Effect of biofeedback on nursing team coping: a randomized clinical trial

Efeito do *biofeedback* no coping da equipe de enfermagem: ensaio clínico randomizado

Efecto del biofeedback en el coping del equipo de enfermería: ensayo clínico aleatorizado

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Abstract

Objective: To assess the effect of cardiovascular biofeedback on coping levels of nursing professionals at a university hospital, when compared with a computerized activity without self-monitoring.

Methods: This is a randomized clinical trial, with two groups, biofeedback and placebo, carried out with 115 nursing professionals from a university hospital. The groups participated in nine meetings for three weeks. The outcome was assessed by Coping Responses Inventory, Brazilian version, applied prior to the first session and immediately after the final session. The outcome analysis was performed by ANCOVA, considering $\alpha = 5\%$.

Results: The Coping Responses variation had a statistically significant effect. The control group showed an increase of 0.17 points in this variation when compared to the intervention group ($h^2 = 0.07$; p=0.004). The Avoidance Responses variation and Overall Coping Level did not show a statistically significant effect on the group/time interaction (p=0.471 and p=0.786, respectively).

Conclusion: Intervention with cardiovascular biofeedback was shown to have no superior effect than placebo in improving coping levels.

Resumo

Objetivo: Avaliar o efeito do *Biofeedback* cardiovascular sobre os níveis de *coping* dos profissionais da enfermagem de um hospital universitário, quando comparado com uma atividade informatizada sem automonitoramento.

Métodos: Ensaio clínico randomizado, com dois grupos, *Biofeedback* e placebo, realizado com 115 profissionais de enfermagem de um hospital universitário. Os grupos participaram de nove encontros por três semanas. O desfecho foi avaliado pelo Inventário de Respostas de *Coping* no Trabalho, versão brasileira, aplicado prévio a primeira sessão e imediatamente após a sessão final. A análise do desfecho foi feita pela *ANCOVA*, considerando $\alpha = 5\%$.

Resultados: A variação das Respostas de Enfrentamento apresentou efeito estatisticamente significativo, o grupo controle apresentou aumento de 0,17 pontos nesta variação quando comparado ao grupo intervenção ($h^2 = 0,07$; p=0,004). A variação das Respostas de Evitação e do Nível Geral de *Coping* não evidenciou efeito estatisticamente significativo na interação grupo/tempo (respectivamente, p=0,471 e p=0,786).

Conclusão: A intervenção com *Biofeedback* cardiovascular demonstrou não ter efeito superior ao placebo na melhora dos níveis de *coping*.

Resumen

Objetivo: Evaluar el efecto del *Biofeedback* cardiovascular sobre los niveles de *coping* de los profesionales de enfermería de un hospital universitario, en comparación con una actividad informatizada sin automonitoreo.

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Conflicts of interest: nothing to declare.

Métodos: Ensayo clínico aleatorizado, con dos grupos, *Biofeedback* y placebo, realizado con 115 profesionales de enfermería de un hospital universitario. Los grupos participaron en nueve encuentros durante tres semanas. El desenlace fue evaluado por el Inventario de Respuestas de *Coping* en el Trabajo, versión brasileña, aplicado antes de la primera sesión e inmediatamente después de la sesión final. El análisis del desenlace se realizó por *ANCOVA*, considerando $\alpha = 5$ %.

Resultados: La variación en las Respuestas de Afrontamiento presentó un efecto estadísticamente significativo. El grupo control presentó un aumento de 0,17 puntos en esta variación al compararlo con el grupo experimental ($h^2 = 0,07$; p=0,004). La variación de las Respuestas de Evitación y del Nivel General de *Coping* no evidenció un efecto estadísticamente significativo en la interacción grupo/tiempo (respectivamente, p=0,471 y p=0,786).

Conclusión: La intervención con *Biofeedback* cardiovascular demostró que no tiene efecto superior al del placebo en la mejora en los niveles de *coping*.

Clinical Trial Record: NCT04446689

Introduction

Nursing work, involving organizational peculiarities and care demands, sometimes unexpected and complex, can contribute to psycho-emotional illness. This has a significant impact on workers' physical and psychological health, causing physiological responses that reflect negatively on individuals' professional skills, social relationships and behaviors and well-being.[1,2]

The use of coping responses has the potential to help professionals to consciously overcome or minimize the different negative and conflicting situations experienced at work. In this sense, coping can be the punctual solution to a situation of conflict, exhaustion or stress, contributing to the recovery of individual well-being and minimizing psychoemotional illness.[3]

A study developed with nurses in Egypt showed a negative and significant relationship between coping levels and occupational stress of participants (r=-0.57, p<0.01). By educating nurses about the impacts and symptoms of stress and ways to develop problem-solving coping skills, professionals tend to implement and improve such mechanisms for their own benefit and those around them.[3]

Biofeedback tools, whose self-regulation processes occur through the human-machine interface, have been identified as effective for strengthening coping skills, gaining visibility as a non-drug therapeutic tool, isolated or combined with other therapies. They are proven to be effective in managing stress, improving health and performance in different populations, such as athletes, high school and college students, police officers, managers, among others.[4–7]

Usually, untrained individuals breathe erratically and without coherence. In this sense, guided breathing training, according to standardized parameters and using tools such as cardiovascular biofeedback, aims to equip individuals to modulate breathing at an appropriate pace and consciously, for the acquisition of beneficial effects on physical and psychological health.[4]

The cardiovascular biofeedback technique is sensitive to changes in the Autonomic Nervous System (ANS), allowing individuals to learn to modulate their own body's response through information from the heartbeat, and can be considered a coping mechanism.[8] It is noteworthy that no clinical study, to date, has investigated the effects of cardiovascular biofeedback on the coping of nursing professionals during work exercise. [9]

Considering the above, the hypothesis investigated is that professionals who perform cardiovascular biofeedback training with guided breathing show improvement in coping levels, when compared to those who perform an activity without self-monitoring. The present study aimed to assess the effect of cardiovascular biofeedback on coping levels of nursing professionals at a university hospital, when compared with a computerized activity without self-monitoring.

Methods

This is a parallel, double-blind, Randomized Clinical Trial (RCT) comparing two groups. It was carried out from June 2020 to August 2021, together with the nursing group of the *Hospital de Clínicas de Porto Alegre* (HCPA), an institution considered a reference center for health care and research in Rio Grande do Sul. It was conducted as recommended by the Consolidated Standards of Reporting Trials (CONSORT).

The target population was nursing professionals of both sexes, active in the position, admitted for more than 90 days, working in any work shift provided for in the institution, allocated in Surgical Nursing (SNS), Clinical Nursing (ClinNS) or Clinical Hospitalization Nursing (CHNS) Services, which have similar characteristics regarding infrastructure, organization, lighting and type of patient treated, not being a reference for hospitalization of patients with COVID-19, and who had an Overall Stress Level greater than one (OSL>1).

The OSL was determined using the Stress Symptoms Scale (SSS), applied, at most, up to 30 days before the initial session (t0). The SSS assesses physical and psychological symptoms, caused as the body's responses to events considered stressful. Through the arithmetic mean of the items, the OSL is identified, and values greater than one indicate the presence of stress, oscillating between 1.1 (lower stress) and 2.95 (maximum stress).[10] Indicating the presence of the condition of interest to participate in the research.

Professionals on long-term leave (social security benefit and pregnancy or lactation leave) and vacations, or who had returned less than 15 days after these leaves, and those with a pacemaker or heart rhythm pathologies were excluded from the sample.

The sample size calculation was estimated by the stress condition of interest, based on an intervention study that showed a difference in stress levels immediately after the intervention (Cohen's d = -0.33), as well as six weeks after the intervention (Cohen's d = -0.68).[6] Considering a single flow sample, significance level of 5%, power of 90%, standardized effect size (Cohen's d) of at least 0.4 between assessments, and with estimated loss of 5% (with no expected follow-up of participants), a minimum sample of 57 professionals was obtained in the intervention group and 57 professionals in the control, totaling 114 participants.

The researchers selected participants, respecting the eligibility criteria, based on the work scales of each nursing service, using the *Sorteio de Nomes* app for Android®. The researchers randomly selected participants, respecting the eligibility criteria, based on the work schedules of each nursing service, using the *Sorteio de Nomes* app for Android®. The professionals considered eligible were randomized into an intervention group or a control group, and invited to participate in the RCT.

Chunk randomization was chosen, carried out through the website randomization.com, ensuring that the number of participants was equally distributed in the groups. It was carried out by one of the researchers who did not act in the conduct of activities with participants.

After acknowledgment and acceptance by the research subject, the researcher or research assistant scheduled the first session, which took place during the work shift and in a private place close to participants' performance unit. All procedures, regardless of the allocation group, occurred individually and during participants' workday. The inclusion of subjects in the research took place gradually, during the period from June 2020 to August 2021, until reaching a minimum sample of 57 professionals per group.

The socio-employment and health information questionnaire was designed with the aim of collecting socio-biographical, socio-occupational data, health conditions and previous self-reported diseases by participants.

The primary outcome, improvement in coping levels, was assessed by the Coping Responses Inventory (IRC-T), Brazilian version,[11] which demonstrated good internal consistency in a previous study μ= 0.96.[12] IRC-T consists of 48 items that address professionals' coping responses to stressful situations in their work environment. It is divided into two categories and four subcategories: Coping Responses (24 items) - logical reasoning, positive reappraisal, guidance/support, and decision-making; and Avoidance Responses (24 items) - evasive rationalization, resigned acceptance, compensatory alternatives, and emotional overflow.

The IRC-T score is assessed on a Likert scale, which ranges from 0 (never) to 3 (use in large amounts) points. The arithmetic mean of the items in the same category allows the identification of prevalent coping responses and the arithmetic mean of the 48 IRC-T items provides the Overall Coping Level (OCL). It can range from 0 (never use coping

responses), 1 (rarely use), 2 (occasional use) and 3 (frequently use coping), i.e., score > 1 indicates use of coping responses by participants.[12]

The secondary outcome, improvement in HRV parameters, although assessed, will not be the subject of this publication.

Participants in both groups responded to the research protocol in two moments: pre-intervention, prior to the initial or baseline session (t0) and post-intervention, immediately after the last session (t8) of the approach. There is no follow-up forecast, due to the interest in measuring the immediate effect of the intervention on the outcome of interest.

The intervention consisted of training in the cardiovascular biofeedback technique, using EmWave Pro Plus® interface and interactive games. This intervention uses photoplethysmography technology, a reliable, valid and accurate method for capturing and quantifying, in real time, physiological data related to the heartbeat. During the interactive game, from the physiological behavior measured, the software generates continuous and dynamic information so that participants can, gradually, by maintaining the rhythm and concentration in guided and standardized breathing, improve their respiratory and heart rate.[13]

Considering the peculiarities of nursing professionals' work routine, the intervention was defined in nine meetings, which took place three times a week, over three weeks. In the first meeting (t0), baseline measurement of heart rate variability (HRV) and guidance on the dynamics of the next meetings were performed.

In the eight subsequent meetings (t1 to t8), guided deep breathing training was performed, at a controlled and standardized frequency, with the aid of York Biofeedback Breath Pacer (standardized at six breaths/minute, inspiration ratio 50/50, with pause after inspiration of 32% and after expiration of 20%, prevalent in 95% of the population), combined with biofeedback, through interactive games provided by EmWave Pro Plus®, lasting ten minutes per session. Participants were instructed on how to perform guided deep breathing, as well as biofeedback information, captured through the photoplethysmography-type sensor, installed in the participants' ear lobe, and visualized through the interface projected on the computer screen for self-modulation of breathing.

The control consisted of performing a computerized activity without self-monitoring, aiming to maintain blinding between the groups. To this end, the online application Jigsaw Puzzles was defined, which consists of a puzzle with various levels of difficulty and was performed on a tablet.

Each professional participated of the study developing nine sessions. In the first meeting (t0), the baseline HRV measurement was performed and in the eight subsequent meetings (t1 to t8) computerized activities without self-monitoring, lasting ten minutes per session. Likewise, EmWave Plus Pro® was used, being installed in the participants' ear lobe, without the participant seeing the interface projected on the computer screen.

Equipment was cleaned with a cloth moistened with 70% isopropyl alcohol, immediately before and after the activity with each participant.

Blinding was considered so that participants did not know whether they were participating in the intervention group or the control group. The instruments for data collection were self-applied, being delivered to participants in a brown envelope, collected on a date defined between the researched and the researcher and submitted to double typing of data in Excel spreadsheets.

Due to the restriction of research assistants, due to the pandemic, and the peculiarity of the activities in the groups, it was not possible to blind the researchers and assistants who performed them. All research team members were duly trained, aiming to maintain the homogeneity of the approach, guidelines and implementation of the proposed intervention.

Blinding was considered in data analysis. To this end, prior to the statistical consultation, the intervention and control group databases were unified and coded regarding the allocation of participants. Data were analyzed using the SPSS statistical package, version 20.0. The distribution of continuous variables was assessed for normality using the Shapiro-Wilks test. Normally distributed variables were compared using Student's t test and, in case of

asymmetry, they were compared using the Mann-Whitney test. In comparing proportions, Pearson's chi-square or Fisher's exact test was applied.

To assess the effect of the intervention, considering that the measurement took place in two moments, we used ANCOVA analysis of covariances, with Bonferroni adjustment (post-hoc), considering the variation (delta) as the outcome (post-intervention assessment subtracted from the pre-intervention assessment). and adjusted by the respective baseline measurements. The effect size was verified through the partial eta squared(h^2 - variance ratio associated with an effect).

Variation analysis (delta) allowed us to verify the effect of the intervention on the individual variation (intra groups) of coping levels between the two measurement moments: t8-t0. Finally, the variation and comparison between groups made it possible to verify the group versus time interaction.

This study was conducted in accordance with the ethical principles of research involving human beings. It is linked to a matrix project, proposed by the Interdisciplinary Group of Occupational Health (*GISO - Grupo Interdisciplinar de Saúde Ocupacional* - UFRGS), having been registered in Clinical Trials, under the name Biofeedback Effects on Stress, Anxiety, and Quality of Professional Life on Nursing Staff of an University Hospital, under identification NCT04446689. It was approved by the Research Ethics Committee of the HCPA, under CAEE (*Certificado de Apresentação para Apreciação Ética* - Certificate of Presentation for Ethical Consideration) 23346619.0.0000.5327 and Opinion 3.796.246.

Results

We recruited 168 nursing professionals who had symptoms of stress. However, 40 professionals were excluded due to the need to reallocate between sectors, leave and leave the institution. A total of 128 professionals were randomized into the intervention group (IG) and control group (CG), there was a loss of follow-up of six participants in the IG and seven participants in the CG. Therefore, 115 nursing professionals were effectively analyzed. The details are in the flowchart of participant involved in the study (Figure 1), constructed according to CONSORT.

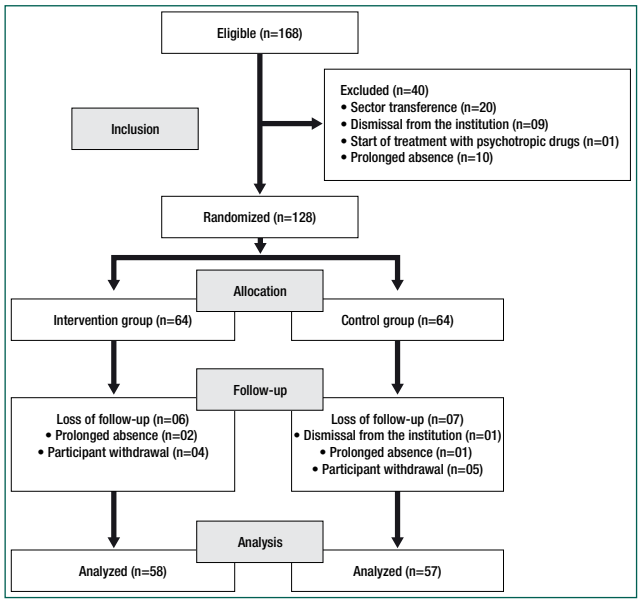

Figure 1. Flowchart of participants involved in the study according to CONSORT

Table 1 presents the description of participants according to sociodemographic, work and health data. It is noteworthy the non-observance of a statistically significant difference between the groups ($p>0.05$), characterizing homogeneity in the sample.

Table 2 presents the mean pre-intervention (t0) and post-intervention (t8) coping level and the time/group interaction (t8-t0) variation. This, in order to present the effect of the intervention on levels of coping in the groups (IG and CG).

The results showed that the Coping Responses variation, in the group/time interaction, had a statistically significant effect ($F(2, 112) = 8.73$, $p = 0.004$) and small effect size ($h^2 = 0,07$). CG showed an increase of 0.17 points in this variation when compared to the IG (95% CI 0.06 - 0.29; p=0.004). The Avoidance Responses variation, for group/time interaction, did not present a statistically significant effect ($F(2, 112) = 0.52$, $p = 0.471$;$h^2 = 0.05$). CG showed an increase of 0.04 points in this variation when compared to the IG (95% CI: -0.07 – 0.15; p=0.471). Also, in the group/time interaction, the results of the OCL variation did not present a sta-

Table 1. Sociodemographic, work and health characterization of participants

Characteristics	Intervention group (n=58)	Control group (n=57)	p-value
Age (years)*	42.2±7.5	44.1±9.3	0.235
Sex (female)**	47(81.0)	52(91.2)	0.190
Professional category**			0.993
Nurse	23(39.7)	22(38.6)	
Nursing assistant	9(15.5)	9(15.8)	
Nursing technician	26(45.6)	26(44.8)	
Shift**			0.923
Morning	18(31.0)	21(36.8)	
Afternoon	22(37.9)	19(33.3)	
Night	13(22.4)	12(21.1)	
Intermediate	5(8.8)	5(8.8)	
Time in nursing (years)*	16.8±6.7	18.3±7.8	0.259
Single employment relationship**	50(86.2)	46(80.7)	0.587
Follow-up for psychological/mental health**	12(20.7)	15(26.3)	0.623
Regular use medication**			0.653
Antihypertensive drug(s)	6(10.3)	10(17.5)	
Psychotropic drug(s)	11(19.0)	11(19.3)	
Beats per minute (bpm)*	81±1.5	79±1.3	0.257
Performs physical activity**	29(50.0)	24(42.1)	0.508
Smoker**	6(10.3)	8(14.0)	0.749
Time of sleep in 24 hours*	6.6±1.5	6.8±1.4	0.299
Consumption of stimulant drink (300 ml or more per day)**	46(79.3)	41(71.9)	0.481

*Mean + standard deviation - t test; ** Absolute and relative frequency (%) - Chi-square. There was no significant difference at p<0.05 between IG and CG.

Table 2. Description of the mean pre-intervention (t0), post-intervention (t8) and variation of time/group interaction (t8-t0) in the IG and CG

Coping Responses Inventory	Group p-value	t0*	t8*	Variation (t8-t0)**
Coping Responses	IG	1.66 ± 0.28	1.61 ± 0.35	-0.05 ± 0.40
	CG	1.77 ± 0.44	1.84 ± 0.37	0.07 ± 0.32
	p	0.106	0.001	0.004
Avoidance Responses	IG	0.91 ± 0.33	0.90 ± 0.35	-0.01 ± 0.31
	CG	1.02 ± 0.33	1.00 ± 0.33	-0.02 ± 0.31
	p	0.081	0.113	0.471
Overall Coping Level	IG	1.26 ± 0.21	1.26 ± 0.29	-0.01 ± 0.16
	CG	1.43 ± 0.29	1.42 ± 0.28	-0.01 ± 0.15
	p	0.001	0.002	0.786

Data presented as mean + standard deviation; *t test; **ANCOVA; IG - intervention group; CG – control group; p – statistical significance at p<0.05 level between groups (IG and CG)

tistically significant effect ($F(2, 112) = 0.07$, p = 0.786; $h^2 = 0.001$). CG showed an increase of 0.01 points in the coping level variation when compared to IG (95% CI: -0.05 – 0.07; p=0.786).

Discussion

The effect of the intervention with cardiovascular biofeedback in improving the levels of coping of nursing professionals working in hospital sectors could not be sustained through the IRC-T. It was evidenced that, in the group/time interaction, the Coping Responses variation showed an increase of 0.17 points in CG (placebo), but with a small effect size ($h^2 = 0.07$; p=0.004). The Avoidance Responses variation and OCL showed no statistically significant effect on group/time interaction as well as small effect sizes (respectively, $h^2 = 0.05$; p=0.471 and $h^2 = 0.001$; p=0.786).

Such results are in agreement with a quasi-experimental study carried out with 32 undergraduate nursing students who underwent four weeks of cardiovascular biofeedback training. It was evidenced, in the group/time interaction, that IG significantly increased the perceived coping ability (^{F}=12.78, p<0.001) compared to CG participants.[7] It is important to highlight that, in addition to the peculiarities of the populations and instruments used, nursing students in CG were not submitted to any placebo activity.

The placebo effect, attributed to the expectation of cure, must be considered. Even not knowing the allocation group, when participating in an intervention study, which by its nature is intended to treat, participants feel recognized and cared for, which consequently causes a change in emotional state. Fact that may contribute to the improvement or not of the outcome under assessment.[14]

This fact was corroborated in this study. CG, submitted to placebo activity, showed a statistically significant improvement in coping level for Coping Responses, although with a small effect size.

It is considered that providing opportunities for recreation activities that involve entertainment and the use of manual skills may have potentiated the effect of relaxation in professionals. Triggering positive reassessment coping responses to the stressful work situation or event. Positive reappraisal, a subcategory of Coping Responses of IRC-T, has been identified as one of the main emotion-focused coping strategies used by nursing professionals.[15]

Although it is not directly focused on solving the problem, the positive reappraisal is directed towards an internal source of stress, making it possible to re-signify the situation in a positive way or to create

emotional strategies that alleviate the experience of a stressful situation. This is evidenced in the scientific literature as an important strategy for recovering balance and emotional strengthening, a step prior to logical reasoning and decision-making.[16,17]

It should be noted that Coping Responses had higher averages than Avoidance Responses. Corroborating studies carried out with intensive care and emergency nursing teams, showed that when work requires high psychological demands, the use of coping responses, especially positive reassessment and guidance/support, provide better adaptation to the work context and rapid recovery of satisfaction and well-being, minimizing the risk of illness for nursing professionals. [17,18]

It is noteworthy that mindfulness, meditation and respiratory modulation interventions, such as cardiovascular biofeedback, require the development of self-awareness and self-control to acquire coping skills. Progressively, physiological responses improve, whose benefits tend to be more effective and lasting in maintaining homeostasis and psycho-emotional health at work.[19]

Authors reported, in a case study on a professional athlete who had problems with high emotionality, that after being submitted to a specific protocol of therapy with biofeedback, he showed significant improvement in relation to coping to control body functions. Thus, decreased anxiety, emotional control and increased perception of overall well-being, resulting in better performance in training and competitions.[20]

In this way, the subjective and multidimensional character of coping is highlighted, being influenced by personality characteristics, family and social factors, as well as the environment and labor relations, which are difficult to measure and control in population studies. It must be considered that, even without statistical significance, the reduction in coping levels, especially in the Coping Responses subcategory in the IG, may be linked to the peculiar moment in which the research was carried out, which was conducted during the work shift of nursing professionals who, although they were not working in direct care for patients with COVID-19, were experiencing uncertainties, interference and impact of the pandemic emotionally on their institutional routine.

In this regard, some limitations were identified, such as the impossibility of individualizing the controlled frequency and/or resonant frequency for guided deep breathing training, in view of conducting the study in accordance with the methodological assumptions, which advocate standardization of activities to minimize biases in the research. As well as a resource for measuring limited coping and logistics of sessions that did not occur successively.

Conclusion

Intervention with cardiovascular biofeedback did not demonstrate a superior effect than placebo in improving coping levels, assessed through the IRC-T categories. Although with a small effect size, CG showed a statistically significant increase in coping levels in the Coping Response category when compared to IG. The Avoidance Responses variation and the OCL did not show a statistically significant effect on the group/time interaction.

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Collaborations

Antoniolli L, Macedo ABT, Vega EAU, Pinheiro JMG, Tanaka AKSR and Souza SBC contributed substantially to data conception and design or analysis and interpretation, article writing or relevant critical review of the intellectual content and final approval of the version to be published.

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