Protocol Design

Protocol Design for Large–Scale Cross–Sectional Studies of Surveillance of Risk Factors of Non–Communicable Diseases in Iran: STEPs 2016

Shirin Djalalinia PhD[1,2], Mitra Modirian MD[2], Ali Sheidaei MSc[3,2], Moein Yoosefi MSc[2], Hossein Zokaiee MSc[2], Bahman Damirchilu MSc[2], Zohreh Mahmoudi MSc[2], Negar Mahmoudi MSc[2], Mohammad Javad Hajipour PhD[4], Niloofar Peykari PhD[1,2], Nazila Rezaei MD[2], Rosa Haghshenas MSc[2], Mohammad Hossein Mohammadi MSc[2], Alireza Delavari MD[5], Mohammad Mehdi Gouya MD MPH[6], Shohreh Naderimagham PhD[2], Ahmad Kousha MD[7], Alireza Moghisi MD MPH PhD[7], Alireza Mahdavihezaveh MD MPH[7], Kambiz Abachizadeh MD MPH[8], Reza Majdzadeh PhD[9], Ali Akbar Sayyari MD[7], Reza Malekzadeh MD AGAF[5], Bagher Larijani MD[10], Farshad Farzadfar MD MPH DSC•[2]

Abstract

Introduction: The rise in non–communicable diseases (NCDs) has gained increasing attention. There is a great need for reliable data to address such problems. Here, we describe the development of a comprehensive set of executive and scientific protocols and instructions of STEPs 2016.

Methods/Design: This is a large–scale cross–sectional study of Surveillance of Risk Factors of NCDs in Iran. Through systematic proportional to size cluster random sampling, 31,050 participants enrolled in three sequential processes, of completing questionnaires; physical measurements, and lab assessment.

Results: Out of 429 districts, samples were taken from urban and rural areas of 389 districts. After applying sampling weight to the samples, comparing the distribution of population and samples, compared classification was determined in accordance with the age and sex groups. Out of 31,050 expected participants, 30,541 participant completed questionnaires (52.31% female). For physical measurements and lab assessment, the cases included 30,042 (52.38% female) and 19,778 (54.04% female), respectively.

Discussion: There is an urgent need to focus on reviewing trend analyses of NCDs.To the best of our knowledge, the present study is the first comprehensive experience on systematic electronic national survey. The results could be also used for future complementary studies.

Keywords: Design, Iran, non–communicable diseases, protocol, risk factors, STEPs

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Authors' affiliations: [1]Deputy of Research and Technology, Ministry of Health and Medical Education, Tehran, Iran, [2]Non–communicable Diseases Research Center, Endocrinology and Metabolism Population Sciences Institute, Tehran University of Medical Sciences, Tehran, Iran, [3]Department of Biostatistics, Faculty of Paramedical Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran, [4]The Persian Gulf Biomedical Sciences Research Institute, Bushehr University of Medical Sciences, Bushehr, Iran, [5]Digestive Oncology Research Center, Digestive Disease Research Institute, Shariati Hospital, Tehran University of Medical Sciences, Tehran, Iran, [6]Center for Communicable Disease Control (CDC), Deputy of Health, Ministry of Health and Medical Education, Tehran, Iran, [7]Deputy of Health, Ministry of Health and Medical Education, Tehran, Iran, [8]Department of Community Medicine, School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran, [9]Knowledge Utilization Research Center and Community Based Participatory Research Center, Tehran University of Medical Sciences, Tehran, Iran, [10]Endocrinology and Metabolism Research Center, Endocrinology and Metabolism Research Institute, Tehran University of Medical Sciences, Tehran, Iran.

•**Corresponding author and reprints:** Farshad Farzadfar MD MPH DSc, Non–communicable Diseases Research Center, Endocrinology and Metabolism Population Sciences Institute, Tehran University of Medical Sciences, Tehran, Iran. Address: Second Flour, No. 10, Next to Dr. Shariati Hospital, Jalal Al Ahmad Hwy., North Kargar Ave., Tehran, Iran. Postal code: 1411713137. Tel: 98–21–88631296-7, Email: f–farzadfar@tums.ac.ir.

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Introduction

The aging population and the increase in level of exposure to risk factors for non–communicable diseases (NCDs) have raised in the burden of NCDs in the last three decades.[1–3] The slope of changes is steeper in the developing countries.[2–6] In developed and especially developing countries, policymakers in the health sector need to have access to reliable information on the level and trends of exposures to NCDs risk factors.[2,7] The WHO recommended a comprehensive commitment for reducing 25% of unconditional probability of deaths for four major NCDs of Cardiovascular Diseases (CVDs), Diabetes, Cancers and Chronic Respiratory Diseases through reduction in tobacco use, unhealthy diet, lack of physical activity and harmful alcohol use by 2025, which urges countries to be aware of the distribution of NCDs risk factors exposures.[8]

However, limited reliable information on the distribution of NCDs risk factors exposures remains a major concern for policymakers in the developing countries.[9–11] The concern gets

higher attentions in Iran considering its NCDs action plan and ambition to estimate NCDs risk factors distribution at the sub–national levels.[7,11–14]

The WHO STEPwise approach to risk factor Surveillance, the so–called STEPs, provides a simple, standardized method for collecting, analyzing and disseminating relevant information helps countries to build and strengthen their capacity for conducting surveillance.[15]

The instruments of STEPs 2016 in Iran cover three different levels of assessment: step 1) demographic, epidemiologic, and risk–related behavioral information; step 2) physical measurements; and step 3) lab measurements of a nationally representative sample of Iranian adults.

The STEPs surveys have been implemented in Iran in 2005, 2006, 2007, 2008, 2009 and 2011. In all of these surveys, the two fist steps have been conducted. In 2055, 2007, 2011, lab measurements were included as the third part of the survey.[16,17]

Despite numerous strengths, previous STEPs as the only complete reliable national data sources, suffer from several shortcomings. For instance, considerable challenges were faced in cleaning the data because of the change in the content of questions and non–standardized coding processes.[13,17] The missing data and implausible ranges were other important problems that mostly derived from using paper questionnaires and manual data entry. Also, some uncertainty comes from variations of sampling method in different surveys.[18–20]

Considering these facts, a purposeful attempt, with maximum enjoyment of the opinions of experts and key informants, was made to design the comprehensive set of administrative and supervisory protocols for the STEPs 2016. In this paper, we describe how we develop a comprehensive set of executive and scientific protocols and instructions that meet the needs of the survey.

Methods/Design

Using peer discussion interaction method, a set of complex processes of expert peer review were resumed to integrate the scientific recommendations for each of the instructions and complementary documents.

These processes were followed by iterated drafting of protocol specifications and pilot tests. Also, as a large scale national survey, the feasibility of conducting was evaluated in association with implementation in a national–level scale. In all these reviews, we focused on the survey objective as the main conveniences of project which is determining the prevalence of main preventable risk factors of NCDs in Iran (including smoking, poor nutrition, low physical activity, high blood pressure, overweight and obesity, high blood glucose, and high blood lipids) by age and sex groups.

Processes of implementation

Based on the comprehensive study on the six rounds of implementation of STEPs in Iran and considering other countries' experiences, the required specifications for outcomes analysis were transferred to comprehensive study protocol specification procedures.

After development of protocols that cover several areas (including information technology, questionnaire and guide for interviewers, physical measurements, laboratory measurement and Bio–banking, capacity building and training, supervision, sampling, feasibility assessment, statistical analyses and ethical consideration), by the Non–Communicable Diseases Research Center of Endocrinology and Metabolism Research Institute of Tehran University of Medical Sciences, all documents were distributed among the members of the scientific committee for their final comments and agreements.

Information Technology Protocols

To accelerate and facilitate the implementation of the processes and to increase and improve the accuracy of data registration and transmission, we developed a specific protocol based on Information Technology (IT) standards and guidelines. Moreover, we included many measures to control the quality and optimize the management of processes which were entirely run and managed in a web–based fashion.[20–23]

This comprehensive protocol contains three specialized tasks of Android Application for data gathering, Web-based dashboard for reporting and monitoring, and Windows-based application for Laboratory Information Management System (LIMS). For importing questions and base data into database, we developed a third party application that reads tagged questionnaire and imports related data to database faster.[24,25]

All communications between all Android tablets and the server use HTTPS protocol and all communications between tablets and servers are based on JSON technology. We used Apache Tomcat web service with related web methods for middle interpreter between Android tables and SQL server database. For better performance in communication between Android tablets and web service, lowering server network traffic, and better compress–decompress data, JAVA-based web service was used.[2,21,25]

In this part, we provide a brief description of scientific and executive protocols and instructions that were enrolled in implementing Iran STEPs 2016:

All three sequential processes of starting with gathering information on key risk factors by the use of questionnaires (Step 1), physical measurements (Step 2), and lab assessment (Step 3) were completely assessed and developed based on standard requirement of reliable national survey.[22,24]

Questionnaire and guide for interviewers

Considering the questionnaires which were used in 2005, 2006, 2007, 2008, 2009, 2011, after revision of some topics, evaluation of questions' consistency and assessment of validity and reliability, a practical version of the questionnaire have been developed in which demographic, behavioral information (e.g. nutrition, physical activity, smoking and alcohol consumption), history of metabolic risk factors and injuries, health care utilization, screening programs and treatment are targeted as the main interests. The final approved version has been used for digitalization of data gathering.

Physical measurements protocol

Through expert panels and consistent with WHO protocols and aligned with previous round of study, these instructions contain standards for measurement of anthropometric variables, blood pressure, pulse rate, and individuals' pedometer information. We also standardized details of calibration for both tools and measurement processes. For this purpose, a total of 572 tablets (Lenovo A3000), 261 scales (Inofit), 261 blood pressure measuring devices (Beurer), 261 height measuring instruments and 220 pedometers (Xiaomi) were prepared and distributed.

Laboratory measurement and Bio–banking

We aimed to store the biological samples that will be randomly collected from all provinces (city/village) of Iran. Using the auto analyzer (Cobas C311 Hitachi High–Technologies Corporation. Tokyo Made in Japan) approved by Health Reference Laboratory, the levels of Total Cholesterol, Glucose, HDL–C, ALT, and Triglyceride were assessed from the plasma. Moreover, for all participants, HbA1c of whole blood was measured. The urine tests included sodium (Na) and creatinine (Cr) measurements.

To evaluate the validity of urine Na, the 24–hour urinary excretion of Na was assessed in a sub-sample of 550 participants randomly selected from all over the country. In order to the assess the accuracy of 24–hour urine collection, following detailed explanations and the require process for informed consent, using Potassium Amino Benzoic Acid (POTABA) tablets, over recorded 24 hours, urine was collected in specific provided container.

These are the first stored samples that are representative of the Iranian population. In this project, the bio–banking of biological samples (e. g. blood, plasma, buffy coat and DNA) collected from 20560 participants will be set to support the modern research directions in medicine such as omics (Genomics, Transcriptomics, Proteomics, and Metabolomics) and personalized medicine.[26–28]

Temperature and transport requirements

Maintaining the optimal conditions for the transfer of biological samples using the updated standards for promotion of quality of biological samples and biomolecules maintenance, we developed the comprehensive participatory protocol and related instructions.[29,30]

Blood and urine sample collection and transport were performed at a temperature < 4 ºC. Using specific designed package including five tubes containing whole blood (5 cc), buffy coat (1 cc), plasma obtained from tube containing sodium fluoride (3 cc), plasma obtained from tube containing lithium heparin (3 cc) and urine (6 cc), the gathered biological samples were transferred to the central processing/archiving laboratory of study in NCDRC. Through a detailed time-binding action plan, the processes from collection to the central processing/archiving lab were managed in the shortest time (less than 18 hours).

All samples were transported in vaccine transport boxes. During transportation, in each cold box, a digital thermometer recorded the temperature of environment of the biological sample. These enable us to keep biological samples from freezing/ thawing.

Instructions and Packages for Capacity Building and Training

There is also a comprehensive package of hierarchical training steps in different levels of study partners. These documents contain curricula and educational materials which are prepared for all steps of scientific and executive processes.

Training was managed in two levels of national and provincial, as Training of Trainers (TOT) model.

Many specific training courses were conducted for all of teams at two executive levels of universities and cities. The trainers were selected from experts of NCDs field of medical universities and the accreditation approvals for all of co–researchers were approved through online evaluations. In total, during the training process, in each specific domain at national level, about 50 experts were trained as trainers for sub–national training. At provincial level, more than 1500 individuals participated in training programs.

Supervision protocol

For supervising the STEPs 2016, we used national and sub–national monitoring and supervising plan to be done before, during, and after the survey conduction. Based on supervising standards, before the program, the infrastructures, preparedness and training courses were monitored by a group of experts in Ministry of Health and Medical Education (MOHME).

During the implementation, at the same time, better monitoring was achieved through three paths of quality control including 1) completing the key–questions in a sub–sample of individuals; 2) ongoing online controlling of recorded date and 3) direct observation of interviews by field visit.

After finishing the program, all recorded data reviewing and the possible missed data were repaired by direct contact with participants via feed–back to provincial staffs in fields. Finally, the results were assessed by scientific committee of program held in NCDRC, MOHME, and National Institute For Health Researches (NIHR).

Sampling protocol

For proportional to size sampling, we designed a systematic cluster random sampling frame through which 31,050 participants (3105 clusters) were selected from urban and rural areas of 31 provinces of Iran. To estimate the minimum sample at the 95% confidence level, the most sparsely populated province of the country with 384 samples (Ilam) was considered as the basis of calculations. The sample size of other provinces was calculated

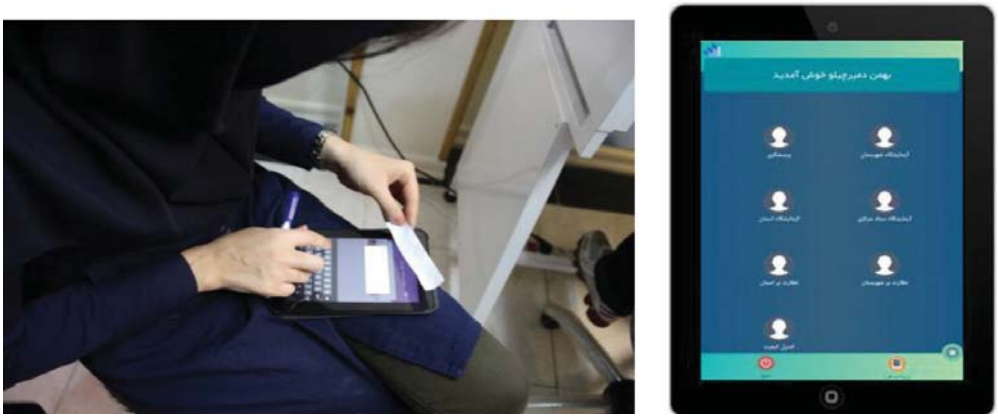

Figure 1. Electronic questionnaire

Figure 2. Processes of laboratory measurement and Bio–banking

according to the population ratio of each to the referenced province. To consider the effect of sampling design and to control non–response error, 10% was added to the estimated samples of each province. With a view to reducing costs and increasing productivity, it was decided that for provinces with 800 or more samples through weighting methods, half of calculated sample size taken along with the twice weight in estimating.[22,31–33]

In this regard, national individual ID and postal code were used as part of individual characteristics in the questionnaire that has to be validated by interviewer through seeing national ID card.

The eligible population for study was defined according to the criteria of being among 18 ≤ years old Iranian adults that resided in Iran at the time of data collection. The first and second steps of study have been run for all selected samples and the third step was considered for those who were 25 ≤ years of age. Data were collected from individuals who agreed to participate and completed inform consent forms. The software features enabled us to analyze non–participation in each of study steps.

Feasibility assessment and simulation

The feasibility of the protocol and probable power points and shortcomings of study were examined by a feasibility study which simulated all executive parts in a real implementation of the project in a simulated study. The results of this phase provide us with a better conception of executive details and more revision, especially concerning software.

Statistical analyses

The data are first used for presenting the descriptive statistics of interested variables, by sex and age subgroups at national and sub–national levels. Moreover, the provincial estimation, the specifications of geographical data sampling enable us to provide the interest outcomes in small area levels. Data can be also used for association between subgroup variables and can be included as a main component of trend analysis in comprehensive researches.

In order to achieve a representative sample of Iranian target population, exact weights were calculated, consisting of provincial weight (province with more than 800 sample size get weight 2),

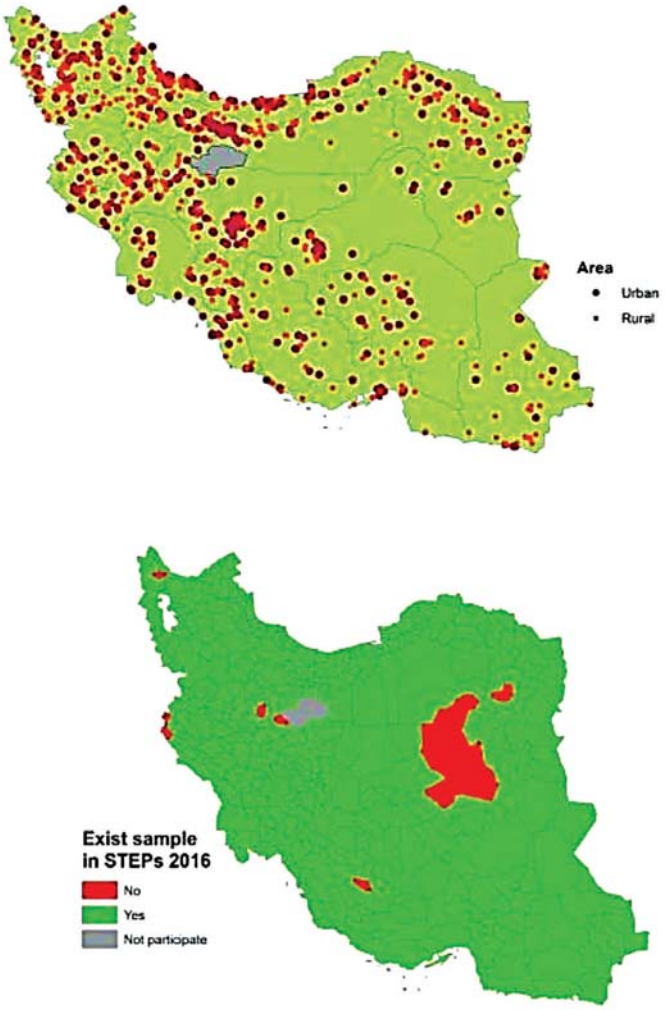

Figure 3. The distribution of sampling point according to residential areas

sampling weight (each subject in sample is representation of several peoples in general population), three weights specific for each steps (for individual who did not participate in that step), same age–sex group weight (we only enter one person from two individuals who were in same age–sex group in a household), householder weight (it was necessary to include householder as the first sample in each household) and finally, non–response weight (for persons who did not participate in the study).

Ethical considerations

Ethical approval for the study was obtained from the Ethical Committee of National Institute for Medical Research Development (NIMAD) (ID:IR.NIMAD.REC.1394.032). Participation in the study was voluntary. Regarding moral consideration, the objectives and methods of the study were described for all of eligible individuals and written informed consent was obtained from all those who accepted to participate. For those who participated in the 24–hour urine collection test, a complementary informed consent process was undertaken, containing all required processes and explanation on Potassium Amino Benzoic Acid (POTABA) test.

Results

Based on the specification of design and sampling frame, the present survey provides the maximum extent for estimation of levels of prevalence of NCDs risk factors and diseases. In STEPs 2016, out of 429 Iranian districts, samples were taken from urban and rural areas of 389 districts (Figure 3).

As another point through comprehensive efforts to engage individuals to participate in the study, only ten provinces did not achieve the full estimated samples, nine of which had more than 99% achieved percentage. Qom province refused to participate in the study (Figure 4).

After applying sampling weight to the samples, comparing the distribution of population and samples, Kolmogorov–Smirnov test was performed and compared classification was determined in accordance with the age and sex groups. Probability sample tests showed that the study population is representative at the national and provincial levels.

Out of 31,050 expected participants, 30,541 participant completed questionnaires Step 1, of whom 52.31% were female. For physical measurements and lab assessment, the cases included 30,042 (52.38% female) and 19,778 (54.04% female),

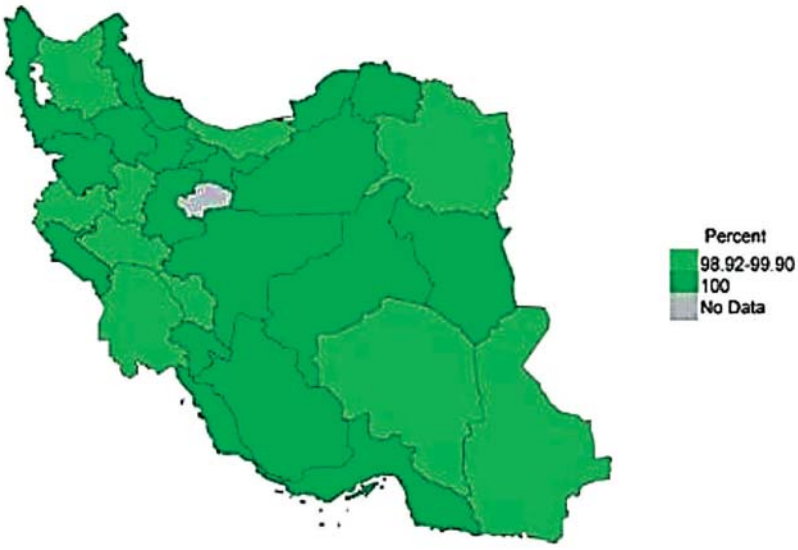

Figure 4. The distribution of achieved percent in cluster sampling

Table 1. The distribution of study participants according to study steps, sex, age groups, at national level

Age groups	Questionnaires (Step 1)		Physical measurements (Step 2)		Lab assessment (Step 3)	
	Male	Female	Male	Female	Male	Female
18–24	1261	1542	1242	1520	- - -	- - -
25–34	3426	3865	3360	3801	2085	2671
35–44	3137	3358	3078	3310	2125	2571
45–54	2638	2935	2593	2892	1879	2257
55–64	2100	2279	2062	2240	1551	1743
65–69	647	791	631	779	450	573
70 ≤	1357	1205	1341	1193	1000	873
Total	**14566**	**15975**	**14307**	**15735**	**9090**	**10688**

respectively (Table 1). There were also some differences between participation rate in urban and rural areas (Figure 5).

Totally, 9048 (29.63%) of samples were in rural areas. On the other hand, 8886 (29.58%) and 6965 (35.22%) of participants for physical measurements and lab assessment, respectively, were living in rural areas.

Discussion

The United Nations (UN) and the World Health Organization (WHO), in comparison with mortality in 2010, have called for a 25% reduction in mortality from NCDs in age groups of 30 – 70 years old, by 2025, adopting the slogan "25 by 25".[6] In addition, at the same time, Iran has committed to specific attention on NCDs to comply by the commitments of Sustainable Development Goals (SDGs).[6,7]

In order to achieve these goals, one of the effective strategies focuses on public health interventions.[32,33] In order to plan and conduct these interventions, we need an exact vision of distribution of metabolic risk factors and life style that could be provide through STEPs. Thus, STEPs 2016 could be used as the accurate basis of evidence-based interventional programs of health system and better policy making for NCDs.

In order to develop administrative and supervisory protocols for the STEPs 2016, we took advantage of the scientific resources of academic partnerships and analytical results of previous six rounds of the implementation of this national survey in Iran.[16–18] In addition, considering the importance of consistency between questions, studied topics, indices, and the corresponding options, we utilized relevant strategies for drawing optimum benefit from the collected information.[15,18]

The valuable experiences of six rounds of implementation of STEPs in Iran have yielded many noticeable strengths and improvements. One of the most important features of this survey is its continuous nature. Considering the national capacities such as rural primary health–care workers, and benefiting from recourse mobilization for better health, awareness of trends of metabolic and lifestyle risk factors in planning for control and prevention of NCDs is crucial.[34–36] Although over time, methods and contents of STEPs have not remained untouched, the overall consistency

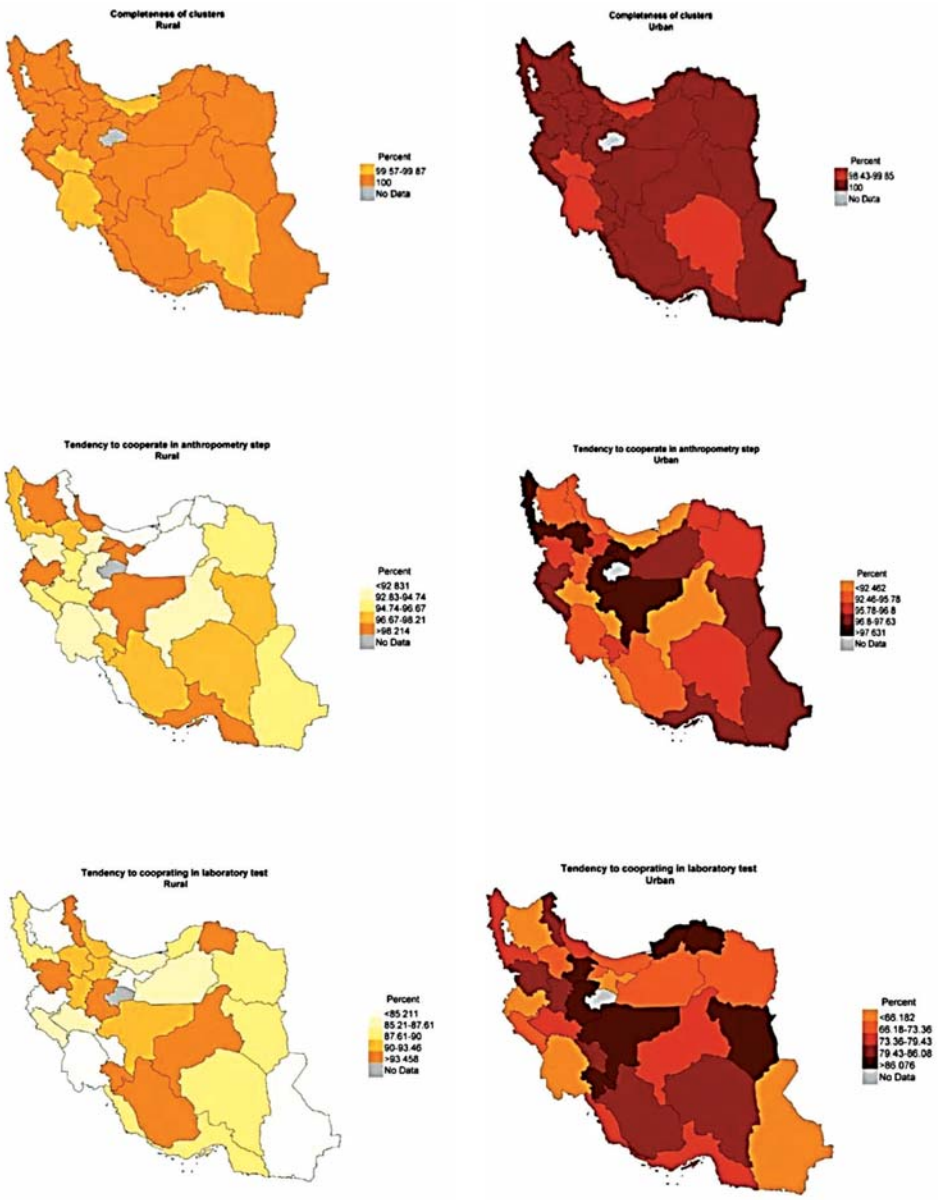

Figure 5. The distribution of study participants according to study steps and residence area, at provincial level

(mostly on contents rather methods) would be a strong point of STEPs over years.[18] Considering a vast variety of exposures and outcomes at sub–national level, providing provincially representative data is undoubtedly the most important privilege of STEPs. In the last round of STEPs in 2011, the questionnaire's scope has been extended to outcomes questions.

Despite previous considerable efforts, there are noticeable gaps and limitations that have been considered in revision of protocols and instructions. Incomprehensiveness and missing components of previous STEPs regarding many critical NCDs risk factors, lack of long term strategic approach for proceeding STEPs, analytical limitation due to sampling issues and lack of cost orientated approaches in design and conduction, were carefully addressed in this round of implementation.

One of the main strengths of this comprehensive protocol is its focus on the standards and regulatory guidelines which had been proposed in the form of a comprehensive package. This package includes all regulatory standards designed for all stages and levels of the study. The aim of monitoring all phases of the study focused on identifying shortcomings and challenges and making qualitative and quantitative improvements in the implementation of the study at the national, provincial, and district levels at different stages, i.e. before, during, and after the implementation of the plan. For that reason, the package defines and clarifies all the stakeholders' different responsibilities, corresponding measures, operational processes, tools, strategies, and expected outcomes. Using a wide communication network (Telephone, SMS, and Virtual Networks "Telegram") and the secure communication platform (HTTPS) for data transformation were other specification of STEPs 2016. All these consideration are taken into account for the first time (Table 2).

We also faced some limitations. Despite our attempts to recourse

Table 2. The specifications of STEPs 2016

Design	Implementation
Sampling	
● Proportional to Size Sample Size ● Systematic Random Sampling ● Possibility of determining Risk Factor Map in megacities	● National individual and postal codes used as a part of individual characteristics in the questionnaire that has to be validated by interviewer through seeing national ID card ● All of sampling methods run through software random selection with the remove the questioner error ● Aim to reduction non-response preventive strategies have been considered in software development ● Determining the time and Place of Interviewing via GPS ● Designing integrated soft wares by NCDRC's staffs
First step	
● Maximum effort to revision and development of questions and information forms based on national objectives, local requirement and consistent with World Health Organization standards ● Eliminating of Error in Data Entry	● Whole Digitalized Study ● Whole Online Study ● Data gathering by Tablets ● Participating of Administrative Teams in Online Exam ● Online sending of supervision checklists 'data
Second step	
● Development of specific comprehensive instruction for anthropometric measures ● Data gathering of daily individuals' steps ● Validity assessment of physical activity data	● Benefiting from standardized calibrated measurement ● Unique brands of all equipment ● Pedometer for Sub-samples ● Monitoring of measurement process (different levels supervision and quality control consideration) ● Participating of Administrative Teams in Online Exam ● Data gathering by Tablets ● Online sending of supervision checklists 'data
Third step	
● New added components to protocol ● HbA1c Test for All Samples ● ALT Test for All Samples ● Urine-Na Test for All Samples ● 24h Urine Sample (POTAPA) for Sub-samples ● Comprehensive training programs for target groups ● Designing Special Educational Films for Interviewers and Lab Experts ● Designing Special Educational Films for digitalized data gathering processed	● Data gathering by Tablets ● All Lab exams by unique brands of devices and kits ● Holder and Vacuum Tubes for Blood Sampling ● Unique Brands of All Sphygmomanometers, Scales, Lab Tubes, SIM Cards, and the Other Equipment ● Secure Methods for Transporting the Biologic Samples ● Unique and Special Boxes for Transmission of Samples ● Equipping a Unique Bio bank ● Unique Tubes for every sample Using Designed Barcodes ● Participating of Administrative Teams In Online Exam ● Designing special educational films for interviewers and lab experts ● Online sending of supervision checklists 'data

mobilization and partnership, there were many limitations in these regards. On the other hand, integrated digitalized data recording, at the first comprehensive national scale, required specific training and exact ongoing follow–up that lead to time consuming activities for the core team.

In conclusion, to the best of our knowledge, the present study is the first comprehensive experience on systematic design and conduction of fully digitalized national survey. Considering the evidence on national requirements for promotion of STEPs survey, we developed a comprehensive set of executive and scientific protocols and instructions that meet the needs of standard national survey. The results could be also used for future complementary studies.

We should focus on reviewing trends analyses of NCDs, clarifying the time priorities of interventions and strategic plan of required immediate intervention. In the next step, benefitting from maximum participation of specialists and all stakeholders, a comprehensive plan must be developed for specialized interventions in each of these areas of lifestyle and metabolic risk factors.

National and sub–national comprehensive action plans are required to target the prevention and control of NCDs and injuries in Iran. Considering the previous experiences and lessons learned from other countries' success could be used for design and implementation of interventions.

Competing Interests

The authors declare that they have no competing interests.

Authors' Contributions

Farshad Farzadfar and Shirin Djalalinia developed the main design of manuscript. All co–authors had contribution and participated in the revision of the manuscript.

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