Journal of Evidence-Based Complementary & Alternative Medicine

J Evid Based Complementary Altern Med. 2017 Jan; 22(1): 18–24. PMCID: PMC5871196
Published online 2015 Oct 11. doi: 10.1177/2156587215610705 PMID: 26456628

Exploring the Effectiveness of External Use of Bach Flower Remedies on Carpal Tunnel Syndrome

A Pilot Study

Saira R. Rivas-Suárez, MD,[1,2] Jaime Águila-Vázquez, MD,[2] Bárbara Suárez-Rodríguez, MD,[2] Lázaro Vázquez-León, MD,[2] Margarita Casanova-Giral, MD,[2] Roberto Morales-Morales, MD,[2] and Boris C. Rodríguez-Martín, PhD[3]

Abstract

Background.

A randomized, pilot, placebo-controlled clinical trial was conducted with the aim of evaluating the effectiveness of a cream based on Bach flower remedies (BFR) on symptoms and signs of carpal tunnel syndrome.

Methods.

Forty-three patients with mild to moderate carpal tunnel syndrome during their "waiting" time for surgical option were randomized into 3 parallel groups: Placebo (n = 14), *blinded* BFR (n = 16), and *nonblinded* BFR (n = 13). These groups were treated during 21 days with topical placebo or a cream based on BFR.

Results.

Significant improvements were observed on self-reported symptom severity and pain intensity favorable to BFR groups with large effect sizes ($\eta^2_{\text{partial}} > 0.40$). In addition, all signs observed during the clinical exam showed significant improvements among the groups as well as symptoms of pain, night pain, and tingling, also with large effect sizes ($\varphi > 0.5$). Finally, there were significant differences between the *blinded* and *nonblinded* BFR groups for signs and pain registered in clinical exam but not in self-reports.

Conclusion.

The proposed BFR cream could be an effective intervention in the management of mild and moderate carpal tunnel syndrome, reducing the severity symptoms and providing pain relief.

Keywords: carpal tunnel syndrome, Bach flower remedies, complementary and alternative medicine

---

Bach flower remedies (BFR) is a complementary therapy that deserves further scientific investigation. Edward Bach was a physician who used highly diluted preparations mainly from many derivatives species of wildflowers in order to help individuals recover their health. This topic had been very controversial, but it could be supported by the new knowledge about nanoparticles and its effects on living systems[1–4] rather than some "unknown healing energy."

Although BFR has showed potentialities for pain management,[5] there is no evidence of its specific action beyond the placebo effect.[6–8] However, recent data suggest that some BFR could have specific effects on inflammation,[9] cardiovascular risk factors,[10] spiritual well-being,[11] and unwanted intrusive thoughts.[12]

In clinical practice, classical selection of the remedy is mostly guided by individuals' mood or their personality traits,[13] but beyond this individualized treatment, there are anecdotic experiences of pain relief among patients with carpal tunnel syndrome (CTS) using a cream based on a BFR combination.[14] Placebo analgesia pathways are well documented,[15–17] and it could result in support for the use of BFR as an ethical self-help placebo.[18–20]

However, uncertainty about treatment allocation in randomized clinical trials could affect both treatment and placebo response.[21,22] On the other hand, in clinical practice patients tend to believe that they receive an "active" treatment, even when they are using a placebo intervention.[21,23] As can be suggested, belief is an amazing healing device,[24] which acts on behavior as a self-fulfilling prophecy.[25] As it has been stated, the contexts involved in randomized clinical trials and clinical practice are quite different.[26] Because of this, our study included a third group in which patients received the intervention as is usual in clinical practice.

CTS is a frequent entrapment neuropathy.[27–30] Primary features of CTS include pain in the hand, unpleasant tingling, pain or numbness in the distal distribution of the median nerve (thumb, index, middle finger, and the radial side of the ring finger), and a reduction of grip strength and function of the affected hand.[27] Surgical and nonsurgical treatments have been suggested for CTS.[31,32] Surgery is usually considered for patients with an experience of conservative treatment failure and those who have severe CTS, while nonsurgical treatments are usually prescribed as an initial option for the patients who suffer from nonconstant symptoms of mild to moderate CTS.[32]

Multiple alternative nonsurgical techniques have been trialed.[30] Complementary and alternative medicine can play an important role as new conservative treatments for CTS.[33–35] Researchers suggest new formats to manage CTS, in order to improve cost-effectiveness using topic treat-

ment applications.[35,36] The topical use of BFR might be a useful resource to many individuals with CTS with the purpose of achieving pain relief. Compared with other alternatives, it is cheap, easy to apply, and entails only a minimal contact with the patients.

The aim of the current pilot study was to evaluate the effectiveness of a cream based on BFR on symptoms and signs of CTS. With the additional aim of assessing the magnitude of the effect caused by the certainness of receiving an intervention, we introduced a *nonblinded* BFR group as is usual in clinical practice.

Methods

Participants

The design consisted of pilot therapeutic interventions in 43 outpatients who were aged between 20 and 89 (mean = 50.90; standard deviation = 13.97), with 93% being females (n = 40). Each individual had been previously diagnosed with CTS (from mild to moderated degree), according to clinical and electrographic criteria. The patients were referred to the Orthopaedic and Rheumatology Services at University Hospital "Arnaldo Milián Castro" with signs and symptoms of CTS for more than 3 months duration. In those with bilateral symptoms, the arm with the most severe symptoms was chosen, and treatment of this arm was randomized.

Every patient had already been treated for symptoms of the CTS without improvements and they were referred to surgical option after been treated conservatively. Physicians invited patients to participate in this study during their "waiting" time for surgical option. The intervention involved outpatients who were randomly allocated into 3 groups: 2 *blinded* groups as is usual in double-blind controlled trials, which were Placebo (n = 14) and BFR (n = 16); and 1 *nonblinded* group, which also received BFR (n = 13) as is usual in clinical practice.

Patients with neurological symptoms and signs suggestive of widespread peripheral neuropathy (such as sensory symptoms in the lower limbs and depressed or absent tendon reflexes) were excluded from the study. The patients were not receiving treatment with non-steroidal anti-inflammatory drugs (NSAID), neither were they subdued to local treatments at least a week before.

The flow of participants through the experiment, including reasons for exclusion, is depicted in Figure 1.

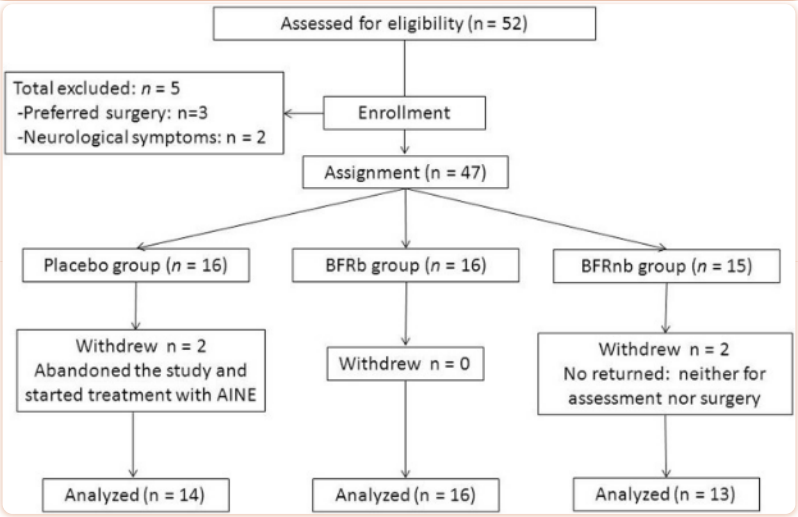

Figure 1.

Consolidated Standards of Reporting Trials (CONSORT) diagram showing the flow of participants through the study. BFRb, *blinded* BFR; BFRnb, *nonblinded* BFR.

Measures

Physician's Report of Signs and Symptoms Clinical exam was employed in order to detect signs of Tinel, Durcan, and Phalen as well as a set of core symptoms (see Table 1). The physician reported the presence or absence of each sign and symptom using a binary code of classification (0 = No or Absence; 1 = Yes or Presence).

Table 1.

Report of Signs and Symptoms During the Baseline Period.

	Positive Reports		PLA	BFRb	BFRnb	$\chi^2(2)$	Sig.	φ
	Freq.	%	Presence/Absence					
Pain	43	100	14/0	16/0	13/0	—	—	—
Night pain	42	97.7	13/1	16/0	13/0	2.121	.346	0.22
Pain after Exercise	39	90.7	14/0	12/4	13/0	7.444	.024	0.41
Pain Hand & Fingers	28	65.1	10/4	11/5	7/6	1.066	.587	0.15
Tingling sensation	42	97.7	13/1	16/0	13/0	2.121	.346	0.22
Numbness	18	41.9	2/12	11/5	11/2	14.878	.001	0.58
Burning	19	44.2	6/8	9/7	4/9	1.903	.386	0.21
Valleix	23	53.5	10/4	11/5	2/11	10.896	.004	0.53
Temperature sensitivity	19	44.2	7/7	10/6	2/11	6.471	.034	0.39
Swelling sensation	32	74.4	12/2	12/4	8/5	2.074	.355	0.20
Thenar atrophy	10	23.3	14/0	11/5	5/8	6.499	.039	0.38
Weakness	31	72.1	13/1	14/2	4/9	15.922	.000	0.61
Tinel	39	90.7	14/0	14/2	11/2	2.200	.333	0.22
Phalen	41	95.3	13/1	15/1	13/0	0.992	.631	0.14
Durcan	41	95.3	14/0	14/2	13/0	3.540	.170	0.28

Abbreviations: PLA, placebo group; BFR, Bach flower remedies; BFRb, *blinded* BFR group; BFRnb, *nonblinded* BFR group.

Patient's Self-Report of Symptom Severity and Daily Pain Intensity

Symptom Severity Scale (SSS) was assessed using the 11 items corresponding to the 11-item subscale of symptom severity from the Boston Carpal Tunnel Syndrome Questionnaire,[37] which is a disease-specific questionnaire referring to a typical 24-hour period in the past 2 weeks.

Visual Analogue Scale of Pain Intensity (VAS) is a daily self-report based on the visual analogue scale.[38,39] The scale was presented as a 10-cm line, anchored by verbal descriptors that follow a Likert-type scale interval, 0 = "no pain" to 10 = "worst imaginable pain." The patients were asked to report their pain intensity every day. Weekly means were calculated during the baseline period (1 week prior to treatment) and during the treatment since the first to third weeks.

Procedure