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).[13] 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.[13] The following formula was used to calculate the content validity index (CVI) for each question: CVI=The number of experts who gave a score of 4 or 3 to a given question out of the possible scores of 4, 3, 2, and 1 / 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.

Table 2. 6HRIHHDOHWLRQQLQLFDWRUV

Target groups	Evaluation type	Indicators
3KLFLDQ	3URFHVVDOWLRQ	1REHURISKLFLDQwho DWWHQHGHGKDWLRQVRQ 1REHURIHVRQUJDQHGSODQGLQVKHSURSRVO 1REHURISDWLHQWVRQ lipids results or dyslipidemia patients follow up's in Q RHIHDWHG the PHORRHHQ QHD RHVHD atients visits
WHDW	6HHQ 6HHQ NQHH	have KOHG , Q of RHOHG , attitudes, U W
WHDW HHQ s	HVDW	RHVHD who HHQ RHVHD RHVHDG patients ' IDHW lipids results or dyslipidemia patients follow up's in W RHIHDWHVHQ , or nutritionists RHVHD RHVHDW the PHORRHHQWKHOHWV
WHDW	HVDW	HQW NQHH , attitudes, RHHDWHVHD HQWHQHRHVHD RHVHD HQW , HQ
HQD HQ	HVDW	RHVHD HVDW RHVHD d RHW RHVHD RHVHD RHVHD RHVHD RHVHD RHVHD
WHDW	HVDW	HQW ' and adolescents' awareness and NQHHHVHD HQW in adolescents' proper practice and healthy lifestyle W rs regarding VHD
HQ VHD D\	HVDW	RHVHD HVDW RHVHD d RHW RHVHD RHVHD RHVHD RHVHD RHVHD RHVHD RHVHD the HORHW s RHVHD RHVHD
WHDW	HVDW	HQW ' and adolescents' awareness and NQHHHVHD HQW in adolescents' proper practice and healthy lifestyle W rs regarding VHD HQ QOHHRHe HVHD

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

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).

Table 3. Basic characteristics of general population based on county

	Isfahan	Bandarabas	Birjand	Shahrekord	Kermanshad	Total
Adults:						
Participants number	1352(55.0)	138(5.6)	159(6.5)	191(7.8)	616(25.1)	2456
Age (mean±SD)	38.7±13.7	38.3±11.2	40.1±14.3	39.9±13.0	41.1±14.4	39.5±13.8
Age group n (%):						
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)
Male gender n (%)	668(49.4)	67(48.5)	64(40.2)	77(40.3)	300(48.7)	1176(47.9)
Urbanization n (%)	1293(95.6)	124 (89.9)	136 (85.5)	170 (89)	488 (79.2)	2211 (90)
Education n (%):						
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)
Children and adolescents:						
Participants number	456(53.6)	36(4.2)	57(6.7)	35(4.2)	266(31.2)	850
Age (mean±SD)	11.9±3.8	11.7±2.7	12.6±3.7	12.3±3.4	12.3±3.5	12.1±3.7
Age group n(%):						
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)	158(59.4)	469(55.2)
Boy gender n (%):	242(53.7)	16(55.2)	32(56.1)	17(48.5)	159(59.8)	462(54.8)

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 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 α = 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 α 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.

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

	Isfahan	Bandarabas	Birjand	Shahrekord	Kermanshad	Total
Patients number	1623(48.7)	444(13.3)	206(6.2)	259(7.8)	799(24)	3331
Age (mean±SD)	57.1±13.5	58.9±12.5	52.6±12.6	55.0±11.1	51.1±12.9	55.5±13.3
Age group n (%):						
19-29	23(1.4)	6(1.3)	5(2.4)	4(1.5)	40(5)	78(2.3)
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)
Male gender n (%)	663(40.8)	162(36.5)	83(40.3)	84(32.4)	289(36.2)	1281(38.4)
Education n (%):						
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)
Patients' relatives:						
Participants number	866(51)	220(12.9)	104(6.1)	142(8.3)	367(21.6)	1699
Age (mean±SD)	43.5±15.8	41.7±13.3	43.9±13.1	40.8±15.5	37.9±14.2	41.9±15.1
Age group n (%):						
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)
Male gender n (%)	384(44.4)	85(38.6)	45(43.3)	45(31.7)	169(46)	728(42.9)
Education n (%):						
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
Physicians:						
Participants number	379(72.5)	29(4.4)	54(9)	57(9.7)	28(4.4)	552
Age (mean±SD)	46.7±10.8	40.0±9.3	45.4±9.3	33.9±9.3	41.5±8.6	44.8±11
Age group n (%):						
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)	11(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)
Male gender n (%)	180(47.5)	13(44.8)	34(57.6)	26(45.6)	12(42.8)	265(48)
Specialty n (%):						
General practitioner	352(92.9)	28(96.6)	51(86.4)	55(96.5)	28(100)	514(93.1)
Specialist	27(7.1)	1(3.4)	8(13.6)	2(3.5)	0(0)	38(6.9)
Health professional:						
Participants number	509(42.7)	322(25)	75(5.8)	51(3.9)	291(22.5)	1248
Age (mean±SD)	37.9±7.4	38.4±7.4	32.6±8.7	36.7±9.2	40.1±7.6	38.2±8.1
Age group n (%):						
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)	1(2)	0(0)	8(0.6)
Male gender n (%)	159(31.2)	53(16.5)	13(17.3)	8(17.4)	82(28.3)	315(25.2)
Job (%):						
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)	20(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)

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 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 1294 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 34.7% 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.[18, 19] Cronbach's alpha greater than 0.6 indicates an appropriate value for internal consistency reliability.[20] 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.[21-23] Furthermore, they have placed a greater emphasis on hypertension and diabetes rather than dyslipidemia.[22, 24-28] Because dyslipidemia has a higher prevalence and lower treatment and control rates than hypertension and diabetes mellitus[11] and its adverse events,[29] 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.[30] 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.[31, 32] 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. [33] 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.

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