

ORIGINAL ARTICLE

Impact of a multidisciplinary approach in clinical research on cardiovascular prognosis and patients' quality of life

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ABSTRACT

Background and aim: Circulatory system diseases, including cardiovascular diseases, are among the leading causes of death worldwide. This study aimed at implementing a structured project to monitor patients attending clinical research consultations in Cardiology, through a multidisciplinary healthcare team.

Research design and methods: A multidisciplinary consultation model was developed and implemented, comparing a control group (Group A, without intervention) and an intervention group (Group B). The study assessed five data collection moments and analysis, including sociodemographic characterization, risk factors, anthropometric assessment, therapeutic adherence (using the Measure Treatment Adherence [MTA] scale), and quality of life (assessed via the EQ Visual Analogue Scale [EQ VAS], part of the EQ-5D-5L scale). Statistical analysis was conducted using SPSS (Statistical Package for the Social Sciences), version 28.0 for Windows.

Results and discussion: The anthropometric assessment showed no significant improvement, with both groups maintaining stable weight and BMI values at pre-obesity levels. The parameters remained stable over the follow-up, suggesting that the multidisciplinary intervention and consistent monitoring helped preserve these health indicators. However, significant improvements in therapeutic adherence and quality of life were observed over time in both groups. The increase in therapeutic adherence was significantly greater in Group B, $t(432) = -9.046$, $p < .001$, as was the increase in quality of life, $t(435) = -5.674$, $p < .001$.

Conclusions: The study highlights the value of structured consultations, supported by a trained and professionalized multidisciplinary team, in enhancing health indicators and the quality of life of patients with cardiovascular diseases. (www.actabiomedica.it)

Key words: clinical investigation, multidisciplinary team, healthcare, cardiovascular risk



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Introduction

Circulatory system diseases, including cardiovascular diseases, are among the leading causes of death both in Portugal (1), and worldwide (2). Patients with these conditions often have associated comorbidities. Cardiovascular diseases contribute significantly to morbidity (3), reduced quality of life (4), and substantial direct and indirect economic costs (5,6). Despite recent advances in pharmacological therapy (7), continued investment in health literacy (8) is essential, particularly by promoting behavioral and lifestyle changes as preventive measures for cardiovascular disease through the management of modifiable risk factors (9,10,11). Studies have shown that sex- and gender-related factors interact in producing differences in CVD outcomes between women and men and may even have opposite effects on clinical manifestations and prognoses (12). Aging is associated with a progressive decline in numerous physiological processes, leading to an increased risk of health complications and disease, notably affecting the heart and arterial system, leading to an increase in CVD including atherosclerosis, hypertension, myocardial infarction, and stroke (13). The planning and implementation of structured patient-monitoring projects within clinical consultations provide a strong foundation for improving care quality and optimizing health outcomes (14,15). A multidisciplinary team of healthcare professionals, working collaboratively with shared goals and clearly defined roles, can enhance these outcomes (16). Productive patient-professional interactions—especially the quality of relationships and communication—are closely linked to the long-term well-being of chronically ill patients (17), which is fundamental in a long-term follow-up such as this. All professionals involved in this project have extended experience and work exclusively in the area of cardiology, including cardiologists, specialist nurses in rehabilitation nursing or general care, and clinical research nurses assigned to the cardiology service. Promoting clinical research in cardiology can benefit from the development and evaluation of structured consultation projects that can be adapted to address identified needs such as communication (18,19). Given the personal and health characteristics of patients and the requirements of

clinical trials, flexibility in project development is indispensable to accommodate evolving clinical demands (20,21). Moreover, analyzing human resource needs throughout the project's duration is crucial to achieving optimal outcomes (22).

Results and discussion

Objective

To implement a structured project to monitor patients undergoing clinical research in Cardiology by a multidisciplinary healthcare team.

Patients and methods

POPULATION AND DESIGN

This retrospective, quantitative, longitudinal, and quasi-experimental study defined the following inclusion criteria: individuals attending clinical research consultations in Cardiology, who provided informed consent, had no cognitive or oral expression impairments, spoke Portuguese, and were willing to participate. Exclusion criteria included age under 18 years old, pregnancy, or significant cognitive impairment. Data was collected at the Cardiology Clinical Research Unit, part of the Research and Development Unit of the Coimbra University Hospital Center, between 2018 and 2020, followed by subsequent analysis. The project developed and implemented a consultation model using a standardized script, involving a multidisciplinary team. It included Group A (control): patients without criteria for inclusion in the clinical trials (despite being high CV risk) and patients not currently under study medication but still monitored in consultations; and Group B (intervention): patients enrolled in clinical trials and under study medication. Efforts were made to match both groups regarding their main characteristics and to adjust for most variables. However, as stated in the manuscript, some differences remained, due to the sample size and individual patient characteristics. The project comprised five clinical visits: baseline, 3 months (M3), 6 months (M6), 12 months (M12), and 18 months (M18). The initial consultation was pivotal, collecting data on sociodemographic characteristics,

risk factors, adherence to trial and concomitant medications, and providing personalized health education based on the consultation script. Continuous anthropometric assessments were conducted throughout the study. Therapeutic adherence was evaluated using the Measure Treatment Adherence (MTA) scale, adapted and validated for the Portuguese population (23), which includes seven items with six Likert-type response options: always (1), almost always (2), frequently (3), sometimes (4), rarely (5), and never (6). Quality of life was assessed using the EQ VAS, part of the EQ-5D-5L scale (24), a vertical visual scale ranging from 0 (“Worst imaginable health status”) to 100 (“Best imaginable health status”). Authorization was obtained to use these instruments. Additional resources, such as telephone follow-ups, were used to reinforce health education or assess medication or behavioral changes when necessary. Patients in clinical trials benefited from free consultations, as all costs were covered by the sponsor.

Statistical analysis

The statistical analysis included both descriptive statistics (absolute and relative frequencies,

means, and standard deviations) and inferential statistics. Inferential analyses were conducted using independent samples t-tests, Fisher’s exact test, Chi-square test of independence, and repeated measures ANOVA. The Chi-square assumption-that no more than 20% of cells have expected frequencies below 5-was verified; when unmet, Monte Carlo simulation was applied. For samples larger than 30, normality was assumed according to the central limit theorem. Variance homogeneity was tested using Levene’s test. The significance level for rejecting the null hypothesis was set at $\alpha \leq 0.05$. All analyses were performed using SPSS software, version 28.0 for Windows.

Results

Consultation guide

A consultation guide was developed and implemented to standardize visit duration, content, and professional involvement, following team discussion and preparation.

Consultation	Activities	Professional involvement
Baseline	Explanation of the study to be carried out and consultation project. Ensure ethical procedures through explanation and signing of the Free and Informed Consent Form by the main researcher and the participant. Data collection Clinical evaluation (BP, HR, weight, height, BMI) Scheduling the next appointment	Clinical Trials Coordinator Nurse Physician
M3	Clinical evaluation (BP, HR, weight, height, BMI) Health education covering the following topics: <ul style="list-style-type: none"> • Diet (Mediterranean diet, salt, fats, vegetables and fruit, alcoholic beverages and coffee) • Importance of physical exercise • Smoking • Importance of compliance with pharmacological therapy (explaining the indications and possible side effects of the medication taken, emphasizing the importance of strict adherence to pharmacological therapy) • Literacy (definition of ACS, atherosclerotic disease and cardiovascular risk factors) Assessment of major concerns and clarification of doubts. Setting goals for the next appointment. Scheduling the next appointment.	Nurse Physician

M6	Clinical evaluation (BP, HR, weight, height, BMI) Health education covering the following topics: <ul style="list-style-type: none"> • Diet (Mediterranean diet, salt, fats, vegetables and fruit, alcoholic beverages and coffee) • Importance of physical exercise • Importance of compliance with pharmacological therapy Assessment of major concerns and clarification of doubts. Setting goals for the next appointment. Scheduling the next appointment.	Nurse Physician
M12	Clinical evaluation (BP, HR, weight, height, BMI) Health education covering the following topics: <ul style="list-style-type: none"> • Diet (Mediterranean diet, salt, fats, vegetables and fruit, alcoholic beverages and coffee) • Importance of physical exercise • Importance of compliance with pharmacological therapy Assessment of major concerns and clarification of doubts. Setting goals for the next appointment. Scheduling of the next appointment.	Nurse Physician
M18	Clinical evaluation (BP, HR, weight, height, BMI) Health education covering the following topics: <ul style="list-style-type: none"> • Diet (Mediterranean diet, salt, fats, vegetables and fruit, alcoholic beverages and coffee) • Importance of physical exercise • Importance of compliance with pharmacological therapy Assessment of major concerns and clarification of doubts. Project finalization (thanks and farewell).	Clinical Trials Coordinator Nurse Physician

Population characteristics

The total sample included 406 individuals, 191 (47%) in Group A and 215 (53%) in Group B. The mean age was 65.6 years, ranging from 36 to 87 years. The majority were male (81.8%) and literate (53.9%). No significant differences were observed between the groups regarding gender, education, profession or area of residence. However, Group A was significantly older than Group B (66.7 vs. 64.6), $t(404) = -2.212$, $p = 0.036$ (Table 1).

In Group B, a significantly higher proportion of patients had diabetes (57.6% vs 33.5%); whereas Group A had a significantly higher proportion of patients with a history of acute myocardial infarction (83.7% vs 71.7%) (Table 2).

In the group comparison, Group B had a significantly higher BMI at both baseline and M18. However, the changes in the evolution of the analyzed variables were not statistically significant (Table 3). Regarding therapeutic adherence and quality of life, Group B presented significantly higher quality-of-life scores at

baseline ($t(432) = -7.469$, $p < .001$). At M18, Group B continued to exhibit significantly higher quality-of-life values ($t(436) = -3.912$, $p < .001$) (Table 4).

Group A: Therapeutic adherence increased significantly from baseline to M18 ($t(242) = -6.852$, $p < .001$). Quality of life also improved significantly from baseline to M18 ($t(241) = -4.293$, $p < .001$).

Group B: Therapeutic adherence showed a significant increase from baseline to M18 ($t(190) = -16.394$, $p < .001$). Quality of life similarly increased significantly from baseline to M18 ($t(194) = -11.941$, $p < .001$) (Table 5).

The increase in therapeutic adherence was significantly greater in Group B, ($t(432) = -9.046$, $p < .001$), as was the increase in quality of life, ($t(435) = -5.674$, $p < .001$) (Table 6).

Discussion

Comparison between groups revealed differences in sociodemographic composition, with Group A consisting of patients followed post-event and Group B

Table 1. Sociodemographic characterization.

	Group A (N = 191)		Group B (N =215)		%
	N	%	N	%	
Age (M; SD)	64,6	10,3	66,7	9,5	.036*
Gender					1.000
Female	39	18,1	35	18,3	
Male	176	81,9	156	81,7	
Education					.865
Can't read/ write	17	7,9	12	6,3	
Can read/ write	117	54,4	102	53,4	
1st cycle	22	10,2	27	14,1	
2nd cycle	29	13,5	24	12,6	
High school	21	9,8	17	8,9	
Higher education	9	4,2	9	4,7	
Profession					.684
Active	133	61,9	114	59,7	
Non-active	82	38,1	77	40,3	
Residence					.648
Rural	161	75,6	140	73,3	
Urban	52	24,4	51	26,7	

Table 2. Health background.

	Group A		Group B		%
	N	%	N	%	
Diabetes	72	33,5	110	57,6	,001***
Hypertension	209	97,2	189	99,0	,291
Smoking	17	7,9	7	3,7	,091
Alcohol	37	17,2	35	18,3	,796
Dyslipidemia	215	100,0	189	99,0	,221
• Atrial fibrillation	22	10,2	15	7,9	,490
• Acute myocardial infarction	180	83,7	137	71,7	,004***
• Stroke	35	16,3	31	16,2	1,000
• Percutaneous coronary intervention	146	68,2	125	65,4	,597

including outpatients enrolled in clinical trials. No significant improvements were observed in the evaluated parameters between or within groups. However, the parameters remained stable over the 18-month follow-up, with no deterioration, suggesting that the multidisciplinary intervention and consistent monitoring contributed to maintaining these health indicators. Systolic and diastolic blood pressure remained within the reference values of international guidelines for this patient population (25), thereby reducing cardiovascular risk. Weight and BMI remained stable at pre-obesity levels, indicating the need for a more structured intervention, potentially involving nutritionists and psychologists for specialized and individualized care (26). Evidence indicates that psychologists perform multiple roles within cardiovascular teams, including clinical care, research, quality improvement, interdisciplinary education, program development, and leadership, as well as psychoeducation and patient support, reinforcing the importance of psychological interventions in cardiovascular rehabilitation, particularly for promoting patients' psychophysical health and well-being (27, 28). Similarly, the role of nutritionists is crucial, as studies point out that a healthy diet is fundamental for primary and secondary prevention, reducing the risk of CVD (29). In patients with high cardiovascular risk, individual characteristics, such as disease progression, the presence of other health conditions, or the occurrence of complications, appear to contribute to the lack of significant improvement in some evaluated parameters. Respiratory infections, ischemia (e.g., acute coronary syndrome), arrhythmia, uncontrolled hypertension, nonadherence to diet, or worsening renal function are among the main complications leading to hospital admission (30). Both groups showed significant increases in therapeutic adherence and quality of life from baseline to M18, with greater improvements in Group B. These findings highlight the effectiveness of the structured multidisciplinary intervention in clinical trials. Adherence to therapy is critical for high-risk patients, improving cardiovascular prognosis and reducing acute events and hospitalizations (31, 32). Enhancing quality of life in this population, with a history of cardiovascular disease and comorbidities, positively impacts multiple health-related dimensions, supporting healthier ageing

Table 3. Anthropometric group comparison.

Consultation	Base	Systolic BP			Diastolic BP			HR			Weight			Height			BMI		
		M	SD	% Sig.	M	SD	% Sig.	M	SD	% Sig.	M	SD	% Sig.	M	SD	% Sig.	M	SD	% Sig.
Baseline	Group A	139,23	17,50	0,39	81,31	11,18	0,17	65	11	0,58	79,3	14,54	0,08	1,67	0,08	0,70	28,48	4,25	0,02*
	Group B	137,70	18,38		79,80	11,03		66	10		81,82	14,65		1,67	0,08		29,68	6,11	
M3	Group A	139,09	19,03	0,16	80,64	11,71	0,08	66,24	11,5	0,06	79,58	14,85	0,14				28,58	4,57	0,11
	Group B	136,54	16,78		78,72	9,89		64,14	10,8		81,75	14,28					29,31	4,45	
M6	Group A	136,43	17,22	0,99	80,35	11,40	0,03*	65,94	11,38	0,36	79,69	14,99	0,22				28,59	4,40	0,68
	Group B	136,42	16,23		77,81	11,52		64,91	10,96		81,52	14,37					28,78	4,81	
M12	Group A	137,27	18,59	0,29	81,10	12,17	0,04*	66,44	11,19	0,53	79,39	14,93	0,21				28,44	4,33	0,13
	Group B	135,38	16,20		78,57	11,27		65,72	11,44		81,28	14,42					29,13	4,58	
M18	Group A	137,8	17,10	0,65	80,71	11,05	0,15	65,76	10,7	0,84	78,72	14,37	0,09				28,06	4,71	0,02*
	Group B	138,6	17,60		78,97	11,70		65,52	11,7		81,27	14,45					29,15	4,63	

Abbreviations: M – Mean SD – Standard deviation * $p \leq .05$ ** $p \leq .01$ *** $p \leq .001$.

Table 4. Therapeutic adherence and quality of life group comparison.

	Group A		Group B		Sig.
	M	DP	M	DP	
Baseline					
• Therapeutic adherence	4,92	0,60	5,01	0,33	.076
• Quality of life	69,73	12,48	69,91	10,42	.001***
M18					
• Therapeutic adherence	5,05	0,58	5,40	0,39	.868
• Quality of life	71,92	13,11	76,60	11,90	.001***

Abbreviations: M – Mean SD – Standard deviation * $p \leq .05$ ** $p \leq .01$ *** $p \leq .001$.

Table 5. Evolution of therapeutic adherence and quality of life.

	Baseline		M18		Sig.
	M	DP	M	DP	
Group A					
• Therapeutic adherence	4,92	0,60	5,04	0,57	.001***
• Quality of life	69,72	12,47	72,00	13,05	.001***
Group B					
• Therapeutic adherence	5,00	0,32	5,39	0,39	.001***
• Quality of life	69,91	10,41	76,60	11,89	.001***

Abbreviations: M – Mean SD – Standard deviation * $p \leq .05$ ** $p \leq .01$ *** $p \leq .001$.

Table 6. Differences in therapeutic adherence and quality of life between Baseline and M18.

	Group A		Group B		Sig.
	M	DP	M	DP	
• Therapeutic adherence	0,12	0,27	0,39	0,32	.001***
• Quality of life	2,28	8,26	6,68	7,82	.001***

Abbreviations: M – Mean SD – Standard deviation * $p \leq .05$ ** $p \leq .01$ *** $p \leq .001$.

(33). These results can be attributed to the patient-professional bond established during consultations, the setting of goals for subsequent visits, health education, and increased patient literacy. Key contributing factors included adherence to the work plan, internal training, sharing challenges and new approaches, creation of tailored support documents, and telephone follow-ups when necessary. As demonstrated in several studies, increasing health literacy in the cardiovascular care reduces cardiovascular risk factors and improves

patient adherence to lifestyle changes and medication (34,35). There is a need to develop strategies to assess literacy growth, in order to optimize health education programs for this group of patients. The use of information technologies could further enhance the literacy improvement process (36). The continuous development and application of hybrid consultation models (combining in-person and telehealth services) could expand the project, as this combination often yields better outcomes than digital-only approaches (37).

Although clinical trials have very well-defined protocols that usually request in-person consultations, practitioners and patients perceive telemedicine as a valuable, cost-effective tool with potential for wider scalability and meaningful improvements in health outcomes. Telemedicine strategies include videoconferencing, telephone consultations, mobile applications, email, and cloud platforms (38, 39).

Limitations

The study would benefit from a larger sample size, longer follow-up, and fully matched groups with no significant demographic, socioeconomic or clinical differences. Comparing these groups with populations from other national and international centers, as well as cohorts with other acute and chronic conditions, would also be valuable. Additionally, the demographic differences in age, as well as the unequal distribution of diabetes and prior myocardial infarction between the groups, represent important limitations that may have influenced the findings.

Conclusions

This article highlights the importance of structured consultations conducted by a trained, professionalized multidisciplinary team in improving clinical outcomes and quality of life for patients with cardiovascular diseases, as well as indirect outcomes such as readmissions and emergency visits.

The greater increases in therapeutic adherence and quality of life observed in Group B validate the effectiveness of the implemented consultation project. The Cardiology Department's clinical research consultations have adopted this consultation model, with adaptations according to the specific characteristics of each clinical trial and patient profile. Further development and expansion of the project are recommended to create a more comprehensive and effective model, potentially incorporating additional professionals like nutritionists and psychologists, and developing a more robust and structured roadmap. Reinforced evaluation strategies are also needed for rigorous and effective

patient monitoring based on observed outcomes. Future efforts should extend this approach to all patients, not only those in clinical trials, to ensure broader access to better monitoring, literacy, disease management, and quality of life.

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