

Bach flower remedies: a systematic review of randomised clinical trials

Edzard Ernst

Universities of Exeter & Plymouth, Exeter, Devon, United Kingdom

Correspondence:

Professor Edzard Ernst
Complementary Medicine
Peninsula Medical School
Universities of Exeter & Plymouth
25 Victoria Park Road
Exeter EX2 4NT
United Kingdom
Edzard.Ernst@pms.ac.uk

Summary

Bach flower remedies continue to be popular and its proponents make a range of medicinal claims for them. The aim of this systematic review was to critically evaluate the evidence for these claims. Five electronic databases were searched without restrictions on time or language. All randomised clinical trials of flower remedies were included. Seven such studies were located. All but one were placebo-controlled. All placebo-controlled trials failed to demonstrate efficacy. It is concluded that the most reliable clinical trials do not show any differences between flower remedies and placebos.

Key words: *Bach flower remedies; efficacy; systematic review; alternative medicine*

Introduction

“Bach Flower Remedies” (also sometimes called “Flower Essences” or “Flower Remedies”) were invented about 80 years ago by the British physician and microbiologist Dr Edward Bach (1886–1936). Dr Bach became convinced that most human illnesses are caused by negative states of mind (e.g., fear, jealousy, despair). He identified 38 remedies – each based on one native flower which, according to his conviction, would alleviate such negative feelings and thus restore health [1]. Further flower remedies have since been added by Bach’s followers. Dr Bach claimed to treat the whole person in an individualised fashion; two patients afflicted by the same mainstream diagnosis might therefore be treated with two different remedies.

Flower remedies are produced by dropping fresh flowers into water; this yields the “mother tincture” to which brandy is subsequently added as a preservative. Thus

they do not contain pharmacologically relevant amounts of constituents of the flowers they originate from. Flower remedies thus have similarities to homeopathic medicines, yet there are clear distinctions between the two systems [2]. According to proponents of flower remedies, their mode of action does not depend on molecular or pharmacological mechanisms but on the subtle “energy” that is transmitted from the flowers to this remedy [3]. This “energy” has so far defied quantification, and critics therefore argue that flower remedies are pure placebos [4].

Flower remedies have become a thriving business. They are readily available from a wide range of outlets and many consumers strongly believe in their effectiveness. A previously published systematic review of flower remedies by the current author [5] is now outdated. A more recent review was focussed specifically on pain and psychological problems and included only four controlled trials [6]. Another review also only included four randomised clinical trials (RCTs) [7]. It is therefore timely and relevant to conduct an update.

Methods

Systematic searches were carried out on the Medline, Embase, Biosis, Cochrane Library and AMED databases. The search terms used were Bach Flower Remedies, Flower Remedies, Flower Essence and Rescue Remedy. Each database was searched from its inception until January 2002. For the current update, these searches were repeated in May 2010. Manufacturers of such preparations and experts in the field were asked for published or unpublished trials and the bibliographies of all papers were searched for further studies. Finally, several specialised journals and the departmental files were searched by hand for further relevant articles. No language restrictions were applied.

Contrary to previous reviews [5, 6], this update was restricted to RCTs. Non-randomised trials, uncontrolled studies, case reports and case series were excluded [8–13]. RCTs with human subjects were considered regardless of the disease or illness they related to and regardless of the outcome measures or the type of control intervention employed. Studies which were not aimed at testing efficacy

but at other issues (e.g., expectancy) were excluded [14, 15].

Data were validated and extracted by the author according to predefined criteria (table 1). When information was insufficient, the authors of the study in question were approached to obtain more details. Methodological quality was assessed using the Jadad scale [16], which quantifies the likelihood of bias inherent in trials on the basis of their description of randomisation, blinding, and withdrawals; this score ranges from a minimum of 0 to a maximum of 5 points. The validity of the primary trials was estimated on a score ranging from 0 to 3 points (one point was given for a positive answer for each of the three questions: Was the study sample relevant? Was the intervention appropriate? Was the outcome measure suitable?). Due to the statistical and clinical heterogeneity of the primary data, no statistical pooling was performed.

ADHD = attention deficit hyperactivity disorder

VAS = visual analogue scale

Results

Seven RCTs met the inclusion criteria [17–23]. Three of them [17–19] had already been available for the previous systematic review [5] and four had been included in the reviews by Thaler et al. [6] or Halberstein et al. [7]. Figure 1 provides a flow chart of the articles located and included.

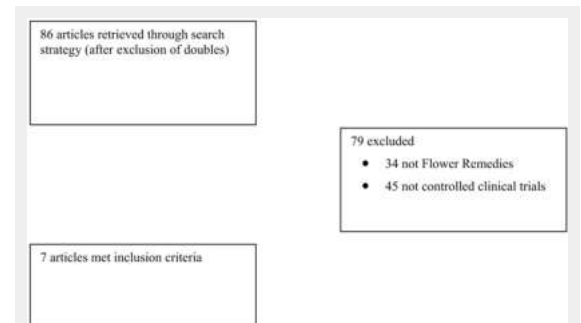


Figure 1

Flow chart of publications.

Table 1
Randomised clinical trials of Flower Remedies (Flower Remedies).

Reference	Study design	Jadad score	Validity score	Sample	Interventions	Main outcome measures	Main result	Comment
von Rühle (1995) [17]	RCT, 3 parallel groups (not placebo controlled, not double-blinded)	2	3	24 pregnant women with overdue births	Individualised flower remedies daily up to date of birth, attention control group (no flower remedies), no such therapies, (all groups had standard care in addition)	Time to birth, type of birth, use of medication during birth, anxiety during birth, well-being	Significantly less medication was used in group A ($p = 0.032$)	Birth was delayed in group A by 5.1 days, in groups B by 6.6 and in group C by 4.4 days
Armstrong (1999) [18]	RCT, double-blind, 2 parallel arms	5	3	100 healthy University students sitting exams	'Rescue Remedy' (1–4 doses during 7 days before and during exams) placebo (same treatment schedule)	Anxiety measured with Spielberger State-Trait-Anxiety Inventory (SSTAI)	No significant differences between groups	Study suffered from high drop-out rate
Walach (2001) [19]	RCT, double-blind, cross-over	5	3	51 healthy students sitting exams	Rescue Remedy (4 drops daily for 2 weeks or more if necessary) placebo (same treatment schedule)	Anxiety measured with Text-Anxiety Inventory	No significant differences between groups	Primary authors conclude that flower remedies are "an effective placebo"
Pintov (2005) [20]	RCT, double-blind, 2 parallel arms	4	3	40 school children with ADHD	A) Rescue Remedy (4 drops 4x per day for 3 months) B) placebo (same treatment schedule)	Performance evaluated by teacher (Conner's questionnaire)	No significant differences between groups	17 drop outs
Toyota (2006) [21]	RCT, double-blind, 2 parallel groups	3	3	40 surgical patients	A) Rescue Remedy in drinking water B) drinking water without Rescue Remedy	Anxiety and tension (VAS)	No significant differences between groups	Write-up is unclear in several aspects
Halberstein (2007) [22]	RCT, double-blind, 2 parallel groups	2	3	111 students under stressful exam situation	A) Rescue Remedy (5 doses during a 3 hour class) B) placebo	Anxiety measured with SSTAI	No significant differences between groups	A subanalysis of high anxiety students favoured A over B
Forshaw (2009) [23]	RCT, single-blind, 3 parallel groups	4	3	62 students under experimental stress	Rescue Remedy (4 drops in water) Placebo (pure water + participants were told that it contained Rescue Remedy) Placebo (pure water + participants were told that it was water)	Stress (VAS)	No significant differences between groups	All groups reported stress reduction regardless of treatment

Key data from the included RCTs are summarised in table 1. The methodological quality of the studies was variable but two scored the maximum of five points on the Jadad scale [18, 19]. All but one RCT [17] were placebo-controlled. The validity score was three in all cases. All but one RCT [17], the one that lacked a placebo group, failed to show significant differences between verum and control groups.

The trial by von Rühle [17] was described by the author as a pilot study. It lacked a placebo group and had a small sample size. Thus its results are not reliable.

The trial by the current author [18] was a randomised, placebo-controlled, double-blind study with a formal sample size calculation. Unfortunately, the drop-out rate turned out to be high. Its results showed no significant effect for flower remedies.

The study by Walach et al. [19] was also rigorously designed with several features similar to our own trial [18]. The main difference was that it had a cross-over design. Its results were almost identical to those of the author's study [18].

Pintov et al. randomised 40 children with attention deficit hyperactivity disorder (ADHD) to receive either Rescue Remedy (4 drops 4 times per day) or placebo for 3 months [20]. The teacher, who was blinded to treatment allocation, evaluated performance with Conner's questionnaire. The results show no significant inter-group differences.

Toyota randomised 40 surgical patients to receive either diluted Rescue Remedies or placebo as premedication before surgery [21]. Anxiety, tension, heart rate and blood pressure showed no difference between the groups. Unfortunately the report is unclear in several respects. The author draws a positive conclusion which is not borne out by the data.

Halberstein et al. randomised 111 student nurses who were exposed to a stressful exam situation into two groups [22]. During a three-hour class, they received five doses of Rescue Remedy or placebo. Anxiety levels did not differ between groups, but a subgroup of exceedingly anxious nurses generated findings that seemed to favour verum over placebo.

Forshaw and Jones randomised 62 students who were submitted to experimental stress into three groups. Group A received four drops of Rescue Remedy in mineral water. Group B received pure mineral water and were told it contained Rescue Remedy and group C drank pure mineral water and were told it was pure water. Stress levels decreased in all groups in a similar manner, and there were no significant treatment effects related to Rescue Remedy [23].

Discussion

The data summarised above confirm that RCTs of flower remedies are possible and demonstrate that several such studies have recently become available. While the previous systematic reviews included three and four RCTs respectively [5–7], the present one is based on seven RCTs. Collectively they fail to produce convincing evidence to suggest that flower remedies are associated with clinical effects that differ from those of placebo.

This systematic review has a number of limitations. Even though the search strategy was comprehensive, there is no certainty that all studies were located. Trials of flower remedies may have been published in journals not listed in electronic databases. Moreover, negative publication bias may have distorted the overall result. It is known that there is a tendency for negative trials to remain unpublished, and journals of alternative medicine publish very few negative results [24]. The paucity of the available data renders the final verdict about the efficacy of flower remedies problematic. Data extraction was only done by one person; the author of this paper. This increases the risk of error and bias in interpreting the findings.

In most countries, flower remedies are marketed not as medicines but as food supplements. Therefore there is no legal requirement to demonstrate efficacy and no health claims are permitted. Yet there is an abundance of literature on flower remedies which does make such claims. Customers are thus attracted to flower remedies with certain expectations, and the question arises whether this has the potential for causing harm to patients. Due to their highly dilute nature, flower remedies are devoid of toxicology. However, flower remedies may be used in cases of severe illness as an "alternative" to effective therapy. In such a scenario, the use of flower remedies could become life-threatening [25].

When professional flower remedy organisations were asked for which indications they would recommend flower remedies [26], they named the following conditions: anxiety/stress, depression, general mental stress, lack of confidence, trauma (emotional and physical), cancer and HIV/AIDS. This systematic review shows that these claims are not based on evidence. Others have stressed that "the basic principles of Bach's theory are settled on ungrounded, deeply intuitive hypotheses, belong to magical thinking, and do promote philosophical approaches that weaken patients-consumers, particularly with regard to sectarian trends" [27]. The implication from the negative clinical evidence and the lack of biological plausibility might be that further research in this area is not warranted.

In conclusion, the most reliable clinical trials of flower remedies available to date fail to show efficacy.

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