

POLish-Norwegian Study (PONS): research on chronic non-communicable diseases in European high risk countries – study design

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Abstract

Objective: A large-scale population study of health and disease would represent the most powerful tool to address these important issues in Poland. The aim is to extensively survey the study population with respect to important factors related to health and wellbeing, and subsequently, the intention is to follow-up the population for important health outcomes, including the incidence and mortality of cancer, cardiovascular disease, and other major causes of morbidity and mortality. The infrastructure for establishing a large cohort of people in Poland is needed; therefore, the PONS (Polish-Norwegian Study) project represents an effort to establish such infrastructure.

Methods The PONS Study is enrolling individuals aged 45–64 years. Structured lifestyle and food frequency questionnaires are administered. Study participants undergo medical check-up, anthropometric measurements and provide blood and urine sample for long-term storage. Fasting glucose and lipids profile are checked in the laboratory.

Results This report describes the design, justification and methodology of the presented prospective cohort study. Recruitment of participants began in September 2010, and by the end of 2011 it is planned to achieve a total of between 10,000 – 15,000 participants.

Summary The PONS study is the first prospective cohort study with blood and urine collection ever conducted in Central and Eastern Europe. It will provide reliable new data on both established and emerging risk factors for several major chronic diseases in a range of different circumstances.

Keywords

prospective study, cohort study, behavioural risk factor surveillance system, health survey, Poland

INTRODUCTION

Despite its rapid economic and social development, Poland is still facing a wide gap in health that separates it from western European countries; the high premature mortality is of particular concern. There is an urgent need to understand the underlying causes of these differences in order to devise rational means of prevention.

The health transformation in Poland is closely linked to the economic and political transformation that occurred in this country. This was accompanied by changes of workplace, improving life and living standard, infrastructural development, mechanization, lifestyle changes and globalization of nutrition.

Our HEM-Closing the gap project [1], as well as other research conducted in many countries, helped define the causes of many non-communicable diseases and allowed the identification of many of the factors responsible for premature morbidity and mortality. However, there are still many mechanisms of causes of the causes of smoking, alcohol consumption or obesity which need further investigation, as well as the impact of environment of living and mechanisms

responsible of health behaviours in local communities. The transition of population from rural areas to work and live in the cities is one of the most dramatic changes that affected Poles, especially in the less developed regions of the country. It was, of course, accompanied by changes in behaviour, culture and lifestyle that included nutrition, alcohol consumption, tobacco smoking, and physical activity. Conducting research on health and its determinants in local communities is crucial for understanding the impact of socio-economic changes on health. Only the results of such research will allow for the preparation of programmes of effective intervention actions for health improvement.

Large scale population studies of health and disease constitute the most powerful tools in addressing these important issues in Poland. Such studies extensively survey the population with respect to the important health and wellbeing-related factors. Some of the participants are followed-up to for important health outcomes, including cancer incidence and mortality, cardiovascular disease, and other major causes of morbidity and mortality.

The infrastructure for establishing a large cohort of people in Poland is needed, thus the PONS project represents an effort to establish such infrastructure. In this work we have collaborated with researchers associated with the HUNT Study in Norway, which is organized under the Norwegian University of Science and Technology in Trondheim. The study is co-funded by the Polish-Norwegian Research Fund

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(PNRF-228-AI-1/07). The current funding is for a baseline assessment of 10,000 – 15,000 participants. Additional funding will be sought to allow expanding the size of the cohort, and to allow subsequent 5-year follow-up assessments of the participants.

The PONS study is designed for assessing the health behaviours, risk factors, biological, genetic, as well as social and environmental factors in order to prepare effective strategy for the improvement of health in the studied populations.

MATERIALS AND METHODS

The PONS study is an open-ended prospective study with very broad research aims. The main purpose of the PONS project is to study the impact of lifestyle factors and biological risk factors on aspects of health, such as the incidence of chronic diseases and quality of life.

The primary objectives of the PONS study are to: 1) describe mortality and morbidity characteristics of common chronic diseases such as cardiovascular diseases, diabetes mellitus, and cancers; 2) determine environmental risk factors (lifestyle, diet, occupational) and life-course causes of common chronic diseases; 3) assess effects of both established and emerging risk factors for different diseases, both overall, and stratified by a range of different circumstances (e.g. at different ages and at different levels of other risk factors); 4) measure and describe the impact of socio-economic changes on health.

Thus, the study is aimed at a broad spectrum of hypotheses, with respect to both exposures and outcomes. By storing both blood (plasma and buffy coat) and urine samples from a large number of participants, the study will allow a reliable assessment of the relevance of many genetic and other factors that will be proposed in the future as correlates or determinants of various common chronic diseases.

CHARACTERISTICS OF THE COHORT

The study is set in the south-eastern part of Poland (*świętokrzyskie province*). In the first phase, PONS aims to recruit 10,000 – 15,000 adults aged 45–64 years from the general population in 2 geographically defined regions: one city urban district -the *city of Kielce* (200,000 residents, among whom there are 60,000 residents aged 45–64 years) and one rural district – *kielecki province* (200,000 residents, among whom 50,000 residents are aged 45–64 years) (Figure 1). These districts contain a diverse but settled mix of long-term residents. The study site was selected carefully based on risk patterns of major chronic diseases and important exposure factors, level of economic development, relative stability of the population, appropriate local infrastructure and long-term local commitment to the project. In the study area, all men and women aged 45–64 years who are permanently resident (110,000 eligible people) were invited to take part in the study. The study was approved by the Ethics Committee within the Cancer Centre and Institute of Oncology in Warsaw, Poland.

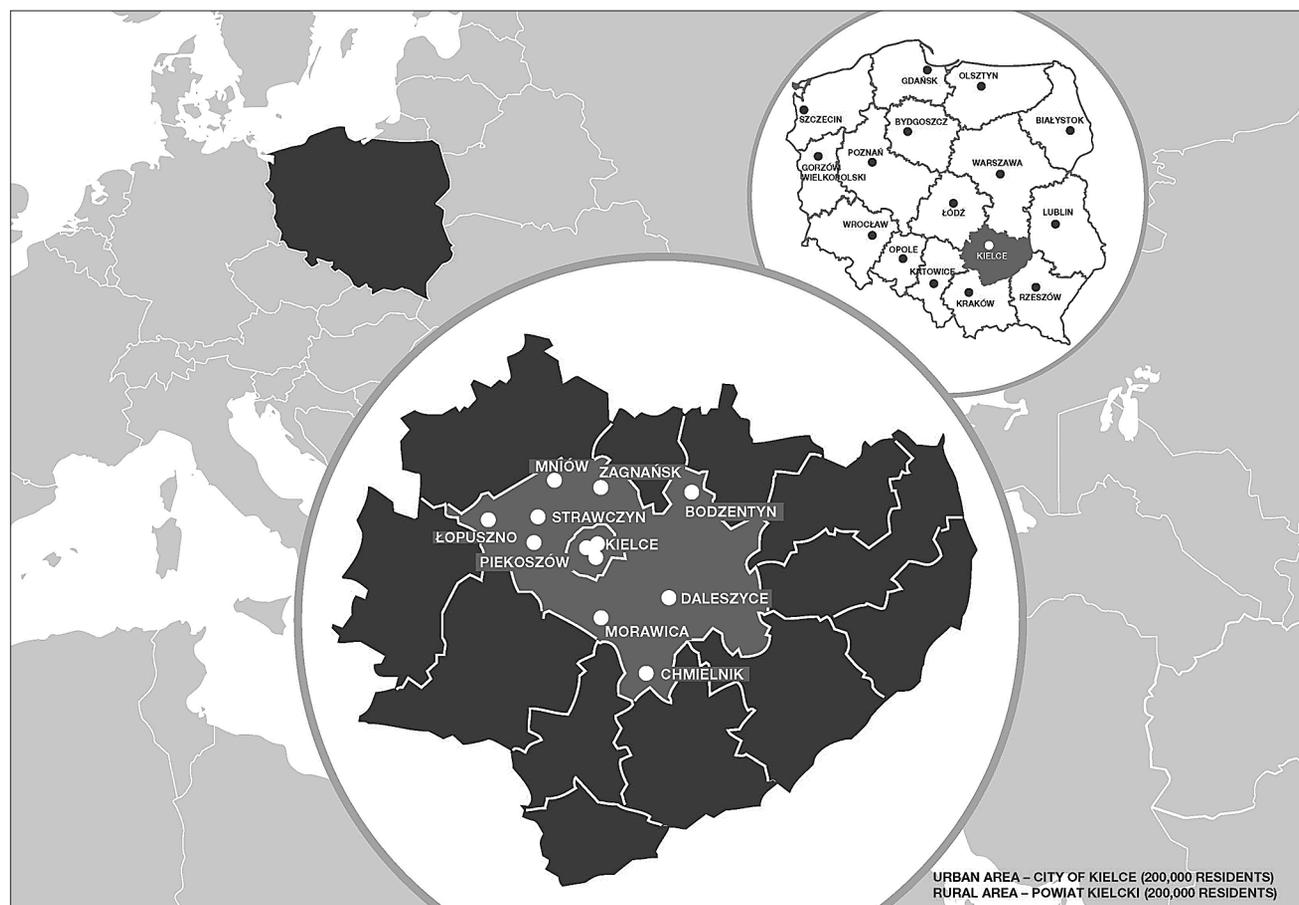


Figure 1. Geographic localization of the PONS study cohort

It is planned that at 5-year intervals, a sample of at least a few thousand participants from the original baseline cohort will be invited for reassessment, including similar questions, measurements, and collection of biological material that were used at baseline. These repeated assessments will be used to study variation over time and to assess random errors in measurements made at baseline.

WHAT HAS BEEN MEASURED?

For a large study to be practically and economically feasible, its procedures need to be simple and streamlined. The full recruitment assessment typically took 60 minutes to complete and it was nearly paperless.

Following informed written consent, which allows blood and urine samples to be used for unspecified research purposes that are of no direct benefit to the participant, each person undergoes an interview (Health State Questionnaire - HSQ), a medical check-up, anthropometric measurements and provides blood and urine samples for long-term storage. Information is collected by a trained interviewer (a nurse) through face-to-face interview and covers a broad range of variables (Table 1), including socioeconomic status, demographic characteristics, prevalent diseases and long-term medication, reproductive history (women), family history of diseases, psychological status, smoking status

and alcohol consumption, as well as dietary questions (Food Frequency Questionnaire - FFQ) and inquiries about physical activity (International Physical Activity Questionnaire - IPAQ). Answers to the HSQ are directly put into a interviewer-administered online questionnaire and sent to the study server via Internet.

Blood pressure (systolic and diastolic, measured twice), heart rate, ECG, lung function (FEV1 and FVC), CO level, height, weight and waist/hip circumference are also measured (Table 2). Results are entered directly into an electronic participant record.

A total of 21 ml fasting blood is collected into 4 tubes: one 10 ml tube, one 5 ml tube, one 4 ml tube and one 2 ml tube. The 10 ml and 5 ml tubes are prepared for transportation to the biobank. The 4 ml and 2 ml tubes are collected by the laboratory assistant for biochemical measurements (glucose and lipid profile: total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides). About 50 ml of urine is collected, and placed into five 2 ml tubes and prepared for transportation.

The biological samples are labeled with the unique participant number and then placed in an insulated box containing several chilled packs, reliably maintaining an internal box temperature of 4°C. Every day at noon, the boxes are transported to the Świętokrzyskie Cancer Centre (the biobank location), where the samples are extracted and placed in freezers.

Table 1. Summary of questionnaire data collected in PONS study

Demographic data
Socioeconomic data
Occupation
Education
Household composition
Income
Personal health behaviours
Alcohol
Smoking
Dietary habits
Frequency of food items consumption
Fruit and vegetables consumption
Cooking oils
Fried food consumption
Physical activity
General health-related data
Self-rated health status
Disease history
Current medications on CVD and diabetes
Pattern of bowel movements
Exposure to passive smoking
Weight change during the last 6 months
Family history
Parental cause of death
Number of siblings
Siblings' medical history
Number of children
Sleeping, mood and mental situation
Self-rated mood status
Traumatic events
Sleep situation
Depression and anxiety
Chronic pain
Reproductive history (for women)
Age of first menstrual period
Menopause status
History of pregnancy
History of breast feeding
History of contraceptive pills use
History of hysterectomy and of ovary/breast surgery

Table 2. Summary of clinical measurements at baseline survey in PONS study

Variables	Number of measurements	Equipment used
Standing height	once	manufactured instrument
Hip circumference	once	standard tape measure
Waist circumference	once	standard tape measure
Weight	once	portable electronic scales
FEV1	three times	Spirometer
FVC	three times	Spirometer
CO level	once	CO meter
Resting blood pressure	twice	Digital BP monitor
Resting pulse rate	twice	Digital BP monitor
ECG	once	Digital ECG monitor
Fasting blood glucose	once	done in the lab
Fasting blood total cholesterol	once	done in the lab
Fasting blood HDL	once	done in the lab
Fasting blood LDL	once	done in the lab
Fasting blood TGL	once	done in the lab

HDL = High Density Lipoprotein; LDL = Low Density Lipoprotein; TGL = triglycerides

All information collected is entered directly into a computer using a laptop-based data entry system developed specifically for the project. The data undergo a regular Quality Assurance procedure providing estimates of reliability and checks against any serious organizational failure. Computer programmes were developed to check the logic and reasonable range of responses throughout the participant record to identify contradictory responses or erroneous data.

SUMMARY

The PONS study is one of the first prospective cohort study with blood and urine collection ever conducted in Central and Eastern Europe. It is carefully designed, with a range of computerized systems for reliable and efficient data collection and management. Recruitment for the first phase of the PONS study of 10,000 – 15,000 participants is expected by the end of 2011. Although the data will not be freely available, specific proposals for future collaboration would be welcomed. Further information can be found on the study website: www.projectpons.pl or through email to the project coordinator: manczukm@coi.waw.pl.

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