Flower therapy and perceived stress in primary health care nursing professionals: randomized clinical trial

Terapia floral e estresse percebido em profissionais de enfermagem da atenção primária: Ensaio clínico randomizado

Terapia floral y estréspercibidoenprofesionales de enfermería de atención primaria: ensayo clínico aleatorizado

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ABSTRACT

Objective: To analyze the effectiveness of Bach flower therapy compared to placebo in reducing perceived stress levels in primary health care nursing professionals.

Method: Pragmatic, parallel randomized clinical trial conducted with 87 primary care nursing professionals with self-identified stress, from October 2021 to June 2022, in the cities of Osasco and São Paulo, Brazil. The intervention group (n=43) received the collective flower formula, and the placebo group (n=44) received only the diluent. Data analysis was performed using the linear mixed model, and effect size was measured by partial Eta squared, significance level 5%.

Results: Data analysis showed a significant reduction in perceived stress levels within groups (p=0.038). However, there was no significant difference between the study groups (p=0.750). Participants in the intervention group reported a greater perception of changes than participants in the placebo group, but without statistical significance (p=0,089).

Conclusion: The floral formula was not more effective than the placebo formula in reducing perceived stress. There was a significant stress reduction among nursing professionals in both study groups, although with a small effect size.

Descriptors: Nursing. Flower essences. Stress psychological.

RESUMO

Objetivo: Analisar a efetividade da terapia floral de Bach em relação ao placebo na redução dos níveis de estresse percebido em profissionais de enfermagem da atenção primária à saúde.

Método: Ensaio clínico randomizado pragmático, paralelo, realizado com 87 profissionais de enfermagem da atenção primária com estresse auto identificado, dos municípios de Osasco e São Paulo, de outubro de 2021 a junho de 2022. O grupo intervenção (n=43) recebeu a fórmula floral coletiva e o grupo placebo (n=44) recebeu apenas o diluente. A análise de dados foi realizada pelo modelo linear misto e o tamanho do efeito foi medido pelo Eta quadrado parcial; nível de significância 5%.

Resultados: A análise dos dados mostrou que houve redução significativa nos níveis de estresse percebido intragrupos (p=0,038), porém não houve diferença significativa entre os grupos de estudo (p=0,750). Os participantes do grupo intervenção referiram maior percepção de mudanças do que os participantes do grupo placebo, mas sem significância estatística (p=0,089).

Conclusão: A fórmula floral não foi mais efetiva do que a fórmula placebo na redução do estresse percebido. Houve redução significativa do estresse nos profissionais de enfermagem em ambos os grupos de estudo, embora com tamanho de efeito pequeno.

Descritores: Enfermagem. Essências florais. Estresse psicológico.

RESUMEN

Objetivo: Analizar la eficacia de la terapia con florales de Bach em relación con el placebo en la reducción de los niveles de estrés percibido en profesionales de enfermería de atención primaria de salud.

Método: Ensayo clínico aleatorizado pragmático, paralelo, realizado con 87 profesionales de enfermería de atención primaria con estrés auto autoidentificado, de octubre de 2021 a junio de 2022, en las ciudades de Osasco y São Paulo. El grupo intervención (n=43) recibió la fórmula floral colectiva y el grupo placebo (n=44) recibió solamente el diluyente. El análisis de los datos se realizó por modelo lineal mixto y el tamaño del efecto se midiópor Eta-cuadrado parcial, nivel de significación 5%.

Resultados: El análisis de los datos mostró que hubo una reducción significativa en los niveles de estrés percibido intragrupo (p=0,038), sin embargo, no hubo diferencias significativas entre los grupos de estudio (p=0,750). Los participantes del grupo intervención informaron una mayor percepción de los cambios que los del grupo placebo, pero sin significación estadística (p=0,089).

Conclusión: La fórmula floral no fue más eficaz que la fórmula placebo para reducir el estrés percibido.Hubo una reducción significativa del estrés en los profesionales de enfermería en ambos grupos de estudio, aunque con un tamaño del efecto pequeño.

Descriptores: Enfermería. Esencias florales. Estrés psicológico.

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■ INTRODUCTION

Primary Health Care (PHC) is the upholder of public health systems in several countries, especially developing ones like Brazil. It is the main entry point for users to the health system, the communication center of the health care network, the coordinator of care and the organizer of the actions and services available in the network[1]. PHC is responsible for health promotion, disease prevention, and care for approximately 90% of all health problems[2,3].

The PHC work environment is highly conducive to the development of stress among workers at this level of care due to their specific demands, tasks and skills required for serving the population[4]. Studies show that PHC nursing professionals experience high levels of stress, which can lead to the development of physical and mental health problems, in addition to decreased work capacity and a worsening of these workers' quality of life. Individuals with high levels of stress are at greater risk of developing Burnout syndrome, anxiety and depression[4,5]. Although during the peak of the COVID-19 pandemic, international scientific literature extensively addressed stress and burnout in nursing and medical professionals in hospitals, the phenomenon in PHC workers[4,5] was little investigated, and there is a knowledge gap regarding interventions that could provide psycho-emotional comfort to these professionals.

Among the strategies that could contribute to coping with stressful situations of nursing professionals, integrative and complementary health practices (PICS) stand out, such as reiki, meditation, aromatherapy, flower therapies and others[6]. This study focused on Bach flower therapy.

Bach flower therapy was systematized by the English homeopathic physician Edward Bach in the 1930s[7] and consists of 38 flower essences, which are natural liquid extracts of flowers and plants, odorless and highly diluted, intended to balance emotional problems[8]. Its use has been recognized and recommended by the World Health Organization since 1956, and has been regulated for use in the Brazilian Unified Health System by the National Policy of Integrative and Complementary Health Practices (*Política Nacional de Práticas Integrativas e Complementares em Saúde*) – PNPIC since 2018[8]. The mechanism of action of floral essences is still unknown, but one of the explanations would be their action through nanoparticles, very small physical substrates that carry information of flowers, with the ability to move through the body via the bloodstream or lymphatic system, and cross cell membranes, being able to perform its function within the cell[9,10].

There is no consensus in the literature regarding the effectiveness of Bach flower therapy and recent studies that used floral essences to reduce stress are scarce. A research conducted with Brazilian teachers from basic education showed significant results in reducing stress measured by Vasconcelos' list of signs and symptoms[11]. A randomized clinical trial with nursing students that aimed to assess the effectiveness of a floral formula in reducing stress did not find significant results when comparing the intervention group with the placebo group evaluated by the Baccaro Test[7]. None of these studies included PHC nursing workers.

The justification for this work is based on the importance of primary care for the country's health system and the need to contribute to the well-being and relief of high levels of stress among nursing professionals, in addition to the search for measurement instruments that better fit to evaluate the effect of flower therapy and in the absence of consensus on the results obtained in the few studies of flower therapy in reducing stress. The objective of this study was to analyze the effectiveness of Bach flower therapy in reducing levels of perceived stress in primary health care nursing professionals, and the hypothesis is that Bach flower therapy is effective in reducing perceived stress in these professionals.

■ METHOD

Study design

This is a randomized, parallel, two-arm, double-blind, placebo-controlled clinical trial. The study followed the CONSORT (Consolidated Standards of Reporting Trials) recommendations for reporting clinical trials[12] and is part of the doctoral thesis entitled "Effectiveness of Bach flower therapy in reducing stress in primary health care nursing professionals: A clinical trial".

To bring the study closer to the daily lives of individuals, we opted for a pragmatic clinical trial, which allows for a population sample with less restrictive characteristics. Unlike explanatory trials, pragmatic trials aim to ensure that the population studied resembles the population to which the intervention will be applied. Furthermore, interventions are more flexible and subject to modification, and the outcomes studied tend to have clinical relevance for research participants[13].

For the sample calculation, information was used from the study that assessed the effect of Bach flower therapy in reducing teachers' stress using the Perceived Stress Scale[11].

Considering the effect size of the longitudinal difference f = 1.88, and for an effect of this magnitude to be declared significant with type I and II errors of 5%, test power of 80% and confidence interval of 95% in a model of ANOVA for repeated measures, it would be necessary to observe at least nine participants in total with all measurements. However, for greater robustness of the study, it was decided to try to reach 50 participants in each study group.

The sample consisted by nurses, nursing assistants and technicians. Professionals who self-identified as stressed, who had worked at the institution for at least six months and agreed to participate in the research and use the formula as indicated were included. Professionals with self-reported alcohol abuse (due to the alcohol preservative in the formulas), who were on vacation or away from their duties and using other integrative practices during the data collection period were excluded to avoid bias in PICS valuation.

A total of 113 nursing professionals completed the electronic questionnaire for participation. From these, 26 did not participate in the study, two because they did not meet the inclusion criteria (removed from their duties due to medical leave) and 24 due to withdrawal before completing the initial electronic questionnaire, resulting in a sample of 87 participants randomized between groups: 44 (51%) in the placebo group (PG) and 43 (49%) in the intervention group (IG) (Figure 1). Participants who voluntarily abandoned the study after receiving the bottle were considered losses. The losses were not replaced during the study.

The study was conducted at Basic Health Units (BHUs) in the city of Osasco (SP), Brazil, and at the Geraldo de Paula Souza School Health Center (CSEGPS), in São Paulo (SP), Brazil. The invitation was sent to all BHUs in Osasco, but there was interest in participation from employees of only 32 of the 40 BHUs in the city. The CSEGPS was included in an attempt to reach the proposed sample for the study. Data was collected from October 2021 to June 2022.

In the city of Osasco, the invitation to participate was made by nursing coordinators to PHC nursing professionals via the WhatsApp® application in the working group. The message included an explanatory video about the project, inviting professionals who felt stressed to participate in the research, and the link to the electronic questionnaire with intention to participate, containing contact details and questions regarding eligibility criteria. At CSEGPS, the invitation was made during the team meeting, where the researcher explained the objectives of the study to professionals, the eligibility criteria, clarified doubts and distributed leaflets

with a QR code to access the electronic questionnaire on intention to participate.

Eligible participants received via WhatsApp® the initial electronic questionnaire containing the bio-sociodemographic and professional instrument and the Perceived Stress Scale (PSS-14). When clicking on the access link to this questionnaire, participants were automatically directed to the Informed Consent Form page. The instruments could only be accessed by agreeing to participate in the study, choosing the option "I agree to voluntarily participate in the research".

The bio-sociodemographic and professional instrument had information about age, gender, marital status, number of children, professional category, education level, time since nursing training, time of nursing work and expected outcome using the formula received.

The PSS-14 is an adaptation of the Perceived Stress Scale that measures the degree to which individuals perceive situations in their lives as unpredictable, uncontrollable and overwhelming. The instrument was validated in Brazil with an internal consistency of 0.82 measured by Cronbach's alpha. Since it does not contain context-specific questions, the PSS-14 can be applied to different age groups to measure stress. The scale consists of 14 items on a zero to four-point Likert scale. The sum of scores ranges from zero to 56 and can be analyzed categorically with five score ranges: < 18 = low stress; 19-24 = normal stress; 25-29 = moderate stress; 30-35 = high stress and > 35 = very high stress[14]. It is important to highlight that, as this is a pragmatic clinical trial and the inclusion criterion is self-identified stress, participants were included in the study even if they were classified as low or normal stress by the PSS-14.

Participants received an identification number, and the randomization list was created in the Research Randomizer software, distributing participants to the IG or PG, in a 1:1 allocation. To ensure blinding in both randomization and packaging of the bottles, these processes were carried out by an independent researcher who did not have an active role in the application of the data collection instruments or in the distribution of the bottles. Neither the participants nor the researcher were aware whether the bottle they received contained the placebo formula or the floral formula.

The IG received the floral formula composed of two drops of Cherry Plum, Elm, Hornbeam, Olive, Star of Bethlehem, Walnut and White Chestnut essences, diluted in a vehicle composed of mineral water and 30% brandy. Seven essences were used, the maximum number recommended by the Bach Center[15]. The PG received the placebo formula, an
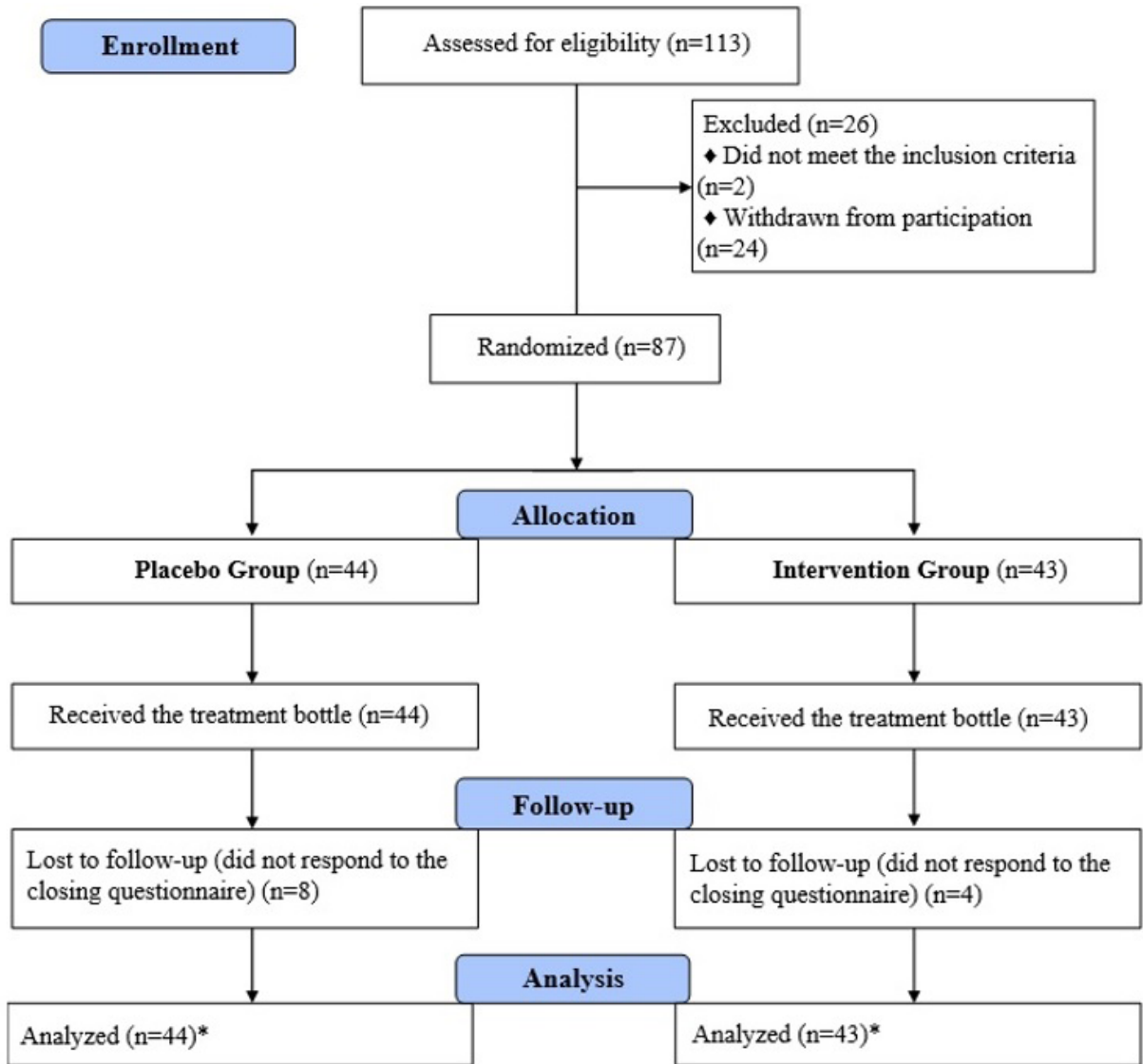
Figure 1 – Flowchart of the clinical trial according to CONSORT. São Paulo, Brazil, 2022
Source: Research data; 2022.

inert vehicle composed of mineral water and 30% brandy, with the same appearance and flavor as the IG. Both the floral formula and the placebo formula were designed and prepared by researchers, both with academic training and experience working as Bach flower therapists.

In the floral formula composition, factors that may be perceived by nursing professionals as stressful were considered.

Cherry Plum was indicated to restore self-control, lucidity and mental clarity, elements that may be compromised during periods of stress. Elm brought the ability to deal with the feeling of overload caused by the responsibilities of personal and professional life. For physical and mental exhaustion, Hornbeam and Olive essences were recommended. Hornbeam provides strength, vitality and freshness

to the mind, and restores pleasure in the daily routine, while Olive acts on exhaustion and depletion, bringing energy to the body and mind. The Star of Bethlehem essence was recommended for possible traumas, losses, and grief that professionals faced during the pandemic period, as it "comforts and mitigates pain and sadness". White Chestnut was included to alleviate excess worries due to the excessive demands of personal and professional life, restoring mental tranquility and discernment, and contributing to improving the quality of sleep. Walnut essence is useful for professionals dealing with emotionally disturbed individuals or who may be emotionally drained, such as therapists and healthcare professionals, as it provides constancy and protects the individual from unwanted external influences[15,16].

The bottle delivery was carried out at the participant's workplace, mostly via delivery service, and a few deliveries were made by the researcher. Instructions for use and storage were sent after bottle delivery, through a document in PDF format sent via WhatsApp®. The recommended dosage was four drops, four times a day, every day, for four weeks. Researchers contacted the participants via WhatsApp® weekly to answer questions, check their adaptation to the treatment and address any needs.

After the treatment period, participants received the electronic closing questionnaire via WhatsApp®, containing the PSS-14 and the final assessment instrument, containing questions about treatment adherence, perception of the study group in which they were allocated, and the perception of change attributed to the use of the formula received.

For sample characterization, descriptive measures of absolute and relative frequencies, and central tendency and variability were used. To compare the groups regarding their homogeneity, the Chi-square or Fisher's exact tests were used for qualitative variables and the Student's t-test for quantitative variables. Data normality was verified by quantile-quantile plot (Q-Q plot).

To evaluate the intervention, linear mixed model (LMM) analysis was used by time and group. This analysis follows the intention-to-treat principle (ITT), that can flexibly model the effects of time, uses all available data and is not affected by losses during follow-up[17]. Therefore, even with participant loss, the LMM analysis allowed the inclusion of individuals who did not complete the study, and data from all participants who met the eligibility criteria and received the bottle were included in the data analysis.

The effect size (ES) was measured by partial Eta square (η^2) and presented according to the classification: 0.01 – small ES; 0.06 – medium ES; 0.14 – large ES[18]. The significance level adopted was 5%. The analysis was performed by a statistician and the software used was R®Studio version 4.2.2.

The project was authorized by the co-participating institutions and approved by the Research Ethics Committees of the School of Nursing of the *Universidade de São Paulo* with opinion No.5,489,450 (CAEE 46333421,1,3003,5421). Its execution complied with the guidelines recommended by Resolution No. 466/2012, and the guidelines of the National Research Ethics Council for data collection in a virtual environment and the General Data Protection Law 13,709/2018. All personal data were anonymized. To ensure information security and reduce the possibility of unauthorized access, all questionnaires were removed from the virtual environment after data collection. The study was approved and published in the Brazilian Clinical Trials Registry (ReBEC) under the code RBR-4wzz4xy.

◼ RESULTS

Bio-sociodemographic and professional characterization

The sample consisted of 92% (n=80) of women, with a mean age of 44.7±9.3 years, 57.5% (n=50) married or in a stable union, with an average of 1.6 ±1.2 children. Regarding professional category, 70.2% (n=61) of the participants were technical level professionals, with an average of 14.8±8.0 years since graduation and 8.3±7.7 years of work in nursing.

Regarding expectations with the use of the formula, 13 (14.9%) participants expected a slight improvement, 35 (40.3%) a moderate improvement, 13 (14.9%) a complete improvement and 26 (29.9%) did not know what to expect from the treatment. No participant reported expecting "no improvement" with the use of the formula.

Table 1 shows the sociodemographic and professional profile and treatment expectations of the participants, by study group.

The groups started the study with an average of 31.1±8.2 points on the PSS-14, classified as high stress, and in the PG there was greater variability in the minimum and maximum values, but the groups were homogeneous (Table 2).

Table 1 – Profile of nursing professionals and treatment expectations by study group(n=87). São Paulo, Brazil, 2022

Variable	Categories	PG		IG		p-value
		n (44)	%	n (43)	%	
Age group	23 –| 30	-	-	3	7.0	0.154§
	30 –| 40	14	31.8	13	30.2	
	40 –| 50	15	34.1	20	46.5	
	50 –| 60	11	25.0	6	14.0	
	60 –| 68	4	9.1	1	2.3	
Gender	Female	41	93.2	39	90.7	0.672¶
	Male	3	6.8	4	9.3	
Marital status	Single	7	15.9	13	30.2	0.178§
	Married/Stable Union	27	61.4	23	53.5	
	Divorced	7	15.9	7	16.3	
	Widowed	3	6.8	-	-	
Number of children	0	8	18.2	10	23.3	0.973§
	1	13	29.5	14	32.5	
	2	13	29.5	11	25.5	
	3	6	13.6	6	14.0	
	4	3	6.9	2	4.7	
	5	1	2.3	-	-	
Education level	High School	20	45.4	23	53.5	0.611¶
	Higher Education	12	27.3	8	18.6	
	Lato Sensu	12	27.3	12	27.9	
Professional category	Assistant	5	11.3	2	4.6	0.150¶
	Technician	23	52.3	31	72.1	
	Nurse	16	36.4	10	23.3	

Table 1 – Cont.

Variable	Categories	PG		IG		p-value
		n (44)	%	n (43)	%	
Time since nursing graduation (years)	0 –| 5	5	11.4	10	23.3	0.245¶
	5 –| 10	6	13.6	5	11.6	
	10 –| 15	15	34.0	7	16.3	
	15 –| 20	9	20.5	13	30.2	
	20 –| 32	9	20.5	8	18.6	
Time working in nursing (years)	0 –| 5	25	56.8	21	48.8	0.818§
	5 –| 10	3	6.8	2	4.7	
	10 –| 15	8	18.2	12	27.8	
	15 –| 20	5	11.4	6	14.0	
	20 –| 37 *	3	6.8	2	4.7	
Expectation	I don'tknow	13	29.5	13	30.2	0.452¶
	No improvement	-	-	-	-	
	Slightimprovement	9	20.5	4	9.3	
	Moderate	17	38.6	18	41.9	
	Complete	5	11.4	8	18.6	

Source: Research data; 2022.
¶Chi-square test; §Fisher's exact test; *Participant probably started in nursing as an attendant, given the maximum time spent in nursing training was 32 years.
PG = placebo group; IG = intervention group

Table 2 – Central tendency and variability measures of the PSS-14 scale of nursing professionals, by study group, before intervention (n=87). São Paulo, Brazil, 2022

	Group	n	Mean	SD	Median	Minimum	Maximum	p-value*
PSS-14	PG	44	30.4	8.9	28.0	8.0	50.0	0.485
	IG	43	31.7	7.5	31.0	16.0	45.0	

Source: Research data; 2022.
* Student t-test
PSS-14 = Perceived Stress Scale; PG = placebo group; IG = intervention group; SD = standard deviation

The reliability of the PSS-14 measured by Cronbach's alpha in this study was 0.898.

A total of 75 individuals completed the study and filled out the closing questionnaire. Regarding the use of the formulas, 10.7% of participants (n=8) used them as directed less than twice a week, 45.3% (n=34) used them as directed three to four times a week and 44.0% (n=33) used it as guided five to seven times a week. Regarding the perception of the study group, 64.0% of participants (n=48) believed they were in the IG, 29.3% (n=22) in the PG and 6.7% (n=5) were unable to state it. When asked about their perception of changes with the treatment, 62.7% of participants (n=47) noticed changes in stress and 37.3% (n=28) reported not noticing changes. When analyzing the perception of change by study group, it was observed that there was a greater proportion of participants who perceived changes in the IG than in the PG, but without statistical significance (Table 3).

Outcome

There was no significant difference in levels of perceived stress between the study groups (Table 4). The PSS-14 score decreased in both groups and based on the categorical classification, there was a reduction from high stress to normal stress at the end of the intervention, with a small effect size (partial $\eta^2 = 0.001$). However, there was a statistically significant reduction in PSS-14 intragroup values, with a small ES (partial $\eta^2 = 0.057$).

Table 3 – Use of the formula as indicated, perception of the study group and perception of change among nursing professionals, by study group (n=75). São Paulo, Brazil, 2022

Variable	Categories	PG		IG		p-value
		n (36)	%	n (39)	%	
Formula use as indicated	Less than 2 times/week	5	13.9	3	7.7	0.505§
	3 to 4 times/week	14	38.9	20	51.3	
	5 to 7 times/week	17	47.2	16	41.0	
Perception of study group	PG	14	38.8	8	20.5	0.209§
	IG	20	55.6	28	71.8	
	I don'tknow	2	5.6	3	7.7	
Perception of change	Yes	19	52.8	28	71.8	0.089¶
	No	17	47.2	11	28.2	

Source: Reserch data; 2022.
¶Chi-square test; §Fisher's exact test;
PG = placebo group; IG = intervention group.

Table 4 – Analysis of the perceived stress outcome among nursing professionals (n=87). São Paulo, Brazil, 2022

	Group	Moment	n	Mean	SD	95%CI	p-value Moment¶	p-valuegroup: Moment§
PSS-14	PG	Pre	44	30.4	8.9	[27.9; 33.1]	0.038*	0.750*
		Post	36	24.1	9.2	[21.4; 27.3]		
	IG	Pre	43	31.7	7.5	[29.4; 33.9]		
		Post	39	24.5	7.9	[21.9; 26.8]		

Source: Research data; 2022.
*LMM; ¶Intragroup; §Betweengroups.
PSS-14 = Perceived Stress Scale; PG = placebo group; IG = intervention group; SD = standard deviation. CI = confidence interval.

■ DISCUSSION

The profile of the study participants was similar to the nursing profile in Brazil, predominantly composed of female technical level professionals, living with a partner and that have children[19,20]. In the present study, the majority of participants were in the age group over 40 years old, although the rejuvenation of nursing is observed, with a total of 61.7% of workers under 40 years old in the country[20]. This data reflected the time spent training and working in nursing, which was longer than the national profile[20].

Regarding perceived stress, participants started the study with a high level of stress. A study conducted in Brazil showed similar stress results among nursing professionals from the Family Health Strategy in São Paulo, with an average perceived stress in the PSS-14 of 44.3±13.3 for nurses and 39.0±13.7 for nursing assistants[21]. Another study conducted with PHC nurses in the city of Ribeirão Preto, São Paulo, showed that 32% of these professionals had considerable stress levels measured by the Work Stress Scale[4]. High levels of stress in PHC were also reported in studies conducted with nurses in Saudi Arabia, in which 30% of participants presented severe or very severe stress measured by the stress subscale of Depression Anxiety Stress Scales – DASS-21[22], and also in China, where high levels of occupational stress measured by the Chinese Community Nurses Stress Scale were found[23]. Another study conducted with nurses in the United Kingdom showed that the average stress in PHC nurses was higher than that of nurses working in other specialties, including pediatrics, mental health, and oncology. In this study, the average stress assessed by the PSS-14 in PHC nurses was 29.6±8.8 points[24].

PHC presents particular stressors since its work processes differ from those in the hospital sector. The elements that contribute to the increased workload in PHC include: complexity and excessive demands, the overestimated territory, the multiple activities foreseen in the model, excessive working hours, management failures, role ambiguity, the lack of commitment from team members, staff shortage, the lack and precariousness of materials, structure and environment and problems in resolution[25].

Regarding the outcome, the floral formula did not show a significant difference from the placebo formula in reducing stress measured by PSS-14, as both study groups showed a reduction in stress to the normal level. In both groups there was a significant reduction in stress, although the IG participants noticed greater changes resulting from the use of the floral formula.

The effect of a treatment is made up of the sum of the real effect of the intervention and the placebo effect, the latter of which cannot be isolated. More than 35% of patients experience therapeutic effects from placebo treatment. The complexity of the placebo effect is due to its multiple components. The biological mechanisms that cause the placebo effect are modulated by psychological mechanisms, such as social/observational learning and expectation. These mechanisms, in turn, are shaped by social, environmental and contextual factors, such as the therapist-patient relationship and treatment characteristics[26,27]. In the present study, the participants' expectations regarding treatment, perception of the study group in which they were allocated and the perception of change with the use of the received formula were evaluated in an attempt to identify the influence of the placebo effect on the intervention.

Expectation is part of the psychological mechanisms that make up the placebo effect and is essential for its occurrence. The most important aspect of the expected response to treatment is its tendency to self-confirm, and in this study the majority of participants expected some improvement in their stress levels, from slight to complete. The strength of the placebo effect is highly correlated with the magnitude of response expectation[27]. In the present study, none of the participants reported expecting "no improvement" with the bottle they received. This expectation may have influenced both the group perception and the positive perception of the results.

The expectation of a good treatment outcome can cause behavioral changes that increase the probability of this outcome, such as greater adherence to treatment[26], which did not occur in the present study, as less than half of the participants used the formula as guidance, five to seven times a week, which may also have impacted the results obtained. It can be assumed that the busy routine of these professionals, consisting of professional life and domestic tasks, would have interfered with the use of the formulas. Another important point is that, as a pragmatic study, the low adherence of participants during the study reflects the reality of nursing professionals' adherence to this therapy.

At the end of the intervention, most participants in both groups reported believing that they were participating in the research in the IG. One of the reasons that may have influenced participants to this belief was the fact that the bottles were labeled as "treatment bottle" in both groups, which created a bias in the study.

The relationship between the caregiver and the recipient of care is therapeutic and can influence the beliefs,

expectations, and mental state of the participants regarding the health and illness process. The therapist-patient relationship can affect the incidence of signs and symptoms, both by motivating behavioral changes and by impacting psychological mechanisms[26,28]. In the present study, contact between the researcher and participants occurred exclusively remotely, using electronic questionnaires and text messages. Nevertheless, at the end of the research, some participants sent messages thanking them for participation, as they felt "cared for" and "looked after". This sense of welcoming may also have contributed to the development of the placebo effect.

Social/observational learning can also interfere with the outcome. Patients who observed others receiving analgesia experienced a reduction in pain due to the placebo effect[29]. During the intervention, many participants became aware of the research through their colleagues who were already participating, and who were reporting positive results with the use of the formula, which may also have contributed to the manifestation of positive effects even with the use of the formula placebo. The therapeutic ritual of consuming the placebo itself can lead the individual to improve their condition[28].

There is no consensus on the results found in national clinical trials that used flower therapy to reduce stress, and in the international literature there are no references on the use of Bach flower to reduce stress levels. In Brazil, a study conducted with teachers found a significant reduction in stress measured with the List of Signs and Symptoms of Stress[11], however another Brazilian study, conducted with nursing students, did not find significant results in stress reduction measured with the PSS-14[7]. The difference in these results can be explained by the use of individualized formulas in the first study, and the use of a collective formula in the second. Bach flower remedies treat the individual, not the disease and, for this reason, they must be indicated according to the needs of the individual being treated. A condition can be treated by two or more different essences. For fear, for example, the essences Aspen, for baseless fear, or Mimulus for fears with known causes[15,16]. It is up to the therapist to correctly diagnose the individual's condition, so that the best indication can be made for the case. For this reason, individual formulas present better results when compared to collective formulas, despite the ease of using the latter in studies with large samples.

Despite the care taken in design and implementation of the protocol of this study, some limitations need to be presented. As this was a pragmatic clinical trial, self-identification of stress was used as an inclusion criterion; however, not all participants who reported being stressed had a high stress rating on the PSS-14 at the beginning of the study. The use of bottle identification as "treatment bottle" may have contributed to the erroneous perception by the participants that they were participating in the study in the IG, despite the blinding information provided by the researchers. Other important points were the use of the collective formula and the duration of using the floral formula for only four weeks. For these reasons, more intervention research is necessary to determine the effectiveness of flower therapy in reducing stress, without the limitations presented in this study.

In the context in which the study was conducted, it was assumed that regardless of having received the flower formula or placebo, the care received, even from a distant interlocutor, and the possibility of self-analysis, could have influenced the reduction of participants' stress, but showing the fragility of the mental health presented by nursing workers. Another important issue concerns the need for more studies with PHC workers, which, despite being neglected in the literature, is extremely important for the country's healthcare system.

■ CONCLUSION

The floral formula composed of Cherry Plum, Elm, Hornbeam, Olive, Star of Bethlehem, Walnut and White Chestnut essences was not more effective than the placebo formula in reducing perceived stress levels. In the analysis of the intragroup outcome, both the intervention group and the placebo group showed a significant reduction in perceived stress levels, but with a small effect size. However, there was a greater perception of a positive effect of the formula in the intervention group, although without statistical significance.

The literature review showed that this is one of the few studies conducted that evaluates the stress of PHC nursing professionals, and the first focusing on stress and Bach flower therapy in these workers. The research pointed out the fragility of nursing's mental health and the need for interventions by managers to reduce stress levels, aiming to maintain health, increase job satisfaction and provide humanized care that guarantees patient safety. It is recommended that future research explore the use of individualized formulas as opposed to the use of collective formula.

■ REFERENCES

1. Ministério da Saúde (BR). Gabinete do Ministro. Portaria nº 2.436, de 21 de setembro de 2017. Aprova a Política Nacional de Atenção Básica, estabelecendo a revisão de diretrizes para a organização da Atenção Básica, no âmbito do Sistema Único de Saúde (SUS). Diário Oficial União. 2017 set 22 [cited 2023 Jul 10];154(183 Seção 1):68-76. Available from: https://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=22/09/2017&jornal=1&pagina=68&totalArquivos=120

2. Moscovici L, Balco EM, Bolsoni M, Degani NC, Marques JM, Zuardi AW. Associations between primary health care strategies and outcomes of mental disorders. Braz J Psychiatry. 2020;42(4):360-6. doi: https://doi.org/10.1590/1516-4446-2019-0659

3. Pinto LF, Soranz D, Ponka D, Pisco LA, Hartz ZM. 40 anos de Alma-Ata: desafios da atenção primária à saúde no Brasil e no mundo [editorial]. Ciênc Saúde Colet. 2020;25(4):1178. doi: https://doi.org/10.1590/1413-81232020254.01012020

4. Aires Garcia GP, Marziale MHP. Satisfaction, stress and burnout of nurse managers and care nurses in Primary Health Care. Rev Esc Enferm USP. 2021;55:e03675. doi: https://doi.org/10.1590/S1980-220X2019021503675

5. Alyahya SA, Al-Mansour KA, Alkohaiz MA, Almalki MA. Association between role conflict and ambiguity and stress among nurses in primary health care centers in Saudi Arabia during the coronavirus disease 2019 pandemic: a cross-sectional study. Medicine. 2021;100(37):e27294. doi: https://doi.org/10.1097/MD.0000000000027294

6. Pereira EC, Rocha MP, Fogaça LZ, Schveitzer MC. Occupational health, integrative and complementary practices in primary care, and the Covid-19 pandemic. Rev Esc Enferm USP. 2022;56:e20210362. doi: https://doi.org/10.1590/1980-220X-REEUSP-2021-0362

7. Albuquerque LMNF, Turrini RNT. Effects of flower essences on nursing students' stress symptoms: a randomized clinical trial. Rev Esc Enferm USP. 2021;56:e20210307. doi: https://doi.org/10.1590/1980-220X-REEUSP-2021-0307

8. Ministério da Saúde (BR). Gabinete do Ministro. Portaria nº 702, de 21 de março de 2018. Altera a portaria de Consolidação no 2/GM/MS, de 28 de setembro de 2017, para incluir novas práticas na Política Nacional de Práticas Integrativas e Complementares – PNPIC. Diário Oficial União. 2018 mar 22 [cited 2023 Jul 10];155(56 Seção 1):74-5. Available from: https://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=22/03/2018&jornal=515&pagina=74&totalArquivos=190

9. Bell IR, Koithan M. A model for homeopathic remedy effects: low dose nanoparticles, allostatic cross-adaptation, and time-dependent sensitization in a complex adaptive system. BMC Complement Altern Med. 2012;12:191. doi: https://doi.org/10.1186/1472-6882-12-191

10. Fusco SDFB, Pancieri AP, Amancio SCP, Fusco DR, Padovani CR, Minicucci MF, et al. Efficacy of flower therapy for anxiety in overweight or obese adults: a randomized placebo-controlled clinical trial. J Altern Complement Med. 2021;27(5):416-22. doi: https://doi.org/10.1089/acm.2020.0305

11. Pinto RH, Sousa SM, Santos CR, Senna SM, Leal LP, Vasconcelos EMR. Efeito da terapia floral no estresse docente: ensaio clínico randomizado. Rev Min Enferm. 2020;24:e-1318. doi: https://doi.org/10.5935/1415-2762.20200055

12. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c332. doi: https://doi.org/10.1136/bmj.c332

13. Doorenbos AZ, Chae D. Pragmatic clinical trials. J Korean Acad Nurs. 2022;52(5):477-8. doi: https://doi.org/10.4040/jkan.22127

14. Bardaquim VA, Santos SVM, Dias EG, Dalri RCMB, Mendes AMOC, Gallani MC, et al. Stress and cortisol levels among members of the nursing team. Rev Bras Enferm. 2020;73(Suppl 1):e20180953. doi: https://doi.org/10.1590/0034-7167-2018-0953

15. Scheffer M. Terapia floral do dr. Bach: teoria e prática. São Paulo: Pensamento; 1991.

16. Monari C. Participando da vida com os florais de Bach: uma visão mitológica e prática. 6. ed. São Paulo: Acalanto; 2018.

17. Gueorguieva R, Krystal JH. Move over ANOVA: Progress in analyzing repeated measures data and its reflection in papers published in the Archives of General Psychiatry. Arch Gen Psychiatry. 2004;61(3):310-7. doi: https://doi.org/10.1001/ARCHPSYC.61.3.310

18. Espírito-Santo H, Daniel F. Calcular e apresentar tamanhos do efeito em trabalhos científicos (3): guia para reportar os tamanhos do efeito para análises de regressão e ANOVAs. Rev Port Inv Comp Soc. 2018;4(1):43-60. doi: https://doi.org/10.31211/rpics.2018.4.1.72

19. Governo do Estado de São Paulo. Fundação Sistema Estadual de Análise de Dados [Internet]. Entre 2000 e 2020, o número médio de filhos passou de 2,08 filhos por mulher para 1,56.2021 set 16 [cited 2023 Jul 10]. Available from: https://www.seade.gov.br/entre-2000-e-2020-o-numero-medio-de-filhos-passou-de-208-filhos-por-mulher-para-156/

20. Machado MH, coordenadora. Perfil da enfermagem no Brasil: relatório final [Internet]. Rio de Janeiro: Fiocruz; 2017 [cited 2023 Jul 10]. Available from: https://biblioteca.cofen.gov.br/wp-content/uploads/2019/05/relatoriofinal.pdf

21. Leonelli LB, Andreoni S, Martins P, Kozasa EH, Salvo VL, Sopezki D, et al. Perceived stress among Primary Health Care Professionals in Brazil. Rev Bras Epidemiol. 2017;20(2):286-98. doi: https://doi.org/10.1590/1980-5497201700020009

22. Abdoh DS, Shahin MA, Ali AK, Alhejaili SM, Kiram OM, Al-Dubai SAR. Prevalence and associated factors of stress among primary health care nurses in Saudi Arabia, a multi-center study. J Family Med Prim Care. 2021;10:2692-6. doi: https://doi.org/10.4103/jfmpc.jfmpc_222_21

23. Guo H, Ni C, Liu C, Li J, Liu S. Perceived job stress among community nurses: a multi-center cross-sectional study. Int J Nurs Pract. 2019;25:e12703. doi: https://doi.org/10.1111/ijn.12703

24. Kent W, Hochard KD, Hulbert-Williams NJ. Perceived stress and professional quality of life in nursing staff: how important is psychological flexibility? J Context Behav Sci. 2019;14:11-9. doi: https://doi.org/10.1016/j.jcbs.2019.08.004

25. Biff D, Pires DEP, Forte ECN, Trindade LL, Machado RR, Amadigi FR, et al. Nurses' workload: Lights and shadows in the family health strategy. Ciênc Saúde Colet. 2020;25(1):147-58. doi: https://doi.org/10.1590/1413-81232020251.28622019

26. Zion SR, Crum AJ. Mindsets matter: a new framework for harnessing the placebo effect in modern medicine. Int Rev Neurobiol. 2018;138:137-60. doi: https://doi.org/10.1016/bs.irn.2018.02.002

27. Kirsch I. Response expectancy and the placebo effect. Int Rev Neurobiol. 2018;138:81-93. doi: https://doi.org/10.1016/bs.irn.2018.01.003

28. Leibowitz KA, Hardebeck EJ, Goyer JP, Crum AJ. The role of patient beliefs in open-label placebo effects. Health Psychol. 2019;38(7):613-22. doi: https://doi.org/10.1037/hea0000751

29. Bajcar EA, Babel P. How does observational learning produce placebo effects? a model integrating research findings. Front Psychol. 2018;9:2041. doi: https://doi.org/10.3389/fpsyg.2018.02041

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The authors declare that there is no conflict of interest.

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