SPIMEU

Determinants of Successful Implementation of Selective Prevention of Cardio-metabolic Diseases across Europe

Final report on feasibility studies

Deliverable 8.3

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Abstract

Background

Cardiovascular are considered as the first cause of morbidity and mortality globally (WHO). The SPIM EU project (http://spimeu.org/) aims in contributing to the reduction of cardio-metabolic morbidity and mortality in EU Member States by implementing innovative evidence based on selective prevention actions in general practice in five EU Member States representing various health care systems.

Aim

The overall aim of the study is to test the feasibility of implementing the first steps of tailored selective prevention programs, in five EU Member States (SWE, DNK, CZE, NLD, GRE).

Methods

This is a feasibility study within the framework of the SPIMEU project with primary objective to identify factors that hamper or favor the implementation of the initial steps (i.e. identification, invitation and risk profiling of eligible persons) of a selective prevention program in specific primary care settings in five EU Member States representing different health care systems. The design is tailored to each of the primary care settings in the five EU Member States (SWE, DNK, CZE, NLD, GRE). A generic methodology was applied in all five EU Member States (the 'core method') and some aspects of the methodology were customized to each setting in the respective Member State (the 'tailored method'). Ethical approval was essential and obtained from ethical committees within the five countries.

Results

Two hundred eligible individuals were identified and invited to participate in the selective prevention program in each country. The majority (65% to 100%) of participants accepted to complete the risk-assessment profile in all countries. This selective prevention program managed to identify in some extent (7% to 22%) healthy individuals who were at high-risk for CVD in all participating countries with exception of Sweden.

Most participants identified this prevention program as feasible and useful, while they stated that they were willing to try to change their life-style towards a healthier one. In parallel, participating GPs stated that they recognized such prevention programs as a legitimate part of their job and that they would continue to support this project.

Conclusion

The findings of the feasibility studies leaded to the formulation of certain recommendations regarding the acceptability and efficiency of selective prevention programs in different health care systems. The outcomes of this study provided input for the toolbox (WP2) of possible measures to tailor the implementation of selective prevention actions in all EU Member States taking their respective social, cultural, political and health care system contexts into account.

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FIRST PART: GENERAL PROTOCOL DESIGN

Introduction

Background and rationale

Cardiovascular diseases caused more than 17, 7 million deaths worldwide in 2015 and they are considered as the first cause of morbidity and mortality globally (WHO). Furthermore, the guideline on cardiovascular risk management of the European Society of Cardiology states that "*GPs have a unique role in identifying individuals at risk of, but without established CVD, and assessing their eligibility for intervention*" (Piepoli et al, 2016). Selective prevention aims to identify high-risk individuals in order to provide preventive actions for them.

The SPIM EU project aimed in "*contributing to the reduction of cardio-metabolic morbidity and mortality in EU Member States by establishing the feasibility of implementing innovative evidence based selective prevention actions in general practice in five EU Member States representing various health care systems*" (http://spimeu.org/). Also, SPIMEU project intended to contribute to "*the implementation of an innovative approach to identify persons-at-high-risk for cardio-metabolic diseases by establishing its feasibility in different EU Member States with their typical health care systems*" (http://spimeu.org/). In order to facilitate this aim, selective prevention was selected serve as the most suitable option. By the end of the project, the consortium aimed to provide a toolbox for tailoring selective prevention actions that could be implemented in all EU Member States (please, find further information in D2.4).

For the needs of WP8 and in context of the study in the five participating countries of the project, quantitative data were collected. Two separate questionnaires (one for invited clients/patients and one for GPs) were created. Thus, two separate online forms were formed for each country (see image below).

This deliverable conveys three sections; the first part reports the introduction, aim and research questions that guided the design and implementation the feasibility studies in five participating countries. The second part conveys the specification for

the methodology that each participating country followed as well as references of the REDCAP online platform that was used for online data entry (https://redcap.med.auth.gr/ & https://www.project-redcap.org/). The third part reports the results of the feasibility studies. The results presentations follows the research questions and the outcomes that are presented in the "Methods" section, which makes the report easier to read and follow. Also, in the final part of the report the recommendation for the methodology and the health policy maker are included. Finally, in the appendix section all questionnaires, consent forms and copies of the bioethical approval that was retrieved in each country are included.

Aim

WP8 aimed in testing the feasibility of the implementation of the first steps of a selective prevention program, namely the identification, invitation and completed the risk assessment of eligible persons. The implementation was be based on above-mentioned principles, but tailored to the context of primary care in the countries represented in the SPIMEU project (the Czech Republic, Denmark, Greece, Sweden & the Netherlands).

Thus, the overall aim of the study was to test the feasibility of implementing the first steps of tailored selective prevention programs, (designed on the basis of the WP7 guiding principle) in five EU Member States (SWE, DNK, CZE, NLD, GRE).

The research questions that guided the feasibility study were meant to explore the acceptability and practicality of the identification, invitation and risk profiling of eligible persons as first steps of a selective prevention program, and more specifically:

1. How many of the invited participants accepted participation in the selective prevention program, and what were their characteristics?
2. How many of those who accepted participation completed the risk profile assessment and what was their risk profile?
3. To what extent did *participants* consider the first steps of the program as feasible, useful and relevant for their health status, do they intend to undertake risk-reducing actions and what barriers do they experience in understanding such actions?

4. To what extent did *primary care professionals* consider the program as feasible, useful and relevant, and what changes would they propose, if any, for a successful customised implementation?

Methods

Study design

The feasibility study within the framework of the SPIMEU project aims in identifying factors that hamper or favor the implementation of the initial steps (i.e. identification, invitation and risk profiling of eligible persons) of a selective prevention program in specific primary care settings in five EU Member States representing different health care systems. A distinction will be made in the Methods section between the generic methodology which will be applied identically in all five EU Member States (the 'core method') and aspects of the methods which can be customized to the setting in the respective Member State ('tailored method').

Study setting and sampling

Core method

Setting: general practice

Eligible participants: persons listed in (or regularly attending) a participating practice, aged 40-65 years without any known cardiometabolic disease or condition according to their medical record (hypertension, cardiovascular disease, diabetes mellitus, chronic renal disease, hypercholesterolemia).

Procedure to identify cardiometabolic risks

Core method

The following elements are the sequential steps that will be evaluated. It is expected that only a subgroup of the persons will flow to each subsequent step.

- Personal invitation of 200 eligible persons per country for participation (step A).

- Completing a risk assessment according to a validated tool based on the ESC guideline for cardiovascular risk management or a national guideline, endorsed by a relevant national society or authority (step B).
- Evaluation of the the cardiometabolic risk of the patient in his/her general health status (step C).

Tailored method

- Size and number of participating general practices.
- Method of approaching eligible persons.
- Age range of eligible persons may be different (but must include 40-65 year olds).
- Selection of a validated risk assessment tool and performance of measurements accordingly.
- Ways of communication with the invited persons for performing measurements and discussing the results of the risk assessment (e.g. invitation for a consultation or telephone call, GP or practice nurse, etc.).

Outcome measures and measurements

Core methods

Primary outcome measures of this feasibility study will be:

a) The number of invited eligible participants who participate in the selective prevention program;
b) The average time per person whose risk assessment has been completed needed for the implementation of the selective prevention program in the practice. The amount of time they spend on: (1) selecting eligible patients, (2) inviting them, (3) performing additional tests or answering questions of patients due to this feasibility study. This will be the ‘denominator’, the numerator will be the number of persons who have completed the risk assessment. The amount of time used for CVD risk assessment is not part of the calculation of average time.
c) The extent to which participants who completed the risk assessment considered it useful and relevant for their health status, whether they are

willing to undertake any risk-reduction actions to modify their lifestyle (according to their risk assessment results), and the barriers they experienced in order to modify their lifestyle into a healthier one. To measure this outcome semi-closed questions on which patients can express their opinion will be used". (see Appendix 2).

d) The extent to which the implementation of such a selective prevention program is feasible, practical and acceptable according to primary care professionals.

Specification of outcome measures

- Proportion of invited persons who respond positively to the invitation for participation; this will be calculated on the basis of a careful administration in the participating practices;
- Proportion of participating persons whose risk assessment is completed (i.e. whose risk score can be calculated) and their risk score. The results and the scores will be calculated on the basis of a careful administration in the participating practices;
- Opinions of participating persons regarding the feasibility of the program and their willingness to decrease their cardiometabolic risk (if applicable); this will be measured by a written questionnaire to be completed at the moment of being invited (see below);
- Opinions of primary care professionals regarding the feasibility of the program; specifically they will be asked if consider it as an important element, to elicit their preference on integration and state their opinion on short- and long-term implementation. A written questionnaire would be used for that purpose. (see below).

Participant questionnaire (see also appendix 1)

All persons who are being invited to participate received, together with the invitation, a questionnaire/instrument to be completed. This questionnaire is meant to collect information on:

- demographic characteristics of participants (age, sex, education);

- life-style behaviors: smoking, physical exercise, diet factors, BMI, alcohol consumption;
- the acceptability of being invited for establishing a health-risk profile, as well as the experiences from its content and methods;
- the willingness to decrease their risk (if applicable) by changing their risk behavior.

As much as possible, items from validated surveys will be chosen, such as ESS (European Social Survey - http://www.europeansocialsurvey.org), translated to the national language (please, see the full report about the database in D8.2).

Primary care professionals' questionnaire

The questionnaire for primary care professionals explored the extent to which the procedure to identify persons at high risk for a cardiometabolic disease can be performed in terms of resources, time, and commitment. Questions for professionals regarding the feasibility of implementing the selective prevention program in their daily practice, the time allocated to implement the program, the disciplines involved, and whether they consider the program as an important element of their services will be included. Practicality also, was assessed by evaluating the extent of missing data. In each participating practice the health care professional who was most involved with the implementation of the program (the contact person or 'key performer') was asked to complete this questionnaire after completion of the study activities in the respective practices. NOMAD questionnaire (Finch et., al, 2015) (please, see the full report about the database in D8.2).

SECOND PART: Specification for the implementation for each partner country

Netherlands

A total of 200 patients from 5 general practices were invited, 40 patients per practice. The patients were between 45-65 years old without (treatment for) cardiometabolic diseases. The selection was a random selection per practice.

The Dutch team used a 2-step approach. All invited patients received the questionnaire containing questions to number 29 (see appendix 1).

The last part of the questionnaire sent to all patients contained the question whether they would want to participate in a health check. If yes, they were asked to complete the risk score test. After completing the risk score test, patients were asked to return the questionnaire and the risk score test by the provided envelope. If the calculates risk score was above 30 (men) or 35 (women), patients were advised to make an appointment with their GP for a complete risk assessment.

Patients that made an appointment for this complete risk assessment obtained a second questionnaire containing the remaining questions (regarding willingness to change and relevance). The patient received an envelope to return the questionnaire. The GP completed also a small questionnaire about this consult.

The risk score test is the one included in the Dutch Guideline "Prevention Consultation Cardiometabolic Risk", thereby already used in the Netherlands and familiar for GPs.

Czech Republic

A total of 200 patients from 10 general practices/ GPs were invited, 20 patients per practice/per one GP. The study took place in Prague region and in Central Bohemian region (five practices/GPs in each region). The patients were between 40-65 years old without (treatment for) cardiometabolic condition according to their medical records. (i.e. persons without treated hypertension or hypercholesterolemia, cardiovascular disease, diabetes mellitus, chronic renal disease). Eligible patients were invited personally by GPs during routine visits. Each GP included 20 patients. The first part of the questionnaire was presented personally by a GP or GP nurse. After the first

part, patients had the option of deciding whether to continue with performing measurements and discuss the results of the risk assessment. If yes: blood pressure, height, weight and waist circumference were measured followed by risk assessment using SCORE chart. After a discussion about a healthy lifestyle, the participants were given the second part of the questionnaire.

The validated risk assessment, which was used is the "SCORE Chart: 2016 ESC/EAS Guidelines for the Management of Dyslipidaemias".

Denmark

We recruited two GPs from two clinics – one in Odense and one in Copenhagen. We then invited 200 patients (100 from each of the GPs' patient lists) to participate. Our eligibility criteria for invitation to the study excluded patients who had been diagnosed with a cardiometabolic disease and/or were not between 40 and 65 years old. Of the original sample of 200 patients, 62 patients (31%) agreed to participate.

We mailed hard copy invitations, consent forms, and risk assessment materials, as well as pre-paid return envelopes to patients. The invitation informed prospective participants of the nature of the study, including the inherent possibility of participating in a health check at their GP. The risk assessment included all items up to question 29. If participants agreed to participate, they followed the instructions in the invitation and filled out the consent form and risk assessment questionnaire, and mailed it back to us.

We then assessed each participating patient's risk of cardiometabolic disease based on validated algorithms. Health profiles based on these risk assessments were then generated and mailed back to each participant. Those participants who scored above a certain threshold were prompted to make an appointment with their GP for a health check. Those who scored below the threshold were informed that their participation in the study was complete.

Those participants who were deemed to be at risk and who made an appointment for a health check were given the rest of the patient questionnaire (tapping willingness to change and relevance of the intervention) by their GP to fill out and send back to us after their appointment. Similarly, the GPs were asked to fill out AUDITs after each patient health check.

Greece

The study took place in the Prefecture of Heraklion, one of the four districts of the region of Crete. The UoC research team recruited three different general practices (two in an urban setting and one in rural area). The data collection took place the Municipality of Heraklion (urban area) and the Municipality of Gortina (rural area) from December 2017 to February 2018. A total of 3 GPs participated. The Heraklion district, has 304.270 inhabitants (150.810 men and 153.460 women) (NSSG, 2011). The Municipality of Heraklion has 173.450 inhabitants (85.210 men and 88.240 women) and the Municipality of Gortina has 15.632 inhabitants. (NSSG, 2011).

A written inform consent was be provided to all participants. The UoC research team provided all information about the developed online database for the data collection process. We invited 200 patients that were listed (or regularly attending) in the participating general practices, aged 40-65 years without any known cardiometabolic disease or condition, according to their medical records (hypertension, cardiovascular disease, diabetes mellitus, chronic renal disease, hypercholesterolemia).

The validated risk assessment tool was implemented entitled: “SCORE Chart: 2016 ESC/EAS Guidelines for the Management of Dyslipidaemias” (Eur Heart J. 2016; see appendix 2) and the performance evaluation was be conducted based on “NOMAD measurement instrument” (Finch et. al., 2015).

Sweden

Two hundred patients 40-65 years old, listed on one health care center in Stockholm county, Stuvsta vårdcentral, were invited by letter to participate. They had not been at the care center for at least 18 months, to exclude all treated for CVD or diabetes, as we are not allowed to read patients records without patient consent for research purposes in Sweden.

Patients were sent an invitation letter and the questionnaire before the screening along with information regarding telephone hours to book an appointment at the health care center. Despite given specific telephone hours, the phone was answered at all hours to maximize participation. During the phone call the participants booked an appointment for the screening, were asked to come to the health care center at least one day before their appointment for glucose and total cholesterol tests and received information how

to prepare for the test. Furthermore, they were reminded to sign the consent form and fill in the questionnaire and bring them along for the screening appointment.

During the screening (or health dialog) it was made sure that the participants had signed the consent form and answered the questionnaire. Blood pressure, height, weight and waist circumference were measured followed by showing the participants their test results and SCORE (http://www.lakartidningen.se/Klinik-och-vetenskap/Rapport/2017/04/Nya-SCORE-visar-fa-med-hog-risk-att-do-i-hjartinfarkt-eller-stroke/). After a discussion about a healthy lifestyle, the participants were given the second part of the questionnaire.

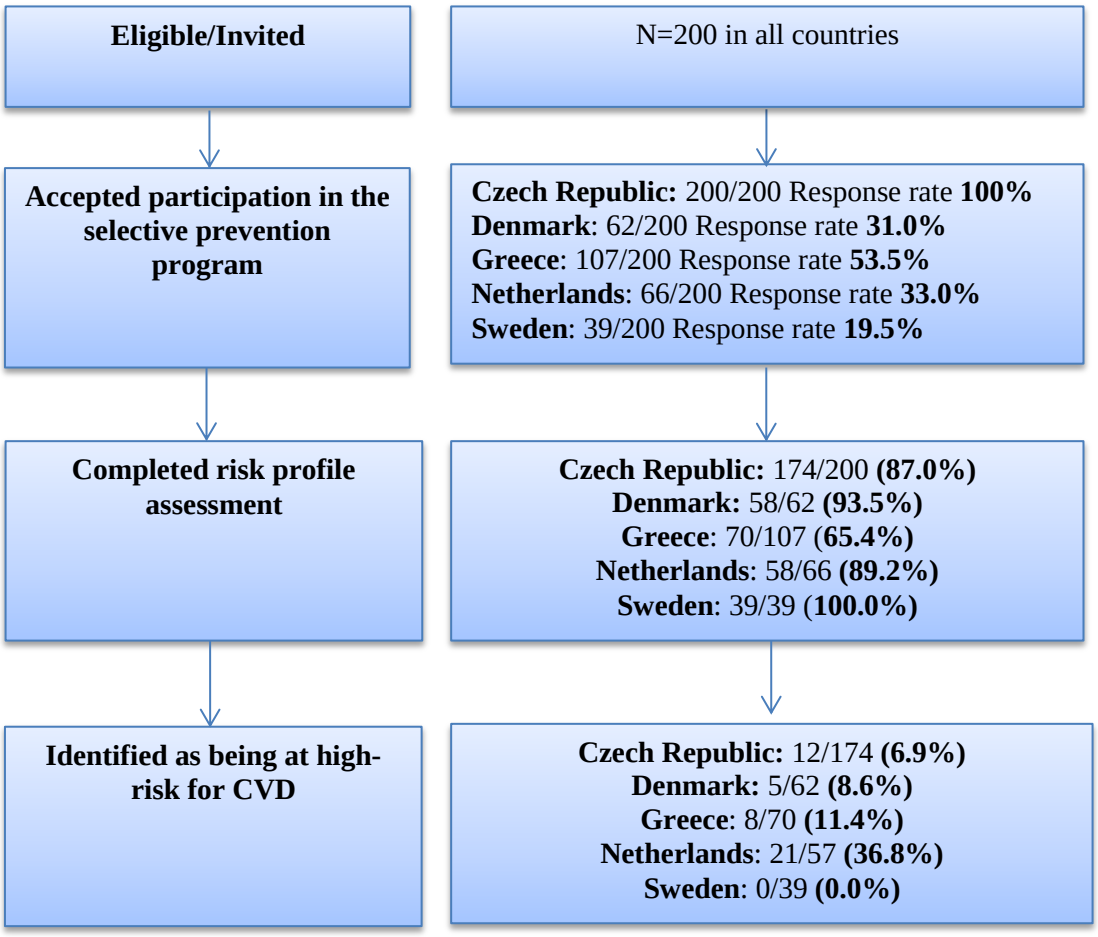
THIRD PART: Results

1. Participants and their main characteristics

i. Recruitment and participation rates

Two hundred eligible individuals were identified and invited to participate in the selective prevention program in each country. In the Czech Republic all 200 of invited persons accepted participation (response rate of 100%). In Denmark 62 of the 200 invited individuals accepted participation (response rate of 31 %), in Greece 107 of the 200 invited individuals accepted participation in the program (response rate 54 %), in the Netherlands 66 out of the 200 individuals accepted participation (response rate 33 %) and finally in Sweden 39 out of the 200 invited individuals accepted participation (response rate 20 %). Details of this process can be found in the **Flowchart** of the study.

Flowchart diagram of the Study



ii. Main characteristics of participants

The basic demographic characteristics of participants are summarized in Table 1. In all participating countries besides Denmark the majority of participants were females. The mean age of participants was 50.0 (± 8.8) years in the Czech Republic, 55.5 (± 6.3) years in Denmark, 52.7 (± 8.5) years in Greece, 54 (± 10.3) years in the Netherlands and 51.1 (± 6.3) years in Sweden.

In all participating countries the majority of participants were married with a median number of housemates of two (in Denmark and in the Netherlands) or three (in the Czech Republic, Greece and in Sweden). As regards the level of education in all countries except Greece most participants had attended either college or university while in Greece the majority of participants had completed a secondary education.

In all countries most participants were currently working either full-time or part-time and had a health insurance or were fully covered by the public health system of their country. Finally in all participating countries except Greece most participants stated that their income was correspondingly or higher compared to their country's average. In Greece the majority stated that their income was below country's average.

Table 1. Basic demographic characteristics of participants per country

Country	**Czech Rep.**	**Denmark**	**Greece**	**Netherlands**	**Sweden**
	n=200	n=62	n=107	n=66	n=39
Gender (n,%)					
Female	121 (60.5%)	29 (46.8%)	34 (59.8%)	36 (54.5%)	24 (69.2%)
Male	79 (39.5%)	33 (53.2%)	43 (40.2%)	30 (45.5%)	12 (30.8%)
Age (years)					
Mean (SD)	50.0 (8.8)	55.5 (6.3)	52.7 (8.5)	54.0 (10.3)	51.1 (6.3)
Marital status (n,%)					
Married/live in partner	142 (72.8%)	44 (71.0%)	85 (79.4%)	47 (71.2%)	33 (84.6%)
Divorced	32 (16.4%)	7 (11.3%)	7 (6.5%)	9 (13.6%)	4 (10.3%)
Single, never married	16 (8.2%)	10 (16.1%)	6 (5.6%)	9 (13.6%)	1 (2.6%)
Widowed	5 (2.6%)	1 (1.6%)	9 (8.4%)	1 (1.5%)	1 (2.6%)

Number of housemates					
Median (min, max; IQR)	3 (0,6;2)	2 (0,5;1)	3 (1,6;2)	2 (1,5;2)	3 (1,6;2)
Number of children in the household					
Median (min, max; IQR)	1 (0,4;2)	0 (0,3;2)	1 (0,4;2)	1 (0,3;2)	1 (0,4;1)
Highest educational level achieved (n,%)					
None	0 (0.0%)	0 (0.0%)	5 (4.7%)	0 (0.0%)	0 (0.0%)
Primary	1 (0.5%)	1 (1.9%)	19 (17.8%)	1 (1.5%)	0 (0.0%)
Secondary	34 (17.2%)	8 (14.8%)	52 (48.6%)	12 (18.2%)	0 (0.0%)
College/university	163 (82.3%)	45 (83.4%)	31 (29.0%)	53 (80.3%)	39 (100.0%)
Years of full-time education					
Mean (SD)	14.3 (2.9)	17.5 (4.9)	11.4 (4.5)	14.5 (4.7)	15.0 (3.3)
Work status (last 7 days) (n,%)					
Working full-time	131 (65.5%)	37 (59.7%)	62 (57.9%)	32 (48.5%)	36 (92.3%)
Working part-time	30 (15.0%)	11 (17.7%)	22 (20.6%)	17 (25.8%)	2 (5.1%)
Pensioner	11 (5.5%)	8 (12.9%)	9 (8.4%)	12 (18.2%)	1 (2.6%)
Unemployed	4 (2.0%)	4 (6.5%)	14 (13.1%)	3 (4.5%)	0 (0.0%)
Disabled	24 (12.0%)	2 (3.2%)	0 (0.0%)	2 (3.0%)	0 (0.0%)
Do you have health insurance? (n,%)					
Yes	192 (96.0%)	26 (41.9)	84 (79.2%)	66 (100.0%)	27 (69.2%)
No	3 (1.5%)	4 (6.5%)	21 (19.8%)	0 (0.0%)	7 (17.9%)
Not applicable/fully covered by public health	5 (2.5%)	32 (51.6%)	1 (0.9%)	0 (0.0%)	5 (12.8%)
How would you describe your income compared to your country's average (n, %)					
Lower	44 (22.0%)	21 (34.4%)	67 (62.6%)	5 (7.7%)	3 (7.7%)

Correspondingly	61 (30.7%)	22 (36.1%)	23 (21.5%)	35 (53.8%)	8 (20.5%)
Higher	84 (42.2%)	17 (27.9%)	0 (0.0%)	24 (36.9%)	24 (61.5%)
Don't know	10 (5.0%)	1 (1.6%)	17 (15.9%)	1 (1.5%)	4 (10.3%)

2. Participation in the risk assessment and risk profile

i. Participation in the risk-assessment

In the Czech Republic 87.0% of those who accepted participation completed the risk profile assessment, in Denmark this rate was 94 %, in Greece was 65 %, in the Netherlands 89 % and finally in Sweden all who accepted participation completed the risk profile assessment (100.0%). Details of this process can be found in the **Flowchart** of the study.

ii. Risk profile of participants

a. Physical activity

Details regarding the physical activity of respondents can be found in the Table 2 below. In the Czech Republic about 15% of participants were classified have a sedentary life-style, in Denmark this figure was 8%, in Greece 20%, in the Netherlands 12% and in Sweden 10%. Roughly one out of four participants were classified as under-active in the Czech Republic, Denmark, the Netherlands and in Sweden, while in Greece that figure was double where almost half participants (48%) were found to be underactive.

On the contrary, half or more of participants were classified as having an active life-style in the Czech Republic (46%), in Denmark (67%), the Netherland (60%) and in Sweden (67%), whereas in Greece the respective figures were 21%. In activities to increase muscle strength were engaged 29% of respondents in the Czech Republic, 20% in Denmark, 6% in Greece, 38% in the Netherlands and 69% in Sweden. Finally in activities to improve flexibility (such as yoga or stretching) were engaged 48% of respondents in the Czech Republic, 23% in Denmark, 9% in Greece, 62% in the Netherlands and 59% in Sweden.

Table 2. Physical activity of participants per country					
Country	**Czech Rep.**	**Denmark**	**Greece**	**Netherlands**	**Sweden**
	n=200	n=62	n=107	n=66	n=39
Sedentary (I rarely or never do any physical activities)	29 (14.7%)	5 (8.1%)	21 (19.6%)	8 (12.1%)	4 (10.3%)
Underactive (I do some light or moderate physical activities, but not every week)	62 (31.6%)	12 (25.0%)	51 (48.1%)	13 (20.0%)	10 (25.6%)
Underactive/regular-light (I do some light physical activity every week)	146 (74.1%)	38 (67.9%)	75 (70.1%)	39 (60.9%)	33 (84.6%)
Underactive/regular (I do moderate physical activities every week, but less than 30 minutes a day or 5 days a week)	91 (46.4%)	29 (52.7%)	36 (33.6%)	29 (44.6%)	22 (56.4%)
Underactive/regular (I do vigorous physical activities every week, but less than 20 minutes a day or 3 days a week)	59 (30.1%)	12 (23.5%)	10 (9.3%)	16 (24.2%)	16 (41.0%)
Active (I do 30 minutes or more a day of moderate physical activities, 5 or more days a week)	58 (29.4%)	26 (47.3%)	13 (12.1%)	28 (42.4%)	15 (38.5%)

Active I do 20 minutes or more a day of vigorous physical activities, 3 or more days a week.	33 (16.8%)	11 (20.0%)	10 (9.3%)	11 (17.5%)	11 (28.2%)
I do activities to increase **muscle strength**, such as lifting weights or calisthenics, once a week or more.	58 (29.3%)	11 (19.3%)	6 (5.6%)	25 (37.9%)	27 (69.2%)
I do activities to improve **flexibility**, such as stretching or yoga, once a week or more.	94 (47.7%)	13 (23.2%)	10 (9.4%)	17 (62.2%)	23 59. 0%)

b. Smoking and alcohol consumption

Results regarding smoking and drinking habits of participants are presented in **Table 3**. In the Czech Republic 61% of the respondents were never smokers, in Denmark this rate was 40%, in Greece 33%, in the Netherlands 56% and in Sweden 72%. The highest rates of current daily smokers was observed in Greece 43%, followed by Denmark (17%), the Czech Republic (14%), Sweden (5%) and the Netherlands (3%). Occasional smokers were 8% in Greece and Denmark, 7% in the Czech Republic, 5% in the Netherlands and none of the respondents in Sweden.

As regards alcohol consumption in Greek participants stated that they drink at a median of seven standard drinks per week, followed by participants from Denmark (four standard drinks per week), Sweden (three standard drinks per week), the Czech Republic and the Netherlands (two standard drinks per week in both countries). Furthermore, more than 10% of participants in all countries stated that they drink four/five standard drinks on a single occasion once/week or more frequent.

Table 3. Smoking and drinking habits of participants per country					
Country	**Czech Rep**	**Denmark**	**Greece**	**Netherlands**	**Sweden**
	n=200	n=62	n=107	n=66	n=39
Do you smoke tobacco?					
I have never been a tobacco smoker	122 (61.0%)	24 (40.0%)	35 (32.7%)	36 (56.3%)	28 (71.8%)
I quit over six months ago	34 (17.0%)	20 (33.3%)	16 (15.0%)	22 (34.4%)	8 (20.5%)
I quit less than six months ago	3 (1.5%)	1 (1.7%)	1 (0.9%)	1 (1.6%)	1 (2.6%)
Occasionally	13 (6.5%)	5 (8.3%)	9 (8.4%)	3 (4.7%)	0 (0.0%)
Everyday	28 (14.0%)	10 (16.7%)	46 (43.0%)	2 (3.1%)	2 (5.1%)
On average, how many standard drink per week?					
Median (min, max, IQR)	2 (0,40;6)	4 (0,60;8)	7 (0, 46;9)	2 (0,70;7)	3 (0,30;5)
How often do you have more than four (if you are female) or five (if you are male) standard drinks on a single occasion?					
Everyday or nearly everyday	4 (2.0%)	4(6.5%)	3 (2.8%)	2 (3.1%)	0(0.0%)
Once a week	29 (14.5%)	8 (12.9%)	12 (11.3%)	8 (12.5%)	4 (10.3%)
Once a month	48 (24.0%)	18 (29.0%)	11 (10.4%)	8 (12.5%)	8 (20.5%)
Rarely	86 (43.0%)	29 (46.8%)	31 (29.2%)	25 (39.1%)	24 (61.5%)
Never	33 (16.5%)	3 (4.8%)	49 (46.2%)	21 (32.8%)	3 (7.7%)

c. Dietary habits of participants

Questions regarding the dietary habits of participants are presented in **Table 4**. As regards the frequency of vegetables and/or root vegetables consumption, 82% of participants in Sweden, 80% in the Netherlands, 61% in Denmark, 44% in the Czech Republic and 12% in Greece stated that they consumed them once/day or more frequent. Regarding the frequency of fruit consumption, 71% of participants in the Netherlands, 56% of participants in Sweden, 54% of participants in the Czech Republic, 47% in Denmark and 22% in Greece stated that they consumed them once/day or more frequent. Eighty-five percent of participants in Sweden, 74% in the Netherlands, 50% in Denmark, 38% in the Czech Republic and 33% in Greece stated that they consumed a main of fish or shellfish once/week or more often. Finally, 36% of participants in the Czech Republic, 30% of participants in Greece, 17% of participants in the Netherlands, 10% of participants in Denmark and none in Sweden stated that they consumed pastries, chocolates, candy and/or soft drinks on a daily basis. The mean Body Mass Index (BMI) of participants was 26.7 (±5.7) Kg/m2 in the Czech Republic, 26.5 (±4.2) Kg/m2 in Denmark, 25.8 (±3.9) Kg/m2 in Greece, 25.2 (± 4.1) Kg/m2 in the Netherlands and 24.1 (± 3.1) Kg/m2 in Sweden. In the Czech Republic 37 (19%) participants were classified as obese, 10 (16 %) in Denmark, 16 (15%) in Greece, 4 (6%) participants in the Netherlands and 2 (5%) participants in Sweden.

Table 4. Dietary habits of participants per country

Country	**Czech Rep**	**Denmark**	**Greece**	**Netherlands**	**Sweden**
	n=200	n=62	n=107	n=66	n=39
How often do you have vegetables and/or root vegetables (fresh or frozen)?					
Once/week or less	22 (11.1%)	2 (3.2%)	32 (29.9%)	0 (0.0%)	2 (5.1%)
A few times/week	89 (44.7%)	22 (35.5%)	62 (57.9%)	13 (20.0%)	5 (12.8%)
Once/day	71 (35.7%)	25 (40.3%)	12 (11.2%)	46 (70.8%)	24 (61.5%)
Twice/day or more	17 (8.5%)	13 (21.0%)	1 (0.9%)	6 (9.2%)	8 (20.5%)
How often do you have fruit and/or					

berries (fresh, frozen, preserved, juice/smoothie)?					
Once/week or less	21 (10.5%)	9 (14.5%)	27 (25.2%)	2 (3.1%)	5 (12.8%)
A few times/week	71 (35.5%)	24 (38.7%)	57 (53.3%)	17 (26.2%)	12 (30.8%)
Once/day	83 (41.5%)	22 (35.5%)	19 (17.8%)	30 (46.2%)	15 (38.5%)
Twice/day or more	25 (12.5%)	7 (11.3%)	4 (3.7%)	16 (24.6%)	7 (17.9%)
How often do you have a main of fish or shellfish?					
A few times/month or less	123 (62.1%)	31 (50.0%)	72 (67.3%)	17 (26.2%)	6 (15.4%)
Once/week	56 (28.3%)	19 (30.6%)	26 (24.3%)	33 (50.8%)	14 (35.9%)
Twice/week	13 (6.6%)	9 (14.5%)	9 (8.4%)	12 (18.5%)	13 (33.3%)
Tree times/week or more	6 (3.0%)	3 (4.8%)	0 (0.0%)	3 (4.6%)	6 (15.4%)
How often do you have pastries, chocolate, candy, and/or soft drink?					
Once/week or less	28 (14.0%)	16 (25.8%)	21 (20.2%)	18 (27.7%)	19 (48.7%)
A few times/week	59 (29.5%)	25 (40.3%)	32 (30.8%)	27 (40.9%)	15 (38.5%)
Nearly everyday	41 (20.5%)	15 (24.2%)	20 (19.2%)	9 (13.8%)	5 (12.8%)
Everyday	72 (36.0%)	6 (9.7%)	31 (29.8%)	11 (16.9%)	0 (0.0%)

d. The risk-assessment tools

Risk assessment was performed using the Heart-SCORE instrument in the Czech Republic, Greece and Sweden, the KRAMRASK risk assessment score was used in Denmark and in the Netherlands the Prevention Consultation cardiometabolic risk instrument (PC CMR) was used. The median raw scores and the quartiles are presented in Table 5. In the Czech Republic 7% of individuals who completed the risk assessment were found to be of high risk. In Denmark this rate was 8.6%, in Greece 11.4% and in Sweden none of the participants was identified as being at high risk. In the Netherlands, 22% of participants were characterized as being at high risk according to the instrument and the cut-off scores that was applied. These results are presented in **Table 5** below.

Table 5. Analysis of the instruments for risk assessment per country					
Country	**Czech Rep***	**Denmark****	**Greece***	**Netherlands*****	**Sweden***
	n=174	n=58	n=70	n=57	n=39
Heart SCORE (European High Risk Chart)					
Median (25%-75%)	1 (0 – 2)	-	1 (0 – 3)	-	0 (0 – 1)
Participants with Heart SCORE ≥ 5%					
(n,%)	12 (6.9%)	-	8 (11.4%)	-	0 (0.0%)
KRAMRASK risk assessment score					
Median (25%-75%)	-	2 (1 – 3)	-	-	-
Danish participants at high-risk					
(n,%)	-	5 (8.6%)	-	-	-
Dutch PC CMR				-	
Median (25%-75%)	-	-	-	22.0 (13.5 – 39.5)	-
Dutch participants at high risk					
(n,%)	-	-	-	21 (36.8%)	-
* The Czech Republic, Greece and Sweden used the Heart SCORE (European High Risk Chart **Denmark used the KRAMRASK risk assessment tool ** The Netherlands used the Prevention Consultation cardiometabolic risk (PC CMR)					

3. **After the risk-assessment** *(evaluation of the feasibility, usefulness and relevance for health status, intention to undertake risk-reduction actions and barriers)*

i. Participant's assessment of the feasibility study

After the risk assessment, participants were asked to evaluate the risk assessment. All questions were responded in a 10-point Likert-scale with 1 being the negative endpoint and 10 being the positive endpoint.

Participants in the Czech Republic and in Sweden replied that this risk assessment were quite relevant to them (median score 7.2 in the Czech Republic and 7.4 in Sweden) and respondents in Greece to a fewer extent (median score 5.9).

Furthermore, this risk assessment action was evaluated as quite useful in the Czech Republic (median score 7.5) and in Greece (median score 7.3) and to a smaller extent useful in Sweden (median score 6.1). Participants in all countries assessed this action as quite or very feasible (median score 7.5 in the Czech Republic, 7.4 in Greece and 9.2 in Sweden).

Finally participants stated that this risk assessment encouraged them to pursue a healthier lifestyle (median score 7.5 in the Czech Republic, 7.6 in Greece and 6.5 in Sweden). All the above results are presented in **Table 6** below.

Table 6. Participants' assessment regarding relevance and feasibility of this selective prevention program per participating country

Country	**Czech Rep**	**Denmark ***	**Greece**	**Netherlands***	**Sweden**
	n=174	n=62	n=70	n=66	n=39
To what extent do you think that this action/ risk assessment was relevant to you? 1=not at all relevant 10= very much					
Median (25% - 75%)	7.20 (5.10 – 8.63)		5.85 (5.47 -7.70)		7.40 (5.10 – 8.00)
To what extent do you think that this action/ risk assessment was useful for your health? 1=not useful 10=very useful					
Median (25% - 75%)	7.50 (6.20 – 9.20)		7.30 (6.98 – 7.83)		6.10 (5.00 – 7.40)
To what extent do you think that this action/ risk assessment was feasible? 1=not feasible 10=very feasible					
Median (25% - 75%)	7.45 (5.10 – 7.45)		7.35 (6.98 – 7.80)		9.20 (8.20 – 9.90)
Do you think that this action/ risk assessment encouraged you to pursue a healthier					

lifestyle? 1=not encouraged 10=very encouraged					
Median (25% - 75%)	7.50 (5.00 – 8.75)		7.55 (7.10 – 7.90)		6.50 (5.10 – 8.70)
*These questions were optional and were not asked in Denmark and the Netherlands as these countries followed a 2-step approach					

ii. Willingness to change

After the risk assessment, participants were asked whether they were willing to change their life-style behavior in order to reduce their risk for cardiovascular disease and/or type-II diabetes. Most participants all countries stated that they were willing to change their life-style behavior (85% of participants in the Czech Republic, 93% of participants in Greece and 82% of participants in Sweden). Main reasons that participants were willing to change included "I think I might have a high risk for CVD/diabetes" (31% in the Czech Republic, 7% in Greece and 26% in Sweden) and "I want to be healthier" (72% in the Czech Republic, 61% in Greece and 62% in Sweden). The above results are presented in **Table 7** below.

Table 7. Participants' willingness to change lifestyle behavior and main barriers per country

Country	**Czech Rep**	**Denmark ***	**Greece**	**Netherlands***	**Sweden**
	n=174	n=62	n=70	n=66	n=39
I am willing to change your life-style behavior in order to reduce your risk for cardiovascular diseases (CVD) and/or Type-2-diabetes	147 (84.5%)		64 (92.8%)		32 (82.1%)
I am willing to change because:					
I think I might have a high risk for CVD/diabetes	51 (31.0%)		5 (7.1%)		10 (25.6%)
I want to be healthier	124 (71.3%)		43 (61.4%)		24 (61.5%)
my partner, family or friends insists to do so	14 (8.0%)		(8.6%)		0 (0.0%)
the doctor persuaded me to do so	14 (8.0%)		15 (21.4%)		0 (0.0%)
*These questions were optional and were not asked in Denmark and the Netherlands as these countries followed a 2-step approach					

iii. *Barriers experienced while undertaking risk-reduction actions*

About one out of three participants who completed the risk assessment in the Czech Republic (35%) stated that they had encountered barriers in order to start to change their lifestyle, in Greece this rate was 13% and in Sweden 15%. Some of the main barriers that were reported were the lack of time (37% in the Czech Republic and 44% in Greece), lack of budget (7% in the Czech Republic and 67% in Greece), lack of motivation (36% in the Czech Republic, 22% in Greece, 33% in Sweden) and too difficult (22% in the Czech Republic, 100% in Greece and 50% in Sweden). The above results are presented in **Table 8** below.

Table 8. Participants' main barriers to change lifestyle behavior per country

Country	**Czech Rep**	**Denmark***	**Greece**	**Netherlands***	**Sweden**
	n=174	n=62	n=70	n=66	n=39
Did you encounter any barrier in order to start to change your lifestyle into a healthier one?					
Yes (n,%)	59 (34.5%)	1 (1.7%)	9 (12.8%)		6 (15.4%)
Which barriers:					
I don't know how to start / where to begin	4/59 (6.8%)	0/1 (0.0%)	3/9 (33.3%)		1/6 (16.7%)
My family/surrounding did not support me	3/59 (5.1%)	0/1 (0.0%)	1/9 (11.1%)		0/6 (0.0%)
I don't have the budget to change my lifestyle	4/59 (6.8%)	0/1 (0.0%)	6/9 (66.6%)		0/6 (0.0%)
I don't have time to change my lifestyle	22/59 (37.3%)	0/1 (0.0%)	4/9 (44.4%)		0/6 (0.0%)
I lack the motivation to change	21/59 (35.6%)	0/1 (0.0%)	2/9 (22.2%)		2/6 (33.3%)
I tried, but it is too difficult	13/59 (22.0%)	0/1 (0.0%)	9/9 (100.0%)		3/6 (50.0%)
Other reason	0/59 (0.0%)	1/1 (100.0%)	0/9 (0.0%)		4/6 (66.7%)

*These questions were optional and were not asked in Denmark and the Netherlands as these countries followed a 2-step approach

4. Health care professional's assessment of the feasibility study

i. Assessment of the selective prevention program using the NoMAD questionnaire

Two dimensions of the NoMAD questionnaire were used; Coherence and Cognitive participation. Detailed responses per item and country can be found in **Table 9** below. As regards the items found under the Coherence dimension, most health care professionals in the Czech Republic disagreed with the statement "I can see how prevention program differs from usual ways of working", on the other hand health care professionals in Greece and Sweden agreed with the above statement. As regards the rest of the statements of the Coherence dimension, there was an agreement in all countries with the statements "Staff in this organization have a shared understanding of the purpose of prevention program", "I understand how prevention program affects the nature of my own work", and "I can see the potential value of prevention program for my work".

As regards the Cognitive participation dimension of the NoMAD questionnaire, health care professionals in the Czech Republic and in Greece somewhat agreed with the statement "There are key people who drive prevention program forward and get others involved". Finally, there was a good level of agreement in health care professionals in all participating countries with the rest of the statements of the Cognitive participation dimension namely "I believe that participating in prevention program is a legitimate part of my role", "I'm open to working with colleagues in new ways to use prevention program" and "I will continue to support prevention program".

Table 9. The NoMAD questionnaire

NoMAD questions per dimension	**Strongly Agree**	**Agree**	**Neither agree nor disagree**	**Disagree**	**Strongly disagree**
Coherence					
I can see how prevention program differs from usual ways of working	**CZ**: 0/10 **GR**: 0/3 **SW**: 1/1	**CZ**: 1/10 **GR**: 2/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 1/3 **SW**: 0/1	**CZ**: 7/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 2/10 **GR**: 0/3 **SW**: 0/1
Staff in this organization have a shared understanding of the purpose of prevention	**CZ**:3/10 **GR**: 0/3 **SW**: 1/1	**CZ**: 6/10 **GR**: 3/3	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1

program		**SW**: 0/1			
I understand how prevention program affects the nature of my own work	**CZ**: 3/10 **GR**: 1/3 **SW**: 1/1	**CZ**: 7/10 **GR**: 2/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1
I can see the potential value of prevention program for my work	**CZ**: 3/10 **GR**: 1/3 **SW**: 1/1	**CZ**: 7/10 **GR**: 2/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1
Cognitive participation					
There are key people who drive prevention program forward and get others involved	**CZ**: 1/10 **GR**: 0/3 **SW**: 1/1	**CZ**: 4/10 **GR**: 2/3 **SW**: 0/1	**CZ**: 2/10 **GR**: 1/3 **SW**: 0/1	**CZ**: 1/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1
I believe that participating in prevention program is a legitimate part of my role	**CZ**: 4/10 **GR**: 0/3 **SW**: 1/1	**CZ**: 6/10 **GR**: 3/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1
I'm open to working with colleagues in new ways to use prevention program	**CZ**: 3/10 **GR**: 0/3 **SW**: 1/1	**CZ**: 7/10 **GR**: 3/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1
I will continue to support prevention program	**CZ**: 3/10 **GR**: 0/3 **SW**: 1/1	**CZ**: 7/10 **GR**: 3/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1	**CZ**: 0/10 **GR**: 0/3 **SW**: 0/1
CZ: Czech Republic, GR: Greece, SW: Sweden					

ii. Barriers encountered during implementation/use of this program in practice

In the Czech Republic eight out of ten health care professionals identified barrier during the implementation of the program. Most commonly reported barriers were lack of time (8/10), not enough remuneration (3/10), discrepancies in the recommendation and/or guidelines (3/10), not clear which professional is responsible for implementation (3/10), no support from government/policy (3/10) and staff shortage (2/10). In Greece all three health care professionals reported barriers during implementation of the program. Most commonly reported barriers included lack of time (3/3), staff shortage (2/3), not effective in their opinion as general practitioners (1/3) and no support from the (practice) management (1/3). In Sweden the health care professional reported not encountering any barriers during implementation.

Health care professionals were asked why not using this risk assessment in practice. In the Czech Republic most health care professionals reported not using this risk

assessment in practice due to lack of time (5/10), due to staff shortage (1/10), due to not enough remuneration available (1/10) and due not having the support from the practice management (1/10). In Greece all three GPs reported not using this risk assessment due to lack of time, one due to staff shortage and one due to the fact that there was no remuneration available at all. In Sweden the health care professional reported not using this risk assessment in practice due to the fact that she is a nutritionist.

5. Additional information about the risk-assessment program

i. Time required for identification and invitation

In the Czech Republic a total of ten (10) GPs participated in the selective prevention program. A median of two (2) (minimum one; maximum three) persons were involved in the process of identification and invitation of eligible participants. Four GPs stated that it took a few hours in order to identify and invite the eligible participants, three GPs stated that it took some days in order to complete this process and three GPs stated that it was a matter of a few minutes.

In Greece three GPs participated in the selective prevention program. Two of them sent invitations upon checking the eligibility criteria based on the electronic health records of their subscribed patients and the other GP based on consecutive visitors on his setting. The first GP stated that it required the effort of two persons for forty minutes in order to identify the eligible participants, the second GP stated that it required a total of ten (10) days in order to identify and invite the eligible participants and the other GP stated that it took five minutes per consecutive visitor in order to perform the required check for eligibility and make the invitation.

In Sweden a total of two persons participated in the process of identification and invitation of eligible participants and the total time that was required for that process was two days.

ii. Time required for risk assessment

In the Czech Republic each risk assessment lasted on average 12.0 (± 4.5) minutes, in Denmark 10.6 (± 6.1) minutes, in Greece 15.6 (± 5.2) minutes and in Sweden 12.6 (± 5.9) minutes.

Discussion

i. Summary of main findings

The majority (65% to 100%) of those who participated in the selective prevention program accepted to complete the risk-assessment in all countries. This selective feasibility prevention program has also managed to identify in some extent (7% to 22%) percentage of healthy individuals who were at high-risk for CVD in all participating countries with exception of Sweden.

Most participants identified this prevention program as feasible and useful, while they stated that they were willing to try to change their life-style towards a healthier one. In parallel to this, participating GPs stated that they recognized such prevention programs as a legitimate part of their job and that they would continue to support this project.

ii. Limitations

This was a feasibility study thus having all the limitation of such study-designs. Due to the fact that participating countries had different PHC systems, this study had a core design which all countries followed yet each country followed its' tailored method of recruitment, invitation and instrument for identification of participants as being at high-risk for CVD. To this end, a direct comparison of results between participating countries is not recommended.

Recommendations

The findings of the feasibility studies that were implemented in the five EU Member States, can lead to the formulation of certain recommendations regarding the acceptability and efficiency of selective prevention programs in different health care systems. These recommendations could have input for creating a toolbox for implementing selective prevention programs (see WP2).

Recommendations relevant to the implementation of selective prevention programs (issues on methodology)

- The implementation of effective selective CMD-prevention should include a validated risk assessment tool for CMD;
- A selective CMD-prevention program that uses a validated risk assessment tool seems to be important when it is implemented in the age group of 40 to 65 years old. It manages to identify a portion of 10% (or greater) of otherwise healthy individuals as having a high risk in the Netherlands, Greece, Denmark and the Czech Republic;
- During a consultation in primary care, a personalized intervention plan in the framework of a selective prevention program, should be initiated based on the individual initial risk profile and the intervention should follow afterwards;
- In a selective CMD-prevention program implemented in the primary care setting with the involvement of GPs seems to be the most effective way of approach;
- The optimal time for the patients to complete the program, including the initial risk assessment and intervention seems to be 15 minutes;
- The implementation of selective CMD-prevention program should include approaches to change the lifestyle behavior of the patient within the daily practice without any additional financial cost.

Recommendations relevant to the implementation of selective prevention programs (issues on health care policy)

Specifications that should be undertaken by the health policy makers include the following:

- The implementation of a selective CMD-prevention programme in primary care that would be considered on a national level with the support of central and regional authorities.
- Cost for selective CMD prevention should be centrally allocated and coordinated by the national government.
- During the implementation of effective selective CMD-prevention, additional support to a multidisciplinary health care team in primary care should be provided in national level.
- A successful implementation of a selective CMD-prevention should include training of a multidisciplinary health care team in primary care by using a validated risk assessment tool with GPs having a leading role.

Ethical considerations

Obtaining Approval from ethical committees will be essential within the five countries. Ethical approval has to be sought as required by national and European law, and is required by many scientific journals. We plan to follow published guidelines for reporting of survey research (Kelley 2003; Bennett et al., 2011). The copies of the approvals from the ethical committees are in Appendix 5.

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Appendixes

Appendix 1a. Client/patient 's questionnaire

Part 1. Sociodemographic data

1. What is your sex?
   Male ❑
   Female ❑

2. Please write down you exact age?

   ..... years old

3. What is your height?

   ..... centimeters

4. How much do you weight?

   ..... kilograms

5. Including yourself, how many people – including children – live here regularly as members of this household at this moment?

   ..... persons

6. Thinking about the people other than yourself who live in your house, what is your relationship with them?

   Spouse/partner ❑ Yes
   ❑ No

   Number of children .....

   Number of others (besides children, spouse/partner).....……

   Please specify relationship.....

7. What is your current marital status?
   a. Married/live-in partner ❑
   b. Divorced ❑
   c. Single, never married ❑
   d. Widowed ❑

8. In which country was your father born? ....

9. In which country was your mother born? .....

10. About how many years of fulltime education have you completed?

Number of years: .....

11. And what is the highest educational level that you completed?

a. No education ❑
b. Primary school ❑
c. Secondary school (up to 16 year old) ❑
d. College ❑
e. University ❑

12. What is your most recent occupation? (For example "Plumber")

.....

13. Which of these descriptions applies most to what you have been doing for the last 7 days?

a. Working full time ❑
b. Working part- time ❑
c. Pensioner ❑
d. Unemployed ❑
e. Disabled ❑

14. Do you have health insurance?

a. Yes ❑
b. No ❑
c. Not applicable (fully covered by public health) ❑

15. How would you describe your income compared to your country's average?

a. Lower ❑
b. Correspondingly ❑
c. Higher ❑
d. Don't know ❑

16. Do you have any one or more of the following diseases or conditions?

	Yes	No
a. High blood pressure?	❑	❑
b. High cholesterol?	❑	❑
c. Angina?	❑	❑
d. Heart attack (myocardial infarction)?	❑	❑
e. Coronary surgery / PTCA (Percutaneous Transluminal Angioplasty)?	❑	❑

f. Heart failure?	❑	❑
g. Transient ischaemic attack (TIA)?	❑	❑
h. Stroke?	❑	❑
i. Depression?	❑	❑

17. Does any member of your family have any one or more of the following diseases or conditions?

	Yes	No
a. High blood pressure?	❑	❑
b. High cholesterol?	❑	❑
c. Angina?	❑	❑
d. Heart attack (myocardial infarction)?	❑	❑
e. Coronary surgery / PTCA (Percutaneous Transluminal Angioplasty)?	❑	❑
f. Heart failure?	❑	❑
g. Transient ischaemic attack (TIA)?	❑	❑
h. Stroke?	❑	❑
i. Depression?	❑	❑

18. Did or do any of your parents, brothers or sisters suffer from a cardiovascular disease (for example a myocardial infarction, stroke, TIA, heart failure) before the age of 60? *Please tick <u>one</u> answer*

❑ Yes
❑ No

Part 2. Physical activity

Physical Activities are activities where you move and increase your heart rate above its resting rate, whether you do them for pleasure, work, or transportation.

The following questions ask about the amount and intensity of physical activity you usually do. The intensity of the activity is related to the amount of energy you use to do these activities.

Examples of physical activity intensity levels:

<table>
<tr>
<td>Light activities
• your heart beats slightly faster than normal
• you can talk and sing</td>
<td> </td>
</tr>
<tr>
<td>Moderate activities
• your heart beats faster than normal
• you can talk but not sing</td>
<td> Fast Walking
 Aerobics Class
 Strength Training
 Swimming Gently</td>
</tr>
<tr>
<td>Vigorous activities
• your heart rate increases a lot
• you can’t talk or your talking is broken up by large breaths</td>
<td> Stair Machine
 Jogging or Running
 Tennis, Racquetball, Pickleball or Badminton</td>
</tr>
</table>

19. **How physically active are you?** *(Check one answer on each line)*

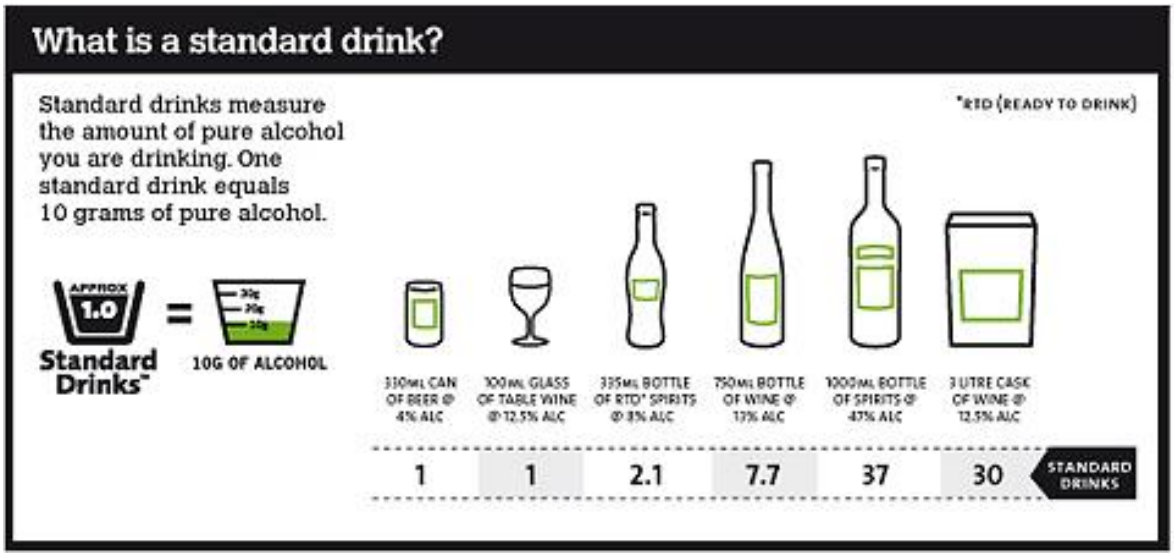
		Does this accurately describe you?	
		Yes	No
1	- I rarely or never do any physical activities.	❑	❑
2	- I do some **light** or **moderate** physical activities, but not every week.	❑	❑
3	- I do some **light** physical activity every week.	❑	❑
4	- I do **moderate** physical activities every week, but less than 30 minutes a day or 5 days a week.	❑	❑
5	- I do **vigorous** physical activities every week, but less than 20 minutes a day or 3 days a week.	❑	❑
6	- I do 30 minutes or more a day of **moderate** physical activities, 5 or more days a week.	❑	❑
7	- I do 20 minutes or more a day of **vigorous** physical activities, 3 or more days a week.	❑	❑
8	- I do activities to increase muscle **strength**, such as lifting weights or calisthenics, once a week or more.	❑	❑
9	- I do activities to improve **flexibility**, such as stretching or yoga, once a week or more.	❑	❑

Part 3. Patient's health risk assessment

20. Generally speaking, how would you define your health?
- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Not so good
- ☐ Poor

21. Do you smoke tobacco?
- ☐ Every day
- ☐ Occasionally
- ☐ I quit less than six months ago
- ☐ I quit over six months ago
- ☐ I have never been a tobacco smoker.

22. On average, how many standard drinks do you have per week?



Number of standard drinks per | | | week

23. How often do you have more than four (if you are female) or five (if you are male) standard drinks on a single occasion?
- ☐ Every day or nearly every day
- ☐ Once a week
- ☐ Once a month
- ☐ Rarely
- ☐ Never

24. How often do you have vegetables and/or root vegetables (fresh or frozen)?
- ☐ Twice a day or more
- ☐ Once a day
- ☐ A few times a week

- ☐ Once a week or less

25. How often do you have fruit and/or berries (fresh, frozen, preserved, juice/smoothie)?
    - ☐ Twice a day or more
    - ☐ Once a day
    - ☐ A few times a week
    - ☐ Once a week or less

26. How often do you have a main of fish or shellfish?
    - ☐ Three times a week or more
    - ☐ Twice a week
    - ☐ Once a week
    - ☐ A few times a month or less

27. How often do you have pastries, chocolate, candy, and/or soft drink?
    - ☐ Every day
    - ☐ Nearly every day
    - ☐ A few times a week
    - ☐ Once a week or less

28. Over the past year, how would you describe your level of physical activity in your spare time?
    - ☐ I work out and participate in competitive sports on a regular basis, several times a week.
    - ☐ I do sports and/or laborsome yard work at least three hours a week.
    - ☐ I walk, bicycle, or do other physical activity at least four hours a week (construction, housework, table tennis, bowling).
    - ☐ I usually spend most of my spare time engaging in sedentary activities such as reading, watching TV, going to the movies, etc.

29. Is there anyone in your immediate family under 70 years old who currently has, or have had (before they turned 70) any of the following conditions?

    - ☐ High blood pressure
    - ☐ High cholesterol
    - ☐ Heart attack
    - ☐ Stroke
    - ☐ Blood clot in lungs or legs
    - ☐ Type 1 diabetes
    - ☐ Type 2 diabetes

30. **Optional additional questions on patients' risk assessment:**

	Question	Yes	No
30.1	Are you a non-smoker?	❑	❑
30.2	Do you drink between one alcoholic drink/month and three alcoholic drinks/day?	❑	❑
30.3	Do you participate in moderate or intense physical	❑	❑

	activity once a week or more?		
30.4	Do you eat processed meats as a main meal more seldom than once a week?	❑	❑
30.5	Do you eat fish at least once every week?	❑	❑
30.6	Do you eat fruit every day?	❑	❑
30.7	Do you eat vegetables every day?	❑	❑

Part 4. Participation in a preventive health check for cardiovascular diseases (CVD) and/or diabetes.

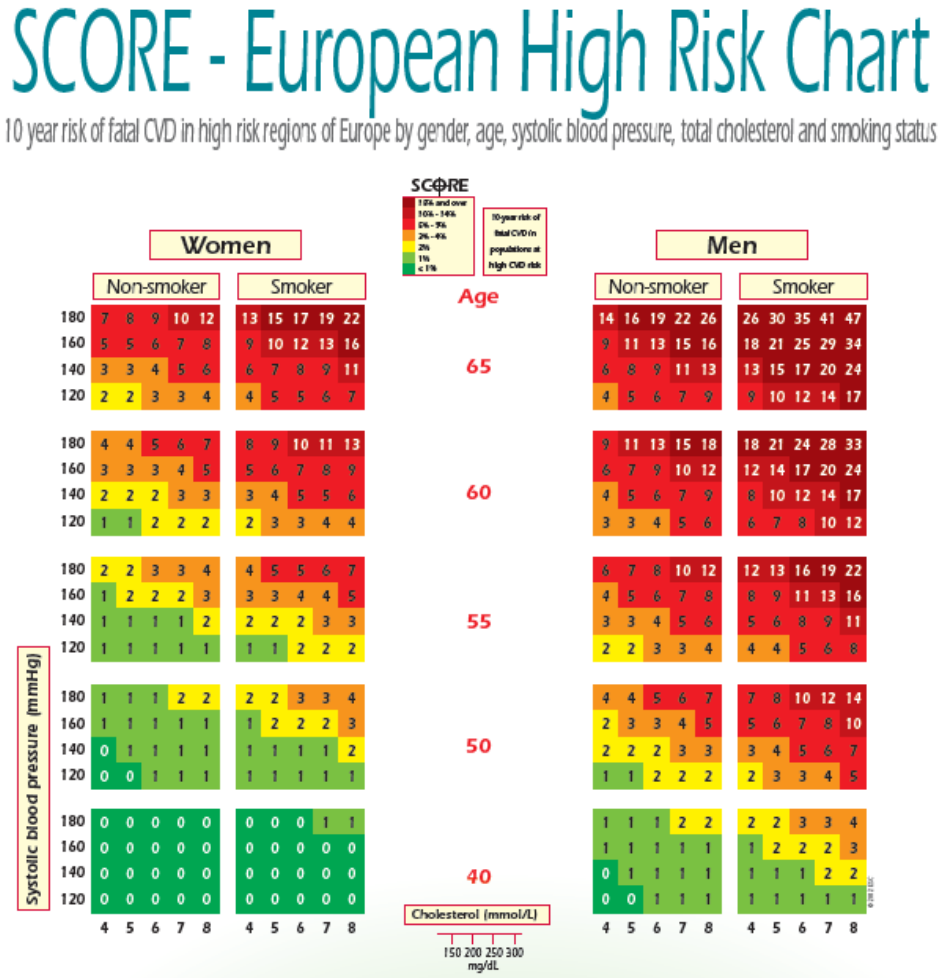
31. Would you participate in a health check for diabetes or CVD?
Please tick <u>one</u> answer

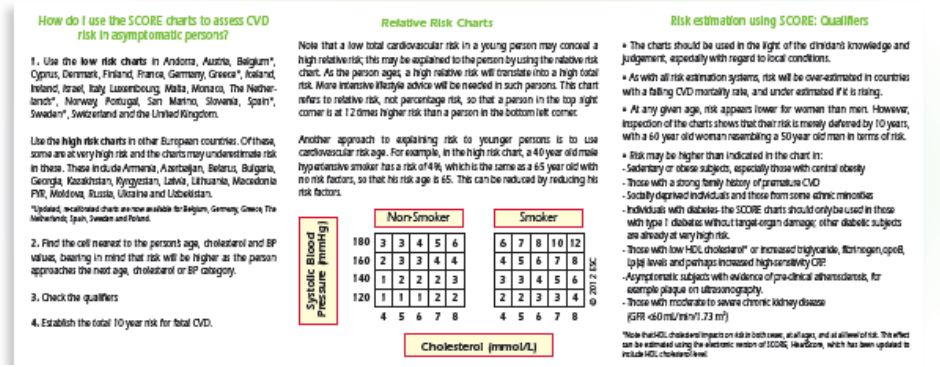
- ❑ Yes Please continue to "Client/patient's health check questionnaire"
- ❑ No Thank you very much for completing this questionnaire. To subscribe to the newsletter or for more information about the **SPIMEU** project go to www.spimeu.org.

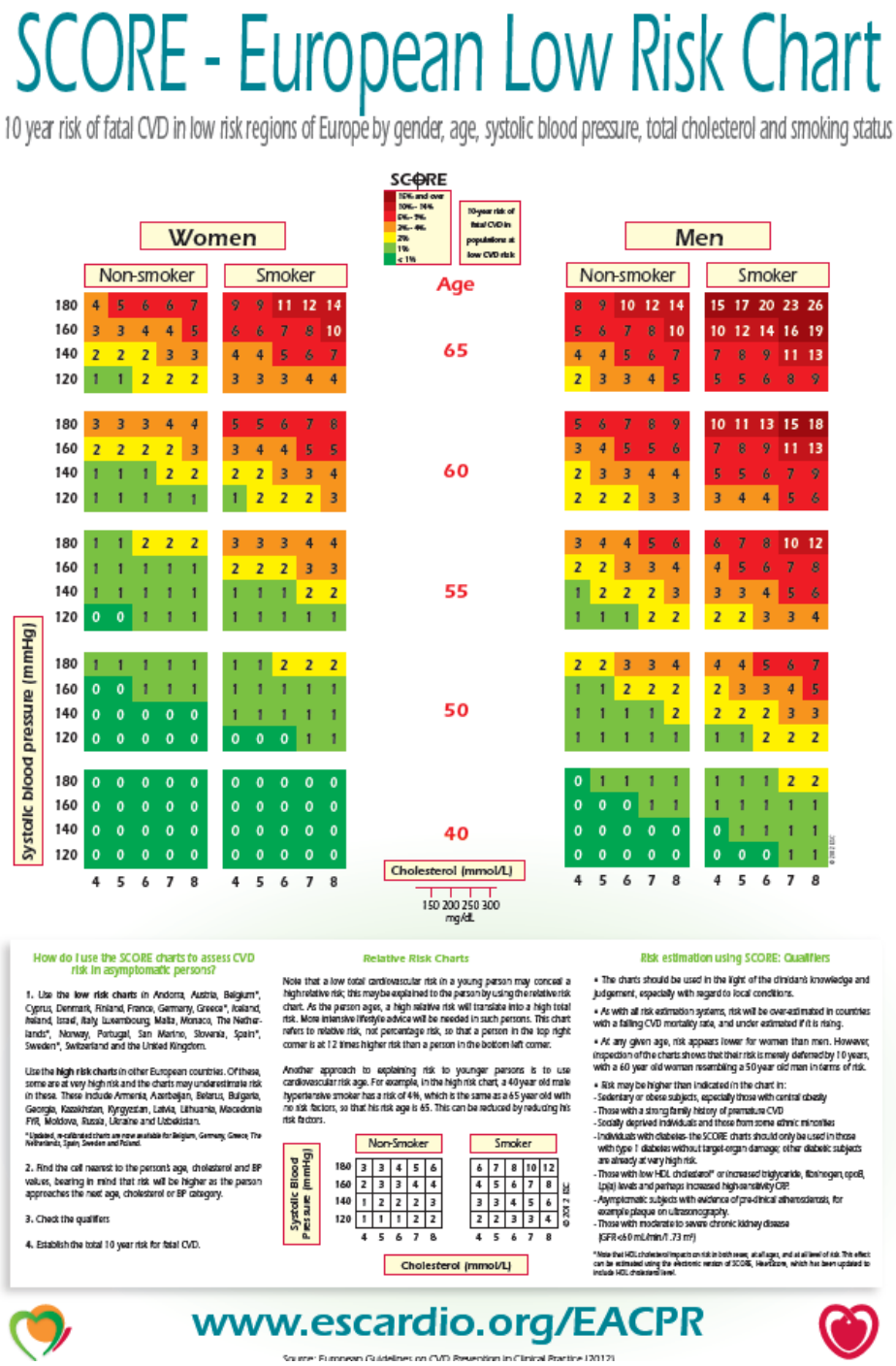
Appendix 1b. Client/patient's health check questionnaire

Part 5. SCORE Chart: 2016 ESC/EAS Guidelines for the Management of Dyslipidaemias (to be completed with the guidance of the accountable Health Professional).

Please, complete the risk assessment according to a validated tool based on the ESC guideline for cardiovascular risk management or a national guideline, endorsed by a relevant national society or authority. For further information, please follow the HeartScore® Web-based version users' guide: http://www.heartscore.org/static_file/HeartScore/Documents/heartscore-user-guide.pdf.







Source: https://www.escardio.org/Education/Practice-Tools/CVD-prevention-toolbox/SCORE-Risk-Charts . Eur Heart J. 2016;37(39):2999-3058. doi:10.1093/eurheartj/ehw272. Eur Heart J | © 2016 European Society of Cardiology and European Atherosclerosis Association. All rights reserved. For permissions please email: journals.permissions@oup.com.

32. Please, write here the estimated SCORE number: _____

33. How much time did it take to complete this questionnaire? _____ minutes

Part 6. Willingness to change your life-style behaviour (smoking, exercise, eating habits, alcohol consumption, medication for reducing blood pressure or cholesterol level during your health check for cardiovascular diseases (CVD) and/or diabetes

34. Would you be willing to change your life-style behaviour (smoking, exercise, eating habits, alcohol consumption, medication for reducing blood pressure or cholesterol level) in order to reduce your risk for cardiovascular diseases (CVD) and/or Type-2-diabetes. *Please tick one answer.*

- ❑ Yes □ please continue to question 35
- ❑ No □ please continue to question 36

35. Yes, I am willing to change. . .
Please tick all the reasons that were important in your decision to participate in the health check.

a. Because I think I might have a high risk for CVD/diabetes □
b. Because I want to be healthier □
c. Only because my partner, family or friends insists to do so □
d. Only because the doctor persuaded me to do so □
e. Other reason: . . . . . .
f. None of the above mentioned reasons □

36. No, I am not willing to change my life-style behavior because . . .
Please tick all the reasons that were important in your decision to not participate in the health check.

a. I think that I am healthy □
b. The information and suggestions for the life-style change is offered online and I do not have access to the Internet □
c. I think I am too young to benefit from a life-style change □
d. I think I am too old to benefit from a life-style change □
e. I did not have time to change □
f. I can't afford to change my life-style, it's too expensive □
g. I don't want to change my life-style □

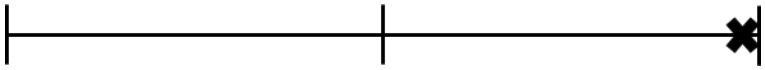
h. Other reason:. . . . .

i. None of the above mentioned reasons

Part 7. Relevance, feasibility and barriers. In the next 5 questions please mark on the line how you think about the mentioned subjects. For example, when you feel very worried to develop a cardiovascular disease you mark the line on the right side of the line (see example).

Example question

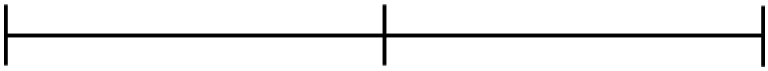
To what extent are you worried about your risk to develop a cardiovascular disease such as a myocardial infarction, stroke or diabetes?



1 (Not worried) 10 (Very worried)

37. To what extent do you think that this action/ risk assessment was relevant to you?

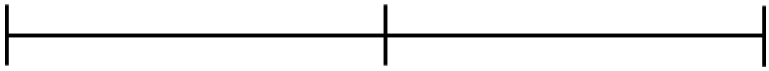
Please mark on the line how relevant this action/ risk assessment *were to you.*



1 (Not at all relevant) 10 (Very much)

38. To what extent do you think that this action/ risk assessment was useful for your health?

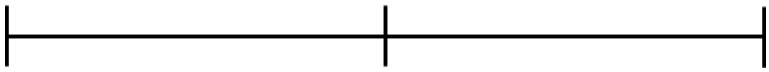
Please mark on the line how useful this action/ risk assessment *was to your health.*



1 (Not useful) 10 (Very useful)

39. To what extent do you think that this action/ risk assessment was feasible?

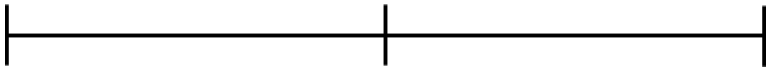
Please mark on the line how feasible this action/ risk assessment *was.*



1 (Not feasible) 10 (Very feasible)

40. Do you think that this action/ risk assessment encouraged you to pursue a healthier lifestyle?

Please mark on the line how encouraged you feel to pursue a healthier lifestyle.



1 (Not encouraged) 10 (Very encouraged)

41. Did you encounter any barrier in order to start to change your lifestyle into a healthier one?

- ❑ No
- ❑ Yes *Please, indicate the barriers you encountered, you can tick more answers*
  - I don't know how to start / where to begin
  - My family/surrounding did not support me
  - I don't have the budget to change my lifestyle
  - I don't have time to change my lifestyle
  - I lack the motivation to change
  - I tried, but it is too difficult
  - Other barriers, namely_____

Thank you very much for completing this questionnaire. To subscribe to the newsletter or for more information about the **SPIMEU** project go to www.spimeu.org.

Appendix 2. Primary care practitioners' questionnaires

Background information for the participating primary care practitioners

This feasibility study within the framework of the SPIMEU project aims in identifying factors that hamper or favor the implementation of the initial steps (i.e. identification, invitation and risk profiling of eligible persons) of a selective prevention program in specific primary care settings in five EU Member States representing different health care systems.

*Inclusion Criteria***:** Eligible participants are those persons listed in (or regularly attending) your participating practice, aged 40-70 years without any known cardiometabolic disease or condition according to their medical record:

- hypertension
- cardiovascular disease
- diabetes mellitus
- chronic renal disease
- hypercholesterolemia

Procedure: The following steps are required for this feasibility study:

- Personal invitation of 200 eligible persons per country for participation.
- Completing a risk assessment according to a validated tool based on the ESC guideline for cardiovascular risk management or a national guideline, endorsed by a relevant national society or authority.
- Evaluation of the cardiometabolic risk in the general practice

Part 1. sociodemographic data of primary care professionals

1. What is your sex?

Male ❑
Female ❑

2. Please write down you exact age?

..... years old

3. What is your occupation?

a. General Practitioner ❑
b. Nurse ❑
c. Other ❑

4. When did you received your degree?

Year: .....

5. How many years of experience do you have?

Number of years: .....

6. What is your current work status?
   a. Working full time ❑
   b. Working part- time ❑
   c. Other ❑

7. Type of employment
   a. Private ❑
   b. Public ❑
   c. Mixed ❑
   d. Other ❑

8. What is your level of education?
   a. BSc ❑
   b. MSc ❑
   c. PhD ❑
   d. Other ❑

Part 2. Barriers

9. Which barriers did you encounter during implementation of this risk assessment protocol?

Please tick all that apply

- ❑ Lack of time
- ❑ Staff shortage
- ❑ No remuneration available at all
- ❑ Not enough remuneration available
- ❑ Discrepancies in the recommendation and/or guidelines
- ❑ Not effective in your opinion as a general practitioner
- ❑ Not effective in opinion of patients
- ❑ Not clear which professional is responsible for implementation
- ❑ No support from (practice) management
- ❑ Competence in prevention and health promotion not sufficient
- ❑ No support from government/ policy
- ❑ No barriers at all
- ❑ Other

_____

10. Why do you not use this risk assessment tool in your practice?

Please tick all that apply

- ❑ Lack of time
- ❑ Staff shortage
- ❑ No remuneration available at all
- ❑ Not enough remuneration available
- ❑ Discrepancies in the recommendation and/or guidelines
- ❑ Not effective in your opinion as a general practitioner
- ❑ Not effective in opinion of patients
- ❑ Not clear which professional is responsible
- ❑ No support from (practice) management
- ❑ Competence in prevention and health promotion not sufficient
- ❑ No support from government/ policy
- ❑ CMD prevention is not a priority in my practice
- ❑ Other

_____

- ❑ I use this protocol in my daily practice

Part 3. Effort devoted for this project

11. How much personnel were utilized for identification and invitation of eligible participants?
    - ❑ One person
    - ❑ Two persons
    - ❑ Three or more persons

12. How much time was needed for identification and invitation of eligible participants?
    _____minutes or
    _____ hours or
    _____ days

Part 4. AUDIT after the dialogue with the client/patient

13. In your opinion, would the patient benefit from lifestyle advice and guidance from a health professional?

    - ❑ Yes
    - ❑ No

14. In terms of lifestyle change, how motivated do you believe the patient is at this point in time?

    - ❑ 1 Not at all motivated
    - ❑ 2
    - ❑ 3
    - ❑ 4
    - ❑ 5
    - ❑ 6
    - ❑ 7
    - ❑ 8
    - ❑ 9
    - ❑ 10 Very motivated

15. In your opinion, how resourceful is the patient in terms of lifestyle change at this point in time?

    - ❑ 1 Not at all resourceful
    - ❑ 2
    - ❑ 3
    - ❑ 4
    - ❑ 5
    - ❑ 6
    - ❑ 7
    - ❑ 8
    - ❑ 9
    - ❑ 10 Very resourceful

16. How confident are you that the patient will achieve his or her desired changes in lifestyle?

- ❑ 1 Not at all confident
- ❑ 2
- ❑ 3
- ❑ 4
- ❑ 5
- ❑ 6
- ❑ 7
- ❑ 8
- ❑ 9
- ❑ 10 Very confident

17. Did you and the patient plan next steps in terms of treatment following the health dialogue?

- ❑ We have scheduled a follow-up GP appointment.
- ❑ Guidance and advice in terms of lifestyle health factors.
- ❑ Adjustment of medical treatment.
- ❑ Assessment of vulnerability factors (stress, anxiety, depression, etc.).
- ❑ Other:_____

18. I have referred the patient to one or more municipal lifestyle-change programs.

- ❑ Yes
- ❑ No

19. If so, what is the focus/foci of the program(s)?

- ❑ Weight loss
- ❑ Exercise
- ❑ Diet
- ❑ Alcohol consumption
- ❑ Smoking
- ❑ Other:_____

20. Patient treatment has been finalized.

- ❑ Yes
- ❑ No

21. If so, with what justification has treatment been finalized?

- ❑ The patient is sufficiently capable of self-care.
- ❑ There are no appropriate lifestyle-change programs.
- ❑ Other:_____

22. How long did the health dialogue take?

- ❑ 10 min.
- ❑ 20 min.
- ❑ 30 min.
- ❑ 40 min.
- ❑ 50 min.
- ❑ 60 min.

Appendix 3. Evaluations questionnaire: NoMad: Implementation measure based on Normalization Process Theory. [Measurement instrument]

Part 5. NoMad questions after the dialogue with client/patient.
Please mark one answer with a tick (✓).

	Section C1	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
23	I can see how prevention program differs from usual ways of working					
24	Staff in this organization have a shared understanding of the purpose of prevention program					
25	I understand how prevention program affects the nature of my own work					
26	I can see the potential value of prevention program for my work					
	Section C2					
27	There are key people who drive prevention program forward and get others involved					
28	I believe that participating in prevention program is a legitimate part of my role					
29	I'm open to working with colleagues in new ways to use prevention program					
30	I will continue to support prevention program					

Thank you very much for completing this questionnaire. To subscribe to the newsletter or for more information about the **SPIMEU** project go to www.spimeu.org.

Appendix 4. A. Written consents

Participant's consent

PLEASE **tick** every box

- ❑ I have read the information, or it has been read to me. I have asked all questions about the project that I want. All my questions have been answered to my satisfaction.
- ❑ I consent voluntarily to participate in completing the questionnaire about implementation of a selective prevention program in specific primary care settings within the framework of the feasibility study of **SPIMEU** project
- ❑ What participants say can be used as anonymous quotations in the reports on the **SPIMEU** project.

Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

Appendix 4. B. Consent form participation of SPIMEU project.

Primary care practitioners' s consent

- ❑ I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the purpose and scope of the study.
- ❑ I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.
- ❑ I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of person taking the consent_____

Signature of person taking the consent_____

Date _____

Day/month/year

Appendix 5. Copy of the received Bioethical approval per participation country in national languages.

Copy from the Czech Republic.

Etická komise
Všeobecné fakultní nemocnice v Praze
ETHICS COMMITTEE
of the General University Hospital, Prague

Na Bojišti 1
128 08 Praha 2
tel.: 224964131
e-mail: eticka.komise@vfn.cz

Vážený pan
Doc. MUDr. Bohumil Seifert, Ph.D.
Ústav všeob.lékařství 1.LF UK a VFN v Praze,
Albertov 7, 121 08, Praha 2

16.11.2017
č.j.: **1946/16 S-IV**

Etická komise VFN projednala na svých zasedáních 24.11.2016 a 16.11.2017 Vámi předložený individuální výzkumný projekt **č. 1946/16 S-IV – individální výzkum**

Název studie/*Title of CT*: Determinanty úspěšné implementace selektivní prevence kardiometabolických onemocnění v Evropě (SPIMEU)

Žadatel/*Applicant*: Doc. MUDr. Bohumil Seifert, Ph.D., Ústav všeobecného lékařství 1.LF UK a VFN v Praze, Albertov 7, 121 08, Praha 2

Lhůta pro podání písemné zprávy o průběhu KH od jeho zahájení/ *Time schedule for submission of the written Annual Report:* ☒ 1x ročně/*Once a year* ☐ Jiná lhůta/*Other*
Úhrada nákladů spojených s posouzením žádosti a vydáním stanoviska /*Reimbursement of costs related to assessment of the EC:* ☐ Ano/*Yes* ☒ Ne, důvod/*No,reasons*: Nesponzorovaný projekt
Datum doručení žádosti / *Date of submission of the Application Form:* 11.11.2016

Datum jednání EK+čas/*Date and time of Ethics Committee's session:*
24.11.2016 (15,30 –18,00 hod.) – **pozastaveno,** připomínky zaslány e-mailem, seznam členů bude dodán s konečným stanoviskem;
• Opravené dokumenty dodány: 12.10.2017 pod **čj. 1646/17 A, IS,D;**
16.11.2017 (15,30 – 18,20 hod.) – **souhlas**
Seznam míst hodnocení s označením míst, ke kterým se EK vyjádřila jako místní EK a kde vykonává dohled

Místo hodnocení / Jméno zkoušejícího *Trial Site / Name of Investigator*	***Místní EK*** *Local EC*	***Adresa místní EK*** *Address*
Doc. MUDr. Bohumil Seifert, Ph.D., Ústav všeobecného lékařství 1.LF UK a VFN v Praze, Albertov 7, 121 08, Praha 2	☒	EK při VFN, Na Bojišti 1, 128 08 Praha 2

Seznam hodnocených dokumentů / *List of all submitted documents:*

Název dokumentu, verze, datum *Document title, version, date*	Schváleno */Approved*		Na vědomí / *Taken into account*	
	ANO *Yes*	NE *No*	ANO *Yes*	NE *No*
Průvodní dopis ze dne 8.11.2016	☐	☐	☒	☐
Dotazník: Část 1 - 6, nedatován	☒	☐	☐	☐
Stanovisko holandské Etické komise z 3.11.2016	☐	☐	☒	☐
1646/17 A, IS, D				
Průvodní dopis ze dne 12.10.2017	☐	☐	☒	☐
Dotazník pro pacienty, nedatováno	☒	☐	☐	☐
Dotazník pro parktické lékaře, nedatováno	☒	☐	☐	☐
Informovaný souhlas účastníka, nedatováno	☒	☐	☐	☐
Souhlas praktického lékaře/lékařky, nedatováno	☒	☐	☐	☐
Seznam spolupracujících praktických lékařů (WP8), nedatováno	☐	☐	☒	☐
Základní informace pro zúčastněné praktické lékaře, nedatováno	☐	☐	☒	☐
Tabulka SCORE © 2016 jako nástroj hodnocení rizik	☐	☐	☒	☐
Protokol studie proveditelnosti, SPIM-EU, nedatováno	☒	☐	☐	☐

Stanovisko etické komise:
EK vydává / *EC issues*
☒ Souhlasné stanovisko/*Favourable opinion*
☐ Nesouhlasné stanovisko/*Unfavourable opinion*

EK VFN vydává **souhlas**né stanovisko k provedení studie: Determinanty úspěšné implementace selektivní prevence kardiometabolických onemocnění v Evropě (SPIMEU) v Ústavu všeobecného lékařství 1.LF UK a VFN v Praze.

Etická komise
Všeobecná fakultní nemocnice
v Praze
Na Bojišti 1
128 08 Praha 2

Podpis předsedy EK / *Signature of Chairperson*

MUDr. Josef ŠEDIVÝ, CSc.

1 | 3

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ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ
7η ΥΓΕΙΟΝΟΜΙΚΗ ΠΕΡΙΦΕΡΕΙΑ ΚΡΗΤΗΣ
ΔΙΕΥΘΥΝΣΗ: ΠΡΟΓΡΑΜΜΑΤΙΣΜΟΥ & ΑΝΑΠΤΥΞΗΣ
ΠΟΛΙΤΙΚΩΝ ΠΑΡΟΧΗΣ ΥΠΗΡΕΣΙΩΝ ΥΓΕΙΑΣ &
ΚΟΙΝΩΝΙΚΗΣ ΑΛΛΗΛΕΓΓΥΗΣ
ΤΜΗΜΑ ΕΡΕΥΝΑΣ & ΑΝΑΠΤΥΞΗΣ
Ταχ. Δ/νση: : 3° χλμ Ε.Ο. Ηρακλείου – Μοιρών,
Εσταυρωμένος, Τ.Κ. 71500,
Ηράκλειο Κρήτης, ΤΘ 1285
Πληρ.: **Α. Μανουράς**
Τηλ: 2813404433
Fax: 2810300412
Email:amanouras@hc-crete.gr

Ηράκλειο, 08 Αυγούστου 2017
Αρ. Πρωτ.: 13682 /09-08-17
Φάκελος: Έρευνα

ΠΡΟΣ: κ. Λιονή Χρήστο,
Καθηγητή Ιατρικής Σχολής
Πανεπιστημίου Κρήτης.

ΚΟΙΝ.:1. Τομέας Κοινωνικής Ιατρικής
Ιατρικής Σχολής Πανεπιστημίου
Κρήτης.
2. Συντονιστές Δ/ντές Κ.Υ.
7ης Υ.ΠΕ Κρήτης.

Θέμα: «Έγκριση διεξαγωγής ερευνητικού προγράμματος»
Σχετ.: Η με αρ. πρωτ. 13581/07-8-17 αίτηση του κ. Λιονή Χρήστου, Καθηγητή Γενικής Ιατρικής & Π.Φ.Υ. Ιατρικής Σχολής Πανεπιστημίου Κρήτης.

Σας ενημερώνουμε ότι εγκρίνουμε να διεξαχθεί το Ευρωπαϊκό Πρόγραμμα SPIM –EU (Determinants of successful implementation of selective prevention of cardiometabolic diseases across Europe), το οποίο εντάσσεται στο πλαίσιο δράσης του Τρίτου Προγράμματος της Ευρωπαϊκής Ένωσης.

Στόχος του προγράμματος είναι η μείωση της εμφάνισης των καρδιο-μεταβολικών νοσημάτων. Για να επιτευχθεί ο σκοπός αυτός, θα διεξαχθούν μελέτες για την ανάγνωση της στάσης των Επαγγελματιών Υγείας και του γενικού πληθυσμού, σε σχέση με δράσεις

πρόληψης και εκτίμησης του κινδύνου, θα χρησιμοποιηθούν ερωτηματολόγια, τηλεφωνικές επικοινωνίες ή και συνεντεύξεις πρόσωπο με πρόσωπο των επισκεπτών στα Κέντρα Υγείας και των Επαγγελματιών Π.Φ.Υ. (Γενικών Ιατρών και Νοσηλευτριών).

Η Έγκριση δίνεται με την δέσμευση ότι πριν τη δημοσίευση των αποτελεσμάτων της έρευνας, θα προσκομίσετε περίληψη των αποτελεσμάτων της έρευνας στην Διοίκηση 7ης Υ.ΠΕ Κρήτης, και με την προϋπόθεση της τήρησης όλων των κανόνων ηθικής και δεοντολογίας, της προστασίας των προσωπικών δεδομένων και τη γραπτή συγκατάθεση των συμμετεχόντων, καθώς και της μη οικονομικής επιβάρυνσης της 7ης Υ.ΠΕ Κρήτης και των Μονάδων Υγείας που εποπτεύει.

Είμαστε στη διάθεσή σας για κάθε διευκρίνιση.

Ο ΥΠΟΔΙΟΙΚΗΤΗΣ

ΔΗΜΗΤΡΑΚΟΠΟΥΛΟΣ ΣΤΕΛΙΟΣ

Εσωτ. Διανομή: 1. Γραφείο Διοικήτριας 7ης Υ.ΠΕ Κρήτης,

2. Υποδιοικητές 7ης ΥΠΕ Κρήτης

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UMC Utrecht

Medisch Ethische Toetsingscommissie

Divisie Julius Centrum voor Gezondheidswetenschappen
en Eerstelijns Geneeskunde
Afdeling huisartsengeneeskunde
t.a.v. dr. M. Hollander
Huispost : STR6.131

Mw. Dr. W.A. Groenewegen
Telefoon 088-7556376 (ma t/m do)
Heidelberglaan 100
Postbus 85500
3508 GA Utrecht
Huispost D 01.343
E-mail metc@umcutrecht.nl
Info www.umcutrecht.nl/metc

Datum
19 oktober 2017

Ons kenmerk
WAG/mb/17/031540

Onderwerp
METC-protocolnummer 17-702/C
Advies niet-WMO onderzoek

Uw kenmerk

Geachte mevrouw Hollander,

De Medisch Ethische Toetsingscommissie (METC), erkend op 11 november 1999 ex artikel 16 van de WMO heeft zich in de vergadering van 17 oktober 2017 beraden over het onderzoeksvoorstel nummer 17/702, getiteld **"SPIMEU project. Determinants of successful implementation of selective prevention of cardiometabolic diseases across Europe"**, ingediend door prof .dr. N.J. de Wit, met als verrichter UMC Utrecht.

De METC van het UMC Utrecht heeft zich op het standpunt gesteld dat het ingediende onderzoeksvoorstel niet in de zin van de WMO getoetst hoeft te worden. Hierbij heeft de commissie overwogen dat er geen sprake is van het onderwerpen van proefpersonen aan handelingen of het opleggen van een gedragswijze zoals bedoeld in de definitie van medisch-wetenschappelijk onderzoek in de WMO (art. 1b).

De commissie attendeert u er op dat zij alleen heeft beoordeeld of het onderzoek onder de reikwijdte van de WMO valt. Er heeft geen inhoudelijke toets van het onderzoek plaatsgevonden.

De commissie heeft de volgende documenten in haar afweging meegenomen:

Onderwerp	Datum Ontvangst
A1. Aanbiedingsbrief dd 10-10-2017 11;25	10-10-2017
A1. Formulier (niet-)WMO dd 09-10-2017	10-10-2017
C1 onderszoeksprotocol versie 1 dd 9 okt 2007	10-10-2017
E1 versie 1 dd 9 okt 2017 Informatie brief voor patiënten	10-10-2017
F1 versie 1 9 okt 2017 Vragenlijsten patiënt	10-10-2017
C1 onderszoeksprotocol versie 1 dd 9 okt 2007	10-10-2017
F1 Risico test voor vrouwen	10-10-2017
F1 Risicottest voor mannen	10-10-2017

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SDU

Jens Søndergaard
Institut For Sundhedstjenesteforskning

Udtalelse

26.02.2018

Journal nr. 18/5728
ZEES

Du har den 22. august 2017 foretaget anmeldelse til RIO af behandling af personoplysninger udelukkende i videnskabeligt eller statistisk øjemed.

Det fremgår af anmeldelsen, at behandlingen drejer sig om personfølsomme oplysninger herunder generelle helbredsoplysninger af projektet benævnt " Determinants of successful implementation of selective prevention of cardiometabolic deseases across Europe (SPIMEU)."

Projektet forventes at være færdigt 1. april 2018, og personoplysningerne vil blive slettet, anonymiseret eller arkiveret senest 1. april 2023. Bemærk, at personoplysninger ikke må opbevares i længere tid end nødvendigt af hensyn til det formål, hvortil oplysningerne er indsamlet.

Da der behandles fortrolige personoplysninger i projektet skal sikkerhedsbekendtgørelsens kapitel 1-3 overholdes, hvorfor du bedes rette henvendelse til Erik B. Madsen (erikm@sdu.dk) for at finde den bedste it-løsning for projektet.

Din anmeldelse er omfattet af universitetets fællesanmeldelse til Datatilsynet, journalnummer 2015-57-0008.

RIO meddeler hermed tilladelse til, at behandlingen af de pågældende personoplysninger kan påbegyndes.

Du skal i den forbindelse særligt være opmærksom på følgende krav til behandlingen:

- Personoplysningerne må kun bruges til forskning eller statistik, og må ikke indgå i administrativ eller konkret sagsbehandling. Oplysningerne må heller ikke anvendes som grundlag for konkrete retlige eller faktiske foranstaltninger over for de omhandlede personer eller andre personer.

Syddansk Universitet
Campusvej 55
5230 Odense M
T 65 50 10 00
www.sdu.dk

Fra: Signe Riktrup Jensen
Til: Trine Thilsing
Cc: Jens Søndergaard
Emne: SV: Forespørgsel om anmeldepligt til det Videnskabsetiske Komitesystem
Dato: 27. juni 2016 10:37:14
Vedhæftede filer: image001.png

Kære Trine Thilsing.

De Videnskabsetiske Komitéer for Region Syddanmark har modtaget nedstående forespørgsel om anmeldepligt. Forespørgslen er registreret på journalnummer S-20162000-96.

Ud fra de oplysninger, der foreligger, har Komitéen besluttet, at projektet **ikke** er anmeldepligtigt til det videnskabsetiske komitésystem, jf. § 14, stk. 1 i lov om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter.

Der er ved afgørelsen lagt vægt på, at der synes at være tale om en spørgeskema –og interviewundersøgelse uden intervention i komitélovens forstand, hvorefter projektet falder uden for rammerne af komitélovens definition af et sundhedsvidenskabeligt forskningsprojekt.

Projektet skal muligvis anmeldes til Datatilsynet eller indberettes til en eksisterende "paraplygodkendelse", og der skal muligvis indhentes tilladelse til projektet fra Sundhedsstyrelsen, såfremt projektet indebærer videregivelse af patientjournaloplysninger – se mere her: http://www.sst.dk/Tilsyn%20og%20patientsikkerhed/Patientjournaloplysninger.aspx

Sagen er behandlet af formanden for Komité 1, dr. med. Birger Møller.

Denne afgørelse kan, jf. komitélovens § 26, stk. 1, indbringes for Den Nationale Videnskabsetiske Komité, senest 30 dage efter afgørelsen er modtaget.

Klagen samt alle sagens dokumenter sendes til:
Den Nationale Videnskabsetiske Komité
Holbergsgade 6
1057 København K
Tlf.: 72 26 93 70
Mail: DKetik@DKetik.dk

Venlig hilsen

Signe Riktrup Jensen
Chefkonsulent
Kvalitet og Forskning

E-mail: srj@rsyd.dk
Direkte: 76638220
Mobil: 20598930

logo

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EPN Regionala etikprövningsnämnden i Stockholm

Protokollsutdrag 2017/3:11
Avdelning 3 **2017-11-15**

Diarienummer:
2017/2053-31
Föredragande:
Karolina Nowinski

Sökande: Karolinska Institutet
Behörig företrädare: Gunnar Nilsson
Projekt: SPIMEU - Ett sameuropeiskt forskningsprojekt om selektiva förebyggande åtgärder av kardiometabola sjukdomar, Work Package (WP) 8 - Genomförbarhet av screening för kardiometabola sjukdomar på vårdcentraler
Forskare som genomför projektet: Axel C Carlsson

BESLUT

Nämnden begär att sökanden kompletterar ansökan enligt följande:

1. Utöka informationen om bakgrunden till den andra delstudien i förhållande till den första studien om att identifiera risk för hjärtkärlsjukdomar.
2. I studiens andra del om svåra barndomstrauman och med hänsyn till studiepopulationens storlek ifrågasätter nämnden om frågorna i denna delstudie kan besvaras.
3. Beskriv hur samarbetet med WONSA sker, vem gör analyser och var ligger data. Beskriv även WONSAs roll i studien i forskningspersonsinformationen.
4. Beskriv vilken beredskap som finns för deltagare i del 2 att få professionellt stöd och hjälp efter att ha fyllt enkäten, risk för oro?, 24-timmars hjälp per telefon?, profession hos den som besvarar telefon eller mail hos WONSA? Nämnden ifrågasätter om inte sådana frågor bör besvaras på plats och önskar en kommentar.
5. På information och samtycke till deltagande personer och personal ska studiens titel anges i sin helhet och de ska struktureras likartat enligt anvisningar och inkluderande information om personuppgiftslagen (PUL).
6. Beskriv vilka journaldata som samlas in.
7. Förtydliga samtycket så att det blir tydligt att man kan delta i första, men avstå från andra delen av studien.
8. Inkludera information att vare sig man deltar i studien eller inte så påverkas inte framtida behandling.

Kompletteringen ska i **ett exemplar** ha kommit in till nämnden senast den **11 december 2017**. Om kompletteringen inte kommer in i tid kommer ärendet att bedömas av nämnden i befintligt skick.

Nämnden lämnar över åt den vetenskaplige sekreteraren att avgöra ärendet sedan kompletteringen gjorts.

Postadress
FE 289
171 77 STOCKHOLM
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202200 1578

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Tomtebodavägen 18A plan 3
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EPN **Regionala etikprövningsnämnden i Stockholm** | **PROTOKOLL** Avdelning 3 | **2017/3:11** 2017-11-15

Ordförande
Håkan Julius

Ledamöter med vetenskaplig kompetens
Agneta Nordenskjöld *(barnkirurgi)*, vetenskaplig sekreterare
Lennart Balk *(toxikologi)*
Kristian Borg *(neurologi)*
Yvonne Forsell *(psykiatri, geriatrik, psykiatrisk epidemiologi)*
Karolina Nowinski *(klinisk farmakologi, internmedicin, kardiologi)*
Ilona Koupil *(ojämlikhet i hälsan)* *deltog inte i 2017/2030 pga. jäv.*
Tommy Linné *(pediatrik)*
Joy Roy *(kirurgi)*
Guro Gafvelin *(molekylär immunologi)*

Ledamöter som företräder allmänna intressen
Lisbeth Crabo Ljungman
Sven-Inge Nylund
Per-Arne Hammarström
Maria Modig

Administrativ sekreterare
Jenny Karte ~~och Kristin Mattsson~~

RÄTTELSE 2017 11 16
Kristin Mattsson deltog inte i mötet.

§ 1 Ordföranden förklarar sammanträdet öppnat.

§ 2 Ansökningar om etisk granskning av forskningsprojekt, se **Bilaga.**

§ 3 Ordföranden meddelar att nästa sammanträde i avdelning 3 äger rum **onsdagen den 13 december.**

§ 4 Ordföranden förklarar mötet avslutat.

Håkan Julius
Ordförande

Agneta Nordenskjöld
Vetenskaplig sekreterare

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Dnr: 2017/2053-31
Sökande: Karolinska Institutet
Behörig företrädare: Gunnar Nilsson
Projekt: SPIMEU - Ett sameuropeiskt forskningsprojekt om selektiva förebyggande åtgärder av kardiometabola sjukdomar, Work Package (WP) 8 - Genomförbarhet av screening för kardiometabola sjukdomar på vårdcentraler
Forskare som genomför projektet: Axel C Carlsson

Nämnden har vid sammanträdet den 15 november 2017 lämnat över till den vetenskaplige sekreteraren att avgöra ärendet sedan kompletteringar gjorts.

Sedan sökanden kommit in med begärda kompletteringar fattar den vetenskaplige sekreteraren följande

BESLUT

Nämnden godkänner forskningen.

På nämndens vägnar 2017 -11- 30

Agneta Nordenskjöld
Vetenskaplig sekreterare

Postadress FE 289 171 77 STOCKHOLM
Besöksadress Tomtebodavägen 18A Solna
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