

The association between energy, vitamin D and calcium intakes and bone health among wheelchair users

A Cross-Sectional Study

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Master Thesis

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Emilie Moberg

Abstract

Background: The low mechanical loading of bones among wheelchair users leads to an increased risk of osteoporotic fractures and associated complications related to low bone mineral density (BMD). Low bone mineral density can also be related to insufficient energy intake and suboptimal dietary intake of the micronutrient vitamin D and calcium. Vitamin D deficiency is common in this population.

Objectives: The primary outcome was to investigate the associations between energy, vitamin D and calcium intake and BMD (Z-scores) of the lumbar spine, hip, and femoral neck among wheelchair users. The secondary outcome was to investigate the associations between dietary intakes of vitamin D and the corresponding blood level, as well as associations between dietary intake and blood bone markers including CTX-1, P1NP and bALP. The main hypothesis is that energy availability, vitamin D and/or calcium status among wheelchair users will be positively associated with BMD (Z-score) of the spine, hip and/or femoral neck.

Methods: Dietary intake was assessed with 3 unannounced 24-hour dietary recalls within a 2-week period. Bone mineral density and body composition were measured by Dual-Energy X-ray Absorptiometry and S-vitamin D, S-PTH, S-CTX-1, S-P1NP and S-bALP by a fasted, venous blood sample. Differences between groups were tested with Mann Whitney U, and Pearson and Spearman correlation analyses were performed with a significance level $\alpha=0.05$.

Results: Both the median vitamin D and calcium intake were above the Nordic Nutrition Recommendations (NNR), 14.6 $\mu\text{g}/\text{day}$ and 1021 mg/day , respectively, and the subjects presented sufficient energy intakes. However, suboptimal S-vitamin D levels were present in 3 of 4 wheelchair users and 83 % of the subjects presented a Z-score ≤ -2.0 at lumbar spine, hip, or femoral neck. None of the EI parameters or vitamin D intake was significantly correlated with measurements of BMD, but the relationship between calcium intake and Z-score of the hip was significantly correlated ($r_{\text{sp}}=0.606$, $P=0.037$). In addition, there was a significant correlation between S-vitamin D and the blood bone marker CTX-1.

Conclusion: Despite an overall sufficient energy, vitamin D and calcium intake, low BMD were prevalent in this thesis, which might indicate that the lack of mechanical loading of bones is the main determinant for bone loss in this population. Further research is needed to determine whether the daily recommendations of vitamin D and calcium are adequate for this population and whether insufficient intakes and/or low energy availability further magnifies the impaired bone health among wheelchair users.

Table of Contents

1 Background	1
1.1 Wheelchair users.....	1
1.1.1 Definition of the Population.....	1
1.1.2 Disabilities and Associated Implications.....	1
1.2 Bone Health.....	4
1.2.1 Bone Remodeling and Calcium Homeostasis.....	4
1.2.2. Assessment of Bone Health and Osteoporosis.....	5
1.2.3 Bone Health among Wheelchair users.....	8
1.3 Energy Availability and Bone Health.....	9
1.3.1 Energy Availability (EA) and Relative Energy Deficiency in Sports (RED-S).....	9
1.3.2 Wheelchair bound para-athletes and Low Energy Availability.....	10
1.4 The role of vitamin D and calcium in Bone Metabolism.....	10
1.4.1 Vitamin D metabolism and assessment of vitamin D status.....	10
1.4.2 Assessment of Calcium status.....	13
1.4.3 Vitamin D and Calcium status of wheelchair users.....	13
2 Objectives and Hypothesis	14
3 Subjects and Methods	14
3.1 Study population and design.....	14
3.1.1 Study Design.....	14
3.1.2 Test period.....	15
3.1.3 Subjects.....	16
3.2 Assessment of dietary intake.....	18
3.2.1 24 h dietary recalls.....	18
3.2.2 Coding of food intake.....	20
3.2.3 Evaluation of dietary energy intake.....	20
3.2.3.1 Estimation of resting metabolic rate (RMR).....	20
3.2.3.2 Estimation of a physical activity level (estPAL).....	21
3.2.4 Calculation and evaluation of Energy Availability(EA).....	22
3.2.5 Guidelines of nutrient intake.....	23
3.3 Blood Samples.....	23

3.3.1 Serum sampling.....	23
3.3.2 Laboratory analysis.....	24
3.4 Dual-Energy X-ray Absorptiometry.....	24
3.5 Dietary Supplements.....	25
3.6 Statistics.....	27
3.7 Use of chatGPT or other artificial intelligence programs.....	28
3.8 Ethics and data handling.....	28
3.9 Students Contributions.....	28
4 Results.....	29
4.1 Subject characteristics.....	29
4.2 Dietary Intake.....	30
4.3 Vitamin D Status and Measurements of Bone Health.....	32
4.4 Dietary intake of vitamin D and S-vitamin levels.....	33
4.5 The associations between dietary intake and bone health.....	34
4.6 Estimation of Energy Balance and Energy Availability.....	23
5 Discussion.....	36
5.1 Discussion of results.....	36
5.1.1 Summary of Findings.....	36
5.1.2 Study Population.....	37
5.1.3 Dietary intake among Norwegian wheelchair users.....	37
5.1.4 Vitamin D status and the relationship between vitamin D intake and S-vitamin D.....	39
5.1.5 Dietary intake and measurements of Bone Health.....	41
5.1.6 Energy Availability and Bone Health among Wheelchair users.....	42
5.2 Methodological Considerations.....	44
5.2.1 Study design.....	44
5.2.2 Measurements and Data Collection.....	44
6 Conclusion.....	49
7 Practical implications and Future Research.....	50

References

List of Appendices

List of tables

Table 1. Overview of factors influencing bone health.....	5
Table 2. Overview of blood bone formation and bone resorption markers.....	8
Table 3. Norwegian clinical reference values for S-vitamin D.....	11
Table 4. Overview of the Nordic Nutrition Recommendations (NNR).....	23
Table 5. Vitamin D supplementation protocol.....	26
Table 6. Calcium supplementation protocol.....	27
Table 7. Subject characteristics.....	29
Table 8. Dietary intake.....	30
Table 9. S-vitamin D, S-PTH, blood bone markers and BMD measurements.....	33
Table 10. Estimated RMR, EI:RMR, PAL values and Energy Availability (EA).....	36

List of figures

Figure 1. Timeline of the study.....	16
Figure 2. Description of the five-step multiple-pass method for 24-hour dietary recalls.....	19
Figure 3. The correlation between CTX-1 and S-vitamin D.....	32
Figure 4. The correlation between vitamin D intake and S-vitamin D.....	34
Figure 5. Median PAL values and EI:RMR.....	34
Figure 6a. Energy Availability (EA) cut offs for all subjects.....	35
Figure 6b. Distribution of subjects not at risk and at risk of RED-S (LEAF/LEAM-Q).....	35
Figure 7. The correlation between P1NP and Energy Availability (EA).....	35

List of Appendices

Appendix 1. REK Approval

Appendix 2. Informed consent form

Appendix 3. NSD Approval

Appendix 4. Information on 24-hour recall for test day

Appendix 5. SOP for 24-h recall interview

Appendix 6. Picture booklet used for the 24-hour dietary recalls (NORKOST4)

Appendix 7. Background questionnaire (Q1)

Appendix 8. IPAQ-SF (Q2)

Appendix 9. Low Energy Availability in Female Questionnaire (Q4A)

Appendix 10. Low Energy Availability in Male Questionnaire (Q4B)

Abbreviations

AB	Able-bodied
ACSM	American College of Sports Medicine
AMC	Arthrogryposis multiplex congenita
bALP	Bone-alkaline phosphatase
BM	Body Mass
BMD	Bone Mineral Density
BMI	Body Mass Index
CHO	Carbohydrates
CP	Cerebral Palsy
CLIA	Chemiluminescent immunoassay
CTX-1	C-telopeptide cross-links of type 1 collagen
D2	Ergocalciferol
D3	Cholecalciferol
DLW	Doubly labelled water technique
DXA	Dual Energy-X-Ray Absorptiometry
EA	Energy Availability
ECLIA	Electrochemiluminescence immunoassay
EEE	Exercise energy expenditure
EFSA	The European Food Safety Authority

EI	Energy Intake
FAO	The Food and Agriculture Organization
FES	Functional electrical stimulation
FFM	Fat free mass
HVL	Western Norway University of Applied Science
HUNT	Nord-Trøndelag Health Study
IGF-1	Insulin-like growth factor 1
IOC	International Olympic Committee
IPAQ	International Physical Activity Questionnaire
ISCD	International Society for Clinical Densitometry
IU	International Units
KBS	Kostberegningssystem (KBS food and nutrient calculation system)
LARS	Landsforeningen for ryggmargsskadde (National association of SCI)
LBM	Lean Body Mass
LC-MS-MS	Liquid Chromatography with tandem mass spectrometry
LEA	Low Energy Availability
LEAF-Q	Low Energy Availability in Females Questionnaire
LEAM-Q	Low Energy Availability in Males Questionnaire
MET	Metabolic Equivalent of Task
MS	Multiple Sclerosis

MD	Muscular Dystrophy
NAV	The Norwegian Labour and Welfare Administration
NIF Sports	The Norwegian Olympic and Paralympic Committee and Confederation of Sports
NIH	Norwegian School of Sports Science
NNR	Nordic Nutrition Recommendations
NMOL	Nanomole
NTNU	Norwegian University of Science and Technology
NSD	Norwegian Center for Research Data
NTX	N-terminal telopeptide of type 1 collagen
OC	Osteocalcin
P1NP	Procollagen type I N-terminal peptide
PAL	Physical activity level
PICP	Procollagen type 1 C-terminal peptide
PMOL	Picomole
PPIs	Proton pump inhibitors
PTH	Para thyroid hormone
QCT	Quantitative computed tomography
RCT	Randomized Controlled Trial
RDI	Recommended Daily Intake

RED-S	Relative Energy Deficiency in Sport
REE	Resting energy expenditure
REK	Regional Committees for Medical and Health Research Ethics
RMR	Resting metabolic rate
SB	Spina Bifida
SCI	Spinal Cord Injury
SD	Standard Deviation
SSIs	Selective serotonin receptor inhibitors
TDEE	Total daily energy expenditure
TZDs	Thiazolidinediones
USDA	United States Department of Agriculture
UVB	Ultraviolet B
VDR	Vitamin D receptor
WC	Wheelchair
WHO	World Health Organization
25(OH)D	25-Hydroxyergocalcifer

1 Background

The low mechanical loading of bones among wheelchair users leads to an increased risk of osteoporotic fractures and associated complications related to low bone mineral density (BMD) (1, 2). In addition to the lack of loading stimulus, low BMD can also be related to an insufficient energy intake (3) and nutrient inadequacy (4). While there is a gap of knowledge considering how to optimize bone health in wheelchair users, existing literature on non-wheelchair users and high-performance athletes suggest that high impact loading and resistance training (5) combined with optimized nutrition, especially energy availability (EA), vitamin D and calcium intake, are the most effective prevention and treatment of low BMD (3).

1.1 Wheelchair users

1.1.1 Definition of the Population

A wheelchair user is a person who has a limited ability to walk and is dependent on a wheelchair to facilitate mobility (6). There are about 50.000 wheelchair users in Norway (according to NAV) (7) and common physical disabilities that require prolonged use of a wheelchair are spinal cord injuries (SCI), Spina Bifida, Cerebral Palsy (CP), Multiple Sclerosis (MS), Muscular Dystrophy (MD), Arthrogryposis Multiplex Congenita (AMC) and lower-limb amputees. Some users are fully dependent on the wheelchair for mobility, while others are ambulatory users, which means they have a limited ability to walk.

Disabled athletes, also referred to as para-athletes, are athletes with a physical, visual, or intellectual impairment. As of 2019, 11 089 disabled individuals were registered active in sports in Norway (8) and many of them are wheelchair users. El-bandy is the biggest team-sport for wheelchair users, but also para-handball, rugby and ice hockey are popular para-sports in Norway.

1.1.2 Disabilities and Associated Implications

Many disabilities require the use of wheelchairs for mobility, but most research on bone health in wheelchair users has been conducted on individuals with spinal cord injury (SCI). In

addition to low BMD as a result of immobility, wheelchair users may also face nutritional challenges associated with the disability, which can lead to nutrient deficiencies and subsequently impaired bone health. The following section describes the different disabilities, and the implications related to dietary intake, which are relevant for this master thesis.

Cerebral Palsy

Cerebral Palsy (CP) is a group of neurodevelopmental disorders resulting from an injury to the developing brain (9). The etiology of CP is diverse and multifactorial, but the major causative factor is a brain injury during the perinatal period (10). A stroke or acute head trauma to a child at the age of 3-5 can also result in CP (11). The clinical features of CP are varied and dependent of the severity and location of the brain injury (12). The disorder is characterized by abnormalities of muscle tone, movement and motor skills which results in impaired ambulation and, dependent on the severity, wheelchair use. As a consequence of immobility, reduced BMD (Z-score < -1.0 Standard Deviation (SD)) and osteoporosis (T-score < -2.5 SD) is common among individuals with CP and non-ambulatory individuals are at higher risk than ambulatory (13, 14). In addition, common co-occurring impairments include gastrointestinal disorders, such as concurrent constipation, dysphagia, abdominal pain, delayed gastric emptying, abnormal autonomic control of gastrointestinal mobility and prolonged colonic transit (15, 16). Further, an impairment of cognition and vision can affect the nutritional intake and consequently bone health.

Spinal Cord Injury and Spina Bifida

A spinal cord injury (SCI) can cause major motor, sensory and autonomic dysfunctions as a result of the neurological impairments of the spinal cord (17). 90 % of all spinal cord injuries are due to traumatic causes (e.g., a motorbike crash), but it can also be a result of a disease or degeneration (e.g., cancer) (18). Symptoms depend on the severity of the injury and the neuroanatomical location of the lesion. A thoracic or lumbar spinal cord injury causes functional loss in the legs and trunk muscles, as well as organs, innervated below the level of lesion and is referred to as paraplegia. Quadriplegia refers to a cervical spinal cord injury which causes functional loss in all four extremities, including organs innervated below the site of lesion. A complete spinal cord injury causes total paralysis below the level of injury, while an incomplete lesion causes impaired function, although still some degree of sensation and

movement below the injury. As a result of paralysis or loss of function in the legs, individuals with SCI are dependent on a wheelchair to be mobile. As a consequence of the mechanical unloading, neurovascular and hormonal changes caused by the lesion of the autonomic system (19, 20), development of low bone mineral density (BMD) and osteoporosis is common among individuals with SCI (21).

A number of complications associated with a SCI can influence an individual's nutritional status. As a consequence of the injury and immobility, the energy cost of most exercise and activities of daily living becomes considerably lower (22, 23), further, body composition changes due to loss of muscular mass below the level of lesion, which also affects the resting energy expenditure (REE) (24). This makes weight management challenging; thus, obesity is common among individuals with a SCI (25). In addition, a variety of autonomic dysfunctions affect metabolism and dietary intake (26), such as bladder and bowel control, and gastrointestinal problems caused by a neurogenic bowel dysfunction. This often results in concurrent constipation and a slower gastric emptying, which can decrease the uptake of nutrients along the intestine (27).

Spina Bifida (SB) is a congenital condition caused by an incomplete closure of the neural tube during embryonal development. The malformation of the neural tube results in an improper fusion of the posterior spinal bony elements, which leads to an exposed and often damaged spinal cord. This affects the innervation below the lesion, and as SCI, individuals with Spina Bifida experience variable degrees of sensory and motor loss, including autonomic dysfunctions, depending on the severity and neuroanatomical location of the injury (28). Often, the neurological impairment prevents normal ambulation, which results in wheelchair reliance and thus, an increased risk of osteoporosis (29). For individuals with SB, who are primary wheelchair users, implications with respect to mobility, BMD, REE and nutritional challenges are likely comparable to those individuals with SCI experience (30).

Arthrogryposis Multiplex Congenita

Arthrogryposis Multiplex Congenita (AMC) is a group of congenital conditions characterized by multiple joint contractures and fibrotic replacement of normal skeletal muscles which leads to decreased mobility (31). The severity of the condition depends on the number of joints affected and the extent of joint stiffness, which leads to limited mobility, and some individuals are dependent on a wheelchair for ambulation (32). The symptoms may be a result

of the connective tissue disorder itself or an abnormality of the central or peripheral nervous system. (33). Studies have shown that children with arthrogryposis experience lower bone mineral density than age-matched means, especially for those with limited ambulation (34).

Lower limb amputees

Amputation is often a consequence of a vascular disease or trauma (35) and a lower limb amputation means a permanent impairment with decreased mobility which often leads to the use of prosthesis or wheelchair (36). Studies have shown that during the first year after an amputation, which includes long periods of bed rest and reduced ambulation after surgery, amputees can experience large losses of bone mineral density in the hip (37). For unilateral, studies have shown that the affected limb are at greater risk for reduced BMD (38).

1.2 Bone Health

1.2.1 Bone Remodeling and Calcium homeostasis

Bone tissue is a dynamic tissue which continuously becomes remodeled through the actions of the different types of bone cells and the surrounding bone matrix. Calcium is constantly being recycled in this process as it is deposited when osteoblasts form bone tissue, and it is turned over when osteoclasts break down and resorb the tissue. Normal bone remodeling, or bone turnover, is important for fracture healing and the skeleton's adaptation to mechanical use, as well as calcium homeostasis. The skeleton serves as a depot for the storage of excess calcium and as a reservoir during a negative calcium balance, as bone loss will occur to replenish calcium levels in the blood. The calcium concentration in the blood plasma is regulated within narrow limits as calcium plays a vital role in many processes in the human, whereas muscle contraction is one of the most important, and an imbalance can cause serious medical disorders, e.g., cardiac abnormalities (39). The exchange of calcium from the bones is one of many actions used to regulate the calcium concentrations in the blood, as it is a tightly regulated system where the hormonal control of the reabsorption in the kidneys and absorption of calcium in the intestine also interacts in the regulation (40).

1.2.2 Assessment of Bone Health and Osteoporosis

A normal bone remodeling is important for bone health, as this process strengthens the bones and increases the resistance to fractures. Bone mineral density (BMD), the amount of minerals in a certain area of bone tissue, and the bone quality, the structural and material properties of the bone tissue, are good indicators of bone health (41). Studies report that around 50-90 % of the variability in BMD can be related to heritable factors (42), but also non genetic determinants such as dietary factors, physical activity and other clinical factors influence a person's BMD, as described in **table 1** (43). Studies has shown that young adults who participate in high-impact sports like football, basketball and ice hockey present a higher BMD than age-matched who did not perform high-impact sports (44). Physical activity is also of great importance for bone health of wheelchair users (1) and a study performed on paraplegic basketball players reported a higher BMD among the players compared to paraplegic sedentary persons (45)

Table 1. Overview of factors influencing bone health

Factor influencing bone health	Description
Genetics	50-90 % of the variability in BMD are related to heritable factors
Nutrition	Calcium, vitamin D and energy availability. Adequacy of general diet (e.g. protein)
Environmental	Sunlight exposure, smoking status
Hormonal	E.g low oestrogen and/or testosterone
Physical activity	Weight-bearing activities
Medical history	Co-morbidities affecting bone metabolism, e.g. diabetes, pituitary, renal or gastrointestinal disease
Medications	Oestrogen, progesterone, glucocorticoids and anabolic steroids

Although all bones share similar cellular and matrix composition, there are different internal structures which affect the strength of the bone and the bone turnover. Cortical bones are tightly compact bones which are designed for strength, while trabecular bones are highly porous designed to allow for some absorption of forces during motion. Trabecular bones have got a higher rate of turnover, which means that the trabecular bones respond to changes in exercise and diet faster than the cortical bones (46). The vertebra, pelvis and ribs are mostly trabecular bones, and studies show that bone loss among SCI is highly site-specific and progressing with different patterns and timelines in cortical and trabecular bone compartments (21).

Osteoporosis is a systemic skeletal disease characterized by an imbalance in the bone remodeling process as the bone resorption exceeds the bone formation, which results in

decreased BMD and an increased risk of low-energy fractures (47). The diagnosis is based on BMD measurements as it is a “silent disease” due to the absence of symptoms before the occurrence of fractures (48) and the hip, spine and forearm are the most common sites of osteoporotic fractures among able-bodied (49). Osteoporosis is a multifactorial metabolic bone disorder with a strong genetic component and a public health problem because of the morbidity, mortality and costs associated with its complications; fractures (50).

Assessment of Bone Mineral Density

Bone mineral density is a measure of the amount of minerals, such as calcium and phosphate, in a certain area of bone tissue, expressed as g/cm^2 , and the gold-standard method to assess BMD is a Dual Energy-X-Ray Absorptiometry (DXA) (51). It is a simple and safe low-dose x-ray scan which can measure bone mineral density in the clinically important sites of the spine, hip, and forearm, as well as a whole-body scan. BMD measurements are given as absolute values (g/cm^2) and relative values presented as Z-scores or T-scores. Z-score is a statistical measure that indicates how many standard deviations an observation is away from the mean of the distribution. A Z-score for BMD represents the number of standard deviations (SD) above or below the mean BMD of an age, gender and ethnic group matched individual (50). Z-scores are calculated by subtracting an age, gender and ethnic group matched mean BMD from the individual’s measured BMD, and expressing the difference relative to the age, gender, and ethnic group matched population’s SD:

$$Z\text{-score} = \frac{\text{Measured BMD} - \text{Matched population* mean BMD}}{\text{Matched population* SD}}$$

** Age, gender, and ethnic group matched population*

A T score represents the number of SD above or below the mean BMD of a healthy young adult of the same sex (50) and T-scores are calculated in a similar way as Z-scores, except that the reference is a young, healthy adult population. BMD measurements can be used to diagnose osteoporosis, to assess a patient’s risk of fracture, and to monitor response to a treatment (50). There is a consensus that spine and hip BMD measurements in postmenopausal white women should be interpreted using the World Health Organization (WHO) T-score definitions of osteoporosis and osteopenia (52, 53). Osteoporosis is defined

by the WHO as a T-score $< - 2.5$ SD. Osteopenia is a clinical term used to describe a decrease in bone mineral density (BMD) below normal reference values and it is defined by the WHO as a T score between -1 and -2.5 SD. BMD measurements is a powerful predictor of fracture for non-wheelchair users, with fracture risk doubling for each standard deviation below peak bone mass (54, 55) and studies performed on individuals with SCI showed that the WHO-derived BMD categories may be useful in classifying fracture risk in SCI as well (56). In men with SCI, it has been shown that each unit of SD (t-value) decrement in BMD at the femoral neck increases the risk of fracture by 280 % (57).

The International Society for Clinical Densitometry (ISCD) recommend that the WHO criteria for diagnosing osteopenia and osteoporosis should only be applied for postmenopausal women and men aged 50 and older (58). Z-scores, not T-scores, are preferred BMD reporting in females prior to menopause and males under age 50, and a Z-score ≤ -2.0 is defined as "below the expected range for age" and a Z-score > -2.0 is "within the expected range for age". The ISCD also recommended that osteoporosis should not be diagnosed in these populations based on a BMD measurement alone, but only when low BMD are measured together with a present secondary clinical risk factors, that reflect an elevated short-term risk of bone mineral loss and fracture.

Blood bone markers

BMD is a major determining factor of bone strength and a good indicator of the fracture risk, but BMD measurements cannot determine the pathophysiological mechanisms underlying bone loss. Bone cell activity, and bone turnover, can be indirectly evaluated by measurement of specific biochemical markers of bone formation and bone resorption (59). The most commonly used blood bone markers are described in **table 2**. Evaluation of the levels of these markers in the blood gives valuable information about bone turnover and overall bone health. When bone turnover is high, as in the case of osteoporosis, both bone resorption and formation markers are elevated. While changes in BMD require a few months to be detected, these blood bone markers can be used to monitor minor and acute changes in bone turnover and an increase of bone resorption markers, e.g. CTX-1, have been seen already 3 months post SCI (60). An increase of bone formation markers is also reported, but often returns to a normal level 12 months post injury (61), while markers of bone resorption have been reported to be elevated during the chronic phase as well.

Table 2. Overview of blood bone formation and bone resorption markers

Blood bone formation markers	Blood bone resorption markers
<u>Products of collagen synthesis:</u> Procollagen type I N-terminal peptide; P1NP Procollagen type I C-terminal peptide; PICP	<u>Products of protein matrix degradation of type I collagen:</u> Cross-linked C-telopeptide of type I collagen; CTX-1 Cross-linked N-telopeptide of type I collagen; NTX
<u>Osteoblastic enzyme:</u> bone-alkaline phosphatase; bALP	
<u>Non collagenous protein:</u> Osteocalcin; OC	

It is well known that vitamin D deficiency causes an increase in bone resorption, presumably from the rise in parathyroid hormone (PTH), and blood bone markers have been suggested as markers of long-term vitamin D status (62), but The European Food Safety Authority (EFSA) concludes that more research is needed to establish the relationship between blood bone markers and vitamin D status (63). Biological factors also influence the level of activity and during growth and puberty blood bone markers increases, thus, reference values are different depending on age and sex, and the reference values for adults are valid for adults above 25 years old (64).

1.2.3 Bone Health among Wheelchair users

The low mechanical loading of bones among wheelchair users leads to an increased risk of low BMD and osteoporotic fractures, compared to the able-bodied population (1, 2). In addition, SCI experience neurovascular and hormonal changes due to the injury which affects the bone tissue and a rapidly decrease in BMD is observed the first 1-2 years post injury and then continuously throughout the chronic phase, but at a slower rate (21). Both BMD of the hip (non-functional body part) and the spine (functional body part) appear low in individuals with SCI (65). The most common sites for fractures in the SCI population are the femoral neck and hip, and the distal femur and proximal tibia, and the fracture risk is associated with low BMD of the respective sites (2).

25 % of individuals with SCI experience at least one fracture throughout life, whereas 70 % of those fractures occur due to a low-impact injury such as moving from wheelchair to the bed (66), and 50 % of the fractures results in secondary complications which includes infections, pressure ulcers, increased muscle spasticity, depression, ossification at the fracture site, stiffness, and a further decrease in bone health (21). Based on a recent systematic review (67),

69% of wheelchair users with SCI experience a fall each year, which can potentially cause serious fall-related injury and negative psychosocial consequences, e.g., increased fear of falling again, and a low BMD increases the risk of a fracture as a result of a fall.

1.3 Energy Availability and Bone Health

1.3.1 Energy Availability (EA) and Relative Energy Deficiency in Sport (RED-S)

Energy availability is defined as the dietary energy available to sustain normal physiological function after subtracting exercise energy expenditure, relative to the fat free mass (FFM) of the subject. EA is expressed as kcal/kg FFM and an optimal EA is defined as > 45 kcal/kg FFM day, which equals energy balance and sufficient energy to support the normal functions of the body. Low energy availability (LEA) has been defined as under a threshold of daily 30 kcal/kg FFM and this particular type of energy deficiency is associated with an uncoupling of bone turnover; an increase in bone resorption and a decrease of bone formation, which can lead to a decrease in BMD (68). The cut off for LEA are based on controlled laboratory trials in females showing that there is a clear effect on hormonal markers of the reproductive system, e.g., suppressed estradiol, and altered markers of bone turnover when short-term EA < 30 kcal/kg FFM (68-70).

The term “Relative Energy Deficiency in Sport” (RED-S) refers to impaired physiological function including, but not limited to, metabolic rate, menstrual function, bone health, gastrointestinal function, immunity and mental health caused by short- or long-term LEA (3). The syndrome of RED-S impairs health and performance in both males and females (71) and a screening tool for early identification of female athletes in risk of LEA, The Low Energy Availability in Female Questionnaire (LEAF-Q), has been developed and validated. It is a self-reported questionnaire designed to detect physiological symptoms related to long term LEA and contains questions regarding injuries and illness, gastrointestinal and reproductive function. Female participants who score > 8 on questions 1-3 regarding gastrointestinal symptoms, injuries, and menstrual dysfunction, are considered at risk for LEA, as described by Melin et al (72). A similar questionnaire regarding LEA in male athletes, The Low Energy Availability in Males Questionnaire (LEAM-Q), is developed by the same authors as those of LEAF-Q, but only one parameter, low sex drive, was able to distinguish between LEA control and cases in the validation study (73).

1.3.2 Wheelchair bound para-athletes and Low Energy Availability

There is very little research about the prevalence and consequences of LEA and RED-S in para-athletes and in addition, it is more challenging to identify the risk factors of RED-S as it is difficult to distinguish whether they are related to LEA or a consequence of the athlete's impairment. Wheelchair bound para-athletes may have got different energy requirements, reduced resting metabolic rate (RMR), impaired gastrointestinal health, bone mineral density and hormone status due to their impairment. However, it has been suggested that individuals with a disability may experience an increased risk of LEA and that the risk of LEA is dependent on disability type and severity of the impairment (30). Wheelchair bound para-athletes may face several nutritional challenges to fuel properly due to bladder and bowel control, nausea or constipation related to the use of medication, limited access and/or ability to prepare food, weight control and low nutritional knowledge, which can increase the risk of LEA (74). Egger and Flueck attempted to estimate EA in elite wheelchair Para-athletes and reported LEA in 73% of the measured days in female athletes and 30% of the days in male athletes (75). It must be emphasized that the cutoff thresholds for LEA are validated in able-bodied (AB) female athletes and whether they are applicable for wheelchair-users is unknown.

1.4 The role of Vitamin D and Calcium in Bone Metabolism

1.4.1 Vitamin D Metabolism and Assessment of Vitamin D status

Vitamin D is a fat-soluble vitamin and has two main forms; D2, ergocalciferol, and D3, cholecalciferol, which is synthesized in the skin, from the precursor 7-dehydrocholesterol, by the action of ultraviolet B (UVB) radiation. In foods vitamin D exists mainly as D3, but D2 can be found in some mushrooms. Whether vitamin D comes from oral ingestion or from the skin, it must undergo two hydroxylation, first in the liver to become 25 - Hydroxyergocalciferol (25(OH)D), the circulating form of vitamin D which is also used to determine a person's vitamin D status in the blood, and thereafter in the kidneys, to become the biological active 1,25-Dihydroxyvitamin D (1,25(OH)₂D). Free 1,25(OH)₂D performs its biological functions in the target tissues by activation of the high-affinity nuclear vitamin D receptor (VDR), and thereby regulate gene transcription. One of the major physiologic functions of vitamin D is to maintain serum calcium and phosphorus levels within a

physiologic range to maintain a variety of metabolic functions and bone metabolism. A decline in calcium levels is recognized by calcium-sensing cells in the parathyroid gland and stimulates the release of PTH, which promotes the conversion of 25(OH)D to 1,25(OH)2D in the kidneys. 1,25(OH)2D binds to VDR in the small intestine and through the actions of the nuclear receptor upregulates the calcium transports channels and transport proteins, thus increasing calcium absorption. Vitamin D also interacts with VDR in osteoblasts by stimulating them to become mature bone-resorbing osteoclasts, which removes calcium and phosphorus from the bone to maintain normal calcium and phosphorus levels in the blood. In addition, 1,25(OH)2D stimulates calcium reabsorption from the glomerular filtrate in the kidneys, which also contributes to increasing the calcium levels in the blood (76).

Assessment of Vitamin D status

Serum 25(OH)D reflects the amount of vitamin D attained from both cutaneous synthesis and dietary sources, and can be used as a biomarker of vitamin D status in adult populations (77). The cut offs for diagnostic status, according to the Norwegian clinical reference values provided by Fürst Medical Laboratory (78), are shown in **table 3**.

Table 3. Norwegian clinical references values for S-vitamin D for diagnostic status (78)

Cut-offs serum vitamin D (25(OH)D)	Diagnostic status
> 350 nmol/L	Toxic
> 50 nmol/L	Adequate
< 50 nmol/L	Suboptimal levels
< 25 nmol/L	Clinical deficiency

A review from Cranney et al reported that there was fair evidence from studies of an association between circulating 25(OH)D concentrations with some bone health outcomes (79). Vitamin D deficiency and suboptimal vitamin D status has been associated with significantly higher PTH levels among postmenopausal women with osteoporosis (80) and thus consequently accelerated bone turnover, bone loss, and risk of osteoporotic fractures (81). As such, the use of PTH suppression has been suggested as a determinant of optimal 25(OH)D levels, however, a review and meta-analysis on RCTs investigating vitamin D supplement and the response of 25(OH)D, PTH, BMD, bone markers and calcium absorption,

reported large heterogeneity across the results when using PTH as a biomarker of vitamin D status (63, 82).

Vitamin D blood levels from 80 nmol/L and up to 125 nmol/L have been suggest as a goal for optimal training induced adaptation and bone health among athletes (71, 83-85), as studies have shown that S-vitamin D levels < 80 nmol/L can increase the risk of stress-fractures (86) and that vitamin D levels in the upper reference range (90-100 nmol/L) were correlated with higher BMD measures (87). In addition, observational studies have found a decreased risk of many chronic diseases and acute illness when 25(OH)D > 80 nmol/L (76) and that elevating serum 25(OH)D from ~40 to >75 nmol/L with supplemental vitamin D3 (100µg/day) may benefit skeletal muscle recovery, regeneration, and hypertrophy (88).

An optimal vitamin D status can be achieved by regularly exposing the skin (minimum 25 % of body surface) to the sun (UVB), but at the latitude of the Nordic countries (55° N–72° N), vitamin D deficiency can occur if the diet is low in vitamin D. In addition to sun exposure and dietary intake, subjects-specific determinants such as skin pigmentation, age, and genetics also influence vitamin D status (89). According to the Nordic Nutrition Recommendations (NNR 2012) (90) a daily dietary intake of 10 µg of vitamin D is sufficient for adults < 75 years old to maintain an optimal vitamin D status (> 50 nmol/L). For people with little or no sun exposure and elderly (> 75 years), an intake of 20 µg/day is recommended, and the latter is mainly due to the decline of 7-dehydrocholesterol in the skin with age and the efficiency of conversion of this precursor into vitamin D is less effective compared to the younger population. The main dietary sources of vitamin D in the Norwegian population are fatty fish, fortified margarine, butter and milk, and cod liver oil supplements (89). Norkost 3 (2010), a national dietary survey among adults in Norway, reported an average vitamin D intake of 10.7 µg/day, including dietary supplement, and 5.8 µg/day without supplements (91, 92). A systematic review from Holvik et al (2008) concluded that Vitamin D status is sufficient in the majority of the adult Norwegian population, but also that levels are insufficient in a relatively large proportion of the population, and there is a drop in vitamin D status in late winter (93). Data from Tromsøundersøkelsen and Nord-Trøndelag Health Study (HUNT) support these findings and the latter report that 64 % of adults from the cohort-population presented S-vitamin D values < 50 nmol/L during wintertime (94).

1.4.2 Assessment of Calcium status

Calcium is an essential mineral and calcium balance is determined by the dietary calcium intake and the amount of calcium absorbed from the intestine, and by the urine and endogenous fecal excretion. A larger proportion of calcium is absorbed by the active, vitamin D-dependent process when calcium intake is low (95), but whether low calcium intakes lead to calcium deficiencies depends on one's ability to adapt and conserve calcium (96). There are few biochemical markers which reflect calcium status as blood serum levels of calcium is tightly regulated. Recommendations for calcium intake are based on the amount of calcium needed to maintain calcium balance and an optimal bone remodeling rate (97), and according to the NNR 800 mg calcium/day is sufficient for healthy adults. Dairy foods are the major source of calcium in the diet and pulses, nuts, seeds, and green vegetables have variable amounts of calcium. Norkost 3 reported that the average calcium intake for both men and women in Norway were sufficient, 1038 mg/day and 811 mg/day respectively (91, 98).

Patients diagnosed with osteoporosis are recommended a dietary intake of 1000-1500 mg calcium/day and 20 µg vitamin D, and supplements are often used to secure a sufficient intake (99). The evidence that calcium supplementation alone reduces fracture incidence is limited and inconclusive (100), but calcium supplementation in combination with vitamin D might be effective in reducing fractures (71, 84, 85, 101).

1.4.3 Vitamin D and calcium status of wheelchair users

Wheelchair users often have a smaller energy budget, as a consequence of a lower energy intake related to a decrease in energy expenditure compared to the A-B population, and a nutrient dense diet might be necessary to meet their daily micronutrient requirement. Studies demonstrate that athletes with SCI are at risk for several nutrient inadequacies as a consequence of an insufficient dietary intake (102) and a high prevalence of vitamin D deficiency has been reported both in patients with chronic SCI (103, 104) and elite athletes with SCI (105). This could be related to poor dietary intake, geographic location (northern latitudes), time spent outdoors, clothing, challenges around grocery shopping and food preparations or due to the nature of the impairment. In addition, altered GI function associated with SCI and frequent use of anticonvulsants, which decrease serum vitamin D and reduce calcium absorption (106), may also put an individual with SCI at greater risk for micronutrient deficiencies compared to healthy individuals (4).

2 Objectives and Hypothesis

This master thesis is a sub-study of an ongoing Randomized Controlled Trial (RCT), The Bone Wheel study, where the primary aim is to investigate the effects of resistance training and nutritional counselling for improving bone health in wheelchair users with an initially low-normal to low BMD of the spine ($Z\text{-score} \leq 0.0$).

The primary aim of this master thesis was to investigate the associations between energy, vitamin D and calcium intake and BMD ($Z\text{-scores}$) of the lumbar spine, hip, and femoral neck at baseline.

Secondary aims were to investigate the associations between dietary intakes of vitamin D and calcium and

- a) The corresponding blood level of S-vitamin D
- b) Blood bone markers including CTX-1, P1NP and bALP

The main hypothesis was that energy availability (EA), vitamin D and/or calcium status among wheelchair users will be positively associated with BMD of the lumbar spine and/or hip/femoral neck.

3 Subjects and Methods

3.1 Study population and design

3.1.1 Study Design

This current master thesis is a cross-sectional study which includes baseline data from the RCT The Bone Wheel study, where the participating wheelchair users perform a 24-week resistance training and nutrition program. Prior to the baseline measurements there was a screening process, and 30 wheelchair users were subjected to a BMD examination (DXA). Background and medical questionnaires were included at the screening to ensure eligibility of the participants for inclusion to the study. The Bone Wheel study is a multi-site RCT, and screening and baseline testing was performed at both the Norwegian School of Sports Science (NIH) in Oslo and at Western Norway University of Applied Science (HVL) in Bergen.

Screening day

On the screening day, the subjects arrived at their local test facility either in the morning after an overnight fast or in a 4-hour fasted state, for assessment of BMD and body composition (DXA). The subjects also had to perform the key exercises of the intervention protocol and complete questionnaires about their background, health, and medications (Q1; Background questionnaire) and physical activity (Q2; International physical activity questionnaire – short form (IPAQ-SF (107, 108))). Those who fulfilled the criteria (Z score of lumbar spine ≤ 0 SD) were included in the study and invited back to baseline testing.

Baseline Test Day

The subjects arrived at their local test facility in the morning after an overnight fast to perform a venous blood sample test for assessment of blood bone markers, S-vitamin D and S-PTH. An additional DXA scan was performed for the subjects who did not perform the scan in an overnight fasted state on screening day. During the test day the subjects also completed the LEAF-Q or LEAM-Q (Q4), and they were provided information about the 24-hour dietary recalls assessment, which were conducted in the subsequent test period. At the end of the test day the subjects received the mixed powder supplement (Friesland Campina, the Netherlands).

Home-based test period

Within a 2-week period after the baseline test day, the subjects completed a dietary assessment through 3 unannounced 24-hour dietary recalls. The master student was responsible for the planning and the logistics of conducting the dietary recalls with all participants, both the intervention and control group. All dietary recalls were performed by the master student. The dietary assessment was the main focus in this master thesis and is described more thoroughly than secondary methods, such as blood sampling and DXA scans.

3.1.2 Test Period

December 2022 to February 2023.

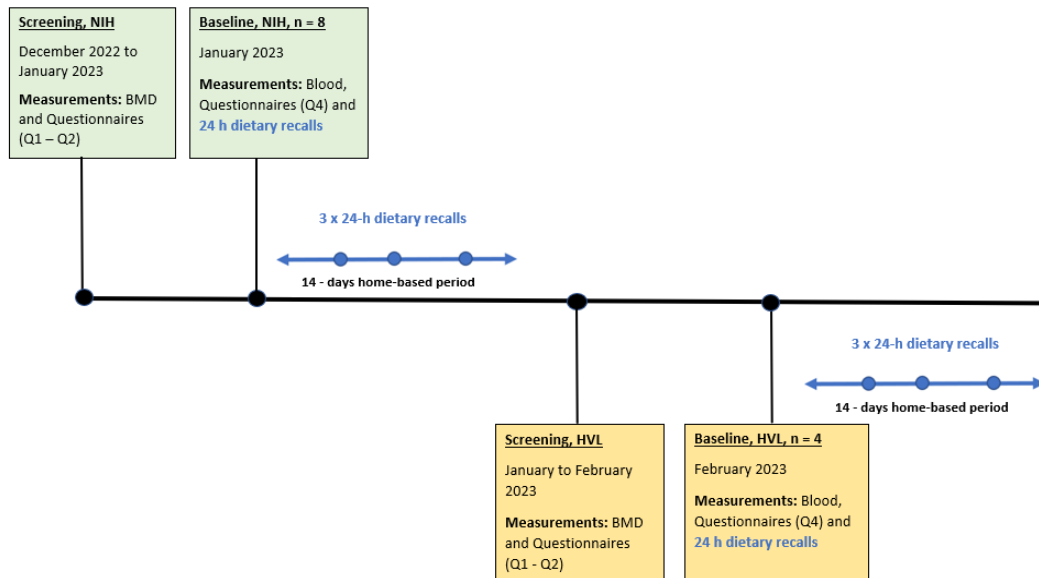


Figure 1. The timeline of the study including screening and baseline test days at both NIH, Oslo, and HVL, Bergen. Above the line, marked in green; the timeline of the test period in Oslo is described and below the line; the timeline of the test period in Bergen is described and marked as yellow.

3.1.3 Subjects

Eligible subjects for this study were wheelchair users both sport active and non-active, with an initially low-normal to low BMD of the spine ($Z\text{-score} \leq 0.0$), primary aid for mobility being a manual wheelchair, i.e. $\geq 50\%$ of the time, 18-60 years old, congenital (i.e., CP, spina bifida, dysmelia, hip dysplasia), acquired disabilities (i.e., SCI, amputation) or paraplegic wheelchair users with SCI level at thoracic vertebra Th6 or lower, and have got the ability to perform key exercises (e.g., overhead press).

The recruitment of the study participants was done through the network of the partners; NIH, HVL, The Norwegian Olympic and Paralympic Committee and Confederation of Sports (NIF), Sunnaas Rehabilitation hospital, Norwegian University of Science and Technology (NTNU) and Idrettsklynge Vest. A participant information document and a “onepager” for online platforms, such as Facebook and Instagram, was distributed to all the project partners, foundations, rehabilitations centers and user organizations such as “Stiftelsen VI”, “Cato senteret”, “CP foreningen”, “Landsforeningen for ryggmargsskadde” (LARS) and to their platforms such as webpages, member magazines/newsletters, and social media for recruitment purpose. Finally, the head of the project reached out to national sports federations and their respective coaches to recruit para-athletes.

Exclusion Criteria

1) Tetraplegic wheelchair users; 2) injury acquired < 2 years ago; 3) change in health and/or medication within the last 3 months, 4) fracture within the last 6 months, 5) pregnancy or planned pregnancy during the study period; 6) language or cognitive barriers affecting the ability to understand all aspects of the study, 7) patients with progressive neurological disease, serious or uncontrollable epilepsy, endocrine diseases (including diabetes mellitus type 1 or 2, thyroid disorders, calcium homeostasis disorders and metabolic bone diseases, pituitary gland disorders, sex hormone disorders), cancer, serious mental disorders, or comorbid medical conditions affecting either a) nutritional function: i.e., malabsorption problems due to previous surgery in the gastrointestinal tract, inflammatory bowel disease, coeliac disease, eating disorders, chronic pancreatitis, liver or kidney disease (those that cannot convert vitamin D to its active form in the body), other conditions affecting vitamin D or calcium absorption; b) musculoskeletal system: i.e., congenital systemic skeletal dysplasia affecting bone density, inflammatory arthritis conditions (such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and lupus), ongoing tendinitis or muscle injuries not compatible with the exercise intervention; c) cardiovascular system: i.e. congenital heart failure, congenital connective tissue disorders affecting the aorta and/or arteries, other cardiovascular conditions not compatible with the exercise intervention; 8) the use of certain medications: bisphosphonates, hPTH (teriparatide), Denosumab, Raloksiphen, Prednisolone/steroids/androgenic steroids, high dose oestrogen (including medroxyprogesterone acetate contraceptives) immunosuppressive medications/chemotherapies, vitamin K, anti-epileptic medication (Lamotrigine, Phenytoin, Phenobarbital, Carbamazepine, Primidone), proton pump inhibitors (PPIs), selective serotonin receptor inhibitors (SSRIs), thiazolidinediones (TZDs), anticonvulsants, hormone deprivation therapy, calcineurin inhibitors, and isotretinoin; 9) other therapies that aim to increase bone mineral density, e.g., vibration therapy, functional electrical stimulation (FES); 10) alternative medicine that interfere with vitamin D or calcium metabolism or affect bone mineral density.

Heterogeneity in Study Population

A broad range of disabilities were eligible for inclusion to the Bone Wheel Study, which makes this study population a heterogeneous group. This present sub-selection included only a small heterogeneous group, which must be considered when interpreting the data.

3.2 Assessment of dietary intake

3.2.1. 24-hour dietary recalls

Information about the dietary intake of the subjects was collected through 24-hour dietary recalls, which were conducted within a 2-week period after the baseline test day. Three unannounced 24-hour dietary recalls performed through a video call, on two weekdays and one weekend day selected randomly within the 2-week test period, were conducted for each subject to get a representative view of their dietary intake in this period. Prior to this test-period the subjects were instructed not to make any changes to their diet or eating pattern. This retrospective method was applied to place minimal burden on the subject while obtaining information on their dietary intake (109, 110). The 24-hour dietary recall approach applied in this study was based on the 5-step multiple-pass method developed by the United States Department of Agriculture (USDA), which is developed to increase the accuracy of the recall. This method has been validated in both men and women (111, 112) and in respect to wheelchair users, this method has also been used to assess energy and micronutrient intake of Brazilian para-athletes (113) and Norwegian para-athletes (114). The method consists of five steps: 1) time and occasion at which foods were consumed; 2) quick list; which is an uninterrupted listing by the subject of foods and beverages consumed; 3) detailed cycle, which elicits descriptions of foods and amounts eaten aided by the use of a picture booklet with images of different portion sizes for different foods and dishes; 4) forgotten food list and 5) the finale probe review. The steps are further described in **Figure 2**. In respect to the Norwegian population, a modified version has also been used to assess dietary intake among Norwegian adults in the latest Norwegian National Dietary Survey (Norkost 3) (91, 115).

Dietary data collection was performed at two sites, both in Oslo, NIH, and Bergen, HVL, in January and February 2023, respectively. All dietary recalls were performed by one practitioner. Prior to the interviews all participants received a picture booklet by email, with images of different portion sizes for foods and dishes, as well as pictures of tableware, and this was used during the recalls to estimate the portion sizes and volumes consumed. They were informed how to use the booklet and how the stepwise methods of the interviews were performed. The forgotten food checklist included both questions about foods frequently forgotten to report, and questions regarding situations associated with food consumption such as grocery shopping. The interview also included registration of training sessions performed within the 24-hours to capture dietary intake in relation to exercise.

The recalls were conducted through a video call. The participants could display their own tableware, to compare against the pictures of the booklet, and food labels during the video call. For mixed dishes, the participants were asked to describe the dish in detail and if possible, send the recipe by email after the interview. If the participant reported any dietary supplement or sports nutrition products, the participant was asked about the label of the supplement, the dosage, and nutritional values of the products. The participants were also asked to send online information and/or a picture of the product by email, after the interview.

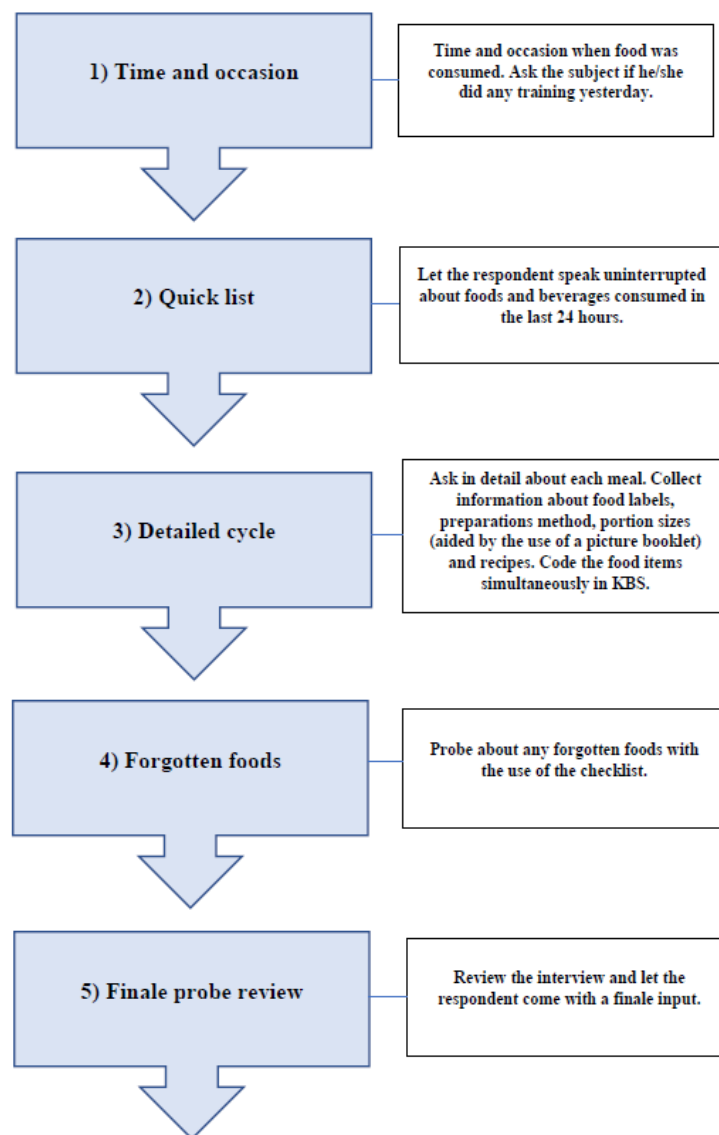


Figure 2. Description of the five-step multiple-pass method for 24-hour dietary recalls Adopted and modified figure from Conway et al. (112)

3.2.2 Coding of food intake

The food and nutrient calculation software “Kostberegningssystem” version 7.4 (KBS, Oslo, Norway) with the database AE-22 (116), was used for calculations of the dietary data collected through the recalls. The master student performed the coding of the food intake, through KBS, during the third step of the interview to increase the accuracy of the food choices, volumes and portion sizes reported by the subjects. When a food item reported by the participant was missing in the KBS database, a substitution was made by coding a similar food item. If there was no alternative food item in the database or if the item was differing in energy content of more than $\pm 10\%$ from a comparable food in the KBS database, a new food was registered. The participant was asked to send information about the product by email, after the interview, and based on the ingredients and nutrient information a new food was registered in KBS. The substitutions and registration of new foods were documented in a food substitute protocol to ensure standardized choices of food substitutes for all recalls.

3.2.3. Evaluation of the dietary energy intake

To evaluate the participants energy intake (EI), the average energy intake was divided by the respective predicted resting metabolic rate (RMR) of the participant, based on the Cunningham predictive equation (117), to calculate an EI:RMR ratio. The EI:RMR ratio was then further compared against an estimated physical activity level (estPAL) value assigned to each participant. PAL values represent the amount of energy that an individual expends on physical activity relative to the amount of energy they expend at rest. A PAL value equal to EI:RMR is thought to represent energy balance with total energy daily expenditure (TDEE) matching the EI (118). As neither RMR nor the overall physical activity of the subjects were measured in this study, estimations had to be performed to conduct the evaluation of the energy intake.

3.2.3.1 Estimating resting metabolic rate (RMR)

In this master thesis, the Cunningham equation (117) was applied to estimate the RMR of the subjects. As there is no RMR equation recommended for wheelchair users, an equation using lean body mass (LBM) as a predictor, such as Cunningham et al, may be useful for wheelchair users since LBM explains a great deal of variation in RMR (24). Wheelchair users

seems to have a lower RMR compared to adults without disabilities, however, Gomes et al showed that this difference was not present after adjusting for body mass and/or LBM (119). Studies also show that LBM is greater in active persons with SCI than sedentary matched controls (24) which argue that LBM is an important factor when estimating RMR for a population of both active and non-active wheelchair users in this current master thesis. The Cunningham equation is also recommended for athletes (85, 120). Data concerning LBM was derived from the DXA scan and LBM was defined as total body mass minus fat mass and bone mass.

3.2.3.2. Estimating a physical activity level value (estPAL)

There is a paucity in the literature describing the activity level and energy expenditure of para-athletes and the wheelchair-bound population, and non-exercise activities was not registered, as such, little was known about the overall activity level of the subjects. Therefore, an estPAL value based on the categorization by The Food and Agriculture Organization (FAO)/World Health Organization (WHO)/ The United Nations University (UNU) (118) was set for each individual. PAL values are expressed as a ratio of the total daily energy expenditure (TDEE) to the resting energy expenditure and are typically used to estimate an individual's daily energy requirements. A PAL value of 1.4-1.69, 1.7-1.99 and 2.0-2.40 are categorized as sedentary, moderate, and vigorous lifestyle, respectively, by FAO/WHO/UNU for non-wheelchair users. Due to movement being primarily restricted to the upper body, the energy cost of most exercise and activities of daily living performed by persons who use a wheelchair result in a considerably lower energy cost than those reported in the general population (23, 121, 122), therefore, modified PAL values were estimated in this current master thesis by calculating 75 % of the original PAL values. A PAL value of 1,05-1.29, 1,30-1,49, 1,5-1,8 was categorized as sedentary, moderate, and vigorous lifestyle, respectively.

Determination of the subject's physical activity category was based on the subject's IPAQ-SF physical activity score (107) reported at baseline. The IPAQ-Short Form (SF) is a self-report questionnaire that is commonly used to measure physical activity levels and the IPAQ-SF used in this master thesis is an adapted version for disabled individuals (108). The questionnaire consists of seven questions regarding physical activity performed over the past seven days and it classifies the responder into low, moderate, or high physical activity categories based on established cut off points. A subject who scored into a low IPAQ-SF

physical activity category were assigned estPAL values corresponding to the category “sedentary”, a moderate IPAQ-SF physical activity category was assigned estPAL values corresponding to “moderate” and a high IPAQ-SF physical activity category was assigned estPAL values corresponding to “vigorous”. In addition to evaluate the subject’s energy intake, the estimated PAL values were also used for prediction of the total daily energy requirements for the subject by multiplying the estRMR and estPAL values.

3.2.4 Calculation of Energy Availability

Energy Availability (EA) is expressed in kcal/kg fat-free mass (123). EA is calculated through the assessment of dietary energy intake (EI), exercise energy expenditure (EEE) and fat-free mass (FFM), using the following formula:

$$\frac{\text{Energy Intake (EI)} - \text{estimated Exercise Energy Expenditure (estEEE)}}{\text{kg Fat Free Mass (FFM)}} = \text{Energy Availability} \frac{\text{kcal}}{\text{kgFFM}}$$

In the present thesis EI was assessed through 24-hour recalls and FFM was assessed by the use of a DXA examination. FFM was defined as total body mass minus fat mass. Exercise Energy Expenditure (EEE) was not measured in this study. Therefore, an estimated EEE (estEEE) was calculated as follows:

$$\text{calculated RMR (calRMR)} \times \text{estPAL value} = \text{estimated Total Daily Energy Expenditure (estTDEE)}. \text{ estTDEE} - \text{calRMR} = \text{estimated Exercise Energy Expenditure (estEEE)}.$$

The highest estPAL value, from the range of PAL values assigned to the subject based on the physical activity category, was used in this calculation, to make sure that the highest possibly daily exercises expenditure was used to estimate the energy availability for the subject. As there are no known cut off values for wheelchair bound people, the cut off values for female able-bodied athletes were used, although it may be lower amongst male athletes (69, 124). These cut-off values are defined as follows: Sufficient EA >45 kcal/kg FFM/day, reduced EA <45 kcal/kg FFM/day and low EA (LEA) <30 kcal/kg FFM/day.

3.2.5 Guidelines of nutrient intake

The intake of carbohydrates (CHO) and protein intake of the subjects was assessed against athlete-specific guidelines for non-para-athletes, from the American College of Sports Medicine (ACSM) (85), as there are currently no available guidelines for para-athletes or wheelchair bound persons (125). These recommendations suggest that protein and CHO consumption should be relative to kg body mass (BM). A protein intake of 1.2-2 g/kg BM/day were assumed to be adequate. The CHO recommendations varies from 3.0 to 12.0 g/kg BM/day, as the recommendations are exercise specific considering both type of exercise, volume, and intensity, but for para-athletes with substantially less active muscle mass proportional to their body weight, it is recommended to use the lower end of the range and as such, the recommendations are 3.0-5.0 g/kg BM/day (4). In addition, the intake of CHO, protein and fat were assessed as the macronutrient's percent contribution of total energy, expressed as Energy % (E%), and assessed against the NNR 2012 (NNR) (90). The daily intake of the micronutrients vitamin D and calcium was assessed against NNR 2012 as well, and an overview of the NNR is presented in **table 4**.

Table 4. Overview of the Nordic Nutrition Recommendations (NNR) (90)

Nutrient	Recommendations (NNR 2012)
Carbohydrate	45-60 E%
Protein	10-20 E%
Total Fat	25-40 E%
- Saturated Fat	< 10 E%
- Monounsaturated fat	10-20 E%
- Polyunsaturated fat	5-10 E%
- Omega-3	1 E%
- Omega-6	5 E%
Vitamin D	10 µg
Calcium	800 mg

3.3 Blood Samples

3.3.1 Serum sampling

Blood was drawn by bioengineers at NIH with the subject being in an overnight fasted state between 08:00 and 10:00 am. Blood was collected in four serum vacutainers and all serum

vacutainers were allowed to clot in room temperature for 30-60 min before processing in the centrifuge for 12 minutes at 1500 x g. Two of the serum vacutainers were stored in a fridge at 4 degrees Celsius, until shipping to Fürst Medical Laboratory for analysis of S-vitamin D and S-PTH. One serum vacutainer was used for analysis of S-vitamin D and one for analysis of S-PTH. To determine low or adequate vitamin D status, S-vitamin D measures were assessed against reference values provided by Fürst Medical Laboratory (78) and the athlete specific optimal level of >80 nmol/L (71, 83-85), and S-PTH measures were assessed against values provided by Fürst Medical Laboratory (78). The third serum vacutainer, which was sent for analysis of the blood bone markers CTX-1, bALP and PIN1 were stored in a freezer, at -20 degrees Celsius, until shipping to Hormonlaboratoriet for analysis. All blood bone markers were analyzed at the same time. To determine adequate CTX-1, bALP and/or PIN1 status, measures were assessed against reference values provided by Hormonlaboratoriet (64). One serum vacutainer was stored in the freezer, at -80 degrees, at NIH, as backup samples to potential analyzing in the future.

3.3.2 Laboratory analysis

Analyses of S-Vitamin D and S-PTH were carried out at the center for blood analysis, Fürst Medical Laboratory (Fürst Laboratory, Oslo, Norway). The analytical technique used for assessing for S-Vitamin D was Liquid Chromatography with tandem mass spectrometry (LC-MS-MS) and an intact PTH chemiluminescence immunoassay (Advia Centaur-XPT, Siemens) were used for analysis of S-PTH. Analysis of the blood bone markers CTX-1 and PIN1 were performed by the use of an electrochemiluminescence immunoassay (ECLIA) and bALP was analyzed by a chemiluminescent immunoassay (CLIA). All analyses were carried out at Hormonlaboratoriet, Oslo, Norway.

3.4 Dual-Energy X-ray Absorptiometry

Dual-energy X-ray absorptiometry (Lunar iDXA, GE Healthcare, Madison, USA) was applied to assess bone mineral density and body composition. Prior to the test-day, the subjects were instructed to refrain from vigorous exercise 24 hours before the start of testing, and not to consume any food or drinks after 10 PM the day before the test day. To ensure the subjects were in a neutral hydration status, the subjects were instructed to drink at least 2 liters of

water the day before and not to drink anything in the morning prior to the scan. Body mass was measured prior to the scan with the subject wearing minimal clothing, using a calibrated regular Seca scale (Electronic Flat Scale 877) or a wheelchair scale (Seca 676) subtracting the weight of the wheelchair. Participants were asked to void the bladder prior to the weighing. Height was measured with a fixed stadiometer or with the subject in supine position on the DXA scan, using tape to mark the top of the head and the bottom of the feet. The distance between those marks was then measured.

The DXA scanner was calibrated in the morning prior to the tests and all scans were performed by a trained researcher. The participants were scanned in minimal clothing, without wearing any external metal objects. To obtain a valid measurement, the subjects were positioned as best as possible according to the manufacturer's guidelines (Lunar iDXA, GE Healthcare, Madison, USA). Any adjustment in positioning to support the most optimal position for the subject according to their disability was carefully documented. The DXA scanning modules for lumbar spine and femoral neck were used to determine the BMD of the lumbar spine and femoral neck, respectively. In addition to this, a whole-body scan was also performed. Whole and regional lean bone mineral density (BMD), total body mass, lean body mass and fat mass were analyzed by the DXA enCore software (version 18, GE Healthcare, Madison, WI, USA). Scanning regions that included internal metal objects were removed before analysis to avoid any disturbances (126). BMD Z-scores and T-scores of the subjects were calculated by the same software and expressed as standard deviations (SD) from the DXA reference database, which is an able-bodied population with age- and sex-matched controls. In addition to BMD z-scores and t-scores, the BMD of the subjects was also expressed as g/cm^2 .

3.5 Dietary Supplements

Dietary data from the baseline measurements, assessed through 24-hour dietary recalls, together with S-vitamin D and BMD Z-scores, assessed by DXA, were used to determine the need of dietary supplements for the participants in the upcoming study period. Doses administered were determined by the master student, a registered dietician and head of the project Kristin L. Jonvik, PhD candidate, nutritionist Linn C. Risvang and medical advisor Ingeborg B. Lidal.

Vitamin D

Evaluation of vitamin D status was done by analyzing the blood levels of S-vitamin D, 25(OH)D, at baseline. To make sure that the subjects presented optimal vitamin D levels to support the intervention of the RCT, suboptimal levels and clinical low values, according to Norwegian clinical reference values, and levels below 80 nmol/L, which is suggested as suboptimal for athletes, was supplemented as described in **table 5**. The vitamin D supplementation was given in a short-term (four weeks) and a high dose (89-169 µg/day), which the IOC suggest being appropriate for restoring vitamin D-deficiency in athletes (84). Studies has shown that a high-dosage (1250 µg/week) for 8 weeks, along with supplemental calcium, safely and effectively corrects secondary hyperparathyroidism (127) and a RCT performed on SCI athletes reports that a daily dose of 150 µg vitamin D seems to be sufficient to reach an optimal vitamin D status after 6 weeks (128). The supplement given was a commercially available supplement in Norway: “Nycoplus D3-vitamin, 40 µg or 80 µg”. In addition, all subjects consumed the Friesland Campina powder supplement on three days of the week during the whole study period (24 weeks) and each serving contains 180 kcal, 30 g whey protein, 250 mg calcium and 20 µg vitamin D. The total supplementation dosages are described in **table 5** and the highest total daily dosage is considered safe as EFSA reports that vitamin D has a no observed adverse effect level (NOAEL) of 250 µg/day (129).

Table 5. Vitamin D supplementation protocol and an overview of total supplementation of vitamin D including Nycoplus Vitamin D3 supplement and the Friesland Campina supplement

S-vitamin D	Nycoplus Vitamin D supplement dosage (µg/day)	Friesland Campina Supplement (µg/week)	Total supplementation (µg/day)
< 80 nmol/L	80 µg/day for 4 weeks	60 µg/week	89 µg/day for 4 weeks
< 50 nmol/L	120 µg/day for 4 weeks	60 µg/week	129 µg/day for 4 weeks
< 25 nmol/L	160 µg/day for 4 weeks	60 µg/week	169 µg/day for 4 weeks

Calcium

There is no appropriate indicator of calcium status, but Z-scores based on a bone mineral density scan may be indicative of chronic low calcium intake and an indicator of an individual’s risk of future fractures. A systematic review from Cranney et al (79) concluded that calcium plus vitamin D supplementation, compared to a placebo group, can reduce the fracture risk and subjects who presented a Z-score < - 2.00 at lumbar spine, hip or femoral

neck, were supplemented with calcium, as described in **table 6**, to make sure that the subjects presented a sufficient calcium intake to support the intervention of the RCT (71, 99, 130). Subjects who presented a Z-score > -2.00 but had a daily calcium intake below the NNR 2012 recommendations (800 mg/day), included the Friesland Campina supplement, were also supplemented to make sure that the subjects fulfilled the recommendations during the RCT, and the total supplementation is described in **table 6**. The calcium supplement was a commercially available supplement in Norway, “NycoPlus Kalsium 500 mg, Calcium carbonate”.

Table 6. Calcium supplementation protocol and an overview of total calcium supplementation including the Nycoplus calcium supplement and the Friesland Campina supplement

Daily intake of calcium (mg/day) and BMD Z-score	Nycoplus Calcium supplement dosage (mg/day)	Friesland Campina Supplement (mg/day)	Total supplementation (mg/day)
< 800 mg/day included the Friesland Campina supplement	500 mg/day	107 mg/day	607 mg/day for 12 weeks
< 800 mg/day included Friesland Campina and 500 mg calcium	1000 mg/day	107 mg/day	1107 mg/day for 12 weeks
<1500 mg Calcium/day incl Friesland Campina and Z-score BMD lumbar spine/hip/femoral neck < -2.00	500 mg/day	107 mg/day	607 mg/day for 12 weeks
<1000 mg Calcium/day incl Friesland Campina and Z-score BMD lumbar spine/hip/femoral neck < -2.00	1000 mg/day	107 mg/day	1107 mg/day for 12 weeks
<500 mg Calcium/day incl Friesland Campina and Z-score BMD lumbar spine/hip/femoral neck < -2.00	1500 mg/day	107 mg/day	1607 mg/day for 12 weeks

3.6 Statistics

Statistical analyses were performed with SPSS version 29.0.0.0 (IBM Corp, Armonk, NY, USA). All data was tested for normality before analysis by assessing histograms in addition to comparing mean and median and assessment of the Kolmogorov-Smirnov Tests of Normality. Means \pm Standard Deviation (SD) and Median and 25th and 75th percentiles were used to present the data for normally distributed data and non-normally distributed data, respectively. As this was a cross sectional study with a small sample size, most statistics were descriptive. Investigations of association between variables were performed with Pearson correlation coefficient for normally distributed data (r) and Spearman (r_{sp}) correlation coefficient for non-normally distributed data. Comparison between two sub-groups were analyzed with Mann-

Whitney U as assumptions of normality could not be made. A p-value of < 0.05 was considered to be significant.

3.7 Use of chatGPT or other artificial intelligence programs

ChatGPT was not used in this thesis.

3.8 Ethics and data handling

The study was approved by Regional Committees for Medical and Health Research Ethics (REK, number 458384) and Norwegian Center for Research Data (NSD, number 501156). All subjects had to sign an informed consent prior to testing and all eligible participants were included in the study. The study was conducted in accordance with the Declaration of Helsinki (131) and all data was collected according to Good Clinical Practice guidelines and stored at protected research facilities at NIH. The processing of personal data was performed according to the Norwegian Personal Data Act (Personvernloven), and anonymity of the participants was ensured. All data was made electronically and stored in a protected internal network at NIH. In total 13 people had access to the data. After the test-period, each subject received feedback with their individual test results, as well as nutritional counseling based on the dietary recalls and blood values, and the data was anonymized with a participant number before analysis.

3.9 Students contributions

The master student's contribution to this study was 1) preparation of Standard Operation Procedures (SOPs) regarding the nutrition part of the study 2) preparation of test days; 3) practical assistance during test days including accommodating subjects, assisting on DXA scans, handling of blood samples; 4) providing participants information regarding the dietary recalls; 5) conducting three 24-hour dietary recalls for each participant and the subsequent coding of recalls in KBS; 6) analysis of the dietary data, 7) determination of the needs of dietary supplements for the subjects and 8) providing feedback to the participants in form of a written report.

4 Results

4.1 Subject characteristics

In total 30 wheelchair users were screened for inclusion and 12 of the subjects were included in this master thesis, four females (33%) and eight males (67%), and five different disabilities were represented. Nine subjects had a congenital disability; six subjects were diagnosed with Cerebral Palsy, two Spina Bifida and one subject had Arthrogryposis Multiplex Congenita, and three subjects had an acquired disability; two subjects had a Spinal Cord Injury and one lower limb amputee. Subject characteristics, including anthropometric data, duration in years for wheelchair (WC) use > 50 % of awake time and the number of athletes among the subjects, are displayed in **Table 7**. The mean body weight of the group was 72.7 kg, and the mean Body Mass Index (BMI) of the group was 25.7 kg/m². BMI for the one subject with lower limb amputee was calculated based on the post-amputation adjusted body weight (132, 133). There were no significant differences in anthropometrical measures between female and male subjects except for height and lean body mass (LBM).

Table 7. Subject characteristics

	All (n =12)	Female (n=4)	Male (n=8)
	Median (P ₂₅ , P ₇₅) ^a	Median (P ₂₅ , P ₇₅)	Median (P ₂₅ , P ₇₅)
Age (years)	34 (26.8, 44.8)	38.5 (27.3, 46.0)	33.0 (21.5,44.8)
Height (cm)	168 (154,185)	150 (146, 163)	179 (167,187)*
BM^b (kg)	72.9 (64.6,85.2)	66.3 (48.7, 70.8)	77.3 (68.9, 89.1)
LBM (kg)	43.2 (36.0,52.6)	32.6 (27.6, 37.9)	48.0 (42.7, 53.9)*
FM^b (%)	38.5 (30.2, 47.0)	44.3 (36.7, 55.1)	35.7 (28.6, 41.9)
BMI^b (kg/m²)	26.0 (22.0,29.8)	26.8 (21.3, 31.5)	26.0 (22.0, 27.4)
Duration of WC use (years)	18 (5.0,26)	25 (21,35)	11 (2.5,22)
Number of athletes (n)	7	2	5

Note. BM = Body mass; LBM = Lean body mass, FM = Fat mass, BMI = Body Mass Index, WC= Wheelchair
^a25th- and 75th-percentile, ^bNormally distributed data, but presented as median and 25th and 75th-percentile due to non-normally distributed data in the variables sub-group *p<0.05 difference between females and males, tested with Mann Whitney U

4.2 Dietary intake

Table 8. Dietary intake including energy, protein, carbohydrate, total fat, vitamin D and calcium for all subjects, and for female and male subjects

	All (n=12) Median (P ₂₅ , P ₇₅) ^a	Female (n=4) Median (P ₂₅ , P ₇₅)	Male (n=8) Median (P ₂₅ , P ₇₅)	Recommended Daily Intake (RDI)
<u>Energy</u>				
Kcal/day	2094 (1970, 3136)	1805 (1592, 2084)	2526 (2065, 3458)*	-
Kcal/LBM ^e	57.0 (45.4, 66.5)	57.0 (48.2, 65.3)	58.0 (42.3, 67.6)	-
<u>Protein</u>				
g/day ^e	98.1 (85.9, 108)	79.1 (72.1, 89.6)	106 (96.2, 116)*	-
g/kg	1,25 (1.13,1.60)	1.15 (1.03, 1.88)	1.40 (1.20, 1.60)	1.2-2.0 ^b
E% ^c	17.6 (14.2, 21.5)	17.9 (14.6, 22.0)	17.6 (14.0,21.5)	10-20 ^d
<u>Carbohydrate</u>				
g/day	231 (173, 370)	166 (142,188)	280 (230, 385)*	
g/kg	3.0 (2.4,4.4)	2.7 (2.3,3.0)	3.9 (2.6, 4.4)	3.0-5.0 ^b
E% ^c	43.8 (35.0,46.9)	35.9 (33.3, 41.6)	45.8 (41.4, 49.3)	45-60 ^d
<u>Total fat</u>				
g/day	73.7 (69.8,134)	73.6 (66.9,88.3)	90.8 (69.8,165)	
E% ^c	35.6 (30.5,40.8)	37.8 (32.0,40.9)	33.9 (27.6,40.2)	25-40 ^d
<u>Vitamin D</u>				
µg/day	14.6 (7.10, 24.3)	20.0 (10.0, 51.7)	11.7 (5.40, 20.8)	10 ^d
w/o supplements µg/day	5.85 (3.25, 10.9)	9.95 (4.43, 14.1)	4.85 (2.43, 8.43)	
<u>Calcium</u>				
mg/day	1021 (751.0, 1404)	751.0 (744.0, 1051)	1234 (866.8, 1493)	800 ^d

Note. LBM = Lean body mass, RDI = Recommended daily intake. ^a25th- and 75th-percentile ^bRecommendation American College of Sports Medicine (ACSM) (85) ^cPercentage (%) contribution to energy ^dRecommendation Nordic Nutrition Recommendation 2012 (NNR2012) (90) ^e Normally distributed data for the whole group, but presented as median and 25th and 75th percentile due to non-normally distributed data in the sub groups * p<0.05 difference between females and males, tested with Mann Whitney U

There was a significant difference in absolute energy ($P=0.048$), protein ($P= 0.008$) and carbohydrate intake ($P=0.008$) between female and male subjects. When grams of protein and carbohydrate intake were calculated based on BM, the median intake for males was within the range of recommended intake based on the guidelines from the ACSM (85), but females presented a median intake slightly below the minimum recommendation for both protein and carbohydrate. The median contribution to energy from carbohydrate (E %) was slightly below the lower recommendations for the whole group and females presented both a median E% and a 75th percentile below the lower recommendations of 45 E%.

There was no significant difference in any of the energy intake parameters or dietary intake of carbohydrates and protein between athletes and non-athletes. The median carbohydrate intake was 3.4 g/kg/day for athletes and 2.5 g/kg/day for non-athletes. Thus, athletes presented a median intake within the recommendations, but non-athletes presented an intake slightly below the recommendations. Both groups met the recommended daily protein intake, although in the lower range, as median protein intake was 1.3 g/kg for athletes and 1.2 g/kg for non-athletes. There was no significant difference in dietary intake of vitamin D or calcium between the two groups. However, athletes presented a substantially lower median intake of vitamin D, 9 µg/day, compared to 17 µg/day for non-athletes. The median calcium intake was 890 mg/day for athletes and 1151 mg/day for non-athletes.

The median vitamin D intake was 14.6 µg/day and 42 % of the subjects had an intake below the Norwegian recommended daily intake. When calculating the dietary intake without vitamin D supplement, the median intake was 5.85 µg/day and 75 % of the subjects presented an intake below the daily recommendation. The median absolute calcium intake was 1021 mg/day and 33 % of the subjects did not meet the NNR for healthy adults. 83 % of the subjects presented a Z-score ≤ -2.0 at lumbar spine, hip, or femoral neck, which is defined as "below the expected range for age", and within this sub-group all but one had a dietary intake of calcium below the adequate bone-building recommendation of 1500 mg/day (71, 130). Thus, all subjects within this sub-group, except one, received additional calcium supplementation according to the protocol of the RCT.

There was no significant association between vitamin D or calcium and absolute energy intake. Absolute protein intake and calcium intake were significant correlated ($r_{sp}= 0.776$, $P=0.003$), as well as the relationship between daily dairy products and both calcium

($r_{sp}=0.814$, $P=0.001$) and protein ($r_{sp}=0.637$, $P=0.026$). 42 % of the subjects fulfilled the current recommendations of a daily intake of 3 dairy products.

4.3 Vitamin D Status and Measurements of Bone Health

The S-vitamin D data was normally distributed, and the mean S-vitamin D was 38.4 ± 14.2 nmol/L. Two subjects presented clinical low values and seven had suboptimal levels according to Norwegian reference values. None of the subjects presented values above the athlete specific optimal level of 80 nmol/L. The mean S-PTH was 6.98 ± 2.7 pmol/L and 42 % presented levels above the reference values, however, there was no significant correlation between S-Vitamin D and S-PTH ($r=-0.224$, $P=0.484$), or a correlation between S-PTH and any blood bone marker. None of the subjects presented blood levels above the reference values for any of the blood bone markers, but two subjects were below 25 years old and thus different reference values were applicable for those two due to puberty. Analysis included all subjects showed a trend towards a negative correlation between S-vitamin D and the blood bone marker CTX-1 ($r_{sp}= -0.56$, $P= 0.058$) and when excluding the two youngest subjects the correlation was significant ($r_{sp}= -0.65$, $P= 0.042$).

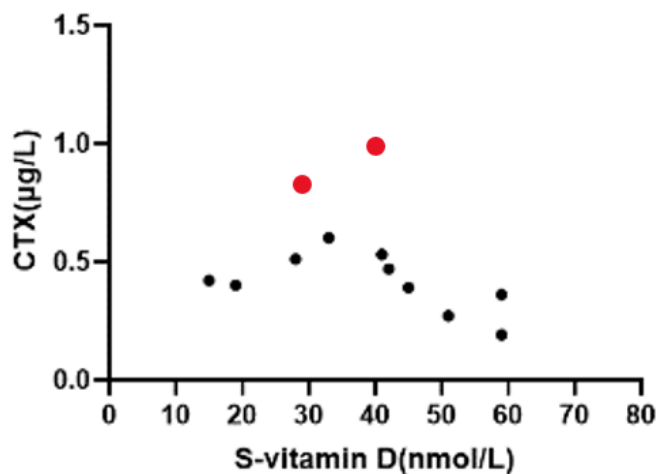


Figure 3. The correlation between CTX-1 and S-vitamin D. Subjects < 25 years old are marked in red.

Table 9. S-Vitamin D, S-PTH, Blood Bone Markers and Z-scores for lumbar spine, hip, and femoral neck

	All (n=12)	Athletes (n=7)	Non-Athletes (n=5)
	Median (P ₂₅ , P ₇₅) ^a	Median (P ₂₅ , P ₇₅)	Median (P ₂₅ , P ₇₅)
S-vitamin D ^b (nmol/L)	40.5 (28.3,49.5)	40.0 (19.0,51.0)	41.0 (30.5, 52.0)
S-PTH ^b (pmol/L)	7.20 (4.78,8.95)	5.90 (4.40,8.80)	8.00 (6.05,9.20)
<u>Blood Bone Markers</u>			
CTX-1 (µg/L)	0.45 (0.37, 0.58)	0.42 (0.27,0.82)	0.51 (0.38,0.57)
P1NP (µg/L)	62.5 (46.3, 77.8)	73.0 (45.0,114)	62.0 (51.0,71.0)
bALP ^b (µg/L)	13.0 (10.3, 15.0)	13.0 (8.50,15.0)	13.0 (10.5,18.0)
<u>Bone Mineral Density</u>			
Z-score lumbar spine	-1.20 (-1.82, -0.65)	-1.10 (-1.90 -0.80)	-1.40 (-2.05,-0.55)
Z-score mean hip	-2.05 (-2.55, -1.17)	-2.30 (-3.20, -1.10)	-1.40 (-2.15,-1.10)
Z-score mean femoral neck	-1.95 (-2.70, -1.00)	-2.40 (-3.40, -1.30)	-1.00 (-2.00,-0.90)

Note. CTX-1= Cross-linked C-telopeptide of type 1 collagen, P1NP= procollagen type I N-terminal peptide, bALP=bone-alkaline phosphatase ^a25th- and 75th-percentile, ^b= normally distributed data for the whole group, but presented as median and 25th and 75th percentile due to non-normally distributed data in the subgroups * Potentially statistical differences between athletes and non-athletes were tested with Mann Whitney U

4.4 Dietary intake of vitamin D and S-vitamin levels

25 % of all the subjects presented optimal S-vitamin D values (> 50 nmol/L) according to Norwegian reference values and none were above the athlete specific optimal level of 80 nmol/L. There was a trend towards a relationship between vitamin D intake and measured S-vitamin D ($r_{sp}= 0.560$, $P=0.058$), see **figure 4**. All subjects with a S-vitamin D level > 50 nmol/L had an intake above the recommended daily intake of vitamin D and among the subjects with S-vitamin levels < 50 nmol/L 44 % had an intake above the recommended intake.

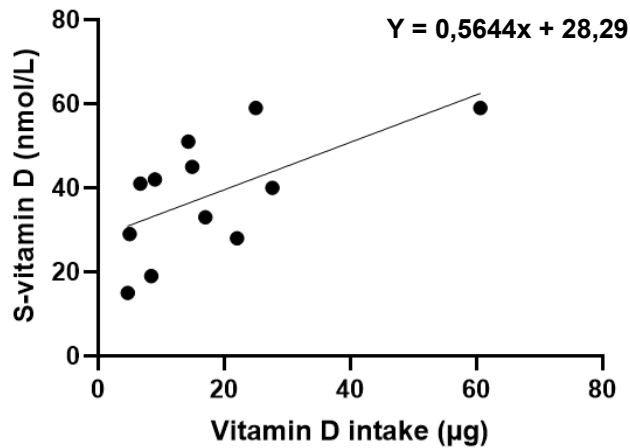
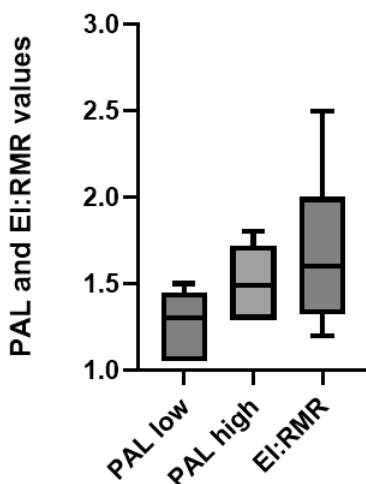


Figure 4. The correlation between vitamin D intake and S-vitamin D

4.5 The associations between dietary intake and bone health

None of the EI parameters or vitamin D intake was correlated with Z-score of lumbar spine, hip, or femoral neck. Vitamin D intake was significantly negatively correlated with the blood levels of the blood bone marker bALP ($r_{sp}=-0.656$, $P=0.021$) when all subjects were included, but there was no significant correlation when the subjects < 25 years old were excluded ($r_{sp}=-0,548$, $P=0,101$). The relationship between calcium intake and Z-score of the hip was significant correlated ($r_{sp}=0.606$, $P=0.037$). There was no significant difference in Z-scores or blood bone markers between those who met the daily recommendations for calcium (800mg) or vitamin D (10µg), and those who did not.

4.6 Estimation of Energy Balance and Energy Availability (EA)



All but one subject presented an EI:RMR above their corresponding lowest estimated PAL value (PAL^{low}) and 83 % of the subjects presented an EI:RMR above their highest estimated PAL value (PAL^{high}). There was a significant correlation between the estimated PAL values and EI:RMR ($r_{sp}=0.635$, $P=0.027$) and a significant correlation between EI and estimated PAL values ($r_{sp}= 0.723$, $P=0.008$).

Figure 5. Median PAL values, low and high, and EI:RMR for all subjects. Box: 25th and 75th percentile, whiskers: min, max.

17 % of the subjects presented an estimated EA below the cut off for Low Energy Availability (LEA) (<30 kcal/kg FFM/day) and 33 % of the subjects presented a sufficient EA (>45 kcal/kg FFM/day). Athletes presented a higher EA than non-athletes, but there was no significant difference in EA between the two groups. In total three out of twelve subjects were at high risk of RED-S as identified by LEAF-Q (one female) and LEAM-Q (two males) and among the three subjects only one presented an estimated EA below 30 kcal/kg FFM/day. The median EA among the subjects at risk were 34 kcal/kg FFM/day and the median EA among subjects not at risk were 44 kcal/kg FFM/day. The estimated EA was significantly positively correlated with the blood bone marker P1NP ($r_{sp}=0.58, P=0.048$) when all subjects were included in the analysis. However, when excluding the subjects < 25 years old the correlation was not significant ($r_{sp}= 0.515, P=0.128$).

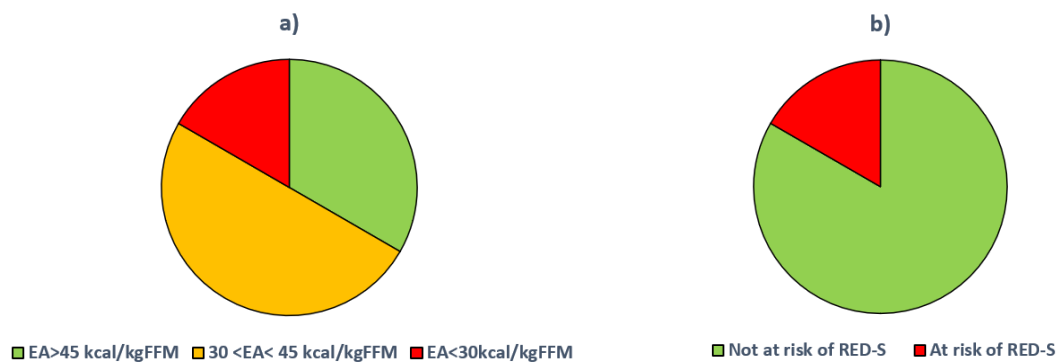


Figure 6a. Energy Availability (EA) cut offs for all subjects, **Figure 6b.** Distribution of subjects not at risk and at risk of RED-S (LEAF/LEAM-Q)

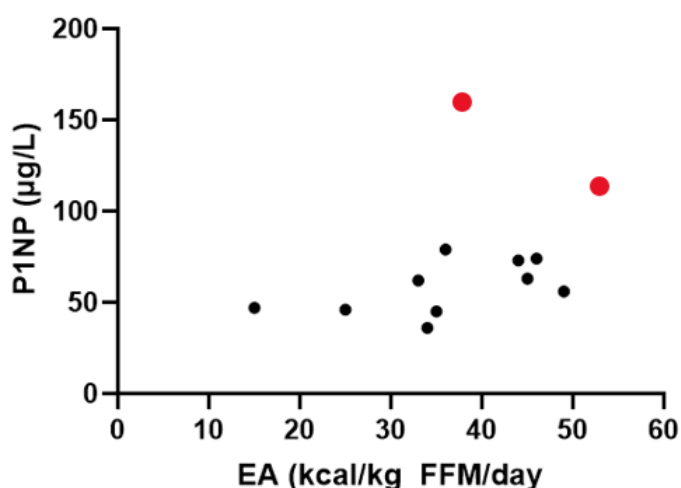


Figure 7. The correlation between P1NP and Energy Availability. Subjects < 25 years old are marked in red.

Table 10. Estimated resting metabolic rate (RMR), Energy Intake:estRMR, Estimated Physical Activity Level (PAL) low and high values, and estimated Energy Availability (EA) for all subjects

	All (n=12)	Athletes (n=7)	Non-Athletes (n=5)
	Median (P ₂₅ , P ₇₅) ^a	Median (P ₂₅ , P ₇₅)	Median (P ₂₅ , P ₇₅)
estRMR^b	1455 (1289,1656)	1514 (1354,1676)	1346 (1180,1583)
EI:estRMR^b	1.60 (1.33,2.00)	1.70 (1.40,2.10)	1.50 (1.25,1.80)
estPAL values^c			
estPAL value low	1.30 (1.05,1.45)	1.30 (1.30, 1.50)	1.05 (1.05,1.30)
estPAL value high	1.49 (1.29,1.72)	1.49 (1.49,1.80)	1.29 (1.29,1.49)
estEA^b	37 (33,46)	38 (34,46)	36 (30,47)

Note. RMR = Resting Metabolic Rate; EI = Energy Intake; estPAL= estimated Physical Activity Level; EA = Energy Availability ^a25th- and 75th-percentile ^b= normally distributed data for the whole group, but presented as median and 25th and 75th percentile due to non-normally distributed data in the sub-groups ^c Estimated and modified values based on the original PAL values from FAO/WHO/UNU *Potentially statistical differences between athletes and non-athletes were tested with Mann Whitney U

5 Discussion

5.1 Discussion of results

5.1.1 Summary of Findings

Despite an overall sufficient energy, protein, vitamin D and calcium intake, 83 % of the subjects presented a Z-score < - 2.0 at lumbar spine, hip or femoral neck, and suboptimal S-vitamin D levels (< 50 nmol/L) were present in 3 of 4 wheelchair users. None of the EI parameters or vitamin D intake was significantly correlated with measurements of BMD, but the relationship between calcium intake and Z-score of the hip was significant correlated ($r_{sp}=0.606$, $P=0.037$). In addition, there was a significant correlation between S-vitamin D and the blood bone marker CTX-1 when the two subjects < 25 years old were excluded from the analysis.

5.1.2 Study Population

Wheelchair users are a highly heterogeneous group and the study population in this thesis consisted of subjects with a variety of disabilities, medical histories, use of medications, years of wheelchair use, physical activity levels and ages. Both para-athletes and sedentary wheelchair users were included in the study population. Additionally, this study included both females and males which further contributed to variability due to gender differences. Due to an extensive list of exclusion criteria and the fact that the subjects represented a minority group within the general public, the final sample size was relatively small; only 40 % of the thirty screened wheelchair users were included in the final sample size. The major limitation with a small sample size is a low statistical power (134) and in addition, most data were assessed as non-normally distributed, thus sub-group analysis were tested with non-parametric tests which is less powerful than parametric tests (135). It must also be emphasized that this small heterogeneous group consisted of some diagnoses which are not well studied, thus the literature is sparse, and this must be considered when interpreting the data. Selection bias must be recognized as one of the inclusion criteria was a Z-score of lumbar spine ≤ 0.0 and a possibly sampling bias is that subjects with increased health awareness were more likely to participate in this study. Besides the small sample, these factors further limit the external validity and as such the possibility of generalizing the results to other wheelchair users.

5.1.3 Dietary intake among Norwegian wheelchair users

The median absolute energy intake of the subjects was 2094 kcal/day and females presented a significant lower intake compared to males, see **table 8**, which is similar to the reported energy intake in the national dietary survey Norkost 3 (91). The median calculated EI:RMR was above the median estPAL^{high} value and all subjects, except one, presented an EI:RMR above their corresponding PAL^{low} value, which indicate that most of the subjects had an energy intake within or above their estimated daily energy requirements. However, there are a few limitations in the calculation of energy balance for the subjects in this master thesis as neither the subjects RMR nor the TDEE was measured.

The study population consisted of both athletes and non-athletes, and this must be considered when interpreting the dietary data as athletes often have different energy and macronutrient intakes compared to sedentary individuals. In this master thesis the subject's macronutrient

intake was evaluated against both athlete specific recommendations provided by ACSM (85) and the Nordic Nutrition Recommendations (90). The contribution of energy from carbohydrates (CHO), protein and fat for the whole group were similar to the reported intake among Norwegians in Norkost 3 (91), but female subjects presented a lower carbohydrate intake than the reported intake among females in Norkost 3. In regard to the athlete specific recommendations, studies performed on wheelchair-bound athletes have reported that the athletes generally met able-bodied recommendations for macronutrients (102, 136, 137), although the CHO consumption was consistently in the lower range of the guidelines, which is also supported by the findings in this thesis. There was no significant difference in CHO or protein intake between athletes and non-athletes, but the latter presented a median intake of CHO slightly below the lower range of recommendations for athletes. Whether the recommendations are adequate or not to support physical exercise for wheelchair users has not been thoroughly investigated, and it is likely that this will depend on the type of disability, body composition and intensity of training.

There was no significant association between dietary intake of vitamin D and absolute energy intake among the subjects, as such, vitamin D intake was not adjusted for energy intake. The median vitamin D intake was above the daily recommendation (RDI), **see table 8**, and higher than the average intake reported in Norkost 3 (91), but 42 % of the subjects presented an intake below the RDI of vitamin D. Athletes presented a substantially lower median intake of vitamin D, 9 µg/day, compared to 17 µg/day for non-athletes. In general, dietary intakes remains largely unexplored among wheelchair users and para-athletes, but several studies on American and Canadian wheelchair athletes report a high prevalence of vitamin D insufficiencies (125, 136, 137), where the dietary intakes were assessed against a RDI of 5 µg vitamin D. Grams et al investigated dietary intake of elite wheelchair basketball players in Spain, both SCI and amputees, and reported similar findings; low adequacy levels of both vitamin D and calcium intake among the athletes (102). The probability of adequacy micronutrient intake of calcium and vitamin D were significantly positively correlated with total energy intake and provide evidence that a nutrient dense diet is necessary to meet the RDI of micronutrients for wheelchair users, who often display reduced energy intake as a consequence of a decrease in energy expenditure compared to the able-bodied population. However, in this thesis the median total energy intake was similar to those found in the able-bodied population (91). In regard to the calcium intake among the subjects, the median intake for the whole group was above the NNR and higher than the reported intake in Norkost 3

(91), but females presented a median intake slightly below the NNR and in total 33 % of the subjects presented insufficient intakes compared to the guidelines for healthy adults. However, low BMD at the hip and femoral neck were prevalent among the subjects and as such, recommendations apply 1500 mg calcium/day (71, 130) and only one subject with low BMD presented a daily intake of calcium > 1500 mg. These findings might indicate that wheelchair users with low BMD are unaware of the recommendations for optimal calcium intake to limit further bone loss and to potentially improve their bone health. Limited knowledge about nutrition is identified as one of the determinants of dietary behavior among wheelchair users (138) and there seems to be a need for more nutritional counseling to optimize the diet in regard to bone health within this population. The findings of this thesis suggest that a dietary supplement might be necessary to fulfil the nutritional recommendations of calcium, as all of the subjects who presented a Z-score < - 2.0, except one, were given a supplement according to the protocol, as described in **table 6**, to facilitate a potential increase of BMD during the study period (101).

5.1.4 Vitamin D status and the relationship between vitamin D intake and S-vitamin D

There was a non-significant correlation between vitamin D intake and measured S-vitamin D levels in this thesis ($r_{sp}= 0.560$, $P=0.058$) and as the variation of both variables was large, a bigger sample size would have been necessary to confirm a possible relation. Several studies report a relationship between increasing doses of vitamin D and S-vitamin D, but the dose response relationship is not well established (89), and it depends on baseline serum concentration with a greater response observed at lower baseline levels (139).

In this thesis, 3 of 4 subjects had suboptimal S-vitamin D levels and similar prevalence have been reported in Norwegian populations during wintertime (94, 140). In regard to wheelchair athletes, Flueck et al investigated the prevalence of vitamin D deficiency among elite wheelchair athletes in Switzerland and reported that 52.5 % presented suboptimal levels of vitamin D (< 50 nmol/L) during wintertime (105). It is well documented that SCI are at increased risk for vitamin D deficiency (104) and several factors contributes to the high prevalence, e.g., the immobility, lesion level, the presence of pressure ulcers, time spent outdoor, altered gastrointestinal function, use of anticonvulsants and BMI. Barbonetti et al found that high BMI was correlated to a low vitamin D status in individuals with SCI (141) and possibly explanations could be a retention of vitamin D metabolites by the excess of body fat and a decreased cutaneous production as this might be sequestered by the body fat. Weight

management is challenging for wheelchair users, thus, overweight and obesity is common in this population. In this thesis 50 % of the subjects presented a BMI > 25 kg/m² and three subjects presented a BMI > 30 kg/m². In addition, studies suggest that the cut offs should be lowered to identify overweight and obesity among wheelchair users as they often present higher percentage of body fat compared to able-bodied, and that a BMI of >25 should be considered as obese (142, 143). However, in this thesis S-vitamin D was not correlated with BMI ($P=0.435$). Lower functional independence and weekly leisure-time physical activity (LTPA) have previously been correlated to a poor vitamin D status in individuals with SCI as well (141), and whether the correlation occurred because of an increased sunlight exposure during outdoor activities or if a poor vitamin D status caused a decrease in physical function, remains unknown. In this thesis, however, there was no significant difference in S-vitamin D between athletes and non-athletes, or a significant correlation between S-vitamin D and the subjects corresponding PAL values.

Blood samples were taken during the winter months, January-March, in Norway. It has been shown that S-vitamin D levels drop during the winter months at northern latitudes (105, 144), which means that the subjects vitamin D values were probably at the lower point when assessed. Neither the subjects previous sun exposure prior to the test day nor time spent outdoors were measured in this study. These are determinants which probably could explain some of the variation in vitamin D status among the subjects as vitamin D is fat-soluble and can be stored in the adipose tissue and released into the circulation when needed (145), and the calculated half-time of serum 25(OH)D is 82 days (146, 147).

58 % of the subjects presented a vitamin D intake above the RDI of 10 µg/day and among them 43 % presented a vitamin D status above suboptimal levels (> 50 nmol/L). Whether the current recommended daily vitamin D intake is sufficient for wheelchair users in Norway is unknown. It can be speculated that a higher daily recommendation could apply, as wheelchair users spend less time outdoor, have got a higher percentage body fat, impaired neuromuscular performance and per se already are at higher risk of low BMD and fractures, as well as cardiovascular disease (104). Although disuse may be the primary cause of low BMD among wheelchair users, a concomitant vitamin D deficiency might worsen the condition. In addition to an improved bone health, a higher vitamin D level (> 80 nmol/L) is associated with optimized muscle function (148), and this should be of particular interest for wheelchair users who experience muscle wasting as a consequence of the impairment and immobility.

5.1.5 Dietary intake and measurements of bone health

83 % of all subjects presented a Z-score < -2.0 at hip or femoral neck and two subjects presented a Z-score < -2.0 at lumbar spine, which support previous studies who report a high prevalence of low BMD among wheelchair users (2, 13, 14, 29, 37). A recent review from Cranney et al (79) concluded that Vitamin D (>17.5 $\mu\text{g}/\text{day}$) with calcium supplementation, has a small beneficial effect on BMD when compared to a placebo group. Among several studies Lappe et al investigated the association between calcium and vitamin D on bone health and showed that calcium and vitamin D supplementation decreased the risk of stress fractures among female navy recruits (149) and Nieves et al performed a 2-year prospective cohort study where dietary intake was assessed by a self-reported food questionnaire, and found that low-fat dairy products and the major nutrients in milk; calcium, vitamin D and protein were associated with gains in BMD and a lower stress fracture rate among athletes (150). More research is needed on dietary intake and bone health among wheelchair users, but this study contributes to the knowledge, and the findings of this thesis showed that calcium intake and Z-score of the hip was significant correlated ($r_{\text{sp}}=0.606$, $P=0.037$) and calcium intake and absolute protein intake was significant correlated ($r_{\text{sp}}=0.776$, $P=0.003$) as well. The latter was explained by the correlation between daily dairy products and protein intake. Moderate evidence suggest that higher protein intake may have a protective effect on BMD (151), however, the subjects in this thesis presented a sufficient protein intake, which might indicate that optimizing calcium intake, as well as vitamin D status, are more important nutritional factors for improving bone health in this population.

Neither S-vitamin D nor vitamin D intake were significantly correlated with any of the BMD sites in this study, but there was a significant negative correlation between S-vitamin D and the bone resorption marker CTX-1 when excluding the two subjects below 25 years old from the analysis ($r_{\text{sp}}=-0.65$, $P=0.042$). The three subjects who presented a vitamin D status > 50 nmol/L also presented the lowest CTX-1 values, and this might indicate that suboptimal vitamin D status is associated with higher rates of bone turnover. Jorde et al reported that supplementation with vitamin D appears to suppress bone turnover among subjects with suboptimal vitamin D status combined with a high baseline S-PTH (> 6.5 pmol/L), as both P1NP and CTX-1 were significantly reduced among the subjects who presented a post intervention decrease in S-PTH, as well as an increase of S-vitamin D. Thus, the investigators suggested that the decline in blood bone markers appeared to be mediated by the reduction of

PTH (152). However, in this thesis, there was no significant correlation between S-vitamin D and S-PTH, or a significant correlation between S-PTH or any of the blood bone markers.

As many as 75% of the subjects had suboptimal vitamin D values and 42% presented S-PTH levels above reference values, which is associated with higher risk of low BMD and fractures. As such, the findings of this thesis might indicate that vitamin D status could be one of multiple factors which contribute to the high prevalence of low BMD among wheelchair users. More research is needed to investigate how to optimize vitamin D status among wheelchair users and whether the current RDI of vitamin D is adequate for this population.

5.1.6 Energy Availability and Bone Health among Wheelchair users

Although a high percentage of the subjects presented low BMD measurements, only 17% of the subjects presented an estimated energy availability (EA) below the cut off for low energy availability. However, the estimations of EA in this thesis have got several limitations for this study population. The estimated EA values are based on an average, estimated physical activity energy expenditure, calculated by estimated PAL values determined by the subjects IPAQ-SF score at test day, and the energy intake was the subject's average intake based on three days of dietary recall within two weeks after the test day. Thus, the estimated EA in this thesis must be considered as an estimation of the subjects long-term EA. Knowledge about how to estimate EA among wheelchair athletes and the prevalence of LEA is sparse, but Egger and Flueck investigated EA over seven consecutive training days and reported LEA in 73% of the measured days in female athletes and 30% of the days in male wheelchair athletes (75). The dietary data was collected using a weighed seven-day food and training record, RMR and body composition were measured, and daily exercise energy expenditure (EEE) was estimated by using Metabolic Equivalent of Task (MET) scores. As such, an acute EA was calculated for each day, which may over or underestimate energy intake, and must be considered when comparing the data to the long-term EA estimations performed in this thesis. Similar estimations of acute EA, like the method conducted by Egger and Flueck, could have been calculated for each recall day in this thesis, as duration and type of training session was registered during the recalls. However, the number of recalls in this study were limited to three days, there were no objective measurements of the subject's registered training and since the overall aim was to investigate associations between habitual dietary intakes and measurements of bone health at baseline, the current method was conducted to estimate the

subjects long-term EA. In general, there are several pitfalls of estimating EA as there are no clear guidelines on field calculations of EA and what represent exercise for a free-living athlete is unclear (153). In addition, it must be emphasized that the cut offs threshold for LEA are not validated in wheelchair users and more research needs to be conducted to know whether they are applicable for this population in terms of the health consequences. While low BMD may be caused by LEA among the able-bodied population, many wheelchair users, especially SCI, might already have different BMD as a consequence of the disability itself, which makes it challenging to study the bone-related issues of LEA in this population (30).

Loucks et al showed that short-term LEA among females was found to altered markers of bone turnover, and bone formation markers declined linearly with EA (68-70). The estimated EA in this thesis was significant positively correlated with the blood bone formation marker P1NP ($r_{sp}=0.58$, $P=0.048$) when all subjects were included in the analysis, which supports the findings from Loucks. However, when performing the analysis without the subjects < 25 years old, the correlation was not significant. Furthermore, it should be mentioned that the study performed by Loucks et al assessed acute, short-term EA, while this thesis estimated long-term EA.

Pritchett et al investigated the risk of LEA among 9 male and 9 female para-athletes, where most of them were wheelchair users, and 78% of female participants were categorized as at risk of RED-S based on the LEAF-Q score, but none of the athletes were found to have LEA according to the EA cut offs for able-bodied (154). In this thesis only 25 % of all subjects, one female and two males, were at risk of RED-S based on the LEAF-Q or LEAM-Q scores. Together with the low prevalence of estimated LEA by equations, the risk of RED-S appears to be low per se, despite the low BMD in this population. While this might indicate unsuitable LEA threshold for this population and/or measurement errors when estimating EA, the study also suggests that the discrepancy in various EA and BMD measurements might indicate that low BMD was not a consequence of LEA among these wheelchair users. The low mechanical loading of bones is possibly the main determinant for the high prevalence of low BMD and more research needs to be conducted to explore whether energy deficiency further magnifies the impaired bone health among wheelchair users.

5.2 Methodological Considerations

5.2.1 Study design

A cross-sectional study design was employed as this design is best suited for prevalence investigations, and it is relatively inexpensive and feasible to perform (134). The study design also allows to investigate the associations of multiple exposures and outcomes at the same time and describe nutrition-related features of a study population, which can be used to generate further hypothesis for future intervention studies. Since the outcome and exposure variables are measured at the same time it is difficult to determine a causal inference and analysis of this master thesis was limited to evaluate whether dietary factors and measurements of bone health coexisted, as well as the potential associations between the two. A comprehensive screening process, including a detailed background questionnaire, and an extensive exclusion list were applied to prevent and control possible confounding.

5.2.2 Measurements and Data Collection

24-hour dietary recalls

For assessment of habitual energy, macro, and micronutrient intake among the subjects in this thesis repeated 24-hour recalls were applied. While weighed food records are considered to give more accurate measures of an individual's dietary intake (155, 156), the method is also invasive and time-consuming, which might impair compliance, especially in a population of disabled individuals. A food record is also a prospective method which might alter the subject's habitual food intake to simplify recording. A 24-hour recall approach was applied as there is no literacy requirement, the open-ended, retrospective format minimizes the influence on food choices, and the responder burden is relatively small. In addition, the method includes personal contact with a trained interviewer which contributes to the reliability of the collected data (156). All recalls, and the subsequently coding of the dietary intake, were conducted by the same trained interviewer in order to limit differences in interpretation of intake between subjects and standardize the interviews, and the database used for coding was specific to Norwegian foods and the database was updated prior to the study (116).

The goal of this thesis was to collect information on habitual dietary intake and it is important to acknowledge the within-subject variation in dietary intake from day-to-day and to obtain a representative intake multiple recalls are recommended; at least two independent days are needed to apply statistical modelling to estimate habitual intake (157) and minimum four to six recalls for assessment of micronutrients (158). In this thesis, three unannounced, non-consecutive recalls were conducted, which is considered as sufficient for describing nutritional intake on a group level, however, for micronutrients with higher within-person variability and relatively few food sources contribute to the overall intake, more recalls are needed. A larger number of recalls could have obtained more accurate data on the habitual vitamin D intake for each subject as it depends on the intake of certain foods, like fatty fish or the use of a supplement, which may not be ingested on a daily basis. However, a larger number of recalls could also affect the compliance and concerning the efficiency/cost ratio, the additional costs for extra days are relatively high (109). For foods typically consumed daily, such as milk, which is the main source of calcium from the diet, a smaller number of recalls are needed to estimate the habitual intake and three dietary recalls is reported to be sufficient to get accurate data.

The validated five-step multiple pass 24-hour recall method developed by the USDA was applied in this study, which is thought to give a reliable estimation of dietary intake, and validations studies have reported that the method assessed mean energy intake within 10% of mean actual intake (111, 112). As recall bias is a considerable limitation with a retrospective method like 24-h recalls, the multiple step module is thought to increase accuracy of the memory in the respondent. In order to increase the accuracy of the quantification of portion sizes the subjects used a picture booklet with four images of successively larger portions of dishes to estimate the amount consumed. Additionally, the booklet contained pictures of food items, e.g., different shapes of bread slices, and pictures of tableware which was used to increase the accuracy of reported volumes (159). Misreporting is a well acknowledged methodological challenge in dietary assessment methods, and in general, respondents are prone to over-reporting low intakes and under-reporting high intakes, a pattern referred to as the 'flat slope syndrome' (160). Subar et al. (161) evaluated the multiple-pass module with measurement of total daily energy expenditure (TDEE) by using doubly labelled water technique (DLW) and found that mean energy intake was underreported by 16-20 % for females and 12-14 % for males. The Goldberg method, as described by Black et al. (162), was applied in this thesis to identify under and overreported energy intakes by deriving cut offs

values for each individual, and implausible low or high EI were not identified. It must be emphasized that the PAL values used in this calculation were not based on measured physical activity and the method was applied with the assumption that the subjects were weight stable during the test period.

Estimation of resting metabolic rate (RMR) and physical activity level (PAL)

In order to evaluate the subject's energy intake an RMR:EI ratio and PAL values were calculated. Neither RMR nor the subject's total daily energy expenditure (TDEE) was measured in this thesis, which limits the accuracy of these variables. As such, RMR was calculated by the use of the Cunningham RMR equation, which has been reported to demonstrate the best precision to estimate RMR as an alternative to measured resting energy expenditure (REE), among wheelchair athletes (24). However, the model under-predicted REE, explained by the higher REE/FFM ratio of current athletes compared to less active SCI, which must be considered when interpreting the data (24). In general, studies report that RMR equations developed for able-bodied have overestimated REE in non-athletes with SCI (163, 164). The Chun equation, a SCI population-specific equation, has also been reported to show strong agreement within measures among individuals with SCI (165). In addition, a recent study investigating nutrition and bone health among para-athletes, where 27 of 67 para-athletes were wheelchair users, evaluated the level of agreement between para-athletes' measured and predicted RMR, and both the Harris and Benedict and the Chun equations showed good agreement with the measured RMR (166). Both Cunningham and the Chun equations use LBM as a predictor of RMR, which may explain why it is useful as individuals experiencing paralysis or related conditions undergo changes in body composition including increased fat mass and decreased LBM, which is related to a decrease in RMR. However, it must be emphasized that the study population of this thesis was a heterogeneous group and even though similar alternations in body composition were measured for most of the subjects, other factors might also influence the RMR, e.g., athetosis symptoms. Johnson et al (167) investigated total energy expenditure on individuals with CP using DLW and reported a trend towards a higher resting metabolic rate in the non-ambulatory individuals, possibly due to athetosis, but the literature on RMR and spasticity are inconsistent.

Limited information was obtained about the subject's overall activity level; thus, hypothetical PAL values were estimated based on the subjects IPAQ-SF score. Such data may introduce

uncertainties and it needs to be addressed that estimating a PAL value based on an IPAQ-SF score is not a validated and accepted method in research. The IPAQ-SF is a cost-effective method to assess physical activity, but a systematic review report that validation studies revealed overestimated physical activity as measured by objective criterion by an average of 84 % among able-bodied (107). Saebu et al (108) used the adapted version of the questionnaire to investigate total physical activity among young, disabled adults and found a reasonable correlation ($r_{sp}=0.632$, $P < 0.001$) with an alternative measure; a description of leisure time activity with four answering alternatives, which is frequently used by the National Institute of Public Health. In general, predicting energy expenditure from reported physical activity (PA) is more challenging for wheelchair users due to altered movement patterns and variations in metabolically active muscle mass.

The estimated PAL values used in this thesis were based on the categorization from FAO/WHO/UNU, but the values within each category were lowered based on available literature which reports that wheelchair users present a considerably lower energy cost of most exercises and activities than those reported in the general population (23, 121, 122). There was a significant correlation between the estimated PAL values and the EI:RMR, as well as a significant correlation between EI and PAL values, which indicate that the estimation of the PAL values in this thesis could predict the EI and, if assumed that the subjects were weight stable during the test period, the PAL values could also possibly predict the energy expenditure of the subjects. In the previously mentioned study on para-athletes, nutrition and bone health (166), total energy expenditure was measured by doubly labeled water (DLW). These data are currently under preparation but show that among the 27 elite wheelchair athletes the average TDEE:RMR (PAL) was 1.84 which supports the estimation of the PAL values for a vigorous lifestyle in this thesis. In general, the current knowledge on energy expenditure for wheelchair users is limited and must be considered when interpreting these data.

Analyses of Nutritional Biomarker of Vitamin D, S-PTH and Blood Bone Markers

The 25(OH)D concentration measured in serum is considered to be the best marker of vitamin D status (77). The liquid chromatography-tandem mass spectrometry (LC-MS/MS) method was applied to measure 25(OH)D and this method is reported to present high sensitivity and specificity (168, 169). An intact PTH immunoassay, as performed in this study, is reported as

an appropriate method for the detection of PTH (170). The two blood bone markers CTX-1 and PIN1 were analyzed by the use of an electrochemiluminescence immunoassay (ECLIA) which has shown to be a precise and sensitive method (171, 172). All blood samples were assessed in an overnight fasted state between 08:00 and 10:00 as both markers, especially CTX-1 exhibit a circadian rhythm in blood. The blood bone marker bALP was analyzed by chemiluminescent immunoassay (CLIA) which has shown a good agreement with electrophoresis technique for bALP, although various interference of other alkaline phosphatase isoenzymes is reported, which must be considered when interpreting the data (173).

Assessment of BMD

A DXA scan was applied to measure BMD as well as body composition, which is considered as the gold standard for determination of BMD (174, 175) in able-bodied and the technology has also been found to produce accurate measures for wheelchair users as well (2, 21, 176, 177). However, able-bodied reference data and clinical cut offs were used to determine age- and gender-matched stratification of BMD (i.e., Z-scores), and whether these cut offs are transferable to wheelchair users remains unknown. In addition, the measurement of BMD itself is a challenge among wheelchair users as this population often presented deformations, contractures, ossification, or spasticity that prevent an optimal positioning on the scanning bed. The precision of the measurement is highly dependent on the scanning technique and positioning of the subject (178) and it is well known that hip contractures may substantially limit technical quality of BMD measurements at the hip (179). In this thesis BMD was measured at lumbar spine, hip and femoral neck, but some studies shows that the distal femur is a more sensitive bone site for assessing bone loss by DXA in SCI patients (180). Moreover, DXA does not provide information about bone microstructure, which determines the bone's quality and strength. Quantitative computed tomography (QCT) can supply detailed volumetric parameters of trabecular and cortical compartments, but this technique was not performed in this thesis, thus limits the ability to describe detailed components of bone structure relevant to fracture risk (21, 181, 182).

Questionnaires for assessment of Low Energy Availability in Females and Males

The LEAF-Q and LEAM-Q are feasible, inexpensive, and easily administered for the purpose of screening. The LEAF-Q has been validated among able-bodied female athletes; however, neither LEAF-Q or LEAM-Q are validated among para-athletes or wheelchair users, and it must be emphasized that the prevalence of LEA symptoms in para-athletes, especially wheelchair users, needs further investigation as the underlying impairment may confound the results (30).

6 Conclusion

The purpose of this master thesis was to investigate the association between dietary intake and measurements of bone health among wheelchair users with initial low BMD. The main hypothesis was that energy availability (EA), vitamin D and/or calcium status will be positively associated with BMD of the lumbar spine and/or hip/femoral neck. The thesis presented a high prevalence of low BMD among wheelchair users, as well as an overall sufficient energy, vitamin D and calcium intake, which might indicate that the low mechanical loading of bones is the main determinant for bone loss in this population. However, 3 of 4 wheelchair users presented a suboptimal vitamin D status, and even though the subjects presented a sufficient calcium intake when assessed against the NNR, only two subjects presented an adequate intake for individuals with low BMD (≥ 1500 mg calcium/day). In addition, there was a significant positive correlation between calcium intake and Z-score of the hip, which suggests that a higher calcium intake, in addition to an optimal vitamin D status, can possibly improve BMD among wheelchair users.

The findings of this thesis highlight the need for more awareness on how wheelchair users can optimize their diet to prevent bone loss and improve their bone health. A nutrient dense diet seems to be important to fulfill the micronutrient recommendations while at the same time obtain an energy balanced diet, as wheelchair users might have a smaller energy budget than able-bodied. Whether the current recommended daily intake for vitamin D is adequate for wheelchair users can be questioned as several factors might hamper their vitamin D status and the population is per se already at higher risk of low BMD and fractures, than the able-bodied population. Additionally, the findings of this thesis indicate that the prevalence of low energy availability is low among wheelchair users, however, there is a need for more research on the

assessment of low energy availability, as well as the association between energy deficiency and bone health in this population.

In conclusion, none of the energy intake parameters or vitamin D intake were correlated with measurements of bone health, but an optimal vitamin D status in addition to a higher calcium intake seems to be important for optimizing bone health among wheelchair users. This thesis highlights the need for more research on vitamin D and calcium recommendations for this population, and whether insufficient dietary intake and/or low energy availability further magnifies the impaired bone health among wheelchair users with low mechanical loading.

7 Practical implications and Future Research

- Nutritional guidance on how to fulfil the recommendations for both vitamin D and calcium, as well as guidelines for a healthy and energy balanced diet, should be offered to wheelchair users as they are at high risk of low BMD.
- A routinely assessment of vitamin D status seems to be important for wheelchair users, as suboptimal vitamin D status is prevalent even among those who present sufficient vitamin D intakes. More research is needed to determine whether the current recommended daily intake for vitamin D is adequate to maintain optimal S-vitamin D levels among wheelchair users, and an individual assessment might be required.
- The current recommendations of a daily intake of 3 portions of low-fat dairy products to fulfill the RDI for calcium (183) might not be sufficient for wheelchair users, as higher calcium intakes are recommended for people with low BMD. As such, a supplement might be needed to support bone health in this group.
- There is a need for wheelchair bound para-athlete specific guidelines on nutrition and more research on how to assess the energy requirements for this population. Further exploration of nutrition and exercise behavior, including within-day energy balance, is needed to investigate the association between energy deficiency and health-related complications in this population.

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List of Appendices

Appendix 1. REK Approval

Appendix 2. Informed consent form

Appendix 3. NSD Approval

Appendix 4. Information on 24-hour recall for test day

Appendix 5. SOP for 24-h recall interview

Appendix 6. Picture booklet used for 24-hours dietary recalls (NORKOST4)

Appendix 7. Background questionnaire (Q1)

Appendix 8. IPAQ-SF (Q2)

Appendix 9. Low Energy Availability in Female Questionnaire (Q4A)

Appendix 10. Low Energy Availability in Male Questionnaire (Q4B)

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst A	Anne Schiøtz Kavli	22845512	05.09.2022	458384

Kristin Lundanes Jonvik

Prosjektsøknad: Helseeffekter av trening og ernæring hos rullestolbrukere

Søknadsnummer: 458384

Forskningsansvarlig institusjon: Norges idrettshøgskole

Prosjektsøknad godkjennes med vilkår

Søkers beskrivelse

Lav mekanisk belastning på skjelettet gjør at rullestolbrukere har en økt risiko for lav beintetthet og dermed også for brudd og tilhørende komplikasjoner. Forskning viser en høy insidens på 2-3 brudd per 100 pasientår relatert til lav beintetthet hos ryggmargsskade, hvorav 70 % oppstår ved enkel forflytning som fra rullestol til seng. Konsekvensene av slike brudd fører hoshalvparten til sekundære komplikasjoner, som infeksjoner, trykksår, stivhet, depresjon og videre forringelse av beinhelsen. Økt grad av fysisk aktivitet og optimalisering av kosthold kan ha stor påvirkning for generell fysisk og psykisk helse og livskvalitet, men også spesifikt på beinhelse. Trenings- og kostholdstiltak har vist seg effektive for å bedre beinhelse hos den generelle befolkningen. Til nå er det manglende kunnskap om hvordan beinhelse kan optimaliseres hos rullestolbrukere. Det er et behov for forskning på hvordan trening og kosthold kan brukes i forebygging og behandling av lav beintetthet i denne gruppen. I dette prosjektet skal et interdisiplinært team av forskere og praktikere skreddersy et ernærings- og bein-spesifikt treningsprogram for å øke beintetthet hos både idrettsaktive og ikke-aktive rullestolbrukere med lav beintetthet. Ved et randomisert kontrollert studiedesign deles 60 deltakere i intervensjonsgruppe og kontrollgruppe. Deltakerne i intervensjonsgruppen gjennomfører et 24-ukers ernærings- og treningsprogram. Dette består av ernæringsveiledning for optimalisering av kosthold for beinhelse, og 3 treningsøkter per uke med styrketreningsøvelser rettet mot bedring av beintetthet i rygg og hofter. Ved start, halvveis og slutten av intervensjonen gjøres de samme målingene hos begge grupper, hvor hovedparameterne er beintetthet, blodmarkører for beinoppbygning, kroppssammensetning, progresjon i styrkeøvelser og mål på mental helse. Basert på utfallet av programmet vil prosjektgruppen utvikle forskningsbaserte praktiske helsefremmende råd og en plan for implementering for helsepersonell som samarbeider med rullestolbrukere i kommunene. Det vil være stor grad av brukermedvirkning gjennom hele prosjektperioden og tett samarbeid mellom forskningsinstitusjonene, praktikere som arbeider med rullestolbrukere, brukerorganisasjoner og kommune, vil fasilitere direkte implementering av retningslinjene. Prosjektet vil styrke NIF og den frivillige idrettens rolle i å inkludere rullestolbrukere i aktivitet som fremmer helse og trivsel. Prosjektet bidrar med evidensbasert kunnskap for en uniksammfunnsgruppe som er underrepresentert i litteraturen og i idretten. På kort sikt vil vi minske kunnskapshull om beinhelse, fysisk aktivitet og ernæring hos rullestolbrukere for å bedre fysisk og mental helse og livskvalitet. På lengre sikt håper vi å øke forståelsen

for, og dermed også mulighetene til kommunene, sammen med idretten, for å håndtere utfordringer relatert til lavbeintetthet, fysisk inaktivitet og overvekt hos rullestolbrukere.

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst A) i møtet 18.08.2022. Vurderingen er gjort med hjemmel i helseforskningslovens § 10.

REKs vurdering

Formålet med prosjektet er å undersøke om et ernærings- og treningsprogram kan øke bentetthet hos rullestolbrukere.

Rullestolbrukere har økt risiko for lav bentetthet og dermed brudd og tilhørende komplikasjoner som infeksjoner, trykksår, stivhet, depresjon og videre forringelse av beinshelsen. Trenings- og kostholdstiltak har vist seg effektive for å bedre beinshelse hos den generelle befolkningen, men det er behov for forskning på hvordan trening og kosthold kan brukes i forebygging og behandling av lav beintetthet hos rullestolbrukere.

I dette prosjektet vil man inkludere 60 rullestolbrukere i alderen 18-50 år. De må ha lav-normal til lav beintetthet, bruke rullestol minst 50% av tiden, kunne delta i treningsintervensjonen og ikke ha utfordringer som påvirker effekten for å kunne inkluderes i prosjektet.

Deltakere skal rekrutteres ved hjelp av informasjon i aviser og på nettsteder, samt rekrutteres fra rehabiliteringssykehus og brukerorganisasjoner. Parautøvere vil rekrutteres gjennom Norges idrettsforbund og olympiske og paralympiske komitee. Potensielle deltakere vil motta muntlig og skriftlig informasjon om alle prosedyrer og tester fra stipendiat og svare på forespørsel om prosjektdeltakelse til henne eller prosjektleder.

Alle som er interessert i å delta, vil møte til et screeningbesøk (som er stipulert til å ta 1,5 time). Der vil man måle beinmineraltetthet, kroppssammensetning og muskelstyrke i laboratoriet for å undersøke om de oppfyller inklusjonskriteriene. De vil også besvare spørreskjemaer. Man antar at det vil være nødvendig med 150 personer i kartleggingsdelen for å finne 60 personer som kan inkluderes i treningsdelen.

De som oppfyller inklusjonskriteriene og ønsker å være med i treningsdelen av prosjektet, vil så randomiseres til en treningsgruppe som skal gjennomføre strukturert styrketrening over 6 måneder, eller en kontrollgruppe. Alle deltakere vil gjennomføre 3 besøk i lab (ca 1.5 time per gang) med målinger av beintetthet, DXA scan, blodprøve, styrke og funksjon samt besvare spørreskjemaer. I to uker rundt testdagene gjennomføres 3 x intervju om ernæringsinntak. Begge grupper vil få kosttilskudd og råd om optimalisering av kosthold basert på resultater av kostregistrering. Deltakerne skal også fylle ut trenings- og fysisk aktivitetsdagbok. Kontrollgruppen skal loggføre fysisk aktivitet, men skal ikke følge noe treningsprogram, bare fortsette med det de pleier/ønsker. De vil få tilbud om trening med oppfølging etter at studien er avsluttet.

Intervensjonsgruppen vil gjennomføre trening og logging av trening á 3 x 30 minutter i uken over 24 uker. De første fire ukene vil denne treningen gjøres på NIH eller andre

tilknyttede sentre i studien, og deltakerne vil få veiledning. De neste 20 ukene vil de gjennomføre treningen på egenhånd, men få veiledning tre dager.

Følgende spørreskjemaer skal brukes i prosjektet:

Ved screening: Bakgrunnsspørreskjema, inkl. fysisk aktivitet (International Physical Activity Questionnaire og [IPAQ] short wheel).

Ved oppstart, midtveis og ved endt studieperiode: WHO-5 Wellbeing Index, 12-item Basic

Psychological Needs Satisfaction instrument for exercise, delskalaer fra The Profile of Mood States [POMS] og Athlete Burnout Questionnaire [ABQ], Low Energy Availability LEAF og LEAM, Spinal Cord Independence Measure [SCIM] og Transfer Assessment Instrument, en multi-step guide for vurdering av kvalitet i forflytning fra/til rullestol.

Det skal også gjøres fokusgruppeintervju om deltakernes erfaring og opplevelse av treningsintervensjonen for 10 i intervensjonsgruppen. Biologisk materiale som samles inn, vil lagres i en prosjektspesifikk biobank med prosjektleder som ansvareshavende.

Basert på resultatene vil prosjektgruppen utvikle praktiske helsefremmende råd og en plan for implementering for helsepersonell som arbeider med rullestolbrukere i kommunene.

Komiteen anser dette som et nyttig prosjekt som vil kunne gi ny kunnskap om forebygging og behandling av lav beintetthet hos rullestolbrukere, men har enkelte merknader til informasjonsskrivet.

Det er vedlagt et utfyllende informasjonsskriv med god beskrivelse av treningsdelen av prosjektet. Kartleggingsdelen er dårlig beskrevet, og da det planlegges at ca 150 personer skal delta i kartleggingsdelen og kun 60 av disse i intervensjonsdelen, må de få god informasjon om hva deltakelse i screening innebærer for dem. I spørreskjemaene som skal brukes i prosjektet, stilles det mange og til dels invaderende spørsmål, f.eks. om sexlyst. I beskrivelsen av spørreskjemaer som brukes i prosjektet, er det ikke klart hvilken type spørsmål som stilles, og heller ikke begrunnet hvorfor denne informasjonen er relevant for å oppnå formålet med prosjektet. Det nevnes hva som skal samles inn av personinformasjon, men oversikten er ikke komplett. Det er bedre å ikke liste opp hva som samles inn av personinformasjon enn å ha en liste der noe utelates.

Det bes derfor om at det gjøres følgende endringer i informasjonsskrivet:

1. Det må komme tydelig frem at de fleste deltakerne som møter til kartleggingsdelen, ikke vil ha mulighet til å delta i prosjektet fordi de ikke oppfyller inklusjonskriteriene, samt om det vil bli tilbudt noen form for trening eller oppfølging for de som ikke går videre til studien etter screeningbesøket.
2. Det må også komme tydeligere frem hvilke undersøkelser som skal gjøres og type spørsmål som vil stilles i forbindelse med kartleggingen, samt om innsamlede opplysninger vil brukes i prosjektet også for de som ikke kan inkluderes i treningsdelen av prosjektet.
3. Det må komme frem om reiseutgifter vil bli dekket, og i så fall for hvilke oppmøter dersom det f. eks dekkes reiseutgifter til kartlegging og testing, men ikke for trening.
4. Det må oppgis forventet tidsbruk for alt som skal gjøres i prosjektet, inkludert kostintervjuer og loggføring av trening.
5. Det må beskrives type spørsmål som stilles så deltakerne er forberedt på at det kan stilles spørsmål som kan oppfattes som invaderende.

6. Informasjonsskrivet er ikke basert på REKs nyeste mal. Det bes om at formuleringer fra REKs nyeste mal (som finnes på REKs nettsider: <https://rekportalen.no>) brukes under avsnittet «Hva skjer med opplysningene om deg»,
7. Det må presiseres om deltakerne også vil få tilbakemelding på samlede studieresultater og om dette også gjelder de som kun deltar i kartleggingsdelen.

Komiteen godkjenner derfor prosjektet på vilkår av at informasjonsskrivet revideres i henhold til komiteens merknader. Revidert informasjonsskriv med markerte endringer innsendes REK ved å benytte skjema for «Endring og/eller henvendelse» som finnes etter innlogging på <http://rekportalen.no>.

Vedtak

REK har gjort en helhetlig forskningsetisk vurdering av alle prosjektets sider. Prosjektet godkjennes med hjemmel i helseforskningsloven § 10, under forutsetning av at ovennevnte vilkår er oppfylt.

I tillegg til vilkår som fremgår av dette vedtaket, er godkjenningen gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad og protokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Med hjemmel i helseforskningsloven § 25 godkjenner komiteen opprettelsen av en spesifikk forskningsbiobank med Kristin Lundanes Jonvik, Norges idrettshøgskole, som ansvarshavende. Biobanken skal ha samme varighet som prosjektet. Det innsamlede biologiske materialet skal oppbevares aidentifisert og destrueres ved prosjektperiodens utløp.

Komiteens avgjørelse var enstemmig.

Prosjektet er godkjent frem til 14.02.2025. Etter prosjektslutt skal opplysningene oppbevares i fem år for dokumentasjonshensyn. Enhver tilgang til prosjektdataene skal da være knyttet til behovet for etterkontroll. Prosjektdata skal således ikke være tilgjengelig for prosjektet. Prosjektleder og forskningsansvarlig institusjon er ansvarlig for at opplysningene oppbevares indirekte personidentifiserbart i denne perioden, dvs. atskilt i en nøkkel- og en datafil. Etter disse fem årene skal data slettes eller anonymiseres. Vi gjør oppmerksom på at anonymisering kan være mer omfattende enn å kun slette koblingsnøkkelen, jf. Datatilsynets veileder om anonymiserings-teknikker.

Vi gjør samtidig oppmerksom på at det også må foreligge et behandlingsgrunnlag etter personvernforordningen. Dette må forankres i egen institusjon.

Sluttmelding

Prosjektleder skal sende sluttmelding til REK på eget skjema via REK-portalen senest 6

måneder etter sluttdato 14.02.2025, jf. helseforskningsloven § 12. Dersom prosjektet ikke starter opp eller gjennomføres meldes dette også via skjemaet for sluttmelding.

Søknad om endring

Dersom man ønsker å foreta vesentlige endringer i formål, metode, tidsløp eller organisering må prosjektleder sende søknad om endring via portalen på eget skjema til REK, jf. helseforskningsloven § 11.

Klageadgang

Du kan klage på REKs vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes på eget skjema via REK portalen. Klagefristen er tre uker fra du mottar dette brevet. Dersom REK opprettholder vedtaket, sender REK klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag (NEM) for endelig vurdering, jf. forskningsetikkloven § 10 og helseforskningsloven § 10.

Med vennlig hilsen

Kristian Bjøro
Professor dr. med.
Leder

Anne S. Kavli
Seniorkonsulent
REK sør-øst

Kopi til:

Norges idrettshøgskole
Truls Raastad

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst A	Anne Schiøtz Kavli	22845512	14.10.2022	458384

Kristin Lundanes Jonvik

458384 Helseeffekter av trening og ernæring hos rullestolbrukere

Forskningsansvarlig: Norges idrettshøgskole

Søker: Kristin Lundanes Jonvik

REKs svar på generell henvendelse

Vi viser til tilbakemelding innsendt 29.09.2022 vedlagt revidert informasjonsskriv. Komiteen tar til orientering at vilkår for godkjenning er oppfylt.

Med vennlig hilsen
Anne S. Kavli
Seniorkonsulent
REK sør-øst A

Vennlig hilsen
Regional komite for medisinsk og helsefaglig forskningsetikk

Denne e-posten kan ikke besvares. Ta kontakt med ditt sekretariat dersom du har spørsmål. <https://rekportalen.no/#omrek/REK>

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst A	Anne Schiøtz Kavli	22845512	09.12.2022	458384

Kristin Lundanes Jonvik

Prosjektsøknad: Helseeffekter av trening og ernæring hos rullestolbrukere

Søknadsnummer: 458384

Forskningsansvarlig institusjon: Norges idrettshøgskole

Prosjektsøknad: Endring godkjennes

Søkers beskrivelse

Lav mekanisk belastning på skjelettet gjør at rullestolbrukere har en økt risiko for lav beintetthet og dermed også for brudd og tilhørende komplikasjoner. Forskning viser en høy insidens på 2-3 brudd per 100 pasientår relatert til lav beintetthet hos ryggmargsskadde, hvorav 70 % oppstår ved enkel forflytning som fra rullestol til seng. Konsekvensene av slike brudd fører hoshalvparten til sekundære komplikasjoner, som infeksjoner, trykksår, stivhet, depresjon og videre forringelse av beinhelsen. Økt grad av fysisk aktivitet og optimalisering av kosthold kan ha stor påvirkning for generell fysisk og psykisk helse og livskvalitet, men også spesifikt på beinhelse. Trenings- og kostholdstiltak har vist seg effektive for å bedre beinhelse hos den generelle befolkningen. Til nå er det manglende kunnskap om hvordan beinhelse kan optimaliseres hos rullestolbrukere. Det er et behov for forskning på hvordan trening og kosthold kan brukes i forebygging og behandling av lav beintetthet i denne gruppen. I dette prosjektet skal et interdisiplinært team av forskere og praktikere skreddersy et ernærings- og bein-spesifikt treningsprogram for å øke beintetthet hos både idrettsaktive og ikke-aktive rullestolbrukere med lav beintetthet. Ved et randomisert kontrollert studiedesign deles 60 deltakere i intervensjonsgruppe og kontrollgruppe. Deltakerne i intervensjonsgruppen gjennomfører et 24-ukers ernærings- og treningsprogram. Dette består av ernæringsveiledning for optimalisering av kosthold for beinhelse, og 3 treningsøkter per uke med styrketreningsøvelser rettet mot bedring av beintetthet i rygg og hofter. Ved start, halvveis og slutten av intervensjonen gjøres de samme målingene hos begge grupper, hvor hovedparameterne er beintetthet, blodmarkører for beinoppbygning, kroppssammensetning, progresjon i styrkeøvelser og mål på mental helse. Basert på utfallet av programmet vil prosjektgruppen utvikle forskningsbaserte praktiske helsefremmende råd og en plan for implementering for helsepersonell som arbeider med rullestolbrukere i kommunene. Det vil være stor grad av brukermedvirkning gjennom hele prosjektperioden og tett samarbeid mellom forskningsinstitusjonene, praktikere som arbeider med rullestolbrukere, brukerorganisasjoner og kommune, vil fasilitere direkte implementering av retningslinjene. Prosjektet vil styrke NIF og den frivillige idrettens rolle i å inkludere rullestolbrukere i aktivitet som fremmer helse og trivsel. Prosjektet bidrar med evidensbasert kunnskap for en uniksammfunnsgruppe som er underrepresentert i litteraturen og i idretten. På kort sikt vil vi minske kunnskapshull om beinhelse, fysisk aktivitet og ernæring hos rullestolbrukere for å bedre fysisk og mental helse og

livskvalitet. På lengre sikt håper vi å økeforståelsen for, og dermed også mulighetene til kommunene, sammen med idretten, for å håndtere utfordringer relatert til lavbeintetthet, fysisk inaktivitet og overvekt hos rullestolbrukere.

Vi viser til søknad om prosjektendring datert 21.11.2022 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK sør-øst A på fullmakt, med hjemmel i helseforskningsloven § 11.

REKs vurdering

REK har vurdert følgende endringer i prosjektet:

- Endring i tidsbruk. Pilottesting har vist at screening og testing tar mer tid enn forventet, og estimert tidsbruk er derfor justert i informasjonsskriv og protokoll.
- Endring i inklusjonskriterier. Øvre aldersgrense endres fra 50 til 60 år, og menopause legges til som eksklusjonskriterium.
- Personidentifiserbare opplysninger vil kunne være systematisk reidentifiserbare ved kombinasjon av variabler for noen av deltakerne da få parautøvere har samme funksjonsnedsettelsesgrad og idrett
- Protokoll og informasjonsskriv er oppdatert.

Komiteens leder har vurdert endringene og har ingen innvendinger mot at disse gjennomføres som beskrevet.

Vedtak

Komiteen godkjenner med hjemmel i helseforskningsloven § 11 annet ledd at prosjektet videreføres i samsvar med det som fremgår av søknaden om prosjektendring og i samsvar med de bestemmelser som følger av helseforskningsloven med forskrifter.

Prosjektet er godkjent frem til 14.02.2025. Etter prosjektslutt skal opplysningene oppbevares i fem år for dokumentasjonshensyn. Enhver tilgang til prosjektdataene skal da være knyttet til behovet for etterkontroll. Prosjektdata skal således ikke være tilgjengelig for prosjektet. Prosjektleder og forskningsansvarlig institusjon er ansvarlig for at opplysningene oppbevares indirekte personidentifiserbart i denne perioden, dvs. atskilt i en nøkkel- og en datafil. Etter disse fem årene skal data slettes eller anonymiseres. Vi gjør oppmerksom på at anonymisering kan være mer omfattende enn å kun slette koblingsnøkkelen, jf. Datatilsynets veileder om anonymiserings-teknikker.

Vi gjør samtidig oppmerksom på at etter ny personopplysningslov må det også foreligge et behandlingsgrunnlag etter personvernforordningen. Det må forankres i egen institusjon.

Sluttmelding

Prosjektleder skal sende sluttmelding til REK på eget skjema via REK-portalen senest 6 måneder etter sluttdato 14.02.2025, jf. helseforskningsloven § 12. Dersom prosjektet ikke starter opp eller gjennomføres meldes dette også via skjemaet for sluttmelding.

Søknad om endring

Dersom man ønsker å foreta vesentlige endringer i formål, metode, tidsløp eller organisering må prosjektleder sende søknad om endring via portalen på eget skjema til REK, jf. helseforskningsloven § 11.

Klageadgang

Du kan klage på REKs vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes på eget skjema via REK portalen. Klagefristen er tre uker fra du mottar dette brevet. Dersom REK opprettholder vedtaket, sender REK klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag (NEM) for endelig vurdering, jf. forskningsetikkloven § 10 og helseforskningsloven § 10.

Med vennlig hilsen

Kristian Bjørø
Professor dr. med.
Leder

Anne S. Kavli
Seniorrådgiver
REK sør-øst

Kopi til:

Norges idrettshøgskole
Truls Raastad

VIL DU DELTA I FORSKNINGSPROSJEKTET HELSEEFFEKTER AV TRENING OG ERNÆRING HOS RULLESTOLBRUKERE?

FORMÅLET MED PROSJEKTET OG HVORFOR DU BLIR SPURT

Norges idrettshøgskole (NIH) har i et pågående internasjonalt forskningsprosjekt i samarbeid med Sunnaas sykehus, Norges Tekniske- og naturvitenskapelige universitet (NTNU), Høgskolen på Vestlandet (HVL) og idrettshøgskolen i Nederland, kartlagt energibehov, ernæringsstatus og kroppssammensetning hos parautøvere. Studien har avdekket større forekomst av lav bentetthet hos paradeltakerne enn i resten av befolkningen. Forekomsten av lav bentetthet var størst hos de parautøverne som var rullestolbrukere. Redusert bentetthet kan føre til økt forekomst av benbrudd og andre helseutfordringer. Fysisk trening som belaster skjelettet og riktig ernæring kan redusere risiko for disse negative helseutfordringene. Derfor vil vi i neste fase av prosjektet nå undersøke helseeffekter av spesifikk styrketrening i kombinasjon med optimalisering av ernæring hos rullestolbrukere.

Vi henvender oss til deg som rullestolbruker med forespørsel om du vil delta i dette prosjektet.

HVA INNEBÆRER PROSJEKTET FOR DEG?

Dette prosjektet er delt opp i to deler, en kartleggingsdel og en treningsdel. På bakgrunn av kartleggingsdelen vil du, om du oppfyller visse kriterier (se nedenfor under «Invitasjon til videre deltakelse»), bli invitert videre til treningsdelen etter visse kriterier. Før deltakelse i prosjektet vil du fylle ut et spørreskjema for å se om du passer til inklusjonskriteriene med tanke på alder, grad av rullestolbruk, årsak til rullestolbruk (diagnose), skadenivå ved eventuell ryggmargsskade, og helse (sykdom eller andre forhold som hindrer deltagelse i studien).

I treningsdelen trekkes deltakerne tilfeldig til en trenings- og ernæringsgruppe som blir fulgt opp med strukturert styrketrening over 6 måneder, eller til en ernæringsgruppe som fortsetter med sin normale fysiske aktivitet. Alle deltakerne vil motta et kosttilskudd (protein, vitamin D og kalsium) og råd om optimalisering av ernæring relatert til beinohelse. I prosjektet vil vi innhente og registrere opplysninger om deg som innebærer spørreskjemaopplysninger, DXA-skannresultater (kroppssammensetning og beintetthet) og blodprøveresultater, som beskrevet under.

KARTLEGGINGSDELEN

Deltagelse i prosjektet vil innebære at du først besvarer digitale spørreskjema om medisinsk historikk og fysisk aktivitet. Her blir du blant annet stilt spørsmål om medisinerbruk, prevensjonsbruk og menstruasjonssyklus (kvinner), om funksjonsnedsettelsen din (for eksempel hvor stor del av tiden du må bruke rullestol, mage-tarm funksjon og behov for assistanse) og om eventuelt andre sykdommer som kan ha betydning for studien. Ved behov for oppklaring vil vi ta kontakt per telefon for å sjekke av eksklusjons- og inklusjonskriterier.

Deretter møter du til kartlegging av beinmineralitet, kroppssammensetning og muskelstyrke i laboratoriet ved et av teststedene. Avhengig av hvor du bor, vil det være enten NIH (Oslo), NTNU (Trondheim) eller HVL (Bergen). Du bes møte opp fastende (ikke spise eller drikke noe annet enn vann ved behov for inntak av medisiner) på morgenen for måling av kroppssammensetning og beintetthet (DXA-skann) og utprøving av

styrkeøvelser (tilvenning før eventuell testing på testdag 1, se under). Møt derfor i treningstøy/behagelig tøy du kan bevege deg i. Dette besøket varer ca. 2,5 time.

INVITASJON TIL VIDERE DELTAKELSE

Etter kartleggingsdelen vil målingene av beintetthet bli analysert og du vil motta invitasjon til å delta i treningsdelen av studien dersom du oppfyller inklusjonskriteriene. Disse er blant annet å ha lav normal til lav beintetthet, samt tilfredsstillende funksjon til å gjennomføre styrketester – og evt. styrketreningsprogrammet. Dersom du ikke oppfyller inklusjonskriteriene og ikke blir invitert med videre i studien, vil du få beskjed om dette og du vil motta dine resultater av målingene gjort under kartleggingen.

Selv om du ikke skulle bli invitert videre etter kartleggingen, vil målingene og spørreskjemaene brukes i prosjektet. Studien ender da der for deg, men du vil i etterkant av prosjektet få tilbud om veiledet trening og tilgang til det samme treningsprogrammet som blir brukt av deltakerne i treningsdelen.

TRENINGSDELEN

Deltakelse i treningsdelen av studien innebærer å møte opp til testdag 1 før du blir tilfeldig trukket inn i din gruppe (trenings- og ernæringsgruppen eller ernæringsgruppen).

TESTDAG 1

På testdag 1 måler vi utgangspunktet ditt før intervensjonen. Du bes møte opp fastende (kun vann ved behov for inntak av medisiner) på morgenen for blodprøve. Videre består testdagen av følgende tester etter frokost: 1) testing av muskelstyrke (statisk skulderpress, brystpress og liggende roing), 2) testing av funksjon (forflytning fra rullestol til vanlig stol), og 3) gjennomgang av spørreskjemaer (funksjon, mental helse og energitilgjengelighet) som du får tilsendt digitalt og bes fylle inn før oppmøte. I spørreskjemaet om funksjon vil du bli stilt spørsmål relatert til din funksjonsnedsettelse og utførelse av egenpleie, hygiene, sfinkter- og blærefunksjon, samt mobilitet (forflytning). I spørreskjemaet om energitilgjengelighet vil du bli stilt spørsmål som for noen kan oppfattes invaderende, for eksempel om sexlyst (menn) og om menstruasjonsforstyrrelser (kvinner). Disse spørsmålene er viktige faktorer som *kan* indikere lav energitilgjengelighet hos de to kjønnene. Dersom du ikke ønsker å besvare enkelte spørsmål, vil du allikevel ikke ekskluderes fra studien.

Testdagen tar totalt ca. 2,5 time.

BLODPRØVER

Én blodprøve tas i fastende tilstand ved tre besøk. Biomarkører for ernæringsstatus (f.eks. jern, ferritin, triglyserider, vitamin B12, folat, vitamin D), helsestatus (f.eks. Hb, CRP, T3, T4, FSH, LH, østradiol, testosteron) og benmetabolisme (f.eks. PTH, kalsium, CTx, BAP) vil bli vurdert. Analysene utføres ved Fürst laboratorier og Hormonlaboratoriet.

OPTIMALISERING AV ERNÆRING

I løpet av de to ukene rundt testdag 1 vil vi på 3 ulike dager ha en kort ernæringsamtale med deg via telefon eller PC for å kartlegge hva du spiste og drakk dagen før (hver samtale tar ca. 30-40 min). Basert på resultatene av kostregistreringen og blodprøvesvarene dine, vil du få generelle kostråd for god helse og mer spesifikke råd for god beinelse.

Alle deltakere vil få utdelt et kosttilskudd bestående av vitamin D, kalsium og myseprotein, som skal tas 3 dager per uke.

Kartlegging av ernæring og tilbakemelding om inntak og blodprøvesvar gjentas for alle rundt testdag 2 & 3.

TRENINGSINTERVENSJONEN

Randomiseringen (trekkingen) til treningsgruppe eller ernæringsgruppe vil bli gjennomført rett etter testdag 1.

Dersom du blir trukket til treningsgruppen vil du være med på intervensjonen, som innebærer: 4 uker á 3 økter per uke med veiledet styrketrening på teststedet. Hver økt tar ca. 60 minutter. Fra uke 5 trener du disse 3 øktene på eget treningssted, med trening på teststedet en økt hver måned gjennom resten av intervensjonen. I løpet av hele perioden (24 uker) vil du gjennomføre 15 treningsøkter på test- og treningsstedet du deltar ved og 57 treningsøkter på egenhånd.

Dersom du blir trukket til ernæringsgruppen skal du ikke gjennomføre treningsintervensjonen og du skal da bare fortsette med de aktiviteter du allerede normalt gjennomfører.

TESTDAG 2 & 3 (I UKE 12 & UKE 24)

I uke 12 og uke 24 bes alle fra begge grupper møte opp til nye testdager. Du bes møte opp fastende (kun vann ved behov for inntak av medisiner) for måling av kroppssammensetning og bentetthet (DXA-skann) og blodprøve.

På disse testdagene vil du gjennomgå følgende tester: 1) måling av beintetthet og kroppssammensetning i en DXA undersøkelse, 2) blodprøve, 3) testing av muskelstyrke (statisk skulderpress, brystpress og liggende roing), 4) testing av funksjon (forflytning fra rullestol til vanlig stol), og 5) gjennomgang av spørreskjemaer (fysisk aktivitet, funksjon, mental helse og energitilgjengelighet) som du får tilsendt digitalt og bes fylle inn før oppmøte.

OPPFØLGING

Dersom du blir trukket til treningsgruppen bes du loggføre all trening, inkludert din normale fysiske aktivitet, i en app og vil etter de fire første ukene bli kontaktet per telefon eller via app for oppfølging av hvordan treningen går hver andre uke.

Dersom du blir trukket til ernæringsgruppen, skal du loggføre din normale fysiske aktivitet.

Etter hver testperiode (oppstart, midtveis og ved endt studieperiode) vil du (uavhengig av hvilken gruppe du trekkes til) få veiledning i optimalisering av ditt kosthold basert på ernæringskartleggingen og blodprøveverdier. For noen kan det bli aktuelt med et ekstra kosttilskudd av for eksempel vitamin D. Effekten av kostrådene vil bli fulgt opp i den påfølgende testperioden eller tidligere ved behov.

Dersom du blir trukket til ernæringsgruppen, vil du etter endt studieperiode få tilbud om veiledet trening og tilgang til det samme treningsprogrammet som er brukt i treningsgruppen.

FOKUSINTERVJU

Vi vil invitere 10 deltakere fra treningsgruppen til et fokusintervju etter endt treningsperiode, hvor deltakernes erfaringer og opplevelser fra treningen vil diskuteres. Dette er frivillig og begrenser ikke deltakelse i studien ellers. Samtalen vil tas opp med lydopptak etter samtykke fra deltakerne og alt som blir diskutert anonymiseres. Dette gir verdifull informasjon som vil brukes i eventuelle oppfølgingsprosjekter og utarbeidelse av råd og retningslinjer for trening hos rullestolbrukere.

TIDSBRUK

Estimert tidsbruk til testing, intervensjon og trening:

- Kartlegging: ca. 3 timer oppmøte i lab på ditt teststed

- Testing: Totalt 3 dager med ca. 3 timer oppmøte i lab på ditt teststed (ved oppstart, uke 12 og uke 24).
 - o Kostholdsintervjuer: 3 ganger a 30-40 minutter per testperiode (ved oppstart, uke 12 og uke 24) gjennomføres via video-/telefonsamtale på avtalt egnet tidspunkt.
- Styrketrening veiledet på ditt teststed (kun treningsgruppen): 60 minutter 3 dager i uken gjennom 4 uker + 3 ekstra treningsøkter (måned 2, 4 og 5) gjennom intervensjonsperioden.
- Styrketrening på egenhånd (kun treningsgruppen): 60 minutter 3 dager i uken gjennom 20 uker.
- Loggføring av trening/fysisk aktivitet (begge grupper): estimert 2 minutter per dag med aktivitet, minimum 3 dager per uke for treningsgruppen (ca. 2,5 time totalt gjennom studieperioden).
- Fokusintervju (10 deltakere fra treningsgruppen): Ca. 45 minutter på NIH/videosamtale på nett etter at siste testdag er gjennomført.

MULIGE FORDELER OG ULEMPER

MULIGE FORDELER VED Å DELTA I PROSJEKTET:

Du blir involvert i en spennende studie der du vil få mye informasjon om deg selv og din fysiske form. Du vil med din deltagelse i prosjektet bidra til økt kunnskap rundt de utfordringer mange nye rullestolbrukere opplever med tap av muskelmasse og akutt og eller gradvis reduksjon i funksjon. Resultatene fra denne studien vil bidra med ny kunnskap om styrketrening, muskelstyrke, ernæringsinntak, kroppssammensetning og eventuelle helseutfordringer hos rullestolbrukere (som behelse, fysisk helse og mental helse), for rullestolbrukere med spesifikke funksjonsnedsettelse (som ryggmargsskader, ryggmargsbrokk, CP, dysmeli og amputasjon) og for ulike nivåer av fysisk aktivitet. Basert på resultatene vil det lages egne retningslinjer for trening og ernæring for rullestolbrukere.

Undersøkelsene vil muliggjøre at vi kan gi deg personlig informasjon om ditt inntak av næringsstoffer og blodprøveverdier (innen fire uker fra testdagene), samt beinhelse og progresjon i fysiske tester over studieperioden (innen 6 måneder fra siste testdag).

Om du trekkes til treningsgruppen vil du få tett oppfølging på tilpasset styrketrening over 6 måneder. Du vil også, med en normal respons på treningen, være sterkere når du avslutter studien sammenlignet med da du startet.

De som trekkes til ernæringsgruppen vil bli tilbudt oppfølging med trening ved teststedet etter at studien er avsluttet.

Dersom det skulle oppdages helseutfordringer som trenger videre oppfølging, vil du få informasjon og veiledning så fort det lar seg gjøre av medisinsk ansvarlig.

Du vil få tilbakemelding på dine individuelle resultater uavhengig av om du kun deltar på kartleggingsdelen eller deltar i trenings- eller ernæringsgruppen.

MULIGE ULEMPER VED Å DELTA I PROSJEKTET:

Du inviteres til deltakelse i et prosjekt hvor det er mulig du ikke blir invitert videre etter kartleggingen om du ikke tilfredsstillter inklusjonskriteriene. Videre krever noen av målingene tid og innsats fra deg i 2 uker rundt testdagene (kartlegging av ernæringsinntak som beskrevet over), samt kreves det samme til planlegging og gjennomføring av trening og testing over 6 måneder dersom du trekkes til treningsgruppen.

Du vil kunne kjenne litt på stølhøhet i musklene etter styrketestene og i starten av styrketreningen. Dette er vanlig etter maksimale styrketester og etter første styrketreningsøkt og vil normal gi seg etter 48-72 timer. Det

er også en liten risiko for skader som små muskelstrekker under testing og trening, men denne risikoen er svært liten og vil bli minimalisert gjennom god oppvarming og ved en gradvis og kontrollert økning i belastning.

DXA undersøkelsene gir en lavdose med røntgenstråler som tilsvarer ca. 2 dagers normal bakgrunnsstråling i din hverdag. Denne strålingen er derfor ufarlig, men kvinner som er gravide kan ikke gjennomføre DXA undersøkelse.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE DITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Det vil ikke ha noen negative konsekvenser for deg hvis du ikke vil delta eller senere velger å trekke deg. Dersom du trekker tilbake samtykket, vil det ikke forskes videre på dine opplysninger og ditt biologiske materiale. Du kan kreve innsyn i opplysningene som er lagret om deg, og disse vil da utleveres innen 30 dager. Du kan også kreve at dine opplysninger i prosjektet slettes og at det biologiske materialet destrueres. Adgangen til å kreve destruksjon, sletting eller utlevering gjelder ikke dersom materialet eller opplysningene er anonymisert eller publisert. Denne adgangen kan også begrenses dersom opplysningene er inngått i utførte analyser, eller dersom materialet er bearbeidet og inngår i et annet biologisk produkt.

Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder (se kontaktinformasjon på siste side).

HVA SKJER MED OPPLYSNINGENE OM DEG?

Opplysningene som registreres om deg skal kun brukes slik som beskrevet under formålet med prosjektet, og planlegges brukt til 2025. Eventuelle utvidelser i bruk og oppbevaringstid kan kun skje etter godkjenning fra REK og andre relevante myndigheter. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Du kan klage på behandlingen av dine opplysninger til Datatilsynet og institusjonen sitt personvernombud.

Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger (= kodede opplysninger). En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun Kristin L. Jonvik og stipendiat Linn C. Risvang som har tilgang til denne listen.

Publisering av resultater er en nødvendig del av forskningsprosessen. All publisering skal gjøres slik at enkelt deltakere ikke skal kunne gjenkjennes, men vi plikter å informere deg om at vi ikke kan utelukke at det kan skje.

Etter at forskningsprosjektet er ferdig, vil opplysningene om deg bli oppbevart i fem år av kontrollhensyn (2030). Dataene dine skal etter dette bli anonymisert (navneliste som kobler deg til dine rådata slettes) og oppbevares på ubestemt tid for oppfølgingsstudier og arkivering for senere forskning. Anonymiserte rådata vil være tilgjengelig som «open access» gjennom en godkjent nettbasert database.

DELING AV OPPLYSNINGER OG OVERFØRING TIL UTLANDET

Som en del av gjennomføringen av prosjektet kan det bli aktuelt å overføre innsamlede opplysninger om deg til andre land. Aidentifiserte opplysninger kan deles med forskningsgruppene ved samarbeidende institusjoner i Norge og i Nederland, som ledd i forskningssamarbeidet og publisering. Norges Idrettshøgskole er ansvarlig for at overføringen av opplysninger skjer i samsvar med norsk rett og EU sin personvernlovgivning (GDPR). Koden som knytter deg til dine personidentifiserbare opplysninger vil ikke bli utlevert.

HVA SKJER MED PRØVER SOM BLIR TATT AV DEG?

Prøvene som tas av deg skal oppbevares i en forskningsbiobank tilknyttet prosjektet uten kommersielle interesser (vurdert av regional etisk komité) fram til de analyseres. Kristin L. Jonvik er ansvarlig for biobanken.

Biobanken opphører ved prosjektslutt.

FORSIKRING

Deltakere i prosjektet er forsikret dersom det skulle oppstå skade eller komplikasjoner som følge av deltakelse i forskningsprosjektet. NIH er en statlig institusjon og er dermed selvassurandør. Dette innebærer at det er NIH som dekker en eventuell erstatning og ikke et forsikringsselskap.

ØKONOMI

Prosjektet er finansiert av Stiftelsen Dam og Norges idrettshøgskole. Kosttilskuddet som brukes i intervensjonen, produserer og leveres av FrieslandCampina (Nederland) uten noen kommersiell interesse. Det er ingen utfordringer knyttet til etiske eller praktiske sider ved økonomien i prosjektet. Det finnes ingen interessekonflikter mellom finansieringskildene og studien. Deltakerne som inviteres videre etter kartlegging kompenseres for reiseutgifter til testdag 1-3 ved at de mottar et universalgavekort pålydende 500 NOK ved studieslutt.

GODKJENNINGER

Regional komité for medisinsk og helsefaglig forskningsetikk har gjort en forskningsetisk vurdering og godkjent prosjektet (saksnummer 458384).

Norges Idrettshøgskole og prosjektleder Kristin L. Jonvik er ansvarlig for personvernet i prosjektet.

Vi behandler opplysningene basert på rettslig grunnlag i EUs personvernforordning artikkel 6 nr. 1a og artikkel 9 nr. 2a og ditt samtykke.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet eller ønsker å trekke deg fra deltakelse, kan du PhD-stipendiat Linn Christin Risvang som utfører studien, telefon: 90689951, e-post: linncr@nih.no, eller prosjektleder Kristin L. Jonvik, telefon: 94137624, e-post: k.l.jonvik@nih.no.

Dersom du har spørsmål om personvernet i prosjektet, kan du kontakte personvernombudet ved institusjonen på e-post: personvernombud@nih.no eller direkte til Rolf Haavik, telefon: 90733760, e-post: rolf.haavik@habberstad.no.

JEG SAMTYKKER TIL Å DELTA I PROSJEKTET OG TIL AT MINE PERSONOPPLYSNINGER OG MITT BIOLOGISKE MATERIALE BRUKES SLIK DET ER BESKREVET

- Jeg ønsker i tillegg å delta i fokusintervju etter endt studie, dersom jeg trekkes til treningsgruppen (kryss av). Jeg samtykker herved dermed også til lydopptak av intervjuet.

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

Jeg bekrefter å ha gitt informasjon om prosjektet

Sted og dato

Signatur

Rolle i prosjektet

Vurdering

Referansenummer

501156

Type

Standard

Dato

04.11.2022

Prosjekttittel

Helseeffekter av trening og ernæring på beinhelse hos rullestolbrukere

Behandlingsansvarlig institusjon

Norges idrettshøgskole / Institutt for fysisk prestasjonsevne

Prosjektansvarlig

Kristin Lundanes Jonvik

Prosjektperiode

01.11.2022 - 31.12.2025

Kategorier personopplysninger

Alminnelige

Særlige

Rettslig grunnlag

Samtykke (Personvernforordningen art. 6 nr. 1 bokstav a)

Uttrykkelig samtykke (Personvernforordningen art. 9 nr. 2 bokstav a)

Behandlingen av personopplysningene kan starte så fremt den gjennomføres som oppgitt i meldeskjemaet. Det rettslige grunnlaget gjelder til 31.12.2030.

[Meldeskjema](#) 

Kommentar

OM VURDERINGEN

Personverntjenester har en avtale med institusjonen du forsker eller studerer ved. Denne avtalen innebærer at vi skal gi deg råd slik at behandlingen av personopplysninger i prosjektet ditt er lovlig etter personvernregelverket.

Personverntjenester har nå vurdert den planlagte behandlingen av personopplysninger. Vår vurdering er at behandlingen er lovlig, hvis den gjennomføres slik den er beskrevet i meldeskjemaet med dialog og vedlegg.

BAKGRUNN

Prosjektet er vurdert og godkjent med vilkår etter helseforskningsloven § 10 av Regionale komiteer for medisinsk og helsefaglig forskningsetikk (REK sør-øst) i vedtak av 5.9.2022 (deres referanse: 458384). REK godkjenner også opprettelsen av en prosjektspesifikk biobank etter helseforskningsloven § 25.

VURDERING AV BEHOV FOR DPIA

Prosjektet behandler særlige kategorier av personopplysninger (helseopplysninger) om en sårbar gruppe, noe som kan utløse en plikt til å foreta personvernkonsensvurdering (DPIA).

Personverntjenester har vurdert at det ikke var behov for å gjøre en DPIA jf. personvernforordningen art. 35 nr. 1 for dette prosjektet. Dette var basert på en helhetsvurdering der følgende momenter ble vektlagt:

- De registrerte samtykker til bruk av sine personopplysninger
- De registrerte får god informasjon om behandlingen av personopplysningene og sine rettigheter
- Det er kun stipendiat og prosjektleder som har tilgang til koblingsnøkkel
- Prosjektet har en ryddig og oversiktlig dataflyt
- Få personer har tilgang til personopplysningene
- Regionale komiteer for medisinsk og helsefaglig forskningsetikk (REK) har gjort en forskningsetisk vurdering av prosjektet og godkjent det
- Behandlingen har kort varighet

TYPE OPPLYSNINGER OG VARIGHET

Prosjektet vil behandle alminnelige personopplysninger og særlige kategorier av personopplysninger om helseforhold frem til 31.12.2025. Etter prosjektslutt skal opplysningene oppbevares i fem år av dokumentasjonshensyn. Enhver tilgang til prosjektdataene skal da være knyttet til behovet for etterkontroll. Prosjektdata skal da ikke være tilgjengelig for prosjektet

du være knyttet til behovet for etterkontroll. Prosjektdata skal da ikke være tilgjengelig for prosjektet.

Prosjektleder og forskningsansvarlig institusjon er ansvarlig for at opplysningene oppbevares pseudonymisert (av-identifisert) i denne perioden, dvs. atskilt i en nøkkel- og en datafil. Etter disse fem årene skal data slettes eller anonymiseres.

LOVLIG GRUNNLAG

Prosjektet vil innhente samtykke fra de registrerte til behandlingen av personopplysninger. Vår vurdering er at prosjektet legger opp til et samtykke i samsvar med kravene i art. 4 nr. 11 og 7, ved at det er en frivillig, spesifikk, informert og utvetydig bekreftelse, som kan dokumenteres, og som den registrerte kan trekke tilbake.

For alminnelige personopplysninger vil lovlig grunnlag for behandlingen være den registrertes samtykke, jf. personvernforordningen art. 6 nr. 1 a.

For særlige kategorier av personopplysninger vil lovlig grunnlag for behandlingen være den registrertes uttrykkelige samtykke, jf. personvernforordningen art. 9 nr. 2 bokstav a, jf. personopplysningsloven § 10, jf. § 9 (2).

PERSONVERNPRINSIPPER

Personverntjenester vurderer at den planlagte behandlingen av personopplysninger vil følge prinsippene i personvernforordningen:

om lovlighet, rettferdighet og åpenhet (art. 5.1 a), ved at de registrerte får tilfredsstillende informasjon om og samtykker til behandlingen

formålsbegrensning (art. 5.1 b), ved at personopplysninger samles inn for spesifikke, uttrykkelig angitte og berettigede formål, og ikke viderebehandles til nye uforenlige formål

dataminimering (art. 5.1 c), ved at det kun behandles opplysninger som er adekvate, relevante og nødvendige for formålet med prosjektet

lagringsbegrensning (art. 5.1 e), ved at personopplysningene ikke lagres lengre enn nødvendig for å oppfylle formålet.

DE REGISTRERTES RETTIGHETER

Personverntjenester vurderer at informasjonen om behandlingen som de registrerte vil motta oppfyller lovens krav til form og innhold, jf. art. 12.1 og art. 13.

Så lenge de registrerte kan identifiseres i datamaterialet vil de ha følgende rettigheter: innsyn (art. 15), retting (art. 16), sletting (art. 17), begrensning (art. 18) og dataportabilitet (art. 20).

Vi minner om at hvis en registrert tar kontakt om sine rettigheter, har behandlingsansvarlig institusjon plikt til å svare innen en måned.

UNNTAK FRA RETTEN TIL SLETTING

I utgangspunktet har alle som registreres i forskningsprosjektet rett til å få slettet opplysninger som er registrert om dem. Etter helseforskningsloven § 16 tredje ledd vil imidlertid adgangen til å kreve sletting av sine helseopplysninger ikke gjelde dersom materialet eller opplysningene er anonymisert, dersom materialet etter bearbeidelse inngår i et annet biologisk produkt, eller dersom opplysningene allerede er inngått i utførte analyser. Regelen henviser til at sletting i slike situasjoner vil være svært vanskelig og/eller ødeleggende for forskningen, og dermed forhindre at formålet med forskningen oppnås.

Etter personvernforordningen art 17 nr. 3 d kan man unnta fra retten til sletting dersom behandlingen er nødvendig for formål knyttet til vitenskapelig eller historisk forskning eller for statistiske formål i samsvar med artikkel 89 nr. 1 i den grad sletting sannsynligvis vil gjøre det umulig eller i alvorlig grad vil hindre at målene med nevnte behandling nås.

Personverntjenester vurderer dermed at det er grunnlag for å gjøre unntak fra retten til sletting av helseopplysninger etter helseforskningslovens § 16 tredje ledd og personvernforordningen art 17 nr. 3 d, når materialet er bearbeidet slik at det inngår i et annet biologisk produkt, eller dersom opplysningene allerede er inngått i utførte analyser.

Vi presiserer at helseopplysninger inngår i utførte analyser dersom de er sammenstilt eller koblet med andre opplysninger eller prøvesvar. Vi gjør oppmerksom på at øvrige opplysninger må slettes og det kan ikke innhentes ytterligere opplysninger fra deltakeren.

FØLG DIN INSTITUSJONS RETNINGSLINJER

Personverntjenester legger til grunn at behandlingen oppfyller kravene i personvernforordningen om riktighet (art. 5.1 d), integritet og konfidensialitet (art. 5.1. f) og sikkerhet (art. 32).

Ved bruk av databehandler (spørreskjemaleverandør, skylagring, videosamtale o.l.) må behandlingen oppfylle kravene til bruk av databehandler, jf. art 28 og 29. Bruk leverandører som din institusjon har avtale med.

For å forsikre dere om at kravene oppfylles, må prosjektansvarlig følge interne retningslinjer/rådføre dere med behandlingsansvarlig institusjon.

MELD VESENTLIGE ENDRINGER

Dersom det skjer vesentlige endringer i behandlingen av personopplysninger, kan det være nødvendig å melde dette til Personverntjenester ved å oppdatere meldeskjemaet. Før du melder inn en endring, oppfordrer vi deg til å lese om hvilken type endringer det er nødvendig å melde:

<https://www.nsd.no/personverntjenester/fyll-ut-meldeskjema-for-personopplysninger/melde-endringer-i-meldeskjema>

Du må vente på svar fra Personverntjenester før endringen gjennomføres.

OPPFØLGING AV PROSJEKTET

Personverntjenester vil følge opp underveis (hvert annet år) og ved planlagt avslutning for å avklare om behandlingen av personopplysningene er avsluttet/pågår i tråd med den behandlingen som er dokumentert.

Kontaktperson hos Personverntjenester: Lisa Lie Bjordal

Lykke til med prosjektet!



INFORMASJON OM KOSTINTERVJU I BONEWHEEL-STUDIEN

- I løpet av de to neste ukene vil du bli oppringt på 3 tilfeldige dager for å bli intervjuet om hva du spiste og drakk dagen før. Passende tidspunkt avtales med deg på testdag 1.
- Vi ønsker å få et reelt bilde av hvordan du spiser og drikker til vanlig for å kunne gi deg best mulig ernæringsveiledning. Derfor vil vi at du spiser og drikker helt normalt i testperioden – du skal ikke prøve å imponere oss eller tilpasse kostholdet fordi det blir registrert. Slik får vi det riktige bildet av ditt kosthold og kan gi deg spesifikke råd i etterkant.
- Du vil bli oppringt på video (eller eventuelt telefon), og det avtales på forhånd når på dagen som vanligvis passer best for deg. Samtalen tar 30-45 min. Emilie vil sende deg en SMS tidligere på dagen, slik at du vet at du vil bli oppringt senere. Svar da på SMSen om det passer til avtalt tidspunkt.
- Fint om det er mulig å ta samtalen hjemme på kjøkkenet, hvor du kan hente fram tallerken, kopp og glass som du vanligvis bruker for å forklare mengdene mat og drikke. Ha bildebok (tilsendt per mail i forkant av intervju) med bilder av porsjonsstørrelser tilgjengelig under intervju. Hvis du ikke ønsker å ta samtalen på video er det fint om du sender bilder av servise (kopp, tallerken, osv.) du vanligvis bruker (så vi ser størrelsen på de).
- I intervjuet vil du bli spurt om hva du spiste og drakk i løpet av det siste døgnet. Emilie vil hjelpe deg trinnvis med å huske tilbake. Først vil dere gå gjennom tidspunktene for matinntak og deretter se på detaljene i hvert måltid. Emilie vil også spørre kort om hva du gjorde i går, om du evt. gjennomførte trening dagen før, slik at du kan huske om du spiste eller drakk noe rundt ulike aktiviteter. På slutten vil dere gå gjennom det Emilie har notert for å sjekke at ingenting er glemt.

Kontaktinformasjon:

PhD-stipendiat Linn C. Risvang

Tlf: 90689951

Mail: linncr@nih.no

Masterstudent Emilie Moberg

Tlf: 91321897

Mail: emiliem@nih.no

SOP 24-hour dietary recall BoneWheel

- Three unannounced 24-hour dietary recalls will be conducted within two weeks around each test day (baseline/12weeks/24weeks test day). In total nine 24-hour dietary recalls will be performed for each subject in the study
- Estimated time per 24 h dietary recall: 30-45 minutes
- The interview will be conducted in a structured step-by-step manner in order to increase accuracy:
 1. Overview – time and occasion when food and beverages were consumed, and information about yesterday's training (or no training).
 2. Quick list – respondent speaks uninterrupted about food and drinks consumed
 3. Detailed cycle – detailed information on each meal
 4. Forgotten foods list
 5. Final probe – go through the interview and make a summary
- The dietary data will be done by a trained nutritionist and coded in KBS (Kostberegningssystemet, UiO)

Instructions to the participant before the interview:

- Inform the participant that three unannounced 24-hour dietary recalls will be conducted within the next two weeks
- Estimated time is 30-45 minutes each day
- Inform the participant that she/he can bring her/his user-controlled personal assistance to the interview, if she/he wants to
- Inform the participant that he/she will receive a SMS on the day of the interview asking if he/she is available for an interview that day and if yes; the participant will receive an email with a Zoom-link that shall be used for the interview. Contact information will be extracted from the study's interest form <https://www.survey-xact.no/LinkCollector?key=P4U7C84TSP35>, or from the contact form: “Q1.2 BoneWheel Kontaktinformasjon deltaker”
- Instruct the participant to not make any changes to their diet or eating pattern during this period
- Clarify that there is no right or wrong choice of foods
- Inform the participant that he/she will receive a digital picture booklet by email, which shall be used during the interview to estimate their portion sizes. <https://www.med.uio.no/imb/forskning/prosjekter/norkost/>
- Inform the participant that you will ask about her/his training at recall days

Information that shall be given before the first interview (at the very start of the interview):

Inform the participant that the interview will be conducted in a structured step-by-step manner (5step method) in order to increase accuracy. Inform the participant about the order of the interview:

- Step 1-2 is an overview of meals (time and occasion, and quick list) and information about their training
 - Step 3 is a detailed cycle with detailed information on each meal
 - Step 4 is a checklist of potential forgotten foods
 - Step 5 is the finale probe: go through the interview and make a summary in the end
-
- Clarify that the 24-hour period begins from awakening yesterday to awakening the day of the interview (night also included)
 - Clarify that there is no right or wrong choice of foods and that we want detailed information on their actual intake that specific day
 - Inform the participant that food and/or drinks used before/during/after training is also a part of the daily intake
 - Inform the participant that you are coding their food intake into a computer coding program during the step three of the interview, so that they understand if you use some time to find the right code before the next question
 - Ask if the participant got his/her picture booklet nearby

Conducting the interview

Step 1-2: Time and occasion, and quick list: Ask about times and occasions at which food or drink was consumed, a quick list of foods and beverages consumed at each meal, and if they did any training yesterday.

- When did you wake up yesterday?
- When was the first time you consumed anything to drink or eat?
- Let the respondent speak uninterrupted
- If he/she stops, ask about when the next time food/drink was consumed
- Let the respondent make a quick list of foods and beverages consumed
- Ask when the respondent went to bed and if he/she had anything to drink/eat before bed and if they had anything during the night
- Ask the participant if they did any **training yesterday** and if so: ask about the details of the training (time of the day, type of training and duration of the training) and if they had any food or drinks during the training
- Ask the participant if he/she consumed any nutritional supplements, cod oil, antioxidants, herbs, probiotics or other sports nutrition products (like protein supplement) yesterday?
- Ask the participant if this was a normal day, in terms of food intake, for him/her

Step 3: Detailed cycle: Ask the respondent to define the different meals (open question) and ask in detail what he/she consumed at each occasion

- Ask about:

- Food labels (ask the participant to show the food label or food products on camera, if possible, or share screen to show food/label information online)
- Volume and measurement. Ask the participant to use the picture booklet to estimate the portion size.
- Preparation methods. Raw? Fried? Cooked? Added Salt? Spices? Oil? Butter?
- If the participant eats homemade dishes ask about the recipes, amounts, combinations, preparations (oil, butter, salt etc). If possible, ask the participant to send the recipes by email or if its online; send a link to the recipe.
- Ask if the participant ate the whole meal that she/he prepared? Any leftovers?
- If the participant ate bread; ask if they used butter (and what type) and ask detailed questions about what type of spread/topping they used? Any greens on top etc?
- Ask if the participant had something to drink during the meal or in between the meals
- If the participant drunk coffee or tea, ask if they added any milk/cream/sugar
- Sports nutrition products: ask the participant to send pictures of the sports nutrition products (nutrition values and preparation methods (30 g energy powder per 500 ml water etc). The interviewer (nutritionist) will add the products to KBS if it's not already a code for the product (or a similar product).
- Supplements: Ask the participant about the label of the supplement, the dosage and nutritional values of the products. Ask the participant to send picture of the supplement (with the label, dosage and nutritional values) by email after the interview.

Step 4: Forgotten food list: Probe the respondent with a forgotten foods list

- Read the list and ask if she/he ate any of these yesterday
- Tell the respondent to answer yes or no after each question

Forgotten food list:

- Chewing gum or pastilles
- Chips or nuts
- Beer, wine, spirits or any other alcohol
- Cookies, crackers, pastries
- Soda, juice, lemonade
- Coffee, tea
- Water
- Chocolate or ice cream
- Candy
- Fruits or dried fruits
- Snacks vegetables (like carrots)
- Any leftovers from the day before, dinner etc.
- Any fast-food
- Any foods/snacking on the go (gas station, bakery, kiosk, café, grocery shopping etc)
- Any snacking while prepping food/cooking?
- Additional supplements
- Additional sports nutrition products? Protein powder?

Step 5: Final probe:

- Go through the interview at the end and ask if you have forgotten some food/drinks
 - Ask if the participant had anything to eat in between meals
 - Ask if the respondent drunk anything between meals
 - Push “Validate” on KBS and see if there are any missing items (missing volumes etc.) or missing/invalid codes.
 - Check total energy intake and have a look if it’s a reasonable number for the participant
 - Push “save” in KBS and remind the participant that he/she can send the pictures of food labels to my email (if applicable for this participant) and that they can send me additional information about their food intake, if they had forgotten something during this interview.

After the interview:

- After the interview is done you have to extract the data from KBS by downloading an excel file. You do that by pushing “Beregning”. Then choose “personid” under “personfilter” and “løpedagID” under “konsumfilter”. Under “rapport” you choose “**stoffinntak for hver person**”, enhet: “pr person pr dag” and under “stoffer” you chose “enkeltstoffer” and then you choose these nutrients: *water, total energy (kcal and Kj), protein, carbohydrates, added sugars, fiber, fat, saturated fats, transfats, monounsaturated fats, polyunsaturated fats, omega-3, omega-6, vitamin D, iron and calcium*. In total 17 nutrients. Choose “etter konsumfilter” under “persondivisor” and “etter konsumfilter” under Dagdivisor. Then push “beregning” and you can download the excel sheet with the dietary data from the interview.
- After that you choose “**energi prosentfordeling for hver person**” under “rapport” and “beregning”, to download another excel file with energy percentages for each nutrient.
- Then you choose “**matvarer/stoffer per måltid**” under “rapport” and “beregning”, to download another excel file with an overview of what and how much nutrients each meal consists of.
- Extract the data from all the three excel sheets into one excel file. Save the excel file in the folder “BoneWheel” at your computer and then upload the excel file to the BoneWheel OneDrive folder like this: “Testdocuments” + “participant specific folders” + “baseline/12 weeks/24 weeks test day” and then save it to a “24 h dietary recalls” folder and it should be named like this: BW_FPxx_Tx(testdag)_DayX (of 3). Delete the files on your computer.
- Dietary data ready for analyze will be: water/fluid, total energy (kcal(manually calculated) and Kj), protein, carbohydrates, added sugars, fiber, fat, saturated fats, transfats, monounsaturated fats, polyunsaturated fats, omega-3, omega-6, vitamin D, iron and calcium.



Bildehefte

med porsjons- størrelser



En landsomfattende
kostholdsundersøkelse

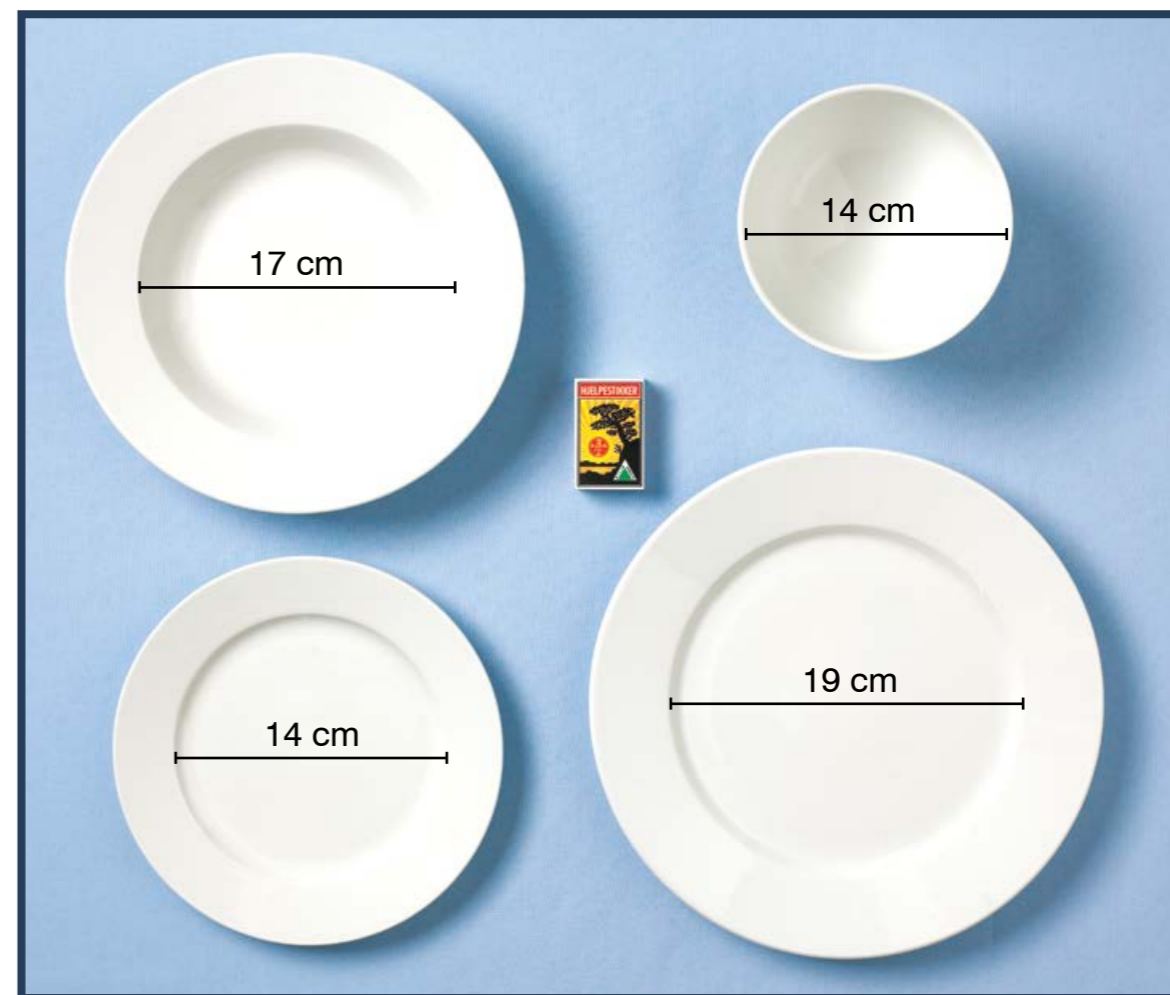
Innhold

Bildnr.	Side	Bildnr.	Side
1.	Størrelse på tallerkenene som er brukt i bildeheftet	3	
2.	Dype tallerkener	3	
3.	Glass	4	
4.	Kopper	4	
5.	Plast- og pappkrus	4	
6.	Grovhetsmerker for brød	5	
7.	Rundstykker	5	
8.	Ovale brødsriver, fasong og tykkelse	6	
9.	Firkantede brødsriver, fasong og tykkelse	8	
10.	Smør og margarin	10	
11.	Kaviar	10	
12.	Leverpostei	11	
13.	Syltetøy	11	
14.	Majonessalat	12	
15.	Ost	12	
16.	Frokostblanding	13	
17.	Cornflakes	13	
18.	Yoghurt	14	
19.	Grøt	14	
20.	Suppe	15	
21.	Omelett	15	
22.	Lasagne	16	
23.	Kjøttsaus	16	
24.	Pizza	17	
25.	Pizza, firkanter	17	
26.	Wok	18	
27.	Gryterett	18	
28.	Taco	19	
29.	Kjøtt i strimler	19	
30.	Helt kjøtt	20	
31.	Kjøttboller, kjøttkaker og burgere	20	
32.	Kylling	21	
33.	Reker	21	
34.	Fiskefilet	22	
35.	Stekt fisk	22	
36.	Spagetti og annen pasta	23	
37.	Ris	23	
38.	Pommes frites	24	
39.	Poteter	24	
40.	Saus	25	
41.	Salat	25	
42.	Grønnsaksblanding	26	
43.	Brokkoli	26	
44.	Bær	27	
45.	Jordbær	27	
46.	Druer	28	
47.	Iskrem	28	
48.	Formkake	29	
49.	Brownie	29	
50.	Bløtkake	30	
51.	Smågodt	30	
52.	Nøtter	31	
53.	Potetgull	31	

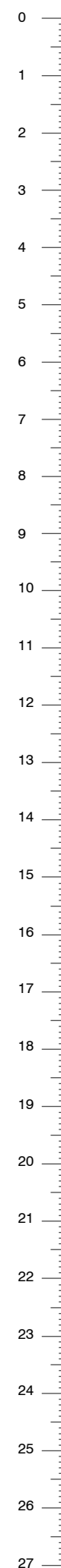
Foto: Alf Börjesson, Eva Brænd, Jon Marius Nilsson
 Design: Anagram Design
 Tegningene av brød: fra EPIC-SOFT bildebok – laget til Kvinner og kreft-studien ved Universitetet i Tromsø, Norge.

Grovhetsmerker for brød: Brødskalamerkene er brukt etter tillatelse fra Baker- og Konditorbransjens Landsforening, som er merkeieier.

1. Størrelse på tallerkenene som er brukt i bildeheftet



2. Dype tallerkener



3. Glass



4. Kopper



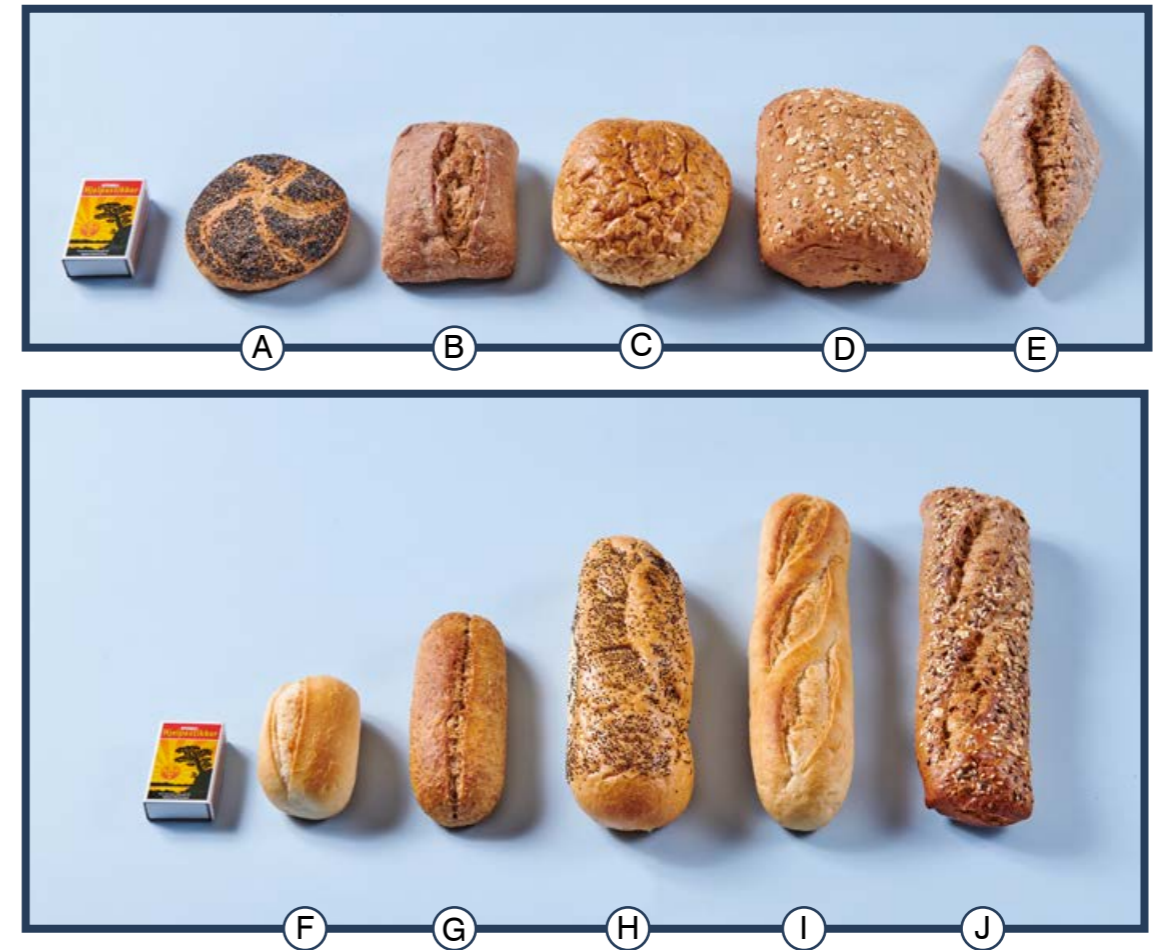
5. Plast- og pappkrus



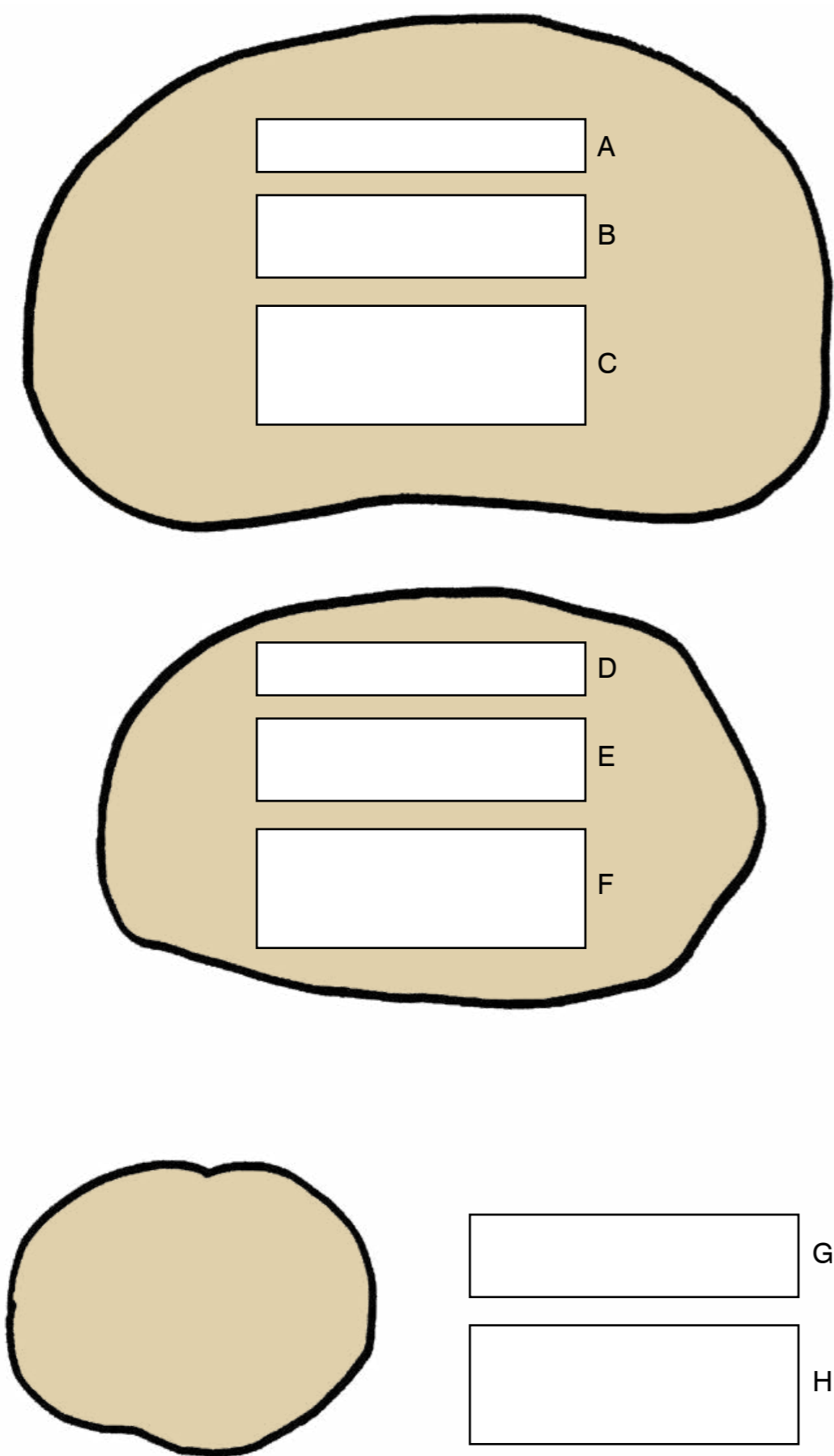
6. Grovhetsmerker for brød



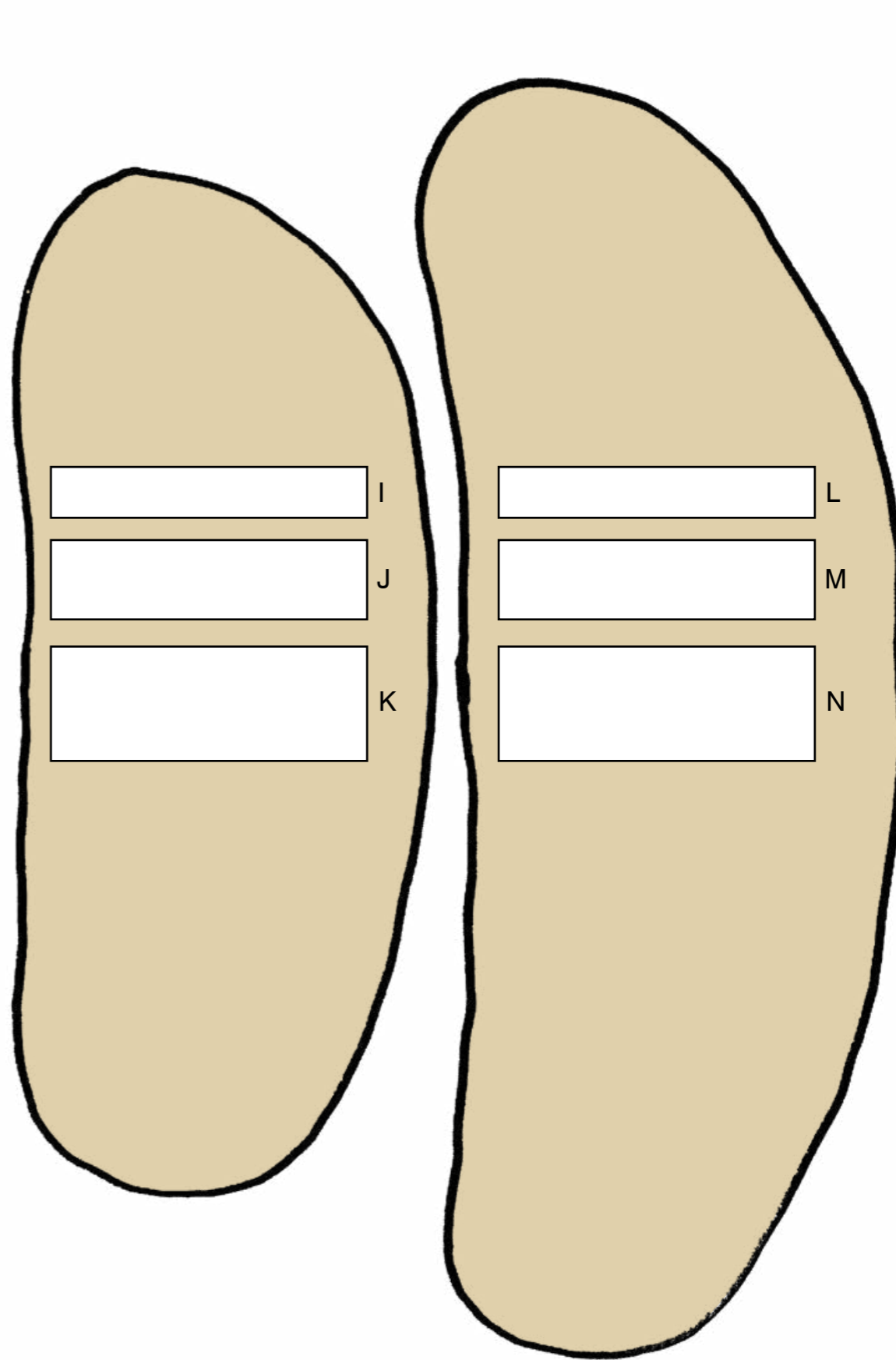
7. Rundstykker



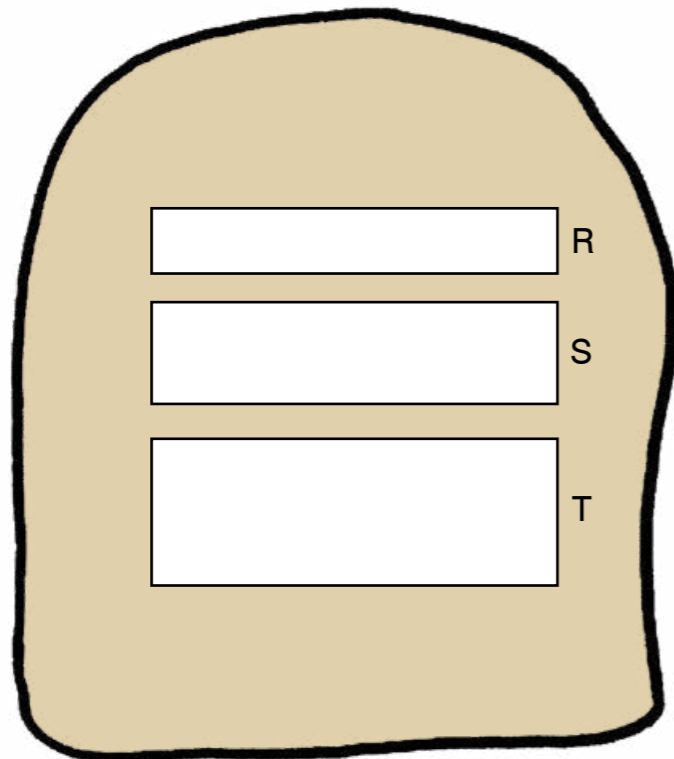
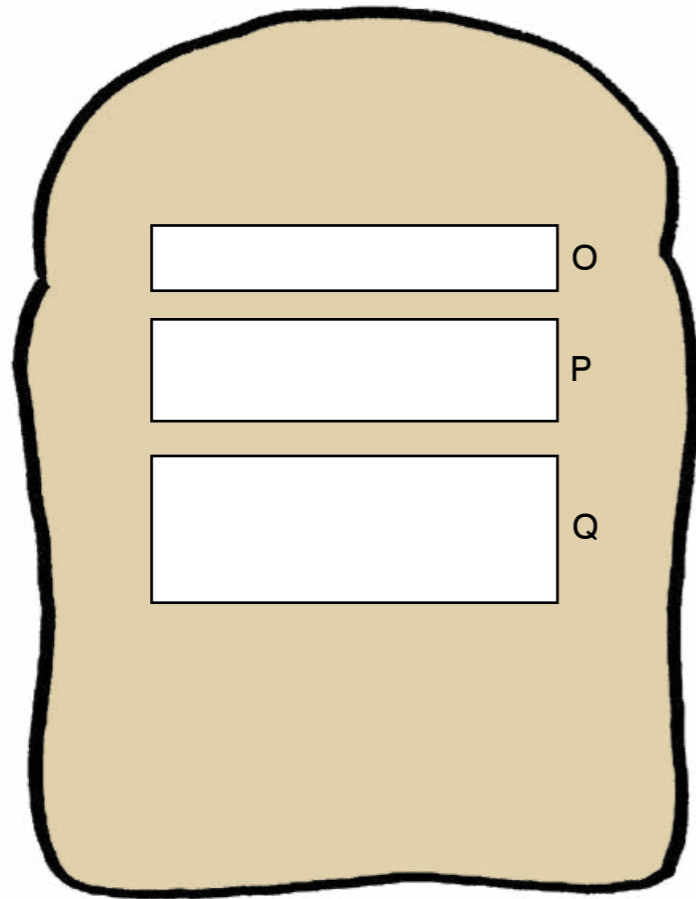
8. Ovale brødsiver, fasong og tykkelse



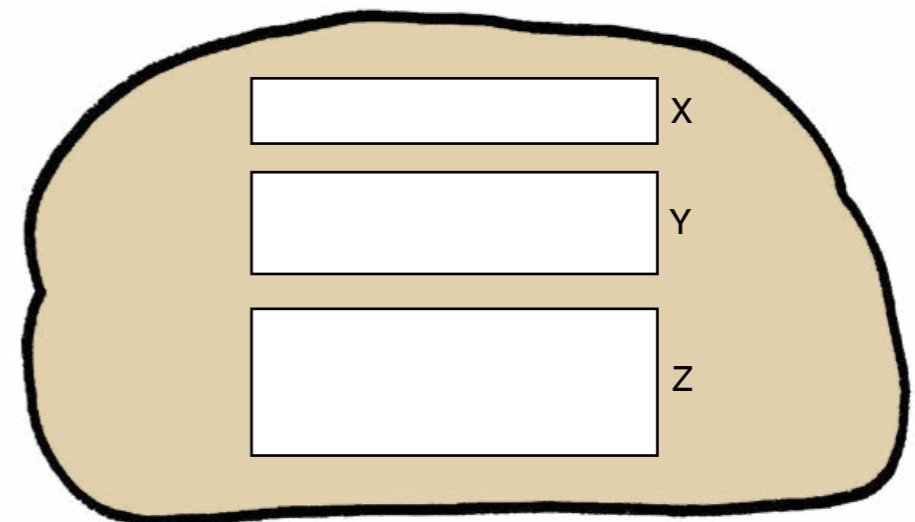
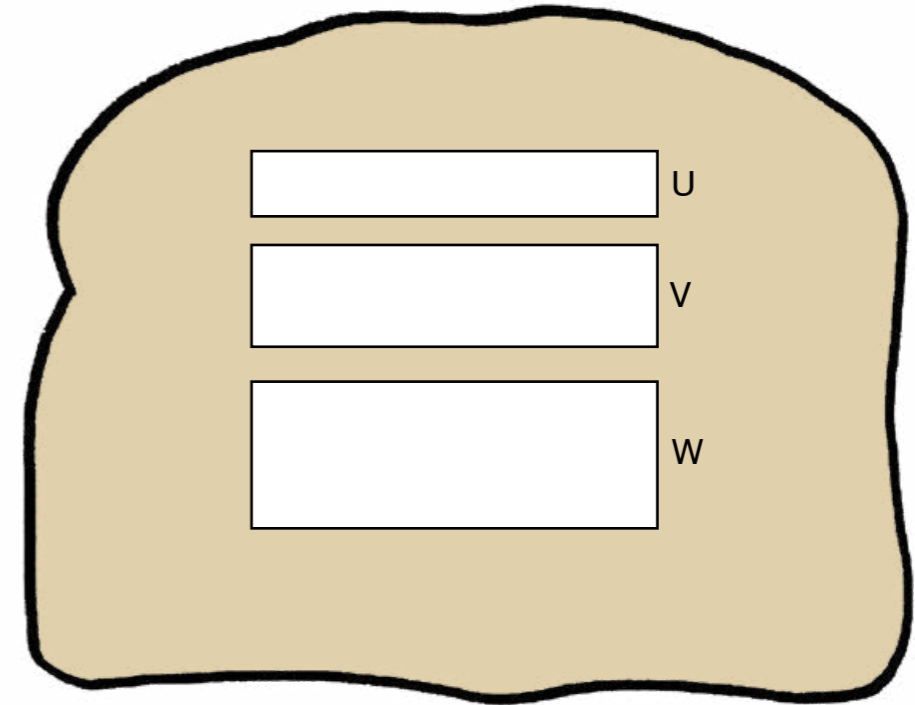
8. Ovale brødsiver, fasong og tykkelse (forts)



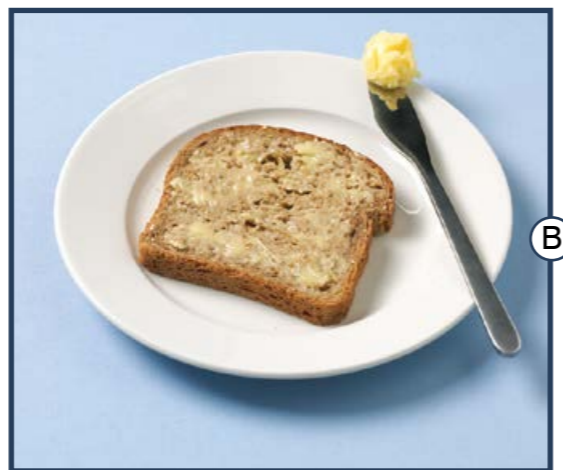
9. Firkantede brødsiver, fasong og tykkelse



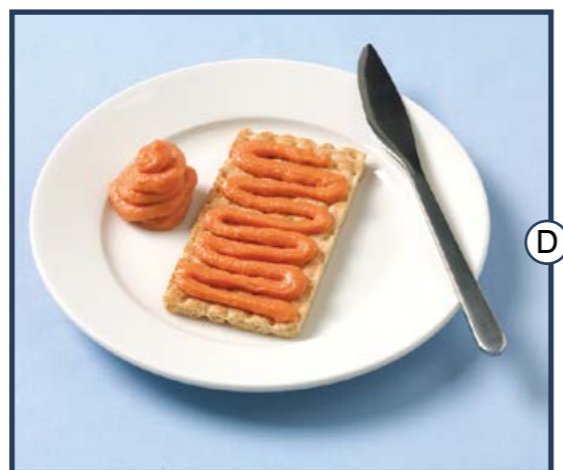
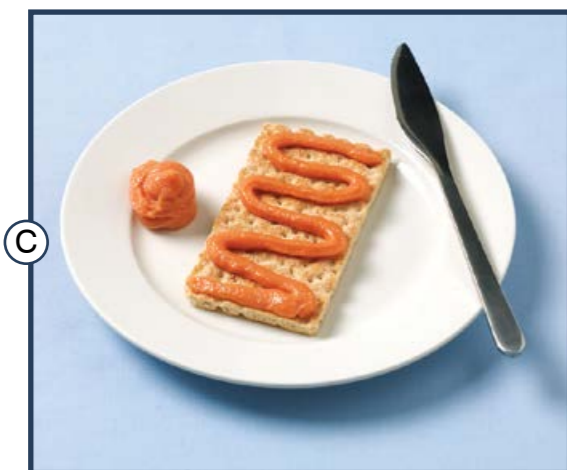
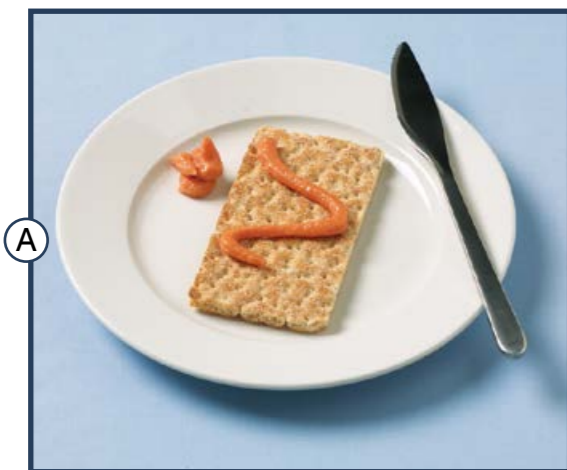
9. Firkantede brødsiver, fasong og tykkelse (forts)



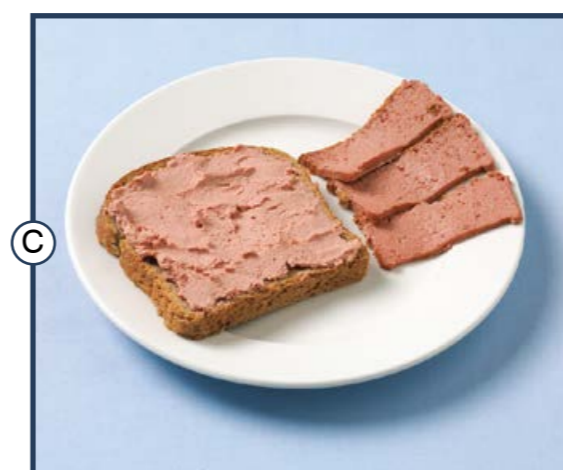
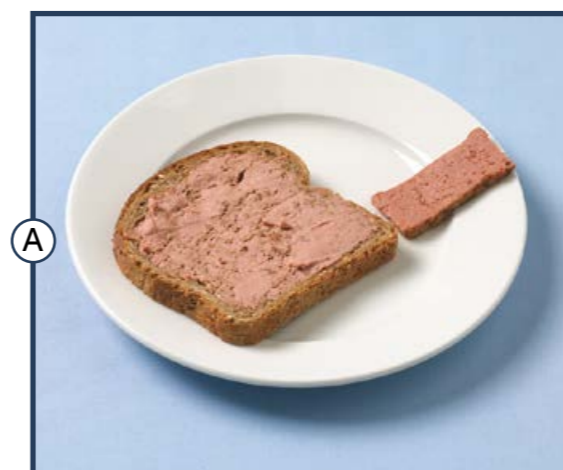
10. Smør og margarin



11. Kaviar



12. Leverpostei



13. Syltetøy



14. Majonessalat



15. Ost



16. Frokostblandning



17. Cornflakes



18. Yoghurt



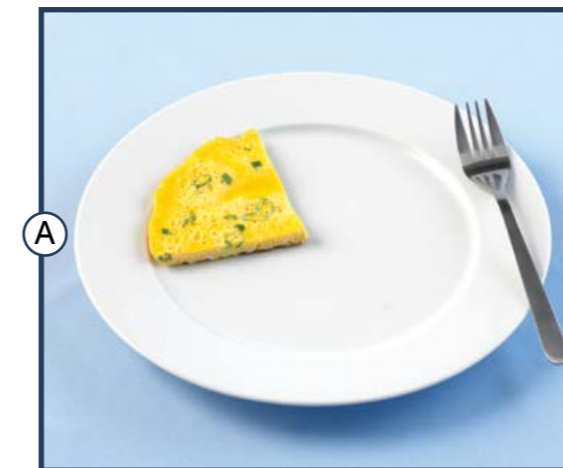
19. Grøt



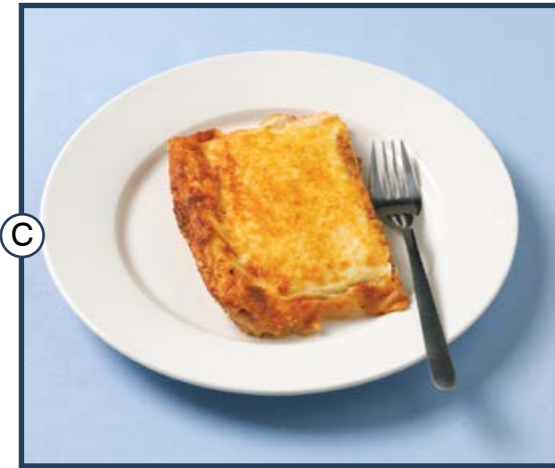
20. Suppe



21. Omelett



22. Lasagne



23. Kjøttsaus



24. Pizza



25. Pizza, firkanter



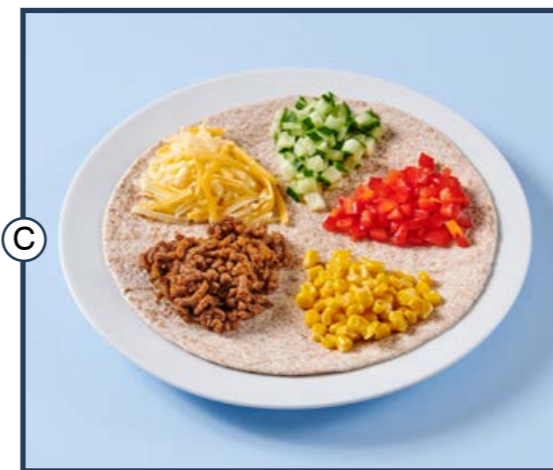
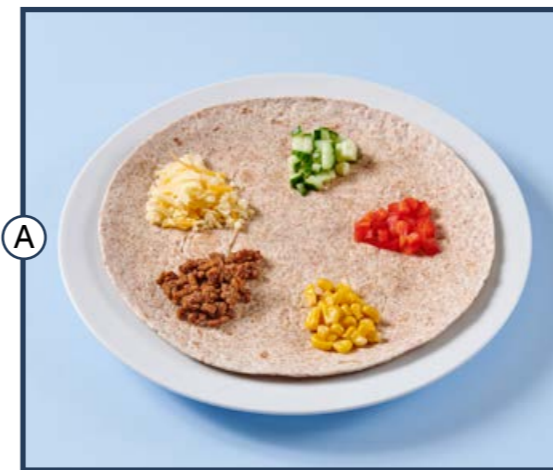
26. Wok



27. Gryterett



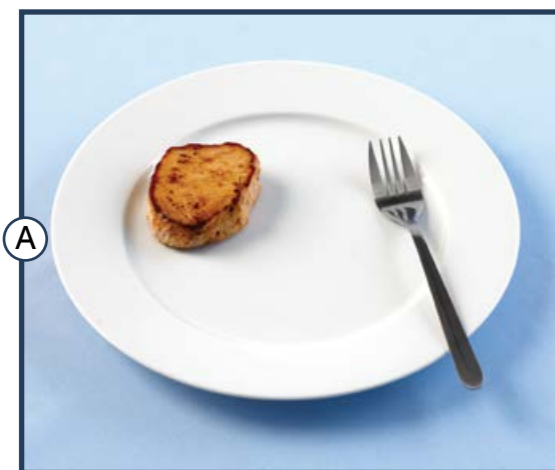
28. Taco



29. Kjøtt i strimler



30. Helt kjøtt



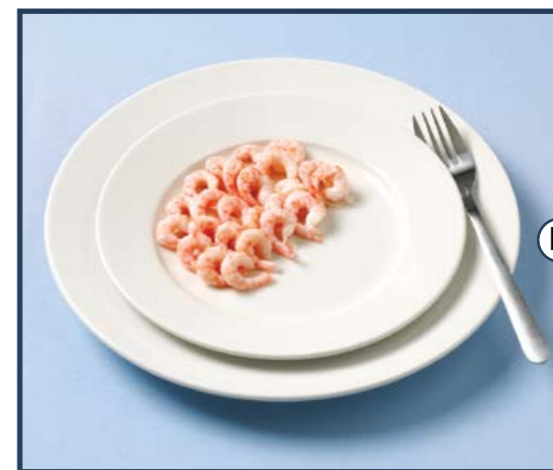
31. Kjøttboller, kjøttkaker og burgere



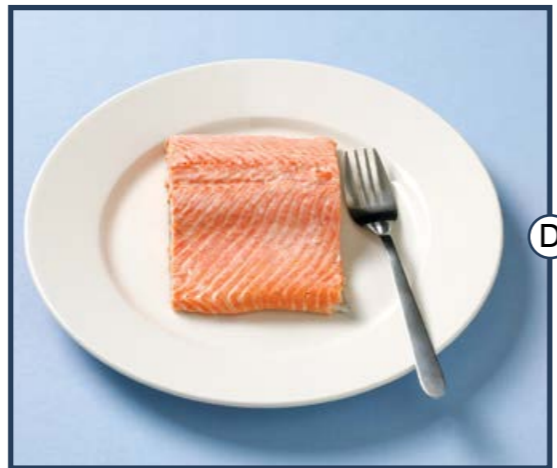
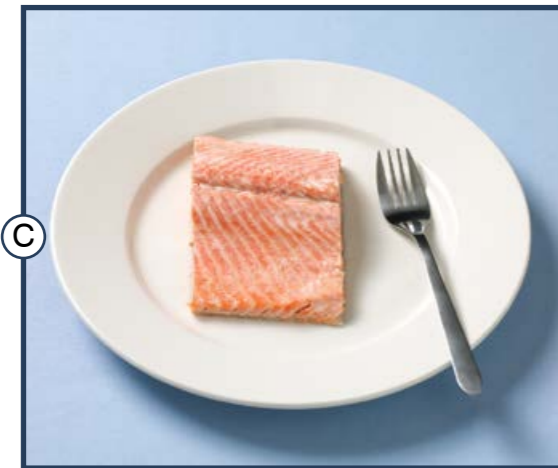
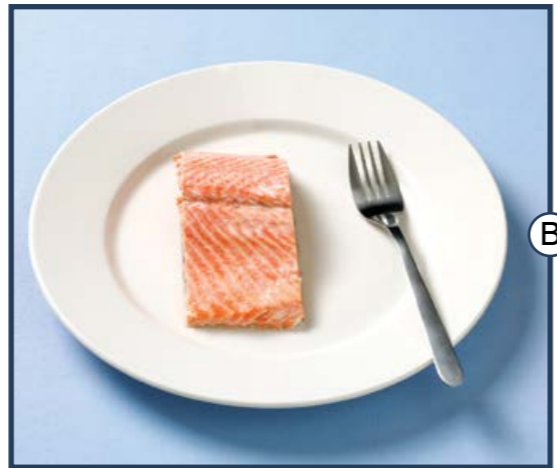
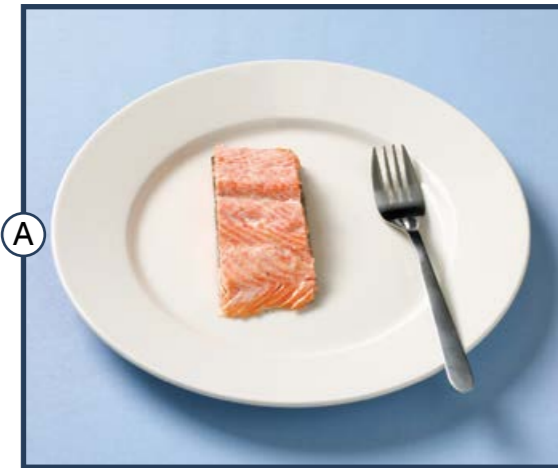
32. Kylling



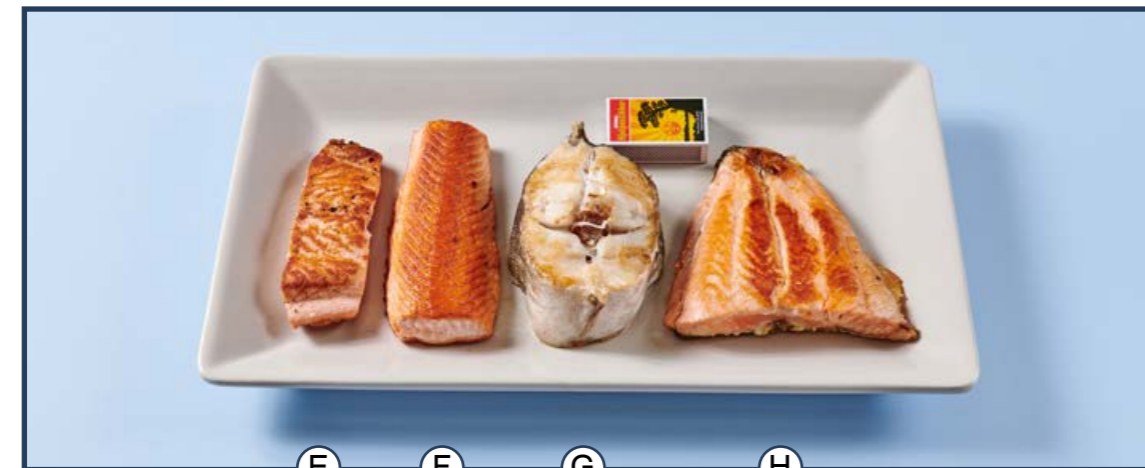
33. Reker



34. Fiskefilet



35. Stekt fisk



36. Spagetti og annen pasta



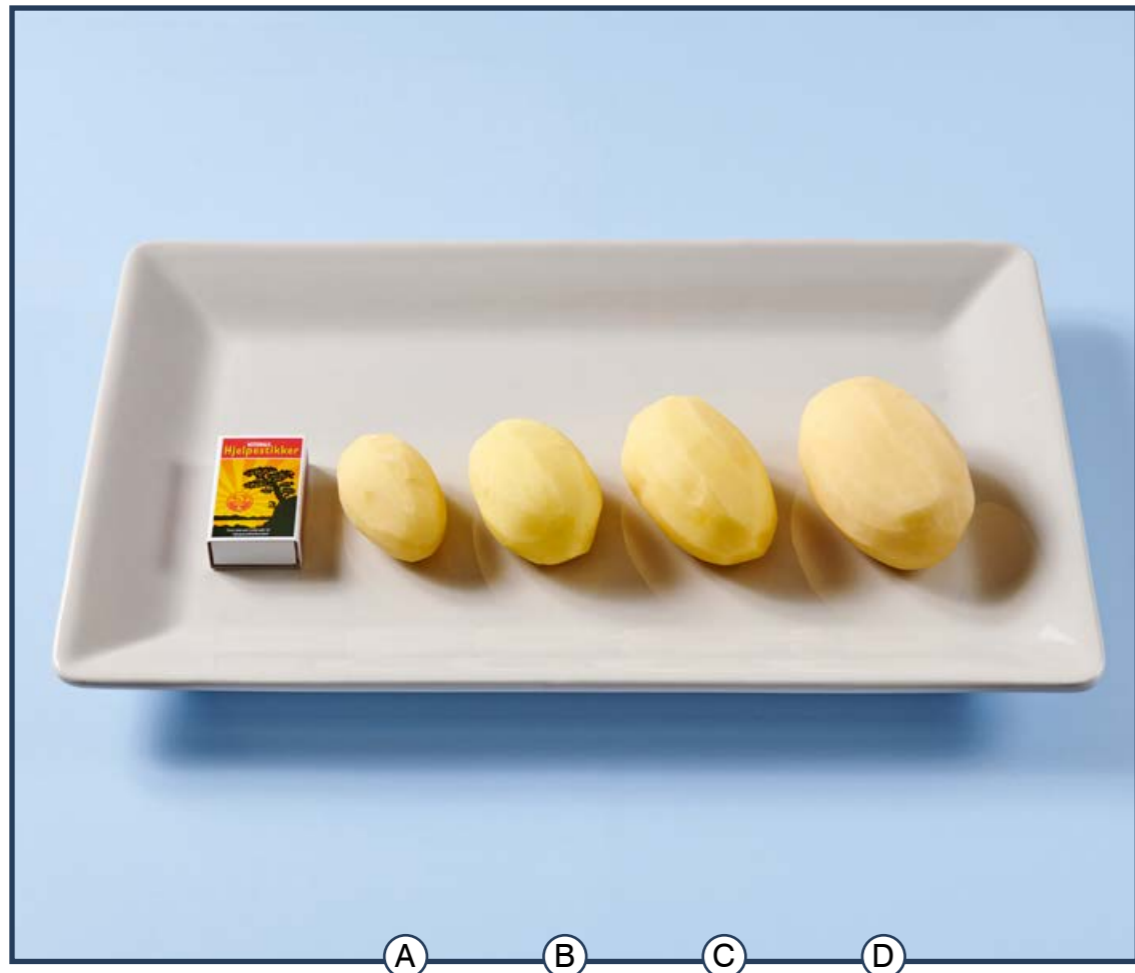
37. Ris



38. Pommes frites



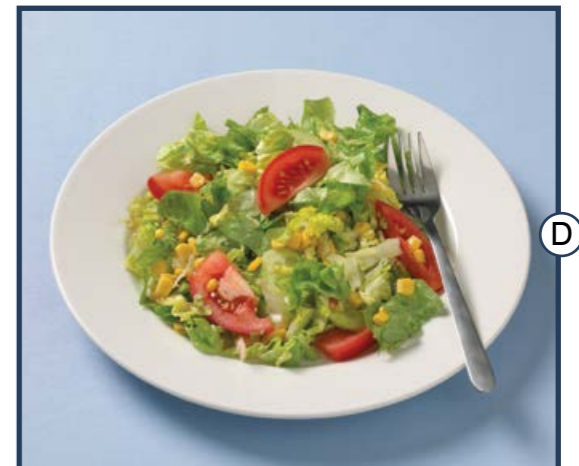
39. Poteter



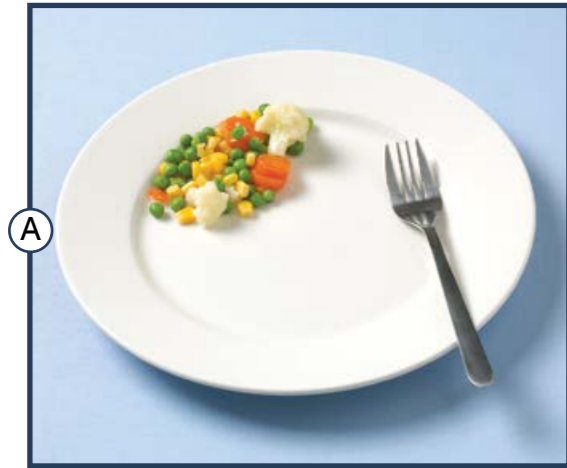
40. Saus



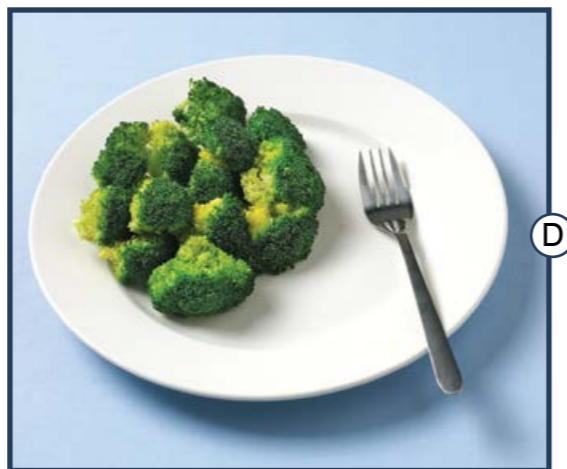
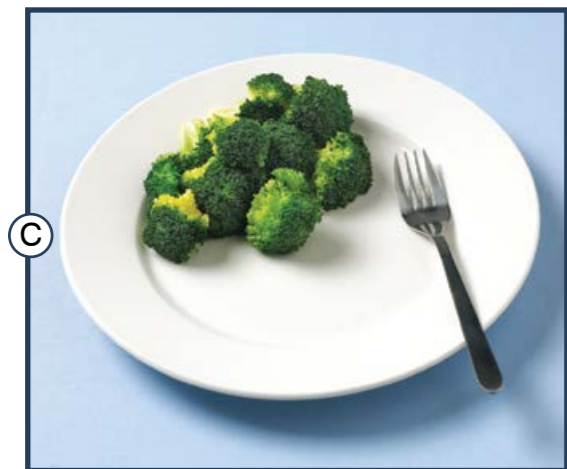
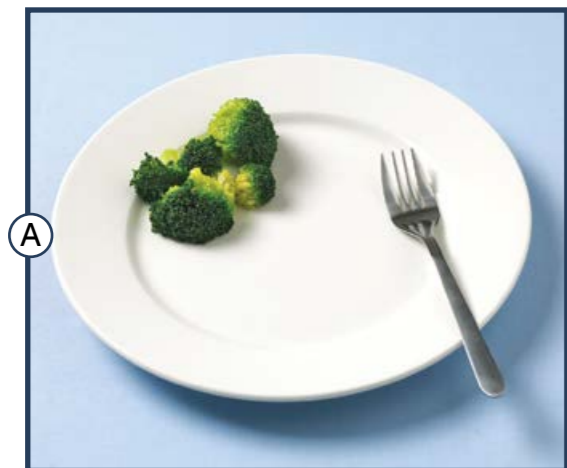
41. Salat



42. Grønnsaksblanding



43. Brokkoli



44. Bær



45. Jordbær



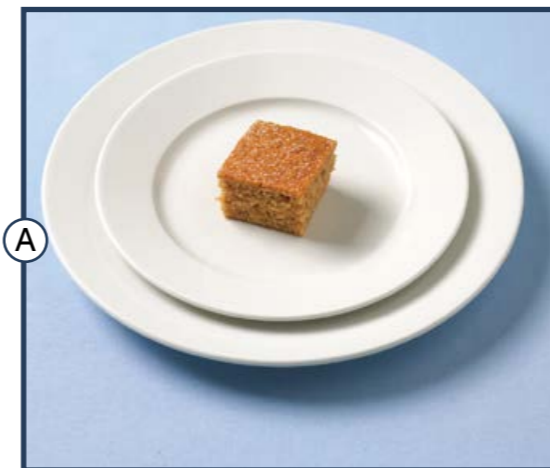
46. Druer



47. Iskrem



48. Formkake



49. Brownie



50. Bløtkake



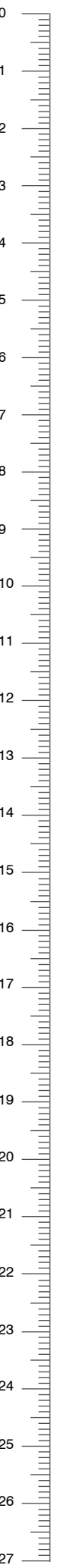
51. Smågodt



52. Nøtter



53. Potetgull





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Background questionnaire (Q1)

BoneWheel Bakgrunn, medisinsk og funksjonsnedsettelse

Vennligst fyll inn ditt FP-nummer (din studie-id) som du har blitt tildelt (eks: 003)

Ved ja/nei spørsmål, sett en hake i boksen med det riktige svaret og beskriv svaret dersom mer informasjon blir etterspurt.

Karakteristikk

Fysiologisk kjønn

- (1) Kvinne
(2) Mann

Tiltalepronomen

- (1) Han/Ham
(2) Hun/Henne
(4) Hen
(3) De/Dem

Fødselsdato

Høyde (cm)

Vekt (kg)

Utdanningsnivå

- (5) Grunnskole 1 - 9/10 år
- (6) Videregående
- (7) Universitet 3 år (Bachelor)
- (8) Universitet 4-5 år (Master)
- (9) Universitet høyere utdanning 5 år +
- (10) Fagbrev

Sivilstatus

- (5) Gift
- (6) Enslig
- (7) Separert
- (8) Skilt
- (9) Enke/enkemann
- (10) Forlovet
- (11) Samboer
- (12) I et forhold

1. Funksjonsnedsettelse

Har du en ryggmargsskade?

- (3) Ja

(2) Nei

A) Hvilken type funksjonsnedsettelse? Flere svaralternativer er mulig.

- (1) Bevegelseshemning/Forflytningshemning
- (2) Synshemning/Redusert synsfunksjon
- (3) Utviklingshemning/Kognitiv funksjonsnedsettelse
- (4) Revmatiske sykdommer (muskelskjelettsykdommer)
- (5) Cerebral parese
- (6) Annet

Hvilken grad CP har du?

- (1) 1
- (2) 2
- (3) 3
- (4) 4
- (5) 5

Kommenter gjerne hvilken type funksjonsnedsettelse

B) På hvilket nivå er ryggmargsskaden din?

- (1) Høyt thorakalt nivå (Th1-Th5)
- (2) Lavt thorakalt nivå (Th6-Th12)
- (3) Lumbalt nivå (L1-L5)
- (4) Lavere enn lumbalt nivå
- (5) Vet ikke

Er ryggmargsskaden din komplett eller inkomplett?

- (1) Komplet (ingen følelse eller bevegelse i noen del av kroppen nedenfor skadenivå)
- (2) Inkomplet (har følelse eller kan bevege noen deler av kroppen nedenfor skadenivå)

Nevrologisk klassifikasjon av ryggmargsskaden ("ASIA" (American Spinal Injury Association) Impairment Scale; AIS)

Hva slags AIS-kategori er din ryggmargsskade?

- (1) A - ingen muskelfunksjon og ingen følelse under skadenivået i ryggmargen
- (2) B - ingen motorisk funksjon under skadenivået
- (3) C - bevart motorisk og sensorisk funksjon under skadenivået, men for lite til at dette gir praktisk nyttig funksjon
- (4) D - muskelfunksjon og sensorisk funksjon under skadenivået som gir praktisk nyttig funksjon
- (5) E - ubetydelige nevrologiske begrensninger som følge av ryggmargsskaden
- (6) Vet ikke

C) Når oppsto skaden?

- (1) Fra fødsel
- (2) Ved et annet tidspunkt

Når oppsto skaden?

Hvordan begrenser din dysfunksjon deg mest?

Øvrige nedsatte funksjoner:

Andre kommentarer:

2. Idrett

Er du, eller har du vært idrettsutøver?

(3) Ja

(2) Nei

Hva er din(e) IPC klassifiseringskode(r)?

Hvilke(n) idrett(er) driver du med nå?

Hvor gammel var du da du startet?

Hvor mange timer i uken trener du i nåværende periode?

Er du på junior/senior landslag i idretten din?

(1) Ja

(2) Nei

Hvor mange år har du vært på junior/senior landslag?

Er du idrettsutøver på heltid?

(3) Ja

(2) Nei

Hva gjør du ved siden av idretten?

(1) Heltidsjobb

(2) Deltidsjobb

(3) Studier

(4) Annet

Hvis annet, kommenter gjerne hva:

Hva er din beste plassering i Norgesmesterskap (NM)/enkeltkonkurranse i Norgescup?

Hva er din beste plassering i VM/PL eller enkeltkonkurranse i verdenscupen?

Andre kommentarer:

2.1 Treningshistorikk

For deg som har en ervervet skade eller amputasjon:

Vil du si at du er fysisk mer aktiv, mindre aktiv eller omtrent like aktiv som før du ble skadet?

- (1) Fysisk mer aktiv
- (2) Mindre aktiv
- (3) Omtrent like aktiv

Hvor ofte har du drevet med følgende treningsaktiviteter på fritiden det siste året?

Aldri Under 1 gang 1 gang pr. uke Flere ganger

	pr. uke		pr. uke	
Svømming	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>
Langrenn	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>
Aerobic	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>
Håndball	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>
Fotball	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>
Ishockey	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>
Basketball	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>
Dans	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>
Turn	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>
Rytmisk gymnastikk	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>
Styrketrening	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>

Kampsport

(1)

(2)

(3)

(4)

Ridning

(1)

(2)

(3)

(4)

Alpint

(1)

(2)

(3)

(4)

Friidrett

(1)

(2)

(3)

(4)

Snowboard

(1)

(2)

(3)

(4)

Golf

(1)

(2)

(3)

(4)

Skøyter

(1)

(2)

(3)

(4)

EL-bandy

(1)

(2)

(3)

(4)

Volleyball

(1)

(2)

(3)

(4)

Rugby

(1)

(2)

(3)

(4)

Bordtennis

(1)

(2)

(3)

(4)

Annet

(1)

(2)

(3)

(4)

Kommenter gjerne hvilken aktivitet i boksen under

Vi er interesserte i å finne ut underliggende grunner for hvorfor personer er delaktige eller ikke i fysisk aktivitet og trening. Ved å bruke skalaen under, vennligst marker i hvilken grad påstandene stemmer for deg.

Hva er grunnen til at du trener?

	Ikke sant for meg 0	1	Delvis sant for meg 2	3	Veldig sant for meg 4
Jeg trener fordi andre sier jeg skal	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>	(5) <input type="radio"/>
Jeg får dårlig samvittighet når jeg ikke trener	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>	(5) <input type="radio"/>
Jeg verdsetter fordelene av trening	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>	(5) <input type="radio"/>
Jeg trener fordi det er gøy	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>	(5) <input type="radio"/>
Jeg skjønner ikke hvorfor	(1) <input type="radio"/>	(2) <input type="radio"/>	(3) <input type="radio"/>	(4) <input type="radio"/>	(5) <input type="radio"/>

jeg skulle måtte trene

Jeg deltar i trening fordi venner/familie/partner mener jeg bør

(1)

(2)

(3)

(4)

(5)

Jeg skammer meg når jeg går glipp av en treningsøkt

(1)

(2)

(3)

(4)

(5)

Det er viktig for meg å trene regelmessig

(1)

(2)

(3)

(4)

(5)

Jeg skjønner ikke hvorfor jeg skal bry meg om å trene

(1)

(2)

(3)

(4)

(5)

Jeg liker treningsøktene mine

(1)

(2)

(3)

(4)

(5)

Jeg trener fordi andre ikke vil være fornøyd med meg om jeg ikke gjør det

(1)

(2)

(3)

(4)

(5)

Jeg ser ikke noe poeng i å trene

(1)

(2)

(3)

(4)

(5)

Jeg føler meg mislykket om jeg ikke har fått trent på en stund

(1)

(2)

(3)

(4)

(5)

Jeg mener det er viktig å gjøre en innsats for å trene regelmessig (1) (2) (3) (4) (5)

Trening er for meg lystbetont (1) (2) (3) (4) (5)

Jeg føler press fra familie/venner om å trene (1) (2) (3) (4) (5)

Jeg blir rastløs om jeg ikke trener regelmessig (1) (2) (3) (4) (5)

Jeg får glede og tilfredsstillelse av å delta i trening (1) (2) (3) (4) (5)

Jeg mener trening er bortkastet tid (1) (2) (3) (4) (5)

Trener du for tiden på treningscenter?

- (1) Ja
- (2) Nei, men jeg har gjort det regelmessig før
- (3) Nei, og jeg har sjelden/aldri gjort det

Er du aktivt medlem av et idrettslag eller en idrettsklubb?

- (1) Ja
- (2) Nei, men jeg har vært medlem før
- (3) Nei, jeg har aldri vært medlem

Navn på idrettslag

Erfaring med styrketrening - med styrketrening mener vi trening hvor du benytter vekter, strikk eller egen kroppsvekt

Har du erfaring med styrketrening?

- (3) Ja
- (2) Nei

Hvilken type?

- (1) Trening med vekter
- (2) Trening med egen kroppsvekt
- (3) Trening med strikk
- (4) Annet

Kommenter gjerne hvilken form for styrketrening

Hvor mange år har du trent styrke?

Trener du styrke nå?

- (3) Ja
- (2) Nei

Hvor mange økter i uka trener du styrke minimum 30 minutter?

- (1) 1
- (2) 2
- (3) 3
- (4) 4+

3. Generell medisinsk

Har du hatt en infeksjon siste 6 måneder? (lungebetennelse, urinveisinfeksjon, etc.)

- (3) Ja
- (2) Nei

Har dette gjort at du har trent mindre / vært mindre fysisk aktiv enn normalt?

- (3) Ja
- (2) Nei

Har du epilepsi?

- (3) Ja
- (2) Nei

Har du en spiseforstyrrelse?

- (3) Ja
- (2) Nei

Hvilken type?

- (1) Anorexia Nervosa
- (2) Bulimi
- (3) Megareksi
- (4) Overspising (binge)
- (5) OSFED (Other Specified Feeding or Eating Disorder)

Har du andre kroniske sykdommer?

- (3) Ja
- (2) Nei

Kryss av for hvilke(n) kroniske sykdommer du har:

- (1) Progressiv nevrologisk sykdom
- (2) Endokrine sykdommer (diabetes mellitus type 1/2, skjoldbruskkjertelsykdommer, forstyrrelser i kalsiumbalansen, metabolsk bensykdom, hypofysesykdommer, kjønshormonforstyrrelser)
- (3) Kreft
- (4) Alvorlig psykisk lidelse
- (5) Malabsorpsjonsproblemer pga. tidligere operasjoner i mage-tarmkanalen
- (6) Inflammatorisk tarmsykdom
- (7) Cøliaki
- (8) Kronisk pankreatitt (bukspyttkjertelbetennelse)
- (9) Medfødt systemisk skjelettdysplasi
- (10) Kroniske inflammatoriske leddgikt-tilstander (revmatoid artritt, psoriasisartritt, ankyloserende spondylitt, lupus)
- (11) Pågående senebetennelse eller muskelskader som ikke er forenlig med treningsintervensjonen
- (12) Sirkulasjonssystemet (medfødte bindevevsforstyrrelser som påvirker aorta og/eller arterier)
- (13) Lever- eller nyresykdom (de som ikke kan omdanne vitamin D til sin aktive form i kroppen), andre tilstander som påvirker vitamin D eller kalsiumabsorpsjon
- (14) Annet

Kommenter hvilke(n) i boksen under

Plages du av smerter?

- (1) Ja, mye
- (3) Ja, litt
- (2) Nei

Hvor har du smerter?

Får du behandling for dine smerter?

- (3) Ja
- (2) Nei

I løpet av den siste uka, i hvilken grad har smerter begrenset dine vanlige fysiske aktiviteter?

- (1) Ikke i det hele tatt
- (2) Svært lite
- (3) En del
- (4) Mye
- (5) Kunne ikke utføre fysisk aktivitet

Har du spasmer?

- (1) Ja, mye
- (2) Ja, litt
- (3) Nei

Hvor i kroppen sitter spasmene? Fyll inn i tekstboks

Hva slags behandling får du for spasmene?

Har du hatt noen benbrudd de siste 6 månedene?

- (3) Ja
- (2) Nei

Hvor har benbruddene oppstått? Fyll inn i tekstboks

Dato for benbrudd:

Har du tidligere tatt DXA-måling for kroppssammensetning og eller benhelse?

- (3) Ja
- (2) Nei

Har du tidligere fått påvist lav bentetthet?

- (3) Ja
- (2) Nei
- (4) Vet ikke

Fyll ut når i tekstboksen.

Har du fått påvist benskjørhet?

- (1) Ja
- (2) Nei
- (3) Vet ikke

Vennligst indiker hvilke(n) behandling du mottar per i dag:

- (1) Medisinsk behandling (vennligst list opp under del 8. Medisiner)
- (2) Trening/fysioterapi inkl. vibrasjonsterapi eller funksjonell elektrostimulering (FES)
- (3) Annen behandling
- (4) Ingen behandling

Ved annen behandling, spesifiser gjerne i tekstboks:

Har du nedsatt kognitiv funksjon?

- (3) Ja
- (2) Nei

Beskriv gjerne hvordan den nedsatte kognitive funksjonen påvirker deg:

Har du noen utfordringer med å kommunisere muntlig?

(3) Ja

(2) Nei

Beskriv hvordan muntlig kommunikasjon kan være utfordrende for deg:

Andre kommentarer:

4. Ernæring

Har du matallergi?

(3) Ja

(2) Nei

Hva er du allergisk mot? (f.eks. laktoseintoleranse, peanøttallergi). Vennligst fyll inn i tekstboksen.

Hva slags reaksjon får du?

Har du fått påvist cøliaki?

(3) Ja

(2) Nei

Har du fått påvist Morbus Chron's eller ulcerøs kolitt?

(3) Ja

(2) Nei

Har vekten din endret seg i løpet av det siste året?

(3) Ja

(2) Nei

Hvor mange kg opp/ned?

Har du et avslappet forhold til mat og vekt?

(3) Ja

(2) Nei

Har det alltid vært slik?

(3) Ja

(2) Nei

Har du måttet avstå fra idrett/fysisk aktivitet pga. ernæringsmessige årsaker, f.eks. tap av menstruasjon, utmattelse grunnet lavt energiinntak?

(3) Ja

(2) Nei

Beskriv i tekstboksen under:

Har du tidligere hatt lavt nivå av vitamin D?

(1) Ja

(2) Nei

(3) Vet ikke

Når er dette sist fastslått?

Endret du kosthold / tok du kosttilskudd?

(3) Ja

(2) Nei

Har du vært til kontroll for ny blodprøve?

(3) Ja

(2) Nei

Dato for blodprøvetaking:

Har du tidligere hatt lavt nivå av jern?

(1) Ja

(2) Nei

(3) Vet ikke

Når er dette sist fastslått?

Endret du kosthold / tok du kosttilskudd?

(1) Ja

(2) Nei

(3) Vet ikke

Har du vært til kontroll for ny blodprøve?

(3) Ja

(2) Nei

Dato for ny blodprøvetaking:

Har du unormale verdier av andre ernæringsparametre? (f.eks. vitamin B12, folsyre, magnesium, kalsium, natrium, kalium)

- (1) Ja
- (2) Nei
- (3) Vet ikke

Endret du kosthold / tok du kosttilskudd?

- (3) Ja
- (2) Nei

Har du vært til kontroll for ny blodprøve?

- (3) Ja
- (2) Nei

Dato for ny blodprøvetaking:

Røyker du?

- (3) Ja
- (2) Nei

Hvor lenge har du røyket? Oppgi svaret i år, måneder eller uker.

Hvor ofte røyker du?

- (1) Hver dag

- (2) Hver uke
- (3) Hver måned
- (4) Sjeldnere

Hvor mange røykpakker i uken? (20-pakker)

- (1) 1-3 pakker i uken
- (2) 4-6 pakker i uken
- (3) 7+ pakker i uken

Hvor mange røykpakker i mnd.? (20-pakninger)

- (1) 1-3
- (2) 4-6
- (3) 7-9
- (4) 10+

Snuser du?

- (3) Ja
- (2) Nei

Hvor lenge har du benyttet deg av snus? Oppgi svaret i år, måneder eller uker.

Hvor ofte snuser du?

- (1) Hver dag
- (2) Hver uke
- (3) Hver måned
- (4) Sjeldnere

Hvor mange bokser i uken?

- (1) 1-3 bokser i uken
- (2) 4-6 bokser i uken
- (3) 7+ bokser i uken

Hvor mange bokser pr. mnd.?

- (1) 1-3
- (2) 4-6
- (3) 7-9
- (4) 10+

Drikker du alkohol?

- (3) Ja
- (2) Nei

Hvor ofte?

- (1) Hver dag
- (2) Hver uke
- (3) Hver måned
- (4) Sjeldnere

Hvor mange enheter i uken ca.?

- (1) 1-3
- (2) 4-6
- (3) 7-9
- (4) 10+

Hvor mange enheter i mnd. ca.?

- (1) 1-3
- (2) 4-6
- (3) 7-9
- (4) 10+

Plages du av overoppheting?

- (1) Ja
- (2) Nei

Svette du lite på ikke-funksjonelle kroppsdeler?

- (3) Ja
- (2) Nei

Bruker du nedkjølingsstrategier utover å drikke?

- (3) Ja
- (2) Nei

Får du ernæringsveiledning?

- (3) Ja
- (2) Nei

Har du hatt noen trening / undervisning om ernæring?

- (3) Ja
- (2) Nei

Følger du noen diett / kostholdsregime i dag?

- (3) Ja
- (2) Nei

Hvilken diett/kostholdsregime følger du?

Andre kommentarer:

5. Magetarmfunksjon

Har du stomi?

- (1) Ja
(2) Nei

Hva slags?

- (1) Ileostomi
(2) Colostomi

Har du utfordringer med absorpsjon av næring fra tarmen?

- (1) Ja
(2) Nei
(3) Vet ikke

Opplever du at stomiens plassering hindrer deg i fysisk aktivitet?

- (3) Ja
- (2) Nei

Har du sonde for næringsinntak?

- (3) Ja
- (2) Nei

Anslå hvor stor del av næringsinntaket (%) ditt er via sonde. La det stå blankt om du er usikker.

Indiker hvilken type sonde:

- (1) Naso gastrisk
- (2) PEG
- (3) PEJ

Andre kommentarer:

6. Assistanse

Har du brukerstyrt personlig assistent?

- (3) Ja

(2) Nei

Hvor mange timer/uke?

Bruker du rullestol hele tiden?

(3) Ja

(2) Nei

Hvor lenge har du brukt rullestol mer enn 50% av våken tid? Oppgi svaret i år, mnd. (eks: 2 år, 6mnd.)

Bruker du gåstol?

(3) Ja

(2) Nei

Bruker du krykker?

(3) Ja

(2) Nei

Hvilken type stol? (Sett ett eller flere kryss)

(1) Elektrisk

(2) Manuell

(3) Manuell med hjelpemotor

(4) Annet

Hvis annet, spesifiser gjerne hva i tekstboksen under:

Bruker du protese?

- (3) Ja
- (2) Nei

Hvor sitter protesen? (arm eller bein, venstre eller høyre og startpunkt)

Bruker du protesen både i trening og hjemme? (Sett ett eller flere kryss)

- (1) Trening
- (2) Hjemme
- (3) Begge

Bruker du andre hjelpemidler?

- (3) Ja
- (2) Nei

Beskriv hvilke andre hjelpemidler du bruker:

Hvilke transportmidler håndterer du? (Sett ett eller flere kryss)

- (1) Kjøre bil
- (2) Håndsykler

(3) Tar offentlig transport

Andre kommentarer:

7. Kvinnehelse

Menstruerer du?

(1) Ja

(2) Nei

Når startet din siste menstruasjon?

Er dette grunnet overgangsalder?

(3) Ja

(2) Nei

Behandles du for overgangsplager?

(3) Ja

(2) Nei

Ved opphørt menstruasjon, vennligst oppgi hvor lang tid den er opphørt (år, mnd., uker):

Bruker du noen form for høydose prevensjonsmiddel, f.eks. p-stav eller p-sprøyte?

(1) Ja

(2) Nei

Hvilken form for høydose prevensjonsmiddel? Vennligst fyll inn i tekstboks under

Er du gravid?

(3) Ja

(2) Nei

Planlegger du graviditet innen de neste 12 månedene?

(3) Ja

(2) Nei

Andre kommentarer:

8. Medisiner og kosttilskudd/homeopatiske midler

Har du i løpet av de siste 6 månedene brukt medisiner? Eks; kortikosteroider, kolesterolsenkende, bisfosfonat (osteoporose), betennelsesdempende, smertestillende

- (3) Ja
- (2) Nei

Hvilke?

- (1) Bisfosfonater
- (2) Teriparatide
- (3) Denosumab
- (4) Raloksifen
- (5) Prednisolon/steroider/androgene steroider
- (6) Høydose østrogen (inkludert medroksyprogesteronacetat prevensjonsmidler)
- (7) Immundempende medisiner/kjemoterapi
- (8) Vitamin K
- (9) Antiepileptisk medisin (lamotrigin, fenytoin, fenobarbital, karbamazepin, primidon)
- (10) Protonpumpehemmere (PPI)
- (11) SSRI – selektive serotoninreopptakshemmere
- (12) Tiazolidindioner (TZDs)
- (13) Antikonvulsiva (krampestillende midler)
- (14) Androgen deprivasjonsterapi
- (15) Kalsineurinhemmere
- (16) Isotretinoin
- (18) Testosteronbehandling
- (17) Andre

Kommenter hvilke(n) i boksen under

Har du i løpet av de siste 6 månedene brukt kosttilskudd? Eks; Vitamin D, vitamin C, vitamin B12, magnesium, tran, ZMA, folsyre, multivitamin, jern

(3) Ja

(2) Nei

List gjerne opp hvilke i kommentarfeltet under:

Bruker du homeopatiske midler?

(3) Ja

(2) Nei

Beskriv hvilke og hvordan disse brukes:

Takk for din besvarelse! Avslutt besvarelsen ved å trykke på "Finish".

IPAQ-SF (Q2) Fysisk aktivitet BoneWheel

Vennligst fyll inn ditt FP-nummer (din studie-id) som du har blitt tildelt (eks: 003)

Vi er interessert i informasjon om ulike former for fysisk aktivitet som du driver med i dagliglivet. Spørsmålene gjelder tiden du har brukt på fysisk aktivitet **de siste 7 dagene**. Vennligst svar på alle spørsmålene uansett hvor fysisk aktiv du selv synes du er.

Tenk på aktiviteter du gjør på jobb/studier, som en del av hus- og hagearbeid, for å komme deg fra et sted til et annet, og aktiviteter på fritiden (rekreasjon, mosjon og sport).

Tenk på all **meget anstrengende aktivitet** du har drevet med **de siste 7 dagene**.

Meget anstrengende aktivitet er aktivitet som krever hard innsats og får deg til å puste mye mer enn vanlig.

Ta bare med aktiviteter som varer minst 10 minutter i strekk.

Har du drevet med meget anstrengende aktivitet de siste 7 dagene?

- (1) Ja
- (2) Nei

1. Hvor mange dager i løpet av de siste 7 dagene har du drevet med meget anstrengende fysisk aktivitet som tunge løft, rulle rullestolen eller (hånd)sykling fort?

1a) Hvor mange timer/minutter brukte du vanligvis på meget anstrengende fysisk aktivitet på en av disse dagene? (eks: 1t:15min, 0t:20min). Er du usikker, lar du feltet stå blankt.

1b) Hvilken type meget anstrengende aktivitet gjorde du?

Tenk på all **middels anstrengende aktivitet** du har drevet med **de siste 7 dagene**.

Middels anstrengende aktivitet er aktivitet som krever moderat innsats og får deg til å puste litt mer enn vanlig. Ta bare med aktiviteter som varer minst 10 minutter i strekk.

2. Hvor mange dager i løpet av de siste 7 dagene har du drevet med middels anstrengende fysisk aktivitet som å bære lette ting, rulle rullestolen eller (hånd)sykling i moderat tempo? Ikke ta med rolig fart rulling i rullestol, det kommer i neste spørsmål.

2a) Hvor mange timer/minutter brukte du vanligvis på middels anstrengende fysisk aktivitet på en av disse dagene? (eks: 1t:15min, 0t:20min). Er du usikker, lar du feltet stå blankt.

2b) Hvilken type middels anstrengende aktivitet gjorde du?

Tenk på tiden du har brukt på manuell **rulling** i rullestolen de **siste 7 dagene**.

Dette inkluderer rulling på jobb og hjemme, fra et sted til et annet, på tur eller som trening på fritiden.

3. Hvor mange dager i løpet av de siste 7 dagene, rullet du i minst 10 minutter i strekk for å komme deg fra ett sted til et annet?

3a) På en vanlig dag hvor du rullet for å komme deg fra et sted til et annet, hvor lang tid brukte du da totalt på å forflytte deg?

Oppgi svaret i timer og minutter pr. dag (eks: 2t:15min, 0t:45min). Er du usikker lar du feltet stå blankt.

Generelle aktiviteter

Det siste spørsmålet omhandler tids- og energikostende aktiviteter i hverdagen.

4. Er det noen utfordrende, tids- eller energikostende aktiviteter du normalt gjør i hverdagen som ikke er nevnt i tidligere spørsmål/svar, som f.eks. forflytning inn/ut av rullestol, sporter, husarbeid osv.?

Treningshistorikk

(1) null

Takk for din besvarelse!

Ta gjerne runde tilbake gjennom sidene og sjekk at du har besvart alle spørsmålene, ved å trykke på "Previous".

Dersom du har hoppet over noe bevisst er dette helt i orden.

Trykk "Finish" for å levere.

Low Energy Availability in Female Questionnaire (Q4A) Spørreskjema til kvinnelige idrettsutøvere og ikke-utøvere

Vennligst fyll inn ditt FP-nummer (din studie-id) som du har blitt tildelt (eks: 003)

1. Skader

A) Har du vært skadet i løpet av det siste året og dermed hatt fravær fra eller vært markant begrenset i forhold til din trenings-/konkurranssevne?

- (1) Nei, slett ikke
- (2) Ja, 1-2 ganger
- (3) Ja, 3-4 ganger
- (4) Ja, 5 ganger eller flere

A1) Hvor mange dager i løpet av det siste året har du ikke trent eller deltatt i konkurranse som planlagt på grunn av skader?

- (1) 1-7 dager
- (2) 8-14 dager
- (3) 15-21 dager
- (4) 22 dager eller flere

Hvilke typer skader har du hatt i løpet av det siste året?

Evt. kommentarer eller utdyping angående skader:

2. Magefunksjon

A) Føler du deg oppblåst eller oppsvulmet i magen, også når du ikke har menstruasjon?

- (1) Ja, flere ganger/dag
- (2) Ja, flere ganger/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjeldent eller aldri

B) Har du kramper og/eller magesmerter, som ikke kan relateres til din menstruasjon?

- (1) Ja, flere ganger/dag
- (2) Ja, flere ganger/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjeldent eller aldri

C) I gjennomsnitt, hvor ofte har du avføring?

- (1) Flere ganger/dag
- (2) 1 gang/dag
- (3) Hver 2. dag
- (4) 2 ganger/uke
- (5) 1 gang/uke eller sjeldnere

D) Hvordan pleier din avføring å være?

- (1) Normal (fast eller bløt)
- (2) Meget tynn, som diaré
- (3) Hard og tørr

Evt. kommentarer eller utdyping angående magefunksjon:

3. Prevensjonsmiddel

A) Bruker du p-piller?

- (1) Ja
- (2) Nei

Hvorfor bruker du p-piller? Hvis annet; huk av og kommenter gjerne i tekstboks under

- (1) Prevensjonsmiddel
- (2) Redusere menstruasjonsmerter
- (3) Redusere blødningsmengden
- (4) For å regulere menstruasjonsyklus i forbindelse med konkurranser etc.
- (5) Hvis ikke, uteblir menstruasjonen
- (6) Annet _____

Har du brukt p-piller tidligere?

- (1) Ja
- (2) Nei

Når og hvor lenge?

B) Bruker du noen annen form for hormonell prevensjon? (f.eks. p-stav, hormonspiral)

- (1) Ja
- (2) Nei

Hvilken type? Hvis annet; huk av i boks og kommenter gjerne hva i tekstboks under.

- (1) P-plaster
- (2) P-stav
- (3) Hormonspiral
- (4) Annet _____

4. Menstruasjon

Har du hatt menstruasjon?

- (1) Ja
- (2) Nei

A) Hvor gammel var du da du fikk din første menstruasjon?

- (1) 11 år eller yngre
- (2) 12-14 år
- (3) 15 år eller eldre

(4) Husker ikke

B) Kom din første menstruasjon naturlig? (av seg selv)

(1) Ja

(2) Nei

(3) Husker ikke

Hva ble gjort for å igangsette din menstruasjon? (Sett ett eller flere kryss)

(1) Hormonbehandling

(2) Vektøkning

(3) Redusert treningsmengde

(4) Annet

C) Har du normal menstruasjon?

(1) Ja

(2) Nei

(3) Vet ikke

C1) Når hadde du sist menstruasjon?

(1) 0-4 uker siden

(2) 1-2 måneder siden

(3) 3-4 måneder siden

(4) 5 måneder eller lenger siden

C2) Har du regelmessig menstruasjon? (hver 28.-34. dag)

(1) Ja, som regel

(2) Nei, som regel ikke

C3) Hvor mange dager pleier du å ha blødning?

- (1) 1-2 dager
- (2) 3-4 dager
- (3) 5-6 dager
- (4) 7-8 dager
- (5) 9 dager eller mer

C4) Har du noen ganger problemer med kraftig menstruasjonsblødning?

- (1) Ja
- (2) Nei

C5) Hvor mange menstruasjonsblødninger har du hatt i løpet av det siste året?

- (1) 12 eller flere
- (2) 9-11
- (3) 6-8
- (4) 3-5
- (5) 0-2

C6) Hvor lenge er det siden du sist hadde menstruasjon?

- (1) 2-3 måneder siden
- (2) 4-5 måneder siden
- (3) Mer enn 6 måneder siden
- (4) Jeg er gravid og har derfor ikke menstruasjon
- (5) Jeg bruker minipiller og har derfor ikke menstruasjon

D) Har din menstruasjon uteblitt helt i 3 måneder eller lengre uten at det skyldes graviditet eller minipiller?

- (1) Nei, det har aldri skjedd

- (2) Ja, det har skjedd tidligere
- (3) Ja, jeg opplever det nå

E) Opplever du at din menstruasjon endrer seg ved økt treningsintensitet, -frekvens og/eller -varighet?

- (1) Ja
- (2) Nei

E1) Hvordan opplever du at din menstruasjon endrer seg? (sett ett eller flere kryss)

- (1) Jeg blør mindre
- (2) Jeg blør i færre dager
- (3) Min menstruasjon uteblir
- (4) Jeg har kraftigere blødning
- (5) Jeg blør i flere dager

5. Svimmelhet

A) Kjenner du deg svimmel når du reiser deg raskt opp?

- (1) Ja, flere ganger/dag
- (2) Ja, flere ganger/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

B) Opplever du problemer med synet ditt (uskarphet, ser prikker, tunnellsyn etc)?

- (1) Ja, flere ganger/dag
- (2) Ja, flere ganger/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere

(4) Sjeldent eller aldri

6. Temperaturregulering i hvile

A) Fryser du selv om du har normalt med klær på deg?

(1) Ja, flere ganger/dag

(2) Ja, flere ganger/uke

(3) Ja, 1-2 ganger/uke eller sjeldnere

(4) Sjeldent eller aldri

B) Har du mer klær på deg/kler deg varmere enn de utøvere/personer du omgås uavhengig av vær?

(1) Ja, nesten alltid

(2) Ja, noen ganger

(3) Sjelden eller aldri

7. Velvære og restitusjon

A) Trøtthet

A1) Jeg føler meg svært trøtt når jeg kommer hjem fra arbeid/skole

(1) Ja, nesten hver dag

(2) Ja, flere dager/uke

(3) Ja, 1-2 dager/uke eller sjeldnere

(4) Sjelden eller aldri

A2) Jeg kjenner meg overtrøtt

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 dager/uke eller sjeldnere
- (4) Sjelden eller aldri

A3) Jeg har vanskeligheter med å konsentrere meg

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 dager/uke eller sjeldnere
- (4) Sjelden eller aldri

A4) Jeg kjenner meg sløv

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 dager/uke eller sjeldnere
- (4) Sjelden eller aldri

A5) Jeg fremskynder viktige beslutninger

- (1) Ja, alltid
- (2) Ja, ofte
- (3) Ja, iblant
- (4) Sjelden eller aldri

B) Velvære

B1) Jeg har vondt i kroppen

- (1) Ja, nesten hver dag

- (2) Ja, flere dager/uke
- (3) Ja, 1-2 dager/uke eller sjeldnere
- (4) Sjelden eller aldri

B2) Musklene mine føles stive og ømme på trening

- (1) Ja, nesten på hver treningsøkt
- (2) Ja, på mange treningsøkter
- (3) Ja, iblant på noen treningsøkter
- (4) Sjelden eller aldri

B3) Jeg har muskelverk/er støl etter trening

- (1) Ja, nesten på hver treningsøkt
- (2) Ja, på mange treningsøkter
- (3) Ja, iblant på noen treningsøkter
- (4) Sjelden eller aldri

B4) Jeg føler at jeg blir lett skadet

- (1) Ja, alltid
- (2) Ja, i de fleste treningsperioder
- (3) Ja, i noen treningsperioder
- (4) Sjelden eller aldri

B5) Jeg har hodeverk

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 dager/uke eller sjeldnere
- (4) Sjelden eller aldri

B6) Jeg kjenner meg fysisk utmattet

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 dager/uke eller sjeldnere
- (4) Sjelden eller aldri

B7) Jeg kjenner meg sterk og har god progresjon i styrketreningen min

- (1) Ja, alltid
- (2) Ja, i de fleste treningsperioder
- (3) Ja, i noen treningsperioder
- (4) Sjelden eller aldri

C) Søvn

C1) Jeg sover tilstrekkelig

- (1) Ja, nesten hver natt
- (2) Ja, flere netter/uke
- (3) Ja, 1-2 netter/uke eller sjeldnere
- (4) Sjelden eller aldri

C2) Jeg sovner fornøyd og avslappet

- (1) Ja, nesten hver kveld
- (2) Ja, flere kvelder/uke
- (3) Ja, 1-2 kvelder/uke eller sjeldnere
- (4) Sjeldnere eller aldri

C3) Jeg våkner utsovet

- (1) Ja, nesten hver morgen
- (2) Ja, flere morgener/uke
- (3) Ja, 1-2 morgener/uke eller sjeldnere
- (4) Sjelden eller aldri

C4) Jeg sover urolig

- (1) Ja, nesten hver natt
- (2) Ja, flere netter/uke
- (3) Ja, 1-2 netter/uke eller sjeldnere
- (4) Sjelden eller aldri

C5) Min søvn forstyrres lett

- (1) Ja, nesten hver natt
- (2) Ja, flere netter/uke
- (3) Ja, 1-2 netter/uke eller sjeldnere
- (4) Sjelden eller aldri

C6) I løpet av den siste måneden, hvor mange timer faktisk søvn har du fått i gjennomsnitt per natt? (PS: dette kan skille seg fra antall timer du tilbringer i sengen). Oppgi svaret i timer pr. natt

D) Restitusjon

D1) Jeg restituerer meg (henter meg inn igjen) bra fysisk

- (1) Ja, etter nesten hver treningsøkt
- (2) Ja, etter mange treningsøkter

- (3) Ja, iblant etter noen treningsøkter
- (4) Sjelden eller aldri

D2) Jeg føler meg i god fysisk form

- (1) Ja, alltid
- (2) Ja, ofte
- (3) Ja, iblant
- (4) Sjelden eller aldri

D3) Jeg kjenner meg energisk

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 dager/uke eller sjeldnere
- (4) Sjelden eller aldri

D4) Kroppen min føles sterk

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 dager/uke eller sjeldnere
- (4) Sjelden eller aldri

E) Energinivå

E1) Jeg føler meg veldig energisk til vanlig

- (1) Ja, nesten hver dag
- (2) Ja, flere dager i uken
- (3) Ja, en til to ganger i uken eller mindre

(4) Sjelden/aldri

E2) Jeg føler meg energisk før trening og er klar til å prestere

(1) Ja, nesten hver dag

(2) Ja, flere dager i uken

(3) Ja, en til to ganger i uken eller mindre

(4) Sjelden/aldri

E3) Jeg føler meg glad og på topp i livet utenfor idretten

(1) Ja, nesten hver dag

(2) Ja, flere dager i uken

(3) Ja, en til to ganger i uken eller mindre

(4) Sjelden/aldri

E4) Jeg føler meg mer nedstemt og mindre glad enn jeg pleier eller ønsker å være

(1) Ja, nesten hver dag

(2) Ja, flere dager i uken

(3) Ja, en til to ganger i uken eller mindre

(4) Sjelden/aldri

F) Sexlyst

Din sexlyst kan være en markør for balansen mellom trening, hvile og restitusjon.

a) Jeg vil beskrive min generelle sexlyst som:

(1) Høy

(2) Moderat

- (3) Lav
- (4) Sex er ikke så interessant

b) Min sexlyst den siste måneden har vært:

- (1) Sterkere enn vanlig
- (2) Som vanlig
- (3) Litt mindre enn vanlig
- (4) Mye mindre enn vanlig

G) Hvilke ernæringsmessige tiltak tror du kunne bidra positivt i forhold til å: 1) redusere skader/sykdom, og 2) øke dine idrettslige prestasjoner?

Takk for din besvarelse!

Ta gjerne runde tilbake gjennom sidene og sjekk at du har besvart alle spørsmålene, ved å trykke på "Previous".

Dersom du har hoppet over noe bevisst er dette helt i orden.

Trykk "Finish" for å levere.

Low Energy Availability in Male Questionnaire (Q4B) Spørreskjema til mannlige utøvere og ikke-utøvere

Vennligst fyll inn ditt FP-nummer (din studie-id) som du har blitt tildelt (eks: 003)

1. Svimmelhet

A) Kjenner du deg svimmel når du reiser deg raskt opp?

- (1) Ja, flere ganger/dag
- (2) Ja, flere ganger/uke
- (3) ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

B) Opplever du problemer med synet ditt (uskarphet, ser prikker, tunnellsyn etc)?

- (1) Ja, flere ganger/dag
- (2) Ja, flere ganger/uke
- (3) ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

2. Magefunksjon

A) Føles din mage ”oppblåst”?

- (1) Ja, flere ganger/dag
- (2) Ja, flere ganger/uke

- (3) ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

B) Har du kramper og/eller magesmerter?

- (1) Ja, flere ganger/dag
- (2) Ja, flere ganger/uke
- (3) ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

C) Hvor ofte har du avføring i gjennomsnitt?

- (1) Ja, flere ganger/dag
- (2) Ja, flere ganger/uke
- (3) ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

D) Hvordan pleier din avføring å være?

- (1) Normal (fast og myk)
- (2) Løs, som diaré
- (3) Hard og tørr

Eventuelle kommentarer til magefunksjon:

3. Temperaturregulering i hvile

A) Fryser du selv om du har normalt med klær på deg?

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

B) Har du mer klær på deg/kler deg varmere enn de utøvere/personer du omgås uavhengig av vær?

- (1) Ja, nesten alltid
- (2) Ja, noen ganger
- (3) Sjelden eller aldri

4. Helseproblemer som gir avvik fra trening og/eller konkurranse

I det følgende kommer noen spørsmål om hvor ofte du har vært tvunget til å endre dine trenings- og konkurranseplaner og hvor ofte du ikke har kunnet prestere maksimalt på trening og konkurranse på grunn av idrettsskade eller sykdom siste 6 måneder.

Med akutt skade menes plutselig oppståtte skader som har klart definert årsak eller starttidspunkt (eks overtråkk, muskelstrek). Med belastningsskade menes gradvis oppståtte skader som følge av overbelastning over tid (eks. beinhinnebetennelse, achillessenebetennelse, stressfraktur).

A) Hvor mange akutte skader har du hatt i løpet av de siste 6 måneder?

B) Hvor mange belastningsskader har du hatt i løpet av de siste 6 måneder (om samme belastningsskade kommer tilbake regnes hver ny skadeperiode som 1 skade)?

C) Hvor mange sykdomsavbrekk fra planlagt trening har du hatt i løpet av de siste 6 måneder?

D) Hvor mange dager på rad har du i løpet av de siste 6 måneder vært fraværende fra trening/konkurranse eller ikke kunnet prestere optimalt på den mest omfattende akutte skaden, belastningsskaden og sykdom i løpet av de siste 6 måneder?

	Ingen	1-7dager	8-14 dager	15-21 dager	>22 dager
Akutt skade	(1) <input type="checkbox"/>	(2) <input type="checkbox"/>	(3) <input type="checkbox"/>	(4) <input type="checkbox"/>	(5) <input type="checkbox"/>
Belastningsskade	(1) <input type="checkbox"/>	(2) <input type="checkbox"/>	(3) <input type="checkbox"/>	(4) <input type="checkbox"/>	(5) <input type="checkbox"/>
Sykdom	(1) <input type="checkbox"/>	(2) <input type="checkbox"/>	(3) <input type="checkbox"/>	(4) <input type="checkbox"/>	(5) <input type="checkbox"/>

Eventuelle kommentarer angående dine skader:

Eventuelle kommentarer angående dine sykdomsperioder:

5. Velvære og restitusjon

A) Trøtthet

A1) Jeg føler meg svært trøtt når jeg kommer hjem fra arbeid/skole

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

A2) Jeg kjenner meg overtrøtt

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

A3) Jeg har vanskeligheter med å konsentrere meg

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

A4) Jeg kjenner meg sløv

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

A5) Jeg fremskyver viktige beslutninger

- (1) Ja, alltid
- (2) Ja, ofte
- (3) Ja, iblant
- (4) Sjelden eller aldri

B) Velvære

B1) Jeg har vondt i kroppen

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

B2) Musklene mine føles stive og ømme på trening

- (1) Ja, nesten på hver treningsøkt
- (2) Ja, på mange treningsøkter
- (3) Ja, iblant på noen treningsøkter
- (4) Sjelden eller aldri

B3) Jeg har muskelverk/er støl etter trening

- (1) Ja, nesten på hver treningsøkt
- (2) Ja, på mange treningsøkter
- (3) Ja, iblant på noen treningsøkter
- (4) Sjelden eller aldri

B4) Jeg føler at jeg blir lett skadet

- (1) Ja, alltid
- (2) Ja, i de fleste treningsperioder
- (3) Ja, i noen treningsperioder
- (4) Sjelden eller aldri

B5) Jeg har hodeverk

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

B6) Jeg kjenner meg fysisk utmattet

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

B7) Jeg kjenner meg sterk og har god progresjon i styrketreningen min

- (1) Ja, alltid
- (2) Ja, i de fleste treningsperioder
- (3) Ja, i noen treningsperioder

(4) Sjelden eller aldri

C) Søvn

C1) Jeg sover tilstrekkelig

- (1) Ja, nesten hver natt
- (2) Ja, flere netter/uke
- (3) Ja, 1-2 netter/uke eller sjeldnere
- (4) Sjelden eller aldri

C2) Jeg sovner fornøyd og avslappet

- (1) Ja, nesten hver kveld
- (2) Ja, flere kvelder/uke
- (3) Ja, 1-2 kvelder/uke eller sjeldnere
- (4) Sjelden eller aldri

C3) Jeg våkner utsovet

- (1) Ja, nesten hver morgen
- (2) Ja, flere morgener/uke
- (3) Ja, 1-2 morgener/uke eller sjeldnere
- (4) Sjelden eller aldri

C4) Jeg sover urolig

- (1) Ja, nesten hver natt
- (2) Ja, flere netter/uke
- (3) Ja, 1-2 netter/uke eller sjeldnere
- (4) Sjelden eller aldri

C5) Min søvn forstyrres lett

- (1) Ja, nesten hver natt
- (2) Ja, flere netter/uke
- (3) Ja, 1-2 netter/uke eller sjeldnere
- (4) Sjelden eller aldri

C6) I løpet av den siste måneden, hvor mange timer faktisk søvn har du fått i gjennomsnitt per natt? (PS: dette kan skille seg fra antall timer du tilbringer i sengen) Oppgi svaret i timer pr. natt.

D) Restitusjon

D1) Jeg restituerer meg (henter meg inn igjen) bra fysisk

- (1) Ja, etter nesten hver treningsøkt
- (2) Ja, etter mange treningsøkter
- (3) Ja, iblant etter noen treningsøkter
- (4) Sjelden eller aldri

D2) Jeg føler meg i god fysisk form

- (1) Ja, alltid
- (2) Ja, ofte
- (3) Ja, iblant
- (4) Sjelden eller aldri

D3) Jeg kjenner meg energisk

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

D4) Kroppen min føles sterk

- (1) Ja, nesten hver dag
- (2) Ja, flere dager/uke
- (3) Ja, 1-2 ganger/uke eller sjeldnere
- (4) Sjelden eller aldri

E) Energinivå

E1) Jeg føler meg veldig energisk til vanlig

- (1) Ja, nesten hver dag
- (2) Ja, flere dager i uken
- (3) Ja, en til to ganger i uken eller mindre
- (4) Sjelden eller aldri

E2) Jeg føler meg energisk før trening og er klar til å prestere

- (1) Ja, nesten hver dag
- (2) Ja, flere dager i uken
- (3) Ja, en til to ganger i uken eller mindre
- (4) Sjelden eller aldri

E3) Jeg føler meg glad og på topp i livet utenfor idretten

- (1) Ja, nesten hver dag

- (2) Ja, flere dager i uken
- (3) Ja, en til to ganger i uken eller mindre
- (4) Sjelden eller aldri

E4) Jeg føler meg mer nedstemt og mindre glad enn jeg pleier eller ønsker å være

- (1) Ja, nesten hver dag
- (2) Ja, flere dager i uken
- (3) Ja, en til to ganger i uken eller mindre
- (4) Sjelden eller aldri

F) Sexlyst

Din sexlyst kan være en markør for balansen mellom trening, hvile og restitusjon.

a) Jeg vil beskrive min generelle sexlyst som:

- (1) Høy
- (2) Moderat
- (3) Lav
- (4) Sex er ikke så interessant

b) Min sexlyst den siste måneden har vært:

- (1) Sterkere enn vanlig
- (2) Som vanlig
- (3) Litt mindre enn vanlig
- (4) Mye mindre enn vanlig

F2) Det er vanlig med ereksjon når man våkner om morgenen.

a) I løpet av den siste måneden har du opplevd dette:

- (1) 5-7 ganger per uke
- (2) 3-4 ganger per uke
- (3) 1-2 ganger per uke
- (4) Sjelden/aldri

b) Sammenlignet med hva du anser er normalt for deg, er dette:

- (1) Oftere enn vanlig
- (2) Omtrent like ofte
- (3) Litt sjeldnere enn vanlig
- (4) Mye sjeldnere enn vanlig

G) Hvilke ernæringsmessige tiltak tror du kunne bidra positivt i forhold til å:

1) Redusere skader/sykdom

2) Øke dine idrettslige prestasjoner?

Takk for din besvarelse!

Ta gjerne runde tilbake gjennom sidene og sjekk at du har besvart alle spørsmålene, ved å trykke på "Previous".

Dersom du har hoppet over noe bevisst er dette helt i orden.

Trykk "Finish" for å levere.

