



Cohort Profile

Cohort Profile: Ravansar Non-Communicable Disease cohort study: the first cohort study in a Kurdish population

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Why was the Ravansar Non-Communicable Disease (RaNCD) cohort set up?

The increase in the incidence and prevalence of chronic diseases is one of the greatest challenges that health care systems face today. Modern lifestyles and increased longevity have led to an increase in exposure to risk factors, which has led in turn to a rise in the incidence of non-communicable diseases (NCDs).¹ Understanding the underlying causes of NCDs in Iran is a priority for the government. Despite effective health promotion programmes by decision makers and health authorities, changes in lifestyle and increasing life expectancy have exacerbated the risk of NCDs.

Cardiovascular diseases are the leading cause of death in Iran, accounting for 39.3% of mortality.^{2,3} After road traffic accidents, cancer is the third most common cause of death. Data reported in 2011 showed that more than four million Iranian adults were suffering from diabetes, a 35%

increase compared with 2004. The prevalence of impaired fasting glucose and diabetes in people aged 25–70 years was 14.6% and 11.4%, respectively.⁴ Overweight and obesity, which have strong associations with NCDs, have shown increasing trends during recent decades.⁵

To address these issues in Iran in a comprehensive and co-ordinated fashion, the Prospective Epidemiological Research Studies of the IrAN (PERSIAN) cohorts have been established with the support and co-ordination of the Digestive Disease Research Institute (DDRI) and the Ministry of Health and Medical Education of Iran (<http://persiancohort.com>). There are currently 19 centres, including RaNCD, following agreed protocols. The primary objectives of the RaNCD cohort study are as follows: A) to determine trends in the incidence of NCDs and other major outcomes (such as hospital admission and death) in people aged 35–65 years living in the Ravansar district, a Kurdish region in western Iran; B) to determine the incidence and

prevalence of important risk factors for NCDs; C) to clarify the associations between risk factors and NCDs and to collaborate with the other PERSIAN cohort centres to maximize the learning from the combined cohort data; and D) to facilitate the implementation of future health interventions based on national evidence.

The RaNCD study is the first cohort study to investigate NCDs in a Kurdish population. Kurdish settlements cover expansive parts of west and northwest Iran, east and southeast Turkey, north and northeast Iraq, and northeast Syria, with an approximate area of 190 000 km² (Figure 1). The population of Kurds is estimated at 45 million, including 5–7 million who are Iranian residents. The RaNCD cohort study is being conducted in the rural and urban areas of Ravansar in the west of Kermanshah province. Kermanshah province has an area of 24 434 km² and about two million people. The city of Kermanshah, centre of the province, is the largest and most important Kurdish settlement in western Iran, with a population of about one million. The Ravansar population is about 50 000, almost all of Iranian Kurdish ethnicity. There are three urban healthcare centres in Ravansar, two rural healthcare centres and 32 active local health care units (Health Houses) in rural areas.

The reasons for selecting the Ravansar district for this cohort study were as follows.

1. The population is mainly Kurd, an ethnicity covering about 45 million people in four countries who are very similar in culture, dietary habits, lifestyle and even genetic background.
2. Ravansar is 45 km from Kermanshah University of Medical Sciences, where the investigators of this study are based, making the research feasible.
3. There is little migration in and out of Ravansar, and therefore losses to follow-up should be minimal.

The design and implementation of the study have been approved by the Ethics Committee of Kermanshah University of Medical Sciences.

Who is in the cohort?

The participants of this study are permanent residents of Ravansar. Inclusion criteria for participant recruitment were: A) age 35–65 years; B) minimum residence of 1 year in Ravansar, with a minimum stay of nine months per year; C) likelihood of staying in Ravansar for the foreseeable future, together with willingness to participate; D) provision of written informed consent; E) capability to communicate with the research team and having Iranian citizenship (according to national ID card and birth certificate).

The pre-pilot ran during January–March 2014. After the pre-pilot, measuring tools and protocols were revised to improve the validity and reliability of the study, as well as to streamline data collection. The principal investigators decided to use the online version of the questionnaire, in accordance with the PERSIAN cohort protocol.

The pilot phase commenced on November 12, 2014. A total of 1100 participants aged 35–65 years were recruited. The strengths and weaknesses of the data collection procedures were identified and revised, and their validity reassessed in a plenary meeting in the DDRI, in sessions attended by principal investigators from all the PERSIAN cohorts. This process resulted in changes to some parts of the questionnaires and the procedures for collecting clinical measurements, taking tissue samples and anthropometry.

After the pilot phase, the main phase of the study started in March 2015.

The study team carried out a dedicated census to select the sample. A trained research assistant, who had good communication in Kurdish and local languages, conducted a door-to-door survey of all residents in urban areas to register their home address and to specify a code for each household. In the rural areas, local health units (Health Houses) had already collected annually updated registration details for all residents. Household members' details, including name, age and relationship, were registered, along with their contact number. The families were told about the project and its objectives and were provided with educational handouts regarding all the processes.

Overall, 15 000 people aged 35–65 years were living in both urban and rural areas of Ravansar district. The investigators decided to include 10 000 people based on all available resources and in agreement with the central PERSIAN team. To increase the feasibility of the study, people were recruited from both urban and rural areas. The size of the sample recruited to the study was proportional to the total population covered by each health centre.

By the end of February 2017, 10 065 participants had been recruited, including the 1100 from the pilot phase (from whom data have been collected using the revised questionnaires and procedures).

All the study staff, including a medical doctor, interviewers, laboratory technicians, executive managers and receptionists, were selected from local applicants by face-to-face interviews with principal investigators.

When one or more members of the household met the inclusion criteria and agreed in principle to participate in the project (93.2% participation rate), a pamphlet was provided that contained information about the research plan, methods and standard testing conditions (e.g. what was meant by 'fasting' in relation to blood and urine

sampling). They were also given a personal invitation and a date was scheduled for attendance at the cohort research centre.

All residents in the included areas of Ravansar district aged 35–65 years, who were willing to participate, were invited to join the study. If people were unwilling to participate, the reason was recorded. From all invitations, 738 people (7.3%) (347 women and 391 men) declined to participate for reasons such as: not having enough time to participate (54.2%); having no intention of having a health assessment at all, as they thought they were healthy enough (32.5%); drug misuse (7.8%); and unwillingness to provide blood for the biobank (5.5%). If an individual was unreachable at home, the research assistant returned up to two times to invite them to join the study. A reminder call was made one day before the appointment. Participants were advised to avoid cutting their nails one week before the appointment and to fast for 8 hours before attending the centre. On arrival, the receptionist confirmed that the person met the inclusion criteria. To confirm age, copies of the participant's birth certificate and national ID card were required. A unique 11-digit code was assigned to each participant. Each participant's name was registered on the website after the consent form had been signed. After enrolment, participants attended the clinical laboratory for blood collection and sampling of hair, nail and urine.

How often have they been followed up?

Study participants are followed up for outcomes including cardiovascular diseases (increased blood pressure, heart attacks and other ischaemic heart diseases), cerebrovascular accidents, cancers, diabetes mellitus, chronic pulmonary diseases (such as asthma, chronic bronchitis, pulmonary emphysema and pneumoconiosis), chronic kidney disease leading to dialysis, cirrhosis of the liver, Parkinson's and Alzheimer's diseases, and deaths. In the follow-up phase, all participants will be interviewed by phone annually, as well as after the occurrence of each event of interest. All data, samples and measurements collected in the recruitment phase will be recollected at regular intervals (5, 10 and 15 years after baseline). Additionally, for those with an event of interest, a blood sample will also be collected as soon as possible. The follow-up stage is to be conducted in both active and passive modes (see Figure 2).

For the annual follow-up, each participant is contacted by telephone (or seen by a physician at the study centre, if necessary). In addition to the active follow-up, passive follow-up involves obtaining self-reports (whenever the participants visit the centre to report the occurrence of an event) and annual reports from disease and death registries.

If an outcome of interest occurs, the outcome review and verbal autopsy (in the case of death) forms are completed by

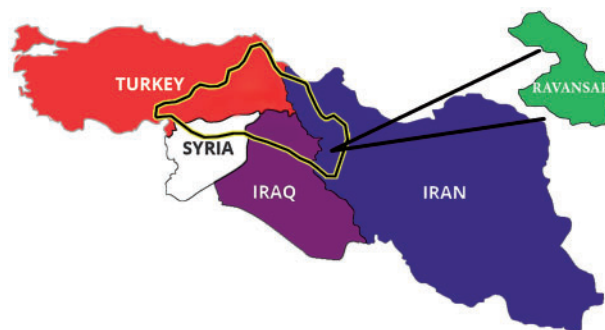


Figure 1. Geographic distribution of Kurdish population (marked area) in four countries (Turkey, Syria, Iraq and Iran) and location of the Ravansar district in Iran.

the physician. Live participants with confirmed outcomes of interest are invited to visit the cohort centre for further investigation. Given the possibility of recall bias for the reporting of any outcomes of interest, the participants are asked to provide the follow-up team with the relevant medical documents. In addition, a medical doctor follows each case (in person) in all hospitals and clinics to investigate the full health profile of the participants and make copies of all relevant documents.

The data recorded in these forms and all the previous follow-up questionnaires, laboratory results, available biological samples and photos of death certificates and other medical documents are assessed by the reviewing physicians at the Outcome Review Committee to confirm the diagnosis. This committee is made up of two reviewing physicians (internists) who complete the diagnosis form for any morbidity or causes of death. If the two physicians disagree on the diagnosis, a third reviewing physician (also an internist) makes a final diagnosis.

Participation in the study ends if the person becomes unwilling to continue participation, cannot read or recall information or provides false reports, migrates, is inaccessible or dies. If the participant is unwilling to continue in the study, the follow-up team reinvites the subject, briefing them on the benefits of participation in the research, including the promotion of personal and public health, and mostly free medical and laboratory services in the study centre. In addition, helpful advice for the prevention of chronic diseases, especially cardiovascular disease (including stroke), will be provided.

We have now finished the first wave of follow-up, with a participation rate of 99.9% (only 14 people missed follow-up due to migration). The second wave of follow-up has been started but is not yet finished.

What has been measured?

The questionnaire consists of 482 items, all filled in at the clinic. It can be divided into three major sections: general, medical and nutritional.

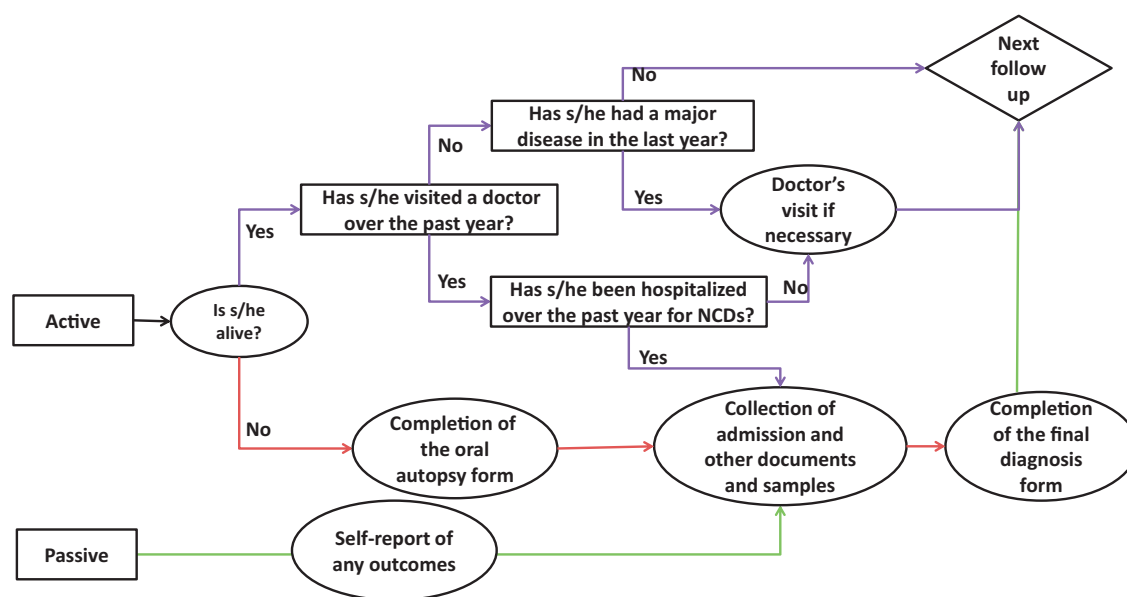


Figure 2 The algorithm of assessment of participants' vital state and medical events in the annual follow-up of the cohort.

a. Questions on socio-economic status, lifestyle, environmental and occupational exposures

Data on socio-economic status and lifestyle were collected through interviews with trained staff before the clinical examinations and after biological and tissue sampling. The objective was to evaluate participants' socioeconomic and demographic status, lifestyle and environmental and occupational exposures (Table 1).

b. General health and medical history

All participants had a physical examination and a private face-to-face medical interview covering the items shown in Table 1.

c. Blood, urine, hair and nail collection and analysis

Blood samples were collected using standard blood drawing vacutainer techniques (while seated and with the use of a tourniquet). Urine samples were collected into sterile collection tubes. The hair (200–300 strands, 1–3 cm long) and nail (all finger and toenails) samples are stored in foil and ziplock bags in cool dry storage.

The blood, urine, hair and nail samples were subdivided, with some used for immediate analysis and the remainder stored at an appropriate temperature in different freezers and refrigerators. All storage equipment is monitored 24 hours a day, 7 days a week, supported by automatic sensors and emergency electric power generators. The measurements made are shown in Table 1.

d. Anthropometric measurements

All participants were asked to remove their shoes, heavy clothes and accessories. The anthropometric measurements

were made using an automated bioelectric impedance machine (InBody 770, BIOSPACE KOREA) with an integrated automatic audiometer (BSM350). Waist circumference was measured at the narrowest point immediately below the lowest rib and above the iliac crest; hip circumference was measured at the level of maximum circumference; wrist circumference was measured on the right arm in a standing position stretching the elbow, on the widest part of the forearm immediately above the ulnar bone. All measurements were made using a non-elastic tape measure, without applying any pressure. The precision of all above measurements is 0.1 cm. The body mass index (BMI) was calculated by dividing weight in kilograms by the height in metres squared (kg/m^2). Waist-hip ratio (WHpR) and waist-height ratio (WHtR) were calculated by dividing waist circumference by hip circumference or height, respectively.

e. Reproductive history

The reproductive history and fertility of female participants were evaluated using the items shown in Table 1.

f. Nutritional status

Nutritional status was assessed using the national Iranian Food Frequency Questionnaire (FFQ). The FFQ assessment asks about consumption of food and drink during the past year. The questionnaire includes 125 food items appropriate for the Iranian population, including bread, cereal, grains, meat and meat products, milk and dairy products, vegetables, fruits, types of oil and oilseeds, sugar, miscellaneous food products, spices and food supplements. Local foods were added into the questionnaire. The nutrition questionnaire also asks about cooking methods, food

Table 1. Measures administered at the baseline and 5-yearly assessments

Classification		Measures and instruments
General	Socio-demographic	Employment status; education; employment history; marital status; number and type of marriages (first-degree or second-degree familial marriage or none); spouse's job; region of residency, number of domestic and international trips; access to landline and mobile phones, the internet and the extent of cell phone use
	Lifestyle	History of smoking; being a passive smoker; alcohol consumption; tea consumption; intake of animal fat, physical activity, sleep quality and daily activities; drug misuse
	Environmental and occupational exposures	Occupational exposures; cooking and heating fuel; number of people per family and type of housing; dwelling status, hygiene status of the dwelling and its facilities; drinking water source; history of exposure to animals; history of exposure to agricultural toxins and household pesticides and extent of use; annual reading rate
Medical	General health and medical history	Current and past medical history, family history, subjective health status, history of past falling and any fracture, pain, digestive symptoms, cardiac angina, neurologic symptoms, history of transfusion, oral health condition, current use of medications, pulse rate and blood pressure measurement plus complete physical examination.
	Blood analysis	Fasting blood glucose; complete blood count (Hemoglobin, white blood cell, red blood cell, platelet, differential of white blood cell, mean corpuscular volume and mean corpuscular hemoglobin concentration); lipid profile analysis (triglyceride, cholesterol, LDL cholesterol, HDL cholesterol); kidney function test (blood urea nitrogen, creatinine); and liver function test (alanine transaminase, aspartate transaminase, alkaline phosphatase and gamma-glutamase transpeptidase)
	Urine analysis	Urine pH, specific gravity, presence of blood, protein, glucose, bilirubin, nitrate, ascorbic acid, leukocytes and microalbumin
	Anthropometric measurements	Full body analysis using advanced bioelectric impedance analyzer; height; waist circumference; hip circumference; wrist circumference; full body composition analysis
Nutrition	Reproductive history	Number of births, live births, miscarriages and stillbirths; history of breastfeeding; age at menarche/menopause; history of contraception and contraception method; use of hormone replacement therapy; history of hysterectomy, tube ligation and oophorectomy; history of infertility; history of breast and cervical cancer screening
	Food Frequency	Food frequency questionnaire (125 items - in the past year)
	Dietary habits	Dietary habits during the past year and current
	Preparation and storage	Food preparation and storage techniques (current)

preservation, food storage, cooking styles and use of herbal medicines and drinks.

For the purpose of annual follow-up, in addition to updating the participant's address and phone numbers, all information about medical history during the past year, including any hospital admission and treatment received (and any changes that occurred), is collected. However, for the 5-year interval follow-up, we plan to repeat the full assessment, similar to the recruitment phase.

Key findings to date

The key demographic findings are shown in Table 2. Of the 10 065 individuals who participated in the RaNCD, 4775 (47.4%) were male, 2492 were illiterate (24.8%) and

only 7.8% had an academic education. Almost 40% of people were living in urban areas.

Overall, only 27.6% of all participants had a normal BMI, while the majority were overweight or obese, especially among women. For waist-to-hip ratio, there was a big difference between men and women. From a total of 8220 people (82.4%) with an abnormal value, 60.4% and 39.6% were women and men, respectively. This is also true of metabolic syndrome. From 3068 people (30.5%) with metabolic syndrome, 66.1% were women. Of the total, 44.1% suffered from dyslipidaemia. Most such participants were men (56.3%). In addition, only 21.0% of people had a level of physical activity equal to or higher than 45 metabolic equivalent (MET) hours per day (Table 3).

The most common chronic diseases, based on self-report, were kidney stones, hypertension, fatty liver and

Table 2. Demographic characteristics of participants in RaNCD cohort study

Variables		Total <i>n</i> (%)	Male <i>n</i> (%)	Female <i>n</i> (%)	<i>P</i> value
Age group (years)	35-45	4428 (44.0)	2116 (47.8)	2312 (52.2)	<0.001
	46-55	3348 (33.3)	1660 (49.6)	1688 (50.4)	
	56-65	2289 (22.7)	999 (43.7)	1290 (56.3)	
Marital status	Married	9076 (90.2)	4638 (51.1)	4438 (48.9)	<0.001
	Single	422 (4.2)	96 (22.7)	326 (77.3)	
	Divorced/widow	567 (5.6)	41 (7.2)	526 (92.8)	
Length of education (years)	Illiterate	2492 (24.8)	619 (24.8)	1873 (75.2)	<0.001
	≤5 years	3844 (38.2)	1379 (35.9)	2465 (64.1)	
	6-9 years	1675 (16.6)	1156 (69.0)	519 (40.0)	
	10-12 years	1270 (12.6)	986 (77.6)	284 (22.4)	
Place of residence	≥13 years	784 (7.8)	635 (81.0)	149 (19.0)	<0.001
	Urban	5964 (59.2)	2935 (49.2)	3029 (50.8)	
	Rural	4101 (40.7)	1840 (44.9)	2261 (55.1)	

Table 3. Anthropometric indices, metabolic syndrome and substance abuse in RaNCD cohort study

Determinants		Total <i>n</i> (%)	Male <i>n</i> (%)	Female <i>n</i> (%)	<i>P</i> value
BMI	Underweight	167 (1.7)	95 (56.9)	72 (43.1)	<0.001
	Normal weight	2752 (27.6)	1630 (59.2)	1122 (40.8)	
	Overweight	4345 (43.5)	2204 (50.7)	2141 (49.3)	
	Class I obesity	2133 (21.4)	684 (32.2)	1449 (67.8)	
	Class II & III obesity	585 (5.8)	110 (18.8)	475 (81.2)	
WHpR	Less than 0.85 and 0.90 in women and men	1762 (17.6)	1472 (83.5)	290 (16.5)	<0.001
	Abnormal	8220 (82.4)	3254 (39.6)	4966 (60.4)	
Metabolic syndrome (ATP III)	No	6995 (69.5)	3735 (53.4)	3260 (24.6)	<0.001
	Yes	3068 (30.5)	1039 (33.9)	2029 (66.1)	
Food consumption	Low salt	2909 (29.0)	1536 (52.8)	1373 (47.2)	<0.001
	Medium salt	3142 (31.3)	1503 (47.8)	1639 (52.2)	
	Salty	3986 (39.7)	1720 (43.1)	2266 (56.9)	
Reused frying oil	No	7205 (71.6)	3483 (48.3)	3722 (51.7)	0.004
	Yes	2860 (28.4)	1292 (45.2)	1568 (54.8)	
Use of alcohol	No	9430 (93.7)	4144 (43.9)	5286 (56.1)	<0.001
	Yes	635 (6.3)	631 (99.7)	4 (0.06)	
Hookah	No	9698 (96.3)	4439 (45.8)	5259 (45.2)	<0.001
	Yes	367 (3.7)	336 (91.6)	31 (8.4)	
Smoking	No	8027 (80.0)	3027 (37.7)	5000 (62.3)	<0.001
	Current	1179 (11.7)	1072 (90.9)	107 (9.1)	
	Former	829 (8.3)	660 (79.6)	169 (20.4)	
Drug abuse	No	9766 (97.0)	4484 (45.9)	5282 (54.1)	<0.001
	Yes	299 (3.0)	291 (79.3)	8 (2.7)	
Use of Flossing	No	8877 (88.4)	4182 (47.1)	4695 (52.9)	0.1
	Yes	1168 (11.6)	578 (49.5)	590 (50.5)	
Dyslipidaemia	No	5625 (55.9)	2256 (40.1)	3369 (59.9)	<0.001
	Yes	4440 (44.1)	2519 (56.3)	1921 (43.7)	
Physical activity (daily METs)	24-36.5	2773 (27.6)	1585 (57.2)	1188 (42.8)	<0.001
	36.6-44.9	5166 (51.4)	1595 (30.9)	3571 (69.1)	
	≥45	2117 (21.0)	1589 (75.1)	528 (24.9)	

diabetes (Table 4). Based on blood pressure and fasting blood sugar measurements, as well as checking the medications of each participant, the prevalence of diabetes and hypertension were 8.19% (men 7.97%; women 8.39%)

and 15.69% (men 12.82%; women 18.27%), respectively. Except for kidney stones, which is different from other NCDs, the prevalence of most NCDs was higher in women than men.

Table 4. Prevalence of chronic diseases base on self-report in RaNCD cohort study

Chronic disease		Total <i>n</i> (%)	Male <i>n</i> (%)	Female <i>n</i> (%)	<i>P</i> value
Diabetes	Yes	1008 (10.03)	388 (8.14)	620 (11.73)	<0.001
	No	8799 (87.52)	4212 (88.36)	4587 (86.76)	
	Unknown	247 (2.46)	167 (3.50)	80 (1.51)	
Hypertension	Yes	1681 (16.71)	542 (11.36)	1139 (21.54)	<0.001
	No	8319 (82.69)	4186 (87.70)	4133 (78.16)	
	Unknown	61 (0.61)	45 (0.94)	16 (0.30)	
Cardiac Ischaemic	Yes	472 (4.69)	193 (4.05)	279 (5.28)	0.002
	No	9582 (95.31)	4575 (95.95)	5007 (94.72)	
Myocardial infarction	Yes	111 (1.10)	64 (1.34)	47 (0.89)	0.1
	No	9943 (98.90)	4703 (98.66)	5240 (99.11)	
Stroke	Yes	98 (0.97)	39 (0.82)	59 (1.12)	0.3
	No	9956 (99.03)	4728 (99.18)	5228 (98.88)	
Fatty liver	Yes	1032 (10.26)	308 (6.46)	724 (13.69)	<0.001
	No	9022 (89.65)	4459 (93.54)	4563 (86.31)	
Chronic lung disease (asthma- tuberculosis)	Yes	200 (1.99)	74 (1.55)	126 (2.38)	0.003
	No	9854 (98.01)	4693 (98.45)	5161 (97.62)	
Thyroid disorders	Yes	738 (7.34)	108 (2.27)	630 (11.92)	<0.001
	No	9316 (92.66)	4659 (97.73)	4657 (88.08)	
Kidney stone	Yes	1830 (18.20)	1008 (21.15)	822 (15.55)	<0.001
	No	8222 (81.78)	3757 (78.81)	4465 (84.45)	
Gallstone	Yes	353 (3.51)	57 (1.20)	296 (5.60)	<0.001
	No	9701 (96.49)	4710 (98.80)	4991 (94.40)	
Rheumatic diseases	Yes	320 (3.18)	67 (1.41)	253 (4.79)	<0.001
	No	9734 (96.82)	4700 (98.59)	5034 (95.21)	

What are the main strengths and weaknesses of the study?

RaNCD, along with the other cohorts from the PERSIAN study, will form a large cohort aiming to investigate the incidence of major NCDs and their risk factors in Iran over 15 years of follow-up. As far as we know, RaNCD is also the first cohort study in the Kurdish regions, so it will shed light on the health of this minority group across a wide geographical area.

Similar to all cohort studies, this study is limited because of selection bias. Individuals who are willing to participate in long-term research may be more concerned about their health than others and may adopt lifestyles that they believe address these concerns. However, RaNCD had a very high level of initial participation. Additionally, the free cost of healthcare services should increase participation among people of lower socioeconomic status.

Can I get hold of the data? Where can I find out more?

The RaNCD cohort is not an open-access database. However, we would encourage external investigators to consider applying to use the data for secondary analyses, to maximize the scientific output from the data. All the information

on how to access the RaNCD public data archive, with a list of current proposals and papers under preparation, can be found on our website: www.persiancohort.com

Profile in a nutshell

- The Ravansar Non-Communicable Diseases (RaNCD) cohort aims to investigate the incidence of major non-communicable diseases and their risk factors in people aged 35–65 years in Ravansar, a Kurdish region in western Iran.
- RaNCD is the first cohort study in the Kurdish regions. It will shed light on the health of this minority group across a wide geographical area.
- RaNCD investigators recruited 10 182 people who are permanent residents of the Ravansar district.
- Each participant will be followed annually for 15 years, both actively (contacted by telephone or seen by a physician at the study centre when necessary) and passively (whenever participants visit the centre to report the occurrence of an event of interest).
- All measurements collected in the recruitment phase will be collected again at regular intervals (5, 10 and 15 years after the baseline).
- From the total cohort, 10 065 eligible people (99.06%) remain for future follow-up.

- The RaNCD cohort study questionnaire consists of 482 items covering three areas: general, medical and nutrition.
- Procedures for data access, information on collaborations, publications and other details can be found at <http://persiancohort.com>

Conflict of interest: None declared.

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