

Bach Flower Remedies – An Appraisal of the Evidence Base

Introduction

The system of Bach flower remedies (BFR) was discovered by the English physician Dr Edward Bach in the early twentieth century. By the early 1930s he had completed his discovery of the 38 remedies and recorded their preparation methods and uses.

Dr Bach's interest in developing this system of medicine was grounded in his experience of both conventional medicine and of homeopathy. The system shares similarities with homeopathy (Morrell 2004; van Haselen 1999), inasmuch as both systems being so-called 'energy' medicines and both requiring a holistic approach by the healthcare practitioner in respect of diagnosis and choice of treatment. Put succinctly, BFRs are selected by¹ or for a patient with the intent of addressing issues associated with that person's psyche. In turn, through resultant changes in attitude and awareness, the physical manifestation of illness abates.

Central to Bach's philosophy was the principle that the body should be encouraged to heal itself – use of his remedies merely aided the process. As is true of homeopathy, he supported the notion of using individually selected remedies for a specific patient. The remedies can be used singly or in individually selected combinations usually up to a maximum of 7 or 8. The only pre-mixed combination remedy Bach described was **Rescue™ Remedy**, a specific blend of five Bach flower remedies. This was described as a 'first aid' remedy to be used, for instance, after a shock or other emergency.

Bach practiced medicine well before the rigours of 'evidence-based medicine' were the mantra of modern healthcare practice. He developed his system methodically over years, writing carefully and precisely about his observations, but also trusting his intuition when the science of the time could give him no satisfactory answer. Over intervening years, from his death in 1936 to now, the system attracted many devoted followers, and indeed, advocates. Most of the evidence they have relied on is empirical – both from personal experience and positive outcome in patients.

Until the 1990s it was true that the BFRs were not supported by modern clinical trial data, but this is no longer true². In recent years a number of attempts have been made to examine the remedy system more formally. The purpose of this paper is to review this evidence base, and set it in the context of the therapeutic experience of those working with the remedies. An earlier, published systematic review will also be discussed (Ernst 2002).

Nelsons have not funded, fully or partially, any of the research described in this document³.

¹ BFRs are used quite extensively in self-medication. Indeed, one of Bach's philosophies was that the system provided an accessible, simple and economical approach meeting the healthcare needs of the masses (well before State provision, i.e. the National Health Service).

² It should be noted that many older drugs (developed prior to the mid 1960s), many of which are still in widespread clinical use, are not supported by multiple modern-standard randomised controlled trials. This is an artefact of history, not poor practice.

³ The opinions expressed in this review are, where not otherwise attributed, those of Nelsons

1. Clinical Research

The whole area of Complementary and Alternative Medicine (CAM), it can be argued, suffers from a lack of good quality research. This should not be interpreted as evidence that CAM, in its many incarnations, does not work. It merely reflects a number of problems; such as a lack of funding, inadequate expertise in research methodology and poor method development.

Since 1979, a number of attempts have been made to examine the efficacy of BFR using modern clinical research methodology: the randomised controlled trial. Although not within the scope of this paper, there is a growing belief (Weatherley-Jones, 2005) that though this is a widely accepted method of researching the safety and efficacy of orthodox interventions in medicine (e.g. conventional medicines, surgery), it may not be appropriate for highly individualised treatment in holistic medicine (such as homeopathy, and, indeed, BFR prescription).

This section reviews nine studies, which have been identified by searching publicly accessible bibliographic databases such as Medline, Embase, AMED and examining the citations of identified papers, which are described below. See Table 1 for a summary of study design, sample size, interventions and main outcome measures of these studies.

1.1 Weisglas, 1979

This is a volunteer study that attempts to evaluate the effectiveness of BFR in influencing creativity and the feeling of 'well-being'. Thirty-nine volunteers were recruited into this randomized and controlled trial, thirty-one completing the evaluation. The design required randomization to one of three, parallel, groups: one receiving placebo remedy, one a remedy mix of four BFR, and the final group a mix of seven BFR. The study was conducted double-blind.

To examine creativity and well-being, Weisglas used the Adjective Check-list to test for any change in creativity. To examine well-being, he used Lüscher's Colour Test. Finally, to explore possible placebo-response, he determined whether the volunteer's belief system affected outcomes.

When compared with the placebo group, there were improvements in well-being and enhancement of creativity. These changes were more prominent in the group receiving a mix of four BFR. Of particular interest is the finding that the remedies acted independently of the user's belief system – evidence that militates against a hypothesis that the effectiveness of the remedies is merely that of placebo⁴.

1.2 Von Rühle, 1995

A slightly unusual model, von Rühle examined the efficacy of BFR in a group of pregnant women (primiparie, i.e. first child) who were at least 5 days overdue. This was an open study (blinding was not possible), and although controlled, not

⁴ Two mechanisms are believed responsible for the so-called placebo effect: the response expectancy theory and conditioning theory. For further information: "Understanding the Placebo Effect in Complementary Medicine" Ed. David Peters. Publ. Churchill Livingstone 2001. ISBN 0443 06031 2

placebo controlled. Twenty-four pregnant and overdue women were randomized into one of three parallel groups. One group received individualized BFR, the second group 'attention' and the third (control) group did not receive any intervention. Outcomes measured included: time to birth, type of birth, medication use around the time of birth, anxiety during birth and general feeling of well-being. Anxiety was measured using the State-Trait Anxiety Index (STAI), a validated measurement tool.

With the exception of medicines usage, there were no significant differences in outcome for all measures between the three groups. However, the difference in medicines usage (i.e. orthodox medicines to control pain and nausea) was significantly less ($p=0.032$) for the group receiving BFR when compared with the other two groups. Indeed, seven of the eight subjects in the BFR group used no medication. Furthermore, the investigator reports that these mothers tended to deliver with less assistance, suggesting less anxiety (but this is not clear in the STAI results).

1.3 Campinini, 1997

This was an open study on one hundred and fifteen patients (91 completed) suffering either anxiety (including stress) or depression. Very simple in design, patients were assessed and individualized mixes of up to five of the remedies prescribed. They were followed up with fortnightly assessments over several months (up to 16 for a proportion of patients) by therapists and outcomes were reported as either 'nil', 'partial' or 'complete' recovery.

Although there are a number of quality issues in the running of this small trial, it nevertheless yields some interesting data. Although the natural history of minor psychiatric disorders is that they are often transitory, 89% of this group of patients made a partial to complete recovery. For the majority that made a partial to full recovery, this took place within the first 18 weeks.

Like Weisglas (see above), Campinini also examined trust in the remedy system. One would expect that if the effect were purely that of placebo, that your chances of responding favorably to the intervention (of BFR) would be higher if you believed in the system than if you were skeptical of their value. This hypothesis doesn't appear to be supported in this trial – of the 11 patients who were assessed as 'nil' response, 10 were 'believers', a surprising finding, as, arguably, you would have anticipated most of the 'nil' responders to be skeptics if BFRs were merely placebos.

1.4 Armstrong and Ernst, 1999

On paper, and at first sight, this appears to be a well-designed and rigorous evaluation of a BFR composite ("Five Flower Remedy"⁵).

⁵ The "Five Flower Remedy" used in this study, and the Cram (2001(b)) study below apparently contains the same five Bach flower remedies as *Rescue Remedy*, the brand sold by Nelsons. However, it is not a medicinal product, and may not be prepared to the exacting medicinal standards of *Rescue Remedy* (a licensed medicine).

One hundred otherwise healthy university students volunteered and were randomised to one of two groups: one received the true (verum) remedy and the other a matched placebo. The study was conducted under double-blind conditions. Outcome measures evaluated were anxiety, measured with the Spielberger State Trait Anxiety Inventory – a validated method.

The cause of anxiety in this student population was examination stress. Unusually, and not in accordance with the usual method of administering this 'emergency' remedy mix, the investigators had the subjects administering remedy from eight days before the examination and their Spielberger end assessment. Whereas Bach recommended *Rescue Remedy* for acute situations, it is likely that for the more 'chronic' nature of exam stress over a longer period of time, he would have recommended a more individualised selection of the other 38 remedies (e.g. Larch for lack of confidence or Mimulus for known fears) according to the individual response. This may explain the outcome of the study where no significant difference was found between the groups in respect of the primary outcome (anxiety).

Very noteworthy in this 'negative' study is the unusually high drop-out rate (55%). Further, it would have been interesting to know more about the use amongst this student population of the more traditional student aids to stress management such as their smoking, drinking and illicit drug use. The authors do let us know that participants in the study smoked less and consumed less alcohol (but we are not told whether there are intergroup differences).

1.5 Walach et al, 2001

Sometimes mistakenly referred to as a trial of *Rescue Remedy*, because it investigates efficacy of BFR in examination stress, this time using the German version of the Test Anxiety Inventory. Sixty-one volunteers were recruited (55 completed) into this randomised, double-blind and controlled, partial cross-over, trial. All volunteers were otherwise healthy students about to sit their examinations.

A rather unusual combination of ten BFR was designed by a consultant and, like in Armstrong and Ernst (above), dosed over a several week run-in. A matched placebo was prepared and dosed identically.

At the end of the trial no significant difference was detected between either group. Surprisingly, for both groups (verum and placebo control) there was a significant decrease in test anxiety.

1.6 Cram, 2001(a)

This non-randomised trial examined the efficacy of BFR in moderate to major (but not severe) depression; both grades that will have major impact on wellness, and, indeed, quality of life.

Twelve patients were admitted to this multi-centre 'within-subject' design. During the first month, subjects were assessed and continued to receive their 'usual' care – all but one had been receiving psychotherapy and eight were being

treated with allopathic antidepressants (for an average of 17 months). During the second month flower remedies were added to the subjects' usual care. The choice of flower remedy was individualised to each subject. Treatment continued for a further two months and patients were assessed throughout using the Hamilton Depression Score (HAMD) and the Beck Depression Inventory (BDI). Results were evaluated using a repeated measures design.

Most of the patients recruited had a long history (more than five years) of depression. Using the flower remedies in addition to the subjects' usual care significantly improved their depression during the experimental phase, "The adjunctive use of flower essence in the treatment of depression was associated with a 50% decrement in BDI and HAMD ratings. These findings do not appear to be related to the clinical trial site, the number of essences given or the number of flower essence combinations used during the therapy." Mean BDI decreased from a baseline value of approximately 20 to 11, and HAMD from baseline average 21 to 10 at three months.

1.7 Cram, 2001(b)

In another trial, Cram investigated the effect of "Five Flower Formula" on the stress response. This double-blind, placebo controlled study examined the response of 24 volunteers to the Paced Serial Arithmetic Task. Assessments involved physiological measurements using a surface electromyography – its electrodes being placed on six sites on the volunteers' bodies. Additionally, autonomic nervous system activity (a surrogate indicator of stress) was assessed by measuring peripheral hand temperature and skin conductance (methods associated with the so-called polygraph lie detector).

Placement of the electromyography electrodes included the two 'usual' sites (frontal and cervical), these sites coinciding with two of the Chakras⁶. The other four chosen sites coincided with most remaining Chakras.

The results of this study are difficult to interpret, and the author / investigator doesn't help in his narrative. Of interest is that the group receiving the flower remedies exhibited a significantly smaller stress response, under the test conditions, when measured at two Chakras: the cervical (throat) and T6 paraspinal (heart). This is the first study that has measured an apparent physiological change.

1.8 Mehta, 2002

This pilot study examined the additional use of BFRs in children suffering Attention Deficit / Hyperactivity Disorder (ADHD). Ten children aged between 5 and 12 years that were partially hospitalised were randomised to receive either BFR or a placebo (i.e. 5 children in each group). The children continued to receive their standard stimulant medication during the study and were assessed for any improvement using the Childhood Attention Profile (CAP) and Columbia Impairment Scale (CIS) measures. Assessments were recorded at 3 weeks and

⁶ Chakras are points on the body (there are seven) that tantric philosophy suggests are 'energy centres'. Many of these locations are close to the spine.

3 months and the remedies used included *Rescue Remedy*, vervain, crab apple and walnut (although the author does not explain whether they were individually prescribed or administered as a mixture).

At the end of the study three of the children in the BFR group were not hospitalised and were off all ADHD medication (including BFR), and were described as 'functioning well'. In the placebo group, in contrast, three of the children had moved to inpatient hospitalisation. The two remaining children in each group remained on medication and are described as being of 'intermediate levels of functioning'. Mean CAP and CIS scores had decreased in both treatment groups by the second follow-up. But only scores for CAP were significant at the $p=0.05$ level. Interestingly, the difference between the groups' CAP scores were 4.4 at baseline, and had increased to 7.0 at three weeks ($p=0.03$) and 7.2 at three months ($p=0.03$).

Although a pilot study, and difficult to interpret in relation to the natural course of the disorder and the very small numbers recruited, the study provides limited evidence of an incremental benefit of adding-in BFR to standard (stimulant) treatment in children diagnosed ADHD.

1.9 Hyland et al, 2005

This is a piece of psychological research, not conventional clinical research, but it is worth including a brief description in this paper as it confirms something seen in earlier studies – that expectancy of outcome doesn't appear to affect actual outcome in subjects using BFR. For a placebo to work, it is commonly argued that the patient (or subject) has an expectancy that it will provide a benefit that they can, at least, subjectively report (e.g. less pain, feeling better). In Hyland and colleagues' research 124 volunteers self-selected remedies and after use rated how they perceived change in the emotional condition that they had chosen to remedy. Psychological assessments of expectancy, attitude to complementary medicine, spirituality and absorption were also conducted, using validated scales.

On its own, expectancy significantly correlated with outcome, but failed to predict when controlling for spirituality. When spirituality and expectancy were combined in an analysis of the data, only spirituality appeared to be significant. The authors conclude that the placebo response is not fully understood.

For healthcare professionals this research may be difficult to interpret, but it is interesting that the authors appear to have chosen to use BFR as good example of 'mere placebo medicine' and achieved a result they hadn't bargained on (possibly because it isn't placebo).

1.10 Pintov et al. 2005

This recent small study evaluated BFR in forty children (aged 7-11 years) suffering Attention Deficit and Hyperactivity Disorder (ADHD). Although described as a trial of BFR, it is a trial of a specific mix of five remedies ("Five Flower Remedy"). Disappointingly, no individualization of prescription has taken place and the choice of combination is probably inappropriate for the condition.

Twenty children were randomized to verum and placebo groups receiving their allotted treatment four times a day for three months. Children were assessed by teacher or parent-completed questionnaire – at baseline and then monthly. It's not clear whether the same person made all assessments in each individual child.

At the end of the study 17 children (9 in verum group) had dropped out (>42%) due to the "difficulty in following the program". Although there was no significant difference in outcome between the two groups, there were obvious improvements in both groups over the test period.

2. Systematic Review - Ernst, 2002

A recent (Ernst, 2002) systematic review⁷ identified all research available in the public domain at time of writing (all are reviewed above).

The author's conclusion has been much quoted and most often misinterpreted: "The hypothesis that flower remedies are associated with effects beyond a placebo response is not supported by data from rigorous clinical trials". What the study primarily indicates is the lack of quality research or rigorous trial data in this field. At best, the research presented could only be described as pilot or Phase 1 feasibility research – aiming to establish practicability of methods more than truly evaluating the efficacy of the remedies.

The usual (media) interpretation of the conclusion, that flower remedies are no better than placebo, is not supported by either the author's appraisal of the research, nor ours. Indeed, whereas two trials in his review showed no difference in effectiveness between BFRs and placebo, the others suggested a positive effect.

See *Table 2: Studies⁸ included in Ernst review (after rejection of others on grounds of quality)*.

3. Clinical Use – UK and International Experience

Not only are BFRs used extensively in the community, we are aware of quite wide use in secondary (hospital) patient care, particularly in such areas as preoperatively to control anxiety, midwifery and in palliative care. Furthermore, many homeopaths state a preference for the BFRs when treating certain patients with minor emotional problems.

Mark Masi (2003), a psychologist at National-Louis University in Elgin, Illinois reports that he has, for the past few years, integrated the use of BFR in his psychotherapy practice. In this short report he presents two cases where he used the remedies in depressed patients. Both suffered chronic (more than 2 years) major depression, and both were females in their forties. One of the patients had not responded to three different regimes of conventional drug treatment and the other patient was taking an antidepressant (sertraline 100mg/d) but suffered repeated periods of dysphoria. Both

⁷ NB this is not a clinical study, it is a review of completed studies

⁸ On reviewing this work we note that the CAM citation for Dr Jeffrey Cram's study in depression appears only to report the twelve patient non cross-over study in the paper cited above.

patients appeared to make significant progress when BFR was added in to their management, measured using Beck's Depression Inventory (BDI). 'Ms A's' BDI fell from an initial scoring of 35 to 11 over twelve weeks and 'Ms B's' from 12 to 2. Remedies were individualised in both patients.

At a recent (2004) midwifery conference⁹, the Northampton General Hospital NHS Trust, reports on the recent training in Bach's system by two of its midwives and their intention to use it with their anxious and depressed patients. Similarly, a Bach Foundation Registered Practitioner has recently addressed both a Royal College of Nursing meeting on complementary therapies¹⁰ and a Royal Society of Medicine meeting that reviewed the current use of complementary medicine in palliative care¹¹.

Homeopaths are known to integrate use of BFRs in the management of some of their patients and Nelsons know of two NHS Consultants (at two of the five NHS Homeopathic Hospitals) and a number of GPs who have regularly used the remedies with patients attending their clinics. One of the UK's leading private GP practices in the UK's West Country similarly advocate use of the remedies as part of a complementary (and integrated) approach to patient care.

4. Safety of the Remedies

Clinical research, and subsequent clinical use of a medicine or remedy, both present an excellent opportunity to record and analyse any information that emerges that may suggest possible toxicity or other detrimental effect of the intervention. None of the studies reported any significant adverse event suffered by volunteers receiving a BFR, or combination thereof.

Similarly, the very few spontaneous reports of suspected adverse events reported directly to Nelsons, where the report is validated by a qualified healthcare practitioner, have included common symptoms of illness: headache, diarrhoea and sickness. Given the patients' underlying conditions it would be difficult to attribute these symptoms to the remedies; but the possibility of homeopathic aggravation cannot be overlooked.

5. Discussion

Since the 1990s the Bach flower remedies have been supported by a growing body of data, mainly in the form of what can only reasonably be described as pilot studies, and although, in total, results appear equivocal, an alternative interpretation of the combined data is that there may appear be a trend towards supporting usefulness of Bach flower remedies in the management of, at the very least, anxiety and depression.

The use of the test, or examination, anxiety model hasn't yielded positive results, but there remains the obvious possibility that this may be due to methodological problems,

⁹ MIDIRS and The Prince of Wales's Foundation for Integrated Health Joint Conference and Exhibition 13th & 14th October 2004.

¹⁰ Royal College of Nursing Complementary Therapies in Nursing Forum Annual Conference 'Complementary therapy practice: independence and isolation', 16-17 September 2005

¹¹ "Complementary therapies in palliative care - revisiting the evidence base." January 18th 2006 – joint with Palliative Care Research Society. Venue: Royal Society of Medicine (UK).

such as inappropriate dosage schedules, incorrect choice of remedies and small study populations. The earlier trial (Armstrong and Ernst) was based on a possibly inappropriate choice of remedy combination. Further, the later Walach study evaluated an unusual combination of remedies, certainly not one described by Bach and not in the strictest traditions of using individualised prescription.

If we were to agree with Professor Ernst's conclusion that the remedies' activity was that only of placebo we would have to ignore the positive outcome in the Campinini and Cram studies in depressed patients, and the two earlier studies (Weisglas and von Rühle). We would also have to overlook the finding that outcomes seemed not to be affected by expectancy (surely, a pre-requisite of placebo response). We would also have to turn a 'blind-eye' to the quality issues in some of the studies that render the firm and definitive conclusions, made in the systematic review, of limited value.

Finally, whilst the outcome of clinical research plays an important part of a therapist's evaluation on the suitability of any approach, such evaluations will also factor history of successful use and personal experience. Bach flower remedies have been widely used for more than seventy years, and the widespread satisfaction and growing use adds undoubted weight to the clinical outcomes described in the research mentioned above.

6 Conclusion

Bach flower remedies are a form of traditional, or complementary, medicine supported by both extensive clinical and lay use over seventy years, and several modern clinical studies. The body of data reassures us of their safety and attests to their usefulness in twenty first century healthcare.

References

Armstrong, N. C. & Ernst, E. 1999, "A randomised, double-blind, placebo-controlled trial of Bach Flower Remedy.", *Perfusion*, vol. 11, pp. 440-446.

Campanini, M. 1997. "Terapia con i fiori di Bach: risultati di un monitoraggio su 115 pazienti (Bach flower therapy: results of a monitored study of 115 patients)." *La Medicina Biologica* 3, 37-43.

Cram, J. R. 2001a, "A Psychological and Metaphysical Study of Dr. Edward Bach's Flower Essence Stress Formula", *Subtle Energies*, vol. 11, no. 1.

Cram, J. R. 2001b. "Flower essence therapy in the treatment of major depression: preliminary findings." *International Journal of Healing and Caring* 1, 1-18.

Ernst, E. 2002, ""Flower remedies": a systematic review of the clinical evidence", *Wien.Klin.Wochenschr.* 114, no. 23-24, 963-966.

Hyland, M., Geraghty, A.W.A., Joy, O.E.T. et al. 2005. "Spirituality predicts outcome independently of expectancy following flower essence self-treatment." *Journal of Psychosomatic Research*. (In Press)

Masi, M.P., 2003. "Bach flower therapy in the treatment of chronic major depressive disorder." *Alternative Therapies*. Vol. 9, no. 6, 112 and 108-109.

Mehta, S.K. 2002. "Oral flower essences for ADHD", *Am Ac of Child and Adolescent Psychiatry*, vol. 41, no. 8, 895.

Morrell, P. 2004 "The Bach Flowers and Homeopathy." *Homeopathy International*. Online: www.homeoint.org/morrell/articles/bach.htm

Pintov, S., Hochman, M., Livine, A. et al. 2005. "Bach flower remedies used for attention deficit hyperactivity disorder in children - A prospective double blind controlled study." *European Journal of Paediatric Neurology* (In Press)

Rühle, G. 1995. "Pilot study on the use of Bach flower essences in primiparae with post-date pregnancy." *Erfahrungsheilkunde*. 44, 854-860

van Haselen, R. A. 1999, "The relationship between homeopathy and the Dr Bach system of flower remedies: a critical appraisal", *Br.Homeopath.J.*, vol. 88, no. 3, pp. 121-127.

Walach, H., Rilling, C., & Engelke, U. 1 A.D., 2001. "Efficacy of Bach-flower remedies in test anxiety: a double-blind, placebo-controlled, randomized trial with partial crossover", *J Anxiety Disord*, vol. 15, no. 4, pp. 359-366.

Weisglas, M. S. 1979. "Personal growth and conscious evolution through Bach flower essences." Not published - in PhD Thesis.

Weatherley-Jones, E. 2005. "Homeopathy: a complementary view." *Trends in Pharmacological Sciences*, Vol 26, no.11, 545-546.

Table 1: Clinical Trials Design

Investigator	Design	Sample	Interventions	Main Outcome Measures
Weisglas (1979)	RCT, double-blind, 3 parallel groups	N=39 (31 completed) healthy volunteers	Randomised to receive either: 1. Placebo 2. Mix of four remedies 3. Mix of seven remedies	1. Creativity assessed using the 'adjective check list' 2. Well-being measured with Lüscher Colour Test 3. Whether belief system affected outcomes
Von Rühle (1995)	RCT, 3 parallel groups (neither placebo controlled, nor double-blinded)	N=24, pregnant women with overdue births	All had standard care but varied: 1. Individualised flower therapies to birth 2. Attention control group 3. No other intervention	1. Time to birth 2. Type of birth 3. Use of medication during birth 4. Anxiety during birth 5. Feeling of well-being
Campanini (1997)	Open	N=115, aged 2 years up to 65 years suffering either anxiety, depression or stress	Individualised Bach flower remedies as either single remedies or mixture (max 5 remedies). Patients assessed fortnightly	Improvement/resolution of condition as assessed by therapist. Outcomes classified either as 'nil', 'partial' or 'complete'
Armstrong (1999)	RCT, double-blind, two parallel arms	N=100 (45 completed) healthy university students sitting exams	1. <i>Five Flower Remedy</i> 1-4 doses during the 7 days before exams and during the exams 2. Placebo (same dosing schedule)	Anxiety – measured with Spielberger State Trait Anxiety Inventory
Walach (2001)	RCT, double-blind, partial cross-over	N=61 (55 completed) healthy students sitting exams	1. Composite mixture of ten remedies (4 drops daily for 2 weeks or more as necessary) 2. Placebo (same treatment schedule)	Anxiety measured with Test Anxiety Inventory (German version TAI-G)
Cram (2001a)	Open, 'within subject' design	N=12 suffering mild to moderate depression	One month usual care followed by three months usual care plus flower remedies (individually prescribed)	Hamilton Depression Score (HAMD) and Beck Depression Inventory (BDI)
Cram (2001b)	Double-blind, placebo controlled, outcome study. No information on randomisation	N=24, stressed using Paced Serial Arithmetic Task	1. <i>Five Flower Remedy</i> no dose stated 2. Placebo	1. Stress response measured by electromyography 2. Autonomic nervous system activity measured – skin temperature and conductivity
Mehta (2002)	Placebo-controlled and randomised	N=10, children partially hospitalised with diagnosis of ADHD N=124, healthy adult volunteers	1. Flower Remedy 2. Placebo	Childhood Attention Profile (CAP) and Columbia Impairment Scale (CIS)
Hyland (2005)	Psychological evaluation attempting to correlate outcomes with psychological parameters		Self-selected remedies	Psychological assessments of expectancy, attitude to complementary medicine, spirituality and absorption conducted
Pintov (2005)	Placebo-controlled and randomised	N=40, children diagnosed with ADHD	1. <i>Five Flower Remedy</i> 2. Placebo	Teacher or parent-completed questionnaire

Table 2: Studies included in Ernst review

REFERENCE	STUDY DESIGN	SAMPLE	INTERVENTIONS	MAIN OUTCOME MEASURES	MAIN RESULT	COMMENT
von Rube (1995)	RCT, 3 parallel groups (not placebo controlled. not double-blinded)	24 pregnant women with overdue births	A) individualised flower remedies daily up to date of birth. B) attention control group (no flower remedies). C) no such therapies (all groups had standard care in addition).	A) time to birth. B) type of birth. C) use of medication during birth. D) anxiety during birth. E) well-being.	Significantly less medication was used in group A (p = 0.032).	birth was delayed in: group A by 5.1 days, in group B by 6.6 days, in group C by 4.4 days.
Armstrong (1999)	RCT. double-blind. 2 parallel arms	100 healthy University students sitting exams	A) "Five Flower Essence" (1-4 doses during 7 days before and during exams). B) placebo (same treatment schedule)	anxiety measured with Spielberger State-Trait-Anxiety Inventory.	No significant differences between groups.	study suffered from high drop-out rate.
Walach (2001)	RCT. double blind. cross-over	51 healthy students sitting exams	A) Special composite remedy (4 drops daily for 2 weeks or more if necessary). B) 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".
Cram (2002) see footnote 6 above.	open cross-over trial (not randomised. not placebo controlled, not double-blind)	12 patients with moderate depression, 18 with major depression	A) usual care plus individualised flower remedies (65 different). B) usual care alone (mostly psychotherapy) Each treatment phase lasted 1 month.	Hamilton Depression Score. Bach Depression Inventory.	Significant improvement during experimental phase.	no randomisation, no control for placebo effects, small sample size.

Note: a number of studies described in this document were identified by Prof. Ernst, but not included in his review as they failed to meet his inclusion criteria (quality-based).