Intention and regular physical activity behavior and associated factors in individuals with coronary artery disease

Intenção e comportamento da prática regular de atividades físicas e fatores associados em indivíduos com Doença Arterial Coronariana

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ABSTRACT

The study measured the intention to engage in physical activities (PA) during hospital stay and Behavior after two months, as the factors associated to both outcomes in patients with coronary artery disease. A longitudinal study was conducted in adults diagnosed with coronary artery disease admitted to a reference cardiology hospital, in southern Brazil. The sample was composed by 150 men and women interviewed twice, first during hospital stay and, later, two months after hospital leave. A questionnaire was administered to evaluate demographics, socioeconomics, behavioral and nutritional variables. Psychosocial variables of the Theory of Planned Behavior were also assessed. Mean age of the sample was 58 years (range 30 to 79 years), 51.3% were men and 89.3% were white. At the time of hospitalization, 25.3% of the individuals perform any physical activity for at least 30 minutes a week in the six months preceding the cardiac event and 48.2% showed positive intent to practice. In multivariable analysis, the intention was associated with Perceived Behavioral Control, Perceived Risk and Habit. The prevalence of physical activity two months after hospital discharge was 38.8% and the intention was the only variable determinant of behavior. Actions aiming at behavior change must focus on psychosocial aspects while patients are still in the hospital to improve secondary prevention of coronary by adopting an active behavior.

KEYWORDS

Motor activity; Cardiovascular diseases; Intention; Longitudinal studies.

RESUMO

Este estudo teve o objetivo de medir a ocorrência e os fatores associados à Intenção para prática regular de atividades físicas durante a internação hospitalar e seu respectivo comportamento após dois meses em pacientes com doença arterial coronariana. Estudo longitudinal foi conduzido em adultos diagnosticados com a doença arterial coronariana internados em um hospital de referência em cardiologia, no sul do Brasil. A amostra foi composta por 150 homens e mulheres os quais foram entrevistadas duas vezes, primeiro durante a internação e, mais tarde, dois meses após alta hospitalar. Um questionário foi aplicado para avaliar variáveis demográficas, socioeconômicas, comportamentais e nutricionais. Variáveis psicossociais da Teoria do Comportamento Planejado também foram avaliadas. A media de idade dos partcipantes foi de 58 anos (variando de 30 a 79 anos), 51,3% eram homens e 89,3% de cor da pele branca. No momento da internação, 25,3 % dos indivíduos realizava alguma atividade física por pelo menos 30 minutos por semana nos seis meses que antecederam o evento cardíaco e 48,2 % demonstraram intenção positiva para a prática. Na análise multivariável, a intenção esteve associada com controle comportamental percebido, percepção de risco e hábito. A prevalência de atividade física, dois meses após a alta hospitalar foi de 38,8 % e a intenção foi a única variável determinante do comportamento. Ações destinadas a mudança de comportamento devem ser concentradas em aspectos psicossociais enquanto os pacientes ainda estão no hospital visando melhorar a prevenção secundária da doença coronariana através da adoção de um comportamento ativo.

PALAVRAS-CHAVE

Atividade motora; Doenças cardiovasculares; Intenção; Estudos longitudinais.

INTRODUCTION

Coronary artery disease (CAD) is a major cause for disabling and premature death all over the world and represents nearly 30% of all-cause deaths [1]. The prediction for the year 2020 is that more than 40% of worldwide deaths will be linked to cardiovascular diseases and, in 2030, number of deaths could exceed 24 million per year [2].

Regular physical activity is recommended for people with CAD as a means to prevent and improve several risk factors associated to the disease [3]. Studies have shown consistently that increases in physical activity after a cardiac event is associated to a higher capacity to exercise [3, 4], and is one of the strongest prognostic characteristics in the prevention of new events [5]. Although the benefits of physical activities (PA) are known, few patients are active to obtain health benefits [6]. Among those who began exercising in cardiac rehabilitation programs, 20% give up in the first three months and 50% between six months and one year [7]. According to Petter et al. [8], physical activity adherence among CAD patients is low during and after a cardiac rehabilitation program, and also among those not attending any program.

To identify frequency and reasons why people engage or not in physical activities has been a challenge, especially among subjects suffering from different non-communicable chronic diseases. Thus, to know the determining characteristics of Intention and Behavior of regular physical activity engagement is fundamental in the prevention and treatment of such conditions.

One of the most accepted theoretical behavioral model is the Theory of planned behavior (TPB), which suggests that Intention to action is the main determinant of behavior [9]. The TPB was proposed by Icek Ajzen [9] based on a set of constructs (attitude, subjective norms and perceived behavioral control) to predict and to explain an specific behavior.

Therefore, the aim of the study was to measure the intention to engage in physical activities (PA) during hospital stay and behavior after two months, as the factors associated to both outcomes in patients with coronary artery disease.

METHODS

The study was a longitudinal and subjects were interviewed twice, first during hospital stay and, later, two months after hospital leave.

The sample was composed by men and women, with uncomplicated CAD (stable angina and/or acute myocardial infarction), admitted to the Cardiology Ward of the Santa Casa Hospital (Rio Grande, Brazil), a reference center in southern Brazil. All eligible cases were selected consecutively during hospital stay between June to October, 2010. Those who were considered unable to engage in physical activities due to physical or psychological problems were excluded from the study.

During hospital stay, a pre-tested questionnaire was administered to evaluate demographics, socioeconomics, behavioral and nutritional variables. Psychosocial variables of the Theory of Planned Behavior (TPB) were assessed [9] (intention, attitude, subjective norm, perceived behavioral control), as well as additional variables to TPB model (past behavior [10], habit [11] and perceived

risk [12]). Such variables were assessed through a questionnaire including Likert scale questions. Subjects were contacted by interviewers trained for data collection and the interviews were carried out individually and privately individually and privately in a hospital room.

The model and research questions were taken from the *"Psychosocial Determinants of Physical Activity among Coronary Heart Disease Patients Questionnaire"* developed by Mendez [13] and validated by Mendez et al.[14].

During analysis, the outcome *Intention to practice physical activities*, other TPB psychosocial variables and additional variables included in the model were dichotomized – responses 1 to 3 were considered as negative behavior and 4 to 5 were positive behavior.

We considered physically active, in the six months prior to the cardiac event, subjects reporting regular practice of any leisure-time physical activity for at least 30 minutes, 3 times a week (Past Behavior).

By the end of the two-month period after hospital leave, subjects were phoned to arrange a new interview to keep track of the behavioral and nutritional information, as well as to measure Current Behavior. Active subjects were those reporting regular practice of any physical activity during leisure, performed for at least 30 minutes, three times a week for the two-month period after hospital leave. Minimum frequency and duration of physical activities were based on usual prescriptions for patients with coronary artery disease [15].

Frequency and duration of activities were used to categorize patients as active/inactive and the cutoff point was based on the usual recommendations employed in studies about physical activity in cardiac disease patients, which are distinct from the recommendations for the healthy population [16].

Dataset was built in Epi Info 3.5.1 software for Windows and analysis were done in STATA 10.0. Crude analysis measured the statistical association by chi-square Pearson's for trend and heterogeneity. Multivariable analysis was done with Poisson regression, to control simultaneously confounders in the determination of Intention to engage in regular physical activities (outcome 1) and current behavior with respect to physical activity (outcome 2).

The hierarchical model was composed by four levels for the outcome Intention to engage in regular physical activities: first level included demographic variables (sex, age and skin color), second level was composed by socioeconomic variables (family income, schooling and marital status), third level was behavioral (smoking) and nutritional (body mass index), and fourth level included psychosocial variables (attitude, subjective norm, perceived behavioral control, habit, perceived risk and past behavior). With respect to the outcome current behavior, a fifth level (proximal to the outcome) was included: *intention to practice physical activities*.

The effects of first level variables were controlled for each other; second level's variables were controlled for each other and for the upper level and so forth. We included all variables in the model regardless of p-value during crude analysis. The variables remained in the model if during adjusted analysis presented p≤0.2. The final model included only variables presenting p<0.05.

The present study was approved by the Ethics Committees of the Physical Education School of the Federal University of Pelotas (protocol number 121/2010) and the Cardiology Ward of the Santa Casa Hospital (Rio Grande

– Brazil) and interviews were done after interviewees signed a consent term and were informed of all the procedures of the study.

RESULTS

During the five-month period of recruitment, 150 subjects were enrolled for the first stage of data collection. From the original 150, 29 did not participate in the second stage (two deaths, three refuses and 24 losses to follow-up), resulting in a response rate of 81%. From the non-respondents, 52% were female, 65.5% were married or living with a partner and 69% were in the age group 50-69 years.

Demographics, socioeconomics, behavioral and nutritional information of the sample are displayed in Table 1. Mean age of the sample was 58 years (standard deviation=9.2 years; range 30 to 79 years), 51.3% were men and 89.3% were white. With respect to schooling, 66.0% attended only primary school. Most were married or living with a partner (68%) and more than half had a Family income of up to two minimum wages. Currently 22.7% were smokers, 74.7% was not engaged in any PA in the six-month period prior to the cardiac event and more than 72% presented Body Mass Index (BMI) in the overweight/obesity range (equal or above 25kg/m²).

TABLE 1 – CAD patients sample description. Rio Grande, Brazil.

Variables	N	%
Sex (N= 150)		
Female	73	48.7
Male	77	51.3
Age (years) (N= 150)		
< 49	25	16.7
50-59	59	39.3
60-69	48	32.0
70 +	18	12.0
Skin Color (N= 150)		
White	134	89.3
Non white	16	10.7
Family income (minimum wage) ª (N= 142)		
Up to 1	42	29.6
Up to 2	31	21.8
Up to 3	18	12.7
Up to 4	21	14.8
4 +	30	21.1
Schooling (N= 150)		
None	07	4.7
Primary	99	66.0
High School	37	24.7
College	07	4.6
Marital Status (N= 150)		
Single/Divorced/Widowed	48	32.0
Married/Living with partner	102	68.0
Body Mass Index (N= 149)		
Normal	41	27.5

Variables	N	%
Overweight	63	42.3
Obesity	45	30.2
Smoking (N= 150)		
Non smoker	71	47.3
Smoker	34	22.7
Former smoker	45	30.0
Past Behavior (N= 150)		
Less than once/week	95	63.3
Once/week	08	5.3
Twice/week	09	6.1
Three times or more	38	25.3
Intention (N= 143)		
Negative	74	51.8
Positive	69	48.2
Current Behavior (N= 121)		
Less than once/week	65	53.7
Once/week	4	3.3
Twice/week	5	4.2
Three times or more	47	38.8

[a] National Minimum Wage-U$ 250,00. Variable with highest missing count (n=8)

The prevalence of intention to practice PA at the moment of hospital leave was 48.2% (95%CI 39.8 to 56.7). In crude analysis (Table 2) we observed that the Intention was directly associated to all TPB psychosocial variables (attitude, subjective norm and perceived behavioral control), and additional variables in the model (habit, perceived risk and past behavior). In the adjusted analysis (Table 2), only as variables habit, perceived risk and perceived behavioral control remained significantly associated with the outcome. At hospital leave, subjects that were already engaged in some physical activity (habit), that believed the odds to have a new cardiac event was smaller because they were active (perceived risk) and that perceived less barriers to PA (perceived behavioral control) presented, respectively, 40%, 90% and 240% more intention to practice regular physical activities.

From the subjects presenting positive intention to exercise, 50.9% were considered active two months after hospital leave. The incidence of regular physical activities three times a week for at least 30 minutes two months after hospital leave (current behavior) was 38.8% (95%CI 30.1 to 48.1). Table 3 describes crude and adjusted analysis between current behavior of regular physical activities practice and independent variables studied. We observed that the incidence of current active behavior after two months of hospital leave was higher among subjects with positive Intention for practice (p=0.008). When analyzed together (adjusted analysis) the Intention to practice regular physical activities remained associated to the current behavior after controlling for confounders, showing that physical activity two months after hospital leave was 90% higher among subjects that previously reported positive intention to practice.

TABLE 2 – Prevalence of intention to practice regular physical activity in CAD patients during hospital stay and crude/adjusted analysis between intention and independent variables. Rio Grande, Brazil. (N=150).

Level*	Variables	%	Crude Analysis PR (95%CI)	p	Adjusted Analysis PR (95%CI)	p
1	Sex			0.6***		
	Female	45.7	1.0			
	Male	50.7	1.1 (0.8 to 1.6)			
1	Age (years)			0.6***		
	< 49	52.0	1.0			
	50-59	44.6	0.9 (0.5 to 1.4)			
	60-69	53.3	1.0 (0.6 to 1.6)			
	70 +	35.3	0.7 (0.3 to 1.4)			
1	Skin color			0.4**		
	White	46.5	1.0			
	Non white	57.1	1.2 (0.7 to 2.0)			
2	Family income (minimum wage) [a]			0.8***		
	Up to 1	51.3	1.0			
	Up to 2	41.4	0.8 (0.5 to 1.4)			
	Up to 3	44.4	0.9 (0.5 to 1.6)			
	Up to 4	40.0	0.8 (0.4 to 1.5)			
	4 +	57.1	1.1 (0.7 to 1.7)			
2	Schooling			0.4***		
	None	42.9	1.0			
	Primary	50.0	1.2 (0.5 to 2.8)			
	High School	45.7	1.1 (0.4 to 2.7)			
	College	28.6	0.7 (0.2 to 2.9)			
2	Marital status			0.2**		0.1**
	Single/Divorced/Widowed	43.9	1.0		1.0	
	Married/ Living with partner	55.6	0.8 (0.6 to 1.1)		0.8 (0.5 to 1.1)	
3	Body mass index			0.06***		0.2***
	Normal	38.5	1.0		1.0	
	Overweight	45.9	1.2 (0.7 to 1.9)		1.3 (0.8 to 1.9)	
	Obesity	59.5	1.5 (1.0 to 2.5)		1.4 (0.9 to 2.1)	
3	Smoking			0.7**		
	Non smoker	49.3	1.0			
	Smoker	51.5	1.1 (0.7 to 1.6)			
	Former smoker	41.9	0.8 (0.6 to 1.3)			
4	Attitude			0.01**		
	Negative	11.1	1.0			
	Positive	50.8	4.6 (0.7 to 29.4)			
4	Subjective norm			0.01**		0.07**
	Negative	16.7	1.0		1.0	
	Positive	54.2	3.3 (1.3 to 8.1)		2.0 (0.9 to 4.5)	
4	Perceived behavioral control			0.007**		0.02**
	Negative	8.7	1.0		1.0	
	Positive	54.2	6.2 (1.6 to 23.8)		3.4 (1.2 to 9.7)	
4	Perceived risk			0.003**		0.04**
	Negative	21.6	1.0		1.0	
	Positive	56.2	2.6 (1.4 to 4.9)		1.9 (1.0 to 3.5)	
4	Habit			0.01**		0.04**
	Negative	35.4	1.0		1.0	
	Positive	57.9	1.6 (1.1 to 2.4)		1.4 (1.1 to 2.0)	
4	Past behavior			0.04**		
	Negative	43.9	1.0			
	Positive	61.1	1.4 (1.0 to 2.0)			

* Hierarchical levels for confounders control: adjustment for variables of the same level or higher level, if p<0.2. ** Wald's test for hetero-geneity. *** Wald's test for trend. [a] National Minimum Wage- U$ 250,00.

TABLE 3 – Prevalence of PA practice in CAD patients two months after hospital stay and crude/adjusted analysis between current behavior of physical activity and independent variables. Rio Grande, Brazil. (N=121).

Level*	Variables	%	Crude Analysis		Adjusted Analysis	
			PR (95%CI)	p	PR (95%CI)	p
1	Sex			1.0**		
	Female	40.0	1.0			
	Male	38.7	1.0 (0.6 to 1.6)			
1	Age (years)			0.07***		0.07***
	< 49	55.0	1.0		1.0	
	50-59	41.7	0.8 (0.4 to 1.3)		0.8 (0.4 to 1.3)	
	60-69	30.0	0.6 (0.3 to 1.0)		0.6 (0.3 to 1.0)	
	70 +	30.7	0.6 (0.2 to 1.3)		0.6 (0.2 to 1.4)	
1	Skin color			0.8**		
	White	38.5	1.0			
	Non white	41.7	1.1 (0.5 to 2.2)			
2	Family income (minimum wage) [a]			0.8***		
	Up to 1	44.4	1.0			
	Up to 2	30.4	0.7 (0.3 to 1.4)			
	Up to 3	43.8	1.0 (0.5 to 1.9)			
	Up to 4	46.7	1.1 (0.5 to 2.0)			
	4 +	36.0	0.8 (0.4 to 1.5)			
2	Schooling			0.07***		0.09***
	None	25.0	1.0		1.0	
	Primary	34.6	1.4 (0.2 to 7.8)		1.3 (0.2 to 7.6)	
	High School	47.1	1.9 (0.3 to 10.7)		1.7 (0.3 to 10.2)	
	College	60.0	2.4 (0.4 to 15.3)		2.1 (0.3 to 13.5)	
2	Marital status			0.9**		
	Single/Divorced/Widowed	37.8	1.0			
	Married/Living with partner	39.3	0.9 (0.6 to 1.7)			
3	Body mass index			0.6***		
	Normal	43.8	1.0			
	Overweight	28.9	0.7 (0.4 to 1.2)			
	Obesity	48.7	1.1 (0.7 to 1.8)			
3	Smoking			0.3**		
	Non smoker	40.7	1.0			
	Smoker	25.9	0.6 (0.7 to 1.3)			
	Former smoker	45.0	1.1 (0.7 to 1.8)			
4	Attitude			0.8**		
	Negative	42.9	1.0			
	Positive	38.6	0.9 (0.4 to 2.2)			
4	Subjective norm			0.7**		
	Negative	35.0	1.0			
	Positive	39.4	1.1 (0.6 to 2.2)			
4	Perceived behavioral control			0.4**		
	Negative	27.8	1.0			
	Positive	40.4	1.4 (0.7 to 3.2)			
4	Perceived risk			0.1**		0.2**
	Negative	25.0	1.0		1.0	
	Positive	42.2	1.7 (0.9 to 3.3)		1.6 (0.8 to 3.3)	
4	Habit			0.6**		
	Negative	36.4	1.0			
	Positive	41.3	1.1 (0.7 to 1.8)			
4	Past behavior			0.2**		0.1**
	Negative	35.3	1.0		1.0	
	Positive	47.1	1.3 (0.8 to 2.1)		1.4 (0.9 to 2.2)	
5	Intention					
	Negative	27.1	1.0		1.0	
	Positive	50.9	1.9 (1.2 to 3.2)		1.9 (1.1 to 3.1)	

* Hierarchical levels for confounders control: adjustment for variables of the same level or higher level, if p<0.2. ** Wald's test for hetero-geneity. *** Wald's test for trend. [a] National Minimum Wage- U$ 250,00.

DISCUSSION

We used the theoretical model Theory of Planned Behavior to evaluate the intention to practice regular PA in CAD patients by the time of hospital leave, two months after leave and to measure association of such behavior with other variables. Such theory proposes that the intention to perform the behavior is the main determinant in its adoption, and is influenced by attitudes, social rules and perceived control over the behavior [9]. This theoretical model originated the analysis model used in the present study which was important during multivariable analysis [17]. On that account, this is one of the few studies using such theoretical model with this population [13, 18-19] and developed out of cardiac rehabilitation programs [13, 19]. Besides, it adds up to the scarce literature on the theme [13].

The prevalence of intention found in our study is not in agreement with previous publication. The study by Johnston et al. [19], with 597 CAD patients showed that more than 80% reported positive Intention. In coronary patients, behavioral change needs to address issues of action implementation rather than motivational factors alone [19]. The physician participation, along with the physical education teacher to elaborate the physical activity routines and the explanation about the importance of engagement soon after hospital leave is fundamental to increase intention and practice itself.

According to Reid et al. [6] we still know little about physical activity patterns in CAD patients that are not enrolled in cardiac rehabilitation programs. The authors carried out a prospective cohort study with 782 patients, assessed physical activity trajectory pre and post hospitalization, and observed that only 25.2% of subjects were active during leisure in the period six months prior to the hospitalization. Despite different instruments to measure physical activity, the results agree with ours.

In the present study, two months after hospital leave, only 38.8% of patients were engaged in regular physical activity, while in the study by Reid and colleagues [6], among patients with CAD that chose not to participate in cardiac rehabilitation programs and were interviewed by phone, 71.2% were practicing leisure physical activities two months after hospital leave. The availability of rehabilitation programs, besides medical counseling, may influence the Intention behavior and future engagement in regular physical activities.

Among subjects with positive *intention to practice physical activities*, we observed that nearly half of them failed to engage in regular PA. The gap identified in the relation intention-behavior has also been discussed in researches about different health-related behaviors, as in the study by Sheeram [20] reporting from 26% to 57% of subjects failed to transform Intention to use condoms, cancer screening or physical activity in action.

When we analyzed Intention and current behavior of regular physical activities according to independent variables, we observed that both were not significantly associated to any demographic socioeconomic, behavioral or nutritional variable. This finding agrees with several studies that reported no significant effects of these characteristics on TPB outcomes [21-22]. Though, Spana et al. [23] found association between Intention to walk and smoking, along with a direct correlation with monthly income.

A meta-analysis showed that an individual's attitude was the best predictor of the intention of the behavior [24]. Such finding is not supported by the present study, as we identified that perceived behavioral control, perceived risk and habit were associated to intention to practice regular physical activities. The association between attitude and intention may have been affected by small sample size, impairing statistical power for such investigation.

The strongest association between perceived behavioral control and intention agrees with previous results among cardiac people [13, 19], and other types of patients (diabetes and cancer) [22, 25-26]. However, Ajzen [9], suggests that perceived behavioral control influences more the intention when the behavior is more voluntary.

Some studies show the importance of the Habit as predictor of adherence to exercise [27, 28]. However, Verplanken [28] highlights that most studies about habit published are based on past behavior self-reports and indicates the need for distinguish it, representing behavior frequency, from the Habit, that represents mode of behavior, that is, a regular behavior repeated automatically on stable contexts instead of being performed after decision-making processes. Mendez [13], evaluated physical activity (walking) determining factors in patients with acute coronary syndrome and observed that the Habit was not predictor of intention two months after hospital leave, in disagreement with our results.

The perception that the risk of a new coronary event may decrease by engaging in regular physical activities seems to influence positively the Intention to practice. In a study with ischemic cardiopathic patients, Spana and colleagues [23] observed that the more serious the condition of the patient, the more likely he/she was to be motivated (Intention) to walk. According to Lau-Walker [29], patients with precise perception of their grave clinical situation, were more likely to engage in an active lifestyle and keep it in the long-term. Nonetheless, other studies report that the perceived risk is not associated to Intention in subjects with acute coronary syndrome [13].

The subjective norm was also strongly associated with Intention, but was no longer associated after controlling for confounders, indicating that this variable may be more associated to other factors than to Intention itself. Such finding supports the ideas of some researchers reporting that the subjective norm usually is a weak predictor of behavioral intentions [24, 30]. But, Blanchard et al. [18] state that subjective norm was the more influential psychosocial variable on intention in CAD subjects enrolled in cardiac rehabilitation programs.

With respect to current behavior, the intention to engage in regular physical activities was the only variable associated to the outcome, consistently with other studies among cardiac patients [13, 18]. However, in the study by Johnston et al.[19], the only predictor of the behavior was the perceived behavioral control.

Some positive aspects must be highlighted in our study. Physical activity prior to the cardiac event (past behavior) is fundamental and most previous studies do not present such evaluation. Besides, the use of theoretical models is key when the aim is to study factors associated to physical activity or when planning interventions to promote a specific behavior (such as the increase in physical activity on population level) [17].

On the other hand, some limitations also must be considered. Initially, caution must be taken due to the number of subjects included and loss to follow-up. The number of individuals engaged may have affected the statistical power to verify some associations and the non-respondent rate in the follow-up modified the prevalence of physical activity. Other limitations result from self-reports of physical activity behavior, that are known to be imprecise than objectives measurements of physical activity, and the absence of evaluation of underlying beliefs of TPB constructs, that may provide more detailed information about which beliefs are more relevant to understand the active behavior adoption in patients two months after hospital leave.

In conclusion, our results indicate that the Behavior for regular physical activity in CAD patients two months after hospital leave was determined by intention. Intention on its turn, depends on the individual's perception of how easy is to engage in physical activities (perceived behavioral control); on the belief that physical activity can decrease his/her chances of a new cardiac event (perceived risk); having practiced physical activities in the past (habit). Actions aiming at behavior change must focus on psychosocial aspects while patients are still in the hospital to improve secondary prevention of coronary by adopting an active behavior. This work should be performed by a team that includes doctors and physical education teachers and must begin on the previous period of hospital discharge. In addition, prescription (PE teachers) and monitoring clinic condition of the patient (physicians) should occur periodically and for short periods of time. However, our results should be confirmed by larger studies with longer follow-up periods to draw definitive conclusions.

Authors' contribution

JSO participated of all parts of the study. LA and MRD contributed with statistic analysis and writing the results and discussion. MCS supervised and reviewed all steps of the study.

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