Compliance to the Norwegian Food-Based Dietary Guidelines among patients with colorectal cancer - Validation of a compliance

- Validation of a compliance questionnaire

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**Master Thesis** 

by

SITAS

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June 2013

## Compliance to the Norwegian Food-Based Dietary Guidelines among patients with colorectal cancer

## - Validation of a compliance questionnaire

by Anne Juul Skjetne



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## Abstract

**Background:** This master thesis is a subproject within the Norwegian Foods Study (NFS), which is a diet and lifestyle intervention in colorectal cancer (CRC) survivors. Within the study there was a need for a specific and effective tool for repeated, self-administered assessment of compliance to the Norwegian Food-Based Dietary Guidelines (NFBDG). Therefore, a new questionnaire designed to measure compliance to the NFBDG was developed. The compliance questionnaire is a short food frequency questionnaire that assesses food intake and physical activity the preceding week.

**Aims:** The aim of this master thesis was to validate the compliance questionnaire to the NFBDG among patients with colorectal cancer (CRC). In addition, we examined to which extent the patients complied to the NFBDG after surgery.

**Study design and Methods:** A subgroup (n=17) of newly diagnosed CRC patients from the main NFS population was recruited from Ullevål University Hospital. At the baseline of NFS intervention (i.e. 2-3 months post surgery), the participants were asked to fill out the compliance questionnaire and to use two validation tools; SenseWear Armband (n=13) and 7-days weighted food records (n=15).

**Results:** Significant correlations for intake estimates were found between the compliance questionnaire and the food records for the following variables: fruits and berries including juice, nuts, total red meat, total non-processed meat, alcoholic beverages, juice, beverages with added sugar, foods added sugar and vitamin D (Spearman's correlation coefficient rho  $0.51 - 0.88 \ (p \le 0.05)$ ). There were no significant differences in the absolute intake for any of these categories. On an individual level, the percentage of the participants who achieving full compliance to the guidelines varied from 20 % for total vegetables, fruits and berries to 80 % for intake of fatty fish. On group level, median intake showed 100 % compliance to the guidelines for nuts, total fish, fatty fish, total red meat and juice, and the median compliance to physical activity was 40 % as measured from the Armband.

**Conclusion:** The compliance questionnaire provides good estimates of intake for fruits and berries including juice, nuts, total red meat, total non-processed meat, alcoholic beverages, juice, beverages with added sugar, foods added sugar and vitamin D. In the CRC the highest compliance to the NFBDG was found for intake of fish, red meat, nuts and juice. Moreover the compliance was lowest for intake of fruits and berries, vegetables and alcoholic beverages.

## List of abbreviations

AICR	American Institute for Cancer Research
BMI	Body mass Index
CRC	Colorectal cancer
EE	Energy expenditure
EPIC	European Prospective Investigation Into Cancer and Nutrition
FFQ	Food Frequency questionnaire
KBS	"Kost Beregnings System" (Nutritional calculation system/database)
METs	Metabolic equivalents
MJ	Mega joule
NFBDG	The Norwegian food-based dietary guidelines
NFS	The Norwegian Foods Study
NOWAC	The Norwegian Woman and Cancer Study
RMR	Resting metabolic rate
TNM	Tumor-node-metastasis
UICC	Union for International Cancer Control
WCRF	World Cancer Research Fund
WHO	World Health Organization

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# **1** Introduction

This master thesis is an interim analysis which is part of The Norwegian Foods Study (NFS) that is a diet and lifestyle intervention. The NFS investigates the effect of lifestyle changes based on the Norwegian Food-Based Dietary Guidelines (NFBDG) on development of chronic diseases in colorectal cancer survivors. The study is a collaboration between the Department of Nutrition, University of Oslo and hospitals in the Helse-Sørøst region, and is led by Professor Rune Blomhoff.

## 1.1 Colorectal cancer, diet and physical activity

#### 1.1.1 Cancer survivors

The number of people affected by cancer worldwide is accelerating, and at the same time the number of cancer survivors is increasing. Cancer survivors are people who have or have had a cancer diagnosis (1). In 2002 the prevalence of cancer survivors worldwide was around 25 million, and in 2025 this number is estimated to double (2). Among the most dominating cancers in the world are breast cancer, prostate cancer, lung cancer and colorectal cancer (CRC) (3). CRC is the third most common type of cancer worldwide. Rates of CRC increase with industrialization and urbanization (4). CRC was the second most frequent cancer in Norway in 2010, estimated to be 2044 new cases among men and 1828 new cases among women, and accounted for around 10 % of cancer cases overall. The incidence increases from 50 years and older. The continuing increase in colon cancer now seems to be stabilizing, and thus following the trends that have been observed for rectal cancer. From the period of 1971-75 to 2006-10 the 5-year survival for CRC patients increased from about 35 % to about 65 %, with a somewhat higher survival rate among women than in men (5).

Commonly CRC is grouped in four stages according to the tumor-node-metastasis (TNM) staging system published by the Union for International Cancer Control (UICC) (6). The 5-year relative survival for localized CRC (stage I-II) was around 90 % in 2008, around 70 % with involvement of regional lymph nodes (stage III), and only 10 % for metastasis to distant sites (stage IV) (7).

The population of CRC survivors are growing because of increasing number of new cases, together with higher survival rate (7).

Several studies have showed that these patients have an increased risk of developing other chronic diseases compared to people with no cancer diagnosis (3, 8-10). Although many cancer patients are cured of their disease, many will have an increased risk of other chronic diseases. It's due to the common risk profile, side effects of cancer treatment, genetics and other causes. CRC survivors have therefore a higher risk of developing several chronic diseases such as cardiovascular disease, type 2-diabetes, metabolic syndrome and arthritis (10). Cancer therapies have also been shown to be associated with increased risk of comorbidities (3, 11-13).

#### 1.1.2 Colorectal cancer etiology

Usually CRC arises from benign adenomatous polyps in colon, and some of these adenomas may develop into malignant tumors. Patients with hereditary nonpolyposis colorectal cancer and familial adenomatous polyposis as well as patients with Crohns disease and ulcerative colitis have a higher risk of developing CRC (14, 15).

The World Cancer Research Fund/ American Institute for Cancer Research (1) report from 2007 suggest that 45 % of all CRC cases could be prevented with improved lifestyle. They concluded that there is convincing evidence for increased risk of CRC with high intake of red and processed meat, alcoholic beverages (by men and probably by women), body fatness and abdominal fatness. However, there is convincing evidence that physical activity and foods containing dietary fiber protects against CRC. Consumption of garlic, milk and calcium probably protect against this cancer (1).

# 1.1.3 Effect of lifestyle interventions on risk of chronic diseases after CRC treatment

CRC survivors are particularly interesting with regards to prevention of common comorbidities (e.g. metabolic syndrome, cardiovascular diseases, type 2-diabetes), because many of the diet-related risk factors for CRC are also risk factors for these comorbidities. Factors that reduce the risk of common comorbidities are high intake of vegetables, fruits and other foods with high fiber contents, fish intake and physical activity, while high intakes of red meat, processed meat, saturated fats and overweight/obesity increase risk (16).

Several diet and lifestyle intervention studies have been effective in reducing risk of developing chronic diseases such as type 2-diabetes; The Finnish Diabetes Prevention Study (17) and cardiovascular diseases; the Oslo study (18).

King et al and the RENEW study looked at the effect of adopting a healthy lifestyle and intervention to improve functional decline among elderly cancer survivors. (19) They found that middle-aged people who newly adopted a healthy lifestyle (5 or more fruits and vegetables daily, regular exercise, BMI 18.5-29.9 kg/m<sup>2</sup>, no current smoking), had lower occurrence of cardiovascular disease and mortality, compared to individuals who did not adopt a healthy lifestyle (19). The aims of the RENEW study were to determine whether a telephone counseling and mailed print material based diet and exercise intervention is effective in reorienting functional decline in older overweight cancer survivors (colorectal, breast and prostate cancer) (20-22). Physical activity, dietary behaviors, and overall quality of life increased significantly in the intervention group compared to the control group. In addition the rate of self-reported functional decline was reduced in the intervention group compared with the control group (21).

#### 1.1.4 Physical activity and diet in CRC recurrence and patient survival

Vrieling & Kampman (23) conducted a review to summarize the evidence from epidemiologic studies (studies published up to March 2010) that examined the association of body mass index (BMI), physical activity, and nutrition with CRC recurrence and patient survival. They identified 36 articles that were based on 31 independent studies. Only 9 studies assessed physical activity (n=4) or nutrition (n=5) after diagnosis. There may be a relation between higher leisure-time physical activity after diagnosis and a lower all-cause or colorectal cancer-specific mortality. For dietary factors, statistically significant associations were only shown for single foods, nutrients, and dietary patterns in single studies. In conclusion, only a paucity of data is available on the effect of dietary and other lifestyle factors on CRC recurrence and survival (23).

A randomized controlled pilot study of Bourke et al. (24), investigated the feasibility of a pragmatic lifestyle intervention in patients who had recently completed surgery and chemotherapy for colon cancer and to obtain preliminary data of its impact on important health outcomes. They observed a significant impact on dietary behavior, fatigue, aerobic exercise tolerance, functional capacity, and waist-hip ratio. But these findings need to be confirmed with a larger-scale definitive randomized controlled trial (24).

Pekmezi and Demark-Wahnefried have in a review identified 21 RCTs in the past three years (until 2011) that investigated diet and exercise interventions in cancer survivors. Results suggested that physical activity interventions are safe for this patient group and produce improvements in fitness, strength, physical function, whereas dietary interventions improve diet quality, nutrition-related biomarkers and body weight (25).

#### 1.1.5 Dietary changes among cancer patients

The "Norwegian Women and Cancer cohort study" found that cancer survivors showed little change toward cancer-preventive guidelines, although a more advanced stage (TNM staging system), and being more than 2,4 years post diagnosis was associated with greater change in both diet and smoking behaviours (26). Demark-Wahnefried et al. (27) found by a review of observation and intervention studies, that several studies have showed that cancer survivors change their diets after diagnosis, most commonly in a more healthy direction, by lowering their fat intake and increasing their intake of fruits and vegetables (27). However it is not known how persistent these behavioural changes are. Some recent large-scale studies suggest that health behaviours do not differ much between cancer survivors, colorectal cancer survivors are a less studied group and the research on colorectal cancer and dietary changes is limited (31, 32).

## 1.2 The Norwegian Foods Study (NFS)

#### 1.2.1 Study design NFS

The NFS is a multicenter randomized controlled, parallel two-arm intervention trial (**Figure 1.1**). The participants are recruited one day prior to CRC surgery (hereby referred to as presurgery). About 2-3 months after pre-surgery, the participants are invited to the study centre at the Department of Nutrition at baseline of intervention. 6 months after baseline of intervention they are invited to 6 months follow up. They are randomized into intervention group A or control group B. The intervention lasts for 12 months, with additional follow ups 1, 3, 5, 7, 10 and 15 years after baseline of intervention. The subjects invited to the study are men and women 50-75 years of age with primary CRC TNM stages I-III, recruited from hospitals in the *Helse Sør-Øst* region of Norway (33).

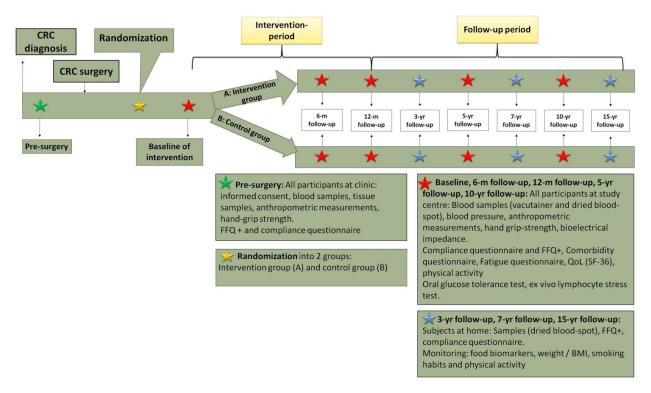


Figure 1.1 Study design for The Norwegian Foods Study.

#### 1.2.2 Study objectives of the NFS

The main objective of NFS is to test whether a diet and lifestyle intervention can reduce the risk of overall mortality, as well as comorbidities and cancer recurrence among CRC survivors. The major aim of NFS is to prevent chronic diseases, however the only dietary recommendations for CRC survivors are concerning food stuffs that may help prevent symptoms related to the treatment.

The objectives of the NFBDG are to improve the overall public health and prevent chronic diseases in the general population. Therefore, the NFBDG are well suited as the basis for the NFS intervention (33).

#### 1.2.3 Diet and lifestyle intervention in NFS

The participants in the NFS are randomized into one of the two study groups. The intervention group are offered to join organized physical activities and diet counselling for improved diet whereas the control group are given offers of organized physical activity only.

Both the intervention- and the control group are given different offers of organized exercise activities that include free training guidance and group sessions led by physiotherapists and sports educators at the hospital. All the participants are also invited to attend inspiration meetings (33).

NFS has developed a detailed diet plan for the intervention group that is in agreement with the NFBDG. It gives priority to foods that may reduce inflammation and oxidative stress and is based on a typical Norwegian food tradition. The portion size of the different food groups are adjusted according to age and gender. The intervention group is offered dietary counselling by clinical nutritionist, cooking lessons, discount cards on a wide range of healthy foods, free foods (sent to their home) and access to a web-page with dietary guidelines, recipes and more, all based on the NFBDG.

NFS expect the intensive intervention to be effective in changing the diet and (physical activity) during the intervention period, and aim to achieve an adherence score to the NFBDG of 80 % to the intervention group after 1 year, compared to baseline of intervention (33).

# **1.3 The Norwegian Food-Based Dietary Guidelines** (NFBDG)

In recent years, there has been a growing global interest to develop dietary guidelines and nutrient recommendations, both to promote public health and to prevent chronic diseases (16, 34). The relationship between diet and health is complex, and the international research in this field is extensive. To summarize this research in a systematic way, the Norwegian National Council of Nutrition organized a working group in 2006 with the mission to update the scientific basis for national recommendations. This work resulted in the NFBDG (16) published in January 2011. These guidelines were developed based on the manuals for systematic literature reviews developed and used by the World Cancer Research Fund (1) and thus accounts for all relevant literature in the field.

Up until now, dietary advice has to a large extent been based on nutrients and their effect on health. Instead of just looking at individual nutrients such as vitamins, minerals and fats the experts have focused on the relationship between whole foods and health. Thus, the NFBDG are more specific as to which food stuff should be consumed and also states the amounts recommended for certain foods such as, fish, meat, vegetables, fruits and whole grains. The aim of this focus on foods rather than nutrients is to facilitate healthier food choices among the general public (16).

A diet based on vegetables, fruits, berries, cereals (whole grain) and fish, have been shown to improve overall public health and to prevent several chronic diseases (such as cardiovascular disease, certain cancers, diabetes type 2, overweight and obesity) (16). Whereas a diet dominated by processed meat, red meat, salt and sugar is associated with higher risk of developing chronic diseases, and energy balance is crucial to maintain a normal weight. Behind each of the key dietary advice there are strong international evidence on the relationship between food and chronic disease (16).

A summary of the thirteen main guidelines of the NFBDG are presented in **Table 1.1** Guidelines 1 and 2 in the NFBDG are based on a holistic assessment of diet and physical activity. Guidelines 3-13 are more precise within each food group, physical activity and supplements. It is generally recommended to choose "keyhole labelled" foods within each food group (16).

Guideline	Sub guidelines					
1. It is recommended a diet primarily from plants, with high amounts of vegetables, fruits,						
berries, whole grains and fish, and limited amounts of red meat, salt, sugar and energy-rich						
foods.						
2. It is recommended to	- The energy intake from food and drink and use of energy through					
maintain the balance	physical activity should be balanced so that the weight is maintained					
between energy intake	within the normal range. Regular physical activity helps to maintain					
and energy expenditure	energy balance.					
3. Eat at least 5 servings	- Five portions correspond to at least 500 grams of vegetables, fruits and					
of vegetables, fruits and	berries every day (one serving equals about 100 g).					
berries every day	- About half of intake should be vegetables and approximately half fruits					
	and berries. One glass of juice can be included maximum as one portion.					
	- It is recommended to eat varied (choose various colours), and that					
	tomatoes and vegetables in the onion family are included in the diet					
	Limit the amount of nuts (about 140 g nuts every week).					
	- Potatoes, legumes, seeds, spices and herbs are not included in the					
	recommended 5 portions of vegetables, fruits and berries, but should be					
	included in a varied diet.					
4. Eat at least 4 servings	- Four servings equals approximately 70-90 g of whole grains per day (75					
of whole grain products	g whole grain per 10 Mega joule (MJ) (2400 kcal))					
each day	- Three slices bread made with wholemeal flour, a large portion of whole					
	grain pasta or wild rice all contribute with about 75 g of whole grains					
	(breakfast cereals, porridge and legumes based on whole grains are also					
	good sources of whole grains.)					
	- At least half of the total intake of grains should be in the terms of whole					
5. Eat fish	grain. - It is recommended that the fish amount should correspond to 300 to 450					
corresponding to 2-3	gram per week					
dinner servings per	- Alternatively fish as dinner is replaced by the equivalent amount of fish					
week	spread. Six servings of fish spread are equivalent to around a dinner plate.					
week	- Both lean and fatty fish should be included, but it is recommended that					
	at least 200 g of intake should be fatty fish.					
6. It is recommended	- Limit the intake of dairy products high in saturated fat, such as whole					
that low-fat dairy	milk, cream, fatty cheese and butter.					
products are included in						
the daily diet						
7. It is recommended	- Limit intake of red meat (beef, sheep, goat, pork) to maximum 500 g per					
that you choose lean	week (This corresponds to 2 dinners with red meat and a limited amount					
meats and lean meat	of meat spread in the week).					
products(preferably	- Choose lean meat (low fat content), preferably non-processed.					
non-processed) and	- Limit intake of processed meat (smoked, salted or preserved with nitrate					
limit intake of red meat	or nitrite).					
and processed meat						
8. It is recommended	- It is recommended that you choose cooking (edible) oils (canola-,					
that you choose cooking	sunflower-, olive-, and soybean oil), liquid margarine or soft margarine,					
oils, liquid margarine or	having a low content of saturated fatty acids and a high content of					
soft margarine	unsaturated fatty acids.					
	- Limit the use of butter and butter mixed margarine because they have a					
	high content of saturated fatty acids and a low content of polyunsaturated					
0.117.4	fatty acids.					
9. Water is	- Water is recommended as a beverage to cover a large part of the liquid					
recommended as	need.					

 Table 1.1 Summaries of The Norwegian Food-Based Dietary Guidelines (16).

beverage	- Skimmed milk and extra skimmed milk can advantageously be used as				
-	drinking in a holistic diet.				
	- Consumption of alcohol is not recommended.				
	Juice can be a part of the recommendation of fruits, berries and				
	vegetables				
10. Reduce intake of	- It is recommended to reduce intake of added sugar to $< 10 \text{ E }$ %.				
added sugar	- It is recommended to limit the use of juice, soda, soft beverages, nectar,				
	sweet biscuits, sweet pastries and candies.				
11. Reduce the use of	- Reduce the use of salt (sodium chloride) to maximum 6 g per day				
salt	(processed foods and ready meals contributes to most with 70-80 % of				
	salt intake).				
12. Supplements may be	- If you have a varied and healthy diet, supplements are unnecessary for				
necessary to ensure	most.				
nutrient intake of some					
population groups					
13. Assure an average of	- Assure an average of at least 30 minutes of moderate physical activity				
at least 30 minutes of	per day (corresponding to quick walk) Time spent on physical activity				
moderate physical	can be divided into sections during the day (with duration of at least 10				
activity per day	minutes or more).				

## 1.4 The compliance questionnaire

To assess compliance to the NFBDG there was a need of an assessment tool for this purpose. In the NFS it was therefore developed a new questionnaire (**Figure 1.2, Appendix 1**) to measure the compliance to the NFBDG among CRC patients. The questions are formulated on the basis of the individual guidelines (The NFBDG) as a short food frequency questionnaire that assesses food intake and physical activity the preceding week.

An essential objective of developing this new questionnaire is primary to measure the effects of the NFS intervention. The questionnaire are going to be handed out and filled out several times by the participants throughout the study (i.e. pre-surgery, at baseline of intervention, through the intervention period and the follow-up period). Therefore it was important to develop an effective assessment tool.

The questionnaire is relatively short (4 pages) to make it easier for the participants to complete. It is shorter than the long FFQ (14 pages) that are used to assess diet over preceding months or year (35). The compliance questionnaire is designed to specific estimate the extent of which the participants follow the NFBDG and not to estimate diet patterns.

The compliance questionnaire is designed to assess food intake and physical activity the preceding week, to identify changes over short time periods. For the participants in the NFS there are expected to detect changes from before to after surgery and during the intervention period, which is not possible to discover using the long FFQ.

Even though the questionnaire is developed within the NFS it is also designed intended to be a useful tool for counseling nutritional and exercise behavioral changes by clinical nutritionists and other health personnel. In a clinical situation it is especially

important to have an effective method both for the patient to complete and for the nutritionist to evaluate.

Typisk Norsk-studien									
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Skjemaet skal leses av en maskin og det er derfo rutene. Bruk blå eller sort kulepenn. Alle svar vil	r vikti behar	g at d idles f	lu set fortrol	ter ty ig.	delige	e krys	is i		
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Ved feil markering, fyll hele ruten slik:									
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	0	1	2	3	4	5	6	7	7+
Hvor mange ganger var du fysisk aktiv mellom 10-20 minutters varighet?									
Hvor mange ganger var du fysisk aktiv mellom 21-30 minutters varighet?									
Hvor mange ganger var du fysisk aktiv mellom 31-60									

Figure 1.2 The compliance questionnaire.

### 1.5 Assessment of food intake and physical activity

#### 1.5.1 Assessment of food intake

Dietary assessment methods are intended to measure a person's food and beverage intake over a certain period of time. These assessments are however difficult due to day-to-day variations, seasonal fluctuations, changing eating habits and rarely consumed food (36). No dietary assessment methods can assess diet without measurement errors (37). Many different dietary assessment methods are available and the methods may be retrospective or prospective. Common retrospective methods are 24-hour recalls, where subjects are interviewed about food intake during the previous 24-hour period, dietary history and food frequency questionnaire (FFQ). Common prospective methods are estimated or weighted food records, where participants continuously register what they eat and drink in a period of about 3-14 days (38).

#### 1.5.2 Assessment of physical activity

Physical activity are defined as any bodily movement achieved by contraction of skeletal muscles that increases energy expenditure (EE) (34).

Ideally, all of the aspects of physical activity such as intensity, duration, frequency and mode of activity should be recorded during physical activity measurements (39).

There exist different methods and apparatus to assess physical activity. For example direct calorimetry measure heat which provides a measure of EE. Indirect calorimetry, for example Double labelled water, measures a person's oxygen expenditure and based on that calculates EE. This method is termed as the gold standard for assessment of EE (40). Other methods that can give a measure of physical activity are combination-apparatus that can register several physical activity variables like pulse, acceleration, skin temperature and body position, for example ActiReg and Armband (39, 40).

#### Metabolic equivalents METs

Armband, the validation tool used to assess physical activity in this thesis, measures physical activity duration using METs. Metabolic equivalents (METs) are a standardized unit independent of time, body weight and gender. The definition of 1 MET is 1 kcal per kilogram of body weight per hour (1 kcal/kg/hour). For a normal person resting energy expenditure

corresponds to 1 MET. The MET-value can give an estimate of a person's physical activity level, and examples of METs values are listed in **Table 1.2**. MET-values up to 3.0 METs correspond to sedentary behaviour. All MET-values above 3.0 is referred to as physical activity: 3.0-6.0 METs moderate physical activity, 6.0-9.0 METs vigorous and 9.0 METs and higher is very vigorous physical activity (34, 41).

Table 1.2 Examples of activities and the related MET-values from "Compendium of Physical Activities" (42).

Activity	METs	Activity	METs
Watching TV (sitting quietly)	1.0	Dancing (aerobic, general)	6.5
Drive	1.1	Jogging (general)	7
Office work	1.2	Bicycling (general)	8
Fishing and hunting	3 - 4	Swimming (breaststroke, general)	10
Walking (5-6 km/h)	4.1	Cross country skiing	7 - 14
Gardening (raking lawn)	4.3	Running	8 - 18

The average METs per day can tell something about the persons general activity-level (**Table 1.3**). Physical active persons, especially those who participate in sports can achieve average METs-values above 2 (41).

 Table 1.3 Average MET-values for typical activity related to lifestyle (41).

Туре	<b>Average METs</b>
Fat inactive person	0.8 - 1.1
Sedentary, relatively inactive person	1.2 - 1.4
Normal person	1.4 - 1.6
Physical active person, athlete	> 1.7

# **1.6 Validation of dietary and physical activity assessment methods**

#### 1.6.1 Validity

In order to study the relationships between food intake and physical activity and health, there is a need for validated methods that yield valid data (37).

Validity of a method means to what extent the method can actually measure what it is intended to measure (35). Validation studies on dietary methods examine how well a method estimates intake, and how the data can be used and interpreted, and provides information about the type of errors that are associated with the method. When new methods are developed, it is therefore essential to validate them. This is done by comparing the results of the method to be tested (test method) with the results of one or more reference methods that are believed to give valid data (37). The quality of a method can also be expressed by its reproducibility, that indicates if a method can give the same results when used repeatedly under the same circumstances (37).

To consider the design and implementation of a validation study satisfactory, there are several criteria that need to be fulfilled;

- I. The reference method should be considered to be more accurate than the test method;
- II. The reference method has to measure the intake at the same level as the test method: Group- versus individual level;
- III. Errors associated with the reference method must be independent of the errors associated with the test method;
- IV. It is ideal to choose two reference methods to strengthen the validation study, by using both data from another dietary-method and biological markers;
- V. The sequence of the reference method and the test method is important; participants should carry out the test method first and then, after an appropriate time lag, the reference method should be carried out;
- VI. The participants in the validation study should be a subgroup of the test-group population.

#### 1.6.2 Absolute and relative validity

To what degree the intake estimates from a method gives valid data on absolute intake are referred to as absolute validity. Absolute validity may be assessed by using biomarkers as reference methods to assess intake of energy expenditure and total energy expenditure. When lack of other gold standard reference methods relative validity are assessed when evaluating the intake of food items and food groups by comparing the intakes from the test method with intake from the reference method. Even if the reference method is considered to give a more accurate estimate of food intake than the test method, it does not measure the true and absolute intake. Relative validity are the term used because the evaluation only can conclude on how well the test method performs *relative* to the reference method (36). Relative validity are assessed in the present thesis.

#### 1.6.3 Validation of food intake by food records

In contrast to the compliance questionnaire, weighed food records are open-ended prospective methods recording the diet in the present (35). It collects data on an individually level, but can also be used on group level. Several days with weighed diet records are often used as the reference method because it is considered to be more accurate than other traditional dietary assessments methods (43-45).

Research have shown that there is a tendency towards underestimating energy intakes using weighted food records and that the degree of underestimation varies between individuals (46, 47) When validating a frequency questionnaire, weighted diet record is a reference-method with partly independent errors because the method is open ended, independent of memory and measuring portion sizes directly. Both dietary-assessment methods have the same errors with the tendency to inaccurately report intake (37).

#### 1.6.4 Validation of physical activity by Armband

Bentsen at al. (39) validated different physical activity monitors in adults participating in freeliving activities, they found that recorded time in moderate to very vigorous intensity varies among physical activity monitors. The Armband is validated in several studies (39, 48, 49). Colbert et al. (49) compared the validity of SenseWear Armband and different surveys with Double labeled water, to measure physical activity energy expenditure in free-living older adults (aged  $\geq$  65 years). They concluded that objective devices are more appropriately to rank physical activity energy expenditure than self-reported surveys in older adults. However, studies have found that Armband underestimates energy expenditure (39, 50, 51).

# 2 Main objective and Aims

The main objective of this master thesis was to validate the compliance questionnaire to the NFBDG among patients with newly diagnosed CRC, using weighed food records and Armband as reference methods for dietary intake and physical activity, respectively.

In addition, we examined to which extent the CRC patients followed the NFBDG about 2-3 months after surgery, which is baseline of intervention in the NFS.

#### The specific aims of this master thesis were:

- To validate the compliance questionnaire to the NFBDG in CRC patients, using Armband and food-records as validation tools.
- To identify compliance to the NFBDG among CRC patients at baseline of intervention in the NFS, that is 2-3 months after surgery for CRC.

## **3 Subjects and Methods**

## 3.1 Subjects

#### 3.1.1 Recruitment

The first patients included in the main study (NFS) made the subgroup for this thesis.

The recruitment took place at Ullevål University Hospital from March 2012 to January 2013. The patients were from the Helse Sør-Øst region of Norway. The flowchart of the number of participants that were recruited including the drop-outs is shown in **Figure 3.1**.

Thirty seven eligible patients were invited to participate in the NFS pre-surgery and 32 of those patients accepted the invitation. At baseline of intervention and 6 months follow-up, 21 participants met at the study centre at the Department of Nutrition, of which all completed the compliance questionnaire. Twenty one were offered weighted food records, of which 18 took it home and 15 completed it. Eighteen participants were offered Armband (that was not ready to be used at the first baseline of intervention, so 3 participants were not offered Armband), of which 13 completed it.

#### 3.1.2 Drop-outs

It was registered 5 participants who did not accept to attend. It was 11 participants who did not meet at baseline of intervention and the reasons were; 4 were excluded, 3 resigned and 1 drown consent, 2 were too ill to meet (prolonged treatment with chemotherapy and one got cerebral haemorrhage), and 1 was unable to attend baseline of intervention before I had continued my master thesis.

Some of the participants did not complete weighted food records due to: one participant died, 1 became ill in the period because of chemotherapy and 4 felt that it was too demanding because of illness or a busy and irregular life circumstance.

Some of the participants did not complete Armband due to: one used pacemaker that is a contraindication, 1 got gout-pain by using electrical objects on the body, and 3 were for unknown reasons unable to use it.

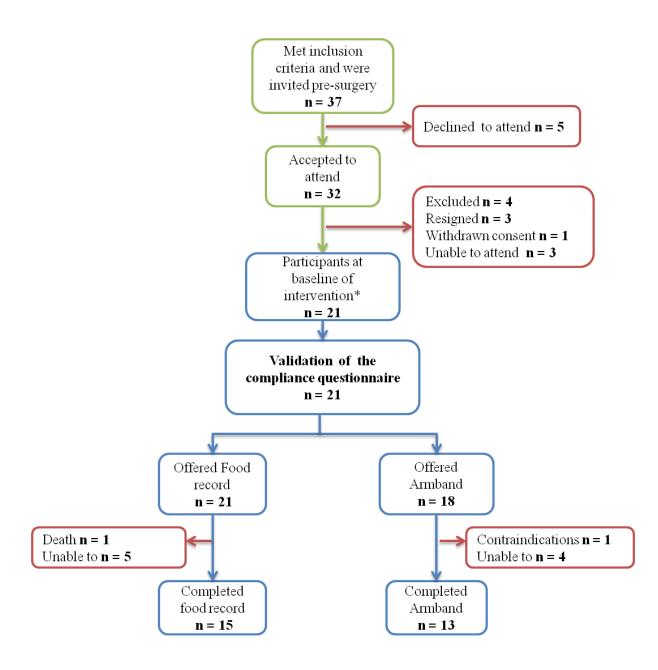
#### 3.1.3 Inclusion criteria

The subjects invited (eligible for inclusion) to the study was men and women between 50-75 years of age and radically treated for CRC with TNM stages I-III.

#### 3.1.4 Exclusion criteria

Exclusion criteria included: CRC stage 0 or IV (TNM stage), ECOG score (cognitive test) and ASA grade subjects (physical status prior to surgery).

Exclusion criteria for physical activity-validation were the contraindications for use of Armband; known metal allergy, eczema or easily irritable skin or when exposed to equipment that may cause electromagnetic interference, for example use of pacemaker because the Armband is not defibrillation proof.



**Figure 3.1 Flow-chart of recruitment and drop-outs for this master thesis.** Thirty seven participants met the inclusion criteria and were invited pre-surgery (green squares), where 32 accepted to attend and 5 declined (red square). Eleven of the participants dropped out (red squares) between pre-surgery and at baseline of intervention\* (blue squares). At baseline of intervention and 6 months follow-up, 21 participants completed the compliance questionnaire. Only 15 participants completed the food records and 13 completed the Armband (17 participants overall formed the validation group). Those who did not use validation tools (red squares) were of different reasons unable to complete it (further explained in section 3.1.2).

\* 2 participants used validation tools at 6 months follow up.

### 3.2 Methods

#### **3.2.1 Permissions/Ethics**

The main study (NFS) is registered in ClinicalTrial.gov (Identifier: NCT01570010) and is approved by The National Committees for Research Ethics in Norway, date 29.04.2011, Registration number 2011/836.

#### 3.2.2 Power calculations

#### Food-intake

The dietary questions were validated in the compliance questionnaire with a 7-Day food record. Sample size calculation was based on SD for fruits and vegetables and fish intake (g), and a significance level of 0.05 with 80 % power. We needed 18 subjects to detect mean difference of 100 g/day for vegetables, 35 subjects to detect mean difference of 100 g/day for fruit intake and 25 subjects to detect mean difference of 70 g/day for fish intake between food records and compliance questionnaire (**Table 3.1**).

#### Table 3.1 Sample size calculations.

	Vegetables	Fruits	Fish
	(g/day)	(g/day)	(g/week)
SD	105 <sup>a</sup>	148 <sup>a</sup>	88 <sup>a</sup>
Expected mean difference	100 <sup>b</sup>	100 <sup>b</sup>	$70^{\circ}$
Sample size n =	18	35	25

<sup>a</sup> Ref: Norkost3 (52)

<sup>b</sup> Ref: Bofetta et al, (53)

<sup>c</sup> Ref: Gonzalez et al, (EPIC) study (54)

Equation (E1) used for power calculations:

$$\mathbf{n} = (\mathbf{SD} / \Delta)^2 * \mathbf{c}$$
(E1)

 $\mathbf{c} = (\alpha \ (2 \text{ sided significance}) = 0.05, 1-\beta \ (\text{desired power}) = 0.80) = 7.9$ 

SD (standard deviation): got from relevant literature

 $\Delta$ : acceptable difference in amount/time between the different methods

#### Sample size based on correlation coefficient

When calculating sample size based on correlation coefficient, the following **Equation 2** was used (55):

$$\left(\frac{1}{2}\log_e\left(\frac{1+\rho}{1-\rho}\right)\right)^2 = f(\alpha, P)\frac{1}{n-3}$$
(E2)

It was estimated a sample size of 38 (n = 38) to detect a correlation coefficient of 0.5 with a power of P = 0.9 and a significance level of  $\alpha$  = 0.05 (55).

#### 3.2.3 Study design

This thesis describes one group of newly diagnosed CRC patients. This is a subgroup of the first patients recruited to the main study, NFS, and includes participants both from the control group and from the intervention group.

An overview of the study design of this master thesis, extracted from the main study, NFS, is shown in **Figure 3.2**. The following visits were included in this thesis:

**Pre-surgery:** The day prior to CRC surgery, at Ullevål University Hospital in Oslo\*, where the patients were recruited to the NFS. The CRC patients were given an invitation and informed consent to participate in the NFS study. If they accepted the invitation to participate they had to sign a consent form before we could start the examination at the same day.

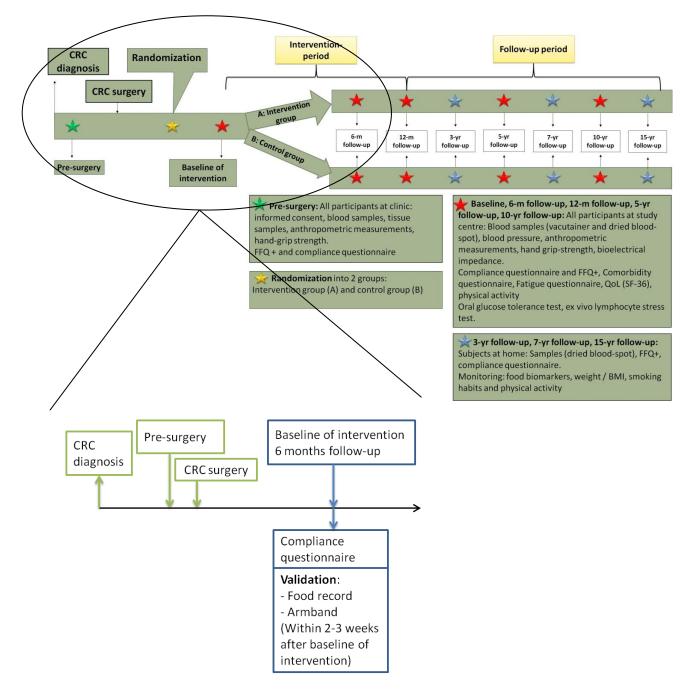
**Baseline of intervention:** Two to three months after pre-surgery, the participants were invited to the study centre at the Department of Nutrition at the University of Oslo. The compliance questionnaire was handed out and the participants filled it in during the visit. In addition the participants received the validation tools: 7-days weighted food records with a digital scale and Armband . The participants completed the reference methods within a period of two weeks after baseline of intervention.

**6 months follow-up:** Two of the participants received the validation tools at this visit, about 6 months after pre-surgery of intervention, at the study centre.

Recruitment of patients for this thesis took place from March 2012 – January 2013 and the validation from August 2012 – March 2013.

At all the visits blood samples were taken (finger-prick and venous), anthropometric measurements (weight, height, waist-hip ratio), and physical test (hand-grip strengths test) were performed and the participants had to answer different questionnaires about dietary intake, lifestyle and state of health.

\* The recruitment Pre-surgery took mainly place at the patient hotel at Ullevål University Hospital, except for the patients who were already hospitalized (inpatient) or during the summer holiday when the patient hotel was closed, then they were recruited at the gastro clinic.



**Figure 3.2 Study design for the NFS with an extract of the study design for this master thesis.** The patients for the NFS and also for this thesis were recruited at Ullevål University Hospital the day before surgery (pre-surgery). Two to three months after surgery, at Baseline of intervention, and at 6 months follow-up, at the study centre at the Department of Nutrition, the participants completed the compliance questionnaire and received the validation tools; Armband and food records, to be completed within 2-3 weeks after Baseline of intervention.

#### 3.2.4 Anthropometric measurements and physical test

The anthropometric measurements weight, height, waist- and hip-circumference and handgrip strength test were measured pre-surgery, at baseline of intervention and at 6 months follow-up, by trained project members included the study nutritionist.

#### Weight

Weight measurement was done using the Marsden portable personal weight (MS-4203) and conducted by a project member. The participants had to empty their pockets for heavy objects such as mobile phone and take off their shoes, watch, belt, etc. It was noted what clothes they wore and deducted half a kilo for clothing. The weight measurement was conducted in the morning. Pre-surgery only about 1/3 of the participants was overnight fasting. At baseline of intervention almost all of the participants except one were overnight fasting. The weight measurement was not adjusted for overnight fasting.

#### Height

Height was self-reported pre-surgery. At baseline of intervention height was measured using an altimeter (Kern MSF 200) and conducted by a project member. The participants had to stand close to the wall with a straight back (with heels, buttocks and parts of the back touching the wall); the head was held straight and steady with eyes directed forward. The altimeter was placed perpendicular to the head.

#### **Body mass index**

Body mass index (BMI) is defined as body weight (kg) divided by height (m) squared (**Equation 3**):

#### $BMI = weight (kg) / (height (m))^{2}$ (E3)

According to the World Health Organization (WHO) definition, the normal/recommended BMI is between 18.5 kg/m<sup>2</sup> and 24.9 kg/m<sup>2</sup>. BMI has a U or J shaped association with total mortality and morbidity. Generally in adults, the BMI that is associated with the lowest mortality and morbidity is approximately 22-23 kg/m<sup>2</sup>. Individuals with BMI of 30 kg/m<sup>2</sup> or more is considered to fall into a category of obesity; persons below 18.5 kg/m<sup>2</sup> are

underweight. But BMI may represent different levels of fatness and body fat distribution depending on gender, age and race or ethnicity. For older people the BMI associated with lowest relative mortality seems to be higher compared to recommendations for younger populations (34).

#### Waist circumference and Waist-hip ratio

Abdominal obesity and waist circumference are one of the components of metabolic syndrome. WHO have made gender-specific waist-circumference cut-off points and risk of metabolic complications associated with obesity. The recommended cut-off points are > 94 cm (men) and > 80 cm (women) for increased risk and > 102cm (men) and > 88cm (women) gives a substantially increased risk. Waist-hip ratio is a measure of abdominal obesity and gives and substantially increased risk for metabolic complications if ratio  $\geq$  0.9 for men and  $\geq$  0.85 for women (56).

For measuring of waist circumference the participant had to lift up their clothes on their upper part of the body. The measuring tape (Sanofi-Aventis/Clas Ohlson) was fastened around the stomach so that the tape went over the navel and the narrowest waist circumference. The participant had to relax the muscles in their stomach and easily breathe out. For measuring of hip circumference the participant had to loosen any belts and pull down the upper part of the pants/skirts etc. and stand with its feet 12-15 cm apart from each other, with the weight evenly distributed on both legs.

#### Hand-grip strength test

Hand-grip strength measured in middle-aged and older people have been shown to be a powerful predictor of functional decline, disability and mortality. Lower grip strength has been associated with increased post-operative complications (57) (58). Grip strengths also declines throughout life for both men and women (59).

A MAP Hand grip dynamometer was used to measure hand-grip strength. Two different strength of the springs was used; 40kg for women and 80kg for men. The participants had to sit with the arm at a 90 degree angle in the air, while the opposite arm was resting. The participants had to squeeze as hard as possible about the gripping device until the

dynamometer started to beep, then the maximum force were read of. The exercise was conducted for both the right and left arm.

It was estimated mean expected grip strength using a model based on age and height developed for the age range of 50-85 years, by Frederiksen et al. (59).

#### 3.2.5 Validation methods

Two reference methods; 7-days food records and SenseWear Armband Mini (model MF-SW) are used to validate food intake and physical activity, respectively, assessed by the test method; the compliance questionnaire (**Table 3.2**).

Estimates of:	Test	Measures	Reference	Measures			
	method		methods				
Food intake	Compliance	Self-	Food	7 days weighted food			
	questionnaire	registered food intake	records	record			
Physical activity	Compliance questionnaire	Self- registered physical activity	Armband	Motion, steps, galvanic skin response, skin temperature, heat flux			

Table 3.2 Methods used to validate food intake and physical activity assessed by the compliance questionnaire.

#### **Compliance questionnaire**

The compliance-questionnaire (**Appendix 1**) is a short food frequency questionnaire, which also includes one question about physical activity. It focuses on intake of vegetables, fruits, berries, nuts, wholegrain, fish, meat and sugar, as well as physical activity. The amounts are based on portion sizes from the Norwegian food and nutrient database (KBS described in a separate section below) and on Norkost3.

To ensure that the questions was comprehensible, well defined and clearly understood, it was tested out on a small subsample, and made some adjustments before it was handed out to the study population.

#### Data assessment

The compliance questionnaire was handed out to the participants at baseline of intervention. The questions included in the compliance questionnaire were grouped into 15 categories. Most of the questions included both frequencies of intake as well as amount. Except for the question about butter, margarine and oils which do not assess amount, but asks for most use of.

#### Data processing and missing values

The compliance questionnaires were scanned and reviewed manually using Teleform<sup>TM</sup> scanning-program (version 10.5.1). In advance of the scanning, common guidelines for how to correct different errors in the questionnaires were made. If amount was missing, but not frequency, the minimum amount variable should be used. If frequency was missing, but amount was not, the minimum frequency above zero was used. If neither quantity nor frequency were given the row were left open and stored as a missing value. If it was given 0 for frequency and given amount, the check for amount was removed. If participants chose more than one option for frequency or amount, average value if possible or the minimum value were used. Data was imported to SPSS and the syntax analyses were run.

#### Syntax

There was made a unique SPSS syntax (**Appendix 2**) for the compliance questionnaire. This syntax was developed in the NFS at the Department of Nutrition (by Hege Berg Henriksen and co workers). The compliance questionnaire has aggregated questions, that via the syntax were sorted into food groups to reflect the NFBDG. The compliance questionnaire asks for frequency and amount per week; in the SPSS syntax there are created encoding that calculates it into amount per day. **Appendix 3** includes an overview of the amounts calculated for the questions in the compliance questionnaire, which was used in the syntax.

#### Percent compliance

In my master thesis it was calculated the percentage of the participants who had an average diet that met the consumption of the quantitative guidelines (vegetables, fruits and berries, nuts, fish, meat, alcohol and juice). And it was estimated percent of the participants that met the guideline of being physical active for at least 30 minutes per day. In addition it was calculated percentage compliance to the median intake and median duration of the quantitative guidelines.

#### **Food records**

The 7-days food records that was used in this thesis, was developed by the Department of Nutrition at the University of Oslo. The 7-Days food records were used together with a scale (Wilfa KW-4) to quantify the intake of various foods and beverages. At every meal throughout the whole day for 7 days the participants registered the amount (in gram, or drink might be provided in decilitre), and type (product name, name of manufacturer, preparation etc.) of all food- and drink products for each meal, along with date and time. It was also possible to add recipes in the back of the record. The participants also registered where the food and drink were ingested (for example at home, at restaurant, at work etc.).

#### Data assessment

The participants received the food-records at baseline of intervention, where they were given oral instructions in how to use them as well as a written user-manual (**Appendix 4**). They brought the records and a digital scale with them and filled it out within 2 weeks after baseline of intervention. The participants recorded their food intake in 7 consecutive days or in 2 periods divided into 3 + 4 days during these two weeks. All weekdays had to be included. After the participants had completed the food-records, the records were returned to the Department of Nutrition by mail in prepaid return envelopes.

#### Data processing and missing values

There were some incomplete registrations in the food records. Missing quantities were given standard portion sizes according to KBS and/or the booklet "measurements and weights of foods" (60) were used. Nonspecific food- /drink products were coded as nonspecific. When cooking method was not included it was sometimes assumed on the basis of the meal; for example when a participant registered salmon on the bread, it was anticipated smoked/cured salmon. If salmon was registered for dinner, it was assumed cooked or fried.

For one of the participants, it missed one day of registration. In the calculations of food intake it was then used an average of six days instead of seven.

#### KBS

The Norwegian food and nutrient database, used in this master thesis, is the 2010 version of the "Kost Beregnings System" (KBS AE-10), developed at the Department of Nutrition, University of Oslo (61). In this Master thesis it was used to retrieve codes for the 7-days weighted food records and to calculate food-intake from the records (62).

Every food and drink item in the food records were assigned a specific code in the food composition database KBS. The food records were manually transcribed into data files (Notepad version 6.1) which were imported into the KBS system. Comments about the food items were registered in an excel file.

The calculations in g/person/day were done in KBS and exported to excel. Further dataprocessing were done in SPSS for analyses. The food records were analyzed for intake of food groups in gram per day.

#### Classification of food-groups by KBS

The classification of food groups used in the correlation-analyzes between the two methods assessing food intake, were based on the NFBDG. The classification of food groups from the food records, were based on the standard categorization of food groups in KBS (AE-10). Some of the food groups in KBS, when it was possible, were specifically adapted in accordance to the NFBDG, by choosing specific subgroups and food codes. There were some limitations in KBS and in the compliance questionnaire that made it difficult to sort all the food groups in according to the NFBDG, because the groupings in KBS are made for another purposes. The classification of food groups are further explained in **Appendix 5** and in section 3.3.

#### Armband

Armband is a lifestyle monitor that based on pooled data calculates values for metabolism/burning of calories and via an actigraph measures the intensity of the physical activity (63).

Armband were ordered from Maribo Medico Sports & Health Science (64). "Armband compendium" and "Armband Quick Guide" were downloaded form (64).

The model used was SenseWear Armband Mini (model MF-SW). This Armband has multiple sensors; among them an accelerometer that measures motion and count steps, and sensors that measure sweat (Galvanic Skin Response), skin temperature and heat flux. It measures total energy expenditure (kcal/min), energy expenditure used on physical activity (kcal/min), METs (metabolic equivalents), physical activity level- and duration, total number of steps, sleep quality, durability and efficiency, time spent lying down, time Armband is ON/OFF body (63).

#### Data assessment

Armband were handed out for the participants at baseline of intervention and used for one week (7 days). The participants were instructed in how to use it and given a written usermanual (**Appendix 6**). The Armband was worn on the right or left arm (on the opposite arm of the dominant one), above the triceps muscle, and data were recorded in 1-minute periods from several sensors. Armband turns itself on when it comes in contact with skin and off when taken off the body. The participants were told to wear it at all times, including while sleeping. The Armband should only be removed for brief periods for bathing or water activities and as needed to vent skin. Armband estimates total duration of physical activity based on total duration Armband is applied; including the time Armband is off body (for example while showering). When Armband is off body it estimates resting energy expenditure.

The Armband-data were used in combination with participant's characteristics that included height, weight, age, gender, handedness and smoking status. (63).

#### **SenseWear Software Professional 7.0**

SenseWear Software Professional 7.0 was downloaded from http://sensewear.bodymedia.com (65) and license for use of the software was obtained from Maribo Medico Sports & Health Science (64). The SenseWear 7.0 Software manual was downloaded from (66), where a modified procedure was made (**Appendix 7**).

#### Data processing

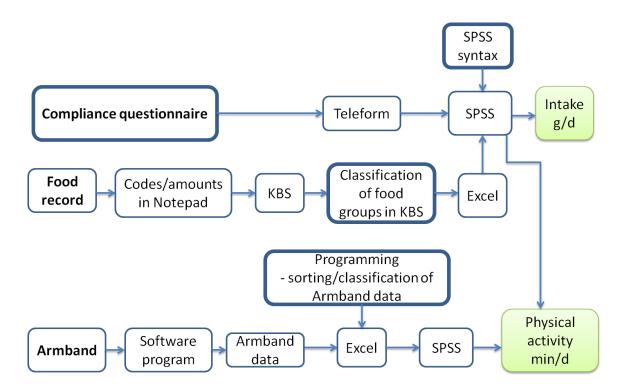
Download of raw data from the Armband to the SenseWear software were done through an USB-cable between the Armband and a computer. It took a few seconds to upload data from the Armband. It was possible to select specific time periods/events from the recorded period; it was selected 7 days for the participants that had worn the Armband for longer than that. Some participant had worn Armband for less than 7 days. To include one day, the Armband had to be on body for at least 19.2 hours per day (80 %) (Personal communication Sveinung Berntsen). All the 13 participants had worn the Armband within the required time span. Physical activity duration (min/d) and intensity (METs) was calculated as a daily average.

From the software program it was possible to generate a SenseWear PDF- Report including graphical presentations that were sent to the participants.

Data from the software program were exported and transferred to Microsoft Office Excel 2007 for further analysis (65). The data used for analysis were duration and intensity of physical activity; total duration of physical activity (min/day) at least 10 min-sessions, with an intensity  $\geq$  3METs.

### 3.3 Development of methods

The compliance questionnaire was developed to estimate dietary intake and physical activity in accordance to the NFBDG. The compliance questionnaire's ability to assess the relative validity of dietary intake and physical activity needed to be established. Thus, this thesis focus on validation of the compliance-questionnaire using 7-days weighed food record and Armband as reference methods. **Figure 3.3** Illustrates the data processing and method-developments (bold) related to the implementation of the validation of the compliance questionnaire; the syntax, classification of food groups in KBS and sorting-/classification of Armband data.



**Figure 3.3 The validation of the compliance questionnaire and method development related to the implementation of the validation.** The compliance questionnaire was scanned in Teleform, then the data was imported to SPSS and sorted by the syntax to match the recommendations of the NFBDG. The weighted food records were coded manually, transferred to Notepad-files and imported to KBS. In KBS the codes were automatically sorted into food groups, in addition sorting were done manually to get the food groups based on the NFBDG. Via analysis in SPSS, gram per day of each food group was estimated. Armband-data were via a software-program exported to excel. Armband-data were sorted by programming in excel (IF-sentences) based on the guideline of physical activity. Via analysis in SPSS duration of moderate physical activity was estimated.

#### 3.3.1 Classification of food groups

Via the syntax made for the compliance-questionnaire the questions about food items was organized according to the NFBDG. Likewise, to be able to validate intake from the compliance questionnaire, intake from the food records were also organised in the same way. Classification of food groups from the food records, were originally based on the standard categorization of food groups in KBS (AE-10). In order to compare the food groups in KBS with the NFBDG, it was necessary to reorganize the structure in KBS, causing several trials and considerations. From the food records it was about totally 500 dietary codes which were to be sorted into about 25 guidelines (including the sub guidelines). This method appeared to be too complicated and laborious and outside the scope of this master thesis. For most of the food groups that we ended up with for the further analysis (Table 4.5, 4.7 and 4.9 in the Results) are explained in **Table 3.3** (in green). In addition the table includes explanations for the food-groups that were not included because of methodological limitations (in red) (further discussed in sections in part 5). The food group classification are based on Table 1.1 and further explained in Appendix 5.

NFBDG <sup>a</sup>	Quantitative guidelines	Food group classification based on food records (KBS) and the compliance questionnaire (syntax)
<b>1.</b> It is recommended a diet primarily from plants, with high amounts of vegetables, fruits, berries, whole grains and fish, and limited amounts of red meat, salt, sugar and energy-rich foods.	-	Holistic guideline that summarize the other guidelines and was not estimated from the compliance questionnaire.
<b>2.</b> It is recommended to maintain the balance between energy intake and energy expenditure	-	The compliance questionnaire does not estimate energy intake, so this is not included in further analyses.
<b>3.</b> Eat at least 5 servings of vegetables, fruits and berries every day	$\geq 500 \text{ g/d}$	Estimated both from the compliance questionnaire and in KBS by sorting of food groups including vegetables, fruits and berries (including 100g juice)
- Vegetables	$\geq$ 250 g/d	Estimated both from the compliance questionnaire and in KBS by sorting of food groups including vegetables
<ul> <li>Onion family (included garlic and leeks)</li> <li>Tomatoes</li> </ul>		Difficult to get total amount from the food records because it is also included in dishes in KBS.
<ul> <li>Fruits and berries, including 100g juice</li> </ul>	≥ 250 g/d	Estimated both from the compliance questionnaire and in KBS by sorting of food groups including fruits and berries (including 100g juice)
- Nuts	$\leq$ 20 g/d	Estimated both from the compliance questionnaire and in KBS

**Table 3.3 Summary of the food group classification based on the NFBDG.** (Based on Table 1.1 and further explained in Appendix 5)

<b>4.</b> Eat at least 4 servings of whole grain	≥ 70-90 g/d	It was possible to estimate amount of
products each day	<u> </u>	whole grain from the compliance
		questionnaire syntax, but this was not
		calculated in KBS, therefore not
<b>5.</b> Eat fish corresponding to 2-3 dinner servings	> 5.4 ~/d	included in further analysis.
5. Eat fish corresponding to 2-5 dinner servings per week	$\geq$ 54 g/d	It was estimated from the compliance questionnaire syntax, and from KBS by
- Fatty fish	$\geq$ 29 g/d	sorting of food groups including fish
	_ * 8 *	and fatty fish.
<b>6.</b> It is recommended that low-fat dairy		It was estimated daily intake by the
products are included in the daily diet and to		syntax in the compliance questionnaire,
reduce high energy dairy products - Low-fat dairy products	"Daily"	but not estimated daily intake form KBS. The amounts of low-fat and high
<ul> <li>High energy dairy products</li> </ul>	"Limit"	energy dairy products are included in
ingli energy and products		further analysis.
7. It is recommended that you choose lean meat		Estimated both from the compliance
preferably non-processed, and limit intake of		questionnaire and from KBS
red meat and processed meat	< 71 - /1	
<ul><li>Total red meat</li><li>Total white meat</li></ul>	$\leq$ 71 g/d Preferably	
- Total Non-processed meat (white and	Total non-	
red)	processed meat	
- Total processed meat (white and red)	intake higher than	
	intake of total	
<b>O T</b> (1) <b>1 1 1 1 1 1 1 1 1 1</b>	processed meat	
<b>8.</b> It is recommended that you choose cooking oils, liquid margarine or soft margarine	Preferably	KBS do not distinguish which fat type used for cooking/baking/frying or on
ons, reque margarne or soft margarne		bread/baguette/roll. The compliance
		questionnaire do not assess gram per
		day of margarine, oils and butter.
- Butter	"Limit"	This was therfore not included in
0 Water is more under a house and	"Preferably"	further analysis.
<b>9.</b> Water is recommended as beverage	Preferably	Cannot compare intake of water with the amount of total beverages, because
		the compliance questionnaire do not
		capture intake of tea and coffee. The
		amounts of water are included in the
	0	analysis.
- Alcoholic beverages	0	Estimated both from the compliance questionnaire and from KBS, but the
		compliance questionnaire do not
		estimate gram alcohol per day.
- Juice	$\leq$ 200 ml	Estimated both from the compliance
	(CT ·	questionnaire and from KBS.
- Beverages with added sugar	"Limit"	Estimated both from the compliance questionnaire and from KBS.
<b>10.</b> Reduce intake of added sugar	< 10 E % added	Not estimated in E % sugar from the
200 results intalle of added bugu	sugar	compliance questionnaire. But
		estimated total amount of food groups
		with added sugar.
<b>11.</b> Reduce the use of salt	"Limit"	Not estimated from the compliance
<b>12.</b> Supplements may be necessary to ensure		questionnaire or from KBS. Estimated amounts both from the
nutrient intake of some population groups		compliance questionnaire and from
- Cod liver oil		KBS.
- Cod liver oil capsules		
- Vitamin D		
- Multivitamin		

<sup>a</sup> Includes the sub guidelines of the NFBDG.

#### 3.3.2 Classification of Armband-data

Armband was used as reference method to assess the validity of the questions about physical activity. The guideline recommends assuring an average of at least 30 minutes of moderate physical activity per day. This includes moderate physical activity in minimum 10-minutes sections. Division into minimum 10-minutes-sections or more, provides a considerable health effect and are required for prevention of chronically diseases (1) (16). The compliance questionnaire captures physical activity for 10-minutes sections and more. There occurred some challenges to sort the physical activity-data from the Armband in the same way. Armband captured level of physical activity every second for 7 days. This gave a large amount of Armband-data for each individual. To sort this in an effective and correct way, there was made IF-sentences (programming in excel). This programming could specifically estimate physical activity with moderate to higher intensity ( $\geq$  3 METs) for 10-minutes sections and more. In addition physical activity was estimated in moderate to vigorous intensity for minimum 10 minutes per period of activity within 13 minutes, allowing brief periods of resting within the period of physical activity. The physical activity classification that we ended up with for the further analysis (Table 4.4, 4.6, 4.8 in the Results) are explained in Table 3.4 (in green).

NFBDG	Quantitative Guidelines	Classification of Armband-data
Physical activity minimum 30 min	≥ 30 min/d	<ul> <li>Physical activity with moderate to vigorous intensity (≥ 3 METs) for minimum 10-minutes sections per period of activity.</li> <li>Physical activity in moderate to vigorous intensity for minimum 10 minutes per period of activity within 13 minutes, was also included to allow for brief periods of rest within a period of physical activity.</li> </ul>

Table 3.4 Classification of Armband-data.

### 3.4 Statistical analysis

Data are analysed by the use of IBM SPSS Statistics version 20.

A p-value  $\leq 0.05$  was considered as an indication of statistical significance.

To evaluate whether the data material was normally distributed or not, Histograms, Normal Q-Q Plots and Kolmogorov-Smirnov (p > 0.05 indicates Normality) were used. Most of the data for participant characteristics were normally distributed and therefore tested by use of parametric tests. Most of the food estimates and physical activity data were not normally distributed and included outliers, but the outliers were within reasonable values. Usually an n < 30 in study-groups indicates that non-parametric tests should be used, not to miss the importance of the outliers in the data-material (67). It was therefore used non-parametric test for data of food intake and physical activity duration.

Continuous data were presented as mean (CI) for normally distributed data. Median values with range (min, max) were used for data not normally distributed. Categorical data was presented as percent.

#### Differences between groups or two sets of data

To find out whether there was a statistically significant difference between two groups (men versus women) on a continuous measure, the Mann-Whitney U Test for non-parametric data that compares medians was used. This test converts the scores on the continuous variable to ranks across the two groups. For normally distributed data, Independent sample t-test was used as a parametric alternative to compare the mean score.

Fishers exact test were used for smoking data and gender-distribution between the group using validation tools vs. the group not using validation tools.

#### **Correlations between methods**

A common method of assessing association between a questionnaire and a reference method, is to estimate the correlation coefficient between the methods (68). The correlation between estimated intake measured by the test- and reference methods, can be used as basis to assess the methods ability to range individuals (35). Pearson product-moment correlation coefficient

(r) or the Spearman Rank Order Correlation (rho) can be used. Both are used to explore the strength of the relationship between two continuous variables. (**69**). Pearson correlation coefficients (r) can only take on values from -1 to +1. A correlation of 0 indicates no relationship at all, a correlation of 1.0 indicates a perfect positive correlation, and a value of -1.0 indicates a perfect negative correlation (69). Spearman correlation was used for continuous data (non-parametric). A correlation coefficient of 0.5 and above is considered good correlation between estimates.

#### **Differences in absolute-intake**

The differences between food intakes estimated by the compliance questionnaire and the food records were tested using Wilcoxon signed rank test (paired data). This test evaluates the agreement between the methods, if the absolute intake estimates from the compliance questionnaire are equally to those obtained using food records. There are good agreements between the methods if there are no significant differences.

#### **Bland-Altman plots**

When a new dietary assessment method is evaluated it is usually compared to another existing method. The Bland-Altman plots are a useful tool for evaluating new dietary assessment methods. The agreement between the two methods is evaluated by a presentation of the absolute difference between the two methods, for each participant, plotted against the calculated mean of both methods. The scatter plot shows variation and any trends in the difference between the two methods. The plot might reveal outlier and systematical errors. The closer each participant is the zero difference, the nearer each participant is an equal duration from both methods (i.e. the better is the agreement between the two methods) (70).

#### **Percent compliance**

It was calculated the percentage of the participants who achieved full compliance to the quantitative guidelines. In addition it was calculated the percentage compliance to the median intake and median duration of the quantitative guidelines.

## 3.5 Software

The different software programs used in this thesis are listed below:

- EndNote Program X6
- IBM SPSS Statistics version 20.0
- KBS version 7.0, AE-10
- Microsoft Office Excel 2007
- Microsoft Office Word 2007
- Notepad version 6.1
- SenseWear Software 7.0 Professional
- Teleform<sup>TM</sup> version 10.5.1 (scanning program)

## 3.6 My contribution to the research project

The NFS is a large and complex randomized controlled trial. The planning and preparation of the trial, recruitment and follow-up of patients, as well as data sampling, processing and analysis require coordination of a large number of scientists and technicians. During this master period I have been part of this large organization and contributed to many aspects of the NFS. In addition to have the privilege to learn about running a randomized controlled trial, the study has also been the primary source of data for my master thesis. An overview of my contribution to the research project relevant to this master thesis is presented in **Table 3.5**.

At the time period the present thesis was conducted, the project group of the NFS consisted of: Professor Rune Blomhoff, Postdoc Ingvild Paur, Postdoc Siv Kjølsrud Bøhn, the PhD students Hege Berg Henriksen and Hanna Ræder, Associated Professor Monica Hauger Carlsen, technician Siv Åshild Wiik, the master students Ane Sørlie Kværner, Mari Bøe Sebelien and myself.

Work assignment	Description	Responsible
Recruitment process at	Invited patients to the NFS. Organized FFQ and compliance questionnaires.	NFS project group, incl. Anne
Oslo University Hospital Ullevål	Clinical examinations such as hand-grip strength, anthropometric measures (weight, waist and hip circumference).	
	Preparation of blood samples: finger-prick- bloodspot cards and treating venous blood samples in lab.	
Baseline of intervention and 6 months	Clinical examinations such as measuring blood pressure, anthropometric measurements. Dietary counselling.	NFS project group, incl. Anne
follow-up	Development of user manuals/procedures for use of the validation tools.	Anne
	Handed out and instructed the participants in use of the validation-tools.	
	Contacting participant from which validation tools was not returned.	
Data processing	Compliance questionnaires: organizing the questionnaires, scanning in Teleform, proofreading	Anne, supervised by Monica H. Carlsen
	Food records: encoded from KBS to notepad files, imported to KBS and proofreading of the import files, personal evaluations of the diet based on each weighted food record	
	Armband: configuration, computing, sent reports to the participants	
Validation	Validation of the compliance questionnaire	Anne in collaboration with:
	with regard to diet and physical activity:	Rune, Monica, Hege: Discussing
	<u>Method development:</u>	classification of physical activity-data and food groups
	Armband (first time used at the Department of Nutrition): Classification of Armband-data	Ingvild: Made the programming for
	Food records: Classification of food groups: Interpretation of how to get estimated intake from food records and compliance questionnaire to fit with the NFBDG	classification of Armband-data into minimum 10 min sections.
Analysis	Statistical analysis	Anne

### Table 3.5 Contributions related to this master project.

## 4 Results

In this interim analysis the compliance questionnaire based on the NFBDG was validated of a subpopulation from the NFS.

The first part of the results shows the characterization of all the participants recruited into the interim analysis and of the group that used validation tools (hereby referred to as the validation group). In the second part, results from the validation are presented. In the last and third part, estimations of compliance to the NFBDG are shown.

## 4.1 Participant characteristics

All the participants recruited into the interim analysis are characterized pre-surgery. The validation group are in addition characterized from baseline of intervention.

### 4.1.1 Characteristics pre-surgery

In January 2013, a total of 31 participants were recruited for the NFS. All of those 31 participants were initially relevant for this interim study, but only 17 participated in the validation at baseline of intervention. A comparison between the participants who used validation tools and those who did not was performed to see whether the validation group was a representative sample of all the participants (**Appendix 8**). Characteristics are based on registrations and measurements conducted pre-surgery, except for the measurement of height measured at baseline of intervention.

There were no significant differences in anthropometric measurements and physical test between the group using the validation tools (n = 17) and those who did not (n = 14).

# 4.1.2 Characteristics of the validation group at baseline of intervention

#### Demographics, anthropometry and physical test

The participants representing the validation group (n = 17) are described in terms of demographics, anthropometry and hand-grip strength test, measured at baseline of intervention\*, with sub-groups presented for gender (men (n = 6) and women (n = 11)) (**Table 4.1**).

As could be expected, there were significant differences in height (p < 0.01), waist/hip-ratio (p = 0.01) and hand-grip strength right arm (p < 0.01) and hand-grip strength left arm (p < 0.01) between men and women.

\*2 of the participants used validation-tools at 6 months follow-up

Variable <sup>a</sup>	Validation group			
	<b>Total</b> (n = 17)	<b>Men</b> ( <b>n</b> = 6)	Women (n = 11)	
	Mean (CI)	Mean (CI)	Mean (CI)	
Demographics				
Age(years)	60.8 (57.7, 63.9)	58.3 (51.1, 65.5)	62.1 (58.5, 65.7)	0.23
Smoking, n	8 (47 %)	2 (12 %)	6 (35 %)	0.62
Anthropometry				
Weight (kg) <sup>c</sup>	82.4 (73.4, 91.3)	91.1 (77.1, 105.1)	77.6 (65.5, 89.7)	0.13
Height (m) <sup>d</sup>	1.71 (1.67, 1.76)	1.79 (1.69, 1.90)	1.67 (1.64, 1.71)	< 0.01*
BMI $(kg/m^2)$	28.1 (25.4, 30.8)	28.5 (24.7, 32.3)	27.9 (23.8, 31.9)	0.82
Waist circumference (cm)	99.6 (92, 107.2)	93.9 (81, 106.8)	102.4 (91.9, 112.9)	0.27
Waist/hip-ratio	0.93 (0.89, 0.97)	0.98 (0.94, 1.03)	0.9 (0.86, 0.94)	0.01*
Physical tests				
Hand-grip strength right (kg) <sup>e</sup>	30.3 (24.4, 36.1)	42 (30.7, 53.2)	23.9 (20.8, 26.9)	< 0.01*
Hand-grip strength left (kg) <sup>e</sup>	27.8 (22, 33.5)	40 (30.3, 49.6)	21.1 (18.1, 24.2)	< 0.01*

 Table 4.1 Characteristics of the validation group at baseline of intervention, divided into men and women.

\*Significant difference between men and women.

<sup>a</sup> Data are presented as mean values with 95 % confidence intervals (CI).

<sup>b</sup> Parametric tests for normal distributed continuous data: Independent sample t-test. Fishers exact test for categorical data.

<sup>c</sup> One half kilo was deducted to account for clothing.

<sup>d</sup> Height was measured by project members at baseline of intervention, by use of an altimeter (Kern MSF 200).

<sup>e</sup> The strength of the springs to the MAP Hand Drip dynamometer is 80kg for men and 40kg for women. It was missing 2 participants for the reasons they were not functionally able to use this apparatus.

#### Characteristics of physical activity

The validation group are characterized in terms of physical activity estimated from the Armband (n = 13) at baseline of intervention (**Table 4.2**). The physical activity data are based on the results from approximately 7 days use of Armband.

On group level the participants were physically active for 51 min/day (median), and 50 of these minutes were at moderate intensity (3.0-6.0 METs). The median MET was of 1.2, and the total energy expenditure was 8.3 MJ per day of which energy expenditure from physical activity accounted for 1.4 MJ per day.

Table 4.2 Characteristics of physical activity of the participants in the validation group.

Variable <sup>a</sup> (n=13)		Validation group
		Median (min, max)
Total Physical activity duration (≥3 METs)	min/d	51 (9, 162)
Moderate (3.0-6.0 METs)	min/d	50 (9, 160)
Vigorous (6.0-9.0 METs)	min/d	0 (0, 2)
Very Vigorous (9.0 METs and higher)	min/d	0 (0, 0)
Average METs/d		1.2 (0.9, 1.6)
Total energy expenditure	MJ/d	8.3 (5.4, 10)
Activity energy expenditure	MJ/d	1.4 (0.2, 2.9)

<sup>a</sup> Data from Armband are calculated in SenseWear Software 7.0 Professional.

#### **Characteristics of the diet**

The diet of the participants as estimated from the weighted food records (n = 15) is shown in **Table 4.3**.

Energy calculations for the group show a median energy intake of 7.0 MJ/day. The energy distribution was a median 19 E % from protein, 36 E % from fat and 42 E % from carbohydrates. Furthermore, the energy percent was a median 5.1 E % for added sugar, 2.1 E % from fiber and 0.7 E % from alcohol.

Variable <sup>a</sup> (n=15)	Units	Validation group	
		Median (min, max)	
Food groups			
Bread	g/d	117 (3, 186)	
Grain products	g/d	26 (2, 141)	
Cakes	g/d	14.3 (0, 159)	
Potatoes	g/d	40 (0, 127)	
Vegetables	g/d	123 (0, 400)	
Fruits and berries (incl. juice and nuts)	g/d	269 (140, 553)	
- Juice	g/d	41 (0, 432)	
Meat, meat products	g/d	106 (5, 404)	
Fish, fish products	g/d	78 (0, 285)	
Egg	g/d	33 (9.3, 94)	
Milk, cream	g/d	390 (91, 660)	
Cheese	g/d	32 (0, 85)	
Butter, margarine	g/d	23 (9, 121)	
Sugar, sweets	g/d	11 (1, 43)	
Beverage	g/d	1191 (389, 3004)	
- Water	g/d	500 (0, 2319)	
- Tea, coffee	g/d	493 (0, 1290)	
- Alcoholic beverages	g/d	23 (0, 493)	
Other <sup>b</sup>	g/d	65 (0, 204)	
Energy and Nutrients			
Energy intake	MJ/d	7.0 (5.2, 13.7)	
Protein	E %	19 (11, 26)	
Fat	E %	36 (25, 53)	
Carbohydrate	E %	42 (26, 49)	
Added sugar	E %	5.1 (2.4, 12.8)	
Fiber	E %	2.1 (1.1, 3.9)	
Alcohol	E %	0.7 (0, 14)	

<sup>a</sup> Data from weighted food records are calculated in KBS (AE10-standard). The food groups are organized in the same way as the food groups from KBS.

<sup>b</sup> Food products included in "Other" in KBS; nutrient preparations, snacks, sauces, powders, spices, vegetarian products, dishes, other and water in dishes.

## 4.2 Validation of the compliance questionnaire

The relative validity of physical activity and food intake estimates from the compliance questionnaire were analyzed using correlation coefficients (rho), difference in absolute intake and absolute-duration, and Bland-Altman plots.

#### 4.2.1 Relative validity of physical activity level

#### **Correlation of physical activity**

In this thesis, physical activity is defined as moderate to vigorous activity lasting 10 minutes or more. The relationship between physical activity estimates from the compliance questionnaire and the Armband was investigated using Spearman's correlation coefficient.

There was no significant correlation between physical activity duration estimates from the compliance questionnaire and Armband measurements, see Table 4.4. In contrast, there was no significant difference in absolute duration between the two measures of physical activity.

Table 4.4 Physical activity duration estimates from the compliance questionnaire and
Armband measurements.

NFBDG <sup>a</sup>	Units	Compliance questionnaire (n = 13)	Armband (n = 13)	p <sup>b</sup>	Correlation	р
		Median (min, max)	Median (min, max)		(rho) <sup>c</sup>	
Physical activity minimum 10 min	min/d	37 (0, 87)	12 (0, 96)	0.28	0.38	0.20
Physical activity minimum 10 min within 13 min	min/d	37 (0, 87)	36 (0, 149)	0.21	0.36	0.23

<sup>a</sup> The classification of Armband-data are based on Table 1.1 and previously described in section 3.3.2.

<sup>b</sup> The differences between physical activity duration estimated by the compliance questionnaire and Armband were tested using Wilcoxon signed rank test (paired data).

<sup>c</sup> Spearman's correlation coefficient (rho).

#### **Bland-Altman plots**

The Bland-Altman plot for the physical activity estimates is shown in **Figure 4.1**. The mean difference was 9.9 min/day and the limits of agreement were +66.26 to -46.45 min/day. The plot shows that the difference between the methods were evenly distributed above and below the mean differences and within the limits of agreement, except for 1 participant where the difference was large. The mean difference show that on group level the compliance questionnaire is overestimating the physical activity.

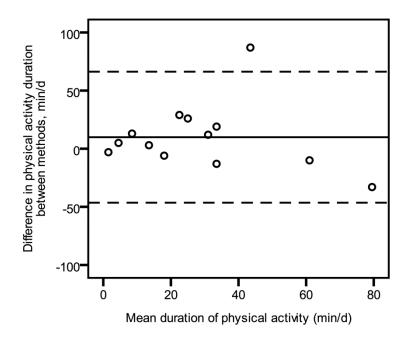


Figure 4.1 Bland-Altman plot of mean duration of moderate physical activity and absolute differences observed between the compliance questionnaire and Armband, min/d. The solid line represents the mean difference between the methods, and the dashed lines represent the upper and lower limits of agreement (mean  $\pm$  1.96 SD) of the observations. Each circle in each plot represents one participant.

#### 4.2.2 Relative validity of food and beverage intakes

#### Correlation of food and beverage intake

The relationship between food group intakes estimated by the compliance questionnaire and weighted food records were investigated using Spearman's correlation coefficient, and are shown in **Table 4.5**. There were significant correlations between the intakes estimated with the two methods for the following variables: fruits, berries and juice (rho = 0.57, p = 0.03), nuts (rho = 0.75, p < 0.01), total red meat (rho = 0.51, p = 0.05), total non processed meat (rho = 0.52, p < 0.05), alcoholic beverages (rho = 0.72, p < 0.01), juice (rho = 0.62, p = 0.02), beverages with added sugar (rho = 0.88, p < 0.001), foods added sugar (rho = 0.53, p = 0.04) and vitamin D intake (rho = 0.52, p < 0.05). Spearman correlation coefficients ranged from 0.05 for low fat dairy products to 0.88 for beverages with added sugar. In addition several of the dietary items showed trends towards correlations with rho approximately equal to 0.5; vegetables (rho = 0.47, p = 0.08), cod liver oil (rho = 0.49, p = 0.07) and cod liver oil capsules (rho = 0.48, p = 0.07).

#### Difference in absolute intake

There were no significant differences between food intakes estimated by the compliance questionnaire and the food records, for most of the food groups, except for low fat dairy products (p < 0.01) for which the food records gave an higher estimate, and for cod liver oil capsules (p = 0.04) for which the food records gave a lower estimate (**Table 4.5**).

NFBDG <sup>a</sup>	Units	Compliance questionnaire (n = 15)	Food records (n = 15)	$\mathbf{p}^{\mathbf{b}}$	Corr. <sup>c</sup>	р
		Median (min, max)	Median (min, max)		(rho) <sup>d</sup>	-
Vegetables, fruits and berries (total)	g/d	319.4 (106.8, 445.4)	379.3 (166.3, 738.1)	0.11	0.21	0.45
Vegetables	g/d	113.6 (20.6, 207.5)	114.6 (0, 396.2)	0.31	0.47	0.08
Fruits, berries	g/d	171.0 (32.8, 331.9)	183.4 (63.7, 396.1)	0.11	0.57	0.03*
including juice	0					
Nuts	g/d	10.9 (0, 50.8)	9.2 (0, 77.1)	0.60	0.75	< 0.01*
Fish (total)	g/d	70 (29, 380)	72.4 (0, 284.6)	0.50	0.30	0.27
Fatty fish	g/d	50 (29, 366)	40.8 (0, 190)	0.26	0.06	0.83
Dairy products	C					
Low fat dairy products	g/d	126 (0, 360)	338.4 (91.4, 659.5)	< 0.01*	0.05	0.86
High energy dairy products	g/d	28 (0, 260)	38 (0, 353.7)	0.50	0.20	0.48
Meat						
Total red meat	g/d	50.5 (0, 171.5)	63.3 (5.2, 404.4)	0.24	0.51	0.05*
Total white meat	g/d	50.5 (0, 115.5)	21.4 (0, 141.7)	0.14	0.30	0.27
Total processed meat	g/d	41 (0, 95.5)	31.3 (5.2, 113.3)	0.91	-0.10	0.73
Total non-	g/d	64.5 (0, 199.5)	53.4 (0, 291.2)	0.83	0.52	< 0.05*
processed meat						
Beverages						
Water	g/d	480 (142, 1440)	500 (0, 2318.6)	0.96	0.15	0.59
Alcoholic beverages	g/d	58 (0, 720)	23 (0, 492.9)	0.77	0.72	< 0.01*
Juice	g/d	114 (0, 480)	40.9 (0, 432.2)	0.25	0.62	0.02*
Beverages with	g/d	0 (0, 258)	0 (0, 141.4)	0.46	0.88	< 0.001*
added sugar						
Food groups with added sugar <sup>e</sup>	g/d	70.3 (0, 356.9)	48.1 (15.1, 284.9)	0.43	0.53	0.04*
Supplements						
Cod liver oil	ml/d	0.00 (0, 10.2)	0.00 (0.0, 7.9)	0.29	0.49	0.07
Cod liver oil	stk./d	0.00 (0, 10.2)	0.00 (0.0, 1.6)	0.04*	0.49	0.07
capsules	Juni/ G	(, 1.)	(0.0, 1.0)	0.07	0.10	0.07
Vitamin D	mcg/d	0.00 (0.0, 14)	0.00 (0.0, 20)	0.47	0.52	< 0.05*
Multivitamin	stk./d	0.00 (0.0, 4.5)	0.00 (0.0, 5.6)	0.60	0.28	0.32
				0.00	0.20	0.52

Table 4.5 Food and beverage intake estimates from the compliance questionnaire and the weighted food records.

\* Correlations were significant at the 0.05 level (2-tailed).

<sup>a</sup> The classification of food groups are based on Table 1.1, previously described in section 3.3.1 and further explained in Appendix 5. <sup>b</sup> The absolute differences between food intakes estimated by the compliance questionnaire and the food records

were tested using Wilcoxon signed rank test (paired data).

<sup>c</sup> Corr. = Correlation

<sup>d</sup> Spearman's correlation coefficient (rho).

<sup>e</sup> Food groups with added sugar also includes beverages with added sugar.

#### **Bland-Altman plots**

Bland-Altman plots of mean intakes and differences observed between the compliance questionnaire and food records for fruits and berries included juice, nuts, total non-processed meat, alcoholic beverages, juice, beverages with added sugar and foods with added sugar are shown in **Figure 4.2**.

#### Fruits and berries including juice

The mean difference and limits of agreement for fruits, berries and juice is -38.9 (140.6, -218.2) g/d (**Figure 4.2 A**). The compliance questionnaire underestimates the mean intake of fruits and berries including juice on group level, but the individual differences between the methods are evenly distributed above and below the mean difference and within the limits of agreement. The limits of agreement are wide. Moreover, there is a trend towards increasing differences with increasing mean intake.

#### Nuts

For nuts the mean difference between the compliance questionnaire and food records is 2.0 g/d with limits of agreement of 30.6, -26.7 g/d (**Figure 4.2 B**). The compliance questionnaire estimates the mean of intake of nuts almost equal as the food record on group level. The individual differences are evenly distributed and relatively centered above and below the mean difference and within the limits of agreement, except for 2 participants where the differences are large.

#### Red meat

The Bland-Altman plot shows that the compliance questionnaire underestimates the mean intake of total red meat with -19.4 (122.1, -160.9) g/d (mean difference and limits of agreement) (**Figure 4.2.C**) on group level. The individual differences between the methods are evenly distributed above and below the mean difference and within the limits of agreement, except for 1 participant where the difference is large.

#### Non-processed meat

The compliance questionnaire estimates the mean intake of non-processed meat almost exactly the same as the food record on group level (**Figure 4.2 D**), with mean difference and limits of agreement 0.1 (117.2, -117) g/d. The individual differences are evenly distributed and relatively centered above and below the mean difference and within the limits of agreement, except for 2 participants where the differences are large.

#### Alcoholic beverages

The Bland-Altman plot for alcoholic beverages shows that the compliance questionnaire overestimates the mean intake of alcoholic beverages on group level (**Figure 4.2 E**). The mean difference and limits of agreement is 14.7 (235, -205.6) g/d. The individual differences are slightly more distributed below than above the mean difference and within the limits of agreement, and the limits of agreement are wide.

#### Juice

The Bland-Altman plot show a mean difference between the methods of 38.4 g/d with limits of agreement of 279.5, -202.8 g/d (**Figure 4.2 F**). The compliance questionnaire overestimates the mean intake of juice on group level, but the individual differences between the methods are evenly distributed above and below the mean difference and within the limits of agreement, except for 1 participant where the difference is large.

#### Beverages with added sugar

The intake of beverages with added sugar is higher when estimated from the compliance questionnaire compared to food records, with a mean difference of 9.2 g/d and limits of agreement of 77.8, -59.4 g/d (**Figure 4.2 G**). The individual differences are within the limits of agreement, except for 1 participant where the difference is large.

#### Food groups with added sugar

The compliance questionnaire overestimates the mean intake of food groups with added sugar on group level. The difference between the methods is 12.1 (185, -161.2) g/d (**Figure 4.2 H**). The individual differences are within the limits of agreement, except for 1 participant where the difference is large. The limits of agreement are wide.

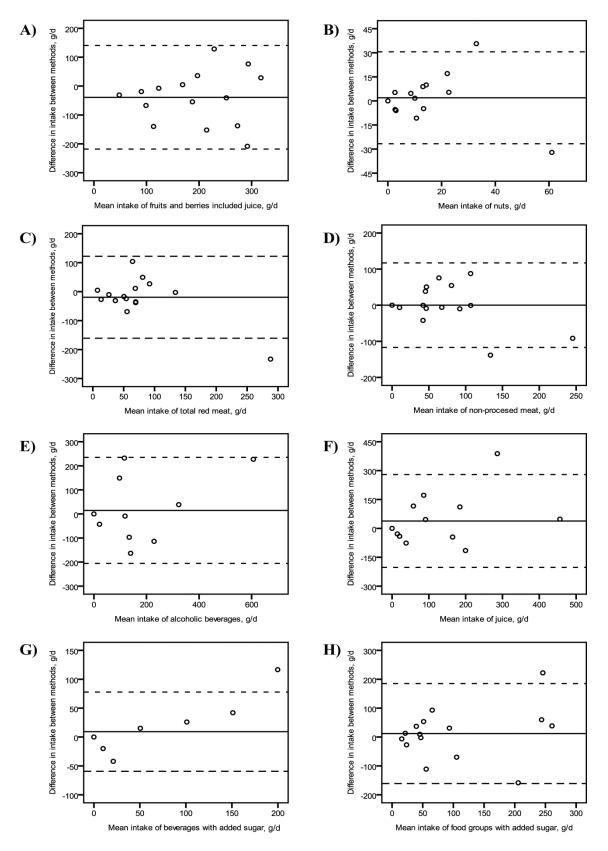


Figure 4.2 Bland-Altman plots of mean intakes and differences observed between the compliance questionnaire and food records A) fruits and berries including juice, B) nuts, C) total red meat, D) total non-processed meat, E) alcoholic beverages, F) juice, G) beverages with added sugar and H) food groups with added sugar. The solid line represents the mean difference between the methods, and the dashed lines represent the upper and lower limits of agreement (mean  $\pm$  1.96 SD) of the observations. Each circle in each plot represents one participant.

## 4.3 Compliance to the NFBDG

In order to quantify compliance, the percentage of participants who fully complied to the quantitative guidelines was calculated. In addition it was calculated percentage compliance to the median intake and median duration of the quantitative guidelines.

# 4.3.1 Percentage of the participants who achieved full compliance to the quantitative guidelines

#### **Physical activity**

As measured by the compliance questionnaire and Armband, the percentages of the participants who met the guideline of being at least moderately physically active for a minimum of 30 minutes per day, is presented in **Table 4.6**.

The percent compliance varied among the different measurements and between the compliance questionnaire and Armband. The compliance was 54 %, measured by the compliance questionnaire and 23 % as measured by Armband, or 62 % if 10 active minutes within 13 minutes were included for Armband.

		Compliance questionnaires	Armband
NFBDG <sup>a</sup>	Recommended quantitative guideline (min/d)	% who met the guidelines	% who met the guidelines
Physical activity minimum 10 min	≥ 30	54	23
Physical activity minimum 10 min within 13 min	≥ 30	-	62

## Table 4.6 The percentage of the participants who achieved full compliance to the guideline on physical activity.

<sup>a</sup> The classification of Armband-data are based on Table 1.1 and previously described in section 3.3.2.

#### Food intake

The percentage of the participants who had an average diet that met the consumption of the quantitative guidelines (vegetables, fruits and berries, nuts, fish, meat, alcohol and juice), measured by the compliance questionnaire and food records, are presented in **Table 4.7**.

The compliance questionnaire and food records gave different estimates of percentage compliance. Compliance were low for estimated intake of total vegetables, fruits and berries, and for fruits and berries and vegetables separately, measured by both methods. However, the compliance was relatively high for nuts, total fish, fatty fish, total red meat, non-processed meat and juice, with compliance ranging from 53-100 %.

		Compliance questionnaires	Food records
NFBDG <sup>a</sup>	Recommended quantitative guidelines (g/d)	% who met the guidelines	% who met the guidelines
Total vegetables, fruits and berries <sup>b</sup>	$\geq 500$	0	20
Vegetables	$\geq$ 250	0	27
Fruits and berries <sup>b</sup>	$\geq$ 250	20	40
Nuts	$\leq 20$	73	93
Total fish	$\geq 54$	80	73
Fatty fish	$\geq$ 29	100	80
Total red meat	≤ 71	60	60
Total non-processed meat	Total non-processed meat intake higher than intake of total processed meat	73	53
Alcoholic beverage	0	47	47
Juice	$\leq$ 200 (100)	80	87

Table 4.7 The percentage of the participants who achieved full compliance to the quantitative guidelines on consumption of vegetables, fruits and berries, nuts, fish, meat, alcoholic beverages and juice.

<sup>a</sup> The food groups used in this table are based on Table 1.1, previously described in section 3.3.1 and further explained in Appendix 5.

<sup>b</sup> Includes maximum 100g juice.

# 4.3.2 Percentage compliance to the median intake and median duration of the quantitative guidelines

#### **Physical activity**

As measured by the compliance questionnaire and Armband, the percentage compliance to the median duration of moderate to vigorous physical activity are presented in **Table 4.8**.

The percentage was 100 % for the guideline on physical activity, measured by the compliance questionnaire and 40 % as measured by Armband, or 100 % if 10 active minutes within 13 minutes were included for Armband.

## Table 4.8 Percentage compliance to the median duration of the guideline on physical activity.

			Compliance questionnaires		Armband	
NFBDG <sup>a</sup>	Units	Recommended quantitative guideline	Duration Median (min, max)	Compliance (%)	Duration Median (min, max)	Compliance (%)
Physical activity minimum 10 min	min/d	≥ 30	37 (0, 87)	100	12 (0, 96)	40
Physical activity minimum 10 min within 13 min	min/d	≥ 30	-	-	36 (0, 149)	100

<sup>a</sup> The classification of Armband-data are based on Table 1.1 and previously described in section 3.3.2.

#### Food intake

Median intake for the quantitative guidelines (vegetables, fruits and berries, nuts, fish, meat, alcohol and juice) are calculated as percentage compliance, measured by the compliance questionnaire and food records, presented in Table 4.9.

The compliance for nuts, fish, meat and juice was 100 % as measured by both methods. For total vegetables, fruits and berries, fruits and berries including juice, and vegetables separately the compliance was between 45-73 % (Table 4.9). Lowest compliance was found for alcoholic beverages, measured by both methods.

Table 4.9 The percentage compliance to the median intake for the quantitative guidelines on consumption of vegetables, fruits and berries, nuts, fish, meat, alcohol and juice.

		Compliance questionnaires		Food records	
NFBDG <sup>a</sup>	Recommended quantitative guidelines (g/d)	Intake Median (min, max)	Compliance (%)	Intake Median (min, max)	Compliance (%)
Total vegetables, fruits and berries <sup>b</sup>	≥ 500	319.4 (106.8, 445.4)	64	379.3 (166.3, 738.1)	76
Vegetables	≥ 250	113.6 (20.6, 207.5)	45	114.6 (0, 396.2)	46
Fruits and berries <sup>b</sup>	$\geq$ 250	171.0 (32.8, 331.9)	68	183.4 (63.7, 396.1)	73
Nuts	$\leq 20$	10.9 (0.50.8)	100	9.2 (0, 77.1)	100
Total fish	≥ 54	70 (29, 380)	100	72.4 (0. 284.6)	100
Fatty fish	$\geq 29$	50 (29, 366)	100	40.8 (0, 190)	100
Total red meat	≤71	50.5 (0, 171.5)	100	63.3 (5.2, 404.4)	100
Alcoholic beverage	0	58 (0, 258)	0	23 (0, 492.9)	0
Juice	≤200 (100)	114 (0.480)	100	40.9 (0, 432.2)	100

<sup>a</sup> The food groups used in this table are based on Table 1.1, previously described in section 3.3.1 and further explained in Appendix 5.

<sup>b</sup> Includes maximum 100g juice.

## **5** Discussion

The discussion is divided into two main parts. Part one describes the study population and methods, whereas part two concerns the discussion of the results. The study population is discussed related to sample size, characteristics and generalizability. The main aim of this thesis was to validate a compliance questionnaire against weighted food records and Armband. These three methods have both advantages and potential limitations, this will be clarified. Furthermore, the process of method development will also be part of the method discussion.

## 5.1 Discussion of Study population and methods

#### 5.1.1 Acceptance rate

Of the 37 invited participants pre-surgery from March 2012 – January 2013, 32 participants (87%) answered yes to the invitation. Twenty one (66%) of those participated on baseline of intervention from June 2012 – March 2013. Fifteen (71%) completed food records and 13 (62%) completed Armband. Seventeen (81%) completed either food-record and/or Armband (the validation group).

In the early planning stage of this thesis it was estimated that 60 patients could be recruited from March 2012 – January 2013, with an expectance-rate of 5 patients per 3 weeks-periods. Start of recruitment of patients from Akershus Hospital was delayed and not initiated until February 2013. Number of participants recruited was therefore lower than expected.

#### 5.1.2 Dropout rate and sample size

It was 5 participants (14 %) who declined to participate pre-surgery. From pre-surgery to baseline of intervention, 11 participants (34 %) dropped out. Of the participants in the validation group, 6 (29 %) and 5 (28 %) dropped out, respectively. The reasons for the relatively high drop-out rate in this thesis were mainly due to either not fulfilling the inclusion criteria or that the participants resigned or were unable to attend. The drop-out rates for the participants who were asked to, or used validation tools, were mostly affected by medical reasons.

It is not uncommon to experience drop-out rates of at least 20 percent for cancer patients participating in longitudinal RCTs, and that the drop-out rate increases with longer duration of the study (71).

#### 5.1.3 Participants characteristics

#### Demographics, anthropometry and physical test

The mean BMI for all the participants at pre-surgery was 29.8 kg/m<sup>2</sup> and 27.5 kg/m<sup>2</sup> for men and women respectively. These BMI-values was nearly identical for the validation group at baseline of intervention. All the BMI values corresponded to overweight (34).

According to WHO cut-off points and risk of metabolic complications (waist-circumference > 102cm (men) and > 88cm (women) and waist/hip-ratio  $\ge 0.90$  (men) and  $\ge 0.85$  (women) (56)), pre-surgery both men and women had a waist circumference and waist-hip ratio that give a substantially increased risk of metabolic complications. This was also true for men and women in the validation group at baseline of intervention, except for men whom waist circumference was just below the cut-off points.

The participants at pre-surgery included 42 % current smokers. The number of smokers was even higher among the participants in the validation group, which included 47 % current smokers. This is considerably higher than in Norkost3, where 21 % were current smokers (52).

As could be expected (59), there were significant differences between men and women in the validation group in height, waist/hip-ratio and hand-grip strength.

Hand-grip strength for the participants in this study was compared to a Danish reference population, using tables with sex-, age-, and height-stratified reference data (59). The hand-grip strength was below the reference values, for both the participants pre-surgery and the validation group at baseline of intervention. For men with a height of 175cm and age of 60 years old, the reference value is 47.2 kg (59), compared to a hand-grip strength of 41 kg among men pre-surgery. The reference value for men 180cm and aged 60years is 47.7 kg (59), compared to a hand-grip strength of 42 kg among men in the validation group at baseline of intervention. For women, the reference value of hand-grip strength with height

170 cm and age of 60 years old is 28.4kg, compared to estimated values of 22.6 kg for women pre-surgery and 23.9 kg for women at baseline of intervention.

#### Physical activity

The participants in the validation group at baseline of intervention were physical active ( $\geq$  3 METs) in a total of 51 minutes per day, measured by Armband. This is above the recommendation, which states to be at least 30 minutes moderate physical active each day (16). Total minutes of physical activity measured by Armband, gives a higher estimate of physical activity duration, compared to the duration measured in minimum 10 minutes sections, measured by the compliance questionnaire. Average METs for the validation group were 1.2, which corresponds to sedentary or relatively inactive lifestyle (41).

#### Diet, energy and nutrients

Energy calculations from KBS for the group that completed food records give a median energy intake of 7.0 MJ/day. The recommendation for energy intake depends on gender, age, weight and physical activity level. The Nordic Nutrition Recommendation 2004 (34) estimates that men weighting 75 kg, being 31-74 years old and having a sedentary behavior, require energy intake of more than 10 MJ/d. In comparison, the recommendation of energy intake for women is about 9 MJ/d. This may indicate that the participants may have underestimated their intake in the food records.

The Nordic Nutrition Recommendation 2004 (34) recommends 10-20 E % proteins, 25-35 E % fat, 50-60 E % carbohydrates,  $\leq 10 \text{ E}$  % added sugar, 2.4 E % fiber and < 5 E % from alcohol. The validation group were in according to this recommendations for protein (19 E %), added sugar (5.1 E %) and alcohol (0.7 E %). The group were not in accordance to these recommendations for fat, that was too high (36 E %), carbohydrates and fiber, that was to low; 42 E% and 2.1 E %, respectively.

#### 5.1.4 External validity

To what extent is the study population in this thesis representative for the group of CRC patients in the NFS? External validity is the term of to what degree the findings from the validation study can be generalized to the target population in which the test method should be used. If the participants in a validation study do not represent the population where they were selected from, the external validity can be weakened (37).

There might be difficult to obtain representative subgroups when participating in a validation study requires a high degree of motivation and activity of the participants –therefore most validation studies are conducted in study samples that are more motivated than the target population where the test-method is used (37).

There were no significant differences in demography, anthropometric measurements and hand-grip strength test between the group using the validation tools and those who did not. This indicates that the demography and physical characteristics might be generalizable to the whole NFS population. However, no comparable data existed on diet and physical activity characteristics for the group who did not participate in the validation. Thus the validation group may have had different food and beverage intake and physical activity habits compared to the group who did not participate in the validation. If social economic status had been obtained, this information could further have described how representative the validation group was.

#### 5.1.5 Design and implementation

The compliance questionnaire is a retrospective questionnaire asking for dietary intake and physical activity during the last week. On the other hand the validation tools Armband and food records are prospective methods recording dietary intake and level of physical activity during 7 days within the next two weeks. Even though these recording methods measures variables on different time scales, they are used within a narrow time period (3 weeks) and we assume little changes in lifestyle behaviour during this period. Nevertheless there cannot be precluded that some of the participants may change their eating and physical activity habits within these 3 weeks.

The validation could be further strengthened by using another reference method for dietary assessment, like biomarkers used as an objective reference method (37). This was considered, but unfortunately not feasible in this thesis because of lack of time for biomarker analysis. Biomarkers for selected dietary items will be analyzed at a later time in the NFS.

#### 5.1.6 Dietary and physical activity assessment methods

#### **Compliance questionnaire**

The short compliance questionnaire has the advantage that it is relatively easy and quick to fill out for the participants, compared to for example the long FFQ. Therefore, it requires less motivation for the participants. This increases the likelihood that the participants complete the questionnaire. The questionnaire is also less labor intensive for the persons who analyze it, compared to the long FFQ, and this makes it possible to give the participants quick feedback on their dietary and physical activity behaviors. These two advantages make the compliance questionnaire more effective as an assessment tool than the long FFQ.

The compliance questionnaire is directed towards the NFBDG and it provides the participants with a "compliance score". No other already existing questionnaires can specifically capture compliance to the NFBDG.

The questionnaire captures intake for one week, and by repeated use, it can capture changes in diet and physical activity over time. Osler et al. (72) found that a short FFQ can quantify food intakes, and was responsive to changes in food intake over time. The participants are affected by the treatment-situation and it may occur rapid changes after surgery. In addition it is

important to capture changes trough the intervention period of the NFS. It might be questioned to what extent one week of dietary assessment is representative for the participants usually diet, but the intention with this new questionnaire is not to assess dietary patterns, such as the long FFQ.

The closed answers in the compliance questionnaire, might influence the participants opportunity to report their real intake/-habits and thereby results in inadequately assessments of intake/habits (73). For several questions in the compliance questionnaire, there is a helping text to specify what is meant and thereby makes it easier for the participants to understand the questions and remember their habits. But to what extent can the questions be conductive? It may cause that some of the participants do not include items not mentioned in the examples.

The compliance questionnaire depends on memory, due to this there is possible that the participants forget some of what they have consumed, and eventually state what they normally consume and not necessarily the real intake from the last week (74, 75). The correlation between the compliance questionnaire and the weighted food records can be impaired due to misreporting (74).

The questionnaire does not assess energy intake, which is a limitation of the method because it makes it difficult to identifying over- or underreporting. Misreporting of food intake, including under- as well as over-reporting are main sources of error in dietary assessment (75).

#### Weighted food records

In contrast to the compliance questionnaire, food records are open-ended and prospective; this is an advantage because it records consumption in real time and prevents errors associated with lack of memory. Open ended questions also give the advantage that it may assess intake in more detail than what is possible from a questionnaire (36).

Bingham et al. (45) compared dietary assessment methods, and found that 7 days estimated food records or open-ended food diary compared to different kinds of 24-hour recalls and FFQs, were most closely associated with individual values of nutrients obtained from 16 days weighted food records.

Recording of food and beverage intake using weighted food records can lead to misreporting of food intakes because the recording may be too demanding for the participants (76).

Weighted food records have the disadvantage that they are experienced as time consuming and cumbersome. As a consequence the participants may change their usual eating habits or report less than actually eaten, to make it simpler to record. This may lead to underreporting (40, 75). The participants may also change their eating pattern in a healthier way or exclude to report unhealthy products due to please the researcher, a phenomenon called "pleasing bias" (68).

Food records are also laborious and time consuming for the researcher because it has to be coded manually.

#### Armband

For a given subject, time in moderate to very vigorous intensity physical activity varies substantially among physical activity monitors (39). The different methods for physical activity assessment have both some disadvantages and advantages. For example direct measurement of energy expenditure by heat production or indirect calorimetry that is an indirectly measurement of energy expenditure by oxygen consumption (VO2), is limited to small populations or short periods because of the cost of assessment to both the investigator and the participant. Bomb calorimeter/respiratory chamber is extremely costly, and Double labelled water only gives an integrated assessment of total energy expenditure during the measurement period. Still, such measurements are useful as criteria for evaluating other methods of physical activity recordings (39).

Armband was used as the physical activity assessment tool in this thesis because it has the advantage of being an objective method, can be used in free-living activities, is user friendly (easy to slip on and off and turns on and off automatically when taken on and off body) and is comfortable to wear (63).

However, Armband is not water resistant and can therefore not record physical activity during water activities. This may underestimate physical activity duration. In this thesis all the participants were asked if they participated in water activities, but no one did.

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#### 5.1.7 Data processing

Data from the three methods are thoroughly checked for incomplete data and different kinds of coding errors. Despite this, some errors may have been overlooked, which may have influenced estimated amounts of food and beverage intake and duration of physical activity.

#### **Compliance questionnaire**

Several of the questionnaires were incomplete filled out with missing data or the participants had filled in for more than one option. Based on the rules described in the methodology section for how to interpret these data, food intake and physical activity might be underestimated.

Hjartåker et al. (73) found in The Norwegian women and cancer study (NOWAC) that the FFQ may overestimate the consumption of some foods and underestimate intake of other foods. This may also be true for the compliance questionnaire.

Missing values can make it difficult when calculating intake; if participants are excluded the sample size may be small or biased. It is common to assume that if it is not filled out it is not consumed, but this is not always true. It is possible to contact the participants subsequently, but if there is a long time since, there is a challenge about memory, and they might have forgot what they consumed (77).

The question about butter/margarine/oils was that question most of the participants incorrectly filled out. They were supposed to select one answer of which kind of fat they mostly used for either cooking/baking/frying or on bread/baguette/roll, but several of the participants selected several of the fat types. This may indicate that the participants for example use nearly the same amount of the different fat types for the same purpose or that they use different fat types for baking than for frying.

#### Food record

One of the participants did not complete the 7-days weighted food record and returned a record for 6-days. For this participant a daily mean consumption was calculated only from the recorded days. This did probably not influence the intake, because this participant ate almost the same every day of these 6 days.

#### 5.1.8 Development of methods

Until now, there have not been any methods estimating dietary intake and physical activity in accordance to the NFBDG, as the compliance questionnaire. During the process of developing this particular questionnaire, there have been some challenges.

#### **Classification of food groups**

The compliance questionnaire estimates most of the food groups based on the NFBDG, with some limitations.

Some of the challenges were in sorting of food groups based on the NFBDG in the KBS program. For instance, accurate intake of tomatoes and onions were difficult to get, because these groups are included in several dishes and products in KBS. For wholegrain products it was hard to estimate grams of wholegrain, because this was not calculated in KBS. There were some uncertainties for divisions of dairy products into "low fat" and "high energy" products. KBS does not calculate if low fat dairy products are included daily. Moreover, KBS did not estimate which fat-type preferably used for which purposes (butter or margarine or oils for cooking/baking/frying or on bread/baguette/roll).

Based on these method challenges, some of the analyses were not included: energy intake, salt intake, butter, margarine and oils, tomatoes and onions, grams of wholegrain.

Some analyses were modified: Instead of calculating E % sugar, there were analyzed the amount of food groups with added sugar. Total amount alcoholic beverages were analyzed instead of gram alcohol. The amounts of "low fat"- and "high energy" dairy products were included.

#### **Classification of Armband-data**

The guideline about physical activity recommends being at least moderate physical active in minimum 30 minutes every day. Time spent on physical activity can be divided into sections during the day with duration of at least 10 minutes or more. In addition, the guideline state that all kind of physical activity have advantageous health effects compared to inactivity (16). The compliance questionnaire did not catch up those participants being physical active for less than 10 minutes per section. According to the data from the Armband, there were

examples of participants being moderate physical active in 30 of 40 minutes, but without any section of 10 minutes or more. Those participants will then not get any count for those 30 minutes spent on physical activity. This categorization of physical activity duration into at least 10 minutes sections could be questioned. Therefore it was also included in the analysis estimation of physical activity in moderate to vigorous intensity for minimum 10 minutes per period of activity within 13 minutes, to allow for brief periods of rest within a period of physical activity.

## 5.2 Discussion of Results

#### 5.2.1 Relative validity

#### Relative validity of physical activity

Overall, the validity of the compliance questionnaire in estimation of physical activity duration was moderate. This evaluation is based on the fact that there was no significant correlation between the compliance questionnaire and Armband. No significant correlation means that the compliance questionnaire does not rank the participants adequately according to physical activity. However, the results also showed no significant differences between the methods with regard to absolute time of physical activity, on group level. This suggests that on group level, if the 10 minutes within 13 minutes definition is used, the compliance questionnaire may adequately estimate physical activity. The Bland-Altman plot (**Figure 4.1**) suggests that the compliance questionnaire overestimates physical activity with 10 minutes. This overestimation may be due to inadequacies in the compliance questionnaire or an actual overestimation by the participants. Overall, the evaluation suggests that the compliance questionnaire may assess physical activity on group level, probably with a slight overestimation. Moreover, the compliance questionnaire is not able, in its currents version, to rank the participants physical activity adequately.

Berntsen and co-workers (39) tested "SenseWear Pro Armband" in free living activities, compared with indirect calorimetry. Time in moderate to very vigorous intensity physical activity was overestimated by 2.9 % by Armband. This may indicate that the compliance questionnaire overestimate time used in physical activity even more than shown in the Bland-Altman plot. Persons with good physical fitness have a tendency to underestimate duration used on moderate to vigorous physical activity, while persons with less physical fitness have a tendency to over report time spent on physical activity (personal communication Sveinung Berntsen). Considering that the participants in this validation study are cancer survivors, and that they have increased risk of functional decline (78), they may have over reported time used in moderate to vigorous physical activity.

The compliance questionnaire may have been inaccurately filled out, due to that the questionnaire depends on the participants memory and is a subjective assessment method (49) (previously discussed in section 5.1.6).

Based on the above results the compliance questionnaire are revised with questions that distinguish between moderate and vigorous intensity and also include duration of physical activity below 10 minutes-sections. The new question will hopefully give a more accurate estimation of physical activity intensity and duration measured by the compliance questionnaire.

#### Relative validity of food and beverage intakes

Overall the results indicates that the compliance questionnaire gave good intake estimates of fruits and berries including juice, nuts, total red meat, total non-processed meat, alcoholic beverages, juice, beverages with added sugar, food group with added sugar and vitamin D. In addition to trends towards good correlations for intakes of vegetables and cod liver oil.

#### Evaluating intake of vegetables, fruits and berries including juice

The correlations between the two methods were significant for fruits and berries including juice, in addition intake of vegetables showed trends towards good correlation. This indicates that the compliance questionnaire may rank the participants adequately according to intake of fruits and berries including juice and probably for vegetables. The median intakes of total vegetables, fruits and berries, fruits and berries including juice, and for vegetables separately, were not significantly different, estimated from the compliance questionnaire and food records, on group level. This suggests that on group level the compliance questionnaire may adequately estimate intake of these food groups. However, the Bland-Altman plot (**Figure 4.2 A**) suggest that the compliance questionnaire underestimated intake of fruits and berries including juice. The plot also showed that all the participants were within the limits of agreement. Moreover there was a trend towards increasing differences with increasing mean intake. Poslusna et al. (75) states that it appears that the more respondents consume, the more difficult it is to report intake accurately, maybe because remembering more foods is challenging. Overall the compliance questionnaire seemed to give valid median intake of fruits and berries and probably for total vegetables, fruits and berries and for

vegetables separately, on group level. In addition to fairly rank the participants according to intake of fruits and berries including juice.

#### Evaluating intake of nuts

The evaluation of nut intake was good. This evaluation is based on the fact that there was significant correlation between the compliance questionnaire and the food records. In addition the results showed no significant differences between the two methods with regard to absolute intake, on group level. The Bland-Altman plot (**Figure 4.2 B**) showed that the compliance questionnaire estimates the mean intake of nuts almost similar as the food record, on group level. Overall the compliance questionnaire seems to give valid median intake of nuts on group level and was fairly able to rank the participants according to intake. Another food frequency questionnaire used on an Norwegian population also gave valid intake of nuts (79).

#### Evaluating intake of fish

The evaluation of fish intake was moderate. No significant correlation was found between the compliance questionnaire and food records for intake of fish, the correlation coefficient was especially low for intake of fatty fish. However, the results also showed no significant differences between the methods with regard to absolute intake of total fish and fatty fish, on group level. This suggests that on group level, the compliance questionnaire may adequately estimate fish intake. Moreover the compliance questionnaire is not able, in its current version, to rank the participants adequately according to fish intake. Based on this a new revised question is developed in the compliance questionnaire which includes fish dishes, in order to better estimate fish intake.

#### Evaluating intake of dairy products

Overall, the validity of the compliance questionnaire in estimation of low fat dairy product was not good, and moderate for estimation of high energy dairy products. This is based on the subsequent evaluation. There were no significant correlations between the two methods for neither estimation of low fat dairy product nor high energy dairy products. The median intake of low fat dairy products was significantly higher estimated from the food records than from the compliance questionnaire. This may indicate that the compliance questionnaire underestimate intake of low fat dairy products. It is possible that the participants when answering the compliance questionnaire did not include dairy products used in dishes (for example from milk-based soups, milk in coffee and tea, porridge, fish gratin etc.). This may lead to underreporting of low fat dairy products from the compliance questionnaire. The participants may also have interpreted the classification of low-fat- and high energy dairy products differently from how it was sorted in KBS. Moreover the median intake of high energy dairy products estimated from the compliance questionnaire were not significantly different from the intakes estimated from the food records. Overall, the evaluation suggests that the compliance questionnaire is not able, in its current version, to rank the participants adequately according to intake of dairy products. On group level the compliance questionnaire may adequately assess intake of high energy dairy products, but not adequately for low fat dairy products in the compliance questionnaire to include dairy products used in dishes, in addition to a customized classification-system sorting high energy- and low fat dairy products in KBS.

#### Evaluating intake of meat

Overall the compliance questionnaire seemed to give valid median intake of total red meat and total non-processed meat and moderate for median intake of total white meat and total processed meat. This is based on the subsequent evaluation. The results showed no significant difference between the methods with regard to median intake of total red meat, total white meat, total processed meat and total non-processed meat, on group level. The Bland-Altman plots suggest that the compliance questionnaire gives almost similar intake of total nonprocessed meat (Figure 4.2 D) as the food record, but slightly underestimates intake of total red meat (Figure 4.2 C), on group level. This suggests that the compliance questionnaire may adequately assess meat intake on group level. For total red meat and total non-processed meat, there were found significant correlation between the two methods. Further there were no significant correlations between the two methods for total white meat or total processed meat. Based on these correlations the compliance questionnaire seems to rank the participants adequately according to intake of total red meat and total non-processed meat, but not adequately according to intake of total white meat or total processed meat. The participants might have problems categorizing what are included in processed meat. The classification of processed vs. non-processed meat may also to some extent have been incorrectly classified in KBS.

#### Evaluating intake of beverages

Overall, the compliance questionnaire seemed to give valid median intake of alcoholic beverages, juice and beverages with added sugar. This is based on the following evaluations. It was found significantly correlations for estimates intake of alcoholic beverages, juice and beverages with added sugar between the two methods. However, estimated intake of water showed low correlation between the two methods. Moreover, there was no significantly different intake estimated between the two methods for water, alcoholic beverages, juice and beverages with added sugar, on group level. The Bland-Altman plots suggest that the compliance questionnaire slightly overestimates the mean intake of alcoholic beverages (**Figure 4.2 E**), beverages with added sugar (**Figure 4.2 G**) and juice (**Figure 4.2 F**). Overall the evaluation suggest that the compliance questionnaire may assess intake of water, alcoholic beverages, juice and beverages with added sugar on group level, probably with slight overestimation. In addition the compliance questionnaire is able to fairly rank the participants according to intake of alcoholic beverages, juice and beverages with added sugar on group level, probably with slight

#### Evaluating intake of sugar

The compliance questionnaire gave good mean estimate of intake of food groups with added sugar (including beverages with added sugar). The correlations between the two methods were significant. This indicates that the compliance questionnaire was fairly able to rank the participants according to intake. The median intake estimated by the two methods was not significantly different from the intakes estimated from the food records. Bland-Altman suggest that the compliance questionnaire slightly underestimates intake of food groups with added sugar (**Figure 4.2 H**), on group level.

#### Evaluating intake of supplements

The median intake of cod liver oil, vitamin D and multivitamin, estimated from the compliance questionnaire were not significantly different from the intakes estimated from the food records. However there was significant difference in absolute intake for cod liver oil capsules. This suggests that the compliance questionnaire may assess intake of supplements, except for the cod liver oil capsules, on group level. There was significant correlation between the methods for D-vitamin intake. Moreover cod liver oil and cod liver oil capsules showed

trends towards significant correlation. This may indicate that the compliance questionnaire is able to rank the participants adequately according to intake of cod liver oil, vitamin D and multivitamin.

It is positive to find several correlations between the methods for several of the different food groups in this interim analysis. In a small sample (e.g. n = 30), you may have moderate correlation that do not reach statistical significance at the traditional p < 0.05 level (69). There might have been found stronger correlations between the methods for the intakes which did not show significant correlations, with a larger sample.

The results indicates that the compliance questionnaire rank the participants adequately according to intake of fruits, berries and juice, nuts, total red meat, total non-processed meat, alcoholic beverages, juice, beverages with added sugar, food group with added sugar and vitamin D, and only fair ranking of participants for intake of vegetables and cod liver oil. The compliance questionnaire was not able to rank the participants adequately according to intake of total vegetables, fruits and berries, fish, dairy products, total white meat and total processed meat, water, cod liver oil capsules and multivitamin. Hjartåker et al. (73) found in the Norwegian Woman and cancer study, that the relative validity of a FFQ was better in ranking individuals for specific foods eaten frequently, than for foods eaten less often.

Moreover, the results also showed no significant differences between absolute food intakes estimated by the compliance questionnaire and the food records for most of the food groups, indicating good agreement between the methods for these groups, on group level. However, with slight over- or underestimation for some of the food groups. This over- and underestimation may be due to inadequacies in the compliance questionnaire or an actual over- or underestimation by the participants.

Based on the above results the compliance questionnaire are revised for those questions that do not give adequately estimates of intake.

#### 5.2.2 Compliance to dietary and physical activity recommendations

A second aim of this thesis was to assess the compliance to the NFBDG within a population of CRC patients.

Vossenaar and co-workers (80) have explored how to create criteria to assess and evaluate compliance to the recommendations from The World Cancer Research Fund/American Institute for Cancer Research (WCRF/AICR) (1). They concluded that such criteria was limited at the time (80).

Little is known about the health effects of specific regional diets (81, 82). Over the last decades, a number of food indexes/adherence-score based on different diets/food-based dietary guidelines have been developed (81-84). One example is the "Diet quality index" which can be used to assess the compliance with different food based dietary guidelines (83) and dietary habits. And thereafter investigate whether adherence leads to a better nutrient intake and could have an health-promoting effect (81, 83). Most of these indexes or scores are however created based on intakes found in a study, rather than based on the existing guidelines.

#### **Compliance to the NFBDG**

On an individual level, the percentage of the participants who achieved full compliance to the quantitative guidelines varied from 20 % for total vegetables, fruits and berries to 80 % for intake of fatty fish.

On group level, 100 % compliance to the median intake of the quantitative guidelines was obtained for; nuts, total fish, fatty fish, total red meat and juice. The median compliance to duration of physical activity was 40 % as measured by Armband.

The percentage compliance to the quantitative guidelines gave different percentages between the compliance questionnaire and Armband or food records. This was especially true for compliance on an individual level. On group level, the percentage compliance was mostly the same between the methods. This indicates that the compliance questionnaire gives a better estimate for percent compliance on group level (72). Overall the compliance measured on group level was higher compared to the compliance measured on an individual level. The method selected for the compliance presented below, depends on the validity of the compliance questionnaire. For the categories were the compliance questionnaire seemed to be relatively valid, results form the questionnaire was used, however percentages measured by Armband and food records are used for less valid categories.

#### **Compliance to physical activity**

The percent of the participants who were physical active in at least 30 minutes every day measured by Armband was 23 %, (62 % if 10 active minutes within 13 minutes were included). The first percent is nearly the same compared with Norkost3, were approximately 20 % of the participants replied that they were in moderate physical activity for a minimum of 30 minutes each day as shown in **Table 5.1** (52). If the second percentage measured by Armband is used, this relatively higher percent compared to Norkos3 may indicate that the use of Armband may have increased the motivation for physical activity. There is also a possibility that the participants have increased duration in physical activity due to physical activity guidance at baseline of intervention.

Table 5.1 Percentage of men and women among participants in Norkost3 who were physically active at least 30 minutes each day, by age group (52).<sup>a</sup>

Age group (year)	Men (n = 862)	Women (n = 924)	Total (n = 1786)
	≥ 30 %	≥ 30 %	≥ 30 %
50-59	19	19	19
60-70	25	20	23

<sup>a</sup> This table is a modified version of table 36 in Norkost3.

On group level the percentage compliance to the median duration of moderate to vigorous physical activity measured by Armband was 40 % (100 % if 10 active minutes within 13 minutes were included). Caswell et al. (85) found that 63 % of the participants in a Scottish CRC patients -population, were physical active in minimum 30 minutes per day.

#### Compliance to food intake

#### Evaluating % compliance to intake of vegetables, fruits and berries

On an individual level the percent of participants who met full compliance for intake of total vegetables, fruits and berries measured by the food records was 20 %. This was a lower percent compared to Norkost3 were about 25 % of the participants had an intake of total vegetables, fruits and berries, in accordance with the NFBDG, shown in **Table 5.2** (52). For intake of vegetables alone, 27 % of the participants met full compliance, this was higher than in Norkost3 (15% of the men had full compliance). The percentage of participants who met full compliance to intake of fruits and berries, was 20 % which was lower than Norkost3 (34 % (men) and 41 % (women)) (**Table 5.2**).

Table 5.2 Average intake and percentage of men and women among participants in
Norkost3 that had an average diet that met the NFBDG (52). <sup>a</sup>

Food	Dietary guidelines	Men		Women	Women					
	(NFBDG) (g/day)	Mean (SD) (g/day)	% who met the guidelines	Mean (SD) (g/day)	% who met the guidelines					
Vegetables	≥ 250	154 (106)	15	155 (105)	13					
Fruits and berries <sup>2</sup>	$\geq 250$	209 (167)	34	232 (153)	41					
Vegetables, fruits and berries <sup>b</sup>	$\geq 500$	363 (213)	22	387 (1979)	25					
Fish, plain	> 54	64 (89)	39	44 (61)	31					
Fatty fish, plain	$\geq 36$	29 (53)	24	22 (39)	21					
Red meat, non processed + processed <sup>c</sup>	< 107	146 (120)	45	89 (74)	67					

<sup>a</sup> This table is a modified version of table 27 in Norkost3.

<sup>b</sup> Includes max 100 g juice.

<sup>c</sup> Recommends maximum of 750 g red meat per week (raw weight).

The percentage compliance for median intake of total vegetables, fruits and berries, fruits and berries and vegetables alone, was almost equal measured by both the compliance questionnaire and food records, meaning that the questionnaire gave a very good estimate of intake on group level. The percentage compliance was 45 % for vegetables and about 70 % for total vegetables, fruits and berries, and fruits and berries including juice. In the Norwegian Woman and Cancer Study (NOWAC) (73), the compliance to the recommendations for fruits was almost equal to that in our population, however the NOWAC study did not include berries and juice. Moreover the compliance for intake of vegetables was 57 % in the NOWAC

study, and thus higher than in our population. The NOWAC study only included women, and higher intake of vegetables are commonly found in women gender (53). In the European Prospective Investigation Into Cancer and Nutrition (EPIC) Cohorts, an almost identical percent compliance for median intake of vegetables was found for a Danish reference population (53).

#### Evaluating % compliance to intake of nuts

For intake of nuts, 73 % of the participants met full compliance measured by the compliance questionnaire. On group level, the compliance was 100 % for median intake of nuts. Adamsson et al. (86) also found 100 % compliance for median intake of nuts in a Swedish reference population who followed a Nordic Diet.

#### Evaluating % compliance to fish intake

On an individual level, 73 % of the participants met full compliance for total fish intake, measured by the food records. This was a higher percent compared to Norkost3 were about a third of the participants were within the recommendation (**Table 5.2**). For intake of fatty fish the percentage who met full compliance was also higher than compared to Norkost3.

On group level the percent compliance for median intake of total and fatty fish was 100 %. Hjartåker et al. (73), also found 100 % percentage compliance for median intake of fish and fish products in the NOWAC study. In The Diet, Cancer and Health cohort study, Kyrø et al. (81) found a lower percentage median intake of fish in a Danish age-matched population, with 78 % compliance for men and 65 % for women.

#### Evaluating % compliance to meat intake

For total red meat (non-processed + processed) the percentage of the participants who met full compliance were 60 %. This was somewhat lower than the women, but higher than the men in Norkost3 (45 % for men and 67 % for women) (**Table 5.2**) (52). On group level the percent compliance for median intake of total red meat were 100 percent. Similar to this finding, Caswell et al. (85) found that the mean intake of red meat was nearly 100 percent.

#### Evaluating % compliance to intake of alcoholic beverages

For intake of alcoholic beverages 47 % of the participants met full compliance. On group level, median intake of alcoholic beverages gave zero % compliance. It should be mentioned that one of the participants had a high consumption rate of alcoholic beverages due to admitted alcoholism. Because the NFBDG do not recommend intake of alcoholic beverages , it is unlikely to find good compliance on group level. In the NOWAC study and the NORDIET study, the percent compliance to intake of alcoholic beverages was also found to be zero (73, 86).

Results from this interim analysis shows that the percentage compliance are generally lower measured on an individual level than on group level. It is positive to find that the percentage compliance are relatively similar for several of the food groups compared to other comparable populations. Moreover the compliance questionnaire seems to give better estimating of compliance on group level.

In the NORDIET study, Adamsson et al. (86) found higher intake of plant foods, fish, egg and vegetable fat and a lower intake of meat products, dairy products, sweets and desserts an alcoholic beverages, in the participants who followed the Nordic diet compared to the intake in the reference population. The NORDIET study concluded that it is difficult to directly generalize the results from the study to other populations with different food cultures, but that the study implicates that healthy traditional food items are important to consider in all populations before recommendations for major changes are made.

# 6 Conclusion

In this master thesis the compliance questionnaire based on the NFBDG was validated in a population of CRC patients. Furthermore, compliance to the NFBDG was assessed in this CRC population.

The compliance questionnaire gave good intake estimates for fruits and berries including juice, nuts, total red meat, total non-processed meat, alcoholic beverages, juice, beverages with added sugar, foods added sugar and vitamin D. In addition, there were trends towards good intake estimates for vegetables and cod liver oil. However, the compliance questionnaire gave less good estimates for duration of physical activity, total vegetables, fruits and berries, total fish, fatty fish, total white meat, total processed meat, water, cod liver oil capsules and multivitamin. Based on this validation, some of the questions in the compliance questionnaire are revised.

The estimated compliance to the NFBDG is based on the compliance questionnaire for the categories for which the questionnaire gave a good estimate of intake. For the remaining categories, compliance to the NFBDG is based on the reference methods. On an individual level, the percentage of the participants who achieved full compliance to the quantitative guidelines was lowest for total vegetables, fruits and berries and highest for intake of fatty fish. On group level, highest compliance was achieved to the median intake for nuts, total fish, fatty fish, total red meat and juice, and for physical activity. Moreover the compliance questionnaire seems to give better estimating of compliance on group level. These estimates of compliance may be used to improve the intervention in the NFS.

Overall, this thesis contributes to the development of a questionnaire which measures compliance to the NFBDG. In the future this compliance questionnaire will not only be used in the NFS, rather might be used for estimating compliance to the NFBDG in larger scale nutrition research projects, and also in the clinic for quick estimates of food intake by health personnel.

# 7 Future perspectives and clinical relevance

#### **Future perspective**

To see if the results are representative for the NFS-study population, and the compliance questionnaire is an adequate tool for assessing compliance to the NFBDG, there is a need of assessment with a larger sample size of CRC patients.

Some of the questions in the questionnaire still need to be changed, to improve the estimation of the actual dietary intake and physical activity. Some questions are already modified based on the results from this thesis. There might also bee advantageous if the questionnaire had an open question which asked in which extent the preceding week is representative for the normally intake. There is also a need to develop a system in KBS that have food-groups that corresponds to the NFBDG.

NFS are developing an adherence score that will be used to reflect the compliance of the guidelines. Adherence to the dietary guidelines will be measured by using an index based on the NFBDG. It will be calculated the percentage compliance of all the relevant guidelines. For guidelines consisting of several sub-guidelines, the compliance of that guideline is stated as the average of all sub-guidelines. For those sub-guidelines that are more important than others are also weighted with a higher score

In the future it would probably be beneficial offer the compliance questionnaire as a digital web-based questionnaire. This makes it possible to give automatic responses to the user of the compliance questionnaire and to the healthcare professionals/researchers. It also makes it possible to reach a geographically dispersed population. In addition, the problem with missing values will be reduced.

In the future, it would also be advantageous to make an attachment to the compliance questionnaire, with illustrations and explanation-texts, and thereby help the participant's to fill in the right intake.

Further validation should also include biomarkers as a second and objective reference-method for validation of food intake of selected dietary items in addition to the weighted food record.

#### **Clinical relevance**

Measuring compliance to the NFBDG could be useful for advising in nutritional and exercise behavioural changes by clinical nutritionists and other healthcare professionals, both for use for patients at particular risk of chronic diseases and for prevention of chronic diseases in the general population.

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# 9 Appendix

Appendix 1 The compliance questionnaire.

- Appendix 2 Syntax for the compliance questionnaire.
- Appendix 3 Overview of the amounts calculated for the questions in the compliance questionnaire, which was used in the syntax.
- Appendix 4 User manual for 7-days weighted food records.
- Appendix 5 Classification of food groups.
- Appendix 6 User manual for Armband.
- Appendix 7 User manual for SenseWear Software Professional 7.0.
- Appendix 8 Characteristics of all participants pre-surgery and comparison between the participants that used validation tools and those who did not, divided into men and women.

Appendix 1: The compliance questionnaire.



## **Typisk Norsk-studien**

### KORT SPØRRESKJEMA OM KOSTHOLD OG FYSISK AKTIVITET DEN SISTE UKEN

Skjemaet skal leses av en maskin og det er derfor viktig at du setter tydelige kryss i rutene. Bruk blå eller sort kulepenn. Alle svar vil behandles fortrolig.

Riktig markering i rutene er slik: X

Ved feil markering, fyll hele ruten slik:

Av hensyn til den maskinelle lesningen - pass på at arkene ikke brettes. Har du spørsmål angående utfyllingen av skjemaet kan du ringe

Hege Berg Henriksen eller Hanna Ræder på prosjekttelefon: 923 00 727

Fornavn, mellomnavn:_	
-	
Etternavn:	

## **1.GENERELLE OPPLYSNINGER**

Mann Kvinne <b>Kjønn</b> 🗌 🗌	Alder ar	Høyde cm	Vekt:

**2. FYSISK AKTIVITET** (vi spør om moderat fysisk aktivitet, f.eks. hurtig gange, fysisk aktvitet i arbeid, hardt husarbeid, gå på ski, svømme eller driver trening/idrett). Tenk på den siste uken når du svarer.

	Gang pr. uke										
	0	1	2	3	4	5	6	7	7+		
Hvor mange ganger var du fysisk aktiv mellom <b>10-20</b> minutters varighet?											
Hvor mange ganger var du fysisk aktiv mellom <b>21-30</b> minutters varighet?											
Hvor mange ganger var du fysisk aktiv mellom <b>31-60</b> minutters varighet?											
Hvor mange ganger var du fysisk aktiv i mer enn <b>60</b> minutters varighet?											
								48847	,		

#### **3. GRØNNSAKER**

				Ga	ng pi	Mengue pr. gang								
	0	1	2	3	4	5	6	7	7+					
Hvitløk (pulver, krydder)										1/4 (ts) 1	1/2	1 3	2 	3
Hvitløk (friske, hermetiske)										(fedd)				
Løk og purre										(ss) 1	2	3	4	5+
Tomat (friske)										1/2 (stk)		2	3	4+
Tomatsaus										1 (dl)	2	3	4	5+
Blandet salat (porsjon a 100 gram)										(liten 1/4 bolle)	1/2	3/4		1 1/2+
Andre grønnsaker (gulrot, kålrot, hodekål, frosne blandinger o.l)										1 (dl)	2	3	4	5+

Manada ny an

#### 4. FRUKT OG BÆR

				Gai	Mengde pr. gang	Mengde pr. gang					
	0	1	2	3	4	5	6	7	7+		
Eple, pære, fersken, nektarin, banan, appelsin										(stk) 1/2 1 2 3+	
Mandarin, klementiner, kiwi										(stk) 1/2 1 2 3+	
Druer										(stk) 1-10 11-20 21-40 41	ł
Bær (jordbær, blåbær, bringebær tyttebær, kirsebær osv)	· 🗌									(dl) <sup>1/2</sup> 1 2 3+	
Tørket frukt (eks. aprikos, fiken)										1-5 6-10 11-15 16+ (neve)	

#### 5. DRIKKE

	Gang pr. uke										Mengde pr.gang							
	0	<1	1	2	3	4	5	6	7									
Vann (springvann, flaskevann)							][	1[		(glass)	. 2	3	4 5+					
Annen drikke uten tilsatt sukker (lettsaft, lettbrus)								] [		(glass)	2	3	4 5+					
Juice (eplejuice, appelsinjuice, mana)								] [		1 (glass)	2	3	4 5+					
Annen drikke tilsatt sukker (nektar brus, saft)	' 🗌							] [		1 (glass) [ 	2	3	4 5+					
Alkohol (øl, vin, brennevin)								] [		1 (glass)	2	3	4 5+					
6. KORN																		
				Ga	ng p	r. uke	9			r	lengd	le pr.	gang					
	0	1	2	3	4	5	6	7	7+		-	-						
Søtet frokostblanding eller grøt, f.eks.Corn Flakes, Honnikorn, Chocofrokost, grøt med sukker o.l.)										1- (dl) [	2 3-4	5-6	7+					
Usøtet frokostblanding eller grøt, f.eks.havregrøt, 4-Korn, usøtet mysli, All Bran o.l.)										1- (dl)	2 3-4	5-	6 7+ ]					
												48	847					

# **7. BRØD OG PÅLEGG** (1/2 rundstykke = 1 skive, 1 baguett = 4 skiver, 1 ciabatta = 2 skiver). NB tenk antall skiver pr dag den siste uken

	Antall skiver pr. dag													
	0	1/2	1	2	3	4	5	6	7	8	9	10	11	12+
Fint brød, 0-25% sammalt hvetemel (loff, baguetter, fine rundstykker, ciabatta)		¦ 🔲												
Halvgrovt brød, 25-50% sammalt hvetemel (helkornbrød, kneipp, grove rundstykker)														
Grovt brød, 50-75% sammalt hvetemel (havrebrød)		; 												
Ekstra grovt brød, 75-100% sammalt hvetemel (mørkt rugbrød)														
Fint knekkebrød (kavring)		<u> </u>												
Grovt knekkebrød (grov skonrok)		¦												
Fete oster som pålegg (Brie, Jarlsberg o.l.)														
Magre oster som pålegg (lettost, lett jarlsberg, lett gulost o.l.)		¦ []												
Fisk som pålegg (makrell i tomat, røkelaks, sardiner)		¦ 												
Rødt kjøtt som pålegg (salami, skinke, roastbiff o.l.)		¦												
Hvitt kjøtt som pålegg (kyllingpålegg, kalkunpålegg)		     +												
Pålegg med sukker (syltetøy, Nugatti o.l.)		¦ 🔲												
8. RIS OG PASTA														

		Mengde pr. gang												
	0	1	2	3	4	5	6	7	7+			_	_	
Polert, hvit ris										(dl)				4+
Upolert, naturris										(dl)	1	2	3	4+
Vanlig pasta										(dl)		2	3	4+
Fullkornspasta										(dl)		2	3	4+

#### **9. MEIERIPRODUKTER**

	Gang pr. uke											Mengde pr.gang				
	0	1	2	3	4	5	6	7	7+		Hien	gue	priga	iig		
Meieriprodukter med høyt fettinnhold (helmelk, fløte, rømme)										(dl)		2	3	4+		
Magre meieriprodukter (skummetmelk, ekstralett melk, lett yoghurt)										(dl)	1	2	3	4+		

#### 10. Hvilken type smør/margarin/olje bruker du mest til :

	Mykt margarin (Soft Flora, Vita, Soft oliven)	Hardt smør (meierismør, Bremykt, melange)	Oljer (olivenolje, soyaolje, rapsolje, vita hjertego)
Matlaging, steking, baking			
På brød, baguette, rundstykke	e   _		



#### **11. FISK TIL MIDDAG**

				U	ang p	I. unc	-			Mengde pr. gang
	0	1	2	3	4	5	6	7	7+	
Fet fisk til middag (laks, ørret, sild, kveite)										(skive a`100 1 2 3 4 5+ gram)
Mager fisk (torsk, sei, hyse, rødspette, breiflabbb)										(skive 1 2 3 4 5+ a`100 gram)

#### **12. KJØTT TIL MIDDAG**

				G	ang p	<b>г. u</b> к	e			Mengae pr. gang
	0	1	2	3	4	5	6	7	7+	
Rent rødt kjøtt (storfe, svin, sau/lam eller geit)										$ (porsjon a 100g) \begin{tabular}{ c c c c c c } $\frac{1}{2}$ & $1-2$ & $3-4$ & $5$ & $6+$ \\ \hline \end{tabular} & $1-2$ & $
Bearbeidet rødt kjøtt (pølser, hamburger, kjøttboller)										(porsjon 1/2 1-2 3-4 5 6+ a 100g)
Rent hvitt kjøtt (kylling, høne, kalkun)										1/2       1-2       3-4       5       6+         (porsjon           6+         a 100g)
Bearbeidet hvitt kjøtt (pølser, hamburger, kjøttboller)									· · · · · ·	(porsjon ½ 1-2 3-4 5 6+ a 100g)

#### **13. NØTTER** (1 neve er 25 gram)

	0	1	2	Gan 3	g pr. 4	uke 5	6	7	7+		Mengde	or.gang
Usaltede nøtter (mandler, peanøtter, valnøtter osv.)										(neve)	1-2 3-4	
Saltede nøtter (mandler, peanøtter, valnøtter osv.)										(neve)	1-2 3-4	5-6 7+

#### **14. KAKER, DESSERT, GODTERI**

				Gan	g pr.	ике					Mengd	le pr.c	Jang	
	0	1	2	3	4	5	6	7	7+					
Kaker, hvetebakst, søt kjeks									(st	1 k) [	L 2	3	4 5	5+ 
Dessert (hermetisk frukt, is, pudding)									[] (dl]	)		3	4 5	5+
Sjokolade, godteri										hg= 1/2 Dg)		2	3 4	
Potetgull, chips									(ne	eve) 1-	2 3-	5 6-1	LO 11	1+
15. KOSTTILSKUDD	(ts =	teskj	e, bs	= ba		kje) I <b>ng pr</b> i								
				0	1	2-3	. uke 4-5	6-7			Meng	de pr.	gang	
Tran										1 ts	1 bs	1 ss		
Trankapsler, Fiskeoljekapsler, o	mega-	3 tilsk	udd						(kapsler)	1	2	3	4+	
Trankapsler, Fiskeoljekapsler, o Vitamin D	mega-	3 tilsk	udd						(kapsler) (kapsler)	)	2 2 	3  	4+  4+ 	
	mega-	3_tilsk	udd							) [] 				
Vitamin D	mega-	3_tilsk	udd						(kapsler)	) [] 	2	3	4+ 4+ 4+	



Appendix 2: Syntax for the compliance questionnaire

String blank (a1).
execute.
COMPUTE BMI=vekt/(hoyde*hoyde/10000).
EXECUTE.
Recode vekt (sysmis=0).
Recode hoyde (sysmis=0).
execute.
Comment Spørsmal 2 Fysisk Aktivitet.
RECODE fysakt1 ('A'=0) ('B'=2.1) ('C'=4.35) ('D'=6.45) ('E'=8.55) ('F'=10.65)
('G'=12.9) ('H'=15) ('l'=18) INTO fr_fysakt1
/fysakt2 ('A'=0) ('B'=3.5) ('C'=7.25) ('D'=10.75) ('E'=14.25) ('F'=17.75) ('G'=21.5)
('H'=25) ('I'=30) INTO fr_fysakt2
/fysakt3 ('A'=0) ('B'=6.3) ('C'=13.05) ('D'=19.35) ('E'=25.65) ('F'=31.95) ('G'=38.7)
('H'=45) ('I'=54) INTO fr_fysakt3 /fysakt4 ('A'=0) ('B'=8.4) ('C'=17.4) ('D'=25.8) ('E'=34.2) ('F'=42.6) ('G'=51.6)
('H'=60) ('I'=72) INTO fr_fysakt4.
EXECUTE.
Recode fr_fysakt1 (sysmis=0).
Recode fr_fysakt2 (sysmis=0).
Recode fr_fysakt3 (sysmis=0).
Recode fr_fysakt4 (sysmis=0).
COMPLITE fr totfvakt dag = fr fvakt1+fr fvakt2+fr fvakt2+fr fvakt4
execute.
Comment spørsmal 3 Grønnsaker. RECODE hvitloktorr1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71)
('G'=0.86) ('H'=1) ('I'=1.2) INTO fr_hvitloktorr1.
Recode hvitloktorr2 ('A'=1.88) ('B'=3.75) ('C'=7.5) ('D'=15) ('E'=22.5) INTO
gr_nvitioktorrz. execute.
Recode hvitlokfrisk1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71)

Recode hvitlokfrisk1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) ('H'=1) ('I'=1.2) INTO fr\_hvitlokfrisk1 /hvitlokfrisk2 ('A'=3) ('B'=6) ('C'=9) ('D'=12) ('E'=18) INTO gr\_hvitlokfrisk2

COMPUTE gr\_tomat\_dag = fr\_tomat1\*gr\_tomat2 . EXECUTE. Recode gr\_gronnsaker2 (sysmis=30) Recode fr\_gronnsaker1 (sysmis=0). Recode gr\_salat2 (sysmis=25). Recode fr\_salat1 (sysmis=0). Recode gr\_tomatsaus2 (sysmis=100). Recode fr\_tomatsaus1 (sysmis=0). Recode gr\_lokpurre2 (sysmis=10). Recode gr\_hvitloktorr2 (sysmis=1.88). COMPUTE gr\_tomatsaus\_dag = fr\_tomatsaus1\*gr\_tomatsaus2 . COMPUTE gr\_lokpurre\_dag = fr\_lokpurre1\*gr\_lokpurre2. COMPUTE gr\_hvitlokfrisk\_dag = fr\_hvitlokfrisk1\*gr\_hvitlokfrisk2 COMPUTE gr\_hvitloktorr\_dag = fr\_hvitloktorr1\*gr\_hvitloktorr2 . Recode gr\_tomat2 (sysmis=32.5). Recode fr\_tomat1 (sysmis=0). Recode fr\_lokpurre1 (sysmis=0). Recode gr\_hvitlokfrisk2 (sysmis=3). Recode fr\_hvitlokfrisk1 (sysmis=0). Recode fr\_hvitloktorr1 (sysmis=0). COMPUTE tot\_gr\_tomat\_dag=gr\_tomat\_dag+gr\_tomatsaus\_dag EXECUTE. /gronnsaker2 ('A'=60) ('B'=120) ('C'=180) ('D'=240) ('E'=360) INTO gr\_gronnsaker2 ('H'=1) ('l'=1.2) INTO fr\_gronnsaker1 /gronnsaker1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) /salat2 ('A'=25) ('B'=50) ('C'=75) ('D'=100) ('E'=180) INTO gr\_salat2 ('I'=1.2) INTO fr\_salat1 /salat1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) ('H'=1) /tomatsaus2 ('A'=100) ('B'=200) ('C'=300) ('D'=400) ('E'=600) INTO gr\_tomatsaus2 ('H'=1) ('l'=1.2) INTO fr\_tomatsaus1 ('H'=1) ('l'=1.2) INTO fr\_tomat1 ('H'=1) ('l'=1.2) INTO fr\_lokpurre1 /lokpurre1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) /tomatsaus1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) /tomat2 ('A'=32.5) ('B'=65) ('C'=130) ('D'=312) INTO gr\_tomat2 /tomat1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) /lokpurre2 ('A'=10) ('B'=20) ('C'=30) ('D'=40) ('E'=60) INTO gr\_lokpurre2

COMPUTE gr\_sotfrokost\_dag= fr\_sotfrokost1\*gr\_sotfrokost2. EXECUTE. Recode gr\_frokost2 (sysmis=75) Recode fr\_frokost1 (sysmis=0). Recode gr\_sotfrokost2 (sysmis=75). Recode fr\_sotfrokost1 (sysmis=0). ('H'=1) ('l'=1.2) INTO fr\_frokost1 Comment Spørsmal 6 Korn. tot\_gr\_fruktbarjuice\_dag=gr\_totfruktbar\_dag+gr\_juicefruktporsjon\_dag END IF. COMPUTE gr\_juicefruktporsjon\_dag=100. else IF gr\_juice\_dag >=200. COMPUTE gr\_juicefruktporsjon\_dag=gr\_juice\_dag/2 do IF(gr\_juice\_dag >0AND gr\_juice\_dag <200)</pre> COMPUTE gr\_juicefruktporsjon\_dag=0. COMPUTE gr\_alkohol\_dag= fr\_alkohol1\*gr\_alkohol2 COMPUTE gr\_annendrikke\_dag= fr\_annendrikke1\*gr\_annendrikke2 COMPUTE gr\_juice\_dag= fr\_juice1\*gr\_juice2 COMPUTE gr\_lettdrikke\_dag= fr\_lettdrikke1\*gr\_lettdrikke2 COMPUTE gr\_vann\_dag= fr\_vann1\*gr\_vann2 Comment Spørsmal 7 Brød og pålegg. EXECUTE. COMPUTE gr\_frokost\_dag= fr\_frokost1\*gr\_frokost2 EXECUTE. /frokost2 ('A'=75) ('B'=175) ('C'=275) ('D'=420) INTO gr\_frokost2 /sotfrokost2 ('A'=75) ('B'=175) ('C'=275) ('D'=420) INTO gr\_sotfrokost2 RECODE sotfrokost1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) EXECUTE tot\_gr\_gronnsakerfruktbarjuice\_dag=tot\_gr\_fruktbarjuice\_dag+gr\_totgronnsaker COMPUTE COMPUTE /frokost1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) EXECUTE ('G'=0.86) ('H'=1) ('l'=1.2) INTO fr\_sotfrokost1

Recode gr\_grovbro (sysmis=0). Recode gr\_melbro (sysmis=0). gr\_paleggmedsukker. gr\_hvittkjottpalegg. Recode hvittkjottpalegg ('A'=0) ('B'=5) ('C'=10) ('D'=20) ('E'=30) ('F'=40) ('G'=50) gr\_rodtkjottpalegg. Recode rodtkjottpalegg ('A'=0) ('B'=5) ('C'=10) ('D'=20) ('E'=30) ('F'=40) ('G'=50) gr\_fiskepalegg. Recode fiskepalegg ('A'=0) ('B'=18) ('C'=36) ('D'=72) ('E'=108) ('F'=144) ('G'=180) Recode feteoster ('A'=0) ('B'=5) ('C'=10) ('D'=20) ('E'=30) ('F'=40) ('G'=50) ('H'=60) gr\_grovknekbrod. Recode grovknekbrod ('A'=0) ('B'=7) ('C'=14) ('D'=28) ('E'=42) ('F'=56) ('G'=70) Recode finknekbro ('A'=0) ('B'=6) ('C'=12) ('D'=24) ('E'=36) ('F'=48) ('G'=60) ('H'=72) gr\_ekstragrovbrod. Recode ekstragrovbrod ('A'=0) ('B'=30) ('C'=60) ('D'=120) ('E'=180) ('F'=240) gr\_grovbro. gr\_melbro. Recode melbro ('A'=0) ('B'=18) ('C'=36) ('D'=72) ('E'=108) ('F'=144) ('G'=180) Recode gr\_ekstragrovbrod (sysmis=0). Recode gr\_finbro (sysmis=0) EXECUTE. Recode paleggmedsukker ('A'=0) ('B'=10) ('C'=20) ('D'=40) ('E'=60) ('F'=80) ('H'=60) ('l'=70) ('J'=80) ('K'=90) ('L'=100) ('M'=110) ('N'=144) INTO ('H'=60) ('l'=70) ('J'=80) ('K'=90) ('L'=100) ('M'=110) ('N'=144) INTO Recode magreoster ('A'=0) ('B'=5) ('C'=10) ('D'=20) ('E'=30) ('F'=40) ('G'=50) ('l'=70) ('J'=80) ('K'=90) ('L'=100) ('M'=110) ('N'=144) INTO gr\_feteoster. ('H'=84) ('I'=98) ('J'=112) ('K'=126) ('L'=140) ('M'=154) ('N'=201.6) INTO ('l'=84) ('J'=96) ('K'=108) ('L'=120) ('M'=132) ('N'=144) INTO gr\_finknekbro. Recode grovbro ('A'=0) ('B'=30) ('C'=60) ('D'=120) ('E'=180) ('F'=240) ('G'=300) ('H'=216) ('l'=252) ('J'=288) ('K'=324) ('L'=360) ('M'=396) ('N'=518.4) INTO ('l'=210) ('J'=240) ('K'=270) ('L'=300) ('M'=330) ('N'=432) INTO gr\_finbro. Recode finbro ('A'=0) ('B'=15) ('C'=30) ('D'=60) ('E'=90) ('F'=120) ('G'=150) ('H'=180) ('G'=100) ('H'=120) ('I'=140) ('J'=160) ('K'=180) ('L'=200) ('M'=220) ('N'=288) INTO ('H'=216) ('l'=252) ('J'=288) ('K'=324) ('L'=360) ('M'=396) ('N'=517.4) INTO ('H'=60) ('l'=70) ('J'=80) ('K'=90) ('L'=100) ('M'=110) ('N'=144) INTO gr\_magreoster ('G'=300) ('H'=360) ('I'=420) ('J'=480) ('K'=540) ('L'=600) ('M'=660) ('N'=864) INTO ('H'=360) ('l'=420) ('J'=480) ('K'=540) ('L'=600) ('M'=660) ('N'=864) INTO

Recode gr_finknekbro (sysmis=0). Recode gr_grovknekbrod (sysmis=0). Recode gr_feteoster (sysmis=0).
Recode gr_magreoster (sysmis=0). Recode gr_fiskepalegg (sysmis=0).
Recode gr_rodtkjottpalegg (sysmis=0). Recode gr_hvittkjottpalegg (sysmis=0).
Recode gr_paleggmedsukker (sysmis=0). EXECUTE.
<b>Comment Spørsmal 8 Ris og pasta.</b> RECODE ris1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86)
('H'=1) ('l'=1.2) INTO fr_ris1 /ris2 ('A'=80) ('B'=160) ('C'=240) ('D'=384) INTO gr_ris2
/indicalinat ( A =0) ( b =0.14) ( C =0.23) ( b =0.43) ( c =0.37) ( i =0.74) ( C =0.60) ('H'=1) ('I'=1.2) INTO fr_naturris1
/naturris2 ('A'=80) ('B'=160) ('C'=240) ('D'=384) INTO gr_naturris2 /vanligpasta1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86)
('H'=1) ('I'=1.2) INTO fr_vanligpasta1 /vanligpasta2 ('A'=120) ('B'=240) ('C'=360) ('D'=576) INTO gr_vanligpasta2
/fullkornspasta1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71)
('G'=0.86) ('H'=1) ('l'=1.2) INTO fr_fullkornspasta1
/fullkornspasta2 ('A'=120) ('B'=240) ('C'=360) ('D'=576) INTO gr_tullkornspasta2. EXECUTE.
Recode fr_ris1 (sysmis=0).
Recode gr_ris2 (sysmis=80). Recode fr_naturris1 (sysmis=0).
Recode gr_naturris2 (sysmis=80).
Recode fr_vanligpasta1 (sysmis=0).
Recode fr_fullkornspasta1 (sysmis=0).
Recode gr_fullkornspasta2 (sysmis=120). EXECUTE.
COMPUTE gr_ris_dag= fr_ris1*gr_ris2.
COMPUTE gr_naturris_dag= fr_naturris1*gr_naturris2 .
COMPUTE gr_vanligpasta_dag= fr_vanligpasta1*gr_vanligpasta2 . COMPUTE gr_fullkornspasta_dag= fr_fullkornspasta1*gr_fullkornspasta2 .

Recode gr\_meierifet2 (sysmis=100) Recode fr\_meierifet1 (sysmis=0) gr\_fullkorn\_sotfrokost\_dag+ gr\_fullkorn\_frokost\_dag COMPUTE gr\_fullkorn\_frokost\_dag=gr\_frokost\_dag\*0.75. gr\_fullkorn\_ekstragrovbrod+gr\_fullkorn\_finknekbro+gr\_fullkorn\_grovknekbrod. gr\_fullkorn\_grovbro+ COMPUTE brod\_totfullkorn\_dag=gr\_fullkorn\_finbro+gr\_fullkorn\_melbro+ EXECUTE. COMPUTE gr\_fullkorn\_grovknekbrod=gr\_grovknekbrod\*1. COMPUTE gr\_fullkorn\_ekstragrovbrod=gr\_ekstragrovbrod\*0.45. EXECUTE. Recode gr\_meierimager2 (sysmis=100) Recode fr\_meierimager1 (sysmis=0). EXECUTE. RECODE meierifet1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) brod\_totfullkorn\_dag+gr\_fullkorn\_naturris\_dag+gr\_fullkorn\_fullkornspasta\_dag+ COMPUTE tot\_fullkorn\_dag= COMPUTE gr\_fullkorn\_sotfrokost\_dag=gr\_sotfrokost\_dag\*0.25. COMPUTE gr\_fullkorn\_fullkornspasta\_dag=gr\_fullkornspasta\_dag\*1. COMPUTE gr\_fullkorn\_naturris\_dag=gr\_naturris\_dag\*1. COMPUTE gr\_fullkorn\_finknekbro=gr\_finknekbro\*0. COMPUTE gr\_fullkorn\_grovbro=gr\_grovbro\*0.3. COMPUTE gr\_fullkorn\_melbro=gr\_melbro\*0.15. COMPUTE gr\_fullkorn\_finbro=gr\_finbro\*0. COMPUTE gr\_meierifet\_dag= fr\_meierifet1 \*gr\_meierifet2 . /meierimager2 ('A'=100) ('B'=200) ('C'=300) ('D'=480) INTO gr\_meierimager2. ('G'=0.86) ('H'=1) ('l'=1.2) INTO fr\_meierimager1 /meierimager1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) Comment Spørsmal 9 Meieriprodukter. EXECUTE. /meierifet2 ('A'=100) ('B'=200) ('C'=300) ('D'=480) INTO gr\_meierifet2 ('G'=0.86) ('H'=1) ('l'=1.2) INTO fr\_meierifet1 EXECUTE.

COMPUTE gr\_meierimager\_dag= fr\_meierimager1 \*gr\_meierimager2 . COMPUTE tot\_gr\_meierfet\_fetostpalegg\_dag=gr\_meierifet\_dag+gr\_feteoster.

COMPUTE COMPUTE tot_gr_bearbeid_kjott_dag=u g+gr_rodtkjottpalegg+gr_hv EXECUTE.	<b>Comment Spørsmal 12 Kjott.</b> RECODE rodtkjott1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) ('H'=1) ('I'=1.2) INTO fr_rodtkjott1 /rodtkjott2 ('A'=50) ('B'=150) ('C'=350) ('D'=500) ('E'=720) INTO gr_rodtkjott2
<pre>fr_bearbeid_hvitt_kjott1*gr_ COMPUTE tot_gr_rodtkjott_ gr_rodtkjottpalegg. COMPUTE COMPUTE tot_gr_hvitt_kjott_dag=gr_h kjottpalegg.</pre>	EXECUTE. COMPUTE gr_fetfisk_dag= fr_fetfisk1 *gr_fetfisk2 . COMPUTE gr_magerfisk_dag= fr_magerfisk1 *gr_magerfisk2. COMPUTE tot_gr_fetfisk_dag=gr_fetfisk_dag+gr_fiskepalegg. COMPUTE tot_gr_fisk_dag=gr_fetfisk_dag+gr_magerfisk_dag+gr_fiskepalegg. EXECUTE.
Recode gr_bearbeid_hvitt_k EXECUTE. COMPUTE gr_rodtkjott_dag= COMPUTE gr_bearbeidetkjot COMPUTE gr_hvitt_kjott_day COMPUTE gr_bearbeid_hvitt	/magerfisk2 ('A'=100) ('B'=200) ('C'=300) ('D'=400) ('E'=600) INTO gr_magerfisk2. EXECUTE. Recode fr_fetfisk1 (sysmis=0). Recode gr_fetfisk2 (sysmis=100). Recode fr_magerfisk1 (sysmis=0). Recode gr_magerfisk2 (sysmis=100).
Recode fr_rodukjott1 (sysmis Recode gr_rodukjott2 (sysmi Recode gr_bearbeidetkjott1 ( Recode gr_bearbeidetkjott2 Recode fr_hvitt_kjott1 (sysm Recode gr_hvitt_kjott2 (sysm	<b>Comment Spørsmal 11 Fisk.</b> RECODE fetfisk1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) ('H'=1) ('I'=1.2) INTO fr_fetfisk1 /fetfisk2 ('A'=100) ('B'=200) ('C'=300) ('D'=400) ('E'=600) INTO gr_fetfisk2 /magerfisk1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86)
/bearbeid_hvitt_kjott1 ('A'=C ('G'=0.86) ('H'=1) ('I'=1.2) INT /bearbeid_hvitt_kjott2 ('A'=E gr_bearbeid_hvitt_kjott2. EXECUTE.	<b>Comment Spørsmål 10 Smør margarin olje.</b> Recode myk_margarin ('A'=1) ('B'=-1) ('C'=1) INTO kategori_myk_margarin /hard_margarin ('A'=1) ('B'=-1) ('C'=1) INTO kategori_hard_margarin. EXECUTE.
/bearbeidetkjott1 ('A'=0) ('B' ('G'=0.86) ('H'=1) ('I'=1.2) INT /bearbeidetkjott2 ('A'=50) ('E gr_bearbeidetkjott2 /hvitt_kjott1 ('A'=0) ('B'=0.14 ('H'=1) ('I'=1.2) INTO fr_hvitt_ /hvitt_kjott2 ('A'=50) ('B'=15)	COMPUTE tot_gr_meierimager_magerostpalegg_dag=gr_meierimager_dag+gr_magreoster. EXECUTE. COMPUTE meierimager=0. DO IF (fr_meierimager1>=1 and fr_meierimager1<=1.2). COMPUTE meierimager=1. END IF.

Comment Spørsmal 13 Notter.

smis=0). nis=50). ott\_dag= fr\_bearbeidetkjott1\*gr\_bearbeidetkjott2. |ag= fr\_hvitt\_kjott1\*gr\_hvitt\_kjott2. |itt\_kjott\_dag= 1is=0). .50) ('C'=350) ('D'=500) ('E'=720) INTO gr\_hvitt\_kjott2 =0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) tt\_dag=gr\_rodtkjott\_dag+ gr\_hvitt\_kjott\_dag. 2 (sysmis=50). vittkjottpalegg. =gr\_bearbeidetkjott\_dag+gr\_bearbeid\_hvitt\_kjott\_da hvitt\_kjott\_dag+gr\_bearbeid\_hvitt\_kjott\_dag+gr\_hvitt g= fr\_rodtkjott1\*gr\_rodtkjott2. kjott2 (sysmis=50). cjott1 (sysmis=0). mis=50). =50) ('B'=150) ('C'=350) ('D'=500) ('E'=720) INTO t\_kjott1 14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) 'B'=150) ('C'=350) ('D'=500) ('E'=720) INTO ITO fr\_bearbeidetkjott1 3'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) \_\_bearbeid\_hvitt\_kjott2. TO fr\_bearbeid\_hvitt\_kjott1 \_dag= gr\_rodtkjott\_dag+gr\_bearbeidetkjott\_dag+ (sysmis=0).

Comment Spørsmal 14 Kaker, dessert, godteri. RECODE kaker1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) ('H'=1) ('I'=1.2) INTO fr_kaker1 /kaker2 ('A'=60) ('B'=120) ('C'=180) ('D'=240) ('E'=360) INTO gr_kaker2 /dessert1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) ('H'=1) ('I'=1.2) INTO fr_dessert1 /dessert2 ('A'=90) ('B'=180) ('C'=270) ('D'=0.43) ('E'=540) INTO gr_dessert2 /sjokolade1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=6.57) ('F'=0.71) ('G'=0.86) ('H'=1) ('I'=1.2) INTO fr_sjokolade1 /sjokolade2 ('A'=100) ('B'=200) ('C'=300) ('D'=400) ('E'=600) INTO gr_sjokolade2 /chips1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=6.57) ('F'=0.71) ('G'=0.86) ('H'=1) ('I'=1.2) INTO fr_chips1 /chips2 ('A'=15) ('B'=30) ('C'=45) ('D'=60) ('E'=90) INTO gr_chips2. EXECUTE. Recode fr_kaker1 (sysmis=0). Recode fr_kaker2 (sysmis=60). Recode fr_dessert1 (sysmis=90). Recode fr_sjokolade1 (sysmis=90).	<pre>RECODE usaltet_notter1 ('A'=0) ('B'=0.14) ('C'=0.29) ('D'=0.43) ('E'=0.57) ('F'=0.71) ('G'=0.86) ('H'=1) ('I'=1.2) INTO fr_usaltet_notter1 /saltet_notter2 ('A'=37.5) ('B'=87.5) ('C'=137.5) ('D'=210) INTO gr_usaltet_notter2 ('A'=37.5) ('B'=87.5) ('C'=137.5) ('D'=210) INTO gr_saltet_notter2. EXECUTE. Recode fr_usaltet_notter1 (sysmis=0). Recode gr_usaltet_notter1 (sysmis=37.5). Recode gr_usaltet_notter2 (sysmis=37.5). EXECUTE gr_usaltet_notter2 (sysmis=37.5). COMPUTE gr_usaltet_notter2 (sysmis=37.5). EXECUTE. COMPUTE tot_gr_notter_dag= fr_usaltet_notter1 *gr_saltet_notter2 . COMPUTE tot_gr_notter_dag=gr_usaltet_notter1 *gr_saltet_notter2 . EXECUTE.</pre>
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EXECUTE. Recode gr\_multi2 (sysmis=1). Recode fr\_multi1 (sysmis=0). Recode gr\_vitD2 (sysmis=15) Recode fr\_vitD1 (sysmis=0). Recode gr\_trankp2 (sysmis=1). Recode fr\_trankp1 (sysmis=0). Comment Spørsmal 15 Kosttilskudd. medsukker+gr\_sotfrokost\_dag. tot\_gr\_sukker\_dag=gr\_kaker\_dag+gr\_dessert\_dag+gr\_sjokolade\_dag+gr\_palegg COMPUTE COMPUTE gr\_sjokolade\_dag= fr\_sjokolade1\*gr\_sjokolade2 . COMPUTE gr\_kaker\_dag= fr\_kaker1\*gr\_kaker2 . Recode gr\_chips2 (sysmis=15). Recode fr\_chips1 (sysmis=0). EXECUTE. COMPUTE gr\_multi\_dag= fr\_multi1\*gr\_multi2 . COMPUTE gr\_vitD2\_dag= fr\_vitD1\*gr\_vitD2 . COMPUTE gr\_trankp\_dag= fr\_trankp1\*gr\_trankp2 . COMPUTE gr\_tran\_dag= fr\_tran1\*gr\_tran2 . Recode gr\_tran2 (sysmis=5). Recode fr\_tran1 (sysmis=0). EXECUTE. RECODE tran1 ('A'=0) ('B'=0.14) ('C'=0.36) ('D'=0.64) ('E'=0.93) INTO fr\_tran1 COMPUTE gr\_chips\_dag= fr\_chips1\*gr\_chips2 . COMPUTE gr\_dessert\_dag= fr\_dessert1\*gr\_dessert2 . EXECUTE. Recode gr\_sjokolade2 (sysmis=100). /multi2 ('A'=1) ('B'=2) ('C'=3) ('D'=4.8) INTO gr\_multi2. /multi1 ('A'=0) ('B'=0.14) ('C'=0.36) ('D'=0.64) ('E'=0.93) INTO fr\_multi1 /vitD2 ('A'=15) ('B'=30) ('C'=45) ('D'=72) INTO gr\_vitD2 /vitD1 ('A'=0) ('B'=0.14) ('C'=0.36) ('D'=0.64) ('E'=0.93) INTO fr\_vitD1 /trankp2 ('A'=1) ('B'=2) ('C'=3) ('D'=4.8) INTO gr\_trankp2 /tran2 ('A'=5) ('B'=7) ('C'=11) INTO gr\_tran2 EXECUTE. /trankp1 ('A'=0) ('B'=0.14) ('C'=0.36) ('D'=0.64) ('E'=0.93) INTO fr\_trankp1

Questions in compliance questionnaire	Amount in calculation
Question 2: Physical acivity <sup>1</sup>	
Physical active 10-20 min	15 min
Physical active 21-30 min	25 min
Physical active 31-60 min	45 min
Physical active above 60 min	60 min
Question 3: Vegetables <sup>1</sup>	
Garlic powder	1  tbs = 15  g, 1  tsp = 7.5  g
Fresh garlic	1  clove = 1  slice = 3  g
Onion and leeks	1  tbs = 10  g
Fresh tomato	Norwegian raw tomato = $65 \text{ g}$
Tomato sauce	1  dl = 100  g
Mixed salad	Small bowl = $100 \text{ g}$
Other vegetables	Sinan court 100 g
Question 4: Fruits and berries <sup>1</sup>	
Apple, pear, peach, nectarine, banana, orange	Large fruit $= 100 \text{ g}$
Mandarin, Clementine, kiwi	Medium fruit = $50 \text{ g}$
Grapes	Small fruit = $10 \text{ g}$
Berries (strawberries, blueberries, raspberries,	Shini huit 10 g
cranberries, cherries, etc.)	dl = 55 g
Dried fruits (e.g. apricots, raisins, figs)	1  fist = 20  g
Question 5: Drinks <sup>1</sup>	1 115t - 20 5
Water	1  glass = 200  g
Other drinks with no added sugar	1  glass = 200  g $1  glass = 200  g$
Juice	1  glass = 200  g $1  glass = 200  g$
Other beverages with added sugar	1  glass = 200  g $1  glass = 200  g$
Alcoholic beverages (beer, wine, liquor)	1  glass = 200  g $1  glass = 200  g$
Question 7: Spreads on bread <sup>1</sup>	1 glass – 200 g
	Weight of one slice $-10$ s
Fatty cheese spread	Weight of one slice $= 10$ g
Lean cheese spread	Weight of one slice = $10 \text{ g}$
Fish spread	36 g
Red meat spread	10 g
White meat spread	10 g
Spread with sugar	20 g
<b>Question 8: Rice and pasta<sup>1</sup></b> Polished white rice	90 = 1 d1
	80  g = 1  dl
Unpolished wild rice	80  g = 1  dl
Plain pasta Wholegrain poste	125  g = 1  d l
Wholegrain pasta	125  g = 1  dl
Question 9: Diary products <sup>1</sup>	1 d1 - 100 c
High energy dairy products	1 dl = 100 g
Low fat dairy products	1  dl = 100  g
Question 11: Fish for dinner <sup>1</sup>	100 ~
Fatty fish	100 g
Lean fish	100 g
Question 12: Meat for dinner <sup>1</sup>	100 ~
Non-processed red meat	100 g
Processed red meat	100 g
Non-processed white meat	100 g
Processed white meat	100 g

**Appendix 3** Overview of the amounts calculated for the questions in the compliance questionnaire (**Appendix 1**), which was used in the syntax (**Appendix 2**).

Question 13: Nuts <sup>1</sup>	
Unsalted nuts	1  fist = 25  g
Salted nuts	1  fist = 25  g
Question 14: Cakes, dessert, candy <sup>1</sup>	
Cakes, wheat pastries, waffles, sweet biscuits,	1 piece = $60$ g (average weight)
Dessert	1  dl = 90  g (average weight)
Chocolate, candy, sweets	1  hg = 100  g
Crisps, chips/nachos, popcorn	1  fist = 1  dl = 15  g
Question 15: Dietary supplements <sup>2</sup>	
Cod liver oil	1  tsp = 5g, 1  bs = 7, 1  tbs = 11  g
Cod liver oil capsules	1  capsule = 1  g
Vitamin D	1  capsule = 15  mcg
Multivitamin	1  tsp = 5  g, 1  bs = 7, 1  tbs = 11  g
<sup>-1</sup> Frequency: $A = 0, B = 0.14, C = 0.29, D = 0.43, E = 0.43$	0.57, F = 0.71, G = 0.86, H = 1, I = 1.2
<sup>2</sup> Frequency: $A = 0, B = 0.14, C = 0.36, D = 0.64, E = 0.000$	

Appendix 4 User manual for 7-days weighted food records.



UNIVERSITETET I OSLO det medisinske fakultet

## Brukerveiledning for kostregistrering

## <u>Kostdagbok</u>

- Spis som normalt.
- Registrer kosten i 7 dager (en uke i strekk eller 3+4 dager i løpet av to uker).
- Bruk en ny side for hvert måltid.
- Noter for hvert måltid:
  - o Dag, dato, klokkeslett
  - o Måltidstype: frokost, lunsj, middag, kvelds eller mellommåltid
  - Navnet på matvaren: f.eks.: "Kneip (Bakers)", "Norvegia hvitost helfet (Tine)", "Ekstra lett lettmelk (Q-meiener)", "hjemmelaget brød" (Skriv oppskrift)-Kun én matvare per rad
  - o Tilberedningsmåte: F.eks.: kokt, stekt, grillet, rå ol.
  - o Mengde (g) av alle matvarene / ingrediensene
- Eventuelle oppskrifter noteres bakerst i heftet
- Husk å få med alt som blir spist/drukket: f.eks.: smør, godterier, fløte i kaffen, pastiller ol.
- Trekk fra det som ikke blir spist opp: f.eks.: epleskrott, bananskall, rester på tallerkenen

## Vekt

Innstillinger: ON/OFF, TARE = nullstilling, UNIT: benevningen skal stilles inn på gram (g).

- Eksempel på hvordan veie et sammensatt måltid:
  - Sett asjetten på vekten og nullstill.
  - o Legg på en matvare (f.eks. brødskive), les av vekten, noter og nullstill.
  - Legg på neste matvare(f.eks. smør/margarin), les av vekten, noter og nullstill osv.
  - Dersom måltidet består av sammensatte retter som f.eks. lapskaus, supper og lignende, veies hele retten i ett, men husk å notere mengden av hver ingrediens dersom retten er hjemmelaget.

### <u>Måltider spist borte</u>

 Dersom det er problematisk å få veid; noter så nøyaktig som mulig hva som ble spist og mengder (dl, spiseskjeer, kopper, antall, størrelser etc.).

## <u>Drikke</u>

Enten

 sett glass/kopp på vekten, nullstill, hell oppi det som skal drikkes og noter vekten.

Eller

notermengdenidl.





**Appendix 5** Classification of food groups from the compliance questionnaire and 7-days weighted food records based on the NFBDG.

NFBDG <sup>1</sup>	Recommended (NFBDG) <sup>2</sup>	Compliance questionnaire <sup>3</sup> (based on the syntax) <sup>4</sup>	7-days weighted food records (based on food groups from KBS) <sup>5</sup>	Comments
3. Vegetables, fruits and berries (total)	500 g/d	3. Vegetables + 4. Fruits and berries + Juice from question 5	Vegetables + Fruits and berries + Juice	Juice counts for only maximum 100g.
- Vegetables	250 g/d	3. Vegetables	Vegetables: - fresh, frozen and conserved (not included legumes or potatoes)	
- Onion family (included garlic and leeks)		Garlic and Onion and leek from question 3	Vegetables: - onion	Difficult to get total amount from the food records because it is also included in dishes in KBS.
- Tomatoes		Fresh tomatoes and Tomato sauce from question 3	Vegetables: - tomatoes (fresh)	Difficult to get total amount from the food records because it is also included in dishes in KBS.
- Fruits, berries and juice	250 g/d	4. Fruits and berries + Juice from question 5 (Not included jam from question 7 or hermetic fruits from question 14)	<ul> <li>fresh,</li> <li>frozen and dried</li> <li>(not included hermetic,</li> <li>jam or lemonade)</li> </ul>	Juice counts for only maximum 100g.
- Nuts	$\leq$ 20 g/d	13. Nuts	Fruits and berries: - just including nuts	
4. Wholegrain products (total)	70 – 90 g/d (≥ 50 % of total grain intake)	<ol> <li>Grains/cereals</li> <li>Bread</li> <li>Rice and pasta</li> </ol>	Bread Cereals, other: - flour, rice and pasta - breakfast-cereals with and without sugar - pasta dishes and pie	It was calculated wholegrain by the syntax for the compliance questionnaire. It was difficult to get direct calculations of total wholegrain from KBS, because wholegrain is not included as a nutrient in KBS. Therefore it was not included for further analysis.
5. Fish (total)	≥ 54 g/d	11. Fish for dinner Fish spread from question 7	Fish, fish products: - fatty fish - lean/half-fatty fish - fish unspecified - fish-products - fish dishes - fish spread (not including shellfish nor feed)	Included fish from fish products and fish dishes, unspecified and spread.
- Fatty fish	≥ 29 g/d	Fatty fish for dinner from question 11 + Fish	- fatty fish - fish spread - fish dishes; sushi	Assumed that almost all fish in fish spread are fatty fish.

		spread from		
		question 7		
6. Dairy products - Low fat dairy products	"Daily"	Low fat dairy products from question 9 and lean cheese spread from question 7	Milk, yoghurt: - low fat milk - milk unspecified - yoghurt - milk flavoured - milk other Cheese: - white cheese; bold/lean - brown cheese; bold/lean	Dairy products that are not "high energy dairy products" is not necessarily "low fat dairy products", therefore it was difficult to set a border between those.
- High energy dairy products	"Limit"	High energy dairy products from question 9 + Fatty cheese spread from question 7	Milk: - whole milk Cream, cream products (included sour cream, not included ice cream) Cheese: - white cheese; high fat and unspecified (high fat) - brown cheese; G35, f33, unspecified and prim	Do not include butter
7. Meat - Total red meat	$\leq$ 71 g/d	Non-processed red meat + Processed red meat from question 12 + Red meat spread from question 7	Meat - all meat products except chicken, turkey and hens products	
- Total white meat		Non-processed white meat + Processed white meat from question 12 + White meat spread from question 7	Meat: - all chicken, turkey and hens meat products	
- Total non- processed meat (white and red)	"Preferably"	Non-processed red meat + Non- processed white meat from question 12	- non-processed meat red + white + unspecified	Do not get non- processed meat from meat spread.
- Total processed meat (white and red)	"Limit"	Processed red meat + Processed white meat from question 12 + Red meat spread + White meat spread from question 7	Meat: - salted/cured, minced, spread, other and dishes	
8. Margarine/Oils	Preferably > butter	Margarine and Oils from question 10	Butter/margarine/oils: - margarine - margarine light - oils	The compliance questionnaire do not capture gram per day of margarine, oils and butter.
- Butter	< Margarine/oils	Butter from question 10	Butter/margarine/oils: - butter	
9. Water	"Preferably"	Water from question 5	Beverages: - drinking water	Can not compare intake of water with the amount of total beverages, because the compliance

- Alcoholic beverages	0	Alcoholic beverages from question 5	Beverages: - beer, wine, spirits	questionnaire do not capture intake of tea and coffee. Can not get gram alcohol from the compliance questionnaire.
- Juice	$\leq$ 200 ml	Juice from question 5	Beverages: - juice	
- Beverages with added sugar		Other beverages with added sugar from question 5	Beverages: - lemonade, soda with sugar	
10. Added Sugar	< 10 E % added sugar	<ul> <li>14. Cakes,</li> <li>desserts, sweets</li> <li>Beverages with</li> <li>added sugar from</li> <li>question 5</li> <li>+ Breakfast</li> <li>cereals with added</li> <li>sugar from</li> <li>question 6</li> <li>+ Spread with</li> <li>sugar from</li> <li>question 7</li> </ul>	Cakes Sugar, sweets: - sugar - honey and sweet spreads - chocolate and candy Breakfast-cereals with sugar Beverages: - lemonade and soda Fruits and berries: - jam - hermetic fruits	Can not estimate E % sugar from the compliance questionnaire.
12. Supplements		15. Supplements	Supplements: (sorted directly on codes)	
- Cod liver oil	(5ml)	Cod liver oil from question 15	Møllers	Recommended if not intake of 200g/week with fatty fish or cod liver oil capsules.
- Cod liver oil capsules	2capsules	Cod liver oil capsules from question 15	Møllers omega-3	Recommended if not intake of 200g/week with fatty fish or cod liver oil.
- Vitamin D	(10mcg)	Vitamin D from question 15	Vitamin D	Recommended if inadequate intake of vitamin D
- Multivitamin	(1stk)	Multivitamin supplements from question 15	Antioxidants Mega-B-stress (B- vitamins) Multivitamin	Recommended if low energy intake

<sup>1</sup> Divided into guidelines and sub guidelines to the new Norwegian Food-Based Dietary Guidelines (**Table 1.1**) <sup>2</sup> The quantitative guidelines. <sup>3</sup> The compliance questionnaire is attached as **Appendix 1**. <sup>4</sup> The syntax to the compliance questionnaire is attached as **Appendix 2**. **Appendix 3** explains the syntax calculations. <sup>5</sup> The classification of food groups from the food records, were based on the standard categorization of food groups in KBS (AE-10). Some of the food groups in KBS, when it was possible, were specifically adapted in accordance to the NFBDG, by choosing specific subgroups and food codes.

Appendix 6 User manual for Armband



UNIVERSITETET I OSLO DET MEDISINSKE FAKULTET

## Brukerveiledning for Armband

## SenseWear Armband Mini (model MF-SW)



Ref.: http://shs2.maribomedico.dk/wpcontent/uploads/2012/06/Armband-kompendium-pdf.pdf

## <u>Når må ikke Armbandbenyttes</u>

- Ved kjent metallallergi, eksem eller lett initabel hud.
- Under strålebehandling.
- Dersom du har pacemaker.
- Sammenmed annet utstyr som kan forårsake elektromagnetiske forstyrrelser (f.eks. i fly, på sykehus, ved bruk av pulsklokke ol.).

## Bruk av Armband

### Hvordan ha den på:

- Festes på baksiden av venstre overarm (triceps), Armbandlogoen skal peke oppover mot skulderen og sølvsensorene på undersiden av Armband skal være i kontakt med huden. Overarmen skal være ren, tørr og uten krem/olje ol. Stroppen strammes så den sitter komfortabelt, men stramtnok så Amband ikke sklir nedover armen, det skal være plass til to fingre under stroppen.
- Brukes 7 dager i strekk: minst 23t/døgn med ca. 1 time hvor den er tatt av for å lufte huden.
- Armband slår seg PÅ automatisk og begynner å lagre datainnen -10 min etter at den er tatt på armen. Aktiveringen indikeres av en Ref:http://www.templehealthcare.com.au/p rekke lydtoner (det eringen AV- og PÅ knapp).



gs-vis/products/bm-seusewear.html

- Når armband kan benyttes: Når deltakeren sover, trener og ellers ved daglige rutiner.
- Når Armband ikke kan benyttes: I dusjen eller på svømming -Armband tåler ikke vann!



## Renhold:

- Rengjør Armband etter å ha svettet eller dersom den blir synlig skitten.
   NB: Husk først å separere Armband fra stroppen: med Armband-logoen pekende oppover, press den hvite delen av Armband ut av den grå delen som stroppen henger fast i.
- Rengjøring av Armband
  - Den siden som berører huden tørkes av med en fuktig klut med mild såpe, sørg deretter for å fjerne såperester og tørk til slutt med en tørr klut.
- Rengjøring av Armband-stroppen
  - o Vaskes for hånd med en mild såpe i varmt vann, skylles og lufttørkes.

## ! Farer ved bruk

- Hudirritasjon (rapportert hos < 1 % av brukerne).
- Det er viktig å følge rådene for hvordan Armband skal regngjøres og festes rundt armen.
- Hvis hudirritasjonen skulle vedvare, avslutt bruken av Armband og eventuelt konsulter med fastlegen.

## Husk å tilbakesende Armband i medfølgende returkonvolutt etter avsluttet bruk!

Takk 🕲

Appendix 7 User manual for SenseWear Software Professional 7.0.

# Prosedyre for bruk av SenseWear Professional Software

## Referanse: BodyMedia®, SenseWear® 7.0 Software Manual:

http://shs2.maribomedico.dk/wp-content/uploads/2012/06/Armband-Guide-pdf.pdf

## Installering

- Last ned SenseWear Software fra sensewear.bodymedia.com: Support > Downloads > Download SenseWear 7.0 (<u>http://downloads.bodymedia.com/SenseWear-7.0.0.2378-20101012.exe</u>).
- 2. Kjør det nedlastede installasjons-programmet.
- 3. Etter få sekunder dukker installasjonsveiviseren opp, følg instruksjonene på skjermen.
- 4. Sett inn **lisensnøkkelen** i en USB port på PCen før start av SenseWear Professional. Windows vil oppdage ny hardware og laste opp nødvendige drivere.

# NB: Under installasjonen kan du få opp et pop-up vindu som indikerer at du ikke har de riktige fullmakter for å installere dette produktet. Hvis du får denne meldingen, kontakt administrator eller IT-avdelingen for hjelp.

## Konfigurering

Følg denne prosedyren for å konfigurere Armband <u>før</u> den brukes:

- 1. Plugg USB-kabelen i en USB-port på din PC.
- 2. Plugg motsatt ende av USB-kabelen i Armband. Windows vil detektere den nye hardwaren og laste inn de riktige driverne. Om du kan motta visuell bekreftelse av installasjonen avhenger av din versjon av Windows
- 3. Du skal nå ha fått et nytt ikon på skrivebordet, Armand-ikonet.



- 4. Dobbeltklikk på Armband-ikonet på skrivebordet for å åpne SenseWear Software.
- 5. Klikk på Configure Armband & Display på toppen av programvinduet.
- 6. Klikk Retrieve Configuration (hent konfigurasjonen).
- 7. Angi riktig informasjon i *Subject info* tab (NB, kan fylles ut etter at Armband har samlet data, før analyse):
  - a. Subject/ID nr.:
  - b. *Date of Birth:*
  - c. *Height*:
  - d. Weight:
  - e. Sex:
  - f. Handedness:
  - g. Smoker:
  - Trykk Continue.
- 8. *Armband Parameters:* Gjør det mulig å kontrollere dato og klokke på Armband (synkroniser med PC-klokken), maskinvare versjon, serienummer, batterinivå og minnekapasitet.
- 9. Klikk *Apply* nederst i vinduet.
- 10. La Armband være koplet til

In order to accurately interpret the data you are retrieving, please specify the following body parameters of the wearer.				
Subject	0123 Current Age			
Date of Birth	Aug 🔻 9 💌 1977 💌 33 yrs			
Height	6' 02" feet' inches" or 188 centimeters* BMI			
Weight	220 pounds or 99.8 kilograms* 28.24			
Sex	Male			
Handedness	Right Handed			
Smoker	Non Smoker			
-	pht values are stored in US customary units on the armband ues may be adjusted slightly.			
	ese changes permanent, go to Configure Armband			

PCen helt til batterilampen blinker grønt for å indikere full ladning.

11. Løs ut Armband fra USB-kabelen. Armband er nå klar for å samle data.

Data innhenting

- 1. For å åpne SenseWear Software Professional: Plugg lisens-nøkkelen i en USB-port og dobbelt klikk på *SenseWear-ikonet* på skrivebordet.
- 2. Hovedskjermen vises: Du får valget mellom 3 knapper øverst under menylinjen: Velg *Retrieve Armband Data*
- 3. Klikk *via USB-cabel* og kople en USB-kabel til Armband og til en av USB portene på PCen.
- 4. Klikk *Retrieve* for å overføre data fra Armband til PCen.
- 5. Et Pop-up vindu dukker opp: Fyll inn *File Name*, evn. *Browse* for å velge hvor du ønsker å lagre filen.
- 6. For å slette data lagret på Armband (nullstille). Huk av for *Clear armband for next use, after data has been saved.*
- 7. Klikk Continue.
- 8. Dersom Armband ikke ble konfigurert før det ble brukt, fyll inn Subject info.
- 9. Pop-up vindu: Armband data retrieved successfully.

Vise og analysere data

- 1. Hvis data akkurat er hentet fra Armband vises de allerede. Dersom du ønsker å vise tidligere lagrede data-filer, gå til *Fil > Open Data File:* Dobbeltklikk på datafilen du ønsker å åpne.
- 2. View & Annotate Armband Data:

seWear Professional		
ew <u>S</u> ettings <u>R</u> ecent Data Files Armband Maint <u>e</u> nan	ice <u>H</u> elp	
Armband Data	Configure Armband & Display	<b>?</b> He
ubject: 0124 (0124_2009_05_22.swd)		
Show sessions and timestamps	+ 🖉 🔀	TUE MAY 19, 12:17 PM FRI MAY 22, 9:52 AI
uesday - May 19, 2009 Vednesday - May 20 hursday - May 21 riday - May 22		WED MAY 20 THU MAY 21 FRI MAY
	c	12:17 PM Eelected Time: 02 day   21 hr   35 min on-body Time: 02 day   21 hr   04 min umband was worn 99.3% of the time.
Lifestyle Indicators Health Indicators		
	Average METs	Sedentary (up to 3.0 METs)
Lifestyle Indicators Health Indicators Total Energy Expenditure 31601 joules includes off-body estimate of 166 joules	Average METs 1.7	Sedentary (up to 3.0 METs) 59 hrs 14 min
Total Energy Expenditure		
Total Energy Expenditure           31601 joules         includes off-body estimate of 166 joules	1.7	59 hrs 14 min
Total Energy Expenditure           31601 joules         includes off-body estimate of 166 joules           Number of Steps         Includes off-body estimate of 166 joules	1.7 Active Energy Expenditure (3.0 METs)	59 hrs 14 min Moderate (3.0 - 6.0 METs)
Total Energy Expenditure       31601 joules     includes off-body estimate of 166 joules       Number of Steps       24870 steps	1.7       Active Energy Expenditure (3.0 METs)       11821 joules	59 hrs 14 min           Moderate (3.0 - 6.0 METs)           8 hrs 47 min
Total Energy Expenditure 31601 joules includes off-body estimate of 166 joules Number of Steps 24870 steps Lying Down	1.7         Active Energy Expenditure (3.0 METs)         11821 joules         Physical Activity Duration (3.0 METs)	59 hrs 14 min Moderate (3.0 - 6.0 METs) 8 hrs 47 min Vigorous (6.0 - 9.0 METs)
Total Energy Expenditure         31601 joules       includes off-body estimate of 166 joules         Number of Steps         24870 steps         Lying Down         21 hrs 53 min	1.7         Active Energy Expenditure (3.0 METs)         11821 joules         Physical Activity Duration (3.0 METs)	59 hrs 14 min           Moderate (3.0 - 6.0 METs)           8 hrs 47 min           Vigorous (6.0 - 9.0 METs)           13 min
Total Energy Expenditure       31601 joules     includes off-body estimate of 166 joules       Number of Steps       24870 steps       Lying Down       21 hrs 53 min       Sleep	1.7         Active Energy Expenditure (3.0 METs)         11821 joules         Physical Activity Duration (3.0 METs)	59 hrs 14 min Moderate (3.0 - 6.0 METS) 8 hrs 47 min Vigorous (6.0 - 9.0 METS) 13 min Very Vigorous (9.0 METs and higher)

a. Øverst til høyre vises: *Total varighet* på filen og *datainnsamlings-tider* fra Armband har vært PÅ:

> Dato og tidspunkt øverst til høyre og venstre indikerer total varighet av datafilen. > Begynnelsen av hver dag (fra midnatt) er markert i hvitt med en vertikal striplett linje og dato.

> Fargede områder viser perioder hvor Armband har vært PÅ og samlet inn data.

> Horisontale grå linjer viser når Armband har vært AV

> Du kan markere forskjellige tidsperioder innenfor hele varigheten av de innsamlede data med *tids-velgeren*. For å velge start- og sluttidspunkt, dra *tidsvelgeren* under den horisontale boksen. Du kan deretter flytte valgt tidsperiode ved å dra feltet mellom *"widgets"*. Alle verdier for disse valgte tidspunkter blir automatisk oppdatert.

b. Nederste halvdel av skjermen viser en oppsummering av:

> Livsstilsindikatorer: Oppsummering av de utledede Armband data for hele varigheten av den innsamlede datafilen. Data som er interessante å lese av/analysere for validering av kostrådet knyttet til fysisk aktivitet:

- Tid brukt på moderat (eller høyere intensitet av) fysisk aktivitet.
- Energiforbruk og METs.

> *Helseindikatorer*: Graf av noen tilgjengelige biometriske data (blodtrykk eller vekt) som er tastet inn manuelt

c. Øverst til venstre: Huk av for *Show Session and Timestamps:* kronologisk liste med alle PÅ-kroppen økter og tidspunkter: Ved å klikke på en spesifikk dag eller tid på listen vil det utheves i den interaktive *tids-velgeren*.

Vise og redigere Helseindikatorer

- 1. Her vises alle biometriske målinger innenfor dato-intervallet av datafilen. Disse manuelt inntastede målingene vises i grafen. Ved å klikke på pilen ved siden av hver avlesning gir det mulighet til å endre måleenhet.
- 2. Hvis det ikke er biometriske data vil kun **energiforbruk** fremstilles grafisk og vises i tegnforklaringen.
- 3. For å tilføre, endre eller slette en avlesning, klikk Update Health Idicators.
- 4. For å manuelt kunne legge til en ny avlesning, klikk *Add* > et pop-up vind dukker hvor det tastes inn:
  - a. Dato:
  - b. Tid:
  - c. Avlesning:
  - d. Måleenhet:
- 5. For å endre en avlesning, trykk på raden du ønsker å endre, klikk *Edit* (deretter samme som for punkt 4.) > *Save Changes* > *Save*.
- 6. For å slette en avlesning, trykk på raden(e) du ønsker å fjerne og klikk deretter Delete.
- 7. Å trykke *OK*, vil gjelde alle endringer i datafilen og oppdatere *helseindikator-grafen*.

Avansert grafisk fremstilling av data

- 1. Nederst til venstre på skjermen, trykk *Graph:* Nå vises en detaljert graf av alle data samlet inn og hentet for den valgte tidsperioden.
- 2. For å endre valgt tidsperiode, bruk tids-velger boksen øverst på skjermen: Klikk *Data Chooser* knappen > dukker opp et *Data Chooser vindu* > endre data og livsstilsinformasjonen som du ønsker å se i grafen.

## Kommentere data

- 1. Det kan skrives inn kommentarer/merknader for de ulike datafilene ved å gå inn på: *View and Annotate Armband Data*.
- 2. Show Sessions & Timestamps box: viser en liste over tidspunkt for start og slutt på økter når Armband har vært PÅ, samt tidspunkt for hendelser innenfor en økt.
- 3. For å kommentere de ulike øktene klikk på *Session Start time* og "Skift-klikk" på *Session End time* > klikk på *Add Annotation* (ovenfor og til høyre for *Sessions and Timestamps window*) > en liste med kommentarer vil dukke opp > velg en og klikk *OK*.
- 4. Tidspunkt-funksjonen brukes for å fremheve en bestemt hendelse.
- 5. **NB:** For bedre nøyaktighet i merknadene, bruk *Status knappen* på Armband: Dersom det er ønskelig at deltaker setter merknad for tid brukt til trening: Trykk *Status-knappen* ved start og slutt av treningsøkten.

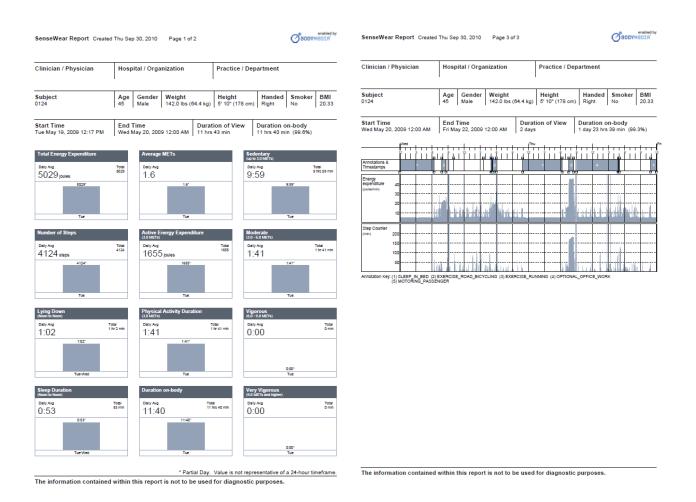
## Lage rapporter

- 1. Åpne ønsket fil.
- 2. Gå til *View and Annotate Armband Data* skjermen > velg tidsperioden du ønsker å se i rapporten.
- Rapporten inkluderer data fra deltaker og kliniker + eventuelle registrerte merknader. Endre disse verdiene ved å trykke på: *My Data Properties* knappen (nederst til venstre). For å få med grafiske data i rapporten klikk *Graph* – knappen. For å endre data klikk *Data Chooser* – knappen.
- 4. Klikk Generate Report fra rullgardinmenyen.

TIPS 1: PDF-formatet kan sees med Adobe ® Acrobat Reader eller andre lese-program. Egner seg for utskrift, lagring og e-post.

TIPS 2: Hvis du vil tilpasse rapportene, gå til *Reports* fanen under *Application Preferences* for flere alternativer.





## Eksportere data

- 1. Det kan eksporteres data i XLS eller CSV-format for Microsoft Excel og andre dataanalyse applikasjoner (krever lisens nøkkel).
- 2. For å eksportere en datafil gå til *View & Annotate Armband Data* skjermen > klikk *Export* knappen (nederst på skjermen) > når du får beskjed; navngi og lagre .*xls* eller .*csv* filen i en mappe (for å vise den eksporterte filen dobbeltklikk på mappen).
- 3. .xls-filen inkluderer 4 kategorier:
  - a. Data: Rå data, utledede verdier, tidsperioder, kommentarer.
  - b. Subject info: Kropps-info.
  - c. Summary: Dag-for-dag oversikt over utledet info.
  - d. *Clinical info*: Notater og relevant info om datafiler for kliniker, blodtrykk, blod glukose, vekt dersom disse er registrert manuelt.

## Programinnstillinger

- 1. Tillater deg å kunne kontrollere virkemåten til enkelte funksjoner i SenseWear Professional Software: Trykk på *Menylinjen* (øverst på skjermen) > *Settings* > *Application Preferences* fra rullgardinmenyen > dukker opp et vindu med fem kategorier:
  - a. *General:* Lar deg velge hvordan dato, tid, høyde og vekt verdiene skal vises og oppgis, og hvordan **energiforbruk-**verdier skal vises (kan velge å inkludere eller ekskludere AV-kropp estimater i totalt energiforbruk-resultater).
    NB: Nøyaktig energiforbruk-verdier kan kun beregnes for perioder når Armband har vært PÅ-kroppen. SenseWear Software inkluderer et estimat for

energiforbruk når Armband er AV-kroppen (men denne funksjonen er mest effektiv når AV-kroppen periodene er korte og stillesittende og energiforbruket er ca. 1,1 METs).

General	Data File	Clinician Info	Activity Levels	Reports		
elect how	r date, time, he	eight and weight v	alues should be o	lisplayed and	entered.	
C Thu	1 30 Sep 2010	15:00, 178 cm, 6	8 kg			
<ul> <li>Thu</li> </ul>	I Sep 30, 2010	03:00 PM, 5'10"	(178 cm), 150 lbs	(68 kg)		
elect how	energy exper	iditure values sho	ould be displayed.			
C 123	145 joules					
<ul><li>130</li></ul>	100 joules (inc	ludes off-body es	timate of 655 joul	es)		
C 234	15 calories					
C 300	0 calories (in	cludes off-body e:	stimate of 655 cal	ories)		

- b. *Data File:* Gjør det mulig å tilpasse formatet for å navngi datafilen når du henter data fra Armband.
- c. *Clinician Info*: Skriv inn info som er spesifikk for klinikeren og organisasjonen som håndterer alle datafiler.
- d. Activity Levels: Du kan spesifisere 2-4 Aktivitetsnivå og SenseWear Professional vil bestemme mengden av tid brukt på hvert nivå. (Et aktivitetsnivå er et METs-område, definert av en øvre og nedre verdi).
  Merk: Den øverste verdien av første aktivitetsnivå (3,0 METs når du bruker standard innstillingene) er også brukt som terskelverdien for å bestemme fysisk aktivitet.

**MERK**: Informasjon som angis i *Klinisk Info, METs* og *Aktivitetsnivået* i *Application Preferences* -vinduet er standardinnstillingene og vil bli brukt på alle nye datafiler. Hvis du ønsker å endre informasjonen i en åpen datafil, klikk *My Data Properties* -knappen (nederst på skjermen).

e. *Reports*: lar deg tilpasse de genererte rapportene: hak av eller fjern hake i boksene for å kontrollere hvilke data som vises i rapportene.

## Tømme minne fra Armband

1. Armband Maintenance > Clear data & Subject Info. NB: Ikke velg *Reboot Armband*.

## Problemløsning

- Besøk: <u>http://sensewear.bodymedia.com</u>
- Ta kontakt med Produktspesialist Anna West: aw@maribomedico.dk

Variable	All participants (n=31)		Participants using validation tools (n=17)			Participants not using validation tools (n=14)	P <sup>a</sup>			
	n	Mean (CI)	n	Mean (CI)	n	Mean (CI)				
Demographics										
Age (years)	31	62.6 (60, 65)	17	60.5 (57.4, 63.7)	14	65.1 (61, 69.2)	0.06			
Age men	13	62.2 (57.8, 66.7)	6	58.7 (50.7, 65.6)	7	65.7 (60.2, 71.2)	0.06			
Age women	18	62.8 (59.5, 66.1)	11	61.8 (58.2, 65.4)	7	64.4 (56.6, 72.3)	0.43			
Smoking, n <sup>b</sup>	24	10 (42 %)	17	8 (47 %)	5	2 (40 %)	0.65			
Gender M:W	31	13:18	17	6:11	14	7:7	0.48			
Anthropometry										
Weight men (kg) <sup>c</sup>	13	92.2 (85.6, 98.7)	6	93.2 (81, 105.4)	7	91.3 (81.2, 101.4)	0.77			
Weight women (kg) <sup>c</sup>	18	77.1 (68.3, 85.9)	11	81.4 (67.6, 95.2)	7	70.3 (61.4, 79.3)	0.21			
Height men (m) <sup>d</sup>		1.76 (1.71, 1.82)	6	1.79 (1.69, 1.90)	7	1.74 (1.68, 1.81)	0.32			
Height women (m) <sup>d</sup>		1.68 (1.66, 1.70)	11	1.67 (1.64, 1.71)	7	1.69 (1.65, 1.74)	0.38			
BMI men $(kg/m^2)$	13	29.8 (27.6, 31.9)	6	29.2 (26.1, 32.3)	7	30.3 (26.5, 34.2)	0.58			
BMI women $(kg/m^2)$	18	27.5 (24.4, 30.6)	11	29.2 (24.5, 33.9)	7	24.8 (21.3, 28.3)	0.15			
Waist circumference men (cm)	13	107.9 (100.8,114.9)	6	103.4 (92.7,114.2)	7	111.6 (100.5,122.8)	0.22			
Waist circumference women (cm)	18	98.5 (89.8, 107.2)	11	102.3 (88.7,115.8)	7	92.6 (82.3, 102.8)	0.26			
Waist/hip-ratio men	13	1.02 (0.98, 1.07)	6	1.0 (0.93, 1.06)	7	1.04 (0.97, 1.11)	0.31			
Waist/hip-ratio women	18	0.93 (0.89, 0.99)	11	0.95 (0.87, 1.02)	7	0.91 (0.83, 1.0)	0.55			
Physical test										
Hand-grip strength right men (kg) <sup>e</sup>	12	41.0 (36.3, 45.8)	6	44.3 (37.5, 51.1)	6	37.8 (30, 45.6)	0.14			
Hand-grip strength right women (kg) <sup>e</sup>	17	22.6 (20.6, 24.6)	11	23.3 (20.6, 26.0)	6	21.4 (17.5, 25.2)	0.35			
Hand-grip strength left men (kg) <sup>e</sup>	12	39.0 (33.4, 44.7)	6	42.8 (35.1, 50.5)	6	35.2 (25.5, 44.8)	0.14			
Hand-grip strength left women (kg) <sup>e</sup>	17	21.5 (19.2, 23.8)	11	22.3 (20, 24.7)	6	19.9 (13.7, 26)	0.29			

**Appendix 8.** Characteristics of all participants pre-surgery and comparison between the participants that used validation tools and those who did not, divided into men and women.

<sup>a</sup> Parametric test for normal distributed continuous data: Independent sample t-test. Fishers exact test for categorical data

<sup>b</sup> Missed smoking status for 7 of the participants.

<sup>c</sup> One half kilo was deducted to account for clothing.

<sup>d</sup> Height was measured by use of an altimeter (Kern MSF 200) by project members baseline of intervention for most of the participants. But for those participants who did not participate at baseline of intervention, self-reported height from pre-surgery was used.

<sup>e</sup> The strength of the springs to the hand grip-meter (MAP) is 80 kg for men and 40 kg for women. It was missing 2 participants for the reasons they were not functionally able to use this apparatus.