

## Rationale, Design, and Initial Findings of Community Trial on Improving the Iranian's Knowledge and Practice of Dyslipidemia Management, Prevention, and Control

Noushin Mohammadifard<sup>(1,2)</sup>, Maryam Maghroun<sup>(3)</sup>, Marzieh Taheri<sup>(4)</sup>, Marjan Mansourian<sup>(5)</sup>, Farid Najafi<sup>(6)</sup>, Hossein Farshidi<sup>(7)</sup>, Tooba Kazemi<sup>(8)</sup>, Masoud Lotfzadeh<sup>(9)</sup>, Kamal Solati<sup>(10)</sup>, Ali Pourmoghaddas<sup>(3)</sup>, Hassan Alikhasi<sup>(11,2)</sup>, Jamshid Najafian<sup>(11)</sup>, Masoumeh Sadeghi<sup>(12)</sup>, Katayoun Rabiei<sup>(13)</sup>, Hamidreza Roohafza<sup>(12)</sup>, **Mahammadreza Sabri**<sup>(13)</sup>, Nizal Sarrafzadegan<sup>(1,2)</sup>

### Original Article

#### Abstract

**BACKGROUND:** To investigate the effects of comprehensive, integrated interventions on dyslipidemia Knowledge and Practices (LIPOKAP) using population and high-risk approaches.

**METHOD:** The baseline of this national, multicentric community trial was conducted on three groups: the general population (adults over the age of 18 and their children aged 6-18), patients with dyslipidemia and their caregivers, and health professionals (physicians, nurses, health providers, and health workers). The general population was selected using multi-stage random sampling, while patients and health professionals were recruited using the consecutive sampling method. The research was carried out in urban and rural areas of five Iranian counties. The sampling method and sample size were similar in baseline and post-intervention surveys. Approximately 8-month intervention programs were carried out on the target groups, which generally included educational strategies. The intervention activities addressed the management, prevention, and control and were tailored to each target group, focusing on lifestyle and self-care.

**RESULTS:** All questionnaires' content validity ratio, content validity index, and Cronbach's alpha were over 0.68, 0.83, and 0.73, respectively. We enrolled 2456 adults and 850 of their children, 3331 dyslipidemia patients, 1699 caregivers, and 1800 health professionals.

**CONCLUSIONS:** The validity and reliability of all developed questionnaires that can examine knowledge and practice changes as a result of intervention activities were acceptable.

**Keywords:** Knowledge, General Practice, Professional Practice, Hyperlipidemias, Dyslipidemias, Surveys, And Questionnaires, Research Design

*Date of submission: 2022-Feb-07, Date of acceptance: 2022-Apr-14*

**How to cite this article:** Mohammadifard N, Maghroun M, Taheri M, Mansourian M, Najafi F, Farshidi H, Kazemi T, Lotfzadeh M, Solati K, Pourmoghaddas A, Alikhasi H, Najafian J, Sadeghi M, Rabiei K, Roohafza H, Sabri M. **Rationale, Design, and Initial Findings of Community Trial on Improving the Iranian's Knowledge and Practice of Dyslipidemia Management, Prevention, and Control.** ARYA Atheroscler 2022; 18(6): 2727.

1- Isfahan Cardiovascular Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran

2- Iranian Heart Foundation (IHF), Iran

3- Interventional Cardiology Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran

4- Heart Failure Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran

5- Department of Epidemiology and Biostatistics, Health School, Isfahan University of Medical Sciences, Iran

6- Research Center for Environmental Determinants of Health, Health Institute, Kermanshah University of Medical Sciences, Kermanshah, Iran

7- Hormozgan Cardiovascular Research Center, Hormozgan University of Medical Sciences, Bandarabbas, Iran

8- Cardiovascular Disease Research Center, Birjand University of Medical Sciences, Birjand, Iran

9- Social Determinants of Health Research Center, Shahrekord University of Medical Sciences, Shahrekord, Iran

10- Department of Psychiatry, Shahrekord University of Medical Sciences, Shahrekord, Iran

11- Hypertension Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran

12- Cardiac Rehabilitation Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran

13- Pediatric Cardiovascular Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran

**Address for correspondence:** Mohammadreza Sabri; Pediatric Cardiovascular Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran. Email: [sabrimrs@gmail.com](mailto:sabrimrs@gmail.com)

## Introduction

Cardiovascular disease (CVD) has become a significant pandemic, particularly in developing countries such as Iran.<sup>1,2</sup> Iran has one of the highest rates of age-standardized CVD prevalence.<sup>2</sup> It has the potential to cause the greatest epidemic unless the trend is reversed by implementing cost-effective preventive strategies.<sup>3</sup>

The link between hypercholesterolemia and CVD has previously been well-documented.<sup>4</sup> A recent meta-analysis found that lowering the low-density lipoprotein cholesterol (LDL-C) by one mmol/L reduces the risk of coronary heart disease (CHD) by 24% and stroke by 20%.<sup>5</sup> Several surveys were conducted in most European countries to assess how well the lipids guidelines are implemented in clinical practice.<sup>6</sup> However, large proportions of CHD patients continue to fall short of the lifestyles, risk factor levels, and therapeutic targets established by guidelines. Controlling dyslipidemia can result in cost savings due to fewer medications, primary care visits, and outpatient attendance.

Even when an effective, well-tolerated agent is prescribed, improving adherence to therapy necessitates educating patients, reminding and encouraging physicians, and developing new medication administration methods.<sup>8</sup>

Dyslipidemia was found in 66.3% of adults and 23.7% of children in Iran.<sup>9,10</sup> While the awareness level is 14.4%,<sup>11</sup> developing extensive multidisciplinary intervention programs to raise dyslipidemia awareness among the population is critical for public health. Aside from encouraging physicians to follow the lipids guidelines and paying attention to screening in adults and children, appropriate interventions are required to improve treatment adherence among patients. This multicentric study has two purposes. First, to assess the general population, patients, and health professionals' knowledge and practice of dyslipidemia prevention, management, and control (LIPOKAP). Second, to investigate the implementation and evaluation of comprehensive intervention strategies.

## Materials and Methods

### *Study design*

The LIPOKAP study was a community-based multicenter trial conducted in three stages: baseline, intervention, and post-intervention. It was carried out in five counties throughout Iran, including Isfahan and Shahrekord in the center, Kermanshah in the west, Bandarabas in the south, and Birjand in the east. From February 2018 to July 2019, baseline recruitment was conducted to examine hyperlipidemia awareness and behaviors in three target populations. The Isfahan Healthy Heart Program (IHHP) model was used to develop the intervention activities and plan how and where to reach the target groups<sup>12</sup>. When people receive educating messages from multiple sites simultaneously, such as children in schools, women in the Municipal Cultural Center, and all family members through mass media, social media, and education in health centers by health providers and physicians, the dose of intervention is increased. The Isfahan University of Medical Sciences ethics committee approved this study (registration number: IR.MUI.RC.1395.4.077). After explaining the study to the participants, a written consent form was obtained from each participant.

### *Participants*

Different approaches were used to select three target populations: the general population (adults and their children and adolescents), patients with dyslipidemia and their caregivers, and health professionals (physicians, health care providers, health care workers, and nurses) were chosen by a different approach.

*General population:* 2600 adults over 18 were selected in Isfahan, Birjand, Bandarabas, Kermanshah, and Shahrekord with total populations of 2174172, 259506, 588288, 1030978, and 340382, respectively, using stratified multi-stage random cluster sampling. Subjects were stratified based on population distribution in each county and urban and rural areas. Clusters were randomly selected

from a list of provincial health centers in each county. Then, adults over 18 were randomly selected within each cluster using their national identification number from Integrated Health System (SIB). They were excluded if they had any dyslipidemia-related disorders that required specific interventions, such as chronic kidney disease, liver disease, cancers, or immune system disorders. Also, pregnant and breastfeeding mothers were omitted. Other CVD risk factors were not excluded from this study. In addition, 50% of their children or adolescents aged 6 to 18 were assigned. They were included if one of their children, sisters, or brothers lived with them between 6 and 18. At the post-intervention stage, the participants in the general population group were independent.

**Patients with dyslipidemia:** This group was chosen from laboratories, public and private clinics, and health centers. Our sample size was calculated to be 2600. However, because the interviews were conducted in the same samples in the post-intervention phases, we interviewed 3400 dyslipidemia patients in five counties. A consecutive sampling method was used to select samples free of all other diseases except dyslipidemia. Other CVD risk factors were not considered as exclusion criteria. Dyslipidemia is any self-reported hyperlipidemia, including hypercholesterolemia, high LDL-C or hypertriglyceridemia, or low level of high-density lipoprotein cholesterol. We interviewed one of the caregivers for 50% of the dyslipidemia patients who accompanied them and were in charge of their medications and treatments.

**Health professionals:** We used a consecutive sampling method to include physicians, whether they were general practitioners or family physicians, cardiologists, internal medicine specialists, neurologists, nephrologists, or endocrinologists, until the sample size calculated is reached. They were discussed in clinics, scientific seminars, and continuing medical education (CME) courses. The consecutive sampling method was also used to select nurses, healthcare providers in urban health centers, and healthcare workers

in rural health centers (Behvarz). The sample size required was 1600. However, to account for any missed follow-ups during the post-intervention phase, we recruited 2100 health professionals in five counties according to population distribution.

#### *Validity of questionnaires*

Various validity assessments were performed on each questionnaire until the final questions were approved. An expert panel assessed the content validity. A pilot study on subjects dissimilar to the study's participants was used to assess the construct validity of knowledge questionnaires.

**Content validity:** In multiple sessions, an expert panel comprised of three cardiologists, one nutritionist, two general physicians, one pediatrician, and one psychiatrist developed a physicians' questionnaire. Eight experts created the health professionals' questionnaire, including nutritionists, psychologists, and general physicians. Twelve experts then evaluated the questionnaires' face and content validity. After receiving expert feedback on the questionnaire's content, the most important and correct contents were chosen by calculating the content validity ratio (CVR).<sup>13</sup> In CVR, experts were asked to specify whether an item in a set was required for operating a construct. Each item was scored between -1 and 1 on a three-point scale of "not necessary, useful but not essential, essential." Greater levels of content validity exist when more significant numbers of panelists agree on a particular item's importance. We included only questions with CVR greater than 0.62 using Lawshe's formula.<sup>13</sup> The following formula was used to calculate the content validity index (CVI) for each question:  $CVI = \frac{\text{The number of experts who gave a score of 4 or 3 to a given question}}{\text{total number of experts}}$ . CVI values greater than 0.79 were considered valid for questions.

**Construct validity:** In the health professional group, we conducted a pilot study with 20% of the calculated sample size of 180 health physicians, 140 health providers, and nurses.

They were chosen from CME session attendees.

The construct validity of an awareness questionnaire for the general population, patients with dyslipidemia, and their caregivers was assessed in both groups using 10% of the calculated sample size (520 subjects). The subjects were selected from people who were referred to the health centers.

*Internal consistency:* Internal consistency was examined for reliability using Cronbach's alpha reliability coefficient. The optimal range of alpha values is between 0.7 and 0.8. The probability of random error was set at 5%.

#### *Data collection*

The baseline questionnaires were administered by trained interviewers who had completed an 8-hour training course. The general population questionnaires were completed by inviting subjects to the nearest health centers. Interviewers were stationed in health centers, public and private clinics, and laboratories to complete the questionnaire for patients with dyslipidemia. In CMEs, health professionals completed the questionnaires by themselves.

Our questionnaires included demographic and socioeconomic data, information about dyslipidemia, and factors that help prevent or control it. Six questionnaires were developed and validated for use in the baseline and post-intervention phases in each target group. Our validated questionnaires in the general population and patients with dyslipidemia included the following questions: the importance of dyslipidemia and its relation to diseases, screening and prevention in adults and children, and dyslipidemia causes and symptoms. Furthermore, we investigated patients' and caregivers' awareness and practice of self-care, the importance of follow-ups, and appropriate adherence to pharmacological and non-pharmacological treatments. The awareness of their caregivers was used to determine how one family's responses are related to dyslipidemia. In addition, we examined the lifestyle habits of the general population and patients with dyslipidemia. Nutrition behaviors were assessed by a validated semi-quantitative

food frequency questionnaire (SFFQ),<sup>14</sup> physical activity by the international physical activity questionnaire (IPAQ),<sup>15</sup> smoking by the Global Adult Tobacco Survey (GATS) questionnaire,<sup>16</sup> alcohol consumption and addiction by validated questionnaires.<sup>17</sup>

The questionnaire for health professionals included questions about the physicians' knowledge and practices regarding their patients with dyslipidemia and whether they follow the existing guidelines for diagnosis, treatment, management, and prevention. Barriers and diseases associated with dyslipidemia, new medications, and recommendations to improve their practice toward their patients were also included. Except for the guidelines and drugs specific to physicians, the core questions were the same for other health professionals. Their questionnaires were self-reported in CMEs or by referring to their places of employment.

#### *Intervention approaches*

From August 2019 to March 2020, the comprehensive intervention approach included intervention strategies tailored for each target group. Gender-specific strategies were developed for adults, children, and adolescents. There were no exclusion criteria for the intervention phase because all educational messages were delivered to the general public and the high-risk population. The intervention's core components were included:

- The significance of dyslipidemia
- Its relationship to disease and screening not only in adults but also in children
- The cause, signs, and symptoms of dyslipidemia
- Lifestyle modification, including healthy dietary habits, quitting smoking and physical activity
- Stress management
- Some particular messages are only for patients with dyslipidemia compromising self-care in patients and their families, follow-ups, and appropriate adherence to treatment.

**Table 1.** Interventions for all groups

Who	What (content)	Where	How (tools)
<b>Physicians</b>			
-General practitioners -Family Physicians -Internists -Cardiologists -Neurologists -Nephrologists -Endocrinologists	- Education on diseases related to dyslipidemia -Its importance in adults and children -Importance of screening among the population, themselves, and their relatives -Importance of following guidelines -Dyslipidemia types -High-risk dyslipidemia groups -Importance of healthy lifestyle change -Importance of proper pharmacological treatments and Patients adherence and follow up -New medications, new trials results, or ongoing trials on dyslipidemia	- Education and development center - Provincial health center -Districts health centers	- Educational seminars (1-5 seminars in each county) -Continuous medical education CME (2-6 CMEs in each county) - Educational brochures/ pamphlets, books, e-books, articles, reports, and pamphlets -Text messages (once/ week)
<b>Other health professionals:</b>			
-Nurses -Health Workers in rural areas (Behvarzes) -Nutritionists	-Education on diseases related to dyslipidemia -Its importance not only in adults but early life -Importance of screening among the population, Themselves and their relatives -High-risk dyslipidemia groups -Importance of healthy lifestyle change -Importance of proper pharmacological treatments -The patients follow and adhere to the treatments prescribed	- Education and development center - Provincial health center -Districts health centers -Faculty of Medicine -Faculty of Nursing -Faculty of Nutrition	-Continuous medical education (2-4 in each county) - Educational seminars in the provincial health center for health providers and Behvarz (2-6 in each county), in hospitals for nurses and nutritionists (2-4 in each county) -Educational brochures/pamphlets, Books, e-books, articles, reports -Text messages (once/week)
<b>General population</b>			
Adults aged>18 years  One of their children aged 6-18 years (50% of samples)	-The importance of dyslipidemia and its relation to diseases -The importance of screening not only in adults but in children -Causes of dyslipidemia -Signs and symptoms of dyslipidemia -Importance of prevention from childhood - Lifestyle modification, including healthy dietary behaviors, quitting smoking, physical activity, and stress management	-Mass media (Radio, TV, newspapers, magazines) -Regular newsletters in offices or large companies or factories) -Public announcements  -Intermediate or high schools	-TV Family programs (2-6 programs in each county) - TV Underline announcements (at least 10 in each county) -TV scientific round tables program Interviews (1-2 programs) - Radio scientific news or interviews (6 programs) -Small campaigns during Celebrations of special days like World Heart, hypertension and diabetes days, and salt awareness week (4-8 events) -Integrating educational messages about dyslipidemia in regular newsletters in offices and factories - 5 brochures on the importance and related diseases and methods of prevention and control of dyslipidemia distributed in health centers, laboratories, and clinics (20000 in 5 cities) - 2 posters (3000 in 5 cities)
<b>Patients with dyslipidemia and their families</b>			
Patients with dyslipidemia  One of their children aged 6-18years if available (50% of samples); if not available, first or second-degree relatives	-The importance of dyslipidemia and its relation to diseases -The importance of screening not only in adults but in children -Causes of dyslipidemia -Signs and symptoms of dyslipidemia - Importance of prevention from childhood – -Lifestyle modification, including healthy dietary behaviors, quitting smoking, physical activity, and stress management -Proper ways of self-care in patients and their families - The importance of follow-ups and appropriate adherence to treatment - Pharmacological and non-pharmacological treatments	-Health Centers in urban and rural areas -Public and private clinics of physicians -Diabetes, hypertension, and nutrition clinics -Laboratories -Hospitals -Mass media	-Educational sessions in rural health centers (each visit) -Self-care education sessions on dyslipidemia for patients and their families in rural and urban health centers (each visit) -Messages in social networks (once/week) - 5 brochures on the importance and related diseases and methods of prevention and control of dyslipidemia distributed in health centers, laboratories, and clinics (20000 in 5 cities) - 2 posters (3000 in 5 cities) -TV Family programs (2-6 programs in each county) - TV Underline announcements (at least 10 in each county) -TV scientific round tables program Interviews (1-2 programs) - Radio scientific news or interviews (6 programs) -Small campaigns during Celebrations of special days like World Heart, hypertension and diabetes days, and salt awareness week (4-8 events) -Integrating educational messages about dyslipidemia in regular newsletters in offices and factories

Based on current European and American Heart Association guidelines, we provided some CMEs for physicians and other health professionals on the management, prevention, and treatment of dyslipidemia. Table 1 depicts various groups' content, location, and intervention tools.

*Evaluation design*

*Process evaluation:* It was done to determine

whether or not the interventions were carried out as planned.

Its indicators were the number of educational sessions held, the number of participants in these sessions, the number of text messages sent, the number of educational materials distributed, and how and where the target population received them.

Tables 2 provide additional information on the process evaluation of each target group.

**Table 2.** Type of evaluation and indicators

Target groups	Evaluation type	Indicators
Physicians	Process evaluation	<ul style="list-style-type: none"> <li>-Number of physicians who attended education sessions</li> <li>-Number of sessions organized as planned in the proposal</li> <li>-Number of patients' files contain lipids results or dyslipidemia patients follow up's in clinics</li> <li>-Number of referrals of dyslipidemia patients to physicians</li> <li>-Number of text messages or emails sent by the medical council or received by physicians on dyslipidemia.</li> <li>-Number of dyslipidemia Patients visits-</li> </ul>
	Outcome evaluation	<ul style="list-style-type: none"> <li>-At least 50% of physicians are aware of and follow lipids guidelines</li> <li>-At least 50% of referred patients have their lipids treated, and 10% of controlled</li> <li>-At least 20% increase in knowledge, attitudes, and proper practice of physicians of their dyslipidemia patients</li> </ul>
Other health professionals:	Process evaluation	<ul style="list-style-type: none"> <li>-Number of Health professionals who attended education sessions</li> <li>-Number of educational sessions organized</li> <li>-Number of patients' files contain lipids results or dyslipidemia patients follow up's in health centers or nutrition clinics</li> <li>-Number of referrals of dyslipidemia patients to physicians by health workers, nurses, or nutritionists</li> <li>-Number of Patients visits by Behvarz in rural areas</li> <li>-Number of mobile texts or emails sent by the medical council or received by health workers</li> </ul>
	Outcome evaluation	<ul style="list-style-type: none"> <li>- 50% increase in knowledge, attitudes, and 30% practice of Health workers of dyslipidemia in their patients and themselves</li> <li>-50% increase in patients receiving non-pharmacological recommendations for dyslipidemia in health centers, public clinics, or nutrition clinics</li> </ul>
General population	Process evaluation	<ul style="list-style-type: none"> <li>-Number of TV family and children programs addressing dyslipidemia-process evaluation</li> <li>-Number of TV underlined announcements</li> <li>-Number of TV scientific round table programs</li> <li>-Number of radio scientific news and interviews</li> <li>-Number of campaigns of dyslipidemia</li> <li>-Number and time of education sessions in schools</li> <li>-Number of newsletters distributed in offices or factories that contain educational messages on dyslipidemia</li> </ul>
	Outcome evaluation	<ul style="list-style-type: none"> <li>-50% increase in adults' and adolescents' awareness and knowledge of dyslipidemia</li> <li>-10% increase in adults and 5% in adolescents' proper practice and healthy lifestyle behaviors regarding dyslipidemia</li> </ul>
Patients with dyslipidemia and family	Process evaluation	<ul style="list-style-type: none"> <li>-Number of TV family and children programs addressing dyslipidemia-process evaluation</li> <li>-Number of TV underlined announcements</li> <li>-Number of TV scientific round table programs</li> <li>-Number of radio scientific news and interviews</li> <li>-Number of campaigns of dyslipidemia</li> <li>-Number and time of education sessions in schools</li> <li>-Number of newsletters distributed in offices or factories that contain educational messages on dyslipidemia</li> <li>- Number of educational sessions in the rural and urban health centers</li> <li>- Number of participants in each session</li> <li>- Number of topics discussed in each session</li> </ul>
	Outcome evaluation	<ul style="list-style-type: none"> <li>-50% increase in adults' and adolescents' awareness and knowledge of dyslipidemia</li> <li>-10% increase in adults and 5% in adolescents' proper practice and healthy lifestyle behaviors regarding dyslipidemia</li> </ul> <p style="text-align: center;">20% increase in self-care of the patient with dyslipidemia</p>

*Outcome evaluation:* The differences between pre-and post-intervention surveys were evaluated this way. Its indicators are knowledge and lifestyle or behavior scores, which include dietary habits, smoking status, physical activity levels, and stress components (Table 2).

## Results

### *Developing questionnaires:*

All knowledge questions had acceptable

CVRs and CVIs in the general population and patients with dyslipidemia (CVR: 0.71-1 and CVI: greater than 0.83) (**Supplementary 1**). The content validity of the self-care questionnaire for caregivers was acceptable (CVR: 0.8-1 and CVI: greater than 0.87) (**Supplementary 2**).

In the first questionnaire design, CVRs of questions for physicians and other health professionals' questions ranged from 0.48- 1 (**Supplementary 3**). CVRs were less than

**Table 3.** Basic characteristics of general population based on county

	Isfahan	Bandarabas	Birjand	Shahrekord	Kermanshad	Total
<b>Adults:</b>						
<b>Participants number</b>	1352(55.0)	138(5.6)	159(6.5)	191(7.8)	616(25.1)	2456
<b>Age (mean±SD)</b>	38.7±13.7	38.3±11.2	40.1±14.3	39.9±13.0	41.1±14.4	39.5±13.8
<b>Age group n (%):</b>						
19-29	426(31.5)	32(23.2)	40(25.2)	43(22.5)	152(24.7)	693(28.2)
30-39	337(24.9)	49(35.5)	48(30.2)	62(32.5)	175(28.4)	671(27.3)
40-49	268(19.8)	36(26.1)	30(18.9)	37(19.4)	122(19.8)	493(20.1)
50-59	169(12.5)	12(8.7)	22(13.8)	27(14.1)	79(12.8)	309(12.6)
60≤	152(11.1)	9(6.5)	19(11.9)	22(11.5)	88(14.3)	290(11.8)
<b>Male gender n (%)</b>	668(49.4)	67(48.5)	64(40.2)	77(40.3)	300(48.7)	1176(47.9)
<b>Urbanization n (%)</b>	1293 (95.6)	124 (89.9)	136 (85.5)	170 (89)	488 (79.2)	2211 (90)
<b>Education n (%):</b>						
0-5	251(18.7)	29(21)	37(23.3)	24(12.6)	212(34.4)	553(22.5)
6-12	667(49.3)	73(52.9)	56(35.2)	70(36.6)	263(42.7)	1129(46)
12≤	434(32.1)	36(26.1)	66(41.5)	97(50.8)	141(22.9)	774(31.5)
<b>Children and adolescents:</b>						
<b>Participants number</b>	456(53.6)	36(4.2)	57(6.7)	35(4.2)	266(31.2)	850
<b>Age (mean±SD)</b>	11.9±3.8	11.7±2.7	12.6±3.7	12.3±3.4	12.3±3.5	12.1±3.7
<b>Age group n(%):</b>						
6-11	215(47.1)	17(47.2)	23(40.4)	18(51.4)	108(40.6)	381(44.6)
12-18	241(52.9)	19(52.8)	34(59.6)	17(48.6)	159(59.4)	469(55.2)
<b>Boy gender n (%):</b>	242(53.7)	16(55.2)	32(56.1)	17(48.5)	159(59.8)	462(54.8)

0.62 on three questions of the physicians' questionnaire and four questions of the other health professionals' questionnaire (**Supplementary 4**). Furthermore, the CVI in six physician questionnaire questions and three other health professional questionnaire questions was less than 0.79.

As a result, we revised these questions and their answers. The CVRs of all questions were then between 0.68 to 1, and the CVI s were between 0.83-1.

The knowledge questionnaire demonstrated internal consistency in the general population and patients with dyslipidemia, yielding a Cronbach alpha value of 0.79. The internal consistency of the hyperlipidemia self-care questionnaire in caregivers was also high (Cronbach alpha of 0.81). The internal consistency of the first 36 questions was 0.63 on the health professionals' questionnaire. The Cronbach's alpha increased to 0.76 after changing both constructions of some questions and deleting six questions, indicating that items have good internal consistency and homogeneity.

Based on the first 33 questions of the physicians' questionnaire, the direct result revealed a lack of internal consistency between items (Cronbach  $\alpha = 0.46$ ). The questions' construction and content were

changed, and the test was repeated for the new questionnaire. Internal consistency in the physicians' questionnaire ranged from 0.67 to 0.72 based on different question selection strategies. Finally, the internal consistency was increased to 0.73 by removing one question. Cronbach  $\alpha$  of 0.74 indicated that the questionnaire of other health professionals had acceptable internal consistency.

*Fundamental characteristics of participants in the first phase*

A total of 2456 adult participants were studied, with a mean age of 39.5±13.8.

The frequency of the male gender was 48%, and 90% resided in urban areas. We enrolled 850 children and adolescents, with a mean age of 12.1±3.7. 54.8% of those were boys. Table 3 depicts the fundamental characteristics of the general population group by county.

According to Table 4, 3331 patients with dyslipidemia and 1699 caregivers participated in this study. The mean age of enrolled patients and caregivers was 55.5 ±13.3 and 41.9±15.1, respectively.

The percentages of male gender were 39.4% and 38.4%, respectively. Table 4 shows the essential characteristics of this group based on residency.

**Table 4.** Basic characteristics of patients with dyslipidemia and their relatives based on county

	Isfahan	Bandarabas	Birjand	Shahrekord	Kermanshad	Total
<b>Patients number</b>	1623(48.7)	444(13.3)	206(6.2)	259(7.8)	799(24.0)	3331
<b>Age (mean±SD)</b>	57.1±13.5	58.9±12.5	52.6±12.6	55.0±11.1	51.1±12.9	55.5±13.3
<b>Age group n (%):</b>						
19-29	23(1.4)	6(1.3)	5(2.4)	4(1.5)	40(5)	78(2.1)
30-39	127(7.8)	26(5.8)	29(14.1)	22(8.5)	132(16.5)	336(10.1)
40-49	287(17.7)	57(12.8)	51(24.8)	52(20.1)	171(21.4)	618(18.5)
50-59	515(31.7)	130(29.3)	65(31.6)	84(32.4)	233(29.2)	1027(30.8)
60≤	671(41.3)	225(50.7)	56(27.2)	97(37.4)	223(27.9)	1272(38.2)
<b>Male gender n (%)</b>	663(40.8)	162(36.5)	83(40.3)	84(32.4)	289(36.2)	1281(38.4)
<b>Education n (%):</b>						
0-5	993(61.2)	299(67.3)	64(31.1)	128(49.4)	459(57.4)	1943(58.3)
6-12	451(27.8)	105(23.6)	55(26.7)	73(28.2)	259(32.4)	941(28.2)
12≤	179(11)	40(9)	87(42.2)	58(22.4)	81(10.1)	445(13.4)
<b>Patients' relatives:</b>						
<b>Participants number</b>	866(51)	220(12.9)	104(6.1)	142(8.3)	367(21.6)	1699
<b>Age (mean±SD)</b>	43.5±15.8	41.7±13.3	43.9±13.1	40.8±15.5	37.9±14.2	41.9±15.1
<b>Age group n (%):</b>						
19-29	200(23.1)	38(17.3)	20(19.2)	37(26.1)	109(29.7)	404(23.8)
30-39	219(25.3)	78(35.4)	15(14.4)	40(28.2)	100(27.2)	452(26.6)
40-49	126(14.5)	37(16.8)	23(22.1)	23(16.2)	62(16.9)	271(15.9)
50-59	145(16.7)	39(17.7)	33(31.7)	24(16.9)	60(16.3)	301(17.7)
60≤	176(20.3)	28(12.7)	13(12.5)	18(12.7)	36(9.8)	271(15.9)
<b>Male gender n (%)</b>	384(44.4)	85(38.6)	45(43.3)	45(31.7)	169(46)	728(42.9)
<b>Education n (%):</b>						
0-5	226(26.1)	38(17.3)	14(13.5)	20(14.1)	65(17.7)	363(21.4)
6-12	404(46.7)	122(55.5)	35(33.7)	44(31)	206(56.1)	811(47.7)
12≤	236(27.2)	60(27.3)	55(52.9)	78(54.9)	96(26.2)	525(30.9)

**Table 5.** Basic characteristics of health professionals based on county

	Isfahan	Bandarabas	Birjand	Shahrekord	Kermanshad	Total
<b>Physicians:</b>						
<b>Participants number</b>	379(72.5)	29(4.4)	54(9.0)	57(9.7)	28(4.4)	552
<b>Age (mean±SD)</b>	46.7±10.8	40.0±9.3	45.4±9.3	33.9±9.3	41.5±8.6	44.8±11.0
<b>Age group n (%):</b>						
19-29	26(6.9)	4(13.8)	4(6.8)	21(36.8)	4(14.3)	59(10.7)
30-39	80(21.1)	8(27.6)	10(16.9)	9(15.8)	6(21.4)	113(20.5)
40-49	122(32.2)	9(31)	16(27.1)	117(19.3)	9(32.1)	167(30.2)
50-59	125(33)	6(20.7)	20(33.9)	12(21)	6(21.4)	169(30.6)
60≤	26(6.9)	2(6.9)	9(15.2)	4(7)	3(10.7)	44(48)
<b>Male gender n (%)</b>	180(47.5)	13(44.8)	34(57.6)	26(45.6)	12(42.8)	265(48)
<b>Specialty n (%):</b>						
General practitioner	352(92.9)	28(96.6)	51(86.4)	55(96.5)	28(100.0)	514(93.1)
Specialist	27(7.1)	1(3.4)	8(13.6)	2(3.5)	0(0.0)	38(6.9)
<b>Health professional:</b>						
<b>Participants number</b>	509(42.7)	322(25.0)	75(5.8)	51(3.9)	291(22.5)	1248
<b>Age (mean±SD)</b>	37.9±7.4	38.4±7.4	32.6±8.7	36.7±9.2	40.1±7.6	38.2±8.1
<b>Age group n (%):</b>						
19-29	62(12.2)	39(12.1)	27(36)	12(23.5)	34(11.7)	174(13.9)
30-39	166(32.6)	115(35.7)	29(38.7)	19(37.2)	91(31.3)	420(33.6)
40-49	173(34)	129(40.1)	17(22.6)	16(31.4)	135(46.4)	470(37.7)
50-59	101(18.8)	39(12.1)	2(2.7)	3(5.9)	31(10.6)	176(14.1)
60≤	7(1.4)	0(0.0)	0(0.0)	1(2)	0(0.0)	8(0.6)
<b>Male gender n (%)</b>	159(31.2)	53(16.5)	13(17.3)	8(17.4)	82(28.3)	315(25.2)
<b>Job (%):</b>						
Health workers	152(29.9)	114(34.5)	21(28)	18(35.3)	124(42.6)	429(34.4)
Health providers	261(51.3)	100(31)	22(29.3)	27(39.2)	126(43.3)	529(42.4)
Nurses	96(18.9)	108(33.5)	32(42.7)	13(25.5)	41(14.1)	290(23.2)

Table 5 shows the health professionals' characteristics based on their county of residence. Markedly, there were 552 admitted physicians with a mean age of 44.8 ±11 and 1248 other health professionals with a mean age of 38.2±8.1. Males made up 48% and

25.2% of the population, respectively. The job frequency in other health professional groups was 34.4% health workers, 42.2% health providers, and 23.2% nurses.

## Discussion

The LIPOKAP study was the first national multicentric community trial in Iran to implement and evaluate the effectiveness of comprehensive population-based intervention programs on improving awareness and practice of dyslipidemia management, prevention, and control among diverse populations, including the general public, high-risk individuals, and health professionals. All developed questionnaires had acceptable validity and reliability. Thus, they can adequately assess the changes in individuals' knowledge and practice following our intervention.

Our questionnaires' content validity was comparable to previous ones developed for similar purposes.<sup>18, 19</sup> Cronbach's alpha greater than 0.6 indicates an appropriate value for internal consistency reliability.<sup>20</sup> Our tools' internal consistency was demonstrated by Cronbach's alpha of 0.79 in public and patients', 0.73 in physicians', and 0.76 in other health professionals' questionnaires. Most studies on CVD risk factors knowledge and practice in Iran have been cross-sectional, with no attempt to implement simple interventions that can lead to increased public awareness.<sup>21-23</sup> Furthermore, they have placed a greater emphasis on hypertension and diabetes rather than dyslipidemia.<sup>22, 24-28</sup> Because dyslipidemia has a higher prevalence and lower treatment and control rates than hypertension and diabetes mellitus<sup>11</sup> and its adverse events,<sup>29</sup> implementing comprehensive national interventions could prevent and control hyperlipidemia and thus reduce the burden of CVD. The multi-component strategies (including dietary advice, physical activity, lifestyle education, smoking cessation, and self-care programs), the spectrum of intervention approaches including mass media, social networks, educational materials, and holding campaigns and a massive targeted population consisting of health professionals and the general public as the audiences of community-based programs in the LIPOKAP study can synergistically work together to increase the effects of our interventions. Moreover,

lifestyle changes in this type of program could be extended to social networks, resulting in a general approach with a more significant impact than an individual level.<sup>30</sup> The difference in the content of delivery approaches via mass media or interpersonal communication, and the intensity of the sessions' interventions, is likely to affect the effectiveness of the lifestyle behavior change program.

Adherence to interventions is predicted by population characteristics such as age, socioeconomic status, and living environment. Several community-based prevention programs in developing countries have revealed that older people, high-risk populations, and highly educated participants are much more likely to participate in prevention programs. In addition, regarding program setting heterogeneity, it is assumed that urban settings have more advantages than rural settings for health behavior modification.<sup>31, 32</sup> Hence, in the LIPOKAP study, similar to previous community programs, we observed various factors, including age, gender, education level, residency setting, household income, awareness, comorbidities, the number of concurrent medications, and drug side effects, influencing an individual's adherence to hyperlipidemia guidelines.<sup>33</sup> Because we used a stratified cluster random sampling method to select subjects in the general population from urban and rural areas in 5 counties based on age, gender, and residency population distribution, our findings on the effect of the intervention can be generalized. Moreover, all lifestyle factors, such as smoking status, nutrition, physical activity habits, and pharmacological and non-pharmacological treatments, have been evaluated before and after interventions to arrive at the following current guidelines.

## Strengths and Limitations

This study is the first national community-based program on dyslipidemia, one of the most prevalent CVD risk factors. Other advantages include diversity in intervention approaches, components, and audiences. Our study has several limitations that should

be considered:

- 1) Due to limited financial resources, we included patients with dyslipidemia based on self-reported data. We could not assess the effectiveness of this community trial on serum lipid levels.
- 2) Due to the spread of the Corona Virus in Iran, our intervention activities have been diluted in the intervention phase's last two months.
- 3) For the same reason, we had to postpone the post-intervention phase. As a result, it may reduce the effectiveness of our intervention.

### Conclusions

Tools developed in this study had acceptable validity and reliability, allowing us to examine changes in the knowledge and practice resulting from intervention activities. The variety of population approaches and intervention fields may improve our intervention program's effectiveness.

### Acknowledgment

We are grateful to all staff in the five counties studied for their assistance in data collection and conducting intervention activities. The International Atherosclerosis Society approved the study, which Pfizer funded under grant number 11531879.

### Declarations

*Ethics approval and consent to participate:* The Ethics Committee of the Research Council of Isfahan University of Medical Sciences in Isfahan, Iran (registration number: IR.MUI.RC.1395.4.077) approved the study. All participants signed a written consent form. Where participants were children (under 16 years old), written informed consent for participation in the study was obtained from their parents or guardian. *Consent for publication:* All authors accept responsibility for the material's release.

*Availability of data and materials:* The datasets generated and analyzed during the current

study are available upon reasonable request from the corresponding author.

*Competing interests:* We have no conflicts of interest.

### Funding

This study has been funded by International Atherosclerosis Society and Pfizer company with grant number 11531879.

### Authors' contributions

N. M. and MR. S. designed the research; N. M., A. P., H. A., J. N., M. S., K. R., and H. R. prepared the questionnaires. N. M., F. N., H. F., T. K., M. L., A. P., H. A., J. N., M. S., K.R., and H. R. conducted research; M. T. and M. M. analyzed data; N. M. wrote the paper. N. M. had primary responsibility for the final content. All authors read and approved the final manuscript.

### Reference

1. Roth GA, Johnson C, Abajobir A, Abd-Allah F, Abera SF, Abyu G, et al. Global, Regional, and National Burden of Cardiovascular Diseases for 10 Causes, 1990 to 2015. *J Am Coll Cardiol* 2017;70(1): 1-25.
2. Sarrafzadegan N, Mohammadifard N. Cardiovascular Disease in Iran in the Last 40 Years: Prevalence, Mortality, Morbidity, Challenges and Strategies for Cardiovascular Prevention. *Arch Iran Med* 2019; 22(4): 204-10.
3. World Health Organization. WHO/Europe International Conference on Cardiovascular Diseases. Saint Petersburg, Russian Federation. 2015.
4. Hedayatnia M, Asadi Z, Zare-Feyzabadi R, Yaghooti-Khorasani M, Ghazizadeh H, Ghaffarian-Zirak R, et al. Dyslipidemia and cardiovascular disease risk among the MASHAD study population. *Lipids Health Dis* 2020; 19(1): 42.
5. Silverman MG, Ference BA, Im K, Wiviott SD, Giugliano RP, Grundy SM, et al. Association between lowering LDL-C and cardiovascular risk reduction among different therapeutic interventions: a systematic review and meta-analysis. *JAMA* 2016; 316(12): 1289-97.

6. Jamé S, Wittenberg E, Potter MB, Fleischmann KE. The new lipid guidelines: what do primary care clinicians think?. *Am J Med* 2015; 128(8): 914.e5-.914.e10.
7. Ai AL, Carretta H, Beitsch LM, Watson L, Munn J, Mehriary S. Medication therapy management programs: promises and pitfalls. *J Manag Care Spec Pharm* 2014; 20(12): 1162-82.
8. Fernandez-Lazaro CI, García-González JM, Adams DP, Fernandez-Lazaro D, Ayuso J, Caballero-Garcia A, et al. Adherence to treatment and related factors among patients with chronic conditions in primary care: a cross-sectional study. *BMC Fam Pract* 2019; 20(1): 132.
9. Sarrafzadegan N, Kelishadi R, Sadri G, Malekafzali H, Pourmoghaddas M, Heidari K, et al. Outcomes of a comprehensive healthy lifestyle program on cardiometabolic risk factors in a developing country: the Isfahan Healthy Heart Program. *Arch Iran Med* 2013; 16(1): 4-11.
10. Kelishadi R, Mohammadifard N, Sarrafzadegan N, Nouri F, Pashmi R, Bahonar A, et al. The effects of a comprehensive community trial on cardiometabolic risk factors in adolescents: Isfahan Healthy Heart Program. *ARYA Atheroscler* 2012; 7(4): 184-90.
11. Shirani S, Kelishadi R, Sarrafzadegan N, Khosravi A, Sadri G, Amani A, et al. Awareness, treatment and control of hypertension, dyslipidaemia and diabetes mellitus in an Iranian population: the IHHP study. *East Mediterr Health J* 2009; 15(6): 1455-63.
12. Sarrafzadegan N, Laatikainen T, Mohammadifard N, Fadhel I, Yach D, Puska P. "Isfahan Healthy Heart Program": A practical model of implementation in a developing country. *Prog Prevent Med* 2018; 3(3): e0014.
13. Ayre C, Scally A. Critical values for Lawshe's content validity ratio. *Measur Evaluat Counsel Develop* 2013; 47(1): 79-86.
14. Mohammadifard N, Haghighatdust F, Kelishadi R, Bahonar A, Dianatkah M, Heidari H, et al. Validity and reproducibility of a semi-quantitative food frequency questionnaire for Iranian adults. *Nutrit Dietet* 2021; 78(3): 305-314.
15. Craig CL, Marshall AL, Sjostrom M, Bauman AE, Booth ML, Ainsworth BE, et al. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sport Ex* 2003; 35(8): 1381-95.
16. Global Adult Tobacco Survey Collaborative Group. Global adult tobacco survey (GATS): core questionnaire with optional questions, version 2.0; 2010.
17. Anisi J, Bahadori MH, Jahanbakhsh M. Developing and validation of identifying people in risk of addiction questionnaire (I.p.R.a). *Int J High Risk Behav Addict* 2013; 1(4): 183-91.
18. Liang N, Zhao Q, He Y, Li J, Yang L. Development and Validity of a Questionnaire on Dyslipidemia Dietary Knowledge. *BioMed Res Int* 2019; 2019: 5382130.
19. Ameh PO, Yakubu K, Miima M, Popoola O, Mohamoud G, Von Pressentin KB. Lifestyle, cardiovascular risk knowledge and patient counselling among selected sub-Saharan African family physicians and trainees. *Afr J Prim Health Care Fam Med* 2019; 11(1): e1-e15.
20. Taber KS. The Use of Cronbach's Alpha When Developing and Reporting Research Instruments in Science Education. *Res Sci Educat* 2018; 48(6): 1273-96.
21. Mazloomi SS, Baghianimoghadam MH, Ehrampoush MH, Baghianimoghadam B, Mazidi M, Mozayan MR. A study of the knowledge, attitudes, and practices (KAP) of the women referred to health centers for cardiovascular disease (CVDs) and their risk factors. *Health Care Women Int* 2013; 35(1): 50-9.
22. Rashidi Y, Manaflouyan H, Pournaghi Azar F, Nikniaz Z, Nikniaz L, Ghaffari S. Knowledge, attitude and practice of Iranian hypertensive patients regarding hypertension. *J Cardiovasc Thorac Res* 2018; 10(1): 14-9.
23. Saeidlou SN, Babaei F, Ayremlou P. Nutritional Knowledge, Attitude and Practice of North West Households in Iran: Is Knowledge likely to Become Practice?. *Maedica* 2016; 11(4): 286-95.
24. Karbalaeifar R, Kazempour-Ardebili S, Amiri P, Ghannadi S, Tahmasebinejad Z, Amouzegar A. Evaluating the effect of knowledge, attitude and practice on self-management in patients with type 2 diabetes. *Acta Diabetol* 2016; 53(6): 1015-23.
25. Niroomand M, Ghasemi SN, Karimi-Sari H, Kazempour-Ardebili S, Amiri P, Khosravi MH. Diabetes knowledge, attitude and practice (KAP) study among Iranian in-patients with type-2 diabetes: A cross-sectional study. *Diabetol Metab Syndr* 2016; 10(1 Suppl 1): S114-9.
26. Niroomand M, Ghasemi SN, Karimi-Sari H,

- Khosravi MH. Knowledge, Attitude, and Practice of Iranian Internists Regarding Diabetes: A Cross Sectional Study. *Diabetes Metab J* 2017; 41(3): 179-86.
27. Farshidi H, Nikparvar M, Rostami-Qeshmi I, Ezzati-Rad R, Piroozan A, Boushehri E. Physicians' knowledge, attitudes, and practice for hypertension management: A cross-sectional study in Hormozgan province, Iran. *ARYA Atheroscler* 2018; 14(3): 132-8.
28. Sabouhi F, Babaee S, Naji H, Hassan Zadeh A. Knowledge, awareness, attitudes and practice about hypertension in hypertensive patients referring to public health care centers in Khor & Biabanak. *Iran J Nurs Midwifery Res* 2011; 16(1): 34-40.
29. Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS, Braun LT, De Ferranti S, Faiella-Tommasino J, Forman DE, Goldberg R. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation* 2019; 139(25): e1082-e1143.
- Del Castillo JA, del Castillo-López ÁG, Dias PC, García-Castillo F. Social networks as tools for the prevention and promotion of health among youth. *Psicologia: Reflexão Crít* 2020; 33(1): 13.
30. Neiderud CJ. How urbanization affects the epidemiology of emerging infectious diseases. *Infect Ecol Epidemiol* 2015; 5(1): 27060.
31. Khosravi A, Kiani Mehr G, Kelishadi R, Shirani S, Gharipour M, Tavassoli A, et al. The impact of a 6-year comprehensive community trial on the awareness, treatment and control rates of hypertension in Iran: experiences from the Isfahan healthy heart program. *BMC Cardiovasc Disord* 2010; 10(1): 1-8.
32. Doğan V, Başaran Ö, Özlek B, Çelik O, Özlek E, Mert KU, et al. Rationale, design, and methodology of the Evaluation of Perceptions, Knowledge, and Compliance with the Guidelines in Real Life Practice: A Survey on the Under-treatment of Hypercholesterolemia. *Turk Kardiyol Dern Ars* 2018; 46(1): 47-53.