Bach Flower Remedies for pain relief and psychological problems

Systematic Review

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Health Technology Assessment

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Summary

Bach flower remedies (BFR) are a form of complementary medicine developed by Dr. Edward Bach in the 1930s. According to Bach, it is the imbalance in a patient's emotional state, rather than just physical causes, which gives rise to illness. The remedies therefore target the improvement of mood, emotional outlook and temperament, as well as personality and general disposition of patients, which in turn can affect a person's health.

BFR target a patient's emotional state in order to improve their health

BFR are used for psychological problems, and it has been said that BFR have the potential to function as a therapeutic agent in pain relief. However, sceptics say that BFR are pure placebos, and that any effect must be caused by placebo or other non-specific effects.

sceptics says that BFR are merely placebos

This systematic review evaluates the evidence about BFR in order to determine whether or not they are effective for pain relief and psychological problems, and how safe they are.

this review evaluates the evidence of BFR for pain relief and psychological problems

Three randomised controlled trials are identified and included in the review. The indications covered by these studies are examination anxiety and Attention-deficit Hyperactivity Disorder (ADHD). According to the evidence, for these conditions, BFR are not more effective than placebo. There is no evidence about BFR for pain, and adverse events with BFR (i.e. the safety of BFR) are also under-reported.

according to the evidence, BFR are not more effective than placebo

There is little evidence about BFR for psychological problems and pain, and the evidence that does exist is of poor quality. Extensive and good quality RCTs are required to obtain a clear picture as to whether BFR are effective for psychological problems or pain, and the risks associated with them.

evidence insufficient and of poor quality

1 Bach flower remedies for pain and psychological problems

1.1 Background

BFR target a patient's emotional state in order to improve their health

Bach flower remedies (BFR) are a form of complementary medicine developed by Dr. Edward Bach in the 1930s. According to Bach, it is the imbalance in a patient's emotional state, rather than just physical causes, which gives rise to illness. The remedies therefore target the improvement of mood, emotional outlook and temperament, as well as personality and general disposition of patients, which in turn can affect a person's health.

The individual patient is prescribed particular remedies depending on the problem at hand. For example, 'impatiens' is used for impatience and irritability, mimulus for fear of known things, shyness and timidity, and olive for those that are drained of energy [1]. Thus BFR are used for psychological problems. However, according to Howard [2], a major factor in pain relief is the relief of anxiety. Thus it has been said that BFR have the potential to function as a therapeutic agent in pain relief [2].

sceptics says that BFR are merely placebos

However, sceptics say that BFR are pure placebos, and that any effect must be caused by placebo or other non-specific effects [3]. This is because flower remedies do not contain pharmacologically relevant amounts of the constituents which they originate from [4]. Proponents of the remedies believe that the remedies are more than a placebo, and that they work through the 'energy' that is transmitted from the flowers to the remedy.

this review summarizes the evidence for BFR

Some RCTs exist to test whether BFR have an effect over and above that of a placebo. This systematic review summarizes studies which have been carried out which are concerned with the use of BFR for pain and for anxiety and similar psychological problems. A systematic review of BFR was carried out by Ernst [4] in 2002. In that review Ernst concluded that 'the hypothesis that flower remedies are associated with effects beyond a placebo response in not supported by data from rigorous clinical trials'.

1.2 Description of treatment

38 individual remedies

There are 38 individual remedies, which are mostly made from the flowers of plants. They can be prepared in two ways. Using the sun method, flower heads are floated on the surface of water in a glass bowl and left in the sunshine. For the boiling method, the flowers are boiled. In both methods, the plant matter is then removed, the water filtered and mixed with an equal quantity of brandy [2].

BFR can be taken in conjunction with other forms of treatment

The remedies can be taken orally or diluted in water, and depending on the symptoms, can be used individually or in combination with up to seven tinctures [5]. They allegedly have no effect on and are not affected by other medications, and as such can be used in conjunction with other forms of treatment [5].

1.3 Indication and therapeutic aim

indications and therapeutic aim

The indications covered in this review are psychological problems of any kind and pain. The therapeutic aim is the alleviation or cure of these conditions.

1.4 Treatment costs

costs not reported

The cost of the Bach flower treatment is not reported anywhere in the literature included in this review.

2 Literature search and selection

2.1 PICO question

PICO question

Are Bach Flower Remedies effective in reducing pain and improving psychological problems such as depression, ADHD (Attention-deficit hyperactivity disorder), stress and anxiety, in comparison with placebo? Are Bach Flower Remedies safe?

2.2 Inclusion criteria

inclusion criteria

Table 2.2-:1 Inclusion criteria

Population	Patients with pain. Patients with psychological problems.
Intervention	Any Bach Flower remedy.
Comparison	Placebo.
Outcomes	Pain reduction. Improvement of psychological problems.
Study design	All prospective studies with a control group.

2.3 Literature search

literature search

The systematic literature search was carried out on 22.11.07 in the following databases.

- Medline via Ovid
- Embase via Ovid
- CCRCT (Cochrane Library) via Ovid
- CDSR (Cochrane Library) via Ovid

The search was limited to English and German language literature and covered the entire time span of the databases.

After the removal of duplicates, 38 bibliographical references were available. The exact search strategy can be requested at the LBI for HTA.

By means of a hand search, 16 additional references were identified, which raised the overall number of hits to 54.

2.4 Literature selection

literature selection

Overall, 54 Articles were available for the literature selection. The selection process is depicted in Figure 2.4-1.

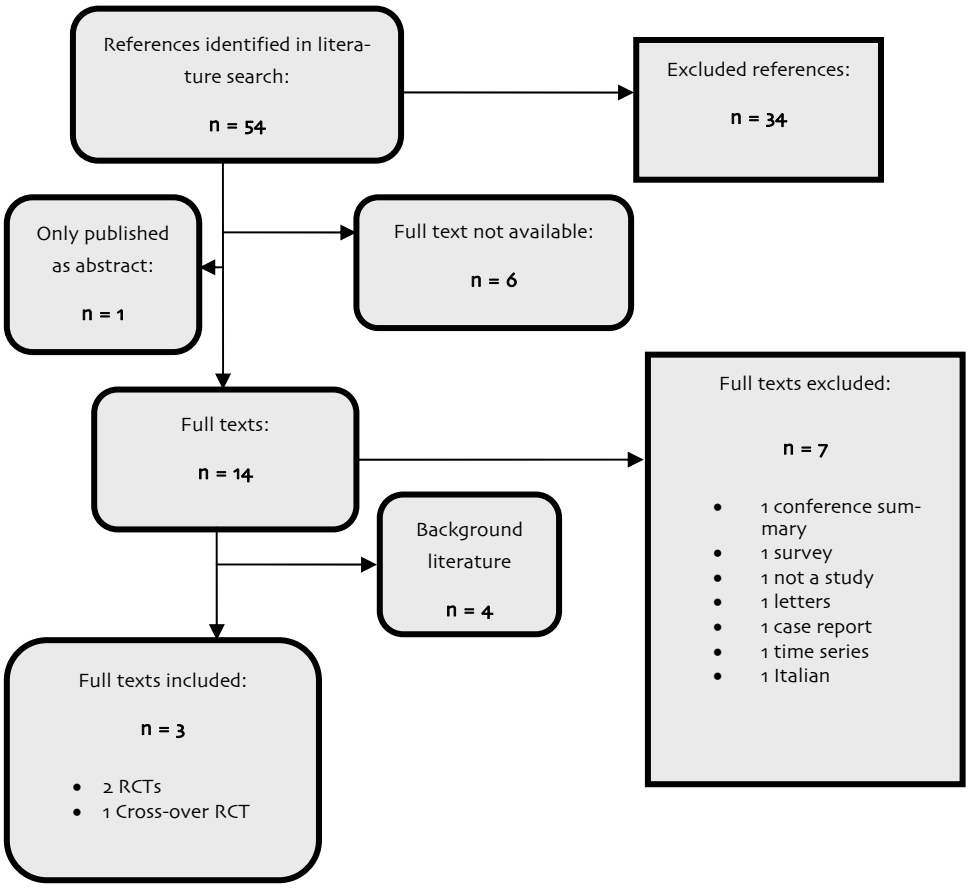

Figure 2.4-1: Depiction of the selection process (QUORUM tree)

3 Assessment of the quality of the studies

assessment of quality of studies carried out by two reviewers

The evaluation of the quality of the studies was carried out by two reviewers, independently of each other. Conflicting views were settled by means of discussion and consensus, or through the involvement of a third person. An exact list of the criteria that were used for the evaluation of the internal validity of the studies can be found in the internal manual of the LBI-HTA [6].

4 Data extraction

The extraction of data was carried out by one person. A second person checked the completeness and accuracy of the data.

extraction of data by one person

4.1 Presentation of the study results

Three RCTs [1,7,8] were included to answer the question as to whether BFR are effective in reducing psychological problems and whether they are safe. These studies looked at BFR for examination anxiety and ADHD. Studies looking at BFR for other psychological problems were not found. No studies were included to answer the question as to whether BFR are effective in reducing pain.

3 RCTs included

Table 4.1-1 Study results

Author, Year, Reference number	Armstrong and Ernst 2001 [1]	Walach et al. 2001 [7]	Pintov et al. 2005 [8]
Country	United Kingdom	Germany	Israel
Sponsor	Not reported	Institut für Grenzgebiete der Psychologie	Not reported
Study design	RCT	Cross-over RCT	RCT
Study quality	Poor	Poor	Poor
Number of patients	100	61	40
Lost to follow up	55 %	9.8 %	42.5 %
Study population	Students with examination anxiety registered to take examinations between May and July 1998	Students with examination anxiety registered to take at least two exams that two weeks apart	Children with clinical diagnosis of any subtype of ADHD
∅ Patient age (years)	Not reported	28	7-11
Indication for BFR	Examination anxiety	Examination anxiety	ADHD
Intervention	1-4 doses of Five Flower Remedy per day	At least 4 drops of BFR suggested as efficacious for test anxiety per day	4 drops of a five flower BFR 4 times per day
Control	Placebo	Placebo	Placebo
Duration of treatment	7 days	4 weeks (two weeks before first test and two weeks before second test)	3 months
Main outcome measures	State-Trait Anxiety Inventory	German Test Anxiety Inventory	Conner's scale
Results	No significant difference in State anxiety score (on the night before examination most likely to cause anxiety)between experimental and placebo groups – 51.5 in BFR group, 54.4 in placebo group (P=0.834)	No significant difference between experimental and placebo group for mean reduction in test anxiety – 5.25 in BFR groups, 7.69 in placebo group (P = 0.55)	No significant difference in mean Conner's scores between experimental and placebo group before (16.59 in BFR group, 17.12 in placebo group) or after (11.90 in BFR group, 13.58 in placebo group) treatment (P not reported).
Adverse events	BFR: 3 subjects – headaches and skin eruptions Placebo: 3 subjects – vomiting before examination, hayfever symptoms, depressive mood	One subject in BFR group reported adverse reactions.	Not reported

Abbreviations:

BFR: Bach Flower Remedies
ADHD: Attention-deficit hyperactivity disorder

4.2 Efficacy

studies on BFR for examination anxiety and ADHD included

The populations that can be treated with BFR vary. This is reflected in that the very different indications of examination anxiety and ADHD were treated in the trials included in this review. The efficacy of BFR is evaluated for each indication.

4.2.1 Efficacy of Bach flower remedies for examination anxiety

1 RCT and 1 cross-over RCT on BFR for examination anxiety

One RCT [1] and one cross-over RCT [7], both of poor quality, reported on the efficacy of BFR in reducing examination anxiety compared with placebo. Both Armstrong and Ernst [1] and Walach et al. [7] found BFR to be no more effective than placebo. Walach et al. found no significant difference between the experimental group and the placebo group for a reduction in test anxiety. The mean reduction in anxiety score in the BFR group was 5.25, and the mean reduction in the placebo group 7.69 (P=0.55). However, flawed randomisation (randomisation was carried out using a list of random numbers, divided at the median) exposed the study to selection bias.

Armstrong and Ernst [1] found no significant difference in the State anxiety score on the night before the examination most likely to cause anxiety between experimental and placebo groups: The score was 51.5 in the BFR group and 54.4 in the placebo group (P=0.834). However, this study suffered an extremely high drop-out rate of 55%, thus exposing the study to selection bias.

BFR found not to be more effective than placebo
strength of evidence is low

Thus the treatment effect is consistent across the two studies, but methodological flaws found in both studies may have biased the results. The strength of the evidence is low.

4.2.2 Efficacy of Bach flower remedies for Attention-deficit Hyperactivity Disorder

1 Rct on BFR for ADHD

One poor quality RCT [8] reported on the efficacy of BFR in treating ADHD. Pintov et al. [8] found that the effect of BFR on improving ADHD was not significantly different from that of a placebo, by comparing Conner's questionnaire scores between an experimental and a placebo group. The mean Conner's score before treatment was 16.59 in the BFR group and 17.12 in the placebo group. After the treatment the corresponding values were 11.90 and 13.58. Pintov et al. reported that there was no significant difference between the groups before or after treatment, but not P-values were given. However, there was a very high dropout rate (42.5%) potentially creating selection bias.

no significant difference between BFR and placebo groups

strength of evidence is very low

Further RCTs of good quality are necessary to determine whether this is a true reflection of the effect of BFR on ADHD. There is only one study with large methodological flaws for this population, thus the strength of the evidence is very low.

4.2.3 Efficacy of BFR for pain relief

No evidence.

no evidence on BFR for pain relief

4.3 Safety

One of the included studies [8] failed to make reference to the safety of BFRs, which may be a reflection of the fact that BFRs are generally regarded as a safe treatment. Armstrong and Ernst [1] reported two cases of headaches and some skin eruptions, while Walach et al. [7] report that one subject had adverse reactions to the Bach flower remedies, without specifying these events any further. It seems likely that BFR are a safe form of treatment, but further studies reporting the side effects of the BFR are required in order to establish their safety.

likely that BFR are safe

further studies required

5 Strength of the Evidence

GRADE system

The GRADE system is used [9] to evaluate the strength of the evidence. GRADE uses the following classifications and definitions to evaluate the strength of the evidence.

- High: further research is very unlikely to change our confidence in the estimate of effect
- Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
- Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
- Very low: any estimate of effect is very uncertain

Table 5-1: Bach flower remedies evidence profile

Number of studies/patients	Design	Methodological quality	Consistency of results	Directness	Size of effect	Other modificatory factors	Strength of the collective evidence
Outcome: Reduction in examination anxiety compared with control							
2/161	RCT	Poor [1]	Yes	Yes	5.25 mean reduction in anxiety score, no significant difference between treatment and placebo	None	Low
Outcome: Connor's score compared with control							
1/40	RCT	Poor[2]	Maybe[3]	Yes	4.69 points reduction in Conner's score, no significant difference between treatment and placebo	None	Very low
Outcome: Pain relief							
No evidence							
Outcome: Adverse events							
1/100	RCT	Poor[4]	Maybe[3]	Yes	3 experimental group subjects had side effects	None	Very low

[1] Armstrong and Ernst: 55% dropout rate. Walach: Flawed randomisation.
[2] Pintov: 42% dropout rate
[3] Only 1 study
[4] Armstrong and Ernst: 55% dropout rate.

6 Conclusion

The evidence about Bach Flower Remedies for psychological problems is very limited. Only three studies that fulfilled the review inclusion criteria were available. Across those studies, results were found to be consistent: BFR are not effective over and above the effects of placebo. However, the studies are of poor quality, largely to high drop-out rates and poor randomisation, and only cover two indications (examination anxiety and ADHD).

very limited evidence

consistent results: BFR not more effective than placebo

No controlled prospective studies evaluating BFR for pain were available. This indicates a substantial gap in the evidence for BFR. Furthermore, reports as to the safety of BFR in the RCTs were inadequate, making a decisive conclusion as to the risks of BFR impossible.

no evidence about BFR for pain

inadequate evidence about safety of BFR

Overall then, there is little evidence about BFR for psychological problems and pain, and the evidence that does exist is of poor quality. Extensive and good quality RCTs are required to obtain a clear picture as to whether BFR are effective for psychological problems or pain, and the risks associated with them.

extensive and good quality RCTs required

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