Original article

Influence of the use of a walking diary on mobility in patients in cardiac rehabilitation phase 1: a randomized clinical trial

Influência do uso do diário de caminhada na mobilidade de pacientes em reabilitação cardíaca fase 1: ensaio clínico randomizado

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ABSTRACT | INTRODUCTION: Inpatient rehabilitation is extremely important for patients recovering from cardiac surgery. Although a walking diary is routinely used in clinical practice, it has yet to be adequately tested and reported in the literature. **OBJECTIVES:** To establish whether the use of a walking diary affects the number of steps taken following cardiac surgery and whether this is related to the patient's level of cardiac anxiety. **METHODS:** An open, controlled, randomized clinical trial was conducted with adult patients submitted to elective valve and/or coronary surgery, who had no motor impairment. All the participants used a pedometer to register the number of steps taken over five consecutive days in the hospital. Twenty-nine individuals were randomized to create an intervention group that used the walking diary as treatment strategy, while twenty-three were allocated to a control group. The Mann-Whitney test was used to compare the number of steps between the two groups, while Spearman's correlation coefficient was performed to evaluate the relationship between the number of steps and the level of cardiac anxiety. Statistical significance was defined as $p<0.05$. **RESULTS:** The groups were similar regarding their demographic, clinical and surgical characteristics. There was no difference between the groups regarding the total number of steps taken: control group=1,496 (477.5 - 2992.5) vs. intervention group=1,468.5 (494.2 - 2,678) (p=0.902). **CONCLUSION:** The use of the walking diary had no effect on the number of steps taken and was unassociated with the level of cardiac anxiety in inpatients following cardiac surgery.

KEYWORDS: Cardiac Rehabilitation. Walking. Mobilization.

RESUMO | INTRODUÇÃO: A reabilitação hospitalar é extremamente importante para pacientes em recuperação de cirurgia cardíaca. Embora o diário de caminhada seja rotineiramente utilizado na prática clínica, ele ainda não foi adequadamente testado e relatado na literatura. **OBJETIVOS:** Estabelecer se o uso do diário de caminhada afeta o número de passos dados após cirurgia cardíaca e se isso está relacionado ao nível de ansiedade cardíaca do paciente. **MÉTODOS:** Foi realizado um ensaio clínico aberto, controlado e randomizado com pacientes adultos submetidos à cirurgia eletiva de valva e/ou coronária, sem comprometimento motor. Todos os participantes usaram um pedômetro para registrar o número de passos dados ao longo de cinco dias consecutivos de internação. Vinte e nove indivíduos foram randomizados para um grupo intervenção para usar o diário de caminhada como estratégia de tratamento, enquanto vinte e três foram alocados para um grupo controle. O teste de *Mann-Whitney* foi utilizado para comparar o número de passos entre os dois grupos, enquanto o coeficiente de correlação de *Spearman* foi realizado para avaliar a relação entre o número de passos e o nível de ansiedade cardíaca. A significância estatística foi definida como $p < 0,05$. **RESULTADOS:** Os grupos foram semelhantes quanto às características demográficas, clínicas e cirúrgicas. Não houve diferença entre os grupos quanto ao número total de passos dados: grupo controle=1.496 (477,5 - 2.992,5) vs. grupo intervenção=1.468,5 (494,2 - 2.678) (p=0,902). **CONCLUSÃO:** O uso do diário de caminhada não teve efeito no número de passos dados e não foi associado ao nível de ansiedade cardíaca em pacientes internados após cirurgia cardíaca.

PALAVRAS-CHAVE: Reabilitação Cardíaca. Caminhada. Mobilização.

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1. Introduction

The globalized, digital society of the 21st century demands that new skills and knowledge be developed in all areas of health. Within this current scenario of practicality, plain and easy access to technology and information, healthcare agents are no longer the sole owners of medical knowledge, with patients now actively discussing and questioning their health-disease processes. The present-day demands have triggered powerful transformations in healthcare practices, enabling professionals to involve the patient in evidence-based decision-making.[1]

Of the populations exposed to risk factors resulting from hospitalization, those submitted to cardiac surgery tend to be individuals with no motor impairment or only mild motor impairments[2,3], therefore, their need for phase-1 rehabilitation is often minimized. Nevertheless, there is dissonance between the healthy functional musculoskeletal profile of the majority of patients following cardiac surgery and the heterogenous hospital mobility registered in several studies[4-8], thus requiring that strategies be identified to reduce this discrepancy.

Although widely used, little is known regarding the actual effectiveness of the walking diary as a means of encouraging patients to walk more. Indeed, up to the present time, no published studies have compared the usage versus the non-usage of this instrument or have even debated its application for this specific purpose. This is an instrument that is applied in clinical practice, however, which outcomes or populations could benefit from its use remains to be confirmed in the literature. Consequently, the objectives of the present study were to determine whether the use of the walking diary would alter the number of steps taken by patients following cardiac surgery and whether the patients' level of cardiac anxiety is related to the number of steps they take following surgery.

2. Methods

This open, controlled, randomized clinical trial was conducted as an intention-to-treat basis analysis at a charitable hospital in Salvador, Bahia, Brazil, that is a national reference center for the treatment of heart disease.

2.1. Ethical issues

This study was conducted in compliance with all national and international guidelines for the performance of clinical trials involving human beings. The internal review board of the Santa Izabel Hospital approved the study protocol under reference CAAE 00751118.6.0000.5520. All participants gave their written consent. The trial was registered at the Brazilian Registry of Clinical Trials (REBEC) under reference RBR-5j2w34.

2.2. Study population

Data collection was performed between January and October 2019 in the cardiac surgery ward. Adult patients of at least 18 years of age scheduled to undergo elective cardiac surgery, either myocardial revascularization or heart valve surgery, were screened for inclusion in the study. Those who had difficulty understanding the procedures involved in the study and those with a motor impairment that would prevent them from walking unaided were excluded.

2.3. Study design and procedures

To conduct the initial screening, the investigators contacted the hospital bed management team, which kept them informed regarding the surgeries scheduled for the following day. Each patient's data was then verified to determine their eligibility. Individuals in the ward who were scheduled to undergo elective cardiac surgery, myocardial revascularization and/or heart valve surgery were

invited to participate in the study and were given information on the study design, its objectives, the procedures involved and the possible benefits. If the patient agreed to participate in the study, they were then asked to sign an informed consent form and their sociodemographic, clinical and surgical data were obtained from their medical chart. Questions were asked of the patient and/or their accompanying person whenever the information on the chart was found to be incomplete.

The International Physical Activity Questionnaire - Short Form (IPAQ-SF)[9] was applied before surgery to identify the patient's physical fitness level prior to admission to the hospital. The participants were then classified as active, moderately active or sedentary, according to the frequency and the amount of time they had spent performing vigorous or moderate physical activity or walking in the preceding weeks.

Participants were randomized following surgery, on the day of their discharge from the intensive care unit (ICU). They were allocated on one of two groups (control or intervention) through a random draw of previously sequentially numbered brown envelopes, each containing two identically cut and folded pieces of paper with the number 1 (50%) or 2 (50%), respectively. The envelopes, organized in a sequential ascending order, were kept in the physiotherapy department. Whenever a patient was discharged from the ICU, the investigator would take the next envelope to be opened, with the first patient receiving envelope number 1, the second patient number 2, and so on. A third individual, who was not part of the data collection team, opened the envelope and removed one of the two pieces of paper from it. The number on the paper represented the group to which the individual was allocated, with 1 being the control group of patients who would not receive the intervention and 2 being the intervention group of individuals who would be given the walking diary.

At the time of discharge from the ICU and transfer to the ward, all the patients (control and intervention groups) were given a pedometer (OMRON 320i, Kyoto, Japan) to count the number of steps they would take over a 5-day period in the ward. The patients were instructed to clip the device to their clothes at hip level and to remove it only to sleep or bathe.

The pedometers were individually calibrated with the measurements of the patients' steps (in cm), weight and height, and were then sealed so that the users were unable to see any of the data recorded there. Twice daily, at random times of the day, the investigators visited each individual to remind them to use the device, thus avoiding possible underestimations of the total number of steps. After five days, the estimated data was recorded on a pedometer record chart.

Since the patients could be discharged from the ICU at different times of the day, to standardize the period over which the number of steps was to be counted, only the three full days during which the device was used were analyzed, eliminating from the analysis the day on which the device was given to the patient and the day on which it was removed. Patients belonging to different groups did not share the same hospital room, therefore, it was impossible for individuals in the control group to have access to the intervention.

In addition to the pedometer, at the time of transfer from the ICU to the ward, the participants allocated to the intervention group were also given a walking diary, which remained with them for five days until the pedometer was removed. This instrument is already used in the hospital and it includes a pre-established walking goal of 250 meters/day.

Whenever they walked (either with the physiotherapist or independently), the participants were instructed to complete the walking diary with the date, time, place where walking occurred, the number of times the course was completed, and the total distance. To do so, the team measured all the corridors available for walking in the hospital and made these data available, particularly the corridor of the unit in which the participants were hospitalized and the corridors of neighboring units that could be visited.

At the moment when the pedometer was removed, the participants' level of cardiac anxiety was evaluated using the Cardiac Anxiety Questionnaire.[10] This 18-item instrument assesses anxiety/fear related to cardiac symptoms, with answers being classified on a 5-point Likert-type scale (0 = never; 1 = rarely; 2 = sometimes; 3 = often; 4 = always). The final score ranges from 0 to 72, with higher scores reflecting a greater level of cardiac anxiety.

Routine physiotherapy was maintained for the participants of both groups and consisted of breathing exercises, active kinesiotherapy or active-assisted kinesiotherapy, and functional exercise progression that ranged from sitting to walking. The hospital's physiotherapists worked with the patients once or twice every 24 hours in accordance with the routine practice established for the cardiovascular ICU or the ward. Physiotherapy sessions lasted on average ten minutes.

The control group also received the pedometer on the day of discharge from the ICU and remained with it for five consecutive days. These remained in the wards with the institution's physiotherapy routine and without other interventions by the research team. It is worth mentioning that both groups received the same guidance regarding the possibility of walking independently and its importance for functional recovery.

2.4. Calculation of sample size

The sample size was calculated using the WINPEPI calculator. The command selected was comparison of means, taking into consideration a standard deviation of 1,093 and 1,194 steps obtained from the study conducted by Lordello et al.[11], for a difference of 1,100 steps based on the studies conducted by Rosier et al.[12], a power of the test of 80% and a significance level of 5% for a two-tailed hypothesis. For this, a total of 20 participants would be required for each group (total = 40). An extra 15% was added to this value to compensate for any possible losses, resulting in a total of 46 individuals (23 in each group).

2.5. Data analysis

The Statistical Package for the Social Sciences (SPSS), version 14.0 for Windows, was used to construct the database and perform the descriptive and analytical analyses. The normality of the distribution of the variables was determined using the Kolmogorov-Smirnov test and descriptive statistics. In cases of disagreement, preference was given to descriptive statistics. The results were expressed as absolute values and percentages (n; %). The continuous variables were expressed as means and standard deviations (± SD) whenever distribution was normal, and medians and interquartile range (IQR) when distribution was not normal.

In the analysis of the homogeneity of the groups, Student's t-test was used to compare means for age, ejection fraction, time of extracorporeal circulation and hemoglobin levels at discharge from the ICU between the two groups (control and intervention). The Mann-Whitney test was used to compare the median time spent in the ICU and on mechanical ventilation, while the chi-square test was used to compare the categorical variables (sex, previous physical activity level, comorbidities and type of surgery) between the groups.

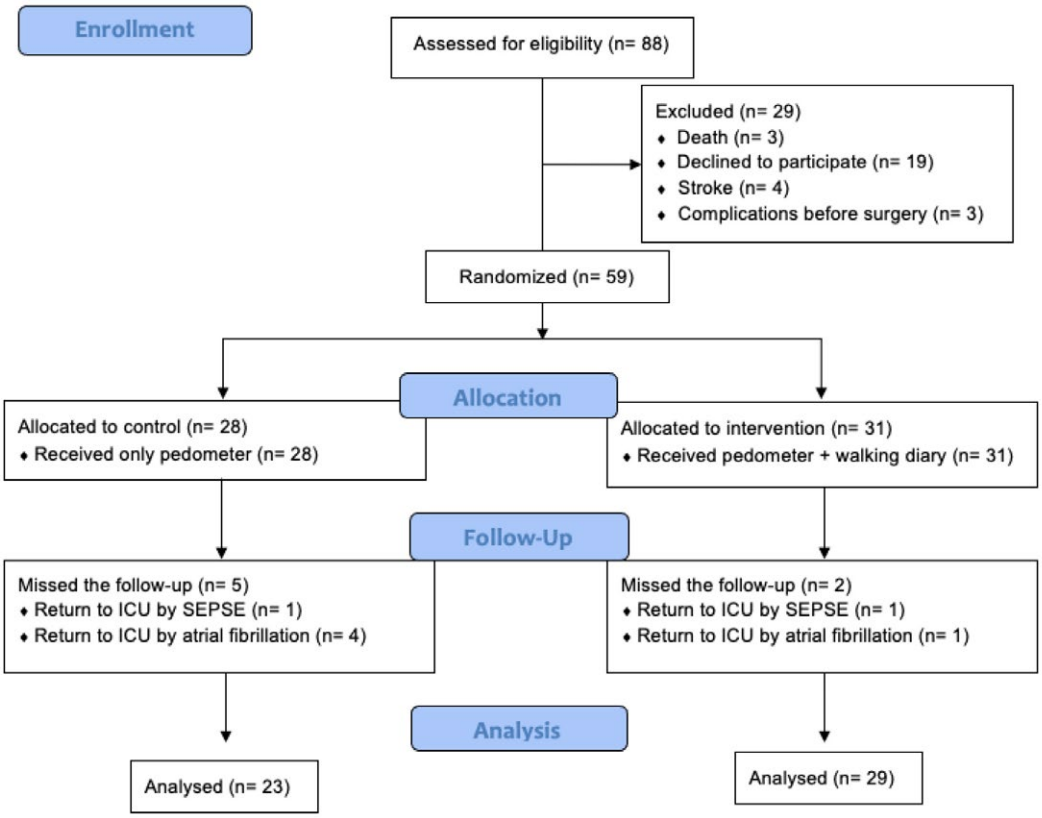
The Mann-Whitney test was used to compare the median number of steps and the total number of steps/day between the two groups, while Spearman's correlation coefficient was used to evaluate the relationship between the total number of steps taken in the two groups and the level of cardiac anxiety.

The analyses were conducted on an intention-to-treat basis, with p-values <0.05 being considered statistically significant.

3. Results

Of the 88 individuals initially evaluated for eligibility, 36 were excluded or lost during the follow-up. Therefore, the final analysis was conducted with 52 participants, 23 randomized to the control group and 29 to the intervention group. Figure 1 illustrates the flow of participants within the study.

Figure 1. CONSORT flow diagram for the study, showing the enrollment, allocation, follow-up and data analysis phases



Source: the authors (2024).

Table 1 shows the demographic, clinical and surgical characteristics of the participants, with no significant statistical differences between the two groups. The mean age of the participants was 59.3 ± 13.3 years, and there was a predominance of males in both groups. The most common surgical procedure was myocardial revascularization.

Table 1. Demographic, clinical and surgical characteristics of the individuals submitted to cardiac surgery in the two study groups (n=52)

	Total (n=52)	Control Group (n=23)	Intervention Grup (n=29)
Demographic characteristics			
Age [years (mean±SD)]	59.3±13.3	60.7±13.8	58.1±13.1
Sex [n (%)]			
Male	40 (76.9)	20 (87)	20 (69)
Clinical characteristics			
BMI [kg/m^2 (mean±SD)]	26.9±3.8	27±3.9	26.8±3.8
Ejection fraction (mean±SD)	63±10.9	60.9±10.3	64.8±11.2
IPAQ SF [n (%)]			
Sedentary	11 (21.2)	6 (26.1)	5 (17.2)
Irregularly active	10 (19.2)	1 (4.3)	9 (31)
Active	30 (57.7)	15 (65.2)	15 (51.7)
Level of cardiac anxiety (mean±SD)	22.5±8.2	22.1±8.2	22.4±8.9
Comorbidities [n (%)]			
Arterial hypertension	40 (76.9)	19 (82.6)	21 (72.4)
Coronary heart disease	21 (40.4)	11 (47.8)	10 (34.5)
Diabetes	16 (30.8)	8 (34.8)	8 (27.6)
Dyslipidemia	12 (23.1)	5 (21.7)	7 (24.1)
Valvulopathies	5 (9.6)	2 (8.7)	3 (10.3)
Current smoker	3 (5.8)	2 (8.7)	1 (3.4)
Past smoker	2 (3.8)	1 (4.3)	1 (3.4)
Rheumatic disease	1 (1.9)	0 (0)	1 (3.4)
Heart failure	1 (1.9)	1 (4.3)	0 (0)
Chronic renal failure	1 (1.9)	1 (4.3)	0 (0)
Surgical characteristics			
Extracorporeal circulation time [minutes (mean±SD)]	100±38	93.8±34.5	104.9±40.4
Mechanical ventilation time (hours) [Median (IQR)]	5.1 (3.6 – 12.3)	5 (2.5 – 17.6)	4.9 (4 – 11.9)
Length of ICU stay (days) [Median (Q25 - Q75)]	3 (2 – 4)	2.5 (2 – 4.2)	3 (2 – 4)
Hb at discharge from the ICU (mean±SD)	9.5±1.5	9.6±1.4	9.4±1.6
Type of surgery [n (%)]			
Coronary cardiac surgery	31 (59.6)	17 (73.9)	14 (48.3)
Valve cardiac surgery	16 (30.8)	5 (21.7)	11 (37.9)
Coronary and valve cardiac surgery	5 (9.6)	1 (4.3)	4 (13.8)

SD = standard deviation; BMI = body mass index; ICU = intensive care unit; Hb = hemoglobin
Source: the authors (2024).

The median number of steps taken by participants was 1,496 (498.5 - 2,763.5), with a median of 1,496 (477.5 - 2,992.5) steps in the control group and 1,468.5 (494.2 - 2,678) steps in the intervention group (Table 2). There was no statistically significant difference between the groups (p=0.902).

Table 2. Comparative analysis of the median number of steps between the intervention and control groups (n=52)

	Total	Control Group	Intervention Group	P-values*
Total number of steps	1496 (498.5 – 2763.5)	1496 (477.5 – 2992.5)	1468.5 (494.5 – 2678)	0.902

*Mann-Whitney test
Source: the authors (2024).

Table 3 shows the median number of steps over the three full consecutive days on which the pedometer was used, comparing the control group with the intervention group. No statistically significant differences were found.

Table 3. Comparative analysis of the median number of steps taken per day between the intervention and control groups (n=52)

Variables	Control Group	Intervention Group	P-values*
Steps on the 2nd day	146 (18 – 565) / 359.6±468.2	364.5 (94.5 – 1060.5) / 595.2±599.8	0.650
Steps on the 3rd day	395 (40.5 – 641.5) / 620.1±1029.2	261.5 (115 – 1048.5) / 670.3±824	0.902
Steps on the 4th day	583.5 (59.2 – 1073.2) / 861.4±1073.6	340 (28.7 - 1147) / 660.9±772.6	0.372

*Mann-Whitney test
Source: the authors (2024).

3.1. Secondary endpoints

When the relationship between the level of cardiac anxiety and the number of steps in the control and intervention groups was evaluated, no statistically significant correlation was found (Table 4).

Table 4. Relationship between the level of cardiac anxiety and the number of steps in the control and intervention groups (n=52)

	Control Group		Intervention Group	
	r	P-value*	r	P-value*
Level od cardiac anxiety	0.16	0.513	-0.254	0.232

*Spearman's correlation
Source: the authors (2024).

4. Discussion

In this study, the use of a daily walking diary as an intervention instrument failed to alter the mobility of patients following cardiac surgery. Irrespective of whether or not the diary was being used, the number of steps taken did not change significantly throughout hospitalization. Furthermore, psychological factors related to the patient's level of cardiac anxiety had no effect on the number of steps taken in this population undergoing phase-1 cardiac rehabilitation.

When the total number of steps taken was compared between the two groups, although the number was numerically greater in the intervention group, the difference found was not significant, either from a statistical or clinical point of view. As an explanation, we hypothesize that in this investigation the type of intervention used was the actual cause of the result encountered here, being also self-limited to the group that used it.

Considering the goal of 250 meters/day, the equivalent of around 650 steps/day, as pre-established in the walking diary, the mean number of steps taken by the participants in the intervention group came very close to these values, suggesting that they may have limited their walking to the distance recommended in the instrument. After reaching that goal, they may then have felt entitled to walk no further. Therefore, the instrument appears to be effective in guaranteeing that the established goal is accomplished but discourages participants from going beyond that goal.

A clinical trial conducted in 2012[13] evaluated the effect of a self-monitored mobility program and, unlike the findings of the present study, reported a significant increase in the number of steps taken by those participating in the program. Although that intervention was similar to the present one in the way participants were the protagonists and co-responsible for their rehabilitation, there are some differences that could explain these diverging results. In that earlier study, the physical activity performed was monitored by recording the number of steps taken on an accelerometer, while in the present study, the individuals had no access to the data on the number of steps recorded, since such access is, in itself, the strongest incentive for walking. Furthermore, the goal applied in the self-monitoring program changed over the weeks, whereas with the walking diary, the goal remained the same, even as time progressed.

Investigators in Australia evaluated a group of patients undergoing phase-1 rehabilitation following successful cardiac surgery and showed that, irrespective of the intervention associated with walking the individuals tended to regain the same healthy or normal level of fitness.[14] This may represent one more explanation for the lack of any difference in the number of steps taken in the group using the walking diary, as shown by the similar mean number of steps in the control and intervention groups.

To the best of our knowledge, this is the first study to evaluate the effect of the use of a walking diary on in-hospital mobility. Since this is a widely used tool in care protocols and an endpoint that is seldom investigated in this setting of phase-1 cardiac rehabilitation, the negative result found merits further consideration concerning the consequences of this finding, since it involves the implementation of a new instrument representing an additional cost to the services that would use it.

As suggested, in this group of patients this instrument appears to ensure that the user completes a pre-established goal; however, it also seems to limit the individual to doing only what is required. Therefore, since this is a functional outcome of great importance in clinical practice and since the possible determinants remain unexplained, it appears that the use of the walking diary could be beneficial if it were to be applied differently, with specific objectives associated with compliance with functional goals, and with mobility increasing over time.

Numerically, there was greater variability in the number of steps taken over time in the control group, with the participants of that group taking a greater mean number of steps/day than those in the intervention group. This finding reaffirms the possibility that the instrument may have indeed limited the number of steps taken in the intervention group. It also confirms that with adequate postsurgical recovery, the walking goal for this group of patients could be increased over time, assuring the physical restoration of functional capacity.

Hospital inpatient mobility and its determinants remain a poorly investigated field in phase-1 cardiac rehabilitation, raising questions regarding possible psychological factors as influencers. Studies have shown a wide variation in the attitude of individuals towards walking[4-8,12,15-17], which was also a finding of

the present study; however, this variability does not appear to be directly associated with anxiety-related psychological issues.

In addition to the physical and cardiorespiratory conditions required for walking, the intervention selected for evaluation in this clinical trial requires a certain degree of effort and willingness from the patient to perform the proposed activity on their own account. In other words, it is a treatment that depends on the patient's motivation[18,19], meaning that the mere application of the intervention by the healthcare team does not guarantee a therapeutic response without the active participation of the patient in their own process of rehabilitation.

According to White et al.[18], compliance with treatments involving active health-related behaviors varies considerably due to the differences in an individual's motivation to perform a specific activity as recommended. Consequently, the components offered by the team that acts directly on the willingness of the participant form an important part of this process. These include outlining goals, giving performance feedback, discussing the importance of the proposed activity, and using playful and accessible forms of instruction.

Within the components of rehabilitation and taking the three pillars defined by Hart et al.[19] into consideration (goal, instruments and mechanism of action), it appears reasonable to consider that the link between the walking diary (the instrument) and an increase in the number of steps (the goal) was not directly met due to factors inherent to the intervention itself. An algorithm is required that would unite ingredients capable of modifying individuals' behavior to interventions such as this one, making the goal more concrete and desirable, not only to the healthcare professional but also to the patient.

As a limitation of the study, although physiotherapy assistance was distributed equally to both groups and the physiotherapist was not previously informed about which group the patient was allocated to, there was the possibility that the patient would spontaneously report to the professional about the use of the diary, which could influence the assistance provided. Furthermore, as a single-center study, inherent limitations of this study type were observed, like minimal heterogeneity among the enrolled patients, which restricted external extrapolation of data.

5. Conclusion

The use of a walking diary failed to alter the number of steps taken by patients following cardiac surgery, and no correlation was found between the level of cardiac anxiety and the mobility of this population.

Authors' contributions

The authors declare that they have made sufficient contributions to the work, including the conception or design of the research, the acquisition, analysis or interpretation of data for the work and the writing or critical review of relevant intellectual content. All authors approved the final version to be published and agreed to take public responsibility for all aspects of the work.

Conflicts of interest

No financial, legal, or political conflicts involving third parties (government, private companies, and foundations, etc.) were declared for any aspect of the submitted work (including but not limited to grants and funding, advisory board participation, study design, manuscript preparation, statistical analysis, etc.).

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