Nutrition, Metabolism & Cardiovascular Diseases (2022) **32**, 1110–1120

Available online at www.sciencedirect.com

Nutrition, Metabolism & Cardiovascular Diseases

journal homepage: www.elsevier.com/locate/nmcd

Uptake and effectiveness of a primary cardiovascular prevention program in an underserved multiethnic urban community☆

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Received 12 July 2021; received in revised form 10 January 2022; accepted 10 January 2022
Handling Editor: A. Siani
Available online 16 January 2022

KEYWORDS
Primary cardiovascular prevention program;
Communities;
Inclusiveness;
Multidisciplinary care

Abstract *Background and aims:* Cardiometabolic risk is increased among disadvantaged people and ethnic minorities. Paradoxically, their uptake of primary cardiovascular prevention is relatively low. New strategies are needed to tackle this public health problem. Aims of this study were to assess the uptake (as well as its determinants) and effectiveness of a primary cardiovascular prevention program for communities devised to facilitate access of disadvantaged and inclusion of ethnic minorities in addition to providing a state-of-the-art interdisciplinary personalized care.

Methods and results: Single center, hospital-based, open study. All the residents in an underserved multiethnic urban community aged 40–65 years (n = 1646, 43.6% immigrants) were proactively invited by post mail to participate in a cardiovascular prevention program and different approaches were adopted to promote accessibility and inclusiveness. Program uptake was 23% and individual features independently associated with program uptake were status of immigrant (OR [CI 95%]: 3.6 [2.6–5.1]), higher educational level (3.6 [2.8–4.7]), and female gender (1.6 [1.2–2.1]). Retention was 82% at 6 months and 69% at 12 months. A predefined outcome of global cardiovascular risk improvement at 12 months in subjects with glycaemia >126 mg/dl, LDL-C >115 mg/dl, systolic blood pressure ≥140 mmHg or BMI >28 at baseline was reached in 35%, 33%, 37% and 7% of the patients, respectively. 20% of smokers quitted and significant favorable changes were reported in diet quality, anxiety, depression and physical activity.

Conclusion: Access inequalities to effective prevention may be counteracted, but increasing global uptake requires further upstream sensitization and awareness actions.

Registered in ClinicalTrials.gov: NCT03129165.

Abbreviations: BMI, body mass index; CI, confidence interval; CVD, cardiovascular diseases; DBP, diastolic blood pressure; FRS, Framingham risk score; OR, Odd Ratio; SBP, systolic blood pressure; SES, socioeconomic status.

☆ The protocol was registered on April 26th, 2017 at www.clinicaltrials.gov; identifier no. NCT03129165.

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https://doi.org/10.1016/j.numecd.2022.01.013

1. Introduction

About 2.2 million women and 1.9 million men die each year from cardiovascular diseases (CVD) in Europe, which represents 47% and 39% of all deaths in females and males, respectively. Moreover, CVD is also the most common cause of premature (age <70 years) death in males [1]. Most of these deaths are due to atherothrombotic events, which are ascribable to a small number of modifiable cardiovascular (CV) risk factors [2]. Structured primary prevention programs may help to identify and reduce these threats, enhancing the health of individuals and communities [3]. However, a number of factors that influence their uptake and effectiveness call for improvement. In fact, the uptake largely varied among different prevention programs for cardiometabolic risk control targeting diverse populations, ranging from 3% to 75% [4–8].

Primary prevention programs are more cost/effective when targeted to populations at high CVD risk, in particular those socially disadvantaged [9]. Indeed, a low socioeconomic status (SES) has a measurable effect on CV health equivalent to traditional risk factors [10]; this fact is mainly attributable to a constellation of biological, behavioral, and psychosocial conditions which are prevalent in disadvantaged individuals [11]. However, previous data have shown that the participation of people with low SES to preventive actions is significantly lower compared with wealthy subjects, which contributes to enhance healthcare inequalities [4]. Substantial obstacles to involve disadvantaged people in primary CVD prevention actions include, on one side, a personal reluctance to take part in these initiatives (due to low health literacy, skepticism, other priorities, etc) and, on the other, a problem of accessibility to the healthcare system, which is a prerequisite to address personal barriers. Thus, a ***facilitated access*** (e.g. preliminary delivery of understandable information about procedures and objectives to make informed decision to participate, easy access to appointments, location at walking distance, flexible hours for encounters, etc) may contribute to engage disadvantaged subjects in primary CVD prevention [12] and this approach, whenever possible, should be pragmatically implemented.

Besides, studies in different countries, including Italy, showed that migrants, mainly from high migratory pressure countries present a higher burden of risk factors for CVD [13–15], with a strong influence of the new environment to which they migrated [16–18]. Migrants also receive less preventive care compared to native citizens, owing to a variable combination of subject- and health system-dependent barriers [19,20]. Some of the subject-dependent barriers include less awareness of CVD risk factors (and consequently less motivation to seek treatment or modify their behavior to prevent negative CVD outcomes), unfamiliarity with processes and entry points to health services, problems of language that lead to significant communication obstacles with health providers, issues concerning their cultural beliefs, problems with obtaining time off work as well as financial constraints [21,22]. The health system-dependent barriers include but are not limited to rigid hours of health service delivery, communication in the local language and lack of cultural mediators or interpreters as well as the need to pay user fees (co-payments) for visits and tests. Solving these problems may be relevant for many European countries in which a mounting exodus from high-pressure migration countries has led to the emergence of numerous multiethnic communities with a large cultural heterogeneity. From a public health perspective, suboptimal prevention in groups where migrants represent a sizeable proportion of the community may not only be an expression of health inequalities but also have negative economic effects for the society [23]. Therefore, the implementation of strategies to encourage ***inclusiveness of ethnic minorities*** in health prevention initiatives is necessary and has been recently urged [20,24].

In addition, given the intricacy of biological and environmental determinants of CV risk, the involvement of multidisciplinary healthcare competences in delivering preventive services is regarded as a Class I level A recommendation [25]. Moreover, the convenience of an ***interdisciplinary care*** was underlined [26].

Lastly, large attention has been recently paid to the concept of ***personalized CVD prevention***, intended as a shift from a “one-fits-all” medicine to an individualized approach. Though the interest in personalized prevention has been mainly focused on improving risk-estimating algorithms through the addition of high-throughput derived biomarkers [27] and modeling of benefit-of-treatment for the choice of interventions [28,29], relevant individual features (i.e. beliefs, cognition, life-skills, health literacy, preferences, expectations, and social context) require personalized attention, as they strongly influence each patient’s decisions related to prevention such as readiness to lifestyle changes and compliance to medications [30–32]. Consequently, applying a forward-looking style of health providers-individual interaction focused on patient empowerment and shared decision making has been proposed as a possible strategy to favor engagement and commitment in CV prevention [33].

Based on these premises, we developed an experimental primary CV prevention pilot program targeting an adult multiethnic urban community with low SES. The program was designed to favor accessibility to disadvantaged people and inclusiveness to ethnic minorities as well as to deliver them an interdisciplinary personalized preventive care. The primary objectives of the study were to assess the extent of program uptake and to identify its sociodemographic determinants. Besides, we assessed the extent of changes in CV risk factors as a measure of program effectiveness.

2. Methods

2.1. Design and study population

This was a single center, hospital-based, multidisciplinary, primary CV prevention study with a pre-post design. The

program was conducted in an urban peripheral quarter of Milan, Italy, composed by 4462 residents of any age at the time of study initiation. All males or females aged 40–65 years, residents in the target quarter at the end of year 2014 (henceforth called "candidates") were identified from administrative files provided by the Municipality of Milan. Out of the candidates who received by post mail a personal invitation letter to take part in the program (see below), 56.4% were native Italians whereas 43.6% were immigrants from 55 different countries, most from Africa (Egypt and Morocco), South or Central America (Peru, Ecuador, El Salvador) or south Asia (Philippines, Sri Lanka). Worth noting, in 2014 the prevalence of immigrants in the target quarter was 2.3-fold higher than in Milan City [22].

2.2. Accessibility and inclusiveness

Strategies adopted to facilitate access of disadvantaged people and to encourage inclusion of ethnic minorities were: a) the program participation was free of charge; b) the candidates were proactively invited by sending them personalized post mail, written in Italian and in their own language for migrants; c) the hospital running the program, where all the face-to-face encounters were carried out, is located within the target quarter, at walking distance from every candidate's household; d) the encounters were performed before or after ordinary working hours or on Saturday morning for people who could not attend during weekdays; e) preliminary illustrative talks were given in public events; f) preliminary explanatory meetings with "influencers" of the main ethnic communities were carried out with the help of interpreters; g) announcements (posters and totems) were positioned in highly frequented places; h) family physicians were involved in promoting the program; i) several articles were published in the local newspaper describing the program; j) a program's website linked to explanatory videos posted in Youtube was created; k) program flyers were printed in 5 languages (Italian, English, French, Spanish and Arab); l) a reserved telephone number was provided for questioning and booking.

2.3. Study procedures

2.3.1. Enrolment and screening

Invitation letters were sent by post mail to the program candidates. We used a paid mail service for return to the hospital of undeliverable items (letters to 26 candidates returned for recipient untraceable, deceased, unknown or relocated; address insufficient, incorrect or non-existent) and the letters were sent again twice (maximum 3 letters) to those who had certainly received the letter at home but had not responded timely to the invitation either positively or negatively.

Besides, a further attempt to involve more subjects was done at early 2018 by posting geolocated Facebook announcements in an area within a radius of 2 km around the hospital.

The baseline encounter was scheduled at 7.00 a.m. Patients were given detailed information about the program and instructions to fill in a comprehensive screening questionnaire (Supplemental material online, S1) on demographic, lifestyle, psychosocial and clinical domains, which included published validated tools, when available [21,34–38].

Non-Italian speakers were screened only when an interpreter was available. After signing a written informed consent, the participants filled in the form, with assistance if necessary. Whenever symptoms suggestive of CVD were reported, a research physician briefly interviewed and examined the subject to assess the plausibility of overt CVD. In case of doubt, a report for the family physician was produced suggesting specific diagnostic tests. A research nurse measured weight, height, waist circumference, heart rate and blood pressure using standard methods. Finally, a venous blood sample was obtained for routine analysis (total cholesterol, HDL-cholesterol, triglycerides, LDL-cholesterol, glucose and creatinine) and a close appointment for a feed-back was fixed. Patients who referred a personal history of overt CVD as well as those whose screening unveiled CVD were considered screening failures (n = 5) and were shifted to a secondary prevention program.

2.4. Feed-back and shared-decision intervention planning

Individual data obtained at screening were analyzed through a predefined algorithm aimed at personalizing the preventive intervention and at optimizing the use of available professional resources. The variables considered to build the algorithm were a combination of the subject's global CV risk and the number and severity of his or her individual risk conditions (Supplemental material online, S2). At the feedback visit, the research nurse explained the significance of the findings and suggested a personal intervention plan to improve the patient's risk profile. The plan included extra-encounters with the team members, if needed according to the algorithm criteria (Supplemental material online, S2). The patient could openly decline one or more of these extra-encounters (e.g. smoking cessation support) without compromising his or her participation to the program. During the extra-encounters, above and beyond the ordinary actions of diagnosis and proposal of therapies, the team members (research nurse, nutritionist, psychologist, social worker and physician) delivered personalized information (verbally and/or printed) to enhance the patient's health literacy, operated components of motivational interviewing to promote changes and applied shared decision-making about options to improve the patient's health. Worth to note, physicians, nutritionists and the research nurse were trained in the motivational interviewing approach of health provider-patient interaction; moreover, the psychologist of the team has large expertise in cognitive psychology and decision-making processes in medicine. Additionally, participants were encouraged to use available local resources to sustain

a healthy life-style (e.g. parks, gyms, social services). A report with the results of the screening was delivered to inform the patients' primary care physician.

2.5. Intermediate follow-up and final encounter

Study participants were reevaluated at 6 months (intermediate follow-up) and at 12 months (final encounter) after enrolment. At these fixed visits (about 15 min long), they filled out a follow-up questionnaire regarding modifiable conditions (Supplemental material online, S3), and the research nurse re-assessed vital signs and body measures and obtained venous blood for glucose and lipid tests.

2.6. Study objectives

The study protocol was registered in ClinicalTrials.gov. Identifier: NCT03129165.

The primary objective was to assess the program uptake, evaluated as the ratio between the number of subjects enrolled living in the target quarter (henceforth called "adopters") and the number of candidates who had certainly received the invitation letter at home.

Secondary aims included assessment of sociodemographic determinants of the program uptake (a comparison between adopters and those who did not respond to the call or refused to take part to the program, henceforth called "decliners"), prevalence of CV risk factors and conditions among adopters, awareness of traditional CV risk factors, accuracy of CV risk perception, use of professional resources, retention in the program and changes in lifestyle (food choices, physical activity, smoking, anxiety and mood), in individual risk factors and in a pre-defined index of global risk change.

Definite diagnoses of risk conditions at baseline were made on the basis of the intake of drugs to control the condition, blood pressure values at screening, body mass index (BMI) and results of laboratory tests. As the diagnoses were based on a one-time assessment, we applied conservative criteria for definite diagnoses of hypertension (systolic blood pressure [SBP] $\geq$ 160 and/or diastolic blood pressure [DBP] $\geq$ 100 mmHg), hypercholesterolemia (total cholesterol $\geq$240 mg/dl) and diabetes (fasting glycemia $\geq$140 mg/dl).

Awareness of traditional CV risk conditions was defined as the participants' knowledge of having a risk condition in patients with a definite diagnosis of that condition.

Accuracy of CV risk perception was estimated as the extent of agreement between the perceived level of the CV risk on a 5-points Likert scale (very low, low, average, high, very high) and the corresponding $\pm$1 or $\pm$ 2 among 5 categories of the Framingham Risk Score (FRS<5%, 5$\leq$FRS<10%, 10$\leq$FRS<20%, 20$\leq$FRS<30%, FRS$\geq$30).

The global CV risk change, predefined by protocol, was assessed as the rate of subjects with abnormal risk factor values at baseline (glycaemia >126 mg/dl, LDL-C >115 mg/dl, SBP $\geq$140 mmHg or BMI >28) who, at the final visit, had improved by $\geq$ 10% at least one CV risk factor without worsening by $\geq$ 10% any other CV risk factor. Changes in other modifiable risk factors assessed were smoking habit, diet quality, physical activity, anxiety and depressive mode.

2.7. Statistical analysis

Continuous variables were compared between adopters and decliners by T-test for independent samples. Categorical variables were compared by chi-squared test. Multivariable logistic regression, including all the demographic features available in the community administrative dataset, was employed to determine independent predictors of program uptake. Retention in the program at 6 and 12 months was computed as the percentage of adopters that returned for assessment at these times among those enrolled and in primary prevention at the baseline encounter. The extent of changes in CV risk factors between baseline and final visit was assessed by paired samples T-test for continuous variables and by chi-squared test for categorical variables.

3. Results

Fig. 1 shows the study flowchart. Between May 2015 and December 2017, 1646 adult inhabitants in the target quarter certainly received to their homes by post mail a personal invitation letter. Though all the adopters received the letter, the means that actually prompted them to join the program was another one in about half (Fig. 1). The program uptake was 23% (n = 372/1646). Sociodemographic determinants of program uptake are depicted in Table 1. In univariate analysis, adopters were about 1 year younger than decliners, and were more frequently female, with higher working category and with higher educational level than decliners, whereas program uptake by native Italians and immigrants as a whole did not differ significantly. The program uptake of immigrants from different countries was proportional to their prevalence among the candidates. In multivariate analysis, sociodemographic variables independently associated with program uptake were status of immigrant (OR [CI 95%]: 3.6 [2.6–5.1]), educational level (3.6 [2.8–4.7]), and female gender (1.6 [1.2–2.1]) (Supplemental material online, S4).

Facebook announcements yielded a minimal incremental response by residents of the target quarter (n = 8), but engaged additional subjects living nearby the quarter (n = 160), totalizing 540 program participants (Fig. 1).

Table 2 shows their main features at baseline. Beyond a high prevalence of overweight or obesity and one or more unhealthy behaviors, definite diagnoses of hypertension, hypercholesterolemia and diabetes were made in 28%, 19% and 7% of the participants, respectively, with 18%, 20% and 25% of the cases, respectively, unaware to be affected. Five subjects referred a clinical history or were newly diagnosed atherosclerotic CVD at screening and were therefore considered screening failures.

Table 3 shows the distribution of CV risk and the accuracy of risk perception in the 535 participants in primary

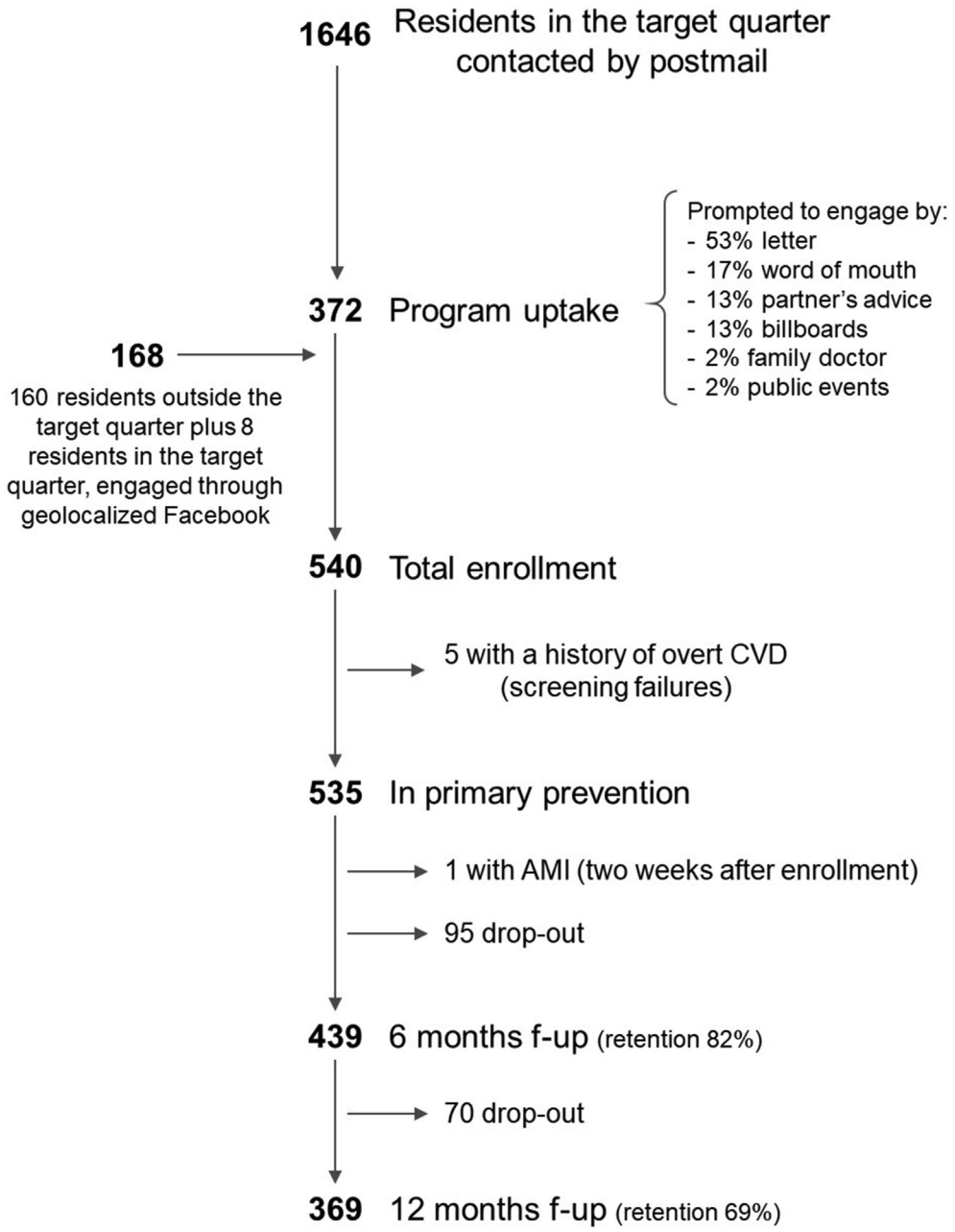

Fig. 1 Flow chart of the study.

prevention who took part in the program. About 40% of the subjects were at moderate or higher CV risk (FRS≥10%) and, among these, 50% underestimated by at least one FRS category and 18% underestimated by at least two FRS categories his or her actual CV risk. Moreover, considering subjects at high or very high CV risk (FRS≥20%, 14% of the cohort), 85% underestimated by at least one FRS category and 38% underestimated by at least two FRS categories their actual CV risk.

Applying the predefined algorithm, participants were assigned the extra-encounters with the professional resources of the team shown in Table 4. A number of patients declined some of these extra-encounters, more frequently those providing smoking cessation support, social worker counseling and/or promotion of physical activity.

Out of the 535 participants in primary prevention enrolled in the program, 432 returned after 6 months for reevaluation and reinforcement (retention 82%) and 369 returned after 12 months for the final visit (retention 69%). In multivariate analysis, sociodemographic variables independently associated with program drop-out before the visit at 12 months were age (OR [CI 95%]: 0.96 [0.94–0.99]), status of immigrant (2.52 [1.64–3.85]) and educational level (0.68 [0.54–0.87]) (Supplemental material online, S5).

Changes in traditional risk factors in the 369 participants who returned after 12 months are shown in Table 5.

Table 1 Sociodemographic determinants of program uptake. Univariate Analysis.

	Invited by post mail	Adopters	Decliners	*p value*
Residents in the target quarter, n (%)	1646 (100)	372 (23)	1274 (77)	
Age (mean ± SD)		52.3 ± 8.1	51.2 ± 8.6	0.015
Gender				<0.0001
Males (%)	51	41	54	
Females (%)	49	59	46	
Origin				0.22
Native citizens (%)	56	59.1	55.6	
Immigrants (%)	44	41	44	
				0.34
Egypt		7.5	6.8	
Peru		6.2	5.5	
The Philippines		4.3	5.4	
Ecuador		3.8	3.9	
Morocco		3.2	3.5	
Romania		1.3	2.5	
Sri Lanka		3.2	2.4	
El Salvador		1.9	1.7	
Senegal		0.5	1.3	
Albania		1.1	1.1	
Eritrea		0	1	
Ukraine		0	0.9	
Mauritius		0.8	0.8	
Tunis		1.3	0.6	
Other countries		5.7	6.9	
Work category				<0.0001
Manual worker (%)	48	39	50	
Service worker (%)	23	21	24	
Office worker (%)	24	35	21	
Unemployed (%)	5	5	5	
Years of study				<0.0001
Up to middle school (%)	61	34	73	
Hight school (%)	32	50	24	
University or higher (%)	7	16	3	

Source data: administrative files provided by the Municipality of Milan.

Table 2 Characteristics of all study participants at baseline (n = 540).

	variables	n (%) or Mean ± SD
Socio-Demographic variables	Males	225 (42)
	Age	52 ± 7.5
	Immigrants	169 (31)
	Education years	12 ± 3.8
	Presence of partner	370 (68)
	Without offspring	96 (18)
	Low social support (FSSQ)	52 (10)
	Working category	
	Unemployed or retired	132 (24)
	Manual worker	86 (16)
	Service worker	204 (38)
	Housewife	30 (6)
	Office worker	88 (16)
Family history	Family history of CVD risk factors	406 (75)
	Family history of CVD events	245 (45)
Lifestyle	Current smokers	107 (20)
	Physical inactive	89 (16)
	MeDAS score	7.1 ± 1.6
	MeDAS score ≤ 5	88 (16)
	PHQ-4 Anxiety	2.2 ± 1.7
	PHQ-4 Anxiety ≥ 3	166 (31)
	PHQ-4 Depression	1.4 ± 1.4
	PHQ-4 Depression ≥ 3	89 (16)
Body measures	BMI	28 ± 5.4
	Overweight	195 (36)
	Obese	164 (30)
	SBP (mmHg)	126 ± 19
	DBP (mmHg)	82 ± 11
	SBP ≥140 (mmHg)	111 (21)
	DBP ≥ 90 (mmHg)	130 (24)
	SBP ≥140 and DBP ≥ 90 (mmHg)	75 (14)
	Grade 2 HTN or on treatment	150 (28)
	Awareness of HTN	123 (82)
Lab tests	Total cholesterol (mg/dl)	204 ± 38
	Total cholesterol > 200 (mg/dl)	291 (54)
	Total cholesterol > 240 (mg/dl)	63 (12)
	Dx of HC	105 (19)
	Awareness of HC	84 (80)
	Glycemia mean (mg/dl)	98 ± 23
	Glycemia 101−125 (mg/dl)	123 (22)
	Glycemia >126 (mg/dl)	28 (5)
	Dx of DBT mellitus	36 (7)
	Awareness of DBT	27 (75)
Framingham Risk Score[a]	FRS	11.1 ± 10.4
	FRS < 5	172 (32)
	5 ≤ FRS < 10	146 (27)
	10 ≤ FRS < 20	144 (27)
	20 ≤ FRS < 30	48 (9)
	FRS ≥ 30	25 (5)

SD: Standard deviation; CVD: cardiovascular disease; MEDAS: Mediterranean Diet Adherence Screener; BMI: body mass index; SBP: Sistolic blood pressure; DBP: Diastolic blood pressure; HTN: Hypertension; Dx: diagnosis; HC: Hypercholesterolemia; DBT: Diabetes; FRS: Framingham Risk Score.

[a] 5 subjects had overt cardiovascular disease at screening and therefore, the FRS was computed in the 535 subjects in primary prevention.

The utilization of CV preventive drugs is described in Supplemental material online, S6, showing that the absolute percent increase in the utilization of antidiabetic, antihypertensive or lipid-modifying drugs between baseline and the end of the study was 0.3%, 4.6% and 3.8%, respectively. Significant changes were also observed when patients on antihypertensive drugs (n = 103, 28%) or lipid-modifying drugs (n = 38, 10%) either at baseline or at 12 months were excluded from the analysis (Table 5).

Categorically, 30% (33 out of 109) of participants with SBP≥140 or DBP≥90 mmHg at baseline reached normal BP (SBP<130 and DBP<85 mmHg), and 20% (51 out of 261) of those with LDL-C above their individual goals at baseline (LDL-C≤115, 100 and 70 mg/dl for subjects with FRS <10%, 10−20% and >20%, respectively) reached these goals at 12 months.

Besides, 20% of current smokers at baseline had stopped smoking at 12 months (confirmed with expired CO), and 16% of obese or overweight participants shifted to a lower weight category. Significant favorable changes in scores of diet quality (7.1 ± 1.6 to 7.5 ± 1.6), anxiety (2.2 ± 1.7 to 1.9 ± 1.5), depression (1.3 ± 1.4 to 1.1 ± 1.3) [all p < 0.001]

Table 3 Estimated cardiovascular risk and accuracy of risk perception in the 535 program participants in primary prevention.

	Framingham Risk Score				
	≤5%	5% < 10%	10% < 20%	20% < 30%	≥30%
Cardiovascular risk perception					
Very low	15	13	12	5	1
Low	59	41	34	5	3
Average	74	73	67	28	14
High	19	13	27	8	6
Very high	5	6	4	2	1
Total	172	146	144	48	25

Note: cells within broken lines and continuous lines correspond to subjects that overestimate and underestimate, respectively, their calculated risk by ≥ 2 categories.

and physical activity (sedentary 16%–7%, $p < 0.01$) were reported.

The predefined composite outcome of global CV risk change (a ≥10% reduction in at least one risk factor without worsening by ≥ 10% any other risk factor) in subjects with glycaemia >126 mg/dl, LDL-C >115 mg/dl, SBP ≥140 mmHg or BMI >28) was reached in 35%, 33%, 37% and 7% of the patients, respectively (Supplemental material online, S7). A 5% BMI reduction, deemed as a reasonable initial change to reduce body weight-associated comorbidities, was reached in 21% of the participants with BMI >28 at baseline, without worsening by ≥ 10% any other risk factor.

4. Discussion

The empirical data produced in this study inform successful measures to reduce some recognized access inequalities to prevention but also show that further strategies are needed to increase overall participation.

The uptake of our program was 23%, which is somewhat lower than analogous initiatives carried out in other contexts. For example, in a primary prevention initiative of the British National Health Service offering cardiovascular risk assessment and management, attendance was 31.4% [5]. Contrastingly, the participation at baseline to a lifestyle consultation for ischemic heart disease reduction in the context of a Danish population was 53% [4]. Indeed, the uptake largely varied among different prevention programs for cardiometabolic risk control, ranging from 3% to 75% [6–8,39]. This high variability is not unexpected and probably depends on methodological issues including the relationship between the inviting health care facility and the target population, the means used for engagement, the personal commitment required and the cultural and cognitive characteristics of the target population. In a recent online Italian survey [40], we found out that the most prevalent negative predictors of participation in preventive actions were logistic barriers (i.e., “I am busy” or “the hospital is far from home and/or work”), disregard (i.e., “I am not interested in prevention”) and fear of the outcome (i.e., “I am worried about the results”). Although in the present study a number of logistic barriers for program uptake were purposely countered, most eligible candidates did not participate, suggesting that other key barriers remained untouched. Future studies are needed to address whether upstream educational and motivational actions may help to overcome disregard and fear of the outcome as well as other possible individual obstacles to involvement in cardiovascular prevention (e.g. inadequate health literacy, prejudices, etc).

A number of actions to promote inclusiveness led to a similar involvement of ethnic minorities and native

Table 4 Algorithm-predefined assignment of extra-encounters with the professional resources of the team.

A: Support proposed upon patients’ risk factors profiling

Number of professional resources proposed	Patients[a] [n (%)]
0	65 (12.1)
1	148 (27.7)
2	155 (29.0)
3	101 (18.9)
4	54 (10.1)
5	8 (1.5)
6	4 (0.7)

B: Referral to and refusal of extra-encounters

Extra-encounters with	Patients[a] referred [n (%)]	Patients[a] who refused [n (%)]	Extra-encounters done [n (mean per patient)]
Physician	136 (25)	1 (1)	204 (1.5)
Nutritionist	213 (40)	14 (7)	509 (2.6)
Psychologist	126 (24)	37 (29)	335 (3.8)
Smoking support	57 (11)	36 (63)	55 (2.6)
Nurse for physical activity guide	63 (12)	28 (44)	60 (1.7)
Social worker	52 (10)	24 (46)	28 (1.0)

[a] Correspond to 535 patients in primary prevention at the baseline encounter.

Table 5 Changes in traditional risk factors in all the program participants retained at 12 months (n = 369) and in subgroups stratified according to lifestyle or lifestyle plus drug treatment for risk factor control.

Variable		Baseline	12 months	Absolute change
		All subjects		
SBP (mmHg)		126 ± 18	120 ± 16	−7.2 [-5.6; −8.8]
DBP (mmHg)		82 ± 11	79 ± 9	−4.3 [-3.4; −5.2]
LDL-C (mg/dl)		126 ± 30	119 ± 28	−7.2 [-4.7; −9.7]
HDL-C (mg/dl)		56 ± 16	57 ± 16	1.2 [2.1; 0.3]
Triglycerides (mg/dl)		102 [71; 135]	97 [71; 134]	−2.0 [-22.0; 22.0]
Glycemia (mg/dl)		98 ± 22	98 ± 21	0.0 [1.9; −2.0]
Body mass index		27.4 ± 5,2	27.0 ± 5,1	−0.3 [-0.2; −0.5]
Abdominal circumference F (cm)		88 ± 12	87 ± 12	−1.0 [-0.3; −1.8]
Abdominal circumference M (cm)		98 ± 11	98 ± 11	−0.8 [0.03; −1.6]
	n	On life-style only treatment		
SBP (mmHg)	266	124 ± 16	117 ± 16	−6.4 [-4.7; −8.1]
DBP (mmHg)	266	81 ± 9	77 ± 9	−3.7 [-2.7; −4.8]
LDL-C (mg/dl)	331	125 ± 29	120 ± 27	−4.8 [-2.5; −7.1]
	n	On-drugs		
SBP (mmHg)	103	139 ± 19	130 ± 16	−9.3 [-5.7; −12.8]
DBP (mmHg)	103	89 ± 12	83 ± 9	−5.8 [-3.8; −7.8]
LDL-C (mg/dl)	38	132 ± 34	103 ± 33	−29 [-16; −42]

Values are expressed as means ± standard deviation or median [q1; q3]. Absolute changes are expressed as means [95% confidence interval]. SBP: Sistolic blood pressure; DBP: Diastolic blood pressure; LDL-C: LDL-cholesterol; HDL-C: HDL-cholesterol; F: females; M: males.

Italians in univariate analysis. Moreover, the different ethnic groups were engaged proportionally to their prevalence among candidates. These results suggest that some of the obstacles that migrants may have to join to this sort of primary care proposals, may be favorably addressed by proactively encouraging their participation and overcoming language barriers. Rather, in multivariate analysis, the status of migrant was independently associated with a 3.6-fold *higher* participation than that of native Italian citizens. Several factors might explain this unpredicted finding: first, though public health services in Italy are universal and legal immigrants have the same rights to public health services as native people [20,41], more migrants may feel not fully supported by primary physicians and thus be willing to adhere to supplementary healthcare; moreover, the explicit communication efforts put forth to involve ethnic minorities may have been perceived by natives as a proposal primarily directed to migrants. In any case, the approach for engagement of ethnic minorities adopted in this study may be considered by policymakers to reduce this meaningful aspect of healthcare inequalities.

Efforts to reduce inequalities in participation related to a low economic status included delivering the program completely free of charge, eluding matters of transportation and scheduling visits outside working hours. This approach was probably successful inasmuch as working category, a proxy measure of economic status, was not associated with study participation in multivariate analyses.

A strong independent determinant of participation was the educational level, which was previously related to health literacy [42]. Illiteracy is a complex upstream barrier to prevention and improvements might be obtained not only by strengthening public policies to increase the general educational level of the population but also, probably more expediently, by enhancing health literacy through communication tools currently available, including social channels and digital persuasive technology [43].

Like in similar previous initiatives [5], males adhered significantly less than females, although age-adjusted CV risk is objectively higher in males than in females [44]. Several factors may explain this gender imbalance. First, CV risk perception differs between genders [45,46]. Among participants to this program, women more frequently overestimated and men underestimated their own objective CV risk (data not shown). If this happened in the whole cohort of candidates, women may have been more inclined than men to adhere. Second, men have less health literacy than women [47,48], which may make a CV prevention program less appealing to the former. The current results are in line with those of the online survey cited above [40], and corroborate a lower proneness of men to take part in preventive initiatives compared to women. Thus, new approaches or strategies to foster the uptake of primary CV prevention by males need to be envisioned.

Cardiovascular risk underestimation was quite common in our cohort. As this misperception can hinder a subject's willingness to improve his or her lifestyle and/or to take preventive medicines, it represents a condition worthy of corrective interventions.

The 69% retention at 12 months observed in the low-SES and multiethnic target population enrolled in our program was even higher than that observed in the Inter99 Study carried out in the south-western part of Copenhagen County [4]. This finding suggests a fairly good

participants' engagement, which is consistent with the highly positive responses to a questionnaire of satisfaction administered at study end (data not shown). As observed for program uptake, a higher educational level was also related to a lower drop-out rate. Contrastingly, the status of immigrant was linked with a higher uptake (see above) but also with a higher drop-out rate, which may result from time restrains of migrants for additional visits, disinterest or reluctance to adhere to preventive advices, or other reasons that worth further scrutiny.

Though most smokers at baseline (63%) declined extra-encounters for cessation, all smokers received at least a minimal intervention, as recommended by guidelines [25]. The final result was striking anyway, as the 20% rate of quitters at 12 months clearly differs from the 5.6% annual smoking cessation rate observed in Italy [49]. About half of participants physically inactive or with low social support declined specific extra-encounters to face these problems, indicating that further upstream actions may be needed to increase uptake of specific aid.

The levels of most CV risk factors as well as the predefined composite outcome changed favorably between the baseline and the final visit, suggesting that program participation was associated with a comprehensive positive benefit in terms of CV risk reduction. Significant reductions in blood pressure and LDL-C were also observed in the predominant subgroup of subjects off- normotensive or LDL-lowering drugs, respectively, indicating substantial effects by lifestyle modifications.

Changes in most individual risk factors were small, as expected for a predominantly behavioral intervention, and a more intensive approach may be needed to achieve the so-called "ideal cardiovascular health" [50,51]. Yet, the comprehensive improvement in CV risk factors of study participants could lead, if maintained in the long term, to a meaningful reduction of CV events. In fact, in a recent study [2], 70% of CVD cases and deaths were attributed to 14 modifiable risk factors, many of which were significantly reduced through the comprehensive intervention herein described.

A major strength of this study is the pragmatic "real world" implementation of actions aimed at removing well recognized barriers for primary CV prevention in a socially disadvantaged population. One limitation may be the pre-post study design without comparison with a "usual care" group. However, a comparative study design was deemed unsuitable as the identification of risk factors at baseline would have triggered the prescription of mandatory interventions also in the control group. Another limit is that the results of the program cannot be specifically ascribed to any individual action, which is a typical problem of complex interventions.

In summary, the implementation of strategies to facilitate accessibility of disadvantaged people and inclusiveness of ethnic minorities may help to reduce prevalent social inequalities in the uptake of an effective interdisciplinary primary CV prevention program for communities. Preliminary sensitization and development of health awareness public actions may be needed to increase overall participation.

Funding

This work was funded by the Italian Ministry of Health, Ricerca Corrente to Centro Cardiologico Monzino, IRCCS, years 2014–2019.

Declaration of competing interest

Nothing to disclose.

Acknowledgements

We thank Dr. Marco Cormio for his help in obtaining candidates' administrative data as well as the Comune di Milano, the Consiglio di Zona 4 for their patronage to our preventive program for the community and Dr. Viviana Biagioli for her valuable suggestions to refine English writing.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.numecd.2022.01.013.

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