, and today it is common to use several methods and models in the same study.

Data analysis is chosen on the background of design and approaches. BL, T1, and T2 is a typical quantitative approach and will be analyzed both on its own, but also compared with data collected in T3 and T4. The qualitative interview will have open-ended questions, and the participants will get the opportunity to reflect on themes defined from the data collection earlier in the study.

3.2 Inclusion and excluding criteria

Participant inclusion criteria; the participants have to be on sick leave or be in danger to be on sick leave because and obesity related problems. The participants have to have a real opportunity for returning to work, full time or part time. The participants have to have a BMI above 30 and be in age between 18 to 67 years old.

Participants excluding criteria;

1. People with a severe eating disorder.
2. People who cannot consent.
3. People with a severe alcohol and drug abuse.
4. People with a severe psychiatric disease.
5. Pregnancy
6. People with a health condition that contraindicates physical activity.
7. People who receive work assessment allowance.
8. People with or wants so seek for disability benefits.
9. People with permanently organized work.

3.3 Recruiting of participants

Recruiting participants in this study are as followed:

1. Before the first stay at Muritunet. The patients will receive an envelope with written information by post a month before their stay. In the envelope, there are two letters. One with detailed information about the study and one letter with a request to consent to the research. After the participants arrive Muritunet, they will receive information about the study, attachment one, given by project secretary. Those who want to participate in the study gives written consent. The project secretary registers the written consents in SPSS at Muritunet. SPSS is a comprehensive software package for statistical analysis and data management.
2. For participants who participate or are finished with the stay at Muritunet. The participants receive by post a written letter with detailed information about the study and two letters with a request to consent in the study. In addition to the letters, there is a prepaid envelope with the address to Muritunet, attachment one. If the person approves to participate in the study, he or she signs the consent and returning it to Muritunet. The project secretary registers the agreement in SPSS. This registration goes to the researcher who can call the participant regarding interview.

3.4 The content of the occupational rehabilitation stay at Muritunet

The participants report data while they are at Muritunet. The rehabilitation stay is as followed with the moment for data collection:

1. Four weeks with an institutional stay at Muritunet (BL)
2. Follow-up:
   a. Eight weeks, telephone contact between therapist at Muritunet and the participant.
   b. 16 weeks, video conference on SKYPE between all the participants and a therapist. Lecture on diets.
   c. 28 weeks, Outpatient stay at Muritunet. Central themes that day is education, conversation, physical test, and forms. (T1)
   d. 40 weeks, telephone contact between therapist at Muritunet and the participant.
   e. 52 weeks, Outpatient stay at Muritunet. Central themes that day is education, conversation, physical test, and forms. (T2)

The participants in the occupational rehabilitation program get both practical and theoretical intervention, in groups and individual. Four main themes; cognitive therapy, physical activity, diets and focus on work-oriented approach. The table under shows both groups based activity and personal follow-up.

Group based intervention	In stay	Time	Follow- up	Time
Cognitive approaches in groups	- Expectation clarification - Sleep - Cognitive methods - Values, will and choice - Goals setting - Motivation - To come home/ what next/ home - Acceptance and commitment therapy	11t 2x 1,5 t	Exchange of experience (by 16, 28 and 52 weeks) Acceptance and commitment therapy (by 28 and 52 weeks)	2x 1,5 t 2x 1,5 t
Physical activity in groups	Education- how to exercise Physical activity in a group	1 t 23,5 t		
Diet	Education - Diets - Food knowledge Making food in practice	 2t 2,5 t 5 t	Diet, lecture- SKYPE (by 16 weeks)	2 t
Work-oriented approach	Education - Rights and duties at work - Work and health. Individual follow-up	 1 t 1,5 t >1 t		
Education, knowledge about obesity	Education - Facts about obesity part one - Facts about obesity part two	 1 t 1 t		
Data-collection	Foams Weight and waist circumference Physical test Skype	1 t 2 t 2 t 1 t	Foams (by 28 and 52 week) Weight and waist circumference (by 28 and 52 weeks) Physical test (by 28 and 52 weeks)	2 t 2 t 2 t
Interdisciplinary intervention (when needed)	Labour consultant, Psychiatric nurse, Physiotherapist, Nutritionist, General Practitioner, Senior Registrar Consultant, Sports Educator, Psychologist, Cognitive Therapist and Occupational Therapist.			
Individual intervention	**Phase one**	**Time**	**Phase two**	**Time**
Personal approach	Therapeutic contact with: Primary contact person for the stay ACT conversation Labour consultant Nutritionist	 4x 0,75 t 6x 0,5t 4x 1t 3x 1t	Prim.contact- conversation (by 4, 28, 40 and 52 weeks)	4 x 0,5t 2 t

	Physiotherapist	4x 1t	Conservation after request with nutrition (by 28 and 52 weeks)	
Contact with work place, NAV or other	Individual after need		Individual after need (by 28 and 52 weeks)	

3.5 Data

This study will use several sources for data to measure changing among the participants. Data from baseline, T1 and T2 will be the foundation to see if there is a correlation between the different factors, as well as to substantiate or to find new findings.

3.6 Quantitative data collection

Foams register and explain changing in life style factors and work participation. The physical test may say something about the participant's physical capacity. In this study foams and a test will measure conditions that affect socio- economic, demographic and individual factors, their expectation of returning to work, the motivation for working and sick-leave, physical activity, physical and mental health, diet and nutrition, and life quality. Information about the date of the stay, diagnoses, and activity is in the journal at Muritunet.

Areas	Time of data collection	Foams
Employment data	BL	ARR foam, socio-demographic data and work status (Nasjonal kompetansetjenseste for arbeidsretta rehabilitering)
	BL, T1 and T2	Short ARR foam
	BL	Return to work self- efficacy (RTWSE 19) [31]
Health data	BL	High, waist circumference, body fat percentage and
	BL, T1, and T2	fat-free mass kg Weight, BMI
	BL	Diagnoses
	BL	Subjective Health Complaints (SCH 25) [32].
Physical capacity	BL	Step-test with Borg scale CR 10
	BL, T1, and T2	Registration of level of physical activity(Health Directorate)
Quality of life	BL, T1, and T2	Quality of life (15D) [33].
Food habits	BL	Thoughts and feelings about food, body and eating behavior. Survey about Binge eating disorder (EDO)[34].
	BL, T1, and T2	Food behavior registration (Health Directorate)

3.7 Register data

NAV and NUDB have reliable information about work participation and education data. The data will contain information about social benefits as sick leave, work assessment allowance, if the participant is registered as a job seeker, changing in work employment, income, about the work place and expected work time pr. Week, occupation code and about education. Collecting data at the end of the study and correlating with data from the foams, journal and qualitative interview.

3.8 Qualitative interview

Participants who complete 12 months of treatment on Muritunet will receive an invitation to participate in a focus group interview. The interview is carried in the T3 phase one to four years after finishing the stay at Muritunet. The interview will focus on health, life style changes, life quality and work participation. Each interview will last about one and a half to two hours. The group interview will consist of 6 to 8 people. The primary purpose is to get a complete picture of the complexity of returning to work, and how life style changes influence the process. The data collection has a

particular focus on the participants experience on what promotes and inhibits the process returning to work in due to their health, physical activity, life quality, workplace, diets and other factors that can contribute.

3.9 Analyse

The goal of this study is to explore the correlation between life style changing and work participation. Four secondary issues will result in using different ways of analyzing the data material. In this way, each issue can be investigated on their own, but also analyzed with each other.

The primary analyzing approach for this study is multivariate logistics regression analysis with a focus on the correlation between several independent variables (X) and dependent variables (Y). In the main issue Y= work, and X= physical activity (x1), diets (x2) and life quality (x3). Work divides into three categories; a) full time working, b) part time working, c) not working. In the secondary issue, is Y= life quality and X= physical activity (x1), diets (x2), and the belief in managing (x3).

In the quality research, thematic methods will be used to analyze the interviews. This method can catch the significant complexity in the text and is the most usual way to analyze a text in qualitative research. This way of analyzing consist of six steps. 1. Transcribing data, 2. Reading and re-reading the data, 3. Coding, 4. Search after subjects, 5. Define and give a name to the subjects, and 6. Choose to illustrate examples of different issues.

3.10 Calculation of sample size

The calculation of the sample size on a group basing on previously participated in a similar occupational rehabilitation intervention for people with a BMI above 30 at Muritunet. Tre research question is leading for the sample size. The calculation is based on the time for data collection baseline and at the end of the intervention at Muritunet T3. The calculation is basing on apriority effect size, p value =0,05 and 80 percent statistical strength.

Goal of changing

1. Work; With a statistical power of 80,4 percent to achieve a clinical and a statistically significant change in 25 percent increasing work participation this study has to have 51 participants with two end point. The calculation is made out of 95 percent confidence interval (95% CL=18,05-31,95).
2. Weight reduction; With a statistical power of 80,2 percent to achieve a clinical and a statistically significant change in 11 kg weight reduction this study has to have 59 participants with two end point. The calculation is made out of 95 percent confidence interval (95% CL=6,82-15,18).
3. Quality of life; With a statistical power of 80,7 percent to achieve a clinical and a statistically significant change on 0,02 this study has to have 55 participants with two end point. The calculation is made out of 95 percent confidence interval (95% CL=0,025- 0,045). In the foam Quality of Life 15D, the SMR is the smallest clinical relevant change 0,015.

This calculation is done with the use of SPSS Sample Power program.

3.11 Organization and cooperation

Volda University College is responsible for this study. Anita Dyb Linge is the project manager and the Ph.D. student. This study is a partnership between Volda UC and Muritunet. The participants are collected from an occupational rehabilitation program for people with a BMI above 30. Data from

baseline, T1, and T2 is from the participants stay at Muritunet. T3 happens where the participants live. T4 is from two different registers. The Ph.D. student is a full-time employee with Volda UC, but work 25 percent at Muritunet.

This study links to Regional Centre for Obesity Research and Innovation at St.Olavs Hospital in Trondheim, and the National Competence Centre for Work-Based Rehabilitation in Rauland.

3.12 User involvement

The user's voice in the project shall contribute to better planning and implementation of the intervention in the study. The user can participate in his or her experience, illuminate challenges, and share their own history. The project manager wishes to seek advice with the user about focus areas and questioners in the quality interview. It can also be useful to use the users to test the questions before the process with interviewing the participants. Muritunet does have other patients with similar challenges who can contribute in the process of quality assurance of the questions. Central Norway Regional Health Authority does also have professional users that can participate in this study.

3.13 Budget

The Central Norway Regional Health Authority is financing the occupational rehabilitation stays at Muritunet.

Volda UC. is funding the Ph.D. student.

3.14 Plan for the progress

	2016	2017	2018	2019	2020
Application Regional Committees for Medical and Health Research Ethics (REC)		X			
Application for finances	X				
Recruiting participants		X			
Data collection/ questioners		X	X	X	
Data collection/ journal		X			
Data collection/ register data				X	
Status report			Årleg		
Articles			X	X	X

Results of the study are publishing in three articles.

3.15 Ethics

Regional Committees for Medical and Health Research Ethics (REC) has approved the study. It has its foundations in laws and guidelines for proper health research and the laws that apply to treatment in the Specialised Health Care services in Norway. Collected data shall be stored anonymous and locked after guidelines from the Personal Data Act, the Health Research Act and the Research Ethics Law. The participants give written consent before participating in the study.

Inconvenience

The participants may experience to fill the foams as bothersome. Individual follow-up of participants has reading and writing difficulties, challenges with the language or concentration problem.

Benefits

1. Participants in the study may increase self-efficacy, get more insight into own health and physical and mental disability through personnel in the Specialised Health Care services.
2. During the interview, participants can improve their understanding of their situation, perspective on their own possible to increase work activity and self-efficacy to returning or continuing to work.

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