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RESEARCH ARTICLE

Impact of pharmacist's intervention on reducing cardiovascular risk in obese patients

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Abstract

Background Obesity is a risk factor for cardiovascular disease, the leading cause of death. Health education, nutritional follow-up, and life style habits modification are key for cardiovascular risk reduction in obese patients. *Objective* To measure the impact of pharmacist's intervention on cardiovascular risk in obese patients. *Setting* A Spanish community pharmacy. *Method* Obese patients (BMI ≥ 30) with (group A, n = 30) and without (group B, n = 14) comorbidities were selected. Variables determined in first visit on-site: anthropometric values (weight, height, waist circumference), blood pressure, glycemic (glucose, HbA1c) and lipid parameters (total cholesterol, HDL-c, LDL-c, triglycerides). The PharmaFit Protocol consisted in a 24-month follow-up focusing (i) monthly on adherence to nutritional guidelines and modification of life style habits, and (ii) bi-monthly on anthropometric variables, blood pressure, and biochemical determinations. Feedback was provided to the primary care physician or specialist. *Main ouitcome measure* Cardiovascular risk estimated by REGICOR score. *Results* Anthropometric variables significantly decreased in all groups. Plasma glucose levels were significantly reduced in group A without changes in HbA1c. Lipid parameters significantly improved in group A, whereas HDL-c significantly raised in all groups. REGICOR score was significantly reduced in group A female (13.8 ± 1.6 vs. 5.8 ± 1, $p < 0.0001$) and male (12.7 ± 1.7 vs. 4.4. ± 0.6, $p < 0.005$) patients, and in group B female patients (3.5 ± 0.7 vs. 1.9 ± 0.4, $p < 0.001$). *Conclusion* Community pharmacist intervention, delivered as a 24-month follow-up and combining health and dietary education, has a highly positive impact on the reduction of cardiovascular risk in obese patients.

Keywords Cardiovascular risk · Community pharmacy · Diabetes · Dyslipidemia · Obesity · Pharmacist's intervention · Spain

Impact on practice

- Pharmacist's intervention in obese patients significantly improves anthropometric and metabolic parameters in both patients with and without comorbidities.
- Pharmacist's intervention delivered as a combination of health and dietary education (PharmaFit Protocol) improves cardiovascular risk (REGICOR) in obese patients with and without comorbidities.

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Introduction

Obesity is one of the most prevalent diseases at present. Overall, about 13% of the world's adult population (11% of men and 15% of women) were obese in 2016 and the worldwide prevalence of obesity nearly tripled between 1975 and 2016 [1]. In Spain, 62.0% of the adult population (> 20 years old) was overweight and 26.6% were obese in 2011. The prevalence of overweight was higher among men (67.7%) than women (56.6%). The proportion of men and women that were obese was 26.5% and 26.7%, respectively [2].

Overweight and obesity are linked to multiple comorbidities, especially cardiovascular diseases which lead to more deaths worldwide than underweight [3, 4]. It is important to highlight that 80% of these deaths could be avoided by generalizing a healthy diet and regular physical activity, accompanied by the abandonment of unhealthy habits (smoking, alcohol intake, precooked meals or lack

of adequate night rest) [4, 5]. Therefore, early detection and treatment of cardiovascular risk (CVR) factors such as hypertension, dyslipidemia and/or diabetes is key for early prevention of obesity-associated comorbidities [4, 5].

There are many studies on the relevant role of the community pharmacist in primary and secondary prevention of cardiovascular diseases [6]. Rotta et al. [7] performed an overview of systematic reviews to assess the evidence of the impact of pharmacists' interventions on the most effective patient outcomes. Interventions focused on hypertension or diabetes mellitus revealed a highly positive impact on patient outcomes, with significant improvements in total cholesterol and LDL cholesterol of dyslipidemic patients [7]. Similarly, a systematic review analyzing the role of community pharmacists' interventions in the reduction of major CVR factors found a substantial benefit in diabetes and hypertension, but an imprecise benefit in lipid management [8]. Many of these interventions included patient education, lifestyle changes (smoking cessation and lipid management) and, in some cases, feedback to the physician.

There are, however, fewer studies assessing the impact of community pharmacist's interventions in obesity management and in the prevention of its associated CVR [9, 10]. The contribution of the community pharmacy in managing obesity has been recognised in the White Paper Pharmacy in England [11]. In Denmark, "slimming courses" held at community pharmacies led to an average weight loss of 5.3 kg for females and 6.2 kg for males. Interestingly, 20% of the patients who had completed the course maintained a weight loss greater than 5 kg at 1-year follow-up [12]. Both the Australian National Health and Medical Research Council [13] and the Lifestyle Challenge Program in USA [14] recommend a multi-disciplinary team approach to weight management including or co-directed by a pharmacist. In fact, community pharmacists see daily more obese individuals in their office than other health sectors [15]. This closer knowledge of its patients allows the community pharmacist to make interventions, follow-up with them and give them feedback, which is essential for effective weight management [15].

In this context, in Spain, the 22,000 community pharmacies are strategic health facilities for prevention actions, given their proximity, accessibility and patient confidence. The capillarity of these establishments, which reach 99% of the population, professionalism and availability without waiting lists, makes the community pharmacy the ideal place to develop health education, prevention and health promotion services aimed at direct and indirect CVR reduction associated to obesity [16].

Aim of the study

The aim of this study was to assess the impact of pharmacist's intervention, delivered as a combination of health education, nutritional follow-up, and modification of life style habits (PharmaFit protocol), to prevent and/or reduce metabolic alterations associated with obesity leading to a reduction in CVR.

Ethics approval

The study was approved by the ethics committee of the Official College of Pharmacists of Madrid. Participants were provided with written information regarding the study and its objectives. Those who agreed participating provided written informed consent.

Methods

Study design and patients

This is an interventional, analytical study performed in a Spanish community pharmacy. Obese patients (BMI $\geq$ 30 kg/m^2; waist circumference greater than 102 cm for men or 88 cm for women) were asked to participate in the study during a health campaign aimed at explaining obesity-associated cardiovascular risk. Recruitment period was 6 months and 74 subjects were assessed for eligibility (Fig. 1). All subjects were provided with full information about the purpose of the study, and those agreeing to participate were interviewed to screen for eligibility. Recruited patients (n = 60) were invited to a first visit in the community pharmacy to determine baseline characteristics on-site (Fig. 2). Anthropometric values, such as weight, height and waist circumference, were assessed. Blood pressure was measured with a sphygmomanometer (Corysan SA, Barcelona, Spain). Percentage of fat mass was determined by lipocaliber bioimpedance (Tanita Innerscan Dual RD-953). Lipid parameters and glycemic parameters were determined on-site after capillary sampling from a finger in non-fasted conditions. Total cholesterol, high-density lipoprotein cholesterol (HDL-c), low-density lipoprotein cholesterol (LDL-c), triglycerides, and HbA1c were determined by Cobas B-101 (Roche Diagnostics, Barcelona, Spain). Plasma glucose was assessed by Accutrend (Roche Diagnostics, Barcelona, Spain). The study was carried out from September 2014 to March 2017, with a monthly interview per patient.

Eligibility criteria

Eligible participants for the study included subjects who were at least 18 years of age. Obese patients (BMI $\geq$ 30 kg/m^2; waist circumference greater than 102 cm for men or 88 cm for women) were separated in two groups: group A

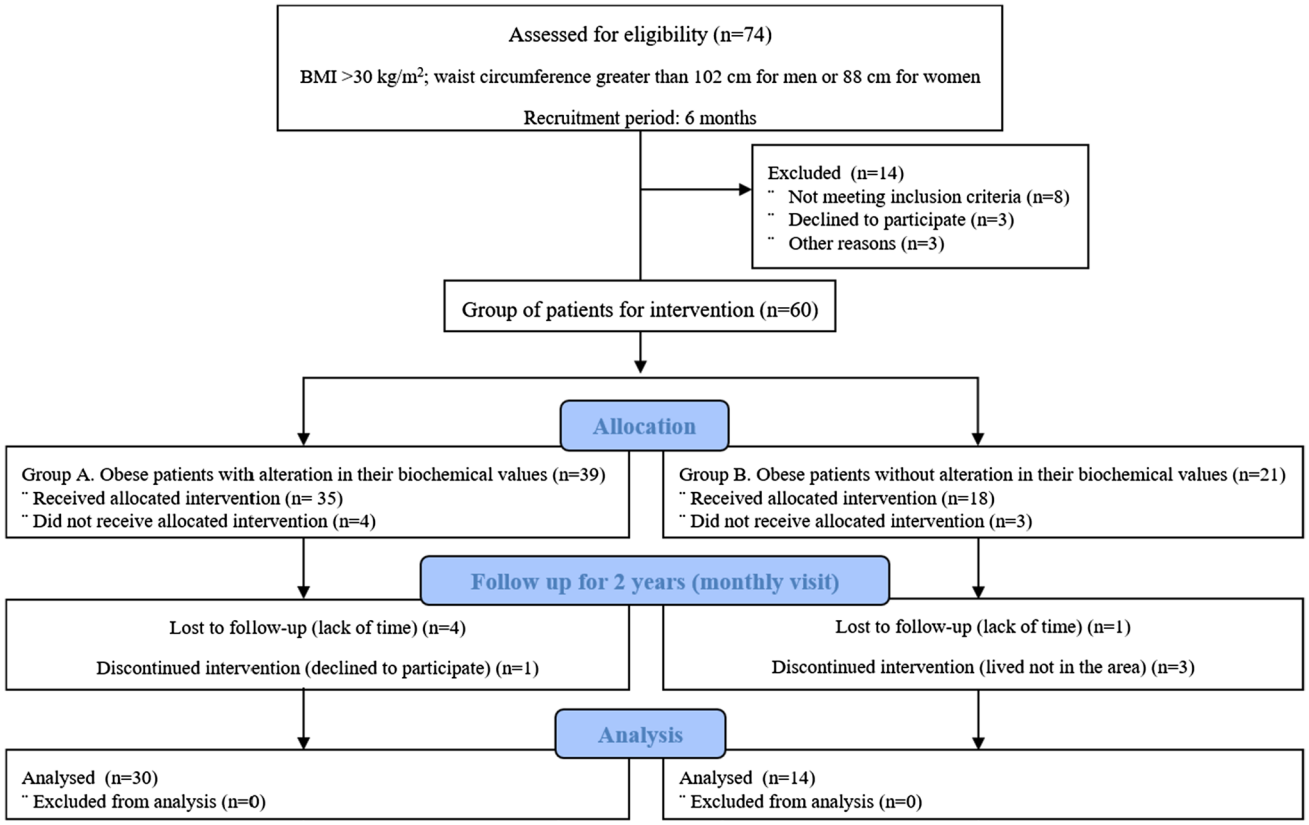

Fig. 1 CONSORT flowchart

with and group B without altered biochemical values. Those patients presenting altered biochemical values (glycemic and lipid parameters) related to their obesity were included in group A. Obese patients without altered clinical parameters were included in group B. Exclusion from the study included pregnancy, lactation, individuals under anticoagulant treatment, as well as geriatric patients with cognitive alterations.

Variables

After the initial visit, a monthly follow-up focused on adherence to nutritional guidelines [17, 18] and modification of life style habits (physical exercise and smoking cessation) [19] was carried out. Follow-up of patient's anthropometric measurements (weight, BMI, waist circumference, % of fat mass) and blood pressure was determined monthly. Biochemical determinations (total cholesterol, HDL-c, LDL-c, triglycerides, and plasma glucose) were performed bi-monthly and glycosylated hemoglobin (HbA1c) was measured every 6 months. All these values were available to the patient in order to provide feedback to the primary care physician or specialist.

According to ESC/EAS Guidelines [20], intervention goals were: total cholesterol < 200 mg/dl, LDL-cholesterol < 130 mg/dl, HDL-cholesterol > 45 mg/dl (female) and > 40 mg/dl (male), triglycerides < 200 mg/dl. Glucose < 120 mg/dl, and HbA1c < 6.5%.

Cardiovascular risk estimation

The changes in CVR stratification were estimated by REGICOR equations from baseline to 24 months. The REGICOR CVR of coronary heart disease was estimated using the REGICOR risk assessment validated for Spanish population [21]. The REGICOR estimates the ten-year risk of a coronary event, acute myocardial infarction or coronary death. Patients with estimates of < 5, 5–9, 10–14 and ≥ 15% were classified as having low, moderate, high risk, and very high risk, respectively.

Statistical analysis

Statistical analysis was performed with Stat View software (SAS Institute, USA). Two-way ANOVA followed by Neuman-Keuls post hoc tests were used. A value of $p < 0.05$ was considered statistically significant. All values are given as mean ± SEM.

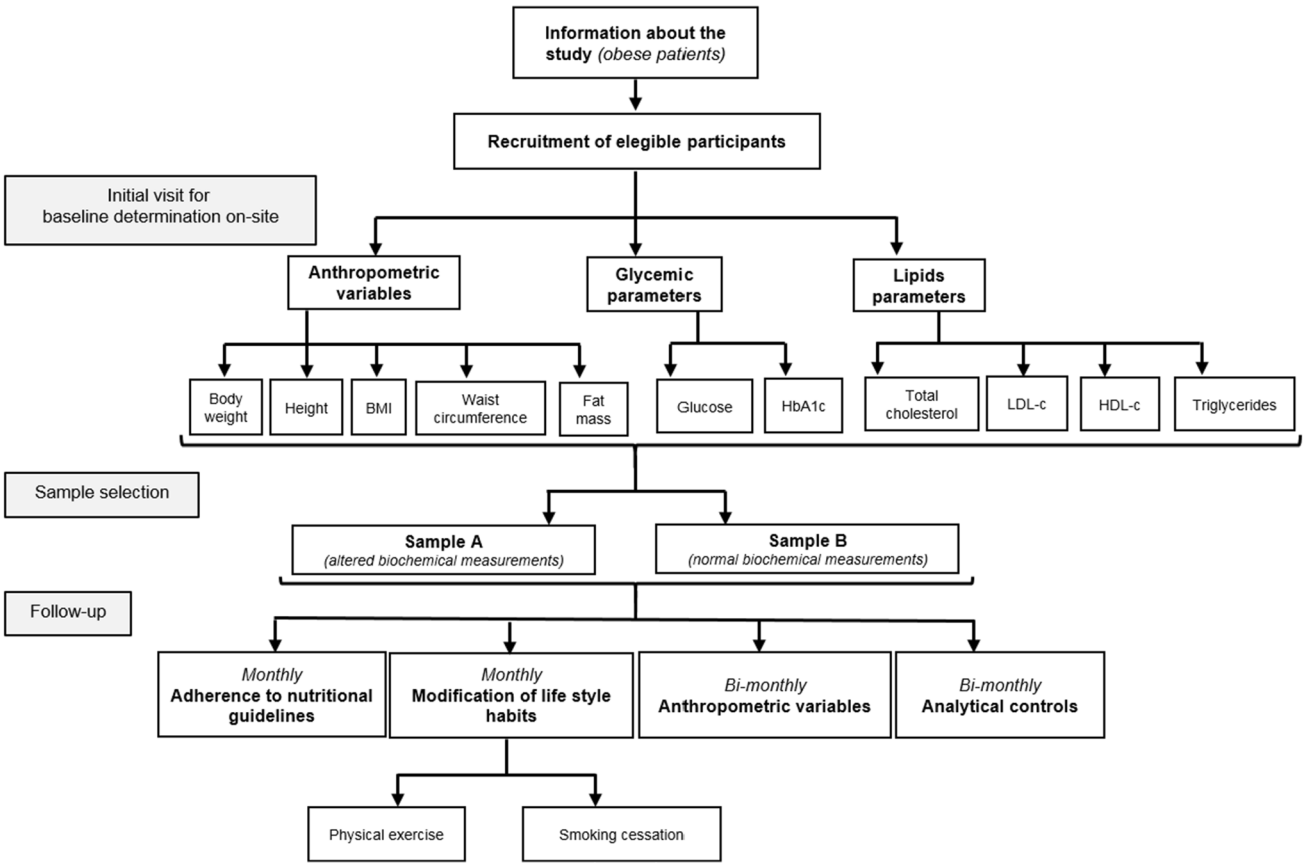

Fig. 2 Flow diagram for pharmafit protocol

Results

Sixty patients met the criteria for inclusion, agreed to take part and attended the follow-up interviews. However, forty-four patients completed the two-year follow up, which is a success rate of 74% (Fig. 1). Table 1 shows their sociodemographic characteristics at baseline (0 months).

Anthropometric variables

Both male A and B groups had a greater body weight than the female groups, being the greater body weight in group A compared to group B ($p < 0.01$, Fig. 3a). In all groups, a downward evolution of body weight was observed during the intervention period. In female patients, weight loss was significant in both groups from month 14 of the follow-up. In male patients, weight loss was significant from month 14 in group A and month 18 in group B. A similar result was observed for BMI (Fig. 3b) and for waist circumference (Fig. 3c) where significant results were obtained from month 18 in all groups. Body weight and BMI reduction was attributed to a loss in fat mass percentage in all groups during the intervention (women A: 35.7 ± 0.8 vs. 31.1 ± 1.2, $p < 0.001$; men A: 27.2 ± 0.5 vs. 23.5 ± 0.6, $p < 0.001$; women B: 29.9 ± 2.2 vs. 26.3 ± 1.4, $p < 0.001$; men B 27.7 ± 0.3 vs. 24.4 ± 1.3, $p < 0.001$).

Glycemic parameters

Figure 4a shows the effect of the intervention on the evolution of plasma glucose levels in women and men during the 24 months of the study. Plasma glucose levels were higher in group A than in group B, in both female and male patients ($p < 0.01$). A reduction of glucose was observed only in group A being significant from month 20 of the intervention in women and month 10 in men. The levels of HbA1c (Fig. 4b) were higher in group A compared to B, both in women and men ($p < 0.01$). No significant changes were observed in HbA1c during the follow-up, although there was a downward tendency during the intervention.

Lipid parameters

Total cholesterol (Fig. 5a) and LDL-c (Fig. 5b) levels were higher in group A than in B, both in women and men ($p < 0.01$). A reduction of total cholesterol level was

Table 1 Sociodemographic and clinical characteristics of the patients included in the study at baseline (0 months) and after 24 months

Number of patients (n)	Group A				Group B			
	Female		Male		Female		Male	
	14		16		7		7	
Age (years)								
18–40	0		1		0		1	
41–65	7		8		5		4	
66–100	7		7		2		2	
	0 months	24 months	0 months	24 months	0 months	24 months	0 months	24 months
Body weight (kg)	81.10 ± 2.97	74.35 ± 2.46*	104.12 ± 3.87	91.10 ± 2.12#	74.55 ± 1.99	69.11 ± 2.02*	91.15 ± 4.03	81.41 ± 3.43*#
Waist circumference (cm)	104.00 ± 3.39	93.14 ± 3.39*	115.62 ± 2.68	105.68 ± 2.25#	90.42 ± 5.84	83.85 ± 5.55*	109.28 ± 4.02	100.00 ± 5.80*#
BMI (kg/m^2)	31.54 ± 1.57	28.85 ± 1.04*	32.96 ± 1.20	29.16 ± 0.75#	29.01 ± 0.88	26.93 ± 1.01*	30.06 ± 1.05	26.84 ± 0.89*#
Fat mass weight (kg)	28.97 ± 1.34	23.23 ± 1.30*	27.77 ± 1.23	21.19 ± 0.74	22.35 ± 1.98	18.22 ± 1.22*	25.25 ± 1.10	19.99 ± 1.53
Lean mass weight (kg)	52.14 ± 1.93	51.07 ± 1.64	74.18 ± 2.34	69.06 ± 1.66#	52.14 ± 1.81	50.71 ± 1.50*	65.85 ± 2.99	61.28 ± 2.50#
Fat mass index (%)	35.71 ± 0.84	29.47 ± 0.10*	27.00 ± 0.51	23.78 ± 0.05#	29.85 ± 2.17	28.00 ± 0.13*	28.00 ± 0.28	24.64 ± 0.05
Total cholesterol (mg/dl)	242.03 ± 7.80	207.42 ± 4.63*	233.43 ± 4.63	203.06 ± 3.71	196.00 ± 3.57	198.42 ± 2.33*	194.29 ± 3.82	191.00 ± 2.63*
HDL cholesterol (mg/dl)	31.64 ± 4.00	71.85 ± 4.16*	39.68 ± 2.17	75.12 ± 2.10	64.57 ± 1.13	91.14 ± 3.53*	70.85 ± 3.06	92.14 ± 4.07*
LDL cholesterol (mg/dl)	165.64 ± 11.34	104.28 ± 8.37*	135.62 ± 5.70	87.75 ± 5.63	115.28 ± 3.37	82.57 ± 4.68*	94.28 ± 5.46	70.85 ± 6.17*
Triglycerides (mg/dl)	223.57 ± 15.53	156.07 ± 6.77*	290.68 ± 11.91	200.62 ± 7.04	81.14 ± 7.23	77.71 ± 6.62*	146.00 ± 2.26	139.14 ± 2.86*
Glucose (mg/dl)	146.78 ± 12.66	114.35 ± 8.22*	157.06 ± 11.08	111.31 ± 3.00#	83.85 ± 4.88	82.29 ± 2.71*	123.85 ± 8.67	113.00 ± 9.83*#
HblAc (%)	7.42 ± 0.34	7.08 ± 0.28	7.56 ± 0.29	6.81 ± 0.17	6.07 ± 0.13	5.91 ± 0.09	6.65 ± 0.29	6.44 ± 0.32
Systolic blood pressure (mmHg)	137 92 ± 3.80	130.85 ± 1.83	141.67 ± 2.15	133.17 ± 1.45	134.28 ± 3.30	127.50 ± 2.06	134,67 ± 3.09	132.64 ± 1.84
Diastolic blood pressure (mmHg)	80.76 ± 2.16	77.90 ± 1.07	85.13 ± 1.36	79.22 ± 1.28#	78.85 ± 2.04	78.00 ± 1.44	83.57 ± 2.18	80.71 ± 1.55#

* $p < 0.01$ with respect to group A; #$p < 0.001$ with respect to their corresponding group of women

observed only in group A. This decrease was significant from month 8 of the follow-up in female and month 12 in male patients. A reduction of LDL-c levels was observed in both groups. This was significant from month 10 in male and female patients from group A, and from month 6 in male and female patients from group B.

Figure 5c shows the effect of the intervention on the evolution of HDL-c levels in women and men during the 24 months of the study. HDL-c levels were higher in group B than in group A, both in female and male patients ($p < 0.01$). An ascending evolution of HDL cholesterol levels was observed in both groups.

Triglyceride levels (Fig. 5D) were higher in group A than in group B, both in female and male patients ($p < 0.01$). A reduction of triglycerides was observed only in group A being the decrease significant from month 14 of the intervention in female and month 6 in male patients.

Blood pressure

Systolic and diastolic blood pressure values were in the normotensive range, i.e. < 140/90 mm Hg) according to the ESH/ESC Guidelines [22] in all patients (Table 1). No significant difference was observed in systolic or diastolic

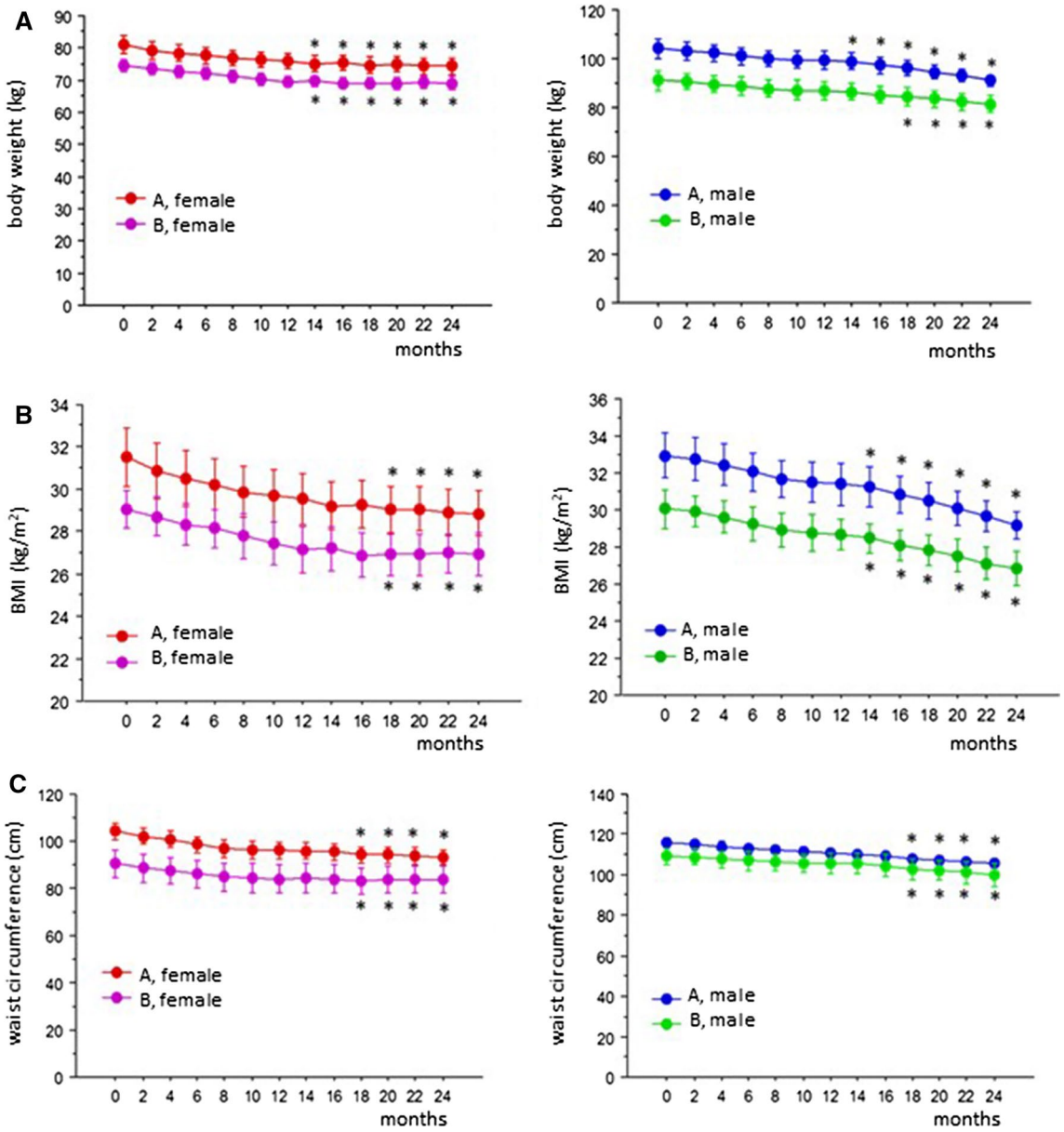

Fig. 3 Evolution of **a** body weight, **b** body mass index (BMI) and **c** waist circumference in the two groups of female (left panels) and male (right panels) patients during the 24 month follow-up. The results are expressed as mean ± standard error of the mean. *$p < 0.01$ compared to the respective value at the beginning of the intervention in each group

blood pressure in either group during the 24-month follow-up period (Table 1).

Change in cardiovascular risk estimation

Table 2 shows the estimation of the risk of a cardiovascular event within 10 years at baseline and 24 months afterwards for each patient. Forty-one out of 44 patients (93%) showed a significant decrease in REGICOR score. In female patients, REGICOR score significantly decreased in both A (13.8 ± 1.6 vs. 5.8 ± 1, $p < 0.0001$) and B (3.5 ± 0.7 vs. 1.9 ± 0.4, $p < 0.001$) groups. In male patients, REGICOR score showed a significant decrease in group A (12.7 ± 1.7 vs. $4.4. \pm 0.6$, $p < 0.005$) but not in group B (5.1 ± 2.3 vs. 3.4 ± 1.1, n.s.).

Table 3 shows the rates of subjects at low, medium, high and very high risk at the baseline and at 24 months irrespective of their sex. It can be observed that the intervention significantly decreased the number of very high and high-risk patients, accordingly increasing the number of low-risk patients significantly.

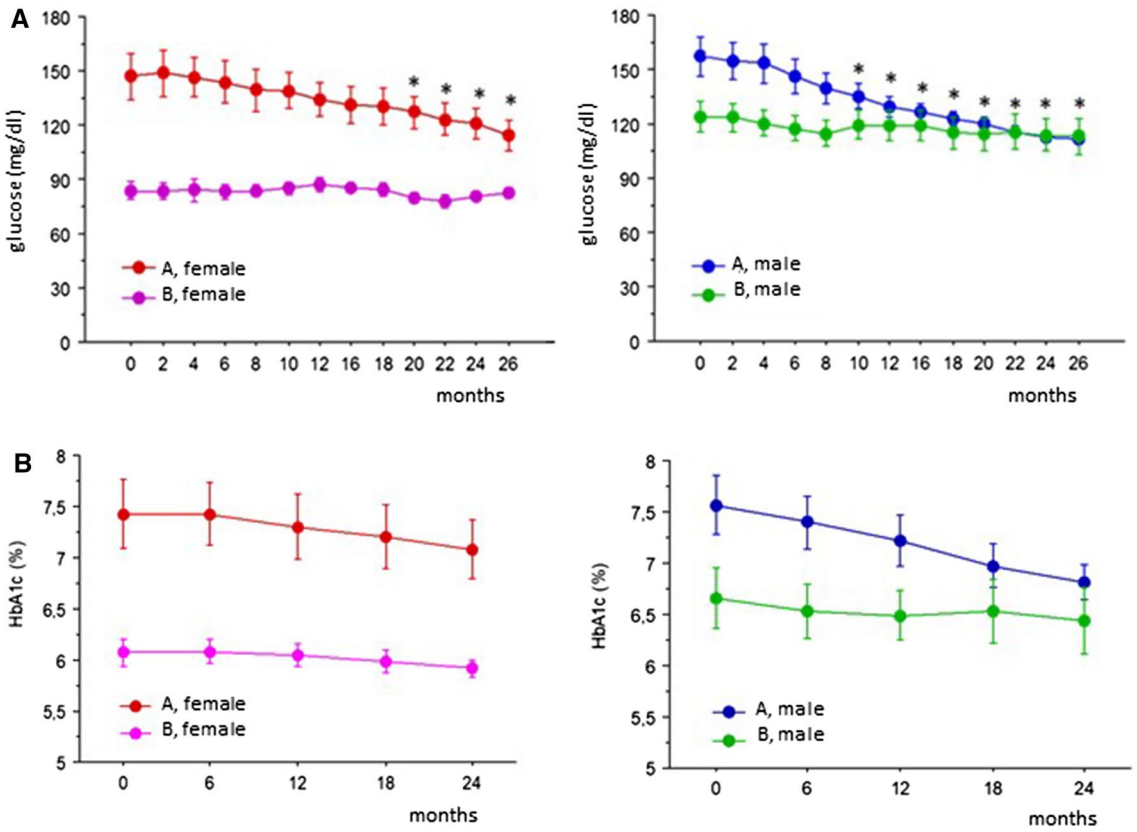

Fig. 4 Evolution of **a** glucose, and **b** glycosilated hemoglobin (HbA1C) in the two groups of female (left panels) and male (right panels) patients during the 24 month follow-up. The results are expressed as mean ± standard error of the mean. *$p < 0.01$ compared to the respective value at the beginning of the intervention in each group

Discussion

This study shows that provision of pharmacist intervention delivered as a combination of health, life style change, dietary education and monthly/bi-monthly follow-up (PharmaFit Protocol) to obese patients improves significantly anthropometric and metabolic parameters in both patients without comorbidities (prevention) and patients with cardiometabolic alterations (reversion), leading to a reduction in CVR REGICOR score in all groups. In fact, community pharmacists are well suited to delivering weight management services, including basic physical assessments such as weight, waist circumference, body fat, blood glucose and lipid monitoring, as well as dietary and pharmacotherapy counseling [9–14, 23]. Additional training could be easily obtained for guidance on physical activity and behavioral counseling [23].

In this study we show the beneficial impact of such an intervention on body weight, BMI, waist circumference and body fat. Similar effects have been observed in previous studies performed by community pharmacists [9, 24]. It is important to note that although a downward tendency was observed from the beginning of the intervention, significant reductions were detected from month 14 (for body weight), from months 14 to 16 (for BMI) and from month 18 (for waist circumference). This stresses the importance of adherence to ensure positive outcomes. In general, patients were satisfied with a monthly visit approach and a bi-monthly control of variables.

Previous studies have shown positive effects of pharmaceutical care in the management of CVR factors [7, 8, 25, 26]. A systematic review of 30 randomized clinical trials with 11,765 patients conducted by Santschi et al. [27] to determine the impact of pharmaceutical care on the management of CVD risk factors among outpatients demonstrated a significant reduction of total cholesterol and LDL-c. In accordance, we show a significant reduction of total cholesterol, LDL-c and triglycerides, as well as a highly significant increase in HDL-c. An added value of our study, is that we demonstrate positive changes for LDL-c and HDL-c even in the obese population without comorbidities, stressing the importance of early pharmaceutical care interventions to preventing an increase in CVR. Other authors, however, point to unclear benefits of pharmacist's intervention in lipid management [7, 8].

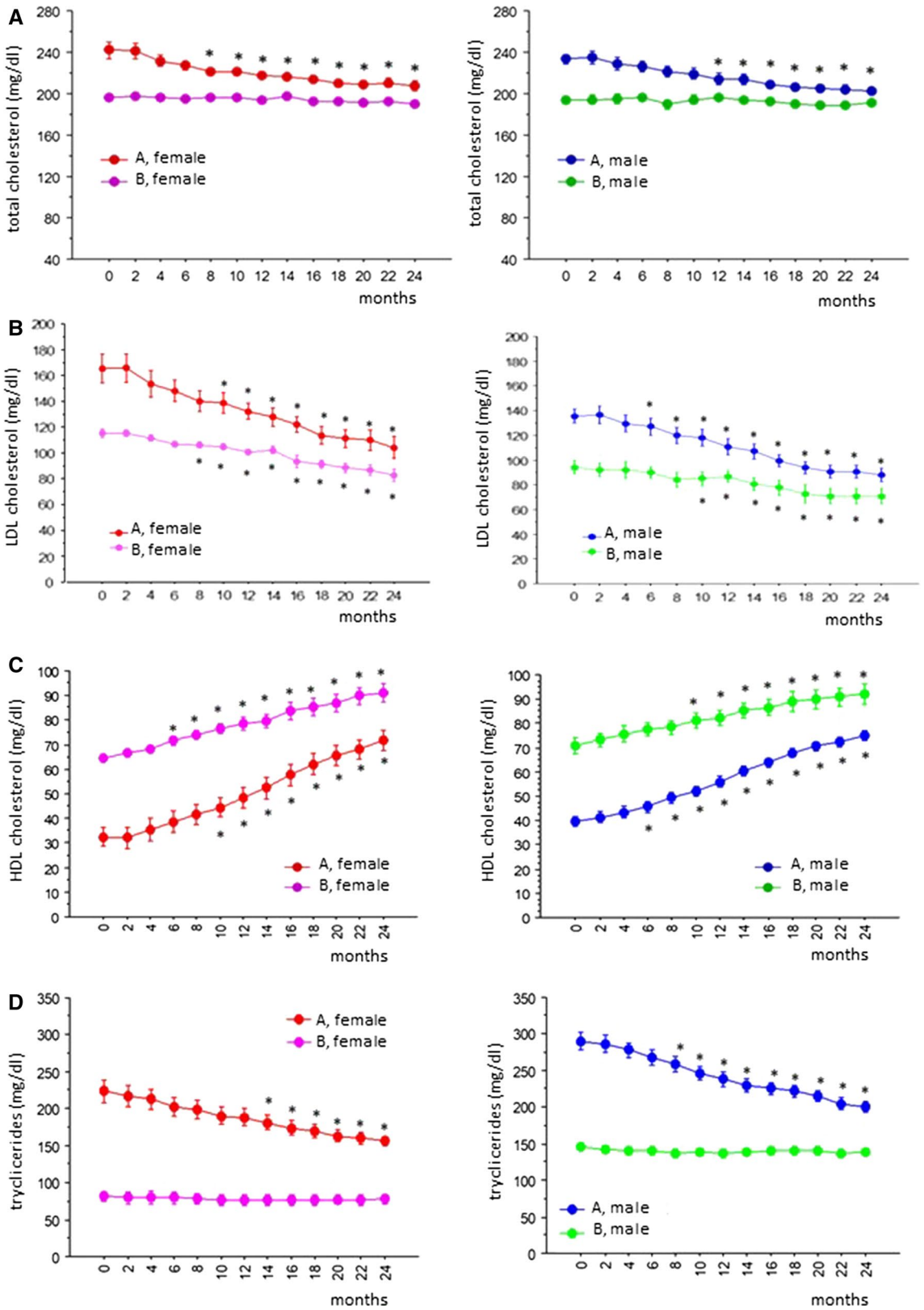

Fig. 5 Evolution of **a** total cholesterol, **b** LDL cholesterol, **c** HDL cholesterol, and **d** triglycerides in the two groups of female (left panels) and male (right panels) patients during the 24 month follow-up. The results are expressed as mean ± standard error of the mean. *$p < 0.01$ compared to the respective value at the beginning of the intervention in each group

Table 2 Estimation of the risk of a cardiovascular event within 10 years (REGICOR) at the start of follow-up and 24 months later for each patient. (Color table online)

Sex	Group	CVR 0 month		CVR 24 month	
		Smoker	Non Smoker	Smoker	Non Smoker
Female	A		7.5		2
Female	A		9		2.5
Female	A		19.5		6.5
Female	A	22.5		14	
Female	A		13.5		13.5
Female	A		11		6.5
Female	A	21		6.5	
Female	A	16.5		4.5	
Female	B		6		2
Female	A		16.5		6.5
Female	B		4		2
Female	A	21		6.5	
Female	B		1		0.5
Female	B	2		2	
Female	A		13.5		4
Female	B		5		2
Female	B		4.5		3.5
Female	A	11		3.5	
Female	A		6		2
Female	B	2		1	
Female	A		5		2.5
Male	A	9		6.5	
Male	B		1		1
Male	A	15		7.5	
Male	B	2.5		2.5	
Male	B	7		7	
Male	A	8		3	
Male	A		9		2.5
Male	A		10.5		1.5
Male	A	21		7	
Male	B		4		1.5
Male	A	13		4.5	
Male	A		7		2
Male	B		2		1.5
Male	A	7.5		1.5	
Male	A		5		2.5
Male	B		1.5		1.5
Male	A	13		6.5	
Male	B	18		8.5	
Male	A		8		4
Male	A	25.5		8.5	
Male	A		5		2
Male	A		25.5		4.5
Male	A	21		6.5	

>15%	Very high risk
10-14%	High risk
5-9%	Medium risk
<5%	Low risk

Table 3 Rates of subjects at "low, medium, high and very high risk" at the baseline and at 24 months irrespective of their sex

Risk	Sample A		Sample B	
	Baseline	24 months	Baseline	24 months
Very high	10	0*	1	0
High	8	2*	0	0
Medium	11	10	2	2
Low	1	18*	11	12

* $p < 0.01$ with respect to baseline

This might be because these studies were not designed as primary obesity management strategies, as in this study.

Our intervention was not associated with changes in blood pressure as in other studies. Reductions in systolic and diastolic blood pressures were previously observed in 19 out of 30 clinical trials reviewed by Santschi et al. [27]. It has to be noted that inclusion criteria for these trials in the systematic review were patients with hypertension or dyslipidemia with only half of patients classified as obese [25]. In our study, despite being obese, all patients were in a normotensive blood pressure range suggesting that those being hypertensive exhibit a well-controlled hypertension.

Both Rotta et al. [7] and Chiazor et al. [8] have shown that interventions focused on diabetes mellitus revealed a highly positive impact on patient outcomes. Considering glycemic parameters, we observe a reduction in plasma glucose during the follow-up but with no significant changes in HbA1C. There is however, a downward tendency for HbA1C and we believe that this would have reached significance if the follow-up would have been extended. In fact, Neto et al. [28] showed significant reductions in HbA1C levels in an intervention performed in elderly diabetic and hypertensive patients over a 36-month period. Again, this confirms the importance of adherence to ensure beneficial outcomes over time.

One of the main findings of our study is that the PharmaFit pharmacist intervention significantly reduces the estimated CVR in both patients with comorbidities (group A) as well as in patients without comorbidities (group B). As expected, patients in group A have a higher benefit of the intervention reducing one or even two risk categories in the REGICOR score. However, almost all patients in group B also reduce their risk despite remaining in the same REGICOR score level. We might attribute the high reduction in REGICOR score in group A to the high increase in HDL-c. This allows to conclude that PharmaFit intervention has a positive impact on coronary risk reduction. Similar results in REGICOR score reduction have been observed in HIV patients on a pharmaceutical care program [29].

As stated above, many pharmacist interventions included patient education, lifestyle changes (smoking cessation and lipid management) [6–8], and, in some cases, feedback to the physician [27]. In our intervention we have been in contact with primary care physicians or specialists providing direct or indirect information through the patient of follow-up. Feedback from these physicians was very positive and encouraging stressing the importance of the searching for multidisciplinary approach of health professionals in effective weight management [15].

Limitations of the study

One of the limitations of this study is that it was conducted only at one community pharmacy including a relatively small sample size. The results may be thus not generalized. In fact, it is intended to extend the next years this protocol to a larger number of community pharmacies in Madrid to assess its impact in a higher number of patients of different urban areas.

Conclusions

Many studies have demonstrated beneficial interventions of pharmacists in the identification of patients at high CVR [7, 8, 25, 30], as well as in management of CV disease [26]. There is, however, not much evidence demonstrating the impact of pharmacist intervention in obesity management and its associated CVR [9, 10]. Our study underscores the benefit of pharmacist's interventions in the management of major CVD risk factors among obese patients with and without comorbidities. This stresses the importance of pharmacist intervention in both the reversal and prevention of CV disease when targeting obese patients. Thus, interventions delivered by community pharmacists as part of the multi-disciplinary team to approach weight management in obese patients [13–15] are key to improve CVD risk factors outcomes among these patient.

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Conflicts of interest Leonor Huete, Francisco Javier Manzano-Lista, Isabel Aranguez and Maria S. Fernández-Alfonso declare that they have no conflict of interest.

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