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# The prevalence of metabolic syndrome and diabetes mellitus in Sami and Norwegian populations. The SAMINOR study.

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#### Original Article

The prevalence of metabolic syndrome and diabetes mellitus in Sami and Norwegian populations. The SAMINOR study.

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Tables 3

Figures 2

#### **Abstract**

#### **Background**

Metabolic syndrome (MetS) is generally recognized as a reliable long-term predictor of adverse health outcomes known to elevate risks of developing type 2 diabetes mellitus. Elevated prevalence rates of MetS and chronic lifestyle diseases have been documented in different indigenous groups. The Sami people are the indigenous group of North Norway. Therefore we wanted to evaluate the prevalence of MetS and diabetes mellitus in relation to ethnicity.

#### Material and methods

SAMINOR is a population based study of health and living conditions in areas home to both Sami and non-Sami populations in North Norway. The survey was carried through in 2003 – 2004. In total, 16,538 males and females aged 36-79 participated and gave informed consent for medical research. Sami affiliation was reported in 5141 people (35 percent).

#### **Results**

The study demonstrated a high prevalence of overweight and obesity in this population.

Obesity and central obesity was most pronounced in Sami women. The prevalence of self-reported diabetes type 2 was 4.3 percent for men and 4.4 percent for women. Almost 19 percent of women and 12 percent of men had MetS.

#### **Conclusions**

The prevalence of MetS was higher in Sami females than in non-Sami females. Non-Sami males showed higher overall prevalence of MetS. The prevalence of MetS increased significantly by age in both ethnic groups. It was therefore somewhat surprising that, irrespective of age, ethnicity seemed not to influence diabetes prevalence.

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### Strengths and limitations of this study

- The SAMINOR study is the first survey to report on the prevalence of diabetes and MetS in a large geographic area of North Norway including both the indigenous and the non-indigenous population.
- The large sample size allowed for detailed analysis of diabetes and MetS in Sami and non-Sami populations of rural North Norway.
- The survey has a relatively high response rate.
- Categorizing people based on ethnicity is a contentious practice. Different studies use different criteria of ethnicity, which makes it difficult to compare results.
- Cross-sectional data cannot assess the effect of lifestyle on the incidence of MetS, and longitudinal cohort studies are therefore needed

The prevalence of metabolic syndrome and diabetes mellitus in Sami and Norwegian populations. The SAMINOR study.

#### Introduction

Chronic disease has become a global problem and a burden on health care services, reaching epidemic proportions. In Norway, as well as internationally, the great majority of patients in health care systems are living with chronic disease.[1-2] Cardiovascular disease (CVD), type 2 diabetes mellitus (T2DM), cancer and chronic obstructive pulmonic disease (COPD) are the most common causes of hospitalization and premature death.[3] Unfavorable health factors such as obesity, insulin resistance, dyslipidemia and hypertension are known to elevate risks of developing CVD and T2DM. Metabolic syndrome (MetS) indicates a cluster of these risk factors. [4-5] MetS is generally recognized as a reliable long-term predictor of adverse health outcomes.[6] Further, MetS has been recognized as a growing, global public health problem. .[7] In addition, several studies demonstrate MetS to be associated with elevated cancer risk.[8-9]

However, information on the prevalence of chronic disease in various ethnicities of North Norway remains sparse. The Sami, Kven and Norwegian ethnic groups are recognized as having inhabited the region in centuries; the Norwegian government acknowledges the Sami people as the indigenous people of Norway.

Several epidemiological studies have documented elevated prevalence rates for chronic lifestyle diseases in a number of different minority groups.[5, 10 -11] Although such disorders have emerged quite recently in indigenous populations — mainly due to changes in lifestyle and diet — they are, however, prevalent in several indigenous populations.[12-13] Publications from the SAMINOR study of North Norway demonstrate that the prevalence of obesity was high in the survey population, especially among Sami women.[14-15] However, information relating specifically to the Sami population remains insufficient.

The SAMINOR study

The cross-sectional data is derived from the SAMINOR study of 2003-2004 (SAMINOR 1). The SAMINOR study was conducted by The Centre for Sami Health Research, Department of Community Medicine, UiT The Arctic University of Norway, in collaboration with the National Screening Program for Cardiovascular Diseases. The survey is described in detail elsewhere.[16]

*The study sample* 

All eligible residents aged 30 and 36-79 years registered in the Central Population Register in 24 selected municipalities were invited regardless of ethnic background (n=27,987). Due to a low response rate among those aged 30 years, our analyses were restricted to the age interval 36-79 years (n=27,151). In total, 16,538 males and females aged 36-79 participated and gave informed consent for medical research. The response rate was 61 per cent. Data was obtained from physical tests and blood samples. Information on ethnicity, and the different diagnostic tools for MetS, were available for 15,112 participants.

Questionnaire design

Information regarding ethnicity, disease and lifestyle were collected using two selfadministrated questionnaires. Ethnicity was measured using the following questions: "What language(s) do/did you, your parents and your grandparents use at home?" The questions were to be answered separately for each relative. The available responses were: "Norwegian",

"Sami", "Kven" and "Other". Multiple answers were allowed. Providing the same response options we also asked: "What is your, your father's and your mother's ethnic background?"

The respondents also reported whether they considered themselves to be Norwegian, Sami, Kven or other (self-perceived ethnicity). Based on these variables we generated two categories of ethnicity: "Sami" and "Non-Sami". Participants reporting at least one Sami identity mark (Sami language spoken by the respondent or at least one parent or grandparent, or Sami ethnic background or self-perceived Sami ethnicity) were placed in the category "Sami". The "Non-Sami" comprise the remainder of the participants.

The study was accredited by the Regional Board of Research Ethics in Northern Norway, and by the Board's Sami Consultant. The survey is in accordance with the Helsinki Declaration of 1975. The National Data Protection Authority (*Datatilsynet*) approved the use of personal information.

#### Screening

Due to the large size of the study sample participants were examined at different times of day. This meant that it was not possible to ask participants to be fasting prior to arrival. Non-fasting blood samples were obtained at the research station. Blood samples were drawn by venopuncture at normal venous pressure in sitting position. Serum was separated at the station within 1.5 hours. Serum was sent by overnight mail to laboratories in Oslo and Tromsø. The laboratory analyses are described in detail elsewhere.[17]

Body mass index (BMI) was based on measurements of weight and height, and expressed as body weight in kilograms/(body height in meters)<sup>2</sup>. BMI categories were defined according to guidelines from The World Health Organization (WHO); 'underweight' corresponding to a BMI<18.5 kg/m², 'standard weight' in the range 18.5–24.9 kg/m², 'overweight' in the range 25 – 29.9 kg/m² and 'obese' ≥30 kg/m².[18]

Waist circumference (WC), which is used to identify abdominal obesity, was measured (to the nearest centimeter) at the umbilicus with the participant standing erect. Two different WC cut-off values were applied to define abdominal obesity to enable the comparison of how the corresponding values influenced the subsequently calculated prevalence of MetS. The US National Institute of Health (NIH) Clinical Practice Guidelines defines central/abdominal obesity as  $WC \ge 102$  cm in males and  $WC \ge 88$ cm in females.[19] In addition, abnormal WC for Europid males are  $\ge 94$  cm and for females  $\ge 80$  cm. These figures are based on cross-sectional data from Europids and were included in the analyses.[18,20]

Trained personnel measured blood pressure, using Dinamap –R. automatic device.

Measurements were initiated after subjects had been seated for two minutes with their arms resting on a table. Blood pressure was measured three times, with one- minute intervals. The mean value of the second and third reading was used in the analysis.

#### Diabetes mellitus

Because all blood samples in the SAMINOR study were non-fasting, we used random plasma glucose  $\geq 11.1$  mmol/L, in addition to self-reported diabetes and information about anti-diabetic medication from a questionnaire to define diabetes mellitus. The question about diabetes mellitus was; "Do you have or have you had diabetes?" The available responses were "Yes" or "No". Missing values were classified as "No". In the absence of oral glucose tolerance tests we used random plasma glucose  $\geq 11.1$  mmol/l as a substitute for elevated oral glucose tolerance test.

#### Metabolic syndrome

Several attempts have been made at developing diagnostic criteria for the definition of MetS. [21-23] In 2004, the International Diabetes Federation (IDF), the WHO and the National Cholesterol Education Program Third Adult Treatment Panel (ATP III) produced a consensus statement on the definition of MetS.[24] The latter definition requires central obesity and cut-

off points to be specified according to gender and ethnicity. Central obesity is most commonly measured by WC; cut-off values are based on cross-sectional studies conducted in Europe, The United States and Asia.[18-20, 25] The diagnostic tools are intended for clinical and research purposes. The definition of MetS used in this article adheres to the IDF MetS worldwide definition,[24]: Central obesity plus any two of four additional factors; Elevated triglyceride level > 1.7 mmol/l, reduced HDL-cholesterol < 1.03 mmol/l in males and < 1.29 mmol/l in females, elevated blood pressure (systolic BP  $\geq$  130 or diastolic BP  $\geq$  85 mmHg) and elevated fasting plasma glucose  $\geq$  11.1 mmol/l or previously diagnosed type 2 diabetes. *Statistical analyses* 

All analyses were stratified by gender. Sample characteristics were presented separately by gender and ethnicity as mean values for continuous variables with corresponding 95 per cent confidence intervals. Analyses of variance (ANOVA) were used for tests of ethnic differences (Table 2). Differences according to diabetes mellitus and Mets prevalence were tested by Chi-square tests (Tables 3 and 4). MetS prevalence was also stratified by age (Table 4). Logistic regression analyses were used to test for age influence on MetS with age as a continuous variable (Table 4). Test for differences in number of risk markers between Sami and non-Sami were tested by Chi-square tests (Table 5).

We used the SAS statistical software package, version 9.3 (SAS Institute Inc., Cary, NC, USA).

#### **Results**

The current analysis involved a total of 7,822 female and 7,290 male participants. Sami affiliation was reported by 5,141 participants (34 per cent). Table 1 shows gender-specific and ethnicity-specific characteristics at screening.

**Table 1** Sample characteristics by sex and ethnic group.  $(N=15\ 112)$ 

	Sami (N=2559)	Non-Sami (N=4731)	p-value <sup>2</sup>
Men		Mean (95 % CI) <sup>1</sup>	_
	Mean (95 % CI) <sup>1</sup>	(	
Age (yr)	55.0 (54.8-55.1)	54.8 (54.7-54.9)	0.584
Height (cm)	170.0 (170.0-170.2)	175.7 (175.6 – 175.8)	< 0.0001
Weight (kg)	80.6 (80.4 – 80.7)	85.1 (85.0 – 85.3)	< 0.0001
BMI $(kg/m^2)$	27.8 (27.7-27.9)	27.5 (27.5 – 27.6)	0.009
WC (cm)	93.2 (93.0 – 93.3)	95.0 ( 94.9 – 95.2)	< 0.0001
Non-fasting glu (mmol/L	5.8 (5.8- 5.8)	5.8 ( 5.7 – 5.8)	0.313
HDL-chol (mmol/l)	1.27(1.26 - 1.28)	1.25(1.25-1.26)	0.115
LDL- chol ( mmol/L)	3.87(3.86 - 3.89)	3.80(3.79 - 3.81)	0.004
Cholesterol (mmol/l)	5.98 ( 5.96- 5.99)	5.90 ( 5.90 – 5.90)	0.001
Triglycerids (mmol/l)	1.86(1.85 - 1.88)	1.86 (1.85 - 1.88)	0.970
Systolic BT (mmHg)	135 (135 – 135)	134 (134 -134)	0.168
Diastolic BT (mmHg)	78 (78 -78)	78 (78 – 78)	0.182
Women	Sami (N=2581)	Non-Sami (N=5241)	p-value
	Mean (95 % CI) <sup>1</sup>	Mean (95 % CI) <sup>1</sup>	
Age (yr)	54.2 (54.1 – 54.4)	54.5 (54.4 – 54.6)	0.277
Height (cm)	157.3 (157.2 – 157.4)	162.6 (162.6 – 162.7 )	< 0.0001
Weight (kg)	69.7 (69.6 – 69.9)	72.1 (71.9 -72.2)	< 0.0001
BMI $(kg/m^2)$	28.2(28.1 - 28.3)	27.3 (27.2 – 27.3)	< 0.0001
WC (cm)	86.0 (85.9 – 86.2)	85.5 (85.4 – 85.6)	0.053
Non-fasting glu (mmol/L	5.66 (5.63 – 5.68)	5.57 (5.55 – 5.58 )	0.018
HDL-chol (mmol/l)	1.45 (1.44 – 1.45)	1.49 (1.49 – 1.50)	< 0.0001
LDL- chol ( mmol/L)	3.82(3.81 - 3.83)	3.81(3.80 - 3.82)	0.707
Cholesterol (mmol/l)	5.98 (5.96 –5.99)	5.99 (5.98 –6.00 )	0.617
Triglycerids (mmol/l)	1.54(1.56 – 1.59)	1.53 (1.52 – 1.54)	0.044
Systolic BT (mmHg)	130 (129 – 130)	130 (130 -131)	0.125
Diastolic BT (mmHg)	72 (72 -72)	73 (73 -73)	0.008

<sup>&</sup>lt;sup>1</sup>95% confidence interval

The mean BMI was greater in Sami males, whereas the mean WC was greater in non-Sami males. Sami females, however, showed significantly greater values for mean BMI, WC and lipids.

Table 2 shows the prevalence of diabetes in Sami and non-Sami participants.

<sup>&</sup>lt;sup>2</sup> test of differences, ANOVA, for between Sami versus non-Sami

**Table 2.** Prevalence of diabetes mellitus in the SAMINOR study (N=15112)

	Sami (N=2559)	Non-Sami (N=4731)	p-value <sup>1</sup>
Men	n (%)	n (%)	
Diabetes prevalence	132 (5.2)	212 (4.5)	0.05
Insulin treatment	13 (0.5)	31 (0.7)	
Tablet treatment	45 (1.8)	87 (1.8)	
Insulin and tablet treatment	25 (1.0)	21 (0.4)	
Non- treatment	49 (1.9)	73 (1.5)	

	Sami (N=2581)	Non-Sami (N=5241)	
Women	n (%)	n (%)	p-value <sup>1</sup>
Diabetes prevalence	129 (5.0)	220 (4.2)	0.026
Insulin treatment	13 (0.5)	29 (0.6)	
Tablet treatment	61 (2.4)	71 (1.6)	
Insulin and tablet treatment	20 (0.8)	38 (0.7)	
Non- treatment	35 (1.4)	82 (1.6)	

<sup>&</sup>lt;sup>1</sup>Chi-square test for differences in diabetes prevalence among Sami versus non-Sami

Based on information gathered in questionnaires in addition to random plasma glucose  $\geq 11.1$  mmol/l. Ethnicity appeared not to affect diabetes prevalence.

In Figures 1 (males) and 2 (females) the prevalence figures found — using the various MetS diagnostic tools — are presented.

The most prevalent risk marker for MetS (aside from central obesity) was the presence of elevated systolic blood pressure and high triglyceride levels independent of gender and ethnicity. In contrast, diabetes mellitus contributes the least to MetS for all groups, but was however, more prevalent than in the general study population. Diabetes mellitus was also most frequent in Sami participants relative to non-Sami participants.

Table 3 presents the prevalence of MetS according to WC cut-off points based on European and NIH values.

	European cut off of WC			NIH	cut off of V	VC
	Sami (N=650)	Non-Sami (N=917)	,,,	Sami (N=315)	Non- Sami	, 0
	n (%)	n (%)		n (%)	(N=728) n (%)	
			p- value <sup>1</sup>			p-value <sup>1</sup>
Men			varae			
36-49 yr	194 (22.3)	429 (26.0)	0.038	89 (10.2)	203 (12.3)	0.118
50-59 yr	229 (27.2)	440 (29.7)	0.202	115 (13.7)	238	0.121
60-79 yr	227 (26.9)	489 (30.6)	0.055	111 (13.1)	(16.1) 287	0.002
p-value <sup>2</sup>	0.029	< 0.0001		0.05	(18.0) <0.0001	
	Sami	Non-Sami		Sami	Non-	
	(N=790)	(N=1521)		(N=588)	Sami	
	n (%)	n (%)		n (%)	(N=1091)	
					n (%)	
Women						
36-49 yr	232 (24.4)	369 (19.1)	0.006	161 (16.2)	263	0.056
<b>7</b> 0. <b>7</b> 0	240 (24.5)	155 (20.4)	0.201	155 (22.5)	(13.6)	0.155
50-59 yr	248 (31.5)	455 (29.4)	0.291	177 (22.5)	309	0.155
60-79 yr	310 (38.7)	697 (39.6)	0.641	250 (31.2)	(20.0) 519	0.393
p-value <sup>2</sup>	0.004	<0.0001		<0.0001	(29.5) <0.0001	

<sup>&</sup>lt;sup>1</sup>Chi-square tests for differences in MetS prevalence of Sami versus non-Sami

<sup>&</sup>lt;sup>2</sup> Age effect tested by logistic regression with age as a continuous variable

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The two different WC cut-off values greatly influenced the measured prevalence of MetS. The present study demonstrates that ethnicity is a significant factor for MetS in participants belonging to the lowest age bracket. In the case of males aged between 36 and 49, MetS is less prevalent in the Sami population (in comparison to non-Sami). For females in the same age bracket, however, MetS is more prevalent in the Sami population. When the NIH cutoffs were used, we found that — in the highest age bracket — the non-Sami males showed significantly higher prevalence of MetS in comparison to Sami males. The prevalence of MetS increased significantly by age in both ethnic groups, regardless of which WC cut-off values were used. However, ethnicity could not be established to affect diabetes prevalence. In general, overweight and obesity are common among the participants in the SAMINOR study. From earlier publications based on the SAMINOR study, central obesity has been

shown to be more common in Sami females.[15,26] General obesity in Sami females has also been discussed by Njølstad et al (1998).[27] However, obesity rates were high in non-Sami females as well.[14] For males, central obesity occurred more frequently in the non-Sami population relative to the Sami population.[14-15]

MetS has several different definitions, making it difficult to directly compare and contrast prevalence found in different surveys. WC is the most significant measurement of both central obesity and fat distribution, according to The International Diabetes Federation (IDF).[28] The group that produced the consensus statement on the definition of MetS in 2004 recommended that gender and ethnicity should be the basis for classification of cut-off points. [24] The existing values are based on cross-sectional population survey data from the respective countries. How to define the WC cut-off point in the various indigenous populations has not yet been established; however, an immediate response would be to perform cross-sectional population surveys within indigenous societies. In our study two different cut-off points were used in order to facilitate comparison. The European cut-off values doubled the prevalence of MetS in males and increased prevalence by more than 40 per cent in females (compared to values found when applying NIH WC cut-off values). This was the case in both ethnic groups. But the question of what the WC values should be in terms of optimal prediction of prospective disease in the SAMINOR sample remains unanswered. A follow-up study could provide better answers to questions regarding disease development. Irrespective of cut-off values, elevated blood pressure was the most frequent MetS component present in obese participants. These findings were also demonstrated in a collaborative analysis of ten large cohort studies in Europe. [29] In the ten studies included, obesity coincided with hypertension in up to 85 per cent of cases.

The presence of MetS, as well as its individual components, however, shows considerable variance between populations. Several studies of MetS have been performed in circumpolar

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areas, such as in indigenous peoples of Alaska, Canada and Greenland.[30-32] American Indians and Aboriginal Canadians represent populations in which MetS, obesity and T2DM are becoming more prevalent. [13,30] MetS is also frequently occurring in Greenland's inuit population.[32] A health survey in Greenland showed that central adiposity and obesity are more prevalent in the Inuit population when compared to the corresponding Danish population, but was not associated with the same degree of metabolic disturbance as in the general Danish population.[33] Yet it is debatable which factors in the cluster of MetS are the most significant in the development of chronic lifestyle diseases.

There is a significant relation between T2DM and MetS; the syndrome itself is not a disease, but a rather strong indicator for developing diseases. Thus we prefer to include diabetes in this article to demonstrate the link between the health indicator MetS and diabetes mellitus.[24] In the SAMINOR study diabetes mellitus was identified using a questionnaire, in addition to measured random plasma glucose ≥ 11.1 mmol/L in participants whom did not report diabetes mellitus. As the study was epidemiologically designed conducting two-hour plasma glucose tolerance tests was infeasable. The portable HbA1c instruments available in 2003-2004 were inadequate for conducting HbA1C measurements at rural research stations. In addition, the survey was performed in provincial areas with long distances to the medical laboratory. Our analyses do not differentiate between type 1 and 2 diabetes mellitus due to insufficient information provided by the questionnaire. However, eight of ten diabetes cases in Norway are T2DM.[34] Also, globally, around 80 per cent of diabetes cases are T2DM,[35-37] giving a prevalence rate of 8.3 per cent. This figure is expected to increase; mainly, this is associated with T2DM due to lifestyle changes: about 90 per cent of future total diabetes cases are expected to be T2DM. [36] Diabetes prevalence in our study was between four and five percent, which is a lower rate than the prevalence rate found in the urban population residing in 2007-2008 in the city of Tromsø (8.5%) [38]. This study encompassed participants aged

between 30 and 87, with a mean age of 61. However, in the Tromsø study, fasting plasma glucose, two-hour plasma glucose and HbA1c was measured. It is therefore likely that the present study underreports the diabetes prevalence.

#### Strengths

Our study is the first survey to report on the prevalence of diabetes and MetS in a large geographic area of North Norway including both the indigenous and the non-indigenous population. The large sample size allowed for detailed analysis of diabetes and MetS in Sami and non-Sami populations of rural North Norway; it also reduces the influence of random errors, which cannot fully be controlled for. The survey had a relatively high response rate. Unquestionably, one of the strengths of the study is that clinical data — such as central obesity (upon which MetS relies) — was collected by direct measurement and conducted by trained personnel, providing reliable estimates of obesity prevalence in the participating cohort.

#### Limitations

The cross-sectional study design is suitable for the examination of associations in order to generate hypotheses that may be explored in longitudinal studies. Conversely, however, the design prevents the establishment of causality. Due to the nature of the design, people with severe disease may be missed because they are diseased at home, in long-term hospitalization or having died in the time since the sample list was prepared (i.e., selection bias). On the other hand, the healthy segments of the population tend to not participate in health screenings. Categorizing people based on ethnicity is a contentious practice. Different studies use different criteria of ethnicity, which makes it difficult to compare results.

In summary, cross-sectional studies may be used in the measurement of the burden of disease in a population. However, cross-sectional data cannot assess the effect of lifestyle on the incidence of MetS, and longitudinal cohort studies are therefore needed.

Without question, the prevalence rates for several negative health factors were high in the Sami and non-Sami population. Overweight and obesity were common, especially in the case of Sami females. In males the prevalence of MetS was higher in non-Sami males ( aged between 36 and 49 year). The prevalence of MetS increased significantly by age in both ethnic groups, regardless of which WC cut-off points were used. The measured prevalence of MetS changes according to which WC cut-off values are applied. A cross-sectional survey cannot provide complete and absolute answers; a follow-up study using a longitudinal design is essential. Such a study can provide information on which WC cut-off values best predict disease in the Sami population of Norway.

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#### **Conflict of Interest:**

The authors declare that they have no conflict of interest.

#### **Data sharing**

Extra data is available by emailing ann.ragnhild.broderstad@uit.no

#### **Summary Box**

What is already known on this subject?

In Northern Norway the burden of obesity are especially high among female. Highest prevalence has been demonstrated among the Sami women. In this study we therefore examined several other risk factors for developing lifestyle diseases.

This study showed a high prevalence of the metabolic syndrome among the population in north, independent of ethnic belonging. The burden of metabolic risk factors was highest among women, especially Sami women. Self-reported diabetes was between four and five percent which are slightly higher than the national prevalence rate. In the future, obesity and other metabolic risk factors will contribute to increase burden of lifestyle diseases among the Sami population. Two issues are therefore important to emphasize. Firstly, implement preventive interventions in the multicultural communities, as well as highlight research information to inhabitants and local and central authorities. Secondly, follow the health situation in each community with longitudinal studies to evaluate the effect of preventive efforts.

#### Contributorship statement.

The idea behind the study was conceived by Ann R Broderstad. Both authors participated in the study concept and design. Ann R Broderstad drafted the manuscript. Both authors did the analyses of the tables and figures. Both authors reviewed and approved the final version of the manuscript.

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Figure legends

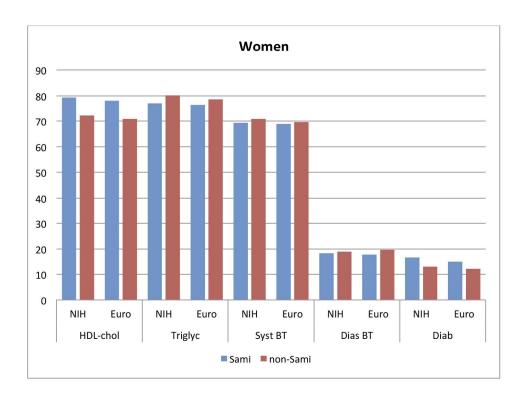
-----Figure 1 colour -----

----Figure 1 black and white ----

-----Figure 2 colour -----

-----Figure 2 black and white -----

Figure 2 . Prevalence of different risk markers in participants with MetS. Women . N= 2311 Euro and N= 1679 NIH



162x165mm (300 x 300 DPI)



### STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	p 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	P 2
Introductionp 4			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	P 4
Objectives	3	State specific objectives, including any prespecified hypotheses	P 5
Methods			
Study design	4	Present key elements of study design early in the paper	P 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	p 5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	P 5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	p 6 -8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	P 6 -8
Bias	9	Describe any efforts to address potential sources of bias	P 6-8
Study size	10	Explain how the study size was arrived at	P 5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	p 8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	P 8
		(b) Describe any methods used to examine subgroups and interactions	P 8
		(c) Explain how missing data were addressed	P 8
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(e) Describe any sensitivity analyses	Not done
Results			

	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility,	P 8-9 and Table 1
	confirmed eligible, included in the study, completing follow-up, and analysed	
	(b) Give reasons for non-participation at each stage	
	(c) Consider use of a flow diagram	Not done
14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential	P 8- 9 and Table 1
	confounders	
	(b) Indicate number of participants with missing data for each variable of interest	No missing data in
		the further analyzes
15*	Report numbers of outcome events or summary measures	Table 1 p 8
16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence	Table 2 p 10, table 3
	interval). Make clear which confounders were adjusted for and why they were included	p 12 fig 1 and 2 p 11
	(b) Report category boundaries when continuous variables were categorized	
	(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not done
18	Summarise key results with reference to study objectives	P 13 - 16
19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and	P 16
	magnitude of any potential bias	
20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	P 14 -16
	similar studies, and other relevant evidence	
21	Discuss the generalisability (external validity) of the study results	P 16
22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	P 17
	15* 16  17  18 19 20 21	(c) Consider use of a flow diagram  (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders  (b) Indicate number of participants with missing data for each variable of interest  15* Report numbers of outcome events or summary measures  (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included  (b) Report category boundaries when continuous variables were categorized  (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period  Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses  Summarise key results with reference to study objectives  Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias  Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence  Discuss the generalisability (external validity) of the study results

<sup>\*</sup>Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

## **BMJ Open**

# The prevalence of metabolic syndrome and diabetes mellitus in Sami and Norwegian populations. The SAMINOR-a cross sectional study.

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The prevalence of metabolic syndrome and diabetes mellitus in Sami and Norwegian populations. The SAMINOR-a cross sectional study.

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Running head; Metabolic syndrome and diabetes among Sami and non-Sami

Keywords Metabolic, obesity, Sami, SAMINOR, diabetes

Words 2964

Tables 3

Figures 2

#### **Objectives**

Metabolic syndrome (MetS) is recognized as a reliable long-term predictor of adverse health outcomes known. Elevated prevalence rates of MetS and chronic lifestyle diseases have been documented in different indigenous groups. We wanted to evaluate the prevalence of MetS and diabetes mellitus in relation to ethnicity in Northern Norway. In addition, we discussed different cut-off values for waist circumference (WC) and what impact this has on the prevalence of MetS.

#### Material and methods

SAMINOR is a population based study of health and living conditions in areas home to both Sami and non-Sami populations. The survey was carried through in 2003 – 2004. All eligible residents in specific age groups were invited. In total, 16,538 males and females aged 36-79 participated and gave informed consent for medical research.

#### Results

This study involved a total of 7,822 female and 7,290 male participants. Sami affiliation was reported by 5,141 participants (34 per cent). The prevalence of MetS was high in both ethnic groups independent of which WC cut off values used. The two different WC cut-off values greatly influenced the measured prevalence of MetS. Diabetes prevalence was significant higher among Sami men and women (5,2 per cent and 5,0 per cent) compared to the non-Sami participants (4,5 per cent and 4,2 per cent).

#### **Conclusions**

In this study we demonstrated a high share of negative metabolic components. The prevalence of diabetes was higher among the Sami participants than among the non-Sami, in both genders, even though the presence of MetS among men were higher among the non-Sami.

These metabolic components have important health implications. Therefore, determining

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initiatives must be made culture and linguistic specific, in order to reduce differences and

- The SAMINOR study is the first survey to report on the prevalence of diabetes and MetS in a large geographic area of North Norway including both the indigenous and
- The large sample size allowed for detailed analysis of diabetes and MetS in Sami and
- Categorizing people based on ethnicity is a contentious practice. Different studies use different criteria of ethnicity, which makes it difficult to compare results.
- Cross-sectional data cannot assess the effect of lifestyle on the incidence of MetS, and

The prevalence of metabolic syndrome and diabetes mellitus in Sami and Norwegian populations. The SAMINOR study-a cross sectional study.

#### Introduction

Chronic disease has become a global problem and a burden on health care services, reaching epidemic proportions. In Norway, as well as internationally, the great majority of patients in health care systems are living with chronic disease.[1-2] Cardiovascular disease (CVD), type 2 diabetes mellitus (T2DM), cancer and chronic obstructive pulmonic disease (COPD) are the most common causes of hospitalization and premature death.[3] Unfavorable health factors such as obesity, insulin resistance, dyslipidemia and hypertension are known to elevate risks of developing CVD and T2DM. Metabolic syndrome (MetS) indicates a cluster of these risk factors. [4-5] MetS is generally recognized as a reliable long-term predictor of adverse health outcomes.[6] Further, MetS has been recognized as a growing, global public health problem. .[7] In addition, several studies demonstrate MetS to be associated with elevated cancer risk.[8-9]

Information on the prevalence of chronic disease in various ethnicities of North Norway remains sparse. The Sami, Kven and Norwegian ethnic groups are recognized as having inhabited the region in centuries; the Norwegian government acknowledges the Sami people as the indigenous people of Norway. The Norwegian health authorities have little systematic knowledge about health status and living conditions among the Sami. National health -and medical registers contribute to comprehensive information and knowledge about health-related lifestyle and disease prevalence. However, information about ethnic background is not permitted by law, in these registers nor in patient's medical records. Therefore, no reliable or updated demographic records on the Sami exists that can be used for health research purposes. Several epidemiological studies have documented elevated prevalence rates for chronic lifestyle diseases in a number of different minority groups.[5, 10-11] Although such disorders

have emerged quite recently in indigenous populations — mainly due to changes in lifestyle and diet — they are, however, prevalent in several indigenous populations.[12-13]

Publications from the SAMINOR study of North Norway demonstrate that the prevalence of obesity was high in the survey population, especially among Sami women.[14-15]

In order to evaluate the health of indigenous and non-indigenous populations of Norway (inhabiting the same geographic area) it was necessary to conduct an epidemiological survey. The present study aims to evaluate the prevalence of MetS and diabetes mellitus in Sami and non-Sami populations residing in selected areas of North Norway. In addition, we will discuss different cut-off values for waist circumference (WC) and what impact this has on the prevalence og MetS.

#### Methods

The SAMINOR study

The cross-sectional data is derived from the SAMINOR study of 2003–2004 (SAMINOR 1). The SAMINOR study was conducted by The Centre for Sami Health Research, Department of Community Medicine, UiT The Arctic University of Norway, in collaboration with the National Screening Program for Cardiovascular Diseases. The survey is described in detail elsewhere.[16]

*The study sample* 

All eligible residents aged 30 and 36—79 years registered in the Central Population Register in 24 selected municipalities were invited regardless of ethnic background (n=27,987). Due to a low response rate among those aged 30 years, our analyses were restricted to the age interval 36—79 years (n=27,151). In total, 16,538 males and females aged 36—79 participated and gave informed consent for medical research. The response rate was 61 per cent. Data was obtained from physical tests and blood samples. Information on ethnicity, and the different diagnostic tools for MetS, were available for 15,112 participants.

### Questionnaire design

An invitation was mailed several weeks before the survey arrived the municipality. The invitation contained information about the time and place, together with a five-page questionnaire. Those who agreed to attend the screening returned the questionnaire to the Norwegian Institute of Public health. These participants received later an invitation to the clinical examination. After the consultation the participants were asked to complete a new questionnaire. Information regarding ethnicity, disease and lifestyle were collected using these two self-administrated questionnaires. The questionnaires were translated into the three main Sami languages, Northern, Lule and South Sami languages. However, as only 1.6% of the participants chose to use the Sami version of the questionnaire, any language problems are probably of little importance in this study. Ethnicity was measured using the following questions: "What language(s) do/did you, your parents and your grandparents use at home?" The questions were to be answered separately for each relative. The available responses were: "Norwegian", "Sami", "Kven" and "Other". Multiple answers were allowed. Providing the same response options we also asked: "What is your, your father's and your mother's ethnic background?" The respondents also reported whether they considered themselves to be Norwegian, Sami, Kven or other (self-perceived ethnicity). We refer to Lund et al (16) for full description of the ethnicity and language questions. Based on these variables we generated two categories of ethnicity: "Sami" and "Non-Sami". Participants reporting at least one Sami identity mark (Sami language spoken by the respondent or at least one parent or grandparent, or Sami ethnic background or self-perceived Sami ethnicity) were placed in the category "Sami". The "Non-Sami" comprised the remainder of the participants.

The study was accredited by the Regional Board of Research Ethics in Northern Norway, and by the Board's Sami Consultant. The survey is in accordance with the Helsinki Declaration of

1975. The National Data Protection Authority (*Datatilsynet*) approved the use of personal information and the study are registered with the number 2002/1525-2.

Screening

Due to the large size of the study sample participants were examined at different times of day. This meant that it was not possible to ask participants to be fasting prior to arrival. Non-fasting blood samples were obtained at the research station. Blood samples were drawn by venopuncture at normal venous pressure in sitting position. Serum was separated at the station within 1.5 hours. Serum was sent by overnight mail to laboratories in Oslo and Tromsø. The laboratory analyses are described in detail elsewhere.[17]

Body mass index (BMI) was based on measurements of weight and height, and expressed as body weight in kilograms/(body height in meters)<sup>2</sup>. BMI categories were defined according to guidelines from The World Health Organization (WHO); 'underweight' corresponding to a BMI<18.5 kg/m<sup>2</sup>, 'standard weight' in the range 18.5–24.9 kg/m<sup>2</sup>, 'overweight' in the range 25 – 29.9 kg/m<sup>2</sup> and 'obese'  $\geq$ 30 kg/m<sup>2</sup>.[18]

Waist circumference (WC), which is used to identify abdominal obesity, was measured (to the nearest centimeter) at the umbilicus with the participant standing erect. Two different WC cut-off values were applied to define abdominal obesity to enable the comparison of how the corresponding values influenced the subsequently calculated prevalence of MetS. The US National Institute of Health (NIH) Clinical Practice Guidelines defines central/abdominal obesity as  $WC \ge 102$  cm in males and  $WC \ge 88$ cm in females.[19] In addition, abnormal WC for Europid males are  $\ge 94$  cm and for females  $\ge 80$  cm. These figures are based on cross-sectional data from Europids and were included in the analyses.[18,20]

Trained personnel measured blood pressure, using Dinamap –R. automatic device.

Measurements were initiated after subjects had been seated for two minutes with their arms

### Diabetes mellitus

Because all blood samples in the SAMINOR study were non-fasting, we used random plasma glucose  $\geq 11.1 \text{ mmol/L}$ , in addition to self-reported diabetes and information about anti-diabetic medication from a questionnaire to define diabetes mellitus. The question about diabetes mellitus was; "Do you have or have you had diabetes?" The available responses were "Yes" or "No". Missing values were classified as "No". In the absence of oral glucose tolerance tests we used random plasma glucose  $\geq 11.1 \text{ mmol/l}$  as a substitute for elevated oral glucose tolerance test.

# Metabolic syndrome

Several attempts have been made at developing diagnostic criteria for the definition of MetS. [21-23] In 2004, the International Diabetes Federation (IDF), the WHO and the National Cholesterol Education Program Third Adult Treatment Panel (ATP III) produced a consensus statement on the definition of MetS.[24] The latter definition requires central obesity and cutoff points to be specified according to gender and ethnicity. Central obesity is most commonly measured by WC; cut-off values are based on cross-sectional studies conducted in Europe, The United States and Asia.[18-20, 25] The diagnostic tools are intended for clinical and research purposes. The definition of MetS used in this article adheres to the IDF MetS worldwide definition,[24]: Central obesity plus any two of four additional factors; Elevated triglyceride level > 1.7 mmol/l, reduced HDL-cholesterol < 1.03 mmol/l in males and < 1.29 mmol/l in females, elevated blood pressure (systolic BP  $\geq$  130 or diastolic BP  $\geq$  85 mmHg) and elevated fasting plasma glucose  $\geq$  11.1 mmol/l or previously diagnosed type 2 diabetes. *Statistical analyses* 

All analyses were stratified by gender. Sample characteristics were presented separately by gender and ethnicity as mean values for continuous variables with corresponding 95 per cent confidence intervals. Analyses of variance (ANOVA) were used for tests of ethnic differences (Table 1). Differences according to diabetes mellitus and Mets prevalence were tested by Chi-square tests (Tables 2 and 3). MetS prevalence was also stratified by age (Table 3). Logistic regression analyses were used to test for age influence on MetS with age as a continuous variable (Table 3).

We used the SAS statistical software package, version 9.3 (SAS Institute Inc., Cary, NC, USA).

### **Results**

The current analysis involved a total of 7,822 female and 7,290 male participants. Sami affiliation was reported by 5,141 participants (34 per cent). Table 1 shows gender-specific and ethnicity-specific characteristics at enrolment in the study.

**Table 1** Sample characteristics by gender and ethnic group.  $(N=15\ 112)$ 

Men	Sami (N=2559)	Non-Sami (N=4731) Mean (95 % CI) <sup>1</sup>	p-value
Wich	Mean (95 % CI) <sup>1</sup>	Wican (55 70 C1)	
Age (yr)	55.0 (54.8-55.1)	54.8 (54.7-54.9)	0.584
Height (cm)	170.0 (170.0-170.2)	175.7 (175.6 – 175.8)	< 0.0001
Weight (kg)	80.6(80.4 - 80.7)	85.1 (85.0 – 85.3)	< 0.0001
BMI $(kg/m^2)$	27.8 (27.7-27.9)	27.5(27.5 - 27.6)	0.009
WC (cm)	93.2(93.0 - 93.3)	95.0 (94.9 – 95.2)	< 0.0001
Non-fasting glu (mmol/L	5.8 (5.8- 5.8)	5.8(5.7-5.8)	0.313
HDL-chol (mmol/l)	1.27(1.26-1.28)	1.25(1.25-1.26)	0.115
LDL- chol ( mmol/L)	3.87(3.86 - 3.89)	3.80(3.79 - 3.81)	0.004
Cholesterol (mmol/l)	5.98 ( 5.96- 5.99)	5.90(5.90 - 5.90)	0.001
Triglycerids (mmol/l)	1.86(1.85 - 1.88)	1.86(1.85 - 1.88)	0.970
Systolic BT (mmHg)	135 (135 – 135)	134 (134 -134)	0.168
Diastolic BT (mmHg)	78 (78 -78)	78 (78 – 78)	0.182
Women	Sami (N=2581)	Non-Sami (N=5241)	p-value
	Mean (95 % CI) <sup>1</sup>	Mean (95 % CI) <sup>1</sup>	•
Age (yr)	54.2 (54.1 – 54.4)	54.5 (54.4 – 54.6)	0.277
Height (cm)	157.3 (157.2 – 157.4)	162.6 (162.6 – 162.7)	< 0.0001
0			

0.008

=== :::::(:::::::::::2)	2.02 (2.01 2.02)	2.22 (2.20 2.02)	
LDL- chol ( mmol/L)	3.82(3.81 - 3.83)	3.81(3.80 - 3.82)	0.707
HDL-chol (mmol/l)	1.45 (1.44 – 1.45 )	1.49(1.49 - 1.50)	< 0.0001
Non-fasting glu (mmol/L	5.66(5.63 - 5.68)	5.57 (5.55 – 5.58)	0.018
	,	,	
WC (cm)	86.0(85.9 - 86.2)	85.5 (85.4 - 85.6)	0.053
BMI $(kg/m^2)$	28.2(28.1 - 28.3)	27.3(27.2 - 27.3)	< 0.0001
Weight (kg)	69.7 (69.6 – 69.9)	72.1 (71.9 -72.2)	< 0.0001

LDL- chol ( mmol/L)	3.82(3.81 - 3.83)	3.81 (3.80 - 3.82)	0.707
	Sami (N=2559)	Non-Sami (N=4731)	
Cholesterol (mmol/l)	5.98 (5.96 –5.99)	5.99 (5.98 –6.00 )	0.617
Triglycerids (mmol/l)	1.54(1.56 - 1.59)	1.53(1.52 - 1.54)	0.044
Systolic BT (mmHg)	130 (129 – 130)	130 (130 -131)	0.125

73 (73 -73)

Diastolic BT (mmHg)

72 (72 - 72)

The mean BMI was greater in Sami males, whereas the mean WC was greater in non-Sami males. Sami females, however, showed significantly greater values for mean BMI, WC and lipids.

Table 2 shows the prevalence of diabetes in Sami and non-Sami participants.

**Table 2.** Prevalence of diabetes mellitus in the SAMINOR study (N=15112)

<sup>&</sup>lt;sup>1</sup> 95% confidence interval

<sup>&</sup>lt;sup>2</sup> test of differences, ANOVA, for between Sami versus non-Sami

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Men	n (%)	n (%)	p-value <sup>1</sup>
Diabetes prevalence	132 (5.2)	212 (4.5)	0.05
Insulin treatment	13 (0.5)	31 (0.7)	
Tablet treatment	45 (1.8)	87 (1.8)	
Insulin and tablet treatment	25 (1.0)	21 (0.4)	
Non- treatment	49 (1.9)	73 (1.5)	
	Sami (N=2581)	Non-Sami (N=5241)	
Women	n (%)	n (%)	p-value <sup>1</sup>
Diabetes prevalence	129 (5.0)	220 (4.2)	0.026
Insulin treatment	13 (0.5)	29 (0.6)	
Tablet treatment	61 (2.4)	71 (1.6)	
Insulin and tablet treatment	20 (0.8)	38 (0.7)	
Non- treatment	35 (1.4)	82 (1.6)	

Diabetes was significant more frequent among the Sami participants than the non-Sami in both gender. Ethnicity appeared therefore to affect diabetes prevalence.

The prevalence of the various diagnostic tools for MetS is presented in Figures 1 (males) and 2 (females).

<sup>&</sup>lt;sup>1</sup> Chi-square test for differences in diabetes prevalence among Sami versus non-Sami

The most prevalent risk marker for MetS (aside from central obesity) was the presence of elevated systolic blood pressure and high triglyceride levels independent of gender and ethnicity.

Table 3 presents the prevalence of MetS according to WC cut-off points based on European and NIH values.

**Table 3.** Prevalence of MetS among Sami and non-Sami, by age groups and gender. N=15112 participants

	Europe	an cut off of	WC	NIH	cut off of V	VC
	Sami	Non-Sami		Sami	Non-	
	(N=650)	(N=917)		(N=315)	Sami	
	n (%)	n (%)		n (%)	(N=728)	
		. ,		. ,	n (%)	
			p-			p-value <sup>1</sup>
N4			value <sup>1</sup>			
Men			0.020			0.110
36-49 yr	194 (22.3)	429 (26.0)	0.038	89 (10.2)	203	0.118
					(12.3)	
50-59 yr	229 (27.2)	440 (29.7)	0.202	115 (13.7)	238	0.121
					(16.1)	
60-79 yr	227 (26.9)	489 (30.6)	0.055	111 (13.1)	287	0.002
_					(18.0)	
p-value <sup>2</sup>	0.029	< 0.0001		0.05	< 0.0001	
	Sami	Non-Sami		Sami	Non-	
	(N=790)	(N=1521)		(N=588)	Sami	
	n (%)	n (%)		n (%)	(N=1091)	
	11 (70)	11 (7.0)		11 (70)	n (%)	
Women					()	
36-49 yr	232 (24.4)	369 (19.1)	0.006	161 (16.2)	263	0.056
J	- ( - )			- ( )	(13.6)	
50-59 yr	248 (31.5)	455 (29.4)	0.291	177 (22.5)	309	0.155
00 03 J1	_ := (= ::= )	(_>(-)		()	(20.0)	
60-79 yr	310 (38.7)	697 (39.6)	0.641	250 (31.2)	519	0.393
55 / 5 J1	210 (20.7)	0), (0).0)		200 (31.2)	(29.5)	
p-value <sup>2</sup>	0.004	< 0.0001		< 0.0001	< 0.0001	
P varae						

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In each age bracket the results are stratified according to ethnicity (Sami and non-Sami). Based on the European WC cut-off points, prevalence of MetS was higher in non-Sami participants in the age bracket 36-49 years. However, when applying the NIH WC cut-off point, a significantly lower prevalence was found for Sami males in the top age group.

<sup>&</sup>lt;sup>1</sup> Chi-square tests for differences in MetS prevalence of Sami versus non-Sami

<sup>&</sup>lt;sup>2</sup> Age effect tested by logistic regression with age as a continuous variable

Non-Sami males showed a higher overall prevalence of MetS (in comparison to Sami males) for both WC cut-off values. In females ethnicity was not significant overall; however when stratified by age, a significantly higher prevalence of MetS in the younger Sami females (in comparison to non-Sami females) was found — when applying the European WC cut-off value. The prevalence of MetS increased with age regardless of gender and ethnicity. The proportion of women with all four risk markers was almost twice as large within the Sami population (in comparison to non-Sami females) for both WC cut-off values (not shown). For males, ethnicity appeared not to affect the number of risk markers found.

### **Discussion**

The prevalence of MetS was high in both ethnic groups. Diabetes prevalence was significant higher among both Sami men and women compared to the non-Sami participants. The two different WC cut-off values greatly influenced the measured prevalence of MetS. The present study demonstrates that ethnicity is a significant factor for MetS in participants belonging to the lowest age bracket.

The two different WC cut-off values greatly influenced the measured prevalence of MetS. The present study demonstrates that ethnicity is a significant factor for MetS in participants belonging to the lowest age bracket. In the case of males aged between 36 and 49, MetS is less prevalent in the Sami population (in comparison to non-Sami). For females in the same age bracket, however, MetS is more prevalent in the Sami population. When the NIH cutoffs were used, we found that — in the highest age bracket — the non-Sami males showed significantly higher prevalence of MetS in comparison to Sami males. The prevalence of MetS increased significantly by age in both ethnic groups, regardless of which WC cut-off values were used.

In general, overweight and obesity are common among the participants in the SAMINOR study. From earlier publications based on the SAMINOR study, central obesity has been shown to be more common in Sami females.[15,26] General obesity in Sami females has also been discussed by Njølstad et al (1998).[27] However, obesity rates were high in non-Sami females as well.[14] For males, central obesity occurred more frequently in the non-Sami population relative to the Sami population.[14-15]

MetS has several different definitions, making it difficult to directly compare and contrast prevalence found in different surveys. WC is the most significant measurement of both central obesity and fat distribution, according to The International Diabetes Federation (IDF).[28] The group that produced the consensus statement on the definition of MetS in 2004 recommended that gender and ethnicity should be the basis for classification of cut-off points. [24] The existing values are based on cross-sectional population survey data from the respective countries. How to define the WC cut-off point in the various indigenous populations has not yet been established; however, an immediate response would be to perform cross-sectional population surveys within indigenous societies. In our study two different cut-off points were used in order to facilitate comparison. The European cut-off values doubled the prevalence of MetS in males and increased prevalence by more than 40 per cent in females (compared to values found when applying NIH WC cut-off values). This was the case in both ethnic groups. But the question of what the WC values should be in terms of optimal prediction of prospective disease in the SAMINOR sample remains unanswered. A follow-up study could provide better answers to questions regarding disease development. Irrespective of cut-off values, elevated blood pressure was the most frequent MetS component present in obese participants. These findings were also demonstrated in a collaborative analysis of ten large cohort studies in Europe [29] In the ten studies included, obesity coincided with hypertension in up to 85 per cent of cases.

The presence of MetS, as well as its individual components, however, shows considerable variance between populations. Several studies of MetS have been performed in circumpolar areas, such as in indigenous peoples of Alaska, Canada and Greenland.[30-32] American Indians and Aboriginal Canadians represent populations in which MetS, obesity and T2DM are becoming more prevalent. [13,30] MetS is also frequently occurring in Greenland's Inuit population.[32] A health survey in Greenland showed that central adiposity and obesity were more prevalent in the Inuit population when compared to the corresponding Danish population, but was not associated with the same degree of metabolic disturbance as in the general Danish population.[33] Yet it is debatable which factors in the cluster of MetS are the most significant in the development of chronic lifestyle diseases.

There is a significant relation between T2DM and MetS; the syndrome itself is not a disease, but consists of a cluster of factors that increase the risk for developing diseases. Thus we prefer to include diabetes in this article to demonstrate the link between the health indicator MetS and diabetes mellitus.[24] In the SAMINOR study diabetes mellitus was identified using a questionnaire, in addition to measured random plasma glucose ≥ 11.1 mmol/L in participants whom did not report diabetes mellitus. As the study had a large number of participants, up to 140 per day, conducting two-hour plasma glucose tolerance tests was considered infeasable. The portable HbA1c instruments available in 2003-2004 were inadequate for conducting HbA1C measurements at rural research stations. In addition, the survey was performed in provincial areas with long distances to the medical laboratory. Our analyses do not differentiate between type 1 and 2 diabetes mellitus due to insufficient information provided by the questionnaire. However, eight of ten diabetes cases in Norway are T2DM.[34] Also, globally, around 80 per cent of diabetes cases are T2DM,[35-37] giving a prevalence rate of 8.3 per cent. This figure is expected to increase due to lifestyle changes.

rate than the prevalence rate found in the urban population residing in 2007—2008 in the city of Tromsø (8.5%) [38]. This study encompassed participants aged between 30 and 87, with a mean age of 61. However, in the Tromsø study, fasting plasma glucose, two-hour plasma glucose and HbA1c was measured. It is therefore likely that the present study underreports the diabetes prevalence maybe as much as up to 50 percent.

Our study is the first survey to report on the prevalence of diabetes and MetS in a large geographic area of North Norway including both the indigenous and the non-indigenous population. The large sample size allowed for detailed analysis of diabetes and MetS in Sami and non-Sami populations of rural North Norway; it also reduces the influence of random errors, which cannot fully be controlled for. The survey had a relatively high response rate. Unquestionably, one of the strengths of the study was that clinical data — such as central obesity (upon which MetS relies) — were collected by direct measurement and conducted by trained personnel, providing reliable estimates of obesity prevalence in the participating cohort.

### Limitations

The cross-sectional study design is suitable for the examination of associations in order to generate hypotheses that may be explored in longitudinal studies. Conversely, however, the design prevents the establishment of causality. Due to the nature of the design, people with severe disease may be missed because they are diseased at home, in long-term hospitalization or having died in the time since the sample list was prepared (i.e., selection bias). The SAMINOR study has used questionnaires to survey self-reported diseases. This approach cannot detect people with undiagnosed symptoms and is limited by recall recall bias. In Norway, it is estimated between 90 00 to 120 000 people with diabetes and nearly as many have undiagnosed disease. [39]

Categorizing people based on ethnicity is a contentious practice. Different studies use different criteria of ethnic categorization, which makes it difficult to compare results. Our definition of the Sami group is rather weak. This may have influenced our results. Since there are no national records with information om ethnic background, it is impossible to know if the response rate among Sami and non-Sami are different. We are therefore unable to assess whether differences in participation have influenced the observed disease burden.

In summary, cross-sectional studies may be used in the measurement of the burden of disease in a population. However, cross-sectional data cannot assess the effect of lifestyle on the incidence of MetS, and longitudinal cohort studies are therefore needed.

### Conclusion

Without question, the prevalence rates for several negative health factors were high in the Sami and non-Sami population. Overweight and obesity were common, especially in the case of Sami females. The prevalence of diabetes was higher among the Sami participants than the non-Sami in both genders, even though the presents of MetS among men were higher among the non-Sami men. However, the prevalence of MetS were in general high among participants in the SAMINOR study, with the highest prevalence for the European cut off values. The syndrome has important health implication but a cross sectional study cannot be used to validate the best ethnic specific values for WC used in the definition of MetS and more data on this issue must be obtained. In addition, determining preventive initiatives is important in the primary and specialist health care system. These initiatives must be made culture and linguistic specific, in order to reduce differences and improve health status in the whole population.

# Acknowledgements

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Chemistry, University Hospital of North Norway, for technical assistance and careful evaluation of blood samples.

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# **Conflict of Interest:**

The authors declare that they have no conflict of interest.

### **Data sharing**

Extra data is available by emailing ann.ragnhild.broderstad@uit.no

# **Summary Box**

What is already known on this subject?

In Northern Norway the burden of obesity are especially high among female. Highest prevalence has been demonstrated among the Sami women. In this study we therefore examined several other risk factors for developing lifestyle diseases.

What this study adds?

This study showed a high prevalence of the metabolic syndrome among the population in north, independent of ethnic belonging. The burden of metabolic risk factors was highest among women, especially Sami women. Self-reported diabetes was between four and five percent which are slightly higher than the national prevalence rate. In the future, obesity and other metabolic risk factors will contribute to increase burden of lifestyle diseases among the Sami population. Two issues are therefore important to emphasize. Firstly, implement preventive interventions in the multicultural communities, as well as highlight research information to inhabitants and local and central authorities. Secondly, follow the health situation in each community with longitudinal studies to evaluate the effect of preventive efforts.

### Contributorship statement.

The idea behind the study was conceived by Ann R Broderstad. Both authors participated in the study concept and design. Ann R Broderstad drafted the manuscript. Both authors did the

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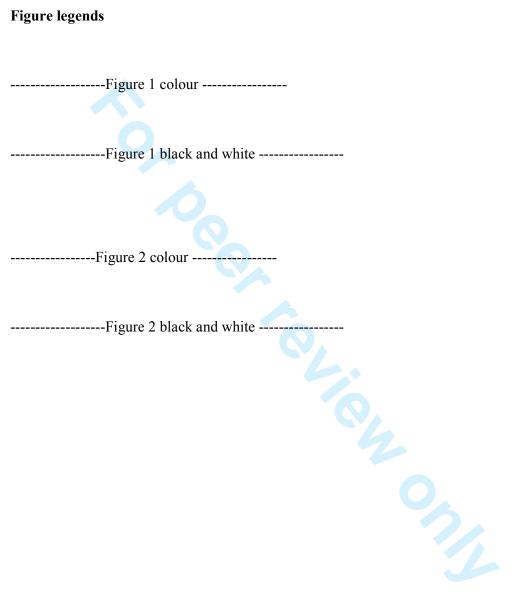
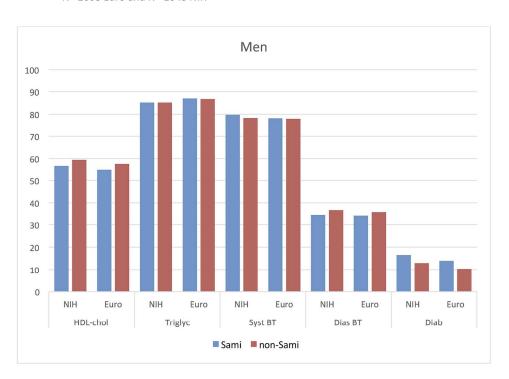
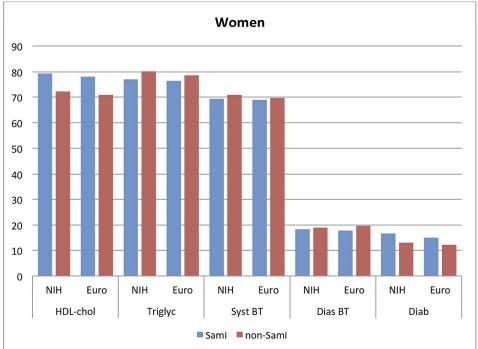


Figure 1. Prevalence of different risk markers in participants with Mets. Men. N=2008 Euro and N=1043 NIH



150x133mm (300 x 300 DPI)

Figure 2. Prevalence of different risk markers in participants with MetS. Women . N= 2311 Euro and N= 1679 NIH



165x169mm (300 x 300 DPI)



# STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	p 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	P 2
Introductionp 4			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	P 4
Objectives	3	State specific objectives, including any prespecified hypotheses	P 5
Methods			
Study design	4	Present key elements of study design early in the paper	P 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	p 5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	P 5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	p 6 -8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	P 6 -8
Bias	9	Describe any efforts to address potential sources of bias	P 6-8
Study size	10	Explain how the study size was arrived at	P 5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	p 8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	P 8
		(b) Describe any methods used to examine subgroups and interactions	P 8
		(c) Explain how missing data were addressed	P 8
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(e) Describe any sensitivity analyses	Not done
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	P 8-9 and Table 1
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	Not done
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	P 8- 9 and Table 1
		(b) Indicate number of participants with missing data for each variable of interest	No missing data in the further analyzes
Outcome data	15*	Report numbers of outcome events or summary measures	Table 1 p 8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Table 2 p 10, table 3 p 12 fig 1 and 2 p 11
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not done
Discussion			
Key results	18	Summarise key results with reference to study objectives	P 13 - 16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	P 16
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	P 14 -16
Generalisability	21	Discuss the generalisability (external validity) of the study results	P 16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	P 17

<sup>\*</sup>Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

# **BMJ Open**

# The prevalence of metabolic syndrome and diabetes mellitus in Sami and Norwegian populations. The SAMINOR-a cross sectional study.

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The prevalence of metabolic syndrome and diabetes mellitus in Sami and Norwegian populations. The SAMINOR-a cross sectional study.

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Running head; Metabolic syndrome and diabetes among Sami and non-Sami

Keywords Metabolic, obesity, Sami, SAMINOR, diabetes

Words 3331

Tables 3

Figures 2

# **Objectives**

Metabolic syndrome (MetS) is recognized as a reliable long-term predictor of adverse health outcomes known. Elevated prevalence rates of MetS and chronic lifestyle diseases have been documented in different indigenous groups. We wanted to evaluate the prevalence of MetS and diabetes mellitus in relation to ethnicity in Northern Norway. In addition, we discussed different cut-off values for waist circumference (WC) and what impact this has on the prevalence of MetS.

# Material and methods

SAMINOR is a population based study of health and living conditions in areas home to both Sami and non-Sami populations. The survey was carried through in 2003 – 2004. All eligible residents in specific age groups were invited. In total, 16,538 males and females aged 36-79 participated and gave informed consent for medical research.

## Results

This study involved a total of 7,822 female and 7,290 male participants. Sami affiliation was reported by 5,141 participants (34 per cent). The prevalence of MetS was high in both ethnic groups independent of which WC cut off values used. No ethnic differences in prevalence of diabetes mellitus was demonstrated. However, ethnicity appeared to affect diabetes treatment and was more in use among Sami women compared to the non-Sami.

### **Conclusions**

In this study it was no ethnic differences in diabetes prevalence, but ethnicity appeared to affect diabetes treatment. Tablet treatment was more common in use among Sami women compared to non-Sami women. We demonstrated a high share of negative metabolic components. These metabolic components have important health implications. Therefore, determining preventive initiatives is important in the primary and specialist health care

system. These initiatives must be made culture and linguistic specific, in order to reduce differences and improve health status in the whole population.

# Strengths and limitations of this study

- The SAMINOR study is the first survey to report on the prevalence of diabetes and MetS in a large geographic area of North Norway including both the indigenous and the non-indigenous population.
- The large sample size allowed for detailed analysis of diabetes and MetS in Sami and non-Sami populations of rural North Norway.
- The survey has a relatively high response rate.
- Categorizing people based on ethnicity is a contentious practice. Different studies use different criteria of ethnicity, which makes it difficult to compare results.

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Cross-sectional data cannot assess the effect of lifestyle on the incidence of MetS, and longitudinal cohort studies are therefore needed

The prevalence of metabolic syndrome and diabetes mellitus in Sami and Norwegian populations. The SAMINOR study-a cross sectional study.

## Introduction

Chronic disease has become a global problem and a burden on health care services, reaching epidemic proportions. In Norway, as well as internationally, the great majority of patients in health care systems are living with chronic disease.[1-2] Cardiovascular disease (CVD), type 2 diabetes mellitus (T2DM), cancer and chronic obstructive pulmonic disease (COPD) are the most common causes of hospitalization and premature death.[3] Unfavorable health factors such as obesity, insulin resistance, dyslipidemia and hypertension are known to elevate risks of developing CVD and T2DM. Metabolic syndrome (MetS) indicates a cluster of these risk factors. [4-5] MetS is generally recognized as a reliable long-term predictor of adverse health outcomes.[6] Further, MetS has been recognized as a growing, global public health problem. .[7] In addition, several studies demonstrate MetS to be associated with elevated cancer risk.[8-9]

Information on the prevalence of chronic disease in various ethnicities of North Norway remains sparse. The Sami, Kven and Norwegian ethnic groups are recognized as having inhabited the region in centuries; the Norwegian government acknowledges the Sami people as the indigenous people of Norway. The Norwegian health authorities have little systematic knowledge about health status and living conditions among the Sami. National health -and medical registers contribute to comprehensive information and knowledge about health-related lifestyle and disease prevalence. However, information about ethnic background is not permitted by law, in these registers nor in patient's medical records. Therefore, no reliable or updated demographic records on the Sami exists that can be used for health research purposes. Several epidemiological studies have documented elevated prevalence rates for chronic lifestyle diseases in a number of different minority groups.[5, 10-11] Although such disorders

have emerged quite recently in indigenous populations — mainly due to changes in lifestyle and diet — they are, however, prevalent in several indigenous populations.[12-13]

Publications from the SAMINOR study of North Norway demonstrate that the prevalence of obesity was high in the survey population, especially among Sami women.[14-15]

In order to evaluate the health of indigenous and non-indigenous populations of Norway (inhabiting the same geographic area) it was necessary to conduct an epidemiological survey. The present study aims to evaluate the prevalence of MetS and diabetes mellitus in Sami and non-Sami populations residing in selected areas of North Norway. In addition, we will discuss different cut-off values for waist circumference (WC) and what impact this has on the prevalence og MetS.

### Methods

The SAMINOR study

The cross-sectional data is derived from the SAMINOR study of 2003–2004 (SAMINOR 1). The SAMINOR study was conducted by The Centre for Sami Health Research, Department of Community Medicine, UiT The Arctic University of Norway, in collaboration with the National Screening Program for Cardiovascular Diseases. The survey is described in detail elsewhere.[16]

*The study sample* 

All eligible residents aged 30 and 36—79 years registered in the Central Population Register in 24 selected municipalities were invited regardless of ethnic background (n=27,987). Due to a low response rate among those aged 30 years, our analyses were restricted to the age interval 36—79 years (n=27,151). In total, 16,538 males and females aged 36—79 participated and gave informed consent for medical research. The response rate was 61 per cent. Data was obtained from physical tests and blood samples. Information on ethnicity, and the different diagnostic tools for MetS, were available for 15,112 participants.

# Questionnaire design

An invitation was mailed several weeks before the survey arrived the municipality. The invitation contained information about the time and place, together with a five-page questionnaire. Those who agreed to attend the screening returned the questionnaire to the Norwegian Institute of Public health. These participants received later an invitation to the clinical examination. After the consultation the participants were asked to complete a new questionnaire. Information regarding ethnicity, disease and lifestyle were collected using these two self-administrated questionnaires. The questionnaires were translated into the three main Sami languages, Northern, Lule and South Sami languages. However, as only 1.6% of the participants chose to use the Sami version of the questionnaire, any language problems are probably of little importance in this study. Ethnicity was measured using the following questions: "What language(s) do/did you, your parents and your grandparents use at home?" The questions were to be answered separately for each relative. The available responses were: "Norwegian", "Sami", "Kven" and "Other". Multiple answers were allowed. Providing the same response options we also asked: "What is your, your father's and your mother's ethnic background?" The respondents also reported whether they considered themselves to be Norwegian, Sami, Kven or other (self-perceived ethnicity). We refer to Lund et al (16) for full description of the ethnicity and language questions. Based on these variables we generated two categories of ethnicity: "Sami" and "Non-Sami". Participants reporting at least one Sami identity mark (Sami language spoken by the respondent or at least one parent or grandparent, or Sami ethnic background or self-perceived Sami ethnicity) were placed in the category "Sami". The "Non-Sami" comprised the remainder of the participants.

The study was accredited by the Regional Board of Research Ethics in Northern Norway, and by the Board's Sami Consultant. The survey is in accordance with the Helsinki Declaration of

1975. The National Data Protection Authority (*Datatilsynet*) approved the use of personal information and the study are registered with the number 2002/1525-2.

Screening

Due to the large size of the study sample participants were examined at different times of day. This meant that it was not possible to ask participants to be fasting prior to arrival. Non-fasting blood samples were obtained at the research station. Blood samples were drawn by venopuncture at normal venous pressure in sitting position. Serum was separated at the station within 1.5 hours. Serum was sent by overnight mail to laboratories in Oslo and Tromsø. The laboratory analyses are described in detail elsewhere. [17]

Body mass index (BMI) was based on measurements of weight and height, and expressed as body weight in kilograms/(body height in meters)<sup>2</sup>. BMI categories were defined according to guidelines from The World Health Organization (WHO); 'underweight' corresponding to a BMI<18.5 kg/m<sup>2</sup>, 'standard weight' in the range 18.5-24.9 kg/m<sup>2</sup>, 'overweight' in the range 25-29.9 kg/m<sup>2</sup> and 'obese'  $\geq 30$  kg/m<sup>2</sup>.[18]

Waist circumference (WC), which is used to identify abdominal obesity, was measured (to the nearest centimeter) at the umbilicus with the participant standing erect. Two different WC cut-off values were applied to define abdominal obesity to enable the comparison of how the corresponding values influenced the subsequently calculated prevalence of MetS. The US National Institute of Health (NIH) Clinical Practice Guidelines defines central/abdominal obesity as  $WC \ge 102$  cm in males and  $WC \ge 88$ cm in females.[19] In addition, abnormal WC for Europid males are  $\ge 94$  cm and for females  $\ge 80$  cm. These figures are based on cross-sectional data from Europids and were included in the analyses.[18,20]

Trained personnel measured blood pressure, using Dinamap –R. automatic device.

Measurements were initiated after subjects had been seated for two minutes with their arms

resting on a table. Blood pressure was measured three times, with one- minute intervals. The mean value of the second and third reading was used in the analysis.

Diabetes mellitus

Because all blood samples in the SAMINOR study were non-fasting, we used random plasma glucose  $\geq 11.1 \text{ mmol/L}$ , in addition to self-reported diabetes and information about anti-diabetic medication from a questionnaire to define diabetes mellitus. The question about diabetes mellitus was; "Do you have or have you had diabetes?" The available responses were "Yes" or "No". Missing values were classified as "No". In the absence of oral glucose tolerance tests we used random plasma glucose  $\geq 11.1 \text{ mmol/l}$  as a substitute for elevated oral glucose tolerance test.

Metabolic syndrome

Several attempts have been made at developing diagnostic criteria for the definition of MetS. [21-23] In 2004, the International Diabetes Federation (IDF), the WHO and the National Cholesterol Education Program Third Adult Treatment Panel (ATP III) produced a consensus statement on the definition of MetS.[24] The latter definition requires central obesity and cut-off points to be specified according to gender and ethnicity. Central obesity is most commonly measured by WC; cut-off values are based on cross-sectional studies conducted in Europe, The United States and Asia.[18-20, 25] The diagnostic tools are intended for clinical and research purposes. The definition of MetS used in this article adheres to the IDF MetS worldwide definition,[24]: Central obesity plus any two of four additional factors; Elevated triglyceride level > 1.7 mmol/l, reduced HDL-cholesterol < 1.03 mmol/l in males and < 1.29 mmol/l in females, elevated blood pressure (systolic BP  $\geq$  130 or diastolic BP  $\geq$  85 mmHg) and elevated fasting plasma glucose  $\geq$  11.1 mmol/l or previously diagnosed type 2 diabetes. *Statistical analyses* 

All analyses were stratified by gender. Sample characteristics were presented separately by gender and ethnicity as mean values for continuous variables with corresponding 95 per cent confidence intervals. Analyses of variance (ANOVA) were used for tests of ethnic differences (Table 1). Differences according to diabetes mellitus and MetS prevalence were tested by Chi-square tests (Tables 2 and 3). MetS prevalence was also stratified by age (Table 3). Logistic regression analyses were used to test for age influence on MetS with age as a continuous variable (Table 3).

We used the SAS statistical software package, version 9.3 (SAS Institute Inc., Cary, NC, USA).

### Results

The current analysis involved a total of 7,822 female and 7,290 male participants. Sami affiliation was reported by 5,141 participants (34 per cent). Table 1 shows gender-specific and ethnicity-specific characteristics at enrolment in the study.

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**Table 1** Sample characteristics by gender and ethnic group.  $(N=15\ 112)$ 

	Sami (N=2559)	Non-Sami (N=4731)	p-value <sup>2</sup>
Men		Mean (95 % CI) <sup>1</sup>	-
	Mean (95 % CI) <sup>1</sup>	,	
Age (yr)	55.0 (54.8-55.1)	54.8 (54.7-54.9)	0.584
Height (cm)	170.0 (170.0-170.2)	175.7 (175.6 – 175.8)	< 0.0001
Weight (kg)	80.6 (80.4 - 80.7)	85.1 (85.0 – 85.3)	< 0.0001
BMI $(kg/m^2)$	27.8 (27.7-27.9)	27.5(27.5 - 27.6)	0.009
WC (cm)	93.2 (93.0 – 93.3)	95.0 ( 94.9 – 95.2)	< 0.0001
Non-fasting glu (mmol/L	5.8 (5.8- 5.8)	5.8 (5.7 - 5.8)	0.313
HDL-chol (mmol/l)	1.27(1.26 - 1.28)	1.25(1.25-1.26)	0.115
LDL- chol ( mmol/L)	3.87(3.86 - 3.89)	3.80(3.79 - 3.81)	0.004
Cholesterol (mmol/l)	5.98 ( 5.96- 5.99)	5.90(5.90 - 5.90)	0.001
Triglycerids (mmol/l)	1.86(1.85 - 1.88)	1.86(1.85 - 1.88)	0.970
Systolic BT (mmHg)	135 (135 – 135)	134 (134 -134)	0.168
Diastolic BT (mmHg)	78 (78 -78)	78(78-78)	0.182
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Women	Sami (N=2581)	Non-Sami (N=5241)	p-value
	Mean (95 % CI) <sup>1</sup>	Mean (95 % CI) <sup>1</sup>	
Age (yr)	54.2 (54.1 – 54.4)	54.5 (54.4 – 54.6)	0.277
Height (cm)	157.3 (157.2 – 157.4)	162.6 (162.6 – 162.7)	< 0.0001
Weight (kg)	69.7 (69.6 – 69.9)	72.1 (71.9 -72.2)	< 0.0001
BMI $(kg/m^2)$	28.2(28.1 - 28.3)	27.3 (27.2 – 27.3)	< 0.0001
WC (cm)	86.0 (85.9 - 86.2)	85.5 (85.4 – 85.6)	0.053
Non-fasting glu (mmol/L	5.66 (5.63 – 5.68)	5.57 (5.55 – 5.58)	0.018
HDL-chol (mmol/l)	1.45 (1.44 – 1.45 )	1.49 (1.49 – 1.50)	< 0.0001
LDL- chol ( mmol/L)	3.82(3.81 - 3.83)	3.81(3.80 - 3.82)	0.707
Cholesterol (mmol/l)	5.98 (5.96 –5.99)	5.99 (5.98 –6.00 )	0.617
Cholesterol (mmol/l) Triglycerids (mmol/l)	5.98 (5.96 –5.99) 1.54(1.56 – 1.59)	5.99 (5.98 –6.00 ) 1.53 (1.52 – 1.54)	0.617 0.044

<sup>&</sup>lt;sup>1</sup>95% confidence interval

The mean BMI was greater in Sami males, whereas the mean WC was greater in non-Sami males. Sami females, however, showed significantly greater values for mean BMI, WC and lipids.

Table 2 shows the prevalence of diabetes in Sami and non-Sami participants.

<sup>&</sup>lt;sup>2</sup> test of differences, ANOVA, for between Sami versus non-Sami

**Table 2.** Prevalence of diabetes mellitus in the SAMINOR study (N=15112)

	Sami (N=2559)	Non-Sami (N=4731)	
Men	n (%)	n (%)	p-value
Diabetes prevalence	132 (5.2)	212 (4.5)	0.19 <sup>1</sup>
Insulin treatment	13 (0.5)	31 (0.7)	
Tablet treatment	45 (1.8)	87 (1.8)	
Insulin and tablet treatment	25 (1.0)	21 (0.4)	
Non-treatment	49 (1.9)	73 (1.5)	
Non-diabetes	2427 (33.3)	4519 (95.5)	0.05 <sup>2</sup>
	Sami (N=2581)	Non-Sami (N=5241)	
Women	n (%)	n (%)	p-value
Diabetes prevalence	129 (5.0)	220 (4.2)	0.11 <sup>1</sup>
Insulin treatment	13 (0.5)	29 (0.6)	
Tablet treatment	61 (2.4)	71 (1.6)	
Tablet treatment Insulin and tablet treatment	61 (2.4) 20 (0.8)	71 (1.6) 38 (0.7)	

<sup>&</sup>lt;sup>1</sup> Chi-square test for differences in diabetes prevalence among Sami versus non-Sami

No differences in prevalence of diabetes mellitus was demonstrated between ethnic groups, however, ethnicity appeared to affect diabetes treatment. Particularly it was more common to use tablet treatments among Sami women compared with non-Sami women. Among Sami men, however, a combination of tablet and insulin treatment was frequently in use compared with non-Sami men.

The prevalence of the various diagnostic tools for MetS is presented in Figures 1 (males) and 2 (females).

<sup>&</sup>lt;sup>2</sup> Chi-square test for differences in treatment level among Sami versus non-Sami

----Figure 2 -----

The most prevalent risk marker for MetS (aside from central obesity) was the presence of elevated systolic blood pressure and high triglyceride levels independent of gender and ethnicity.

Table 3 presents the prevalence of MetS according to WC cut-off points based on European and NIH values.

**Table 3.** Prevalence of MetS among Sami and non-Sami, by age groups and gender. N=15112 participants

	Furone	an cut off of	·WC	NIH	NIH cut off of WC		
	Sami	Non-Sami	WC	Sami	• •		
	(N=650)	(N=917)		(N=315)	Non- Sami		
	n (%)	n (%)		n (%)	(N=728)		
		()		()	n (%)		
			p-			p-value <sup>1</sup>	
Men			value <sup>1</sup>				
_	104 (22.2)	100 (0 ( 0)	0.020	00 (10 0)	202	0.110	
36-49 yr	194 (22.3)	429 (26.0)	0.038	89 (10.2)	203	0.118	
50.50	220 (27.2)	110 (20.7)	0.202	115 (12.5)	(12.3)	0.121	
50-59 yr	229 (27.2)	440 (29.7)	0.202	115 (13.7)	238	0.121	
60. <b>7</b> 0	227 (2( 0)	400 (20 6)	0.055	111 (12 1)	(16.1)	0.002	
60-79 yr	227 (26.9)	489 (30.6)	0.055	111 (13.1)	287	0.002	
p-value <sup>2</sup>	0.029	< 0.0001		0.05	(18.0) <0.0001		
P	g :	N. G :		<b>G</b> :	<b>N</b> T		
	Sami	Non-Sami		Sami	Non-		
	(N=790)	(N=1521)		(N=588)	Sami		
	n (%)	n (%)		n (%)	(N=1091)		
**7					n (%)		
Women	222 (24.4)	260 (10.1)	0.006	161 (16.2)	262	0.056	
36-49 yr	232 (24.4)	369 (19.1)	0.000	161 (16.2)	263	0.036	
50.50	249 (21.5)	455 (20.4)	0.291	177 (22.5)	(13.6) 309	0.155	
50-59 yr	248 (31.5)	455 (29.4)	0.291	177 (22.5)	(20.0)	0.133	
60-79 yr	310 (38.7)	697 (39.6)	0.641	250 (31.2)	519	0.393	
00-79 yl	310 (36.7)	091 (39.0)	0.041	230 (31.2)	(29.5)	0.575	
p-value <sup>2</sup>	0.004	< 0.0001		< 0.0001	<0.0001		
p-value	0.001	0.0001		0.0001	0.0001		

<sup>&</sup>lt;sup>1</sup> Chi-square tests for differences in MetS prevalence of Sami versus non-Sami

In each age bracket the results are stratified according to ethnicity (Sami and non-Sami). Based on the European WC cut-off points, prevalence of MetS was higher in non-Sami participants in the age bracket 36-49 years. However, when applying the NIH WC cut-off point, a significantly lower prevalence was found for Sami males in the top age group.

<sup>&</sup>lt;sup>2</sup> Age effect tested by logistic regression with age as a continuous variable

Non-Sami males showed a higher overall prevalence of MetS (in comparison to Sami males) for both WC cut-off values. In females ethnicity was not significant overall; however when stratified by age, a significantly higher prevalence of MetS in the younger Sami females (in comparison to non-Sami females) was found — when applying the European WC cut-off value. The prevalence of MetS increased with age regardless of gender and ethnicity. The proportion of women with all four risk markers was almost twice as large within the Sami population (in comparison to non-Sami females) for both WC cut-off values (not shown). For males, ethnicity appeared not to affect the number of risk markers found.

#### **Discussion**

The prevalence of MetS was high in both ethnic groups. No differences in prevalence of diabetes mellitus was demonstrated between ethnic groups. It was more common to give treatment for diabetes to both Sami men and women compared to the non-Sami participants. The two different WC cut-off values greatly influenced the measured prevalence of MetS. The present study demonstrates that ethnicity is a significant factor for MetS in participants belonging to the lowest age bracket.

The two different WC cut-off values greatly influenced the measured prevalence of MetS. The present study demonstrates that ethnicity is a significant factor for MetS in participants belonging to the lowest age bracket. In the case of males aged between 36 and 49, MetS is less prevalent in the Sami population (in comparison to non-Sami). For females in the same age bracket, however, MetS is more prevalent in the Sami population. When the NIH cutoffs were used, we found that — in the highest age bracket — the non-Sami males showed significantly higher prevalence of MetS in comparison to Sami males. The prevalence of MetS increased significantly by age in both ethnic groups, regardless of which WC cut-off values were used.

In general, overweight and obesity are common among the participants in the SAMINOR study. From earlier publications based on the SAMINOR study, central obesity has been shown to be more common in Sami females.[15,26] General obesity in Sami females has also been discussed by Njølstad et al (1998).[27] However, obesity rates were high in non-Sami females as well.[14] For males, central obesity occurred more frequently in the non-Sami population relative to the Sami population.[14-15]

MetS has several different definitions, making it difficult to directly compare and contrast prevalence found in different surveys. WC is the most significant measurement of both central obesity and fat distribution, according to The International Diabetes Federation (IDF).[28] The group that produced the consensus statement on the definition of MetS in 2004 recommended that gender and ethnicity should be the basis for classification of cut-off points. [24] The existing values are based on cross-sectional population survey data from the respective countries. How to define the WC cut-off point in the various indigenous populations has not yet been established; however, an immediate response would be to perform cross-sectional population surveys within indigenous societies. In our study two different cut-off points were used in order to facilitate comparison. The European cut-off values doubled the prevalence of MetS in males and increased prevalence by more than 40 per cent in females (compared to values found when applying NIH WC cut-off values). This was the case in both ethnic groups. But the question of what the WC values should be in terms of optimal prediction of prospective disease in the SAMINOR sample remains unanswered. A follow-up study could provide better answers to questions regarding disease development. Irrespective of cut-off values, elevated blood pressure was the most frequent MetS component present in obese participants. These findings were also demonstrated in a collaborative analysis of ten large cohort studies in Europe [29] In the ten studies included, obesity coincided with hypertension in up to 85 per cent of cases.

The presence of MetS, as well as its individual components, however, shows considerable variance between populations. Several studies of MetS have been performed in circumpolar areas, such as in indigenous peoples of Alaska, Canada and Greenland.[30-32] American Indians and Aboriginal Canadians represent populations in which MetS, obesity and T2DM are becoming more prevalent. [13,30] MetS is also frequently occurring in Greenland's Inuit population.[32] A health survey in Greenland showed that central adiposity and obesity were more prevalent in the Inuit population when compared to the corresponding Danish population, but was not associated with the same degree of metabolic disturbance as in the general Danish population.[33] Yet it is debatable which factors in the cluster of MetS are the most significant in the development of chronic lifestyle diseases.

There is a significant relation between T2DM and MetS; the syndrome itself is not a disease, but consists of a cluster of factors that increase the risk for developing diseases. Thus we prefer to include diabetes in this article to demonstrate the link between the health indicator MetS and diabetes mellitus.[24] In the SAMINOR study diabetes mellitus was identified using a questionnaire, in addition to measured random plasma glucose ≥ 11.1 mmol/L in participants whom did not report diabetes mellitus. As the study had a large number of participants, up to 140 per day, conducting two-hour plasma glucose tolerance tests was considered infeasable. The portable HbA1c instruments available in 2003-2004 were inadequate for conducting HbA1C measurements at rural research stations. In addition, the survey was performed in provincial areas with long distances to the medical laboratory. Our analyses do not differentiate between type 1 and 2 diabetes mellitus due to insufficient information provided by the questionnaire. However, eight of ten diabetes cases in Norway are T2DM.[34] Also, globally, around 80 per cent of diabetes cases are T2DM,[35-37] giving a prevalence rate of 8.3 per cent. This figure is expected to increase due to lifestyle changes.

rate than the prevalence rate found in the urban population residing in 2007—2008 in the city of Tromsø (8.5%) [38]. This study encompassed participants aged between 30 and 87, with a mean age of 61. However, in the Tromsø study, fasting plasma glucose, two-hour plasma glucose and HbA1c was measured. It is therefore likely that the present study underreports the diabetes prevalence maybe as much as up to 50 percent. The significance of treatment differences between ethnic groups has not been reported earlier and is difficult to explain. These findings will therefore be addressed in future research.

Strengths

Our study is the first survey to report on the prevalence of diabetes and MetS in a large geographic area of North Norway including both the indigenous and the non-indigenous population. The large sample size allowed for detailed analysis of diabetes and MetS in Sami and non-Sami populations of rural North Norway; it also reduces the influence of random errors, which cannot fully be controlled for. The survey had a relatively high response rate. Unquestionably, one of the strengths of the study was that clinical data — such as central obesity (upon which MetS relies) — were collected by direct measurement and conducted by trained personnel, providing reliable estimates of obesity prevalence in the participating cohort.

#### Limitations

The cross-sectional study design is suitable for the examination of associations in order to generate hypotheses that may be explored in longitudinal studies. Conversely, however, the design prevents the establishment of causality. Due to the nature of the design, people with severe disease may be missed because they are diseased at home, in long-term hospitalization or having died in the time since the sample list was prepared (i.e., selection bias). The SAMINOR study has used questionnaires to survey self-reported diseases. This approach cannot detect people with undiagnosed symptoms and is limited by recall recall bias. In

Norway, it is estimated between 90 00 to 120 000 people with diabetes and nearly as many have undiagnosed disease. [39]

Categorizing people based on ethnicity is a contentious practice. Different studies use different criteria of ethnic categorization, which makes it difficult to compare results. Our definition of the Sami group is rather weak. This may have influenced our results. Since there are no national records with information om ethnic background, it is impossible to know if the response rate among Sami and non-Sami are different. We are therefore unable to assess whether differences in participation have influenced the observed disease burden.

In summary, cross-sectional studies may be used in the measurement of the burden of disease in a population. However, cross-sectional data cannot assess the effect of lifestyle on the incidence of MetS, and longitudinal cohort studies are therefore needed.

#### Conclusion

Without question, the prevalence rates for several negative health factors were high in the Sami and non-Sami population. Overweight and obesity were common, especially in the case of Sami females. No differences in prevalence of diabetes mellitus was demonstrates between ethnic groups. However, ethnicity appeared to affect diabetes treatment and was significantly more frequent in use among Sami women compared to the non-Sami women. However, the prevalence of MetS were in general high among participants in the SAMINOR study, with the highest prevalence for the European cut off values. The syndrome has important health implication but a cross sectional study cannot be used to validate the best ethnic specific values for WC used in the definition of MetS and more data on this issue must be obtained. In addition, determining preventive initiatives is important in the primary and specialist health care system. These initiatives must be made culture and linguistic specific, in order to reduce differences and improve health status in the whole population.

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#### **Summary Box**

What is already known on this subject?

In Northern Norway the burden of obesity are especially high among female. Highest prevalence has been demonstrated among the Sami women. In this study we therefore examined several other risk factors for developing lifestyle diseases.

What this study adds?

This study showed a high prevalence of the metabolic syndrome among the population in north, independent of ethnic belonging. The burden of metabolic risk factors was highest among women, especially Sami women. Self-reported diabetes was between four and five percent which are slightly higher than the national prevalence rate. In the future, obesity and other metabolic risk factors will contribute to increase burden of lifestyle diseases among the Sami population. Two issues are therefore important to emphasize. Firstly, implement preventive interventions in the multicultural communities, as well as highlight research information to inhabitants and local and central authorities. Secondly, follow the health situation in each community with longitudinal studies to evaluate the effect of preventive efforts.

# **Contributorship statement**

The idea behind the study was conceived by Ann R Broderstad. Both authors participated in the study concept and design. Ann R Broderstad drafted the manuscript. Both authors did the analyses of the tables and figures. Both authors reviewed and approved the final version of the manuscript.

#### **Conflict of Interest**

The authors declare that they have no conflict of interest.

# **Funding**

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# Data sharing

No additional data available.

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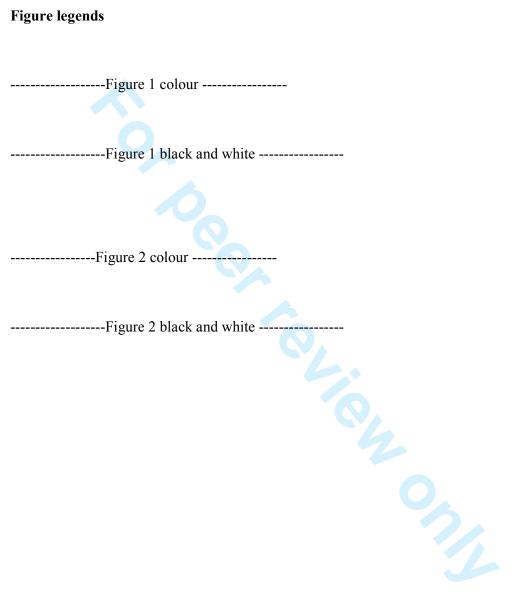
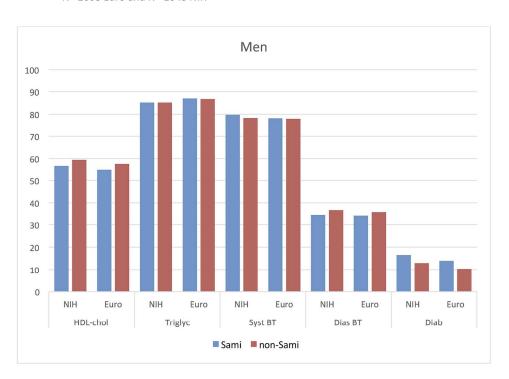
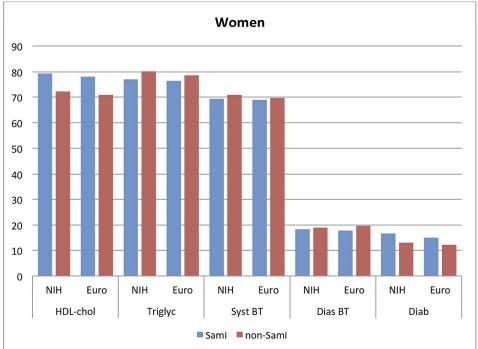


Figure 1. Prevalence of different risk markers in participants with Mets. Men. N=2008 Euro and N=1043 NIH



150x133mm (300 x 300 DPI)

Figure 2. Prevalence of different risk markers in participants with MetS. Women . N= 2311 Euro and N= 1679 NIH



165x169mm (300 x 300 DPI)



# STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	p 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	P 2
Introductionp 4			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	P 4
Objectives	3	State specific objectives, including any prespecified hypotheses	P 5
Methods			
Study design	4	Present key elements of study design early in the paper	P 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	p 5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	P 5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	p 6 -8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	P 6 -8
Bias	9	Describe any efforts to address potential sources of bias	P 6-8
Study size	10	Explain how the study size was arrived at	P 5
Quantitative variables	11		
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	P 8
		(b) Describe any methods used to examine subgroups and interactions	P 8
		(c) Explain how missing data were addressed	P 8
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(e) Describe any sensitivity analyses	Not done
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	P 8-9 and Table 1
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	Not done
Descriptive data 14*		(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	P 8- 9 and Table 1
		(b) Indicate number of participants with missing data for each variable of interest	No missing data in the further analyzes
Outcome data	15*	Report numbers of outcome events or summary measures	Table 1 p 8
Main results 16		(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Table 2 p 10, table 3 p 12 fig 1 and 2 p 11
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not done
Discussion			
Key results	18	Summarise key results with reference to study objectives	P 13 - 16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	P 16
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	P 14 -16
Generalisability	21	Discuss the generalisability (external validity) of the study results	P 16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	P 17

<sup>\*</sup>Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

# **BMJ Open**

# The prevalence of metabolic syndrome and diabetes mellitus in Sami and Norwegian populations. The SAMINOR-a cross sectional study.

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# Original Article

The prevalence of metabolic syndrome and diabetes mellitus in Sami and Norwegian populations. The SAMINOR-a cross sectional study.

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Tables 3

Figures 2

# **Objectives**

Metabolic syndrome (MetS) is recognized as a reliable long-term predictor of adverse health outcomes known. Elevated prevalence rates of MetS and chronic lifestyle diseases have been documented in different indigenous groups. We wanted to evaluate the prevalence of MetS and diabetes mellitus in relation to ethnicity in Northern Norway. In addition, we discussed different cut-off values for waist circumference (WC) and what impact this has on the prevalence of MetS.

### Material and methods

SAMINOR is a population based study of health and living conditions in areas home to both Sami and non-Sami populations. The survey was carried through in 2003 – 2004. All eligible residents in specific age groups were invited. In total, 16,538 males and females aged 36-79 participated and gave informed consent for medical research.

#### Results

This study involved a total of 7,822 female and 7,290 male participants. Sami affiliation was reported by 5,141 participants (34 per cent). The prevalence of MetS was high in both ethnic groups independent of which WC cut off values used. No ethnic differences in prevalence of diabetes mellitus was demonstrated. However, ethnicity appeared to affect diabetes treatment and was more in use among Sami women compared to the non-Sami.

#### **Conclusions**

In this study it was no ethnic differences in diabetes prevalence, but ethnicity appeared to affect diabetes treatment. Tablet treatment was more common in use among Sami women compared to non-Sami women. We demonstrated a high share of negative metabolic components. These metabolic components have important health implications. Therefore, determining preventive initiatives is important in the primary and specialist health care

system. These initiatives must be made culture and linguistic specific, in order to reduce differences and improve health status in the whole population.

# Strengths and limitations of this study

- The SAMINOR study is the first survey to report on the prevalence of diabetes and MetS in a large geographic area of North Norway including both the indigenous and the non-indigenous population.
- The large sample size allowed for detailed analysis of diabetes and MetS in Sami and non-Sami populations of rural North Norway.
- The survey has a relatively high response rate.
- Categorizing people based on ethnicity is a contentious practice. Different studies use different criteria of ethnicity, which makes it difficult to compare results.

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 Cross-sectional data cannot assess the effect of lifestyle on the incidence of MetS, and longitudinal cohort studies are therefore needed

The prevalence of metabolic syndrome and diabetes mellitus in Sami and Norwegian populations. The SAMINOR study-a cross sectional study.

#### Introduction

Chronic disease has become a global problem and a burden on health care services, reaching epidemic proportions. In Norway, as well as internationally, the great majority of patients in health care systems are living with chronic disease.[1-2] Cardiovascular disease (CVD), type 2 diabetes mellitus (T2DM), cancer and chronic obstructive pulmonic disease (COPD) are the most common causes of hospitalization and premature death.[3] Unfavorable health factors such as obesity, insulin resistance, dyslipidemia and hypertension are known to elevate risks of developing CVD and T2DM. Metabolic syndrome (MetS) indicates a cluster of these risk factors. [4-5] MetS is generally recognized as a reliable long-term predictor of adverse health outcomes.[6] Further, MetS has been recognized as a growing, global public health problem. .[7] In addition, several studies demonstrate MetS to be associated with elevated cancer risk.[8-9]

Information on the prevalence of chronic disease in various ethnicities of North Norway remains sparse. The Sami, Kven and Norwegian ethnic groups are recognized as having inhabited the region in centuries; the Norwegian government acknowledges the Sami people as the indigenous people of Norway. The Norwegian health authorities have little systematic knowledge about health status and living conditions among the Sami. National health -and medical registers contribute to comprehensive information and knowledge about health-related lifestyle and disease prevalence. However, information about ethnic background is not permitted by law, in these registers nor in patient's medical records. Therefore, no reliable or updated demographic records on the Sami exists that can be used for health research purposes. Several epidemiological studies have documented elevated prevalence rates for chronic lifestyle diseases in a number of different minority groups.[5, 10-11] Although such disorders

have emerged quite recently in indigenous populations — mainly due to changes in lifestyle and diet — they are, however, prevalent in several indigenous populations.[12-13]

Publications from the SAMINOR study of North Norway demonstrate that the prevalence of obesity was high in the survey population, especially among Sami women.[14-15]

In order to evaluate the health of indigenous and non-indigenous populations of Norway (inhabiting the same geographic area) it was necessary to conduct an epidemiological survey. The present study aims to evaluate the prevalence of MetS and diabetes mellitus in Sami and non-Sami populations residing in selected areas of North Norway. In addition, we will discuss different cut-off values for waist circumference (WC) and what impact this has on the prevalence og MetS.

#### Methods

The SAMINOR study

The cross-sectional data is derived from the SAMINOR study of 2003–2004 (SAMINOR 1). The SAMINOR study was conducted by The Centre for Sami Health Research, Department of Community Medicine, UiT The Arctic University of Norway, in collaboration with the National Screening Program for Cardiovascular Diseases. The survey is described in detail elsewhere.[16]

*The study sample* 

All eligible residents aged 30 and 36—79 years registered in the Central Population Register in 24 selected municipalities were invited regardless of ethnic background (n=27,987). Due to a low response rate among those aged 30 years, our analyses were restricted to the age interval 36—79 years (n=27,151). In total, 16,538 males and females aged 36—79 participated and gave informed consent for medical research. The response rate was 61 per cent. Data was obtained from physical tests and blood samples. Information on ethnicity, and the different diagnostic tools for MetS, were available for 15,112 participants.

An invitation was mailed several weeks before the survey arrived the municipality. The invitation contained information about the time and place, together with a five-page questionnaire. Those who agreed to attend the screening returned the questionnaire to the Norwegian Institute of Public health. These participants received later an invitation to the clinical examination. After the consultation the participants were asked to complete a new questionnaire. Information regarding ethnicity, disease and lifestyle were collected using these two self-administrated questionnaires. The questionnaires were translated into the three main Sami languages, Northern, Lule and South Sami languages. However, as only 1.6% of the participants chose to use the Sami version of the questionnaire, any language problems are probably of little importance in this study. Ethnicity was measured using the following questions: "What language(s) do/did you, your parents and your grandparents use at home?" The questions were to be answered separately for each relative. The available responses were: "Norwegian", "Sami", "Kven" and "Other". Multiple answers were allowed. Providing the same response options we also asked: "What is your, your father's and your mother's ethnic background?" The respondents also reported whether they considered themselves to be Norwegian, Sami, Kven or other (self-perceived ethnicity). We refer to Lund et al (16) for full description of the ethnicity and language questions. Based on these variables we generated two categories of ethnicity: "Sami" and "Non-Sami". Participants reporting at least one Sami identity mark (Sami language spoken by the respondent or at least one parent or grandparent, or Sami ethnic background or self-perceived Sami ethnicity) were placed in the category "Sami". The "Non-Sami" comprised the remainder of the participants.

The study was accredited by the Regional Board of Research Ethics in Northern Norway, and by the Board's Sami Consultant. The survey is in accordance with the Helsinki Declaration of

1975. The National Data Protection Authority (*Datatilsynet*) approved the use of personal information and the study are registered with the number 2002/1525-2.

Screening

Due to the large size of the study sample participants were examined at different times of day. This meant that it was not possible to ask participants to be fasting prior to arrival. Non-fasting blood samples were obtained at the research station. Blood samples were drawn by venopuncture at normal venous pressure in sitting position. Serum was separated at the station within 1.5 hours. Serum was sent by overnight mail to laboratories in Oslo and Tromsø. The laboratory analyses are described in detail elsewhere. [17]

Body mass index (BMI) was based on measurements of weight and height, and expressed as body weight in kilograms/(body height in meters)<sup>2</sup>. BMI categories were defined according to guidelines from The World Health Organization (WHO); 'underweight' corresponding to a BMI<18.5 kg/m<sup>2</sup>, 'standard weight' in the range 18.5-24.9 kg/m<sup>2</sup>, 'overweight' in the range 25-29.9 kg/m<sup>2</sup> and 'obese'  $\geq 30$  kg/m<sup>2</sup>.[18]

Waist circumference (WC), which is used to identify abdominal obesity, was measured (to the nearest centimeter) at the umbilicus with the participant standing erect. Two different WC cut-off values were applied to define abdominal obesity to enable the comparison of how the corresponding values influenced the subsequently calculated prevalence of MetS. The US National Institute of Health (NIH) Clinical Practice Guidelines defines central/abdominal obesity as  $WC \ge 102$  cm in males and  $WC \ge 88$ cm in females.[19] In addition, abnormal WC for Europid males are  $\ge 94$  cm and for females  $\ge 80$  cm. These figures are based on cross-sectional data from Europids and were included in the analyses.[18,20]

Trained personnel measured blood pressure, using Dinamap –R. automatic device.

Measurements were initiated after subjects had been seated for two minutes with their arms

resting on a table. Blood pressure was measured three times, with one- minute intervals. The mean value of the second and third reading was used in the analysis.

Diabetes mellitus

Because all blood samples in the SAMINOR study were non-fasting, we used random plasma glucose  $\geq 11.1$  mmol/L, in addition to self-reported diabetes and information about anti-diabetic medication from a questionnaire to define diabetes mellitus. The question about diabetes mellitus was; "Do you have or have you had diabetes?" The available responses were "Yes" or "No". Missing values were classified as "No". In the absence of oral glucose tolerance tests we used random plasma glucose  $\geq 11.1$  mmol/l as a substitute for elevated oral glucose tolerance test.

Metabolic syndrome

Several attempts have been made at developing diagnostic criteria for the definition of MetS. [21-23] In 2004, the International Diabetes Federation (IDF), the WHO and the National Cholesterol Education Program Third Adult Treatment Panel (ATP III) produced a consensus statement on the definition of MetS.[24] The latter definition requires central obesity and cutoff points to be specified according to gender and ethnicity. Central obesity is most commonly measured by WC; cut-off values are based on cross-sectional studies conducted in Europe, The United States and Asia.[18-20, 25] The diagnostic tools are intended for clinical and research purposes. The definition of MetS used in this article adheres to the IDF MetS worldwide definition,[24]: Central obesity plus any two of four additional factors; Elevated triglyceride level > 1.7 mmol/l, reduced HDL-cholesterol < 1.03 mmol/l in males and < 1.29 mmol/l in females, elevated blood pressure (systolic BP  $\geq$  130 or diastolic BP  $\geq$  85 mmHg) and elevated fasting plasma glucose  $\geq$  11.1 mmol/l or previously diagnosed type 2 diabetes. *Statistical analyses* 

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All analyses were stratified by gender. Sample characteristics were presented separately by gender and ethnicity as mean values for continuous variables with corresponding 95 per cent confidence intervals. Analyses of variance (ANOVA) were used for tests of ethnic differences (Table 1). Differences according to diabetes mellitus and MetS prevalence were tested by Chi-square tests (Tables 2 and 3). MetS prevalence was also stratified by age (Table 3). Logistic regression analyses were used to test for age influence on MetS with age as a continuous variable (Table 3).

We used the SAS statistical software package, version 9.3 (SAS Institute Inc., Cary, NC, USA).

#### Results

The current analysis involved a total of 7,822 female and 7,290 male participants. Sami affiliation was reported by 5,141 participants (34 per cent). Table 1 shows gender-specific and ethnicity-specific characteristics at enrolment in the study.

**Table 1** Sample characteristics by gender and ethnic group. (N=15112)

Men	Sami (N=2559)	Non-Sami (N=4731) Mean (95 % CI) <sup>1</sup>	p-value <sup>2</sup>
	Mean (95 % CI) <sup>1</sup>	1/10 <b>411</b> (20 70 01)	
Age (yr)	55.0 (54.8-55.1)	54.8 (54.7-54.9)	0.584
Height (cm)	170.0 (170.0-170.2)	175.7 (175.6 - 175.8)	< 0.0001
Weight (kg)	80.6 (80.4 - 80.7)	85.1 (85.0 – 85.3)	< 0.0001
BMI $(kg/m^2)$	27.8 (27.7-27.9)	27.5(27.5 - 27.6)	0.009
WC (cm)	93.2(93.0 - 93.3)	95.0 (94.9 – 95.2)	< 0.0001
Non-fasting glu (mmol/L	5.8 (5.8- 5.8)	5.8 (5.7 - 5.8)	0.313
HDL-chol (mmol/l)	1.27(1.26-1.28)	1.25(1.25-1.26)	0.115
LDL- chol ( mmol/L)	3.87(3.86 - 3.89)	3.80(3.79 - 3.81)	0.004
Cholesterol (mmol/l)	5.98 ( 5.96- 5.99)	5.90(5.90-5.90)	0.001
Triglycerids (mmol/l)	1.86(1.85 - 1.88)	1.86(1.85 - 1.88)	0.970
Systolic BT (mmHg)	135 (135 – 135)	134 (134 -134)	0.168
Diastolic BT (mmHg)	78 (78 -78)	78 (78 – 78)	0.182
Women	Sami (N=2581)	Non-Sami (N=5241)	p-value
	Mean (95 % CI) <sup>1</sup>	Mean (95 % CI) <sup>1</sup>	1
Age (yr)	54.2 (54.1 – 54.4)	54.5 (54.4 – 54.6)	0.277
Height (cm)	157.3 (157.2 – 157.4)	162.6 (162.6 – 162.7 )	< 0.0001
Weight (kg)	69.7 (69.6 – 69.9)	72.1 (71.9 -72.2)	< 0.0001
BMI $(kg/m^2)$	28.2(28.1 - 28.3)	27.3(27.2 - 27.3)	< 0.0001
WC (cm)	86.0(85.9 - 86.2)	85.5 (85.4 – 85.6)	0.053
Non-fasting glu (mmol/L	5.66(5.63-5.68)	5.57(5.55 - 5.58)	0.018
HDL-chol (mmol/l)	1.45(1.44 - 1.45)	1.49(1.49 - 1.50)	< 0.0001
LDL- chol ( mmol/L)	3.82 (3.81 – 3.83)	3.81(3.80 - 3.82)	0.707
Cholesterol (mmol/l)	5.98 (5.96 –5.99)	5.99 (5.98 –6.00 )	0.617
Triglycerids (mmol/l)	1.54(1.56 – 1.59)	1.53(1.52 - 1.54)	0.044
Systolic BT (mmHg)	130 (129 – 130)	130 (130 -131)	0.125
Diastolic BT (mmHg)	72 (72 -72)	73 (73 -73)	0.008

<sup>&</sup>lt;sup>1</sup>95% confidence interval

The mean BMI was greater in Sami males, whereas the mean WC was greater in non-Sami males. Sami females, however, showed significantly greater values for mean BMI, WC and lipids.

Table 2 shows the prevalence of diabetes in Sami and non-Sami participants.

<sup>&</sup>lt;sup>2</sup> test of differences, ANOVA, for between Sami versus non-Sami

Table 2. Prevalence of diabetes mellitus and diabetes treatment in the SAMINOR study (N=15112)

	Sami (N=2559)	Non-Sami (N=4731)	
Men	n (%)	n (%)	p-value
Diabetes prevalence	132 (5.2)	212 (4.5)	0.19 <sup>1</sup>
Insulin treatment	13 (0.5)	31 (0.7)	
Tablet treatment	45 (1.8)	87 (1.8)	
Insulin and tablet treatment	25 (1.0)	21 (0.4)	
Non-treatment	49 (1.9)	73 (1.5)	
Non-diabetes	2427 (33.3)	4519 (95.5)	0.05 <sup>2</sup>
	Sami (N=2581)	Non-Sami (N=5241)	
Women	n (%)	n (%)	p-value
Women	n (%)	n (%)	p-value
Women	n (%)	n (%)	p-value
Women	n (%)	n (%)	p-value
Women	n (%)	n (%)	p-value

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Enseignement Superieur (ABES)

Diabetes prevalence	129 (5.0)	220 (4.2)	0.11
Insulin treatment	13 (0.5)	29 (0.6)	
Tablet treatment	61 (2.4)	71 (1.6)	
Insulin and tablet treatment	20 (0.8)	38 (0.7)	
Non-treatment	35 (1.4)	82 (1.6)	
Non-diabetes	2452(95.0)	5021 (95.8)	0.025 2

<sup>&</sup>lt;sup>1</sup> Chi-square test for differences in diabetes prevalence among Sami versus non-Sami

No differences in prevalence of diabetes mellitus was demonstrated between ethnic groups, however, ethnicity appeared to affect diabetes treatment. Particularly it was more common to use tablet treatments among Sami women compared with non-Sami women. Among Sami men, however, a combination of tablet and insulin treatment was frequently in use compared with non-Sami men.

The prevalence of the various diagnostic tools for MetS is presented in Figures 1 (males) and 2 (females).

----Figure 1 -----

----Figure 2 -----

The most prevalent risk marker for MetS (aside from central obesity) was the presence of elevated systolic blood pressure and high triglyceride levels independent of gender and ethnicity.

<sup>&</sup>lt;sup>2</sup> Chi-square test for differences in treatment level among Sami versus non-Sami

Table 3 presents the prevalence of MetS according to WC cut-off points based on European and NIH values.



**Table 3.** Prevalence of MetS among Sami and non-Sami, by age groups and gender. N= 15112 participants

	European cut off of WC			NIH cut off of WC		
	Sami Non-Sami			Sami	Non-	
	(N=650)	(N=917)		(N=315)	Sami	
	n (%)	n (%)		n (%)	(N=728)	
					n (%)	
			p- value <sup>1</sup>			p-value <sup>1</sup>
Men						
36-49 yr	194 (22.3)	429 (26.0)	0.038	89 (10.2)	203	0.118
,	, ,	` ,		, ,	(12.3)	
50-59 yr	229 (27.2)	440 (29.7)	0.202	115 (13.7)	238	0.121
					(16.1)	
60-79 yr	227 (26.9)	489 (30.6)	0.055	111 (13.1)	287	0.002

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p-value <sup>2</sup>	0.029	< 0.0001		0.05	(18.0) <0.0001	
	Sami (N=790) n (%)	Non-Sami (N=1521) n (%)		Sami (N=588) n (%)	Non- Sami (N=1091) n (%)	
<b>Women</b> 36-49 yr	232 (24.4)	369 (19.1)	0.006	161 (16.2)	263	0.056
50-59 yr	248 (31.5)	455 (29.4)	0.291	177 (22.5)	(13.6) 309 (20.0)	0.155
60-79 yr	310 (38.7)	697 (39.6)	0.641	250 (31.2)	519 (29.5)	0.393
p-value <sup>2</sup>	0.004	<0.0001		< 0.0001	<0.0001	

<sup>&</sup>lt;sup>1</sup> Chi-square tests for differences in MetS prevalence of Sami versus non-Sami

In each age bracket the results are stratified according to ethnicity (Sami and non-Sami). Based on the European WC cut-off points, prevalence of MetS was higher in non-Sami participants in the age bracket 36-49 years. However, when applying the NIH WC cut-off point, a significantly lower prevalence was found for Sami males in the top age group. Non-Sami males showed a higher overall prevalence of MetS (in comparison to Sami males) for both WC cut-off values. In females ethnicity was not significant overall; however when stratified by age, a significantly higher prevalence of MetS in the younger Sami females (in comparison to non-Sami females) was found — when applying the European WC cut-off value. The prevalence of MetS increased with age regardless of gender and ethnicity. The proportion of women with all four risk markers was almost twice as large within the Sami population (in comparison to non-Sami females) for both WC cut-off values (not shown). For males, ethnicity appeared not to affect the number of risk markers found.

# **Discussion**

<sup>&</sup>lt;sup>2</sup> Age effect tested by logistic regression with age as a continuous variable

The prevalence of MetS was high in both ethnic groups. No differences in prevalence of diabetes mellitus was demonstrated between ethnic groups. It was more common to give treatment for diabetes to both Sami men and women compared to the non-Sami participants. The two different WC cut-off values greatly influenced the measured prevalence of MetS. The present study demonstrates that ethnicity is a significant factor for MetS in participants belonging to the lowest age bracket.

The two different WC cut-off values greatly influenced the measured prevalence of MetS. The present study demonstrates that ethnicity is a significant factor for MetS in participants belonging to the lowest age bracket. In the case of males aged between 36 and 49, MetS is less prevalent in the Sami population (in comparison to non-Sami). For females in the same age bracket, however, MetS is more prevalent in the Sami population. When the NIH cutoffs were used, we found that — in the highest age bracket — the non-Sami males showed significantly higher prevalence of MetS in comparison to Sami males. The prevalence of MetS increased significantly by age in both ethnic groups, regardless of which WC cut-off values were used.

In general, overweight and obesity are common among the participants in the SAMINOR study. From earlier publications based on the SAMINOR study, central obesity has been shown to be more common in Sami females.[15,26] General obesity in Sami females has also been discussed by Njølstad et al (1998).[27] However, obesity rates were high in non-Sami females as well.[14] For males, central obesity occurred more frequently in the non-Sami population relative to the Sami population.[14-15]

MetS has several different definitions, making it difficult to directly compare and contrast prevalence found in different surveys. WC is the most significant measurement of both central obesity and fat distribution, according to The International Diabetes Federation (IDF).[28]

The group that produced the consensus statement on the definition of MetS in 2004

recommended that gender and ethnicity should be the basis for classification of cut-off points. [24] The existing values are based on cross-sectional population survey data from the respective countries. How to define the WC cut-off point in the various indigenous populations has not yet been established; however, an immediate response would be to perform cross-sectional population surveys within indigenous societies. In our study two different cut-off points were used in order to facilitate comparison. The European cut-off values doubled the prevalence of MetS in males and increased prevalence by more than 40 per cent in females (compared to values found when applying NIH WC cut-off values). This was the case in both ethnic groups. But the question of what the WC values should be in terms of optimal prediction of prospective disease in the SAMINOR sample remains unanswered. A follow-up study could provide better answers to questions regarding disease development. Irrespective of cut-off values, elevated blood pressure was the most frequent MetS component present in obese participants. These findings were also demonstrated in a collaborative analysis of ten large cohort studies in Europe.[29] In the ten studies included, obesity coincided with hypertension in up to 85 per cent of cases.

The presence of MetS, as well as its individual components, however, shows considerable variance between populations. Several studies of MetS have been performed in circumpolar areas, such as in indigenous peoples of Alaska, Canada and Greenland.[30-32] American Indians and Aboriginal Canadians represent populations in which MetS, obesity and T2DM are becoming more prevalent. [13,30] MetS is also frequently occurring in Greenland's Inuit population.[32] A health survey in Greenland showed that central adiposity and obesity were more prevalent in the Inuit population when compared to the corresponding Danish population, but was not associated with the same degree of metabolic disturbance as in the general Danish population.[33] Yet it is debatable which factors in the cluster of MetS are the most significant in the development of chronic lifestyle diseases.

There is a significant relation between T2DM and MetS; the syndrome itself is not a disease, but consists of a cluster of factors that increase the risk for developing diseases. Thus we prefer to include diabetes in this article to demonstrate the link between the health indicator MetS and diabetes mellitus. [24] In the SAMINOR study diabetes mellitus was identified using a questionnaire, in addition to measured random plasma glucose ≥ 11.1 mmol/L in participants whom did not report diabetes mellitus. As the study had a large number of participants, up to 140 per day, conducting two-hour plasma glucose tolerance tests was considered infeasable. The portable HbA1c instruments available in 2003-2004 were inadequate for conducting HbA1C measurements at rural research stations. In addition, the survey was performed in provincial areas with long distances to the medical laboratory. Our analyses do not differentiate between type 1 and 2 diabetes mellitus due to insufficient information provided by the questionnaire. However, eight of ten diabetes cases in Norway are T2DM.[34] Also, globally, around 80 per cent of diabetes cases are T2DM,[35-37] giving a prevalence rate of 8.3 per cent. This figure is expected to increase due to lifestyle changes. [36] Diabetes prevalence in our study was between four and five percent, which is a lower rate than the prevalence rate found in the urban population residing in 2007—2008 in the city of Tromsø (8.5%) [38]. This study encompassed participants aged between 30 and 87, with a mean age of 61. However, in the Tromsø study, fasting plasma glucose, two-hour plasma glucose and HbA1c was measured. It is therefore likely that the present study underreports the diabetes prevalence maybe as much as up to 50 percent. The significance of treatment differences between ethnic groups has not been reported earlier and is difficult to explain. These findings will therefore be addressed in future research.

Strengths

Our study is the first survey to report on the prevalence of diabetes and MetS in a large geographic area of North Norway including both the indigenous and the non-indigenous

population. The large sample size allowed for detailed analysis of diabetes and MetS in Sami and non-Sami populations of rural North Norway; it also reduces the influence of random errors, which cannot fully be controlled for. The survey had a relatively high response rate. Unquestionably, one of the strengths of the study was that clinical data — such as central obesity (upon which MetS relies) — were collected by direct measurement and conducted by trained personnel, providing reliable estimates of obesity prevalence in the participating cohort.

#### Limitations

The cross-sectional study design is suitable for the examination of associations in order to generate hypotheses that may be explored in longitudinal studies. Conversely, however, the design prevents the establishment of causality. Due to the nature of the design, people with severe disease may be missed because they are diseased at home, in long-term hospitalization or having died in the time since the sample list was prepared (i.e., selection bias). The SAMINOR study has used questionnaires to survey self-reported diseases. This approach cannot detect people with undiagnosed symptoms and is limited by recall recall bias. In Norway, it is estimated between 90 00 to 120 000 people with diabetes and nearly as many have undiagnosed disease. [39]

Categorizing people based on ethnicity is a contentious practice. Different studies use different criteria of ethnic categorization, which makes it difficult to compare results. Our definition of the Sami group is rather weak. This may have influenced our results. Since there are no national records with information om ethnic background, it is impossible to know if the response rate among Sami and non-Sami are different. We are therefore unable to assess whether differences in participation have influenced the observed disease burden.

Without question, the prevalence rates for several negative health factors were high in the Sami and non-Sami population. Overweight and obesity were common, especially in the case of Sami females. No differences in prevalence of diabetes mellitus was demonstrates between ethnic groups. However, ethnicity appeared to affect diabetes treatment and was significantly more frequent in use among Sami women compared to the non-Sami women. However, the prevalence of MetS were in general high among participants in the SAMINOR study, with the highest prevalence for the European cut off values. The syndrome has important health implication but a cross sectional study cannot be used to validate the best ethnic specific values for WC used in the definition of MetS and more data on this issue must be obtained. In addition, determining preventive initiatives is important in the primary and specialist health care system. These initiatives must be made culture and linguistic specific, in order to reduce differences and improve health status in the whole population.

# Acknowledgements

We are indebted to the participants of the SAMINOR study, without whom our research would be impossible. We would also like to thank the staff at the Department of Clinical Chemistry, University Hospital of North Norway, for technical assistance and careful evaluation of blood samples.

### **Summary Box**

What is already known on this subject?

In Northern Norway the burden of obesity are especially high among female. Highest

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prevalence has been demonstrated among the Sami women. In this study we therefore examined several other risk factors for developing lifestyle diseases.

This study showed a high prevalence of the metabolic syndrome among the population in north, independent of ethnic belonging. The burden of metabolic risk factors was highest among women, especially Sami women. Self-reported diabetes was between four and five percent which are slightly higher than the national prevalence rate. In the future, obesity and other metabolic risk factors will contribute to increase burden of lifestyle diseases among the Sami population. Two issues are therefore important to emphasize. Firstly, implement preventive interventions in the multicultural communities, as well as highlight research information to inhabitants and local and central authorities. Secondly, follow the health situation in each community with longitudinal studies to evaluate the effect of preventive

The idea behind the study was conceived by Ann R Broderstad. Both authors participated in the study concept and design. Ann R Broderstad drafted the manuscript. Both authors did the analyses of the tables and figures. Both authors reviewed and approved the final version of the

The authors declare that they have no conflict of interest.

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Extra data is available by emailing ann.ragnhild.broderstad@uit.no

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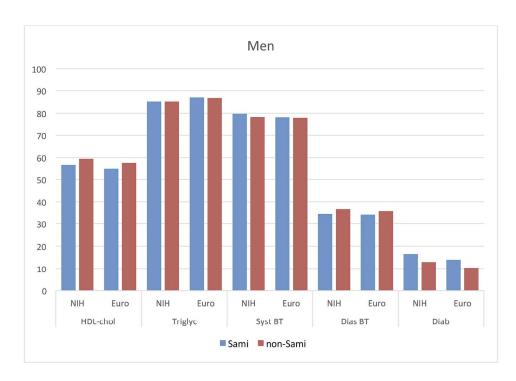
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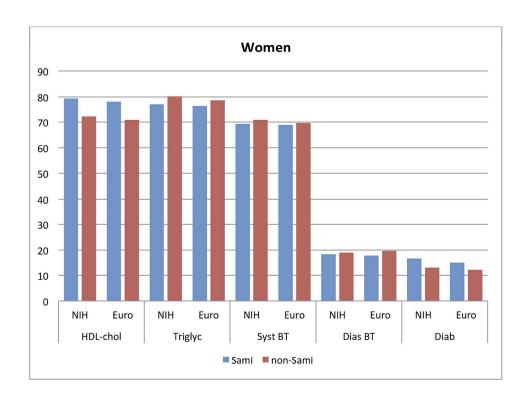
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Figure 1. Prevalence of different risk markers in participants with Mets. Men. N=2008 Euro and N=1043 NIH



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Figure 2 . Prevalence of different risk markers in participants with MetS. Women . N= 2311 Euro and N= 1679 NIH



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## STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	p 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	P 2
Introductionp 4			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	P 4
Objectives	3	State specific objectives, including any prespecified hypotheses	P 5
Methods			
Study design	4	Present key elements of study design early in the paper	P 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	p 5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	P 5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	p 6 -8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	P 6 -8
Bias	9	Describe any efforts to address potential sources of bias	P 6-8
Study size	10	Explain how the study size was arrived at	P 5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	p 8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	P 8
		(b) Describe any methods used to examine subgroups and interactions	P 8
		(c) Explain how missing data were addressed	P 8
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(e) Describe any sensitivity analyses	Not done
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility,	P 8-9 and Table 1
		confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	Not done
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential	P 8- 9 and Table 1
		confounders	
		(b) Indicate number of participants with missing data for each variable of interest	No missing data in
			the further analyzes
Outcome data	15*	Report numbers of outcome events or summary measures	Table 1 p 8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence	Table 2 p 10, table 3
		interval). Make clear which confounders were adjusted for and why they were included	p 12 fig 1 and 2 p 11
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not done
Discussion			
Key results	18	Summarise key results with reference to study objectives	P 13 - 16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and	P 16
		magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	P 14 -16
		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	P 16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	P 17
		which the present article is based	

<sup>\*</sup>Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.