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Difference in FINDRISC score for predicting type 2 diabetes mellitus among Sami and Non-Sami, the SAMINOR 1 Study

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Abstract

Background: Type 2 diabetes mellitus (T2DM) is a major public health problem. Sami people are indigenous people of Norway and have had a transition in lifestyle and diet associated with an increase in obesity and inactivity, which are risk factors to T2DM. Previous studies have revealed higher prevalence of known risk factor to T2DM among the Sami people.

Aim: Using a risk assessment tool, the FINDRISC questionnaire, to investigate if Sami and non-Sami people have different risk for adopting T2DM within ten years.

Method: A cross sectional study, the SAMINOR 1 Study, was conducted in between 2003-2004, in areas with Sami and non-Sami settlement. The study included three questionnaires, clinical examination and blood samples. The FINDRISC score and risk assessment were retrospectively calculated for a study sample of 13 978 participants. Ethnic differences in FINDRISC scores were tested with t-test. Differences in score levels were tested by cross tables with subsequent chi-square tests. Linear hierarchical regressions were conducted to control for confounding. Separate regressions were conducted for women (N=6813) and men (N=6599).

Results: The mean FINDRISC score was higher for Sami than non-Sami women (p <0.001). There were no ethnic differences in mean FINDRISC score for male gender (p 0.573). The results did not change for either of the gender when adjusted for age, education, alcohol consumption and marital status. In the study sample of female, 14.2% of the Sami women and 11.1 % of the non-Sami women had more than over 30% risk (corresponding to a cut off level ≥15, i.e. high and very high risk,) for adopting T2DM within ten years. For male gender, 9.2 % of the Sami men and 8.9 % of the non-Sami men had more than 30 % risk for developing T2DM within a decade.

Conclusion: There were ethnic differences for developing T2DM within ten years. Sami women had significantly higher risk than non-Sami women. For male gender there were no differences in the risk for developing T2DM within ten years.

Keywords: type 2 diabetes mellitus, ethnicity, Sami, non-Sami, FINDRISC score, risk assessment, indigenous

List of abbreviations

NorPD	Norwegian Prescription Database
FINDRISC	Finnish Diabetes Risk Score
Pre-diabetes	When patients have impaired glucose tolerance or impaired fasting glucose
BMI	Body Mass Index
WC	Waist circumference
T2DM	Type 2 diabetes mellitus
GDM	Gestational diabetes mellitus
Kven	Descendants of Finish immigrants who settled down in northern Norway in the 17-1800 because of famine in the Finland
WHO	World Health Organization
Northern Norway	Nordland, Troms and Finnmark County
Central obesity	Waist circumference ≥102 cm for men and ≥ 88 cm for women
First line relatives	Own children, sister, brothers, mother and father
Second line relatives	Grandparents, cousins, uncles and aunts

Content

1.0 Introduction

1.1 The global and local situation

Type 2 diabetes mellitus (T2DM) is a metabolic chronic disease mainly associated with inactivity and obesity in addition to genetic factors (1-3). The prevalence of T2DM has increased globally along with structural environmental changes like urbanization, economic and industrial growth. These changes have led to a transition in lifestyle and diet associated with increase obesity and inactivity and an aging population (2, 4, 5). The International Diabetes Federation (IDF) (2) estimates that diabetes affects approximately 382 million people in 2013, a prevalence of 8.3%. This number is estimated to increase with 55% reaching 592 million by the year 2030, accounting for a prevalence of 10.1% of the world's population. About 90% of the total diabetes cases are expected to be T2DM (2). The number of adults with pre-diabetes, often an undiagnosed state, is expected to increase as well with 50%, from 314 million (a prevalence of 6.9%) in 2013 to 471 million (a prevalence of 8.0%) by 2030 (2).

In Norway there is a national diabetes registry but is not mandatory to report T2DM cases, hence the registry lacks complete coverage. Because of this, population surveys and the Norwegian Prescription Database (NorPD) serve as source for prevalence estimates of diabetes. In 2004, Stene et al reported (6) that the estimated cases of diabetes (both type 1 and type 2) in Norway were between 90-120 000 cases. The prevalence of diabetes for 30 year olds and older were 3.4% and increased up to 8 % among people 70-79 years. Additionally, they predicted undiagnosed diabetes cases to be as many as cases diagnosed (6). From the HUNT population surveys (7) it is reported

that there have been an increase in the prevalence of diabetes. According to the surveys, the prevalence of diabetes increased from 2.9% to 4.3% from 1984 to year 2008, independent of gender (7). In 2012, the NorPD (3) reported the number of drug treated diabetes cases (both type 1 and type2), in the age range 0-74 years to be 125 000. This was is in addition to the untreated cases that are held under control by diet and physical activity, cases that are not diagnosed and cases among institutionalized people. In Norway there is little knowledge about the health status for the population in Northern Norway and in particular for the Sami population. Part of the reason is the political legislation restricting systematic registering of ethnicity. In this thesis we are going to estimate the future risk for T2DM for the Sami and non-Sami groups, in a population based survey, the SAMINOR 1 study. A previous study of the sample have revealed no ethnic differences in the prevalence of T2DM among women and men (8).

Diabetes and the complications from the disease induce a burden for the individual and for the society. For the society there are major financial cost associated with diabetes, ranging from treatment with medication, hospitalization, and treatment of complications, medical equipment and governmental payments of sick leaves, disability pensions and disability support. In 2005 the financial costs in Norway associated with diabetes, where €535 million, constituting 2.6 % of the total health costs (9). This included all hospital admissions cases where diabetes was the primarily or the secondary diagnose. The expected increase of new cases of T2DM and the large amount of undiagnosed case, the individual costs associated with the disease and the total health costs for society, contributes making T2DM a major and important public health problem.

1.2 Indigenous people

Indigenous people are by the IDF particular vulnerable to T2DM due to low socioeconomic status, marginalization or lack of care (2). Indigenous people have generally a higher burden of T2DM cases, T2DM risk factors and complications compare to the general population in their country (2, 10). In a study from 2001, the Inuit's, who are the indigenous people in Alaska, Canada and Greenland ranked among the highest in the age standardized prevalence of obesity in Europe and North America(11). Besides this, the mean waist circumference (WC) among the Inuit women was reported to the highest globally (11). Large WC and obesity are both risk factors to T2DM (12). The increase in T2DM cases among indigenous people are to a large extend related to the transition from a traditional lifestyle and diet to a western lifestyle characteristic with a sedentary lifestyle and consumption of unhealthy food, resulting in an increased burden of obesity (13, 14). Sami people are the indigenous people in Norway. Like other indigenous people, the Sami people have had major changes in lifestyles and diet. From being hunters, fishermen or otherwise engaged in subsistence based on maritime, animal or resources from nature, they have adopted a more westernized diet and lifestyle. In the Norwegian parliamentary report on public health, from 2013 (15), it is stated that there are no systematic differences in health between the Sami and the majority population. This is by Hassler et al (16) suggested to come from an acculturation process with a gradual integration of a traditional and modern lifestyle. The gradual integration together with high living standards compared to other indigenous people, contribute to give good health. Equal access to health care and social services, and the high educational level among Sami are also suggested to be protective

factors for good health (16). However, in the Norwegian parliamentary report on public health (15) they acknowledge the need for more knowledge about the increased trends in obesity and lifestyle related diseases like T2DM among the Sami people. They suggest that undiagnosed diabetes might be more prevalent among the Sami compared to the general population based on SAMINOR 1 study (15).

1.3 Previous health studies on the Sami population

Studies comparing Sami health, mortality and morbidity are restricted to areas to Northern Norway, and particularly to Finnmark County. In a longitudinal study design of the populations in Finnmark county, Njølstad et al (17) reported in 1998 differences in risk factors to diabetes among the Sami, the Kven and the Norwegians people. They found that the Sami women had a similar incidence rate of risk factors to diabetes as other women although they had higher mean Body Mass Index (BMI) and smoked less. Sami men were the ones with highest self-reported overall physical activity. Overall, they reported the Sami people to have lower risk for diabetes compared to the other ethnic groups. Jenum et al (18) conducted a study in three counties in Norway on risk factors to diabetes and cardiovascular diseases and report in 2007 that through the last thirty years, the overall BMI and trends in physical activity are not different for men and women in Finnmark county compared to Oppland and Oslo county. There was an increased in BMI for both men and women and a decrease in physical activity for men only. Previous study on the SAMINOR 1 study population report that women with Sami language as domestic language for three generations had the most pronounced pattern of obesity (19). A dietary study of the SAMINOR 1 sample has revealed five distinct dietary clusters where one, characterized with large intake of reindeer meat, was

associated with Sami population living in the inland area (20). The reindeer pattern group had characteristics that predict them to T2DM as they found the highest proportions of individuals that were overweight (BMI>25 kg/m^2) and physical inactive. In conjunction to the dietary pattern results, another study (21) based on the SAMINOR 1 sample, found that Sami men and women living in inland area had higher mean serum ferritin than non-Sami living in same area, and these differences could be explained by dietary pattern, age and obesity (21). When controlling for known risk factors like age, BMI, physical activity, smoking, family history in addition to confounding from diet, inflammation factors and hepatic enzymes, ferritin still predicted T2DM significantly (22). Serum ferritin is found in other studies to be associated with increased risk for T2DM (22). Together these results indicate that there might be differences in risk factors to T2DM between the Sami and non-Sami populations. The differences in risk factors can be further explored with the FINDRISC questionnaire and can give a complete risk assessment.

1.4 Subject of the thesis

The main subject of this thesis is to use the diabetes screening tool, the FINDRISC questionnaire, to test if the Sami and non-Sami in the SAMINOR 1 study sample have different risks for adopting T2DM within ten years. Additionally, we will use the FINDRISC scores to predict how many are at high and very high risk for diabetes within ten years by setting a cut off at FINDRISC score ≥ 15. Besides this, we will investigate what might be influencing the relationship between ethnicity and FINDRISC score for women and men.

1.5 Background

1.5.1 Diabetes mellitus

Diabetes is present when blood glucose persists being elevated over time. This can be due to absent or insufficient insulin production, or if the human cells cannot utilize insulin properly (23). Insulin is a hormone produced in the pancreas and it is released to the bloodstream in relation to levels of glucose. In a simplified way, the insulin hormone makes human cells able to absorb glucose that is needed by cells and tissue to function, and to absorb glucose for storage. If insulin is missing or its function is reduced, glucose continues being present in the bloodstream. There are mainly three types of diabetes, type 1, T2DM and gestational diabetes (GDM)(2, 23). Diabetes type 1 is often an autoimmune condition where antibodies destroy beta cells that produce the insulin hormone. Usually patients become dependent on insulin injections all their lives for controlling their glucose levels in blood (2, 23). GDM occurs during pregnancy if the body develops resistance to insulin. If this happens, the blood glucose levels are consistently elevated. Half of the women with previous GDM, develop T2DM within five to ten years after delivery (2).

T2DM is caused by a combination of genetic and environmental lifestyle factors (3, 24). Even with genetic predisposition for developing T2DM, there is a need for environmental lifestyle factors to activate the disease (24). Studies have shown that almost 90% of new T2DM cases are caused by five lifestyle factors: diet, physical activity, smoking, alcohol and obesity (24, 25). T2DM has been associated with a lifelong exposure, already starting with intrauterine exposure due to GDM. Also, low birth weight has been associated with an increased risk for T2DM (26). T2DM occurs either if

the insulin hormone is not recognized by the cells in the body, also known as insulin resistance, or if there is not enough insulin produced by the pancreas to absorb the glucose (1, 4). If one of these conditions appears, or more commonly a combination of these conditions occur, high glucose levels persist in the blood known as hyper glycaemia. Consistently high blood glucoses over time affects the heart, blood vessels, nerves and teethes and can cause cardiovascular diseases, reduced vision or blindness, kidney failure, lower limb amputation and inflammation of the gums resulting in loosing of teeth (2). In addition, diabetes patients are also more susceptible for infections than others. People with T2DM have a 2-4 fold increased risk for developing cardiovascular diseases and the increased risk is already present at the pre-diabetic state, when it is undiagnosed (27). Cardiovascular diseases are one of several complications with diabetes and it is the most common cause of death among diabetes patients (2). T2DM has a slow progression and can be present in years without symptoms and the lack of illness makes it hard to recognize and to be diagnosed as T2DM (2, 28). Both national and international studies estimate the undiagnosed diabetes cases to be high (7, 28). Research on preventive measures have revealed that by targeting behavioral factors, like diet and physical inactivity, new cases of T2DM can be prevented and the risk reduce with over 50 % (29).

In the thesis we do not distinguish the different types of diabetes in the statistical analysis. In a description of 7064 men and 7543 females of the SAMINOR 1 sample, it was estimated that type 1 diabetes occurred in 29 individuals and GDM was estimated to nine cases (8).

1.5.2 Ethnicity and lifestyle factors

It is recommended to have a multifactorial approach when dealing with risk factors for T2DM (30, 31). The European Evidence-Based Guidelines for Prevention of Type 2 diabetes (27) from 2010, recognize the need to address cultural differences in the detection and prevention of T2DM. Ethnicity has been reported to be a non-modifiable risk factor to T2DM (27, 31). It is well established that there are ethnic differences in the prevalence of diabetes (2, 32, 33). Studies suggest the ethnic differences in the prevalence of diabetes is due to genetics, "the thrifty gene "hypothesis (13, 34). This hypothesis involves that during evolution certain ethnic groups have developed insulin resistance so that energy could be stored as fat instead of glycogen. This mechanism predispose individuals today to T2DM when exposed to certain adverse conditions like inactivity (34). In other studies ethnicity has also been reported to modify the effect of existing risk factors (35). Even if we address differences in FINDRISC score in relation to ethnicity, ethnicity itself is rarely the source of causal relationship (36). According to Bhopal (36) ethnicity is describes as: "*Ethnicity is a multifaceted quality that refers to the group to which people belong, and/or are perceived to belong, as a result of certain shared characteristics, including geographical and ancestral origins, but with particular emphasis on cultural traditions and languages*" (36, p. 13). Ethnicity has also been associated with "*shared culture and way of life"* (37, p.109). This implies that ethnic groups have shared characteristics, which might not be fixed or easily measured (36). Health is determinate by genetics, lifestyle and personal behavior, and health is also associated with great influenced from environment and cultural factors (38, 39). According to Dahlgren and Whiteheads (39) work addressing social equity, there is a complex coherence between socioeconomic, cultural and environmental factors, that determine lifestyle and working conditions, and finally determine the susceptibility for various diseases. This indicates

that there are relationships that can interfere and hide the true underlying relations between ethnicity, exposure from environmental and risk for T2DM. The effect of culture, social and environmental factors on health involves effect over time, place and context, which mean that people that have same ethnicity can be exposed differently dependent in time, place and context (39, 41).

T2DM is associated with low socioeconomic status (SES) (3, 27). SES is often measured either by education, occupation or income and determines what social position an individual has in a society (40). The higher education, income or highly regarded occupation, the higher social position an individual has. Health follows the social position, the higher the social position, the better the health (41). According to Lahelma (40) education level reflects peoples material and non-material resources. Besides reflecting resources, education itself make people receptive for health information and thereby making people more health conscious and contribute to behave healthier (40, 42). Education is often used as a measure of SES since it is a suitable measure for both genders, it forms an ordinal scale, people are easily grouped according to years of education and education remains stable through a life course since many complete their education at young age (40, 42). Education that is completed at young age is not affected by individuals health status later in life as compared to income and occupation (42). There are some drawbacks by using education since educational structures often change over time and can be skewed for various populations, in particular for older populations which in general have only basic education (40, 42). Income as well as occupation are known measures for SES and often controlled for in statistical analysis. However, there are drawbacks using income and occupation as measures of SES in a cross sectional study since there is a risk for reverse causality, i.e. to determine whether ill health is

influenced by income or occupation, or whether income or employment is causing ill health (40). Income is also related to employment status and unemployment can be a reason for low income. Self-reported income is also considered imprecise since people tend to overestimate their household income and there is also a tendency to have many missing values on self-reported income due to the sensitive nature of the question (40). Additionally, income as a measure of SES is not considered as a good measure among Sami people in the rural areas (16). People in rural areas are more often self- sufficient in relation to food harvesting from nature, and therefore do not depend quite as much on income and monetary values as urban people. Also trading and exchange of food supplies among the people is more common in rural than in urban areas. These factors can make income a poor measure of SES in rural areas.

Age influences the susceptibility to disease most likely through a mix of repeatedly environmental exposure and biological processes related to aging (36). Age is reported to be a strong non- modifiable risk factor to T2DM (27). T2DM occurs usually in adult life and the prevalence of T2DM increases with age. In recent years, the age of onset of T2DM has decreased due to higher level of obesity in the general population. Since T2DM is associated with age we choose to adjust for age.

The health- related lifestyle factors we want to adjust for are smoking and alcohol. Smoking and alcohol consumption are not only related to general health, smoking and alcohol abstinence are described to be independent and modifiable risk factors to T2DM (4, 27). A systematic review with a meta-analysis published in 2007 (43), reports that there is an association between smoking and enhanced risk for T2DM. Heavy smokers are reported to have greater risk for T2DM compared to light smokers, and active

smokers are reported to have higher risk for T2DM than former smokers. The mechanism behind is that smoking make the cells in the body more insulin resistant (1, 44) and increases the visceral fat . Additionally, smoking is closely related to low SES (45). The lower the SES, the more likely people are to smoke and therefore have poorer health outcome.

Alcohol consumption is believed to increase insulin sensitivity (44, 46) and therefore protect from developing T2DM. Studies have found that moderate consumption of alcohol is protective for both females and males (44, 46). Alcohol consumption in Norway is reported to be more frequent among people with high SES, income and education, while binge drinking is associated with low SES (45).

Marriage has a beneficial effect on health, health outcomes and mortality (47). Marriage provides social support to partners, and social support is defined by Sidney Cobb as "*information leading the subject to believe that he is cared for and loved, esteemed, and a member of a network of mutual obligations*" (48, p. 300). The mechanism in social support is described to be a direct effect of support on health or a buffering effect of support. The buffering effect helps to moderate the impact of acute and chronic stressful events in life (38, 47). The influence of marriage on health follows several potential pathways besides buffering stress. Marriage can contribute to make resources available, provide sense of purpose and motivate to behave healthier and to adopt health related information more easily (38, 49). Marital status seems to have a great impact on lifestyle and therefore we choose to control for the influence of marital status.

2. 0 Material and method

2.1 FINDRISC- Finnish Diabetes Risk Score

FINDRISC is an abbreviation for the Finnish Diabetes Risk Score and it is a questionnaire with the purpose to screen populations for individuals at high risk for T2DM. The designers of the questionnaire also suggest that the questionnaire could be available for the general public as a self-administrated test to make people aware of risk factors and take action to improve their health (50). The FINDRISC questionnaire consists of eight questions about age, BMI, waist circumference, use of anti- hypertension medication, history of high serum glucose, family history of diabetes (including GDM), consumption of fruits and vegetables and physical activity (appendix 1) (51). Every question gives a score in relation to how much it predicts the risk of T2DM. The questions on fruit and vegetables and physical activity are inversely related to the risk of T2DM, and included to make participants more aware of the importance of lifestyle choices (27). The total score from the questionnaire predicts the future risk for T2DM within 10 years. The maximum score possible to get is 26.0. The FINDRISC questionnaire is recommended by the IDF (31) and European Evidence Based Guidelines (27) for both detecting undiagnosed T2DM and for predicting future T2DM risk among Caucasians. The Norwegian National Guidelines for diabetes prevention, diagnostics and treatment from 2009 (52), also suggest the use of the FINDRISC questionnaire for detecting individuals at high risk for developing T2DM. According to a review of screening tools for T2DM, the FINDRISC was found to be the most used and most widely validated risk tool (53). There exist several screening tools for detecting risk for T2DM, developed for specific populations. The screening tools perform differently when used in other populations than initially validated on, suggesting that the risk tool should be used only in the

populations they were assessed for (27, 50, 54). The FINDRISC questionnaire has been assessed for a different population than initially designed for in a study population in Greece (55) and in the KORA survey in Germany (54). In the KORA survey they found similar sensitivity as in the original validation report, however, the specificity was poorer. In the KORA survey they concluded that the difference was due to variation of local risk factors among different population, such as BMI, WC and obesity (54). Although the FINDRISC focuses on general risk factors globally relevant for T2DM, there might be a need for local adjustments since the magnitude of different risk factors varies across population (31, 56).

In the FINDRISC questionnaire it is suggested that participants should contact their physician if the score is 15 or higher to get their blood tested for glucose (51). Also, the DE-PLAN (Diabetes in Europe- Prevention using Lifestyle, Physical Activity and Nutritional interventions) project (57) recommend to use the score of 15 to identify individuals at high risk for T2DM, that should be target for preventive measures. Studies conducted to test the performance to the FINDRISC questionnaire to identify individuals at high risk or undiagnosed diabetes, have used the FINDRISC score 15 as cut off, to identify individual that have undiagnosed diabetes and pre-diabetes (55, 58). The cut off 15 is associated with an acceptable high ability to detect T2DM and find high risk individuals with pre-diabetes among Caucasians (55). However, the performance to the FINDRISC is dependent on what biochemical test is performed to confirm the FINDRISC score (58).

2. 2 The SAMINOR 1 Study

The SAMINOR 1 study is a cross-sectional study in areas with Sami and Norwegian settlement. The study was conducted from January 2003 to April 2004 and was collaboration between the Center for Sami Health Research, Department for community medicine, UiT, The Arctic University of Norway and The Norwegian Institute of Public health. The overall aim of the SAMINOR 1 study was to investigate the differences in health and living conditions between the Sami and Norwegian population living in the same geographical area. The SAMINOR 1 study consists of self-reported data from three questionnaires, the initial, the screening and the additional questionnaire, and a clinical examination and blood samples (8, 59). In the clinical examination body height and weight were measured. Body weight and height were measured by electronic scales with participants wearing light clothes without shoes. Body weight was recorded in kilograms and height in centimeters, both with one decimal. From the clinical data BMI was computed by dividing bodyweight divided by square of their height in meters. WC was measured in centimeters by stretching a measuring tape around the umbilicus area in an upright position when breathing normally. Venous non-fasting blood samples were obtained by attendance and blood glucose was measured in serum at a clinical laboratory.

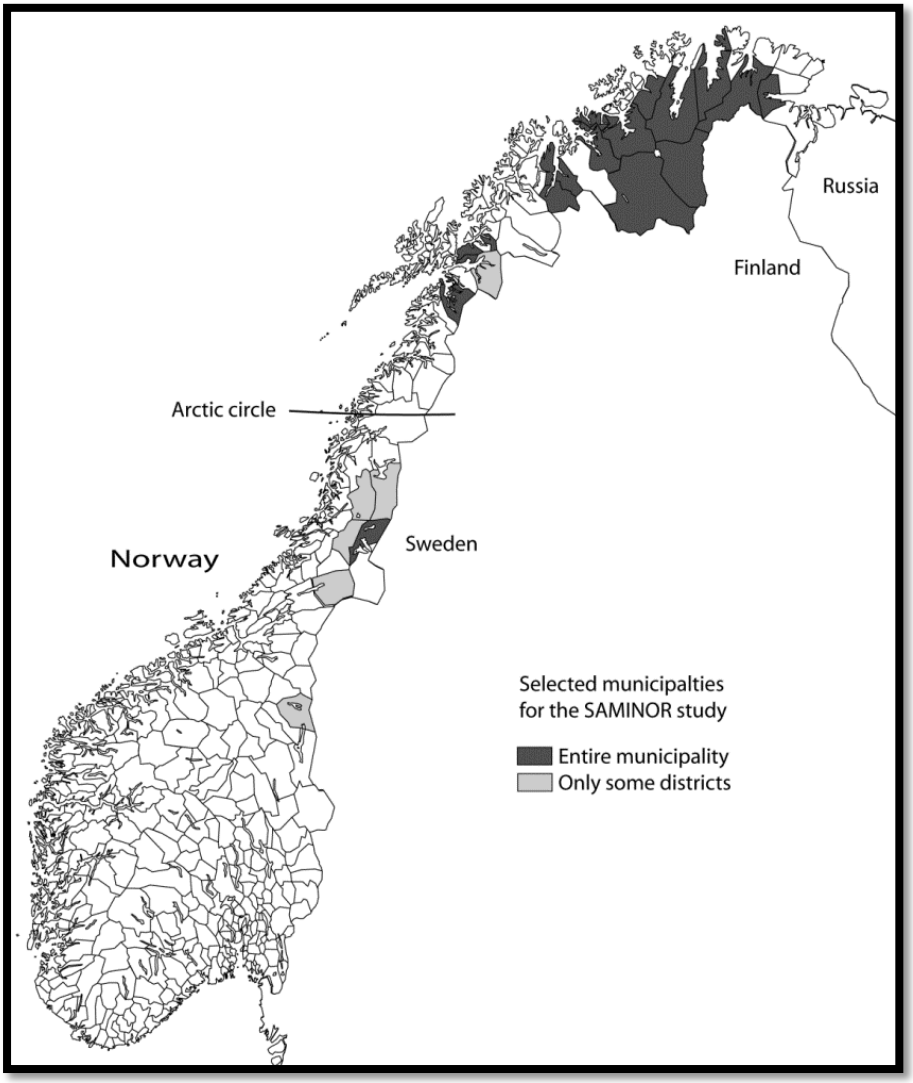

Figure 1. Municipalities included in the SAMINOR 1 study (59).

2.3 Sample size

All inhabitants aged 30 and 36-79 years, registered in the Central Population Register in predefined municipalities and districts in Finnmark, Troms, Nordland and North- and South Trøndelag County were invited. In the districts with known Sami settlement, all eligible inhabitants belonging to the district defined by postal code, were invited to participate. Figure 1 illustrates which areas were represented by the whole municipality and which areas were represented by districts. The eligible population accounted

27 987 individuals (figure 2). The attendance rate among the 30 year olds was low and therefore they were excluded (59). For the thesis it was necessary to have information on the variables that matched the FINDRISC questionnaire and it was essential to have information on ethnicity to be able to do the basic analysis. This information was collected from the SAMINOR initial and screening questionnaires, from the clinical examination and from blood samples. Due to missing values when matching FINDRISC and SAMINOR questionnaire, the sample size decreased to 13 978. The FINDRISC score was controlled for five confounding factors in a hierarchical analysis. To obtain equal numbers in each model in the hierarchical regression, the sample size was attenuated to 13 412, (figure 2).

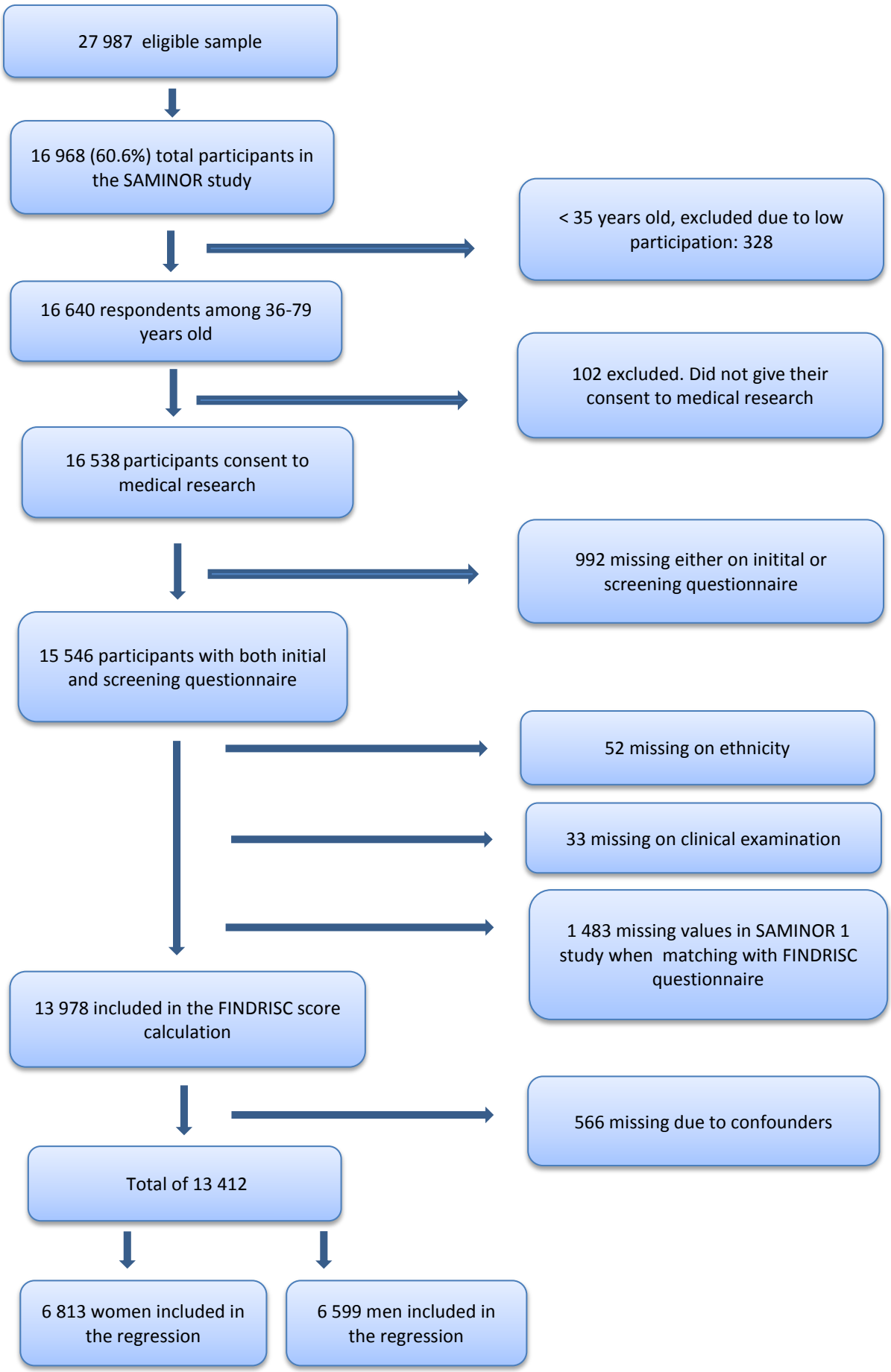

Figure 2. The flow diagram shows sample size at different stages.

2.4 Variables

2.4.1 The dependent variable, total FINDRISC score

The dependent variable was total FINDRISC score, a continuous variable ranging from 0-26. The FINDRISC questionnaire has eight questions with 2-4 options with specified scores (appendix 1). When there was not possible to have a direct match between the FINDRISC and SAMINOR questionnaires, it was necessary to create proxy variables. When creating proxy variables, we were consistent to use only midpoint or least frequency or amount. The variables we created were given scores in accordance with the FINDRISC questionnaire, and this made it possible to predict the FINDRISC score for every participant in our sample. Table 1 shows how we matched questions from FINDRISC questionnaire with questions and answers from SAMINOR 1 study.

Table 1. Descriptions of dependent variable, the FINDRISC score.

	FINDRISC			**SAMINOR**		**Creating variables**
	Question		Score	Question/answer	Options	
Age	Under 45 years 45-54 55-64 Over 65		0 2 3 4	Given in years		Recoded into ten years span to match FINDRISC
BMI	<25 kg/m^2 25-30 > 30		0 1 3	Weight in kilo (kg) Height in meter (m) Computed: Kg/ m^2		BMI categorized into 3 groups to match FINDRISC
WC **Waist Circumference**	MEN <94 cm 94-102 cm >102 cm	Women < 80 cm 80-88 cm >88 cm	 0 3 4	WC given in cm		WC for gender categorized into 3 groups to match FINDRISC

Physical activity	Do you usually have daily at least 30 minutes of physical activity at work and/or during leisure time (including normal daily activity)? No: 2 Yes: 0		How has your physical activity been the last year during leisure time? (Report your weekly average the last year. Consider work path as leisure time). **Light activity** (no sweating/ out of breath) **Hard physical activity** (sweating/ breathless)	Options for light and hard physical activity: None < 1 hour per week 1-2 hours per week ≥ 3 hours per week	The options were recoded into minutes per week: Zero 30 minutes 90 minutes 180 minutes
			The separated reporting for light and hard physical activity were added together and divided in seven to find the number of minutes of physical activity per day.		
Fruit **Berries** **Vegetable**	How often do you eat vegetables, fruit or berries	Not every day: 1 Every day: 0	How often do you eat these food items? • Fruit • Berries • Boiled vegetables • Fresh vegetables	Tic for each item Rarely /never 1-3 times per month 1-3 times per week 4-6 times per week 1-2 times per day ≥3 timers per day	Options were recoded to times per month 0 time 2 times 8 times 20 times 45 times 90 times
			Times per month for the different items were added together and divided in 30 to find the daily consumption. Consumption were recoded into no or yes if consumption was <0.99 and if >1.0 respectively. Potato was left out from consumption of vegetables, since it is not regarded as a vegetable.		
Hyper-tension	Have you ever taken medication for high blood pressure on regular basis?	No: 0 Yes:2	Do you use medication for elevated blood pressure	Never used Currently Previously, not at present time	The categories currently and previously medication use were merged to match *Yes* in the FINDRISC questionnaire

Blood glucose	Have you ever found to have high blood glucose (e.g. health examination, during an illness, pregnancy?)	No: 0 Yes:5	Do you have or have had? Diabetes	No Yes Yes, previously	In the SAMINOR 1 study sample, we merged the categories yes and yes/but previously, to matched Yes in the FINDRISC
			In our sample of the SAMINOR 1 study, the question had 644 missing values and these were coded to *no diabetes*. The reasoning for this is that people do not answer questions that are not relevant for them; hence they do not have the condition in question.		
Diabetes in relatives	Have any of the members of your immediate family or other relatives been diagnosed with diabetes (type 1 or type 2)?	1st line: 5 NO: 0	Tick off relatives who have, or have ever had, any of the following conditions, and report the age when they got the illness: Diabetes	Mother Father Sister Brother Children None	
		2nd line: 3	In the SAMINOR study there were no question that matched the option grandparents and cousins (2nd line) and we were forced to leave out this option. Therefore, for this question it was possible to have either zero or five point.		

Since the FINDRISC is to predict future risk, we performed additional calculation by using non-fasting serum glucose measures with ≥11. 1 mmol/l as cut-off to predict whether or not responders had high blood glucose. The cut- off point of ≥11.1 mmol/l is one out of four diagnostic criteria for T2DM in Norway (52, 60).

2.4.2 The exposure variable- ethnicity

The ethnic distinction between Sami and non-Sami is based on questions about language and family background, and these were extracted from the SAMINOR initial questionnaire. The language question was posed as, *what domestic language(s) do/ did you, your parents and your grandparents have?* The response categories were Sami, Norwegian, Kven or other language, which had to be specified. Responders could give

multiple answers for each of the relatives and for themselves. If the reported language was Sami together with another language, the participant or family member was categorized as being of Sami heritage. The ethnicity question posed was *what is your, your fathers and mothers ethnic background?* The options were as for language, Sami, Norwegian, Kven or other, which had to be specified. Responders were encouraged to report multiple heritages. Again, if one of the options given was Sami, the family member was categorized as Sami. The Sami study group therefore consists of participants that have Sami language or Sami ethnicity in at least one family member, themselves, one parent or one grandparent. The non-Sami study group has responders that report none Sami markers. Throughout the analyses, we have compared Sami to the non-Sami. The non-Sami are considered to be the reference group.

2. 4. 3 Confounders- education, alcohol, smoking and marital status

The total FINDRISC score for female and male study group was adjusted for covariates. Table 2 gives an overview on how the confounding variables were created.

Table 2. Description of confounding variables.

Confounders	**SAMINOR**		**Creating variables**	
	Question	**Options**	**Categories**	
Education	How many years of education have you completed? (Consider every year you have been a student or attended school)	Years	<7 years of education 8 to 12 years ≥13 year of education	Years of education was recoded to an ordinal variable with 3 levels
			In the regression analyses education was coded to dummy variables, with ≥13 years of education as reference	

Alcohol	Approximately how often have you been drinking alcohol during the last year? (Light beer and nonalcoholic beverages should not be included)	Never drunk alcohol Not last year About 1 time per month 2-3 times per month About 1 time per week 2-3 times per week 4-7 times per week	Not last year/ never Monthly or less Weekly or less Every other day or less ≥4 times per week	The groups, *have never drunk alcohol* and *not last year*, were merged. 2-3 times per month and above 1 time per week were merged. In the regression analysis the alcohol variable was transformed to dummies and never/not last year was used as reference category.
Marital status	No information on marital status. Information was obtained from the Central Population Registry.	• Single • Married • Widow/ widower • Divorced • Separated	• Single • Married • Widow/-er • Divorced/ separated	Similar categories for homo- and heterosexual and categories were merged. Groups for divorced and separated were merged. Married was reference group

2.5 Ethics

The SAMINOR 1 study was initiated to accommodate the need for governmental knowledge about health and living conditions among the Sami people of Norway (59). The ethical approval for conducting the SAMINOR 1 study was given by Regional Committee for Medical and Health Research in North. Participants were given written information about the study and asked to sign an informed consent. Participants that had not signed the informed consent were excluded from the research database. Approval for storage and linkage of individual data with national health registries were given by the National Data Inspectorate.

2 .6 Statistical analyses

We used the statistical program, IBM SPSS version 21 for Windows 2010, to do the statistical analyses. All analyses were performed separately for men and women. The statistical test where all 2- sided and the significance level was set to 0.05. Cross tables and chi- square tests were used to explore the relationship between the ethnic groups, sample characteristics, the FINDRISC variables and FINDRISC score levels. When conducting chi-square tests by using cross tables, there were no cells with expected counts less than 5. To test if there were ethnic differences in regards to mean FINDRISC score, we used a two sample t-test. Hierarchical linear regression was run to determine how the exposure variable, ethnicity, was influenced by addition of confounders. The dependent variable was total FINDRISC score, given by summing all the variables included in the FINDRISC questionnaire. The potential confounding variables were included in the hierarchical regression, if the beta value to ethnicity changes more than 10% when the confounder was included in the model. Variables that exerted the ethnicity variable more than 10 % were education, alcohol, smoking and marital status. Smoking was expected to be a confounder but was equally distributed among Sami and non-Sami women and therefore not included in the regression analyses. We did not control for variables included in the dependent variables in the risk of over adjusting. However, we adjusted for age since acquisition of diseases is related to age. We tested the independent variables for interaction. However, significant interactions were not present. Preliminary test were conducted to ensure that there was no violation of the assumptions to the two sample t-test or the hierarchical regression.

3.0 Results

3.1 Characteristics of study sample

Table 3 gives an overview of the characteristics to the participants included in the total FINDRISC score calculation, stratified by gender and ethnicity.

Table 3. Descriptive characteristics of study sample.

	Women (N=7175)			Men (N=6803)		
	Sami (N=2321)	**Non-Sami (N=4854)**	**p-value[a]**	**Sami (N=2337)**	**Non-Sami (N=4466)**	**p-value[a]**
	N (%)	N (%)		N (%)	N (%)	
Age groups			0.041			0.673
<45 years	567 (24.4)	1245 (25.6)		508 (21.7)	975 (21.8)	
45-54	774 (33.3)	1460 (30.1)		713 (30.5)	1380 (30.9)	
55-64	552 (23.8)	1237 (25.5)		646 (27.6)	1267 (28.4)	
≥ 65	428 (18.4)	912 (18.9)		470 (20.1)	844 (18.9)	
Years of education[b]			<0.001			<0.001
0-7 years	446 (20.0)	591 (12.6)		480 (21.0)	580 (13.3)	
8-12 years	991 (44.4)	2371 (50.6)		1169 (51.2)	2353 (53.9)	
≥13 years	793 (35.6)	1728 (36.8)		633 (27.7)	1436 (32.9)	
Marital status			<0.001			<0.001
Single	418 (18.0)	635 (13.1)		700 (30.0)	893 (20.0)	
Married	1370 (59.0)	3172 (65.3)		1339 (57.3)	2967 (66.4)	
Widow/widower	221 (9.5)	443 (9.1)		27 (1.2)	88 (2.0)	
Divorced/separated	312 (13.4)	604 (12.4)		271 (11.6)	518 (11.6)	
Smoking[b]			0.248			0.014
Currently	765 (33.1)	1503 (31.2)		769 (33.1)	1357 (30.5)	
Previously	701 (30.4)	1497 (31.1)		938 (40.4)	1777 (39.9)	
Never	843 (36.5)	1821 (37.8)		615 (26.5)	1316 (29.6)	
Alcohol consumption[b]			<0.001			<0.001
Never and not last year	624 (27.5)	796 (16.6)		307 (13.3)	400 (9.0)	
Monthly or less	946 (41.7)	1986 (41.5)		880 (38.2)	1566 (35.3)	
Weekly or less	601 (26.5)	1567 (32.7)		882 (38.2)	1821 (41.1)	
Every other day or less	84 (3.7)	358 (7.5)		192 (8.3)	544 (12.3)	
≥ 4 times per week	13 (0.6)	78 (1.6)		45 (2.0)	104 (2.3)	

[a] Chi- square test.
[b]Different numbers due to missing values

From table 3 we see that Sami women were more likely to have less than 7 years of education compared to non-Sami. However, the average years of education for Sami and non-Sami women were respectively 11.2 years (SD 4.3) and 11.7 years (SD 3.8). The Sami women compared to the Norwegian were more likely to be single and to be divorced/separated, were less likely to drink alcohol and to be abstainers. Additionally, there are no significant differences between the women when comparing smoking categories. The mean age for Sami and non-Sami women was respectively 53.3 (SD 10.8) and 53.6 years (SD 11.1). The baseline characteristics for men are also reported in table 3. Sami men are more likely to be single, they are more likely to be current and previous smokers, and Sami men are more likely to be abstainers and less likely to consume alcohol frequently. Compared to Norwegian men, the Sami men are also more likely to have less years of education. The average years of education for the Sami men was 10.6 (SD 3.9) years and for the non-Sami men the mean years of education were 11.5 years (SD 3.7).

3.2 Distribution of FINDRISC variables in study sample

Table 4 shows the distribution of the variables included in the total FINDRISC score for Sami and non-Sami men and women.

Table 4. Subject characteristics matching variables in the FINDRISC questionnaire.

	Female				Male		
	Sami (N=2321)	**Non-Sami** (N=4854)	p-value[a]		**Sami** (N= 2337)	**Non-Sami** (N=4466)	p-value[a]
Age	N (%)	N (%)			N (%)	N (%)	
<45	567 (24.4)	1245 (25.6)	0.041		508 (21.7)	975 (21.8)	0.673
45-54	774 (33.3)	1460 (30.1)			713 (30.5)	1380 (30.9)	
55-64	552 (23.8)	1237 (25.5)			646 (27.6)	1267 (28.4)	
>64	428 (18.4)	912 (18.9)			470 (20.1)	844 (18.9)	
BMI (kg/m^2)							
<25	687 (29.6)	1733 (35.7)	<0.001		542 (23.2)	1127 (25.2)	0.109
25-30	882 (38.0)	1945 (40.1)			1207 (51.6)	2290 (51.3)	
>30	752 (32.4)	1176 (24.2)			588 (25.2)	1049 (23.5)	
Physical activity							
No <30 min	1205 (51.9)	2276 (46.9)	<0.001		1135 (48.6)	2101 (47.0)	0.233
Yes >30 min	1116 (48.1)	2578 (53.1)			1202 (51.4)	2365 (53.0)	
Daily consumption of green							
No	343 (14.8)	508 (10.5)	<0.001		613 (26.2)	1003 (22.5)	0.001
Yes	1978 (85.2)	4346 (89.5)			1724 (73.8)	3463 (77.5)	
Ongoing medication for hypertension							
No	1768 (76.2)	3836 (79.0)	0.006		1817 (77.7)	3503 (78.4)	0.514
Yes	553 (23.8)	1018 (21.0)			520 (22.3)	963 (21.6)	
History of high blood glucose							
No	2227 (96.0)	4680 (96.4)	0.331		2242 (95.9)	4301 (96.3)	0.449
Yes	94 (4.0)	174 (3.6)			95 (4.1)	165 (3.7)	
First degree relatives with diabetes							
No	1716 (73.9)	3709 (76.4)	0.022		1800 (77.0)	3591 (80.4)	0.001
Yes	605 (26.1)	1145 (23.6)			537 (23.0)	875 (19.6)	
Waist circumference							
<80	769 (33.1)	1689 (34.8)	0.051	<94	1291 (55.2)	2151 (48.2)	<0.001
80-88	590 (25.4)	1299 (26.8)		94-102	636 (27.2)	1245 (27.9)	
>88	962 (41.4)	1866 (38.4)		>102	410 (17.5)	1070 (24.0)	

[a]Tested by Chi- square test.

In summary, comparing the female study group, Sami women are more likely to be in age group 45-54 years than in the other age groups, more likely to have BMI > 30 kg/m^2 (general obesity), less likely to exercise more than 30 minutes per day, more likely to be using medication for hypertension and to have blood relatives with diabetes and less

likely to consume berries, fruit and vegetables. Sami women had a higher mean BMI compared to non-Sami women, respectively 28.2 (SD 5.1) and 27.2 kg/m^2 (SD 4.8). There was no significant ethnic differences concerning elevated blood glucose, and WC was border line. When considering men, Sami men are less likely to consume fruit, berries and vegetables, they are more likely to have blood relatives with diabetes and less likely to have broad WC. Mean WC for Sami and non-Sami men were respectively 93.0 (SD 10.6) and 94.9 cm (SD 10.5). There are no significant ethnic differences among men in relation to age categories, BMI categories, physical activity level, in self-reported blood glucose and in the use of medication for hypertension.

3.3 Difference in FINDRISC score stratified by gender and ethnicity

Table 5 gives an overview of the distribution of FINDRISC scores in each cut off level, stratified by gender and ethnicity.

Table 5. Distribution of FINDRISC scores in risk categories for female and male study sample.

Risk	**Score**	**Estimation of risk**	**Female**		**P-value[a]**	**Male**		**P-value[a]**
			Sami (N=2321)	Non- Sami (N=4854)		Sami (N=2337)	Non –Sami (N=4466)	
		%	N (%)	N (%)	%	N (%)	N (%)	%
Low risk	**<7**	**1**	780 (33.6)	1759 (36.2)	<0.001	979 (41.9)	1907 (42.7)	0.814
Slightly elevated	**7-11**	**4**	819 (35.3)	1830 (37.7)		827 (35.4)	1583 (35.4)	
Moderate	**12-14**	**16.7**	394 (17.0)	727 (15.0)		316 (13.5)	584 (13.1)	
High	**15-20**	**33.3**	289 (12.5)	487 (10.0)		188 (8.0)	352 (7.9)	
Very high	**>20**	**50**	39 (1.7)	51 (1.1)		27 (1.2)	40 (0.9)	

[a]Chi-square test.

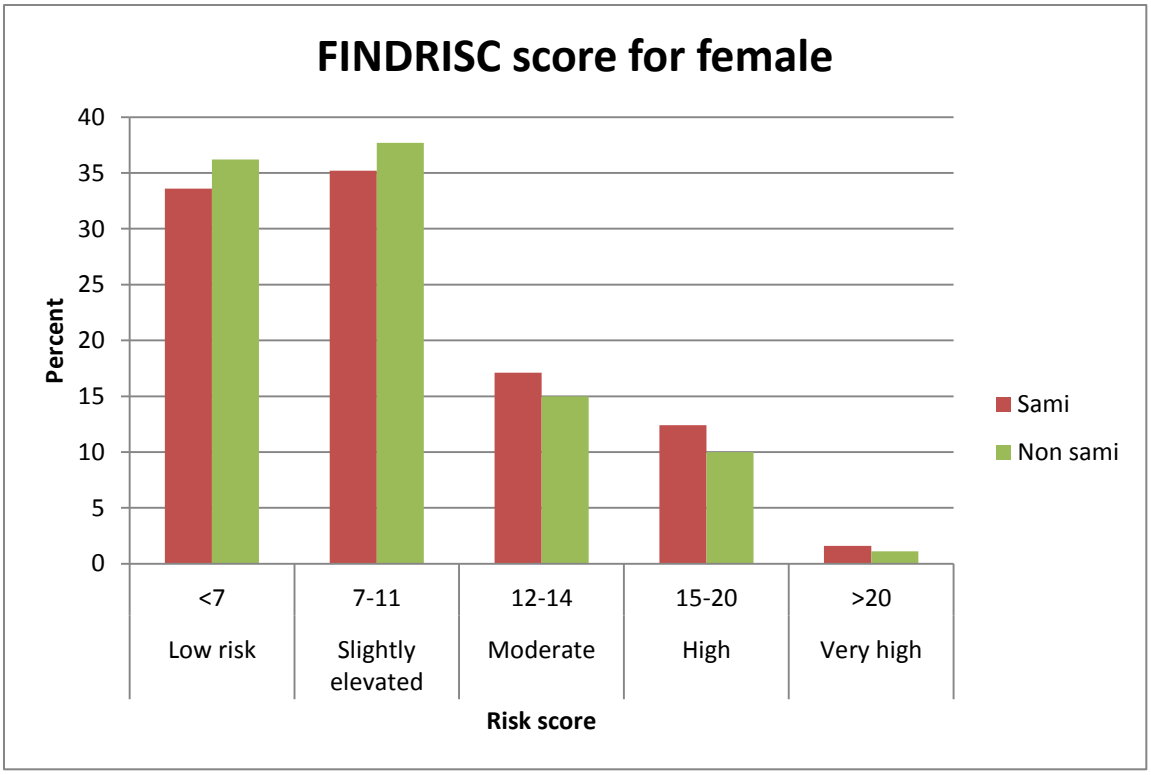

Figure 3. Distribution of total FINDRISC score in risk levels for female study group, (chi-square test p <0.001)

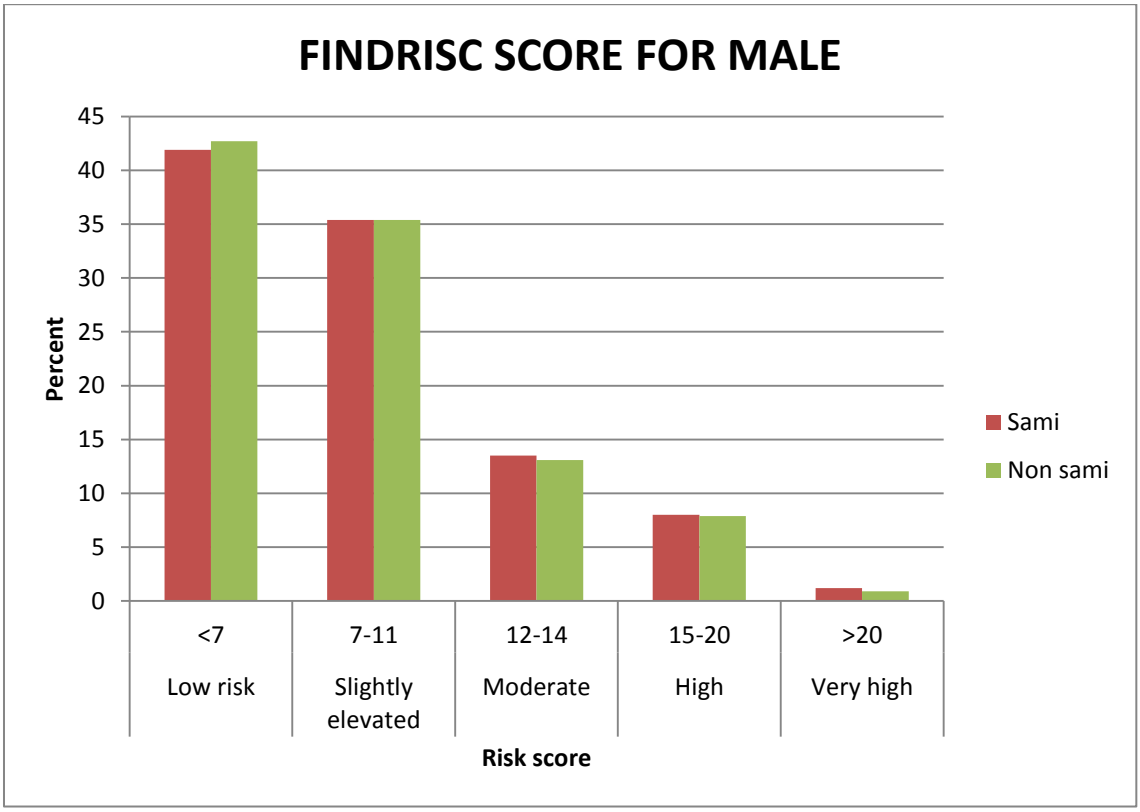

Figure 4. Distribution of total FINDRISC score in risk levels for male study group, (chi-square test p 0.814).

- The mean FINDRISC score for Sami women (mean: 9.1, SD 5.1) was higher than for non-Sami women (mean 8.4, SD 4.9). There was a significant difference of 0.65 (95% Cl, 0.41, 0.90), t-test 5.17, p <0.001.
- The mean FINDRISC score for Sami men (mean: 8.1, SD 4.6) was higher than for non-Sami men (mean 8.0, SD 4.6). There was a non- significant difference of 0.07 (95% Cl, -0.16, 0.30), t-test 0.56, p 0.573.

The distribution in FINDRISC score levels was significantly different for Sami and non-Sami women (table 5 and figure 3). Among the Sami women, 14.2% have higher or very high risk (i.e. FINDRISC score ≥ 15, corresponding to a risk of 33.3%, or every 1 out of 3) for developing for T2DM within ten years. Among the non-Sami women, 11.1 % of the participants had a high or very higher risk for developing T2DM within ten years. The distribution in FINDRISC score levels was not significantly different between Sami and non-Sami men (table 5 and figure 4). Among the Sami men 9.2% had a high or very high risk for T2DM within 10 years. The corresponding number for non-Sami men was 8.8%.

We explored if using non-fasting blood glucose measures with ≥11. 1 mmol/l as cut-off, gave a different results. When using non-fasting glucose in the computation of mean FINDRISC score, the ethnic differences in mean score for female study group remained significantly different, (p <0.001). The non-significant difference for men persisted when using non-fasting glucose. There was a 1.6 % reduction in mean score for women and 1.4% reduction in mean score for male when using non-fasting glucoses compared to self-reported diabetes.

3.3.1 Hierarchical regression including confounders

Table 6 shows how the ethnic differences for women are influenced by confounding variables, i.e. what explains the ethnic differences.

Table 6. Hierarchical regression for female study group. The effect of ethnicity on total FINDRISC score before and after adjusting for confounders, N=6813.

		Model 1		**Model 2**		**Model 3**		**Model 4**		**Model 5**	
		β	95 % CI	β	95 % CI	β	95 % CI	β	95% CI	β	95% CI
Intercept		8.35	(8.21, 8.49)	4.83	(4.26, 4.72)	4.49	(4.26, 4.72)	5.42	(5.07, 5.76)	5.46	(5.11, 5.82)
Ethnicity	Sami	0.60	(0.36, 0.85)	0.62	(0.41 ,0.84)	0.57	(0.35, 0.78)	0.42	(0.20, 0.63)	0.43	(0.21, 0.65)
	Non-Sami (ref)	0		0		0		0		0	
Age in years	45-54			3.15	(2.89, 3.42)	3.05	(2.79, 3.32)	3.08	(2.82, 3.35)	3.08	(2.81, 3.35)
	55-64			5.05	(4.76, 5.33)	4.72	(4.43, 5.02)	4.66	(4.37, 4.96)	4.63	(4.32, 4.93)
	65-79			7.11	(6.80, 7.42)	6.40	(6.03, 6.76)	6.17	(5.81, 6.54)	6.05	(5.66, 6.44)
	< 45 (ref)			0		0		0		0	
Education	≤ 7 years					1.44	(1.06, 1.81)	1.11	(0.73, 1.49)	1.08	(0.70, 1.46)
	8- 12 years					0.81	(0.58, 1.04)	0.66	(0.43, 0.88)	0.65	(0.42, 0.88)
	≥ 13 years (ref)							0		0	
Alcohol	Monthly or less							-0.50	(-0.78, -0.22)	-0.48	(-0.76, -0.20)
	Weekly or less							-1.22	(-1.53, -0.91)	-1.21	(-1.51, -0.90)
	Every other day or less							-1.65	(-2.12, -1.18)	-1.64	(-2.11, -1.17)
	≥ 4 times per week							-1.82	(-2.74, -0.91)	-1.79	(-2.71, -0.88)
	Never (ref)							0		0	
Marital status	Single									-0.12	(-0.42, 0.18)
	Widow									0.32	(-0.07, 0.71)
	Divorced									-0.26	(-0.56, 0.05)
	Married (ref)									0	
Improve-ment	ΔR^2	0.003		0.253		0.008		0.01		0.001	
	F for change in R^2 (df)	22.6 (1,6811)		771.1 (3,6808)		36.8 (2, 6806)		23.0 (4,6802)		2.1 (3,6799)	
	P value	<0.001		<0.001		<0.001		<0.001		0.098	

Table 7 shows how the ethnic difference for men is influenced by confounding variables, i.e. what can influences the ethnic differences.

Table 7. Hierarchical regression for male study group. The effect of ethnicity on total FINDRISC score before and after adjusting for confounding variables, N=6599.

		Model 1		**Model 2**		**Model 3**		**Model 4**		**Model 5**	
		β	95 % Cl	β	95 % Cl	β	95 % Cl	β	95% Cl	β	95% Cl
Intercept		7.97	(7.83 ,8.10)	4.91	(4.69, 5.14)	4.57	(4.31, 4.83)	4.73	(4.32, 5.15)	4.70	(4.28, 5.13)
Ethnicity	Sami	0.04	(-0.19, 0.27)	0.02	(-0.19, 0.23)	-0.02	(-0.23, 0.19)	-0.04	(-0.25, 0.17)	-0.05	(-0.26, 0.17)
	Non-Sami	0		0		0		0		0	
Age in years	45-54			2.48	(2.20, 2.76)	2.47	(2.19, 2.74)	2.48	(2.20, 2.75)	2.47	(2.18, 2.75)
	55-64			4.47	(4.19, 4.78)	4.34	(4.05, 4.63)	4.35	(4.06, 4.64)	4.34	(4.04, 4.64)
	65-79			5.46	(5.15, 5.77)	5.17	(4.83, 5.52)	5.18	(4.83, 5.52)	5.17	(4.81, 5.53)
	< 45 (ref)			0		0		0		0	
Education	≤ 7 years					0.82	(0.47, 1.17)	0.73	(0,38, 1.09)	0.73	(0.37, 1.09)
	8- 12 years					0.62	(0.39, 0.85)	0.57	(0.34, 0.80)	0.57	(0.34, 0.80)
	≥ 13 years (ref)					0		0		0	
Alcohol	Monthly or less							-0.01	(-0.37, 0.34)	-0.02	(-0.38, 0.33)
	Weekly or less							-0.13	(-0.49, 0,22)	-0.15	(-0.50, 0.21)
	Every other day or less							-0.50	(-0.94, -0.05)	-0.51	(-0.95, -0.07)
	≥ 4 times per week							-0.38	(-1.12, -0.37)	-0.4	(-1.14, 0.34)
	Never (ref)							0		0	
Marital status	Single									0.05	(-0.20, 0.30)
	Widow									0.24	(-0.54, 1.03)
	Divorced									0.25	(-0.07, 0.57)
	Married (ref)									0	
Improve-ment	ΔR^2	0.000		0.2		0.004		0.001		0.000	
	F for change in R^2 (df)	0.1 (1,6597)		490 (3,6594)		17.1 (2,6592)		2.1 (4,6588)		0.9 (3,6585)	
	P value	0.74		<0.001		<0.001		0.08		0.44	

In the hierarchical regression for women ethnicity was introduced in model 1, age in model 2, education in model 3, alcohol consumption in model 4 and marital status in model 5 (table 6). Ethnicity contributed significantly to explain the variance in total FINDRISC score for women (model 1, table 6). The beta coefficient to ethnicity increased and remained statistically significant when including age (model 2, table 6), which indicate that the ethnic differences increased when controlling for age. The beta coefficients for the age categories increase gradually with increasing age, indicating enhanced FINDRISC score with increasing age for women. When adding education to ethnicity and age (model 3, table 6), the beta coefficient to ethnicity was reduced but remained significantly, indicating that some of the ethnic differences in FINDRISC score is explained by education but not all. Compared to more than 13 years of education, education less than 13 years increased the FINDRISC score significantly when controlling for ethnicity and age. Adding frequency of alcohol consumption to age and education, attenuated the beta coefficient to ethnicity but it remained statistically significant (model 4, table 6). This indicates that additionally some of the ethnic differences in FINDRISC score are explained by alcohol consumption when controlling simultaneously for age and education and alcohol consumption. Compared to never consumers of alcohol, a frequently alcohol consumption was associated with a lower FINDRISC score for women when controlling for ethnicity, age and education. In the last model (model 5, table 6), marital status was added to the regression and the ethnic differences increased only slightly between Sami and non-Sami women and remained statistical significant.

The variables in model one to four, contributed significantly to improve predicting total FINDRISC score. Among these, ethnicity was associated with the lowest significant contribution to predict the total FINDRISC score. Adding marital status (model 5) to the

regression did not contribute statistically to the model (p 0.098). However, the full model including ethnicity, age, education, alcohol consumption and marital status to predict the total FINDRISC score was by its own statistical significant, R^2=0.275, F(3, 6799)=2.098, p< 0.001, adjusted R^2 was 0.273.

The stepwise hierarchical regression for men is shown in detail in table 7. The stepwise inclusion of variables was similar to the regression conducted for women. For men ethnicity was not associated with a significant contribution in explaining the variance in total FINDRISC score (model 1, table 7). The beta coefficient to ethnicity decreased and remained non- significant when controlling for age (model 2, table 7). However, the beta coefficients for the age categories increased gradually with increasing age, indicating a significant increasing FINDRISC score with increasing age. When adding education to ethnicity and age (model 3, table 7), the beta coefficient to ethnicity was reduced additionally and remained non-significantly, indicating no ethnic differences when controlling for age and education. As for the women, education less than 13 years was associated with a significantly increased FINDRISC score when controlling for age. Adding frequency of alcohol consumption to age and education, attenuated the beta coefficient to ethnicity and it remained statistically non-significant (model 4, table 7). This indicates no ethnic difference when controlling for age, education and alcohol consumption. In the fifth model, marital status was added to the regression and the non-significant relationship between ethnicity and FINDRISC score persisted. For men, ethnicity was associated with a non-significant contribution to explain the variance in total FINDRISC score, p 0.737. The addition of the variable age (model 2) and education (model 3) contributed significantly with a p<0.001, to predict the total FINDRISC score. Adding alcohol consumption (model 4) and marital status (model 5) to the regression

did not contribute significantly to the model ($p > 0.05$). However, the full model including all the variables to predict the total FINDRISC score was statistically significant, $R^2=0.188$ $F (3, 6585)=0.895$, $p< 0.001$, adjusted R^2 was 0.186.

4.0 Discussion

In this study we found that Sami women have a significantly higher mean FINDRISC score compared to non-Sami women. When simultaneously controlling for age, years of education, alcohol consumption and marital status, the differences between Sami and non-Sami women are reduced but remains statistical significantly different. For men there were non-significant ethnic differences in mean score, not even after adjusting for confounders. Over 10% of the women in the study sample had more than 30% risk for T2DM within ten years. Among the men in the study sample, less than 10% had more than 30% risk for T2DM within 10 years.

According to the IDF, the global prevalence of T2DM is slightly higher in men (198 million) compared to women (184 million) (2). According to the Norwegian institute of Public Health, there are more cases of self-reported diabetes among men than women. In addition, treatment with drugs are given more often to men, for both type 1 and type 2 diabetes (3). In our study we have not tested differences in gender, but the FINDRSIC scores indicates that women have higher risk for T2DM compared to men since the mean FINDRISC scores are higher for both Sami and non-Sami women. Also, when computing the relative risk for gender, women have 1.4 higher risk compared to men to develop T2DM within 10 years. According to Colhoun and Chaturvedi (61), women are not being consistently at higher risk for T2DM, except when women have greater obesity levels. In this study we have not tested for gender differences in BMI. However, the obesity (BMI >30 kg/m^2) level in our study is significantly higher among Sami women compared to non-Sami women (table 4), which contribute making the Sami women at higher risk. Parity has been associated with enhanced risk of subsequent T2DM (62), but still there seem to be uncertainty about the relationship (61). One possible explanations

is that parity causes weight gain and overweight (63), which is in the causal pathway to develop T2DM. In our study, we did not investigate the impact of parity on obesity in the female study group. However, in previous studies of the SAMINOR 1 sample (19) it has been reported that Sami women have significantly higher parity compared to non-Sami when controlling for age. Parity can therefore be causing the difference in obesity between the women in the different ethnic groups, and can be an indirect cause to the increased risk for T2DM among Sami women.

The NorPD report medication use according to health regions and region north represents Nordland, Troms and Finnmark County. The majority of participants (93.5%) in our study sample were settled in Northern Norway and therefore it seems appropriate to compare the SAMINOR 1 study sample to the population in Northern Norway. Medications for diabetes treatment are divided by the NorPD into blood glucose lowering medication (A10B) and insulin and insulin analogues (A10). We use blood glucose lowering medication as proxy for medication treated cases of T2DM, since the majority of users are likely to be T2DM patients (64). Statistics from the NorPD from 2012 show that use of medication for T2DM is higher among women in Northern Norway compared to the overall use among women in Norway (appendix 2). In Northern Norway, 42 out of 1000 inhabitants used blood-glucose lowering medication for T2DM in the age group 45-74 years in 2012, while the overall use for women in Norway was 40 per 1000 inhabitants for the same age group (65), (appendix 2). The comparisons strengthen the impression that women in Northern Norway have higher risk for T2DM, and this might be due to higher density of women with Sami origin in the Northern Norway, that have an enhanced risk for T2DM. The Sami and non-Sami men in our study had approximately equal mean FINDRISC scores indicating the same risk for

T2DM within ten years. Report from the NorPD for 2012 show that for men there was no difference between Northern Norway and the overall use in Norway when considering medication treated cases of T2DM (appendix 3). When comparing our results for men with the reports from the NorPD, there is compliance which might indicating no ethnic differences in risk of T2DM among men. The high degree of compliance between our results and the NorPD reports strengthens our study about ethnic differences among women and non-ethnic differences among men. However, comparing FINDRSIC scores for developing T2DM within ten years for a study sample from 2004, with medication treated cases in 2012, might be imprecise. A factor in favor for comparison is that both the SAMINOR 1 study sample and the reports to NorPD are based on non-institutionalized individuals, and therefore it seems appropriate to compare the SAMINOR sample with reports from NorPD. Besides this, there are limitations using NorPD reports to compare with, since the NorPD reports are based on number treated with medications. As already mentioned, T2DM can be asymptomatic for years and people are not always diagnosed and treated with T2DM medication and therefore not recorded in NorPD. Also, T2DM cases can be treated with diet and physical activity only, and therefore not recorded in the NorPD. Additionally, blood glucose lowering drugs can be used for other indications than diabetes, for instance for treating Polycystic Ovary Syndrome, pre-diabetes and metabolic syndrome (64). NorPD do not have information on diagnoses and all cases are counted as diabetes which might overestimating the prevalence of drug treated T2DM cases (64).

In a public health view the FINDRISC questionnaire seems to be a good instrument for screen populations to find groups at high risk for developing, i.e. more than 15 in FINDRISC score. From the third HUNT survey conducted between 2006-2008 (66), it

has been reported that as many as 10% of the adult general population in Norway can have a 30 % risk (corresponding to a FINRISC score ≥ 15, i.e. high or very high risk) for developing T2DM within the next 10 years. This was determined by using the FINDRISC questionnaire to screen for high risk individual that later had a blood test (66). Our results are in accordance with the results from the HUNT survey. Additionally, our results indicate that more than 10 % of the women can have more than 30 % risk for T2DM within ten years (table 5). Among the Sami women there were 14.3 % who had more than 30% risk for T2DM within ten years. The corresponding amount among non-Sami women with the same risk profile was 11.1 %. In the study sample for Sami men there were 9.2% that had more than 30 % risk, while the corresponding number for non-Sami men were 8.8 %. Abbasi et al (67), validated FINDRISC together with other risk assessment tools in a prospective cohort study, and concluded that the most basic prediction models without any biochemical test included, can identify people at high risk for developing diabetes in a time frame of five to ten years. The study also pointed out the most basic models overestimate the actual risk, particularly for those at highest risk (67). The same was observed in our study when we used non-fasting blood glucose measures with > 11.1 as cut- off to determine whether or not participants had T2DM. The FINDRSIC scores were slightly attenuated when using biochemical test to determine presence of T2DM. The small reduction in total risk score could indicate that the FINRISC instrument give an acceptable risk scores and predictions for public health.

In the hierarchical regression we adjusted for age although we risk over adjusting since age groups were already included in the dependent variable. The true relationship between the exposure variable (ethnicity) and the confounders can be blurred by age if

we do not control for age. Model 2 in table 7 and 8 show that the risk for T2DM increases with age, which already is a well- known relationship (3).

Research has revealed that in Western Europe and in the United States of America, the social gradient for T2DM is greater for women than for men and is consistent with the greater difference in obesity in women compared to men (61). Also in Norway, T2DM follows the social gradient and females are reported to be particularly susceptible for the social gradient (52). In our study we used education as a measure of SES. Model 3, in table 6, showed that the differences in FINDRISC score between Sami and non-Sami women attenuated and persisted significantly different when adding education to the regression. Education contributed significantly to explain some of the observed ethnic difference in FINDRISC score, and is a protective factor. Our results for women are therefore in accordance with the aforementioned theory, since the risk for T2DM attenuated with number of years of education, i.e. with increasing social status. For male gender the differences in FINDRISC score remained non - significant, suggesting men being less susceptible for influenced from SES (table 7, model 3).

A systematic review (68) have revealed a U-shaped relationship between alcohol consumption and risk for T2DM. Moderate alcohol consumption had protective effect and high alcohol consumption had a deleterious effect on health for both gender. In the review they found a stronger protective effect from alcohol among women than men (68). Our results for women show that regardless of amount consumption, alcohol consumption is protective (table 6, model 5). The findings for men were similar, although not statistically significant (table 7, mode l5). The results from our regression analyses are based on an assumption of linear relationship between FINDRISC score and

alcohol consumption represented with dummy variables. The regression is therefore only giving a positive relationship and potentially hiding another relationship. In the EPIC InterAct study (69), they found protective effect from moderate alcohol consumption only for women. They suggest that the gender difference might be due to differences in BMI or total body fat distribution and type of beverage consumed. Also, the risk reduction with alcohol consumption was more strongly related to overweight than normal weight individual (69). In our study the Sami women consume significantly less alcohol than non-Sami women and were more often obese, which in total makes Sami women at higher risk for T2DM compared to non-Sami women. Therefore, the protective effect from alcohol might not be real since there is difference in obesity and alcohol consumption. The protective effect from alcohol might be attributable to the lower obesity frequency among non-Sami women. Additionally, the protective effect from moderate alcohol consumption may be a measure of other confounding factors. Studies have revealed that non- drinkers compared to moderate drinkers are often not married and have lower SES, are more likely to have comorbidities and more likely to have poorer mental health (70).

We adjusted for social support by including marital status. Marital status did not contribute explaining differences in FINDRISC score, not for either of the gender. In relations to cardiovascular mortality and morbidity, studies suggest that being married is more beneficial for men than women, and that women have similar support from friendship and relationship to relatives as from marriage (47). The protective effect of social networks seems also to be more beneficial for men compared to women. But still, there is a dispute on whether social support has a non-specific protective effect across all causes of ill health (71). Also, social support might not always be protective. Seemen

et al report that if a social relationship is accompanied by conflicting issues, the relationship might not be beneficial for health (47). In our analyses we might not observe significant effect of marital status due to the nature of hierarchical regression. However, for men it seems that being married protects from getting T2DM although not significant. If marital status had been introduced earlier and not in final model, we might perhaps have observed differences explained by marital status. Smoking was left out from the regression due to non- significant difference between Sami and non-Sami women. Smoking was however significantly different for Sami and non-Sami men. The regression analyses for male study group might have been different if smoking had been included and if the order of models had been different.

4.1 Methodological considerations

The validity of the study is assessed by external and internal validity. External validity refers to the generalizability of the results to other comparable populations, while internal validity tells whether or not results are representative for the study population (72). Our study sample is mainly from rural areas (figure 1) and therefore we cannot generalize our findings to populations living in urban areas. Additionally, generally there is little knowledge about the Sami population, how many they are and how to categorize into Sami or non-Sami groups. Since there are none public registry on the Sami population, there are different ways to categorize people into ethnic groups and scholars do not seem to agree on how to categorize ethnic groups most correctly (36). Because of the limited information on the Sami population and disagreement on how to categorize, we can question the validity to our way ethnic categories and the generalizability of the study.

The use of proxy designed variables to match the variables in the FINDRISC questionnaire when there was no direct match, influence the internal and external validity. Proxy variables were created to answer questions about consumption of fruit, daily physical activity, and if participants ever have had elevated blood glucose. The FINDRISC question, *if participants ever had found to have elevated blood glucose*, is posed imprecisely. We used self- reported diabetes to answer this question and categorized all missing values related to this question as never found to have elevated blood glucose. We answered the question without knowing the medical history to participants and this can underestimate the FINDRISC score for some participants and threaten the internal validity. But since we performed a risk calculation by using non-fasting glucose measures which did not change the total FINDRISC score or the distribution in risk categories substantially, there is reason to believe that the FINDRISC proxy variable matching *ever found to have elevated blood glucose*, is satisfying. One possible threat to external validity might be the lack of information about diabetes in second line relatives. The question whether or not second line relatives have diabetes, was not posed in the SAMINOR 1 study, hence not included in the FINDRISC score calculation. The lack of this information makes the FINDRISC score systematically lower in cases where first degree relatives do not have diabetes.

In this thesis we assess risk factors present at a given time to determine if there is difference in total FINDRISC score. The cross sectional study design is suitable to detect prevalence of risk factors, population characteristics and disease and to examine associations in order to generate hypothesis that can be explored in longitudinal studies (72). The SAMINOR 1 study is based on a large sample size which makes it possible to

detect small differences with statistical power. The large sample size also reduces the influence of random errors, which we cannot control for. The FINDRISC questionnaire is designed from a study population aged 45-64 (27) and the SAMINOR 1 study had a slightly wider age span; 36-79 years. When the study population is in about the same age span as the FINDRISC population, this contributes making the results more trustworthy. Additionally, the survey had a relative good responds rate as surveys typical have about 30-40% non-respondents or even higher (73). These factors contribute to strengthen the reliability of the study.

There are some limitations with our study. As already noted, a cross sectional study collects data at a specific point in time. Even if we have included potential confounding factors in the models, the models for men and women explains only some of the observed variability, respectively 19% and 27%. The disease pattern to T2DM is complex and therefore there are many factors playing in. Confounding can influence non-causal relationships as well as causal (73). A confounding factor has distinctive features that make it special and hard to recognize. It is associated with the outcome and with the exposure, and is not an intermediate step in the causal pathway between exposure and outcome. Additionally, a confounding factor is unequally distributed in the groups being compared. Due to the nature of a cross sectional study, the study is not by designed controlled for confounding. This has to be instead properly done in the stage of analyzing and interpretation of the data (73). There might be differences in cultural and lifestyle factors between the ethnic groups that are compared that we have not controlled for in the present study. Therefore the two ethnic groups might be affected differently by these factors and have different risk (36). Also, the impact from cultural traditions, residence and socioeconomic background can be different within an ethnic

group (36). It is important to interpret results in the light of the background or the context. Additionally, when studying ethnic groups, we need to acknowledge that apparently same variable applied in in different ethnic groups can measure different things.

A study can also be subject for systematic errors, known as bias. Errors influenced results in a certain direction and can affect groups differently, so called differential errors. This kind of errors can give misleading results more seriously than non-differential errors that affect groups similarly (73). The response rate in the SAMINOR 1 study was 60.6% (figure 2) giving a 39.4% of non-respondents. If there are systematically differences in the risk profile or in the exposure status between those who participated and those who did not participate, the study is subject for selection bias (73). Previous studies of the SAMINOR 1 study report that the non- respondents were people at younger age, more likely to be men and were more often single (8). To what degree results are biased is uncertain due to limited information about non-respondents and lack of formal registries on ethnicity to the participants. Additionally, the study might appeal differently to Sami and non-Sami populations, due to the name and purpose of the study. This could give skewed participation of the different ethnic groups. Because we only are aware of these potential selection biases, we cannot by certain know the impact and direction of the bias.

We classified the study sample into Sami and non-Sami subgroups which can introduce by itself misclassification and information bias. The participants were categorized as Sami if they had at least one Sami marker, i.e. having at least one grandparent who were Sami or spoke Sami language regardless of whether they reported other ethnicities or

languages. Bhopal considers family origin and mainly self- reported ethnicity to be the most acceptable method of collecting and categorizing data on ethnicity (36). We chose not to use self-perceived ethnicity since self-perceived ethnicity can change over time and since the self-perceived ethnicity is influenced by other peoples` perception of someone's identity (36). Our simple classification without considering self- perceived ethnicity might mask important variations in lifestyle factors relevant to health and disease measures. However, self- perceived ethnicity among the Sami population has been reported to be an unreliable measure of ethnicity by Høgmo (74) and Albert (75). The Sami population has been exposed to an assimilation process since the 1850 (76, p.21) and until 1960, when the government showed political willingness to reverse the process. The measures conducted to get the Sami population assimilated has been named Norwegianisation by Eriksen and Niemi (77), referred to by Eliassen (76, p. 21). The Norwegianisation made Sami people change their language, lifestyle and consequently change their self- perceived ethnicity (74). Revitalization processes to strengthening the Sami language and ethnicity started in the years from 1970 (76). Due to the revitalization the Sami language and ethnicity was associated with less stigma and more people acknowledge their Sami ethnicity and origin. According to the doctoral dissertation to Ketil L. Hansen, considering the effects of Norwegianisation process, the Sami population today is not one homogenous group (78). There is great variety within the Sami population with regards to language skills, adaptation to cultural habits, settlement and no least to self- perceived ethnicity. By restricting inclusion criteria to ancestors and language, and leaving out self-perceived ethnicity, we might be able to show the variety within the Sami group and this can actually strengthen our study.

4.2 Contribution from the study

Our study confirms what have been predicted from previous studies (paragraph 1.3), that there are ethnic differences which make people with sami origin more likely to develop T2DM, implying disparities in health between Sami and non-Sami individuals.

Additionally, our study contributes giving a risk profile for developing T2DM within a decade, for the Sami and non-Sami groups. Since women are at higher risk for T2DM than men, this put them in risk for complications from T2DM, hence risk for cardiovascular diseases. This study might encourage to action to assign preventive measures and appropriate allocation of health resources to promote health policies. According to our results the preventive measures should be assigned for women, since they appear to be at an enhanced risk. There might also be need to for culturally tailored measures since Sami women were the ones with highest FINDRSIC score. Studies reveal that T2DM can be prevented and onset delayed by targeting the modifiable risk factors like reducing weight, total intake of fat and by increasing physical activity and intake of fibers (29). The earlier a person is diagnosed and preventive measures initiated, the better the chances of preventing complications and large health cost in terms of alternatives use of limited health resources.

4.3 Future studies

The FINDRISC questionnaire estimates the risk for having T2DM within ten years, and it is ten years since the SAMINOR 1 study was conducted. This makes it possible to investigate if the FINDRISC predictions are valid, by checking the incidence of T2DM in the SAMINOR 1 study population in years 2014. This could be done by matching

individual information from the NorPD with participants in SAMINOR 1 study to reveal who have developed medication treated diabetes. It could also be possible to investigate in the SAMINOR 2 study that follows part of the same study cohort, if the non-diseased people from SAMINOR 1 have developed T2DM.

4.4 Conclusion

We investigated if there were ethnic differences in mean score between Sami and non-Sami women and men. Our study suggest that being middle aged women, and having Sami origin is associated with higher risk for T2DM within 10 years due to higher BMI, inactivity, low intake of vegetables, fruits and berries, and due to higher frequency of hypertension and having relatives with diabetes. Since Sami women come off worse in obesity measures and in question about relatives having diabetes, which both contributes substantially to give high FINDRISC scores, the difference might be attributable to these conditions. Additionally, some of the ethnic differences between Sami and non-Sami women were explained by education, alcohol consumption and marital status. For men there were no ethnic differences in the risk for T2DM, even not when adjusted for age, education, alcohol consumption and marital status. However, for both men and women, ethnicity together with age, education, alcohol consumption and marital status significantly predicted the FINDRSIC score. Further, we found that 14.2% of Sami women and 11.1 % of non-Sami women had a 33.3 % risk for developing T2DM within 10 years. For men the percentages were respectively 9.2% and 8.8% for having 33.3% risk for T2DM within a decade.

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Appendix 1. The FINDRISC questionnaire. The total score estimates future risk for T2DM

Finnish Diabetes Association

TYPE 2 DIABETES RISK ASSESSMENT FORM

Circle the right alternative and add up your points.

1. Age

0 p. Under 45 years
2 p. 45–54 years
3 p. 55–64 years
4 p. Over 64 years

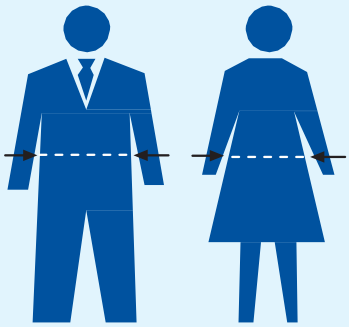
2. Body-mass index

(See reverse of form)

0 p. Lower than 25 kg/m^2
1 p. 25–30 kg/m^2
3 p. Higher than 30 kg/m^2

3. Waist circumference measured below the ribs (usually at the level of the navel)

	MEN	WOMEN
0 p.	Less than 94 cm	Less than 80 cm
3 p.	94–102 cm	80–88 cm
4 p.	More than 102 cm	More than 88 cm



4. Do you usually have daily at least 30 minutes of physical activity at work and/or during leisure time (including normal daily activity)?

0 p. Yes
2 p. No

5. How often do you eat vegetables, fruit or berries?

0 p. Every day
1 p. Not every day

6. Have you ever taken medication for high blood pressure on regular basis?

0 p. No
2 p. Yes

7. Have you ever been found to have high blood glucose (eg in a health examination, during an illness, during pregnancy)?

0 p. No
5 p. Yes

8. Have any of the members of your immediate family or other relatives been diagnosed with diabetes (type 1 or type 2)?

0 p. No
3 p. Yes: grandparent, aunt, uncle or first cousin (but no own parent, brother, sister or child)
5 p. Yes: parent, brother, sister or own child

Total Risk Score

☐

The risk of developing type 2 diabetes within 10 years is

Lower than 7	**Low:** estimated 1 in 100 will develop disease
7-11	**Slightly elevated:** estimated 1 in 25 will develop disease
12-14	**Moderate:** estimated 1 in 6 will develop disease
15-20	**High:** estimated 1 in 3 will develop disease
Higher than 20	**Very high:** estimated 1 in 2 will develop disease

Please turn over

Test designed by Professor Jaakko Tuomilehto, Department of Public Health, University of Helsinki, and Jaana Lindström, MFS, National Public Health Institute.

Finnish Diabetes Association

WHAT CAN YOU DO TO LOWER YOUR RISK OF DEVELOPING TYPE 2 DIABETES?

You can't do anything about your age or your genetic predisposition. On the other hand, the rest of the factors predisposing to diabetes, such as overweightness, abdominal obesity, sedentary lifestyle, eating habits and smoking, are up to you. Your lifestyle choices can completely prevent type 2 diabetes or at least delay its onset until a much greater age.

If there is diabetes in your family, you should be careful not to put on weight over the years. Growth of the waistline, in particular, increases the risk of diabetes, whereas regular moderate physical activity will lower the risk. You should also pay attention to your diet: take care to eat plenty of fibre-rich cereal products and vegetables every day. Omit excess hard fats from your diet and favour soft vegetable fats.

Early stages of type 2 diabetes seldom cause any symptoms. If you scored 12–14 points in the Risk Test, you would be well advised to seriously consider your physical activity and eating habits and pay attention to your weight, to prevent yourself from developing diabetes. Please contact a public-health nurse or your own doctor for further guidance and tests.

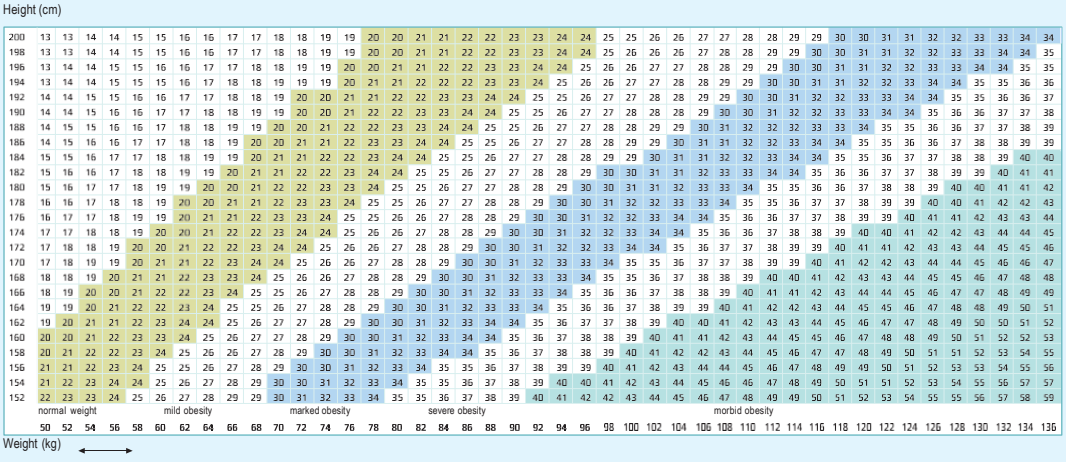
If you scored 15 points or more in the Risk Test, you should have your blood glucose measured (both fasting value and value after a dose of glucose or a meal) to determine if you have diabetes without symptoms.

BODY-MASS INDEX

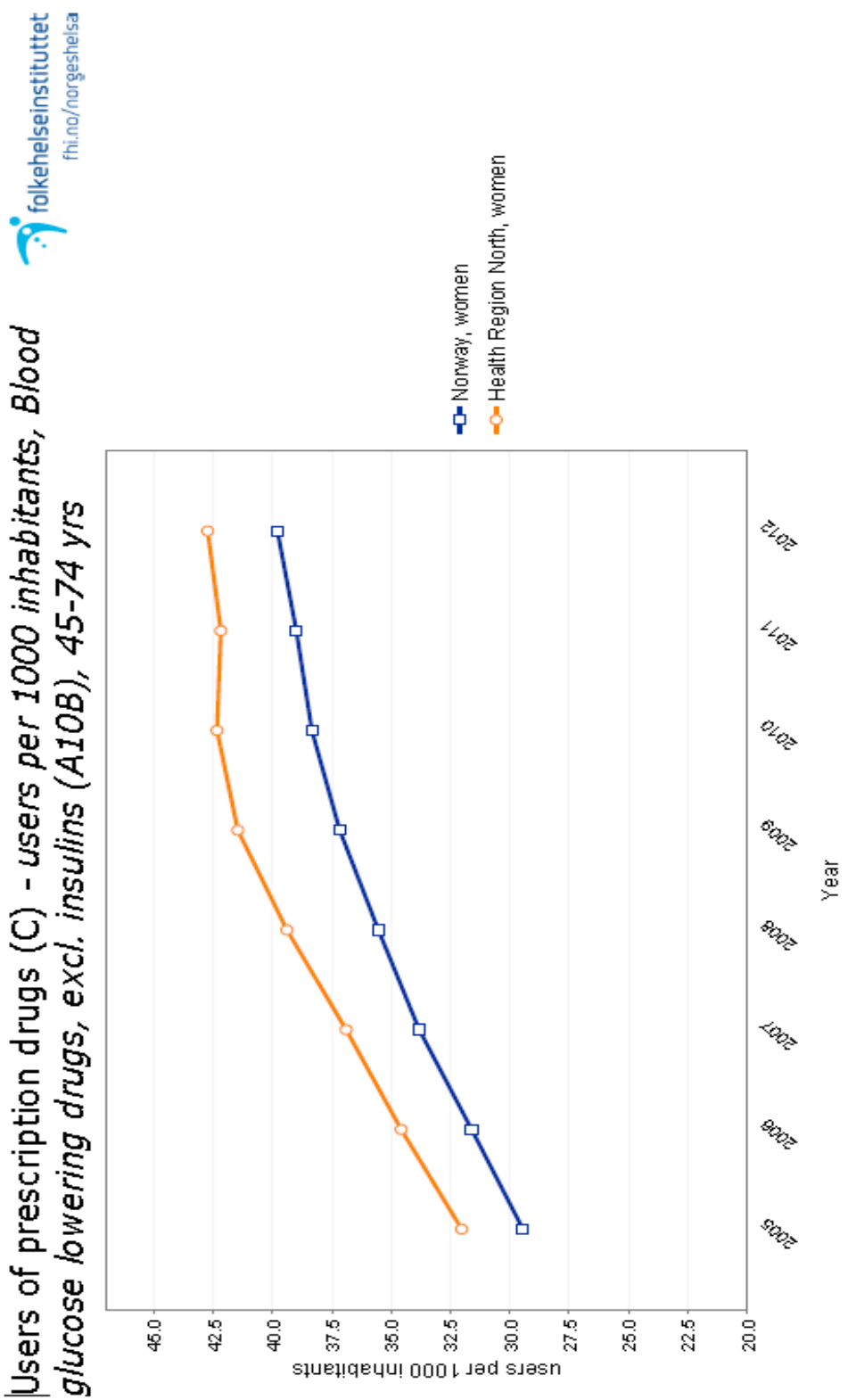
The body-mass index is used to assess whether a person is normal weight or not. The index is calculated by dividing body weight (kg) by the square of body height (m). For example, if your height is 165 cm and your weight 70 kg, your body-mass index will be 70/(1.65 x 1.65), or 25.7.

If your body-mass index is 25–30, you will benefit from losing weight; at least you should take care that your weight doesn't increase beyond this. If your body-mass index is higher than 30, the adverse health effects of obesity will start to show, and it will be essential to lose weight.

BODY-MASS INDEX CHART



Appendix 2. Users of blood glucose lowering drugs are a proxy measure for drug treated cases of T2DM. The graphs show the number T2DM cases per 1000 inhabitants for respectively the whole country and for northern Norway, for women.



Appendix 3. Users of blood glucose lowering drugs are a proxy measure for drug treated cases of T2DM. The graphs show the number T2DM cases per 1000 inhabitants for respectively the whole country and for northern Norway, for men.