

How common is osteosarcopenic obesity syndrome (OSO) in an adult population?

Submission date 14/12/2021	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/12/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/12/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In the Western world, a growing part of the adult population is overweight and fails to obtain the recommended level of physical activity required to promote and maintain a good health profile. Furthermore, with increasing age, bone decreases combined with reduced muscle mass and increased fat mass. These changes increase the risk of fractures and the ability to maintain daily physical functions. These conditions and/or diagnoses (e.g., obesity, reduced muscle mass, and bone health) have previously been considered as separate conditions. More lately, these whole-body complex changes all originate from hormonal factors and low-grade inflammation processes causing cellular changes in the bone, muscle, and fat tissue. Therefore, the aim of this project is to examine the prevalence of two and three of these conditions in an adult population.

Who can participate?

Adult patients who are overweight.

What does the study involve?

In this project, we will include measurement of bone mineral density, body composition (e.g., percent of muscle- and fat mass), muscle strength, physical activity – and nutrition habits, blood samples to examine inflammatory markers in addition to questioners including well-being, quality of life, work ability and mental health.

What are the possible benefits and risks of participating?

Typically, reduced bone mineral density (e.g., osteoporosis or osteopenia) is detected after a serious fracture. In this project, we will conduct this measurement and provide a status of the participants` bone health which might motivate participants to improve bone health before serious fracture. Still, the conduct these measurements, the participants are exposed to a low dose of radiated radiation. Importantly, the doses are very low and comparable with a 6 hour flight with an aircraft.

Where is the study run from?

The data collection will be conducted in five test locations in Norway (Sogndal, Bergen, Kristiansand, Fredrikstad and Lillehammer).

When is the study starting and how long is it expected to run for?
January 2021 to March 2032

Who is funding the study?
Western Norway University of Applied Sciences
The Research Council of Norway

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
254084

Study information

Scientific Title
Osteosarcopenic obesity syndrome

Acronym
OSO

Study objectives

1. Examine the prevalence of having osteosarcopenic obesity syndrome (OSO) (e.g., obesity, sarcopenia, and osteoporosis) among overweight or obese women (e.g., BMI over 25 kg/m²) in Norway
2. Examine the prevalence of having two conditions (sarcopenic obesity and osteopenic obesity) in the same population
3. Examining the age, bone turnover markers, and inflammatory markers as potential moderators and/or risk factors associated with OSO or the dual conditions sarcopenic obesity and osteopenic obesity
4. Examining the well-being, quality of life, work ability, physical activity habits, nutrition habits, muscle strength, muscle quality among individuals with OSO and the dual conditions sarcopenic obesity and osteopenic obesity

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/05/2021, Norwegian National Research Ethics committees (REK sør-øst C, Gullhaugveien 1-3, 0484 Oslo, Norway; +47 22 84 55 11; rek-sorost@medisin.uio.no), ref. 254084

Study design

Observational cross-sectional study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Other

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Osteosarcopenic obesity syndrome (OSO) (obesity, sarcopenia, and osteoporosis)

Interventions

This project has a cross-sectional design meaning that the participants will only be invited to testing once. Each testing session will last approximately 90 minutes. Overweight (BMI >25 kg /m²) women over 50 years will be recruited from five testing locations (Lillehammer, Kristiansand, Fredrikstad/Sarpsborg, Bergen and Sogndal). Within a 45-minute drive, these locations include close to 20% of the Norwegian population. All test locations are related to University Colleges and will involve researchers, students and participants from a broad area of Norway.

DEXA is the gold standard to examine bone mass and bone mineral density in addition to measuring lean mass and body fat. Furthermore, the study will include measurements of muscle strength as sarcopenia causes reduced muscle strength, muscle mass and reduced physical performance (gait speed, handgrip strength, one-leg stance, and sit-to-stand chair). Reduced muscle strength and physical performance increase the risk of falls and fractures.

Questionnaires including well-being, quality of life, work ability, mental health, physical activity habits, and nutrition habits (RAND-36, PROS, PROQOL, IPAQ- IPAQ, and SarQoL) will be included as these outcomes are often overlooked in epidemiology studies. The questionnaires will provide a broader and more in-depth understanding of how these individuals experience the conditions. Furthermore, to gain greater knowledge of the fat infiltration of the muscles, sub-groups will be invited to undergo magnetic resonance imaging (MRI) of the quadriceps to examine muscle quality (muscle volume divided by the muscle force output) and degree of fat infiltration in the muscle. Accordingly, a subpopulation of the participants will be enrolled in analyses of biomarkers of inflammation and bone turnover using blood samples. In addition to 3000 women being enrolled in this project, the researchers aim to use register data from the HUNT study (n = 22,857), the Tromsø Study (n = 3,100) and 100,000 from the UK biobank which all includes adults with DEXA in addition to as many of the outcomes as described above as possible. By including register data from both sexes, will be able estimate the prevalence of OSO in a Norwegian population and a comparable population in the UK.

Intervention Type

Mixed

Primary outcome measure

Bone mineral density, lean mass, and body fat measured using DEXA at a single time point

Secondary outcome measures

Measured at a single time point:

1. Muscle strength in isometric knee extension and grip strength
2. Muscle mass measured using DEXA
3. Physical performance (gait speed, handgrip strength, one-leg stance, and sit-to-stand chair)
4. Well-being, quality of life, work ability, mental health, physical activity habits, and nutrition habits (RAND-36, PROS, PROQOL, IPAQ- IPAQ, and SarQoL)
5. Muscle quality (muscle volume divided by the muscle force output) and degree of fat infiltration in the muscle measured using magnetic resonance imaging (MRI) of the quadriceps
5. Biomarkers of inflammation and bone turnover measured using blood samples

Overall study start date

01/01/2021

Completion date

01/03/2032

Eligibility

Key inclusion criteria

1. Overweight (BMI >25 kg/m²) women over 50 years
2. All adults (independent of age or sex) will be included from the biobank databases

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

50 Years

Sex

Both

Target number of participants

25,000 - 125,000

Key exclusion criteria

Aged under 18 years

Date of first enrolment

01/05/2022

Date of final enrolment

01/05/2030

Locations

Countries of recruitment

Norway

Study participating centre

Western Norway University of Applied Sciences

Røyrgata 6

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Sponsor information

Organisation

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Funder(s)

Funder type
University/education

Funder Name
Høgskulen på Vestlandet

Alternative Name(s)
Western Norway University of Applied Sciences, HVL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Results and Publications

Publication and dissemination plan

The researchers will publish the results in international scientific high-quality peer-reviewed open access journals and present the results at national and international scientific conferences. They will share the information and results with health professionals and the national Ministry of Health and Care Services in order for them to utilize the evidence-based knowledge in future programming decisions. The researchers will make the knowledge gained from the results available also through chronicles, media interviews, regional conferences and meetings with the stakeholders. Finally, popular lectures will be held for local units and associations (e.g., pensioners 'associations, Nasjonalforeningen for Folkehelse, Norske Kvinners Sanitetsforening, osteoporosis associations) involved and contributing to recruiting potential participants.

Furthermore, the findings will be used the international collaborations including comparisons of countries adopting the same outcome measures.

Intention to publish date

01/01/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.

All data will be stored on Western Norway University of Applied Sciences (HVL) research servers. The participants' data will not be stored by name, but with an identification code to ensure anonymity. The connection key between the participants and identification code will be stored separately according to the current rules of storage of personal information in research. All participants can ask for insight into which variables are stored.

Western Norway University of Applied Sciences research servers are restricted to Norwegian laws and regulations and the Western Norway University of Applied Sciences regulations. To gain access to the data sets or available data, the Western Norway University of Applied Sciences are working with Norwegian authorities to establish legal procedures and regulation. At the present point, the solution is not completed. Therefore, please use this contact information atle.saeterbakken@hvl.no to gain an update on the process.

IPD sharing plan summary

Stored in non-publicly available repository, Not expected to be made available