# Multicomponent intervention provided by GPs to reduce cardiovascular risk factors: evaluation in an Italian large sample 

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#### Abstract

Background: The cardiovascular risk increases in a multiplicative way when patients present more risk factors simultaneously. Moreover, the General Practitioners (GPs) play a crucial role in risk factors prevention and reduction. This work aimed to evaluate a multicomponent intervention in the Primary Care Department in an Italian Local Health Unit. Methods: A pre-post study was conducted in Northern Italy (2018). Patients were eligible if: aged between 30 and 60 years, not chronic patients, not affected by hypertension or hypercholesterolaemia. The GPs assessed body mass index, hypertension, abdominal obesity, low-density lipoprotein (LDL) values, glycaemic values, smoking and exercise habit (TO). A counselling by GPs to at-risk patients and a multicomponent health education intervention were performed. Reassessment occurred after at least 3 months (T1). Main analyses were chi-squared tests for gender differences, McNemar or marginal homogeneity tests for changes in paired data ( $P<0.05$ as significant). Results: Participants were 5828 at T0 ( $54.0 \%$ females) and 4953 at T1 ( $53.4 \%$ females). At T0, $99.1 \%$ presented at least one risk factor. Significant changes in paired data were reported for each risk factor. The greatest improvement frequencies occurred in glycaemia values (51.0\%) and hypertension ( $45.6 \%$ ), the lowest in abdominal obesity ( $3.7 \%$ ). Some differences were recorded between genders, e.g. females reported higher improvement frequencies in hypertension ( $P=0.001$ ) and abdominal obesity ( $P<0.001$ ), whereas males in physical activity ( $P=0.011$ ) and LDL values ( $P=0.032$ ). Conclusion: The results showed significant changes for each risk factor, both for men and women. GPs and multicomponent educational interventions could play a key role in reducing cardiovascular risk factors.


## Introduction

Cardiovascular diseases (CVDs) represent a major challenge _worldwide: CVDs constitute $31.80 \%$ of all deaths and $14.66 \%$ of all disability-adjusted life years. ${ }^{1}$ Globally, deaths caused by CVDs raised by $21.1 \%$ from 2007 to $2017 .^{2}$ Specifically, $84.9 \%$ of CVDs deaths is composed of ischaemic heart disease and strokes. ${ }^{2}$

Metabolic syndrome, inappropriate nutrition, physical inactivity, obesity and smoking are among the main modifiable cardiovascular risk factors: besides the single factor, searching for concurrent risk factors is essential since their coexistence can rise the CVDs risk in a multiplicative way. ${ }^{3}$ The metabolic syndrome is a cluster of conditions defined by the presence of three or more of the following factors: abdominal obesity, hypertension, high triglycerides, low high-density lipoprotein (HDL) cholesterol, impaired fasting plasma glucose or diabetes mellitus. ${ }^{4}$ However, many definitions of metabolic syndrome exist and it would be advisable to concentrate on established risk factors rather than the diagnosis of this syndrome to realize prevention and treatment strategies, ${ }^{5,6}$ as the combination of hypertension, abdominal obesity, altered lipids and glucose represents a major public health issue. ${ }^{5,7}$ Onset and progress of metabolic syndrome are also related to tobacco use, and cessation of smoking can decrease the risk of developing such syndrome. ${ }^{8}$ It is worth noting that hypertension is the most relevant, modifiable and independent CVD risk factor. ${ }^{3}$ Besides, obesity contributes largely to the burden of chronic disease and BMI (body mass index) and body fat mass distribution have a role in insulin resistance and
cardiometabolic diseases. ${ }^{9}$ However, metabolically healthy obese are not in low-risk status because of other obesity-related diseases, e.g. respiratory diseases, osteoarthritis or gynaecologic abnormalities. ${ }^{9}$ Moreover, the prevalence of the clustering of abovementioned risk factors rises with age and has a specific sex-related correlation, as sex- and gender-related determinants have an impact on clinical expression of each factor. ${ }^{10}$ Before 50 years old the prevalence is higher among men, whereas after this age it is higher among women. ${ }^{10}$ Biological traits and functional characteristics are connected to the sex-related determinants, e.g. hormonal changes during and after menopause. ${ }^{10}$ Psychological and cultural patterns are linked to gender-related factors, as socio-economic status or unhealthy habits. ${ }^{10}$

Concerning prevention and reduction of risk factors, the General Practitioner (GP) plays a crucial role since he/she should have a total and complete knowledge of the patient, being 'the only clinician who operates in the nine levels of care: prevention, pre-symptomatic detection of disease, early diagnosis, diagnosis of established disease, management of disease, management of disease complications, rehabilitation, terminal care and counselling. ${ }^{11}$ In CVDs prevention, GPs have an essential part in helping patients to adopt a healthy lifestyle and achieve risk factors targets. ${ }^{12}$ In the Italian context, few latest studies focussed on interventions led by GPs and targeted to CVDs risk factors, mostly with small sample or single-component intervention, ${ }^{13}$ limited to a specific age ${ }^{14}$ or based on less recent data. ${ }^{15}$

As outlined above, given the burden of CVDs and the potential role of GPs in correcting modifiable cardiovascular risk factors, an
updated Italian study on a large sample that considers an intervention composed by multiple components and promoted by GPs is still lacking. Thus, this study primary aimed to describe and evaluate a multicomponent intervention conducted by GPs for decreasing the presence of main CVDs risk factors. A secondary purpose was to assess the prevalence of such factors in an Italian large sample. A special attention was given to differences in prevalence and improvements between men and women.

## Methods

A pre-post study was performed in 2018 to assess the decrease of CVDs risk factors in a large sample of patients assisted by GPs working with the Primary Health Care Department of the Agenzia per la Tutela della Salute (ATS) Insubria, a local health unit in the Como and Varese municipality area (Northern Italy). This study was approved by the board of GPs of ATS Insubria. The researchers asked for the participations of all GPs working in the ATS Insubria and those who adhered were trained through education courses to correctly evaluate the risk factors and to give a health education counselling. Educational material was given to the GPs who attended the courses. Different risk factors were evaluated when the patients were enrolled (T0). If the patient was considered at risk, the GP performed counselling and health education interventions to support changes in lifestyle. Supplementary file S1 shows the intervention key points. Participants were re-assessed at least after 3 months (T1) and the data were used to evaluate the changes in risk factors after the intervention.

## The sample

Each GP who accepted to adhere was asked to identify patients to be enrolled from a list of eligible subjects. Such list was provided by the ATS Insubria and included only patients aged between 30 and 60 years old and not classified as chronic patients or affected by hypertension or hypercholesterolaemia. With the aim of intercepting people who have never been recognized to be at cardiovascular risk but who may benefit from this intervention, GPs were asked to select in that list the subjects that in their opinion could be 'at risk' of having cardiovascular risk factors. Thus, there were not strict criteria during the enrolment except for the age and absence of certain chronic illnesses. Each GP was asked to recruit a minimum of 10 patients (if the number of people cared was lower than 1000) or 15 patients (if the number of people cared was higher than 1000). The participants were informed about the study and signed the informed consent.

## Data collection

The GPs were given an excel form to complete with data on the risk factors for patients enrolled at T0. GPs personally measured parameters as body height and weight, blood pressure, waist and hips circumference. GPs assessed the number of hours of physical activity and the number of cigarettes smoked (if any) interviewing each patient. Glycaemia and low-density lipoprotein (LDL)-cholesterol were evaluated through lab-tests. If any of the abovementioned risk factor was altered, the GP could prescribe the proper treatment, primarily through a health education intervention to support changes in lifestyle (if necessary: pharmacological treatment). In particular, changes in lifestyle included healthier diet and increase in physical activity.

Another evaluation of the risk factors identified at T0 was scheduled according to a timing considered adequate by the clinical judgement of the GP. According to the protocol of the project, this second assessment should have been done at least three months after the first evaluation and by the end of November 2018.

The data collected were recorded anonymously by each GP on the form and emailed to the Primary Health Care Department of ATS Insubria by the end of November 2018.

## Statistical analysis

The data collected were converted in categorical variables according to the cut-off presented by international recommendations. BMI was defined according to the World Health Organization (WHO) standards (underweight $<18.5$, normal 18.50-24.99 and overweight $\geq 25$, obese $\geq 30) .{ }^{16}$ Abdominal obesity was assessed through the waist-hip ratio and, according to the WHO recommendations, a patient was considered with abdominal obesity if the ratio was above 0.90 for males and above 0.85 for females. ${ }^{17}$ Hypertension was defined as a systolic blood pressure $\geq 130 \mathrm{mmHg}$ or a diastolic blood pressur$\mathrm{e} \geq 80 .{ }^{18}$ LDL-cholesterol and glycaemic levels were divided in three groups. The LDL values were considered optimal if $<100 \mathrm{mg} / \mathrm{dl}$, above optimal/borderline high if between 100 and $160 \mathrm{mg} / \mathrm{dl}$ and high if $>160 \mathrm{mg} / \mathrm{dl} .{ }^{19}$ The glycaemic values were considered as optimal in fasting patient if $<110 \mathrm{mg} / \mathrm{dl}$; it was considered intermediate hyperglycaemia if the level was between 110 and $126 \mathrm{mg} / \mathrm{dl}$ and hyperglycaemia if $>126 \mathrm{mg} / \mathrm{dl} .{ }^{20}$ Physical activity was considered sufficient if a moderate-intensity aerobic exercising was conducted at least 150 min during the week as recommended for adults (18-64 aged). ${ }^{21}$

The number of risk factors (at T 0 and T 1 ) was calculated by assigning one point to each existing risk factor. Concerning LDL values, both $100-160$ and $>160 \mathrm{mg} / \mathrm{dl}$ represented one point, as well as for $110-126$ and $>126 \mathrm{mg} / \mathrm{dl}$ glycaemia values. One point was assigned for smoking.

For each risk factor, a new variable was created to consider the improvement. Such variables were computed only for participants that presented the risk factor at T 0 and had both T 0 and T 1 data available. For the variables with $>2$ categories, an improvement was considered also in case of a risk reduction, e.g. from $>160$ to $100-$ $160 \mathrm{mg} / \mathrm{dl}$ LDL values or from $11-20$ cigarettes per day to $1-5$. A worsening was coded as 'not improved'.

Descriptive analyses were performed (categorical variables expressed in frequencies and percentages). Age was expressed as median and interquartile range (IQR) since Shapiro-Wilk test reported a non-normal distribution (Mann-Whitney $U$ test used to compare men and women). Chi-squared tests were performed to assess differences between men and women about: risk factors frequencies at T0 and T 1 ; improvements; number of risk factors at T 0 and T 1 .

To explore changes in the paired data, the McNemar test (binary variables) or the marginal homogeneity test (variables with more than two categories) were computed both for the frequencies of risk factors and the number of risk factors. Such analyses were executed for males and females separately and considered only to participants that had both T0 and T1 data available.

A multivariable logistic regression adjusted for age and gender was executed for each risk factor improvement as outcome. To understand whether the presence of certain risk factors at T0 could influence the improvement, all the risk factors (except the one considered as the dependent variable) were entered in the model. Results were expressed as odds ratios (OR) with 95\% CI.

SPSS software (version 25) was used and a two-tailed $P$ values $<$ 0.05 was considered significant. Missing values were excluded by pairwise deletion (except for regression models: listwise deletion).

## Results

## Characteristics of the sample

The participants were 5828 at T0 (54.0\% females) and 4953 at T1 ( $53.4 \%$ females). The median age at T 0 was 51 ( $\mathrm{IQR}=10$ ) with no significant differences between males and females $(P=0.598)$. At T0, most of the sample was overweight (39.6\%) or obese (39.1\%) and

Table 1 Frequencies of risk factors at TO and chi-squared tests between male and female participants

| Risk factors | T0 |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  | Overall ( $n=5828$ ) N(\%) | $\begin{aligned} & \text { Males }(n=2679) \\ & N(\%) \end{aligned}$ | $\begin{aligned} & \text { Females }(n=3149) \\ & N(\%) \end{aligned}$ | $P$-value ${ }^{*}$ |
| BMI category |  |  |  | $<0.001$ |
| Normal | 1192 (20.5) | 360 (13.4) | 832 (26.4) |  |
| Underweight | 47 (0.8) | 5 (0.2) | 42 (1.3) |  |
| Overweight | 2310 (39.6) | 1206 (45.0) | 1104 (35.1) |  |
| Obese | 2279 (39.1) | 1108 (41.4) | 1171 (37.2) |  |
| Hypertension |  |  |  | $<0.001$ |
| No | 3794 (65.1) | 1525 (56.9) | 2269 (72.1) |  |
| Yes | 2033 (34.9) | 1154 (43.1) | 879 (27.9) |  |
| Abdominal obesity |  |  |  | $<0.001$ |
| No | 1186 (20.4) | 283 (10.6) | 903 (28.8) |  |
| Yes | 4627 (79.6) | 2391 (89.4) | 2236 (71.2) |  |
| Physical activity |  |  |  | 0.001 |
| No | 4313 (75.7) | 1934 (73.7) | 2379 (77.4) |  |
| Yes | 1385 (24.3) | 689 (26.3) | 696 (22.6) |  |
| LDL values |  |  |  | 0.051 |
| <100 | 704 (13.5) | 296 (12.5) | 408 (14.4) |  |
| 100-160 | 3435 (66.0) | 1563 (65.9) | 1872 (66.0) |  |
| >160 | 1068 (20.5) | 512 (21.6) | 556 (19.6) |  |
| Glycaemic values |  |  |  | $<0.001$ |
| <110 | 4339 (82.8) | 1849 (77.4) | 2490 (87.4) |  |
| 110-126 | 623 (11.9) | 359 (15.0) | 264 (9.3) |  |
| >126 | 277 (5.3) | 181 (7.6) | 96 (3.4) |  |
| Cigarettes per day |  |  |  | <0.001 |
| Non-smoker | 4555 (80.0) | 1988 (76.2) | 2567 (83.3) |  |
| 1-5 | 222 (3.9) | 103 (3.9) | 119 (3.9) |  |
| 6-10 | 343 (6.0) | 155 (5.9) | 188 (6.1) |  |
| 11-20 | 436 (7.7) | 262 (10.0) | 174 (5.6) |  |
| >21 | 137 (2.4) | 102 (3.9) | 35 (1.1) |  |

Notes: $n=$ sample size. Figures are expressed as number ( $N$ ) and column percentages (\%). BMI, body mass index; LDL, low-density lipoprotein.
*: $P$ values obtained via chi-squared test.
$79.6 \%$ had abdominal obesity. The waist circumference was $>102 \mathrm{~cm}$ in 1534 ( $57.4 \%$ ) men and $>88 \mathrm{~cm}$ in 2152 ( $68.5 \%$ ) women with $P<0.001$ (chi-squared test). The $34.9 \%$ had hypertension and 3 out of 4 practiced physical activity $<150$ min weekly. Only $13.5 \%$ had LDL values below $100 \mathrm{mg} / \mathrm{dl}$, whereas $82.8 \%$ presented glycaemia values below $110 \mathrm{mg} / \mathrm{dl}$. The majority ( $80.0 \%$ ) declared to be a non-smoker. The risk factors frequencies reported significant differences between men and women, except for LDL values ( $P=0.051$ ). Details are presented in table 1 .

At T0, only $10(0.4 \%)$ men and $41(1.3 \%)$ women had no risk factors, while the most frequent number of risk factors was 4, both for males ( $816,30.5 \%$ ) and for females ( $951,30.2 \%$ ). Moreover, 60 ( $2.2 \%$ ) men had 1 risk factor, 202 ( $7.5 \%$ ) 2, 529 (19.7\%) 3, 696 (26.0\%) 5, 302 ( $11.3 \%$ ) 6 and 64 (2.4\%) 7. Instead, 187 (5.9\%) women presented 1 risk factor, 470 (14.9\%) 2, 786 ( $25.0 \%$ ) 3, 509 $(16.2 \%) 5,183(5.8 \%) 6$ and $22(0.7 \%) 7$. The frequency of the risk factors number was different between genders ( $P<0.001$ ).

Considering the above-mentioned differences between men and women, the chi-squared analyses showed at T1 the same $P$-values of T0 both for the risk factor frequencies and for the number of risk factors, except for the LDL values that reported a $P=0.210$.

## Paired data analyses

Table 2 shows significant changes in paired data for each risk factor, both for men and for women. The highest percentage changes occurred in hypertension, physical activity and LDL values, both for men and women. Indeed, among males, the percentage of participants with hypertension changed from $43.4 \%$ to $29.4 \%$, the percentage of people who practiced physical activity from $26.1 \%$ to $36.6 \%$ and the percentage of those whose glycaemic values were higher than $160 \mathrm{mg} / \mathrm{ml}$ from $10.4 \%$ to $6.3 \%$. Similarly, among
females, the percentages changed from $28.9 \%$ to $17.8 \%$, from $22.1 \%$ to $31.5 \%$ and from $22.8 \%$ to $12.6 \%$, respectively (table 2 ). Also, significant changes in both genders have been found in paired data for the number of risk factors (table 3). Both among men and women, it should be noted that the percentage of people with no risk factors did not greatly increase, but there was a higher rise of participants with one to three risk factors at the expense of participants with more than three risk factors.

## Improvements

The greatest frequencies of improvement were reported for glycaemia values ( $51.0 \%$, no significant gender differences) and hypertension ( $45.6 \%$, significant gender differences), whereas the lowest for abdominal obesity ( $3.7 \%$, significant gender differences) and BMI ( $12.6 \%$, no significant gender differences). As mentioned before, the improvement of certain risk factors was significantly different between male and female participants. Females reported higher frequencies of improvement concerning hypertension (women: $50.1 \%$, men: $42.2 \%, P=0.001$ ) and abdominal obesity (women: $5.2 \%$, men: $2.4 \%, P<0.001$ ), while about physical activity (women: $13.4 \%$, men: $16.4 \%, P=0.011$ ) and LDL values (women: $17.5 \%$, men $21.2 \%, P=0.032$ ) males' percentages were higher. Details are presented in table 4.

## Predictors of improvement

No significant effects by the independent variables were reported on the improvement of hypertension, LDL values and cigarettes per day. Presenting glycaemia values above $126 \mathrm{mg} / \mathrm{dl}$ showed a higher probability of improving the BMI category ( $\mathrm{OR}=1.82,95 \% \mathrm{CI}$ $1.26-2.61, P=0.001$ ). The probability of improving the abdominal obesity was reduced by: being male ( $\mathrm{OR}=0.55,95 \%$ CI $0.37-0.80$,

Table 2 Paired data analyses: differences in risk factors frequencies at T0 and T1

| Risk factors | Males( $n=2308$ ) |  |  | Females ( $n=2645$ ) |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | $\begin{aligned} & \text { T0 } \\ & \boldsymbol{N} \text { (\%) } \end{aligned}$ | T1 $N(\%)$ | $P$-value | T0 $N$ (\%) | T1 $N(\%)$ | $P$-value |
| BMI category |  |  | $<0.001$ * |  |  | $<0.001^{*}$ |
| Normal | 292 (12.7) | 365 (15.8) |  | 635 (24.0) | 730 (27.6) |  |
| Underweight | 4 (0.2) | 5 (0.2) |  | 32 (1.2) | 37 (1.4) |  |
| Overweight | 1038 (45.0) | 1092 (47.3) |  | 943 (35.7) | 978 (37.0) |  |
| Obese | 973 (42.2) | 845 (36.6) |  | 1032 (39.1) | 897 (34.0) |  |
| Hypertension |  |  | $<0.001 * *$ |  |  | $<0.001 * *$ |
| No | 1300 (56.6) | 1620 (70.6) |  | 1873 (71.1) | 2167 (82.2) |  |
| Yes | 995 (43.4) | 675 (29.4) |  | 763 (28.9) | 469 (17.8) |  |
| Abdominal obesity |  |  | 0.016** |  |  | $0.003 * *$ |
| No | 233 (10.2) | 255 (11.2) |  | 705 (27.1) | 743 (28.5) |  |
| Yes | 2048 (89.8) | 2026 (88.8) |  | 1898 (72.9) | 1863 (71.5) |  |
| Physical activity |  |  | $<0.001{ }^{* *}$ |  |  | $<0.001$ ** |
| No | 1518 (73.9) | 1301 (63.4) |  | 1805 (77.9) | 1588 (68.5) |  |
| Yes | 535 (26.1) | 752 (36.6) |  | 512 (22.1) | 729 (31.5) |  |
| LDL values |  |  | $<0.001{ }^{*}$ |  |  | $<0.001 *$ |
| $<100 \mathrm{mg} / \mathrm{dl}$ | 118 (12.1) | 141 (14.5) |  | 124 (11.4) | 148 (13.7) |  |
| $100-160 \mathrm{mg} / \mathrm{dl}$ | 606 (62.3) | 704 (72.4) |  | 713 (65.8) | 799 (73.7) |  |
| $>160 \mathrm{mg} / \mathrm{dl}$ | 249 (25.6) | 128 (13.2) |  | 247 (22.8) | 137 (12.6) |  |
| Glycaemic values |  |  | <0.001* |  |  | $<0.001{ }^{*}$ |
| $<110 \mathrm{mg} / \mathrm{dl}$ | 713 (71.6) | 810 (79.3) |  | 901 (81.2) | 976 (88.0) |  |
| $110-126 \mathrm{mg} / \mathrm{dl}$ | 184 (18.0) | 147 (14.4) |  | 147 (13.3) | 97 (8.7) |  |
| $>126 \mathrm{mg} / \mathrm{dl}$ | 106 (10.4) | 64 (6.3) |  | 61 (5.5) | 36 (3.2) |  |
| Cigarettes per day |  |  | <0.001* |  |  | $<0.001 *$ |
| Non-smoker | 1478 (75.5) | 1524 (77.8) |  | 1813 (82.7) | 1828 (83.4) |  |
| 1-5 | 77 (3.9) | 105 (5.4) |  | 80 (3.6) | 110 (5.0) |  |
| 6-10 | 120 (6.1) | 114 (5.8) |  | 132 (6.0) | 141 (6.4) |  |
| 11-20 | 200 (10.2) | 171 (8.7) |  | 137 (6.3) | 96 (4.4) |  |
| >21 | 83 (4.2) | 44 (2.2) |  | 30 (1.4) | 17 (0.8) |  |

Notes: $n=$ sample size at T1. For each variable, the presented results refer to participants that had both T0 and T1 data available. Figures are expressed as number $(N)$ and column percentages (\%).BMI, body mass index; LDL, low-density lipoprotein.
*: $P$ values obtained via related-samples marginal homogeneity test (test for changes in multinomial data).
**: $P$ values obtained via related-samples McNemar test (test for changes in binary data).

Table 3 Paired data analyses: differences in number of risk factors at T0 and T1

| Number of risk factors | Males ( $n=2308$ ) |  |  | Females ( $n=2645$ ) |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | T0 $N$ (\%) | T1 <br> $N$ (\%) | $P$-value | T0 $N$ (\%) | T1 <br> $N$ (\%) | $P$-value* |
| 0 | 8 (0.3) | 21 (0.9) | $<0.001$ | 29 (1.1) | 101 (3.8) | $<0.001$ |
| 1 | 48 (2.1) | 121 (5.2) |  | 142 (5.4) | 318 (12.0) |  |
| 2 | 160 (6.9) | 429 (18.6) |  | 371 (14.0) | 632 (23.9) |  |
| 3 | 451 (19.5) | 746 (32.3) |  | 640 (24.2) | 817 (30.9) |  |
| 4 | 713 (30.9) | 599 (26.0) |  | 830 (31.4) | 506 (19.1) |  |
| 5 | 611 (26.5) | 281 (12.2) |  | 451 (17.1) | 208 (7.9) |  |
| 6 | 260 (11.3) | 91 (3.9) |  | 161 (6.1) | 54 (2.0) |  |
| 7 | 57 (2.5) | 20 (0.9) |  | 21 (0.8) | 9 (0.3) |  |

Notes: $n=$ sample size at T1. The presented results refer to participants that had both T0 and T1 data available. Figures are expressed as number ( $N$ ) and column percentages (\%).
*: $P$ values were obtained via related-samples marginal homogeneity test (test for changes in multinomial data).
$P=0.002$ ); obesity ( $\mathrm{OR}=0.42,95 \%$ CI $0.25-0.70, P=0.001$ ); smoking $11-20$ cigarettes per day $(\mathrm{OR}=0.29,95 \%$ CI $0.09-0.93$, $P=0.038$ ). The higher was the age, the less people were prone to improve abdominal obesity $(\mathrm{OR}=0.97, \quad 95 \%$ CI $0.95-0.99$, $P=0.027$ ). LDL values between 100 and $160 \mathrm{mg} / \mathrm{dl}$ showed to increase the abdominal obesity improvement ( $\mathrm{OR}=2.15,95 \% \mathrm{CI}$ $1.06-4.34, P=0.034$ ). A higher association with physical activity improvement was found for overweight participants $(O R=1.44$, $95 \%$ CI 1.04-2.01, $P=0.031$ ) and people with LDL values between 100 and $160 \mathrm{mg} / \mathrm{dl}(\mathrm{OR}=2.03,95 \%$ CI 1.35-3.05, $P=0.001)$ and above $160 \mathrm{mg} / \mathrm{dl}(\mathrm{OR}=2.58,95 \%$ CI $1.67-3.99, P<0.001)$. About
glycaemia values, the higher was the age, the less the participants were likely to improve $(\mathrm{OR}=0.97$, $95 \%$ CI $0.94-0.99, P=0.009$ ). All data are in Supplementary file S2.

## Discussion

Our primary aim was to assess the changes in frequency of the certain CVDs risk factors after a multicomponent intervention conducted by GPs. It was also possible to estimate the prevalence of these risk factors in a large Italian sample: nearly all the patients

Table 4 Improvements description and chi-squared tests between male and female participants

| Risk factors | Overall ( $n=4953$ ) $N$ (\%) | Males $(n=2308)$ $N$ (\%) | $\begin{aligned} & \text { Females }(n=2645) \\ & N(\%) \end{aligned}$ | $P$-value * |
| :---: | :---: | :---: | :---: | :---: |
| BMI category |  |  |  | 0.066 |
| Not improved | 3484 (87.4) | 1777 (88.4) | 1707 (86.4) |  |
| Improved | 502 (12.6) | 234 (11.6) | 268 (13.6) |  |
| Hypertension |  |  |  | 0.001 |
| Not improved | 956 (54.4) | 575 (57.8) | 381 (49.9) |  |
| Improved | 802 (45.6) | 420 (42.2) | 382 (50.1) |  |
| Abdominal obesity |  |  |  | $<0.001$ |
| Not improved | 3799 (96.3) | 1999 (97.6) | 1800 (94.8) |  |
| Improved | 147 (3.7) | 49 (2.4) | 98 (5.2) |  |
| Physical activity |  |  |  | 0.011 |
| Not improved | 2981 (85.2) | 1326 (83.6) | 1655 (86.6) |  |
| Improved | 517 (14.8) | 261 (16.4) | 256 (13.4) |  |
| LDL values |  |  |  | 0.032 |
| Not improved | 1619 (80.7) | 745 (78.8) | 874 (82.5) |  |
| Improved | 386 (19.3) | 201 (21.2) | 185 (17.5) |  |
| Glycaemia values |  |  |  | 0.683 |
| Not improved | 280 (49.0) | 162 (49.7) | 118 (48.0) |  |
| Improved | 292 (51.0) | 164 (50.3) | 128 (52.0) |  |
| Cigarettes per day |  |  |  | 0.249 |
| Not improved | 599 (69.7) | 327 (68.1) | 272 (71.8) |  |
| Improved | 260 (30.3) | 153 (31.9) | 107 (28.2) |  |

Notes: $n=$ sample size at T1. Figures are expressed as number $(N)$ and column percentages (\%). For each variable, the presented results refer to participants that had the risk factor at T 0 and had both T 0 and T 1 data available. If data at T 1 were missing, participants were excluded from this analysis. Percentages are referred to the total of participants that had the risk factor at T0 and had that data at T1. BMI, body mass index; LDL, low-density lipoprotein.
*: $P$ values were obtained via chi-squared test.
presented at least one of the assessed risk factors and most of the subjects presented four or more risk factors.

In our study, the prevalence of the risk factors was generally higher compared with other population studies. Although participants had no previous diagnosis of chronic diseases and the considered risk factors were not known before T 0 , the higher prevalence could be easily explained considering that the GPs were asked to select subjects with a 'possible risk'. Indeed, according to the 2013 European Union National Health and Wellness Survey, $34.85 \%$ of the 9433 Italian subjects interviewed were classified as overweight, and $12.89 \%$ as obese ${ }^{22}$ and the prevalence of hypertension recorded in the same year in a sample of more than 900000 Italians was $25.9 \%{ }^{23}$ Similarly, even if it outlined a high prevalence of CVDs risk factors, a previous research conducted in the same geographical area of this study on 12249 middle-aged women showed smaller percentages of risk factors, such as obesity, hypertension, hyperlipidaemia, and poor physical activity. ${ }^{24}$ On the contrary, large population studies reported the prevalence of diabetes as $7.1 \%$ in men and $6.8 \%$ in women ${ }^{25}$ and the prevalence of dyslipidaemia around $90 \%$, higher than those found in our study. ${ }^{26}$ These differences could be also explained considering different criteria used to define the outcomes or self-reported measures. ${ }^{25,26}$

Additionally, we assessed differences in prevalence and improvements between genders. This study outlined a significant higher prevalence of obesity, hypertension, hyperglycaemia and smoking habit in men. Women reported lower physical activity. The cluster of risk factors that mostly defines the metabolic syndrome have been reported to be higher in men below 50 years, while it reverses after this age, ${ }^{10}$ which approximately represents the median age of our sample. This gender analysis is interesting considering that different risk factors play different roles in men or women. For example, obesity, especially abdominal obesity, increases the CVD risk specifically in women. ${ }^{27}$ Other studies highlighted that diabetes results in a 3- to 7-fold increased CVD risk in women compared with a 2 - to 3 -fold elevated risk in men. ${ }^{28,29}$ In the light of the above, our work confirmed the urge to develop and implement efficient strategy to reduce the frequency of these risk factors.

Our intervention, performed in the Primary Health context, primarily included an educational approach to promote a healthier lifestyle. Different strategies were used to increase the number of hours of physical activity, reduce tobacco products consumption and promote healthy diets. The highest percentage of improvement was reported for glycaemia values and hypertension, the lowest for abdominal obesity and BMI. Multidisciplinary strategies have been reported to be the most effective, especially if nutrition therapy, physical activity, adequate sleep, alcohol restriction and stopping tobacco use are included. ${ }^{30}$ In particular, many dietary patterns might be useful in decreasing CVDs risk factors, however, all of them must include caloric restriction that is the most effective approach. ${ }^{31}$ Along with dietary changes, ${ }^{30,31}$ a regimen of physical activity with moderate- to high-intensity for a total of 150 min weekly reported a consistent and significant risk reduction in the management of metabolic syndrome, hypertension and diabetes. ${ }^{32}$ Physical activity plays a crucial role in the prevention and treatment of CVDs, hypertension, obesity and diabetes mellitus. ${ }^{33-38}$ A systematic review by Muller-Riemenschneider et al. ${ }^{39}$ provides evidence for the effectiveness of physical activity over $12-24$ months. Intervention effectiveness seems to improve when messages and materials are culturally adapted to the needs of specific population groups. ${ }^{39}$ Additionally, Greaves et al. ${ }^{40}$ performed a systematic review of reviews that assessed interventions on an individual-level aiming to increase physical activity and promote changes in dietary behaviour. The results showed significant and clinically meaningful changes in physical activity and in weight. Interventions targeting both diet and physical activity, as performed in our intervention, resulted to be more effective. ${ }^{40}$ Indeed, almost $15 \%$ of our sample improved their physical activity, showing that it is very likely that part of the effect of the intervention was due to such increase of exercise. However, since other risk factors have higher frequencies of improvement, it seems clear that improvement was also due to other actions of the intervention. For instance, around half of the sample had improved glycaemia values thus suggesting that, although physical activity has been reported to be an important strategy, ${ }^{33}$ concurrent interventions (e.g. exercise and diet) can be more effective. ${ }^{40}$

Besides, Greaves et al. ${ }^{40}$ found no consistent association between gender and intervention efficacy. Coherently, our findings showed improvements both for men and for women and the multivariable models reported no significant associations between gender and the improvement of risk factors. Abdominal obesity represented an exception since males had a reduced likelihood of improving and, thus, the gender- and sex-related determinants should be further explored. Last, in this relevant review, no significant differences were recorded according to provider, setting or delivery mode, suggesting that similar interventions can be successfully developed in a Primary Care setting ${ }^{40}$ as we did.

Our article had some strengths and limitations. The main strength was the great number of participants involved, allowing to assess the changes after the intervention on a large sample. Also, the risk factors were not self-reported but directly measured by GPs. On the contrary, despite the large number of participants, the GPs were working in a specific geographical area, making more difficult to generalize the results. Another limitation was that it was not possible to determine the specific impact of the different actions of the intervention (e.g. physical activity, diet). In particular, it was not possible to evaluate the effect of drug therapy in those cases where such therapy was implemented (e.g. antidiabetic, anti-hypertensive and lipid-lowering medications). Besides, the pre-post study design lacks a comparison/control group limiting the strength of the evidence of the cause-effect relationship. Last, although the considered risk factors were not known in the participants before T0, the prevalence of risk factors should not be considered representative for the Italian population since GPs selected subjects that had a 'probable risk' in their opinion.

Finally, the project represented the opportunity to remind to GPs: the importance of early detection of CVDs risk factors, the tools to assess the individual risk, how to perform the evaluation and develop an effective intervention. Moreover, the evaluation of the changes was performed only on the subjects enrolled at T0, but we can suppose that positive effects on dietary behaviour or tobacco consumption can be recognized in other members of the household and further investigations should be addressed to understand the impact of such multicomponent strategy on people that surround the patient. In conclusion, this article corroborated the need of multicomponent interventions aimed to decrease CVDs risk factors. This study also highlighted the role of GPs as proactive professionals in the field of prevention.

## Conflicts of interest: None declared.

## Data availability

All relevant data are within the article.

## Key points

- Obesity, hypertension, hyperglycaemia and smoking occurred more frequently in men.
- The results showed significant changes in paired data for each risk factor category.
- Glycaemia showed the highest percentage of improvement, abdominal obesity the lowest.
- Women improved more in hypertension and abdominal obesity, men in exercise and low-density lipoprotein.
- The role of General Practitioners as proactive professionals in the field of prevention was highlighted.


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