BEST in Mental Health

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Best Evidence Summaries of Topics in Mental Healthcare

BEST *in* MH *clinical question-answering service*

Question

"In adults with an anxiety disorder or a mood disorder, how effective is homeopathy, compared to any other intervention, in improving patient outcomes?"

Clarification of question using PICO structure

Patients:	Adults with an anxiety disorder or a mood disorder
Intervention:	Homeopathy
Comparator:	Any
Outcome:	Any patient outcomes

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Clinical and research implications

The very limited evidence available suggests that homeopathy has no significant treatment effects, compared to placebo, in people with Generalised Anxiety Disorder, or moderate to severe depression.

High quality, adequately powered trials, with sufficient length of follow-up to adequately assess treatment effects in these conditions, are lacking.

What does the evidence say?

Number of included studies/reviews (number of participants)

We identified two systematic reviews by the same research group, one assessing homeopathy for the treatment of anxiety and anxiety disorders,[1] and one assessing homeopathy for the treatment of depression and depressive disorders,[2] which were considered potentially relevant to this evidence summary. The first systematic review included eight randomised controlled trials (RCTs) and four uncontrolled studies, of which one placebo-controlled RCT was conducted in a population relevant to this evidence summary (adults with Generalised Anxiety Disorder).[1] The second systematic review included two RCTs and five uncontrolled studies, of which one RCT, comparing homeopathy to fluoxetine or placebo, was conducted in a population relevant to this evidence summary (adults with moderate to severe major depressive episodes).[2] One further placebo controlled RCT conducted in adults with moderate to severe major depression,[3] and a non-inferiority trial comparing homeopathy to fluoxetine for moderate to severe depression,[4] were identified.

Main Findings

The only study assessing the effectiveness of homeopathy for the treatment of anxiety disorders, summarised in a systematic review,[1] found no significant difference between homeopathy and placebo on any of the anxiety, depression, or general symptom outcome measures assessed. The RCT comparing homeopathy to fluoxetine or placebo for the treatment of moderate to severe depression, which was identified in a second systematic review,[2] did not report any results because only six participants completed the study. The additional placebo controlled study, which was conducted in people with moderate to severe depression was terminated early due to poor recruitment and was reported to be underpowered.[3] This study also found no significant differences between homeopathy and placebo for any of the depression or quality of life outcomes assessed. Finally, the results of analyses reported in the non-inferiority trial indicated that homeopathy was not inferior to fluoxetine for the treatment of moderate to severe depression, however, the dropout rate from this small study (91 participants randomised) was 40% and no power calculation was reported.[4]

Authors Conclusions

Two systematic reviews, one on anxiety and one on depression, and an additional placebo controlled RCT conducted in people with moderate to severe depression concluded that current evidence on the effectiveness of homeopathy is inadequate. One non-inferiority trial concluded that homeopathy is non-inferior to fluoxetine for the treatment of moderate to severe depression.

Reliability of conclusions/Strength of evidence

The evidence included in this summary was derived from four small, poor quality RCTs. Large, high quality RCTs, with adequate follow-up periods are lacking.

What do guidelines say?

National Institute for health and Care Excellence (NICE) guidelines do not comment upon the use of homeopathy to treat depression.

Scottish Intercollegiate Guidelines network (SIGN) provide the following guidance regarding the use of homeopathy to treat depression:

"One good quality systematic review identified only two RCTs, one of poor quality and one in which only six patients completed the study. There is insufficient evidence on which to base a recommendation." (p.14, 2010)

Neither NICE nor SIGN comment upon the use of homeopathy to treat anxiety disorders.

Date question received: 01/07/2014
Date searches conducted: 09/07/2014
Date answer completed: 12/01/2015

References

Systematic reviews

1. Pilkington, K., Kirkwood, G., Rampes, H., Fisher, P., & Richardson, J. (2006). Homeopathy for anxiety and anxiety disorders: A systematic review of the research. *Homeopathy*, 95, 151–162. doi:10.1016/j.homp.2006.05.005
2. Pilkington, K., Kirkwood, G., Rampes, H., Fisher, P., & Richardson, J. (2005). Homeopathy for depression: a systematic review of the research evidence. *Homeopathy*, 94, 153–163. doi:10.1016/j.homp.2005.04.003

Randomised controlled trial

3. Adler, U. C., Kruger, S., Teut, M., Ludtke, R., Schutzler, L., Martins, F., … Witt, C. M. (2013). Homeopathy for depression: a randomized, partially double-blind, placebo-controlled, four-armed study (DEP-HOM). *PLoS ONE, 8*(9). e74537. doi:10.1371/journal.pone.0074537
4. Adler, U. C., Paiva, N. M. P., Cesar, A. T., Adler, M. S., Molina, A., Padula, A. E., & Calil. H. M. (2011). Homeopathic individualized Q-potencies versus fluoxetine for moderate to severe depression: Double-blind, randomized non-inferiority trial. *Evidence-based Complementary and Alternative Medicine*, 1-7. doi:10.1093/ecam/nep114

Guidelines

Scottish Intercollegiate Guidelines Network. (2010). *Non-pharmaceutical management of depression in adults. A national clinical guideline.* Edinburgh: Scottish Intercollegiate Guidelines Network. http://www.sign.ac.uk/pdf/sign114.pdf

Results

Systematic Reviews

Author (year)	Search Date	Inclusion criteria	Number of included studies	Summary of results	Risk of bias
Pilikington et al. (2006)	08/2005	*Participants*: Participants with anxiety or an anxiety disorder. *Intervention*: Homeopathy, including individualised and complex (homeopathic complexes are fixed combinations of several homeopathic medicine). *Comparison*: Not specified. *Outcome*: Rating scales and patient-focused measures such as satisfaction. *Study design*: The review focused on controlled trials, but uncontrolled trials, observational studies and qualitative studies were also included if anxiety was reported as a clearly defined outcomes.	8 RCTs and 4 additional uncontrolled studies. Only 1 RCT was conducted in a population with anxiety disorder (n=44)	This study aimed to review the clinical research evidence on homeopathy for the treatment of anxiety and anxiety disorders. Only one placebo controlled RCT included in the review was considered relevant to this evidence summary. This trial included 44 adults with a DSM-IV diagnosis of Generalised Anxiety Disorder (GAD). Participants had a Hamilton Anxiety Rating Scale (HAM-A) score >20 and a Hamilton Depression Rating Scale (HAM-D) score <18. Participants were selected from 247 respondents to advertisements; the selection and randomisation processes were unclear. The intervention was individualised homeopathy (single remedy, all dilutions >10^{-30}) for ten weeks. Outcomes were measured pre-, mid- and post-treatment. There were no significant between group	The objective of the review was clearly stated and appropriate inclusion criteria were defined. Ten bibliographic databases were searched, including specialist sources. Clinical trials registers were also searched. There were no language restrictions. Data extraction and quality assessment processes included measures to minimise error and bias (undertaken

				differences on any of the outcome measures assessed: HAM-A; HAM-D; Brief Symptom Inventory; Psychological General Well-Being Index; Beck Depression Inventory; Stata-Trait Anxiety Inventory.	independently by two reviewers), but it was unclear whether this also applied to study selection. The methodological quality of controlled trials was assessed using criteria which included Criteria included: method of randomisation; allocation concealment; level of blinding (if relevant); handling of missing data; withdrawals and dropouts; measures of compliance and outcomes. No assessment of the quality of other types of study was reported.

					Studies were summarised in a narrative synthesis.
Pilkington et al. (2005)	02/2004	*Participants*: Participants with a primary diagnosis of depression or a depressive disorder and those with depression as part of/a result of a physical illness. *Intervention*: Homeopathy, including individualised and complex. *Comparison*: Not Specified. *Outcome*: Depression rating scales and patient-focused measures such as satisfaction. *Study design*: Initially only controlled trials, but when few were identified uncontrolled trials, observational studies and qualitative studies were also included.	2 RCTs and 5 additional uncontrolled studies. Only 1 RCT was conducted in a population with a clear mood disorder diagnosis.	This study aimed to review the clinical research evidence on homeopathy for the treatment of depression and depressive disorders. Only one RCT included in the review was considered relevant to this evidence summary. This trial recruited 11 participants with major depressive episodes of moderate severity and duration > 4 weeks, who had HAM-D score >18. The intervention (n=4) was individualised homeopathy (selected by a trained homeopath, using decision support software, from a limited list of 30 remedies). The remedy remained unchanged throughout the treatment period, but dilution and regimen could be adjusted. Comparators were fluoxetine (20 mg daily increased to 40 mg after 4 weeks if no improvement in HAM-D score) (n=4) and placebo (n=3). Treatment duration was 12 weeks.	The objective of the review was clearly stated and appropriate inclusion criteria were defined. Fifteen bibliographic databases were searched, including specialist sources. Searches were supplemented by reference screening and examination of relevant websites. There were no language restrictions. The authors reported searches for un-published studies, but details were not specified.

				Only six participants completed the study and no results were reported.	Data extraction and quality assessment processes included measures to minimise error and bias (undertaken independently by two reviewers), but it was unclear whether this also applied to study selection. The methodological quality of controlled trials was assessed using criteria which included Criteria included: method of randomisation; allocation concealment; level of blinding (if relevant); handling of missing data; withdrawals and dropouts;

					measures of compliance and outcomes. No assessment of the quality of other types of study was reported. Studies were summarised in a narrative synthesis.

Randomised controlled trials

Author (year)	**Inclusion criteria**	**Number of participants**	**Summary of results**	**Risk of bias**
Adler et al. (2011)	*Participants*: Adults aged 18 and over, who met DSM-IV criteria for depression (single or recurrent). Exclusion criteria: Any other axis I disorder except panic disorder; a diagnosis of a personality disorder; a history of substance abuse in the past year; antidepressant use in the previous 30 days; pregnancy or lacxtation; MADRS score<15; recent suicide attempt or ideation. *Intervention*: Homeopathy (Quinquagintamillesimal potency, or 'Q-potency'). One drop, three times a week	91 (48 received homeopathy; 43 received fluoxetine)	This study was a non-inferiority trial comparing individualised homeopathic medicines (Quinquagintamillesmial (Q-potencies) to fluoxetine for the treatment of acute depression. Eighty nine of the 91 study participants were female and the mean age of study participants was approximately 43 years. There were no significant between group differences in number of children, educational background, duration of illness, or baseline MADRS score. Treatments in the homeopathy group included 20 different homeopathic interventions. Although the inclusion criteria	The randomization sequence (one set of 100 non-unique numbers, ranging from 1 to 2, unsorted) was recorded and sent to the research

	for eight weeks. Where there was no response after 4 weeks the homeopathic prescription (or placebo solution) was changed. The homeopath was allowed to change remedy, potency or posology prescriptions. *Comparison*: 20 mg fluoxetine. Where there was no response after 4 weeks 40 mg of fluoxetine or two placebo capsules were given. *Outcome*: Depressive symptoms (Mean change in Montgomery & Asberg Depression Rating Scale (MADRS) from baseline to 4 and 8 weeks).		for the study specified no anti-depressant use in the previous 30 days, concomitant treatment with clonazepam or diazepam was reported for five patients in the fluoxetine group and two patients in the homeopathy group. It was not clear whether there was any other medication psychoactive use during the study. Non-inferiority analysis, for mean change in MADRS score from baseline, indicated that homeopathic Q-potencies were not inferior to fluoxetine. Eight week response rates were similar in the homeopathy (82.8%) and fluoxetine (84.6%) groups. The dropout rate was 40%.	pharmacist at the start of the study. The senior author and the pharmacist had access to the code of the randomised sequence during the study. Although only two male participants were included in the study, the authors report that one was 'randomised' to each group. The trial used a double-dummy design.

				Treatment group was revealed in the event of clinical worsening or severe adverse events. MADRS scores were assessed by a collaborator, blind to treatment group and outcome. The authors stated that the non-inferiority analysis included all randomised patients, but did not fill in missing data.

				However, the article lists 36 participants as 'excluded'. A pre-specified margin of non-inferiority was reported (Δ 1.45), but there was no sample size calculation.
Adler et al. (2013)	*Participants*: Adults (18-65), diagnosed with major depression (rated moderately severe, (HAM-D 17-24)). Exclusion criteria: diagnosis of a psychotic disorder, alcohol or substance abuse, eating disorder or personality disorder; suicidal ideation or recent suicide attempt; treated with antidepressants, antipsychotics, sedatives/hypnotics or mood stabilisers four weeks prior to screening; treated with complimentary or alternative treatment simultaneously to the study, pregnancy or breast feeding. *Intervention*: Homeopathy (Quinquagintamillesimal potency, or 'Q-potency'), either based upon an extensive case history, or based upon a shorter case	44 (for the extensive case history, 16 received homeopathy, 7 placebo; for the short case history, 14 received homeopathy, 7 placebo)	This study aimed to investigate effect of individualised homeopathic Q-potencies compared to placebo for the treatment of acute major depression, and to compare the effects of an extensive homeopathic case history (case history I) to a shorter conventional case history (case history II). Included patients were mainly female (72.7%) and the mean age was 46.5 ± 10.6 years. The mean disease duration was 8.9 ±10.0 years. Baseline demographic and clinical characteristics appeared similar across the groups, with the exception that the proportion of female participants was generally lower in the placebo groups. Treatments in the homeopathy group included 20 different homeopathic interventions.	A block randomisation with variable block lengths was carried out using a 2:1:2:1 ratio (exposing a smaller number of participants to placebo) and placed in sequentially numbered, sealed opaque envelopes. A

	history. One drop, three times a week for six weeks. *Comparison*: Placebo *Outcome*: Depressive symptoms (Hamilton Rating Scale for Depression). Secondary endpoints were Beck Depression Inventory (BDI) and quality of life (SF-12). Outcomes were assessed at 2, 4, and 6 weeks.		There were no significant differences between the homeopathy and placebo groups for any outcome assessed at any time point. The study was terminated due to recruitment problems, and was reported to be under-powered.	computer generated sequence was used by a statistician not involved in the study. Patients, study psychiatrist and the psychologist who assessed outcomes were blind to treatment allocation. The study physician was un-blinded to case history type. The dropout rate was 16%. Results were reported for

				all specified outcome measures.

Risk of Bias

Systematic reviews

Author (year)	Risk of Bias				
	Inclusion criteria	Searches	Review Process	Quality assessment	Synthesis
Pilikington et al. (2006)	☺	☺	☺	☺	☺
Pilikington et al. (2005)	☺	☺	☺	☺	☺

Randomised controlled trials

Study	RISK OF BIAS					
	Random allocation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective Reporting
Adler et al. (2011)	☹	☹	☹	☺	☹	☺
Adler et al. (2013)	☺	☺	☹	☺	☹	☺

☺ Low Risk ☹ High Risk ? Unclear Risk

Search Details

Source	Search Strategy	Number of hits	Relevant evidence identified
SRs and Guidelines			
NICE	homeopathy depression (9) homeopathy anxiety (12)	21	1
DARE	(Alumina OR (Aluminium adj2 metallicum) OR (aluminium adj2 oxide) OR homeop* OR homoeop* OR (Nat* adj2 sulph*)) 73	73	2
Primary studies			
CENTRAL	#1 MeSH descriptor: [Depressive Disorder] explode all trees7477 #2 MeSH descriptor: [Anxiety Disorders] explode all trees4895 #3 MeSH descriptor: [Homeopathy] explode all trees 224 #4 #1 or #2 11646 #5 #3 and #4 7 #6 depression 33344 #7 anxiety 21834 #8 homeopathy or homoeopathy 537 #9 #4 or #6 or #7 48875 #10 #3 or #8 537 #11 #9 and #10 78 Central only 51	51	2
PsycINFO	1. PsycINFO; exp "DEPRESSION (EMOTION)"/ OR exp MAJOR DEPRESSION/; 113673 results.	1	

	2. PsycINFO; exp ANXIETY/; 51083 results. 3. PsycINFO; 1 AND 2; 10720 results. 4. PsycINFO; homeop*.ti,ab; 333 results. 5. PsycINFO; homoeop*.ti,ab; 28 results. 6. PsycINFO; alumina.ti,ab; 42 results. 7. PsycINFO; (aluminium adj2 metallicum).ti,ab; 0 results. 8. PsycINFO; (aluminium adj2 oxide).ti,ab; 0 results. 9. PsycINFO; (nat* adj2 sulph*).ti,ab; 0 results. 10. PsycINFO; "Arsenicum album".ti,ab; 0 results. 11. PsycINFO; Ignatia.ti,ab; 0 results. 12. PsycINFO; "Natrum muriaticum".ti,ab; 0 results. 13. PsycINFO; sepia.ti,ab; 86 results. 14. PsycINFO; "Baryta carb".ti,ab; 0 results. 15. PsycINFO; 4 OR 5 OR 6 OR 13; 483 results. 16. PsycINFO; 3 AND 15; 1 results.		
Embase	52. EMBASE; exp "DEPRESSION (EMOTION)"/ OR exp MAJOR DEPRESSION/; 36541 results. 53. EMBASE; exp ANXIETY/; 116656 results. 54. EMBASE; 52 AND 53; 2752 results. 55. EMBASE; homeop*.ti,ab; 5696 results. 56. EMBASE; homoeop*.ti,ab; 968 results. 57. EMBASE; alumina.ti,ab; 7787 results. 58. EMBASE; (aluminium adj2 metallicum).ti,ab; 0 results. 59. EMBASE; (aluminium adj2 oxide).ti,ab; 605 results. 60. EMBASE; (nat* adj2 sulph*).ti,ab; 175 results. 61. EMBASE; "Arsenicum album".ti,ab; 46 results. 62. EMBASE; Ignatia.ti,ab; 14 results.	118	

	63. EMBASE; "Natrum muriaticum".ti,ab; 15 results. 64. EMBASE; sepia.ti,ab; 665 results. 65. EMBASE; "Baryta carb".ti,ab; 1 results. 66. EMBASE; 55 OR 56 OR 57 OR 64; 14970 results. 67. EMBASE; 54 AND 66; 1 results. 68. EMBASE; DEPRESSION/; 242319 results. 69. EMBASE; 53 OR 68; 321875 results. 70. EMBASE; depress*.ti,ab; 380412 results. 71. EMBASE; anxiety.ti,ab; 148244 results. 72. EMBASE; 69 OR 70 OR 71; 560923 results. 73. EMBASE; HOMEOPATHY/; 8328 results. 74. EMBASE; 66 OR 73; 18712 results. 75. EMBASE; 72 AND 74; 490 results. 76. EMBASE; CLINICAL TRIALS/; 43002 results. 77. EMBASE; (clinical adj3 study).ti,ab; 105519 results. 78. EMBASE; trial.ti,ab; 463116 results. 79. EMBASE; 76 OR 77 OR 78; 591578 results. 80. EMBASE; 75 AND 79; 47 results. 81. EMBASE; random*.ti,ab; 880685 results. 82. EMBASE; factorial*.ti,ab; 22884 results. 83. EMBASE; (crossover* OR cross-over*).ti,ab; 68711 results. 84. EMBASE; placebo*.ti,ab; 198457 results. 85. EMBASE; (doubl* ADJ blind*).ti,ab; 141236 results. 86. EMBASE; (singl* ADJ blind*).ti,ab; 14330 results. 87. EMBASE; assign*.ti,ab; 237646 results. 88. EMBASE; allocat*.ti,ab; 83217 results. 89. EMBASE; volunteer*.ti,ab; 175225 results. 90. EMBASE; CROSSOVER PROCEDURE/; 39375 results.		

	91. EMBASE; DOUBLE BLIND PROCEDURE/; 114109 results. 92. EMBASE; RANDOMIZED CONTROLLED TRIAL/; 344969 results. 93. EMBASE; SINGLE BLIND PROCEDURE/; 18468 results. 94. EMBASE; 81 OR 82 OR 83 OR 84 OR 85 OR 86 OR 87 OR 88 OR 89 OR 90 OR 91 OR 92 OR 93; 1405126 results. 95. EMBASE; 75 AND 94; 118 results.		
Medline	41. MEDLINE; exp "DEPRESSION (EMOTION)"/ OR exp MAJOR DEPRESSION/; 76759 results. 42. MEDLINE; exp ANXIETY/; 55976 results. 43. MEDLINE; 41 AND 42; 15479 results. 44. MEDLINE; homeop*.ti,ab; 4144 results. 45. MEDLINE; homoeop*.ti,ab; 651 results. 46. MEDLINE; alumina.ti,ab; 6581 results. 47. MEDLINE; (aluminium adj2 metallicum).ti,ab; 0 results. 48. MEDLINE; (aluminium adj2 oxide).ti,ab; 519 results. 49. MEDLINE; (nat* adj2 sulph*).ti,ab; 130 results. 50. MEDLINE; "Arsenicum album".ti,ab; 34 results. 51. MEDLINE; Ignatia.ti,ab; 8 results. 52. MEDLINE; "Natrum muriaticum".ti,ab; 8 results. 53. MEDLINE; sepia.ti,ab; 612 results. 54. MEDLINE; "Baryta carb".ti,ab; 0 results. 55. MEDLINE; 44 OR 45 OR 46 OR 53; 11910 results. 56. MEDLINE; 43 AND 55; 4 results. 57. MEDLINE; DEPRESSION/; 76759 results. 58. MEDLINE; 42 OR 57; 117256 results. 59. MEDLINE; depress*.ti,ab; 319279 results.	76	

	60. MEDLINE; anxiety.ti,ab; 112651 results. 61. MEDLINE; 58 OR 59 OR 60; 416501 results. 62. MEDLINE; HOMEOPATHY/; 4083 results. 63. MEDLINE; 55 OR 62; 13233 results. 64. MEDLINE; 61 AND 63; 163 results. 65. MEDLINE; "randomized controlled trial".pt; 378334 results. 66. MEDLINE; "controlled clinical trial".pt; 88820 results. 67. MEDLINE; randomized.ab; 298867 results. 68. MEDLINE; placebo.ab; 155912 results. 69. MEDLINE; "drug therapy".fs; 1714593 results. 70. MEDLINE; randomly.ab; 215985 results. 71. MEDLINE; trial.ab; 310419 results. 72. MEDLINE; groups.ab; 1372146 results. 73. MEDLINE; 65 OR 66 OR 67 OR 68 OR 69 OR 70 OR 71 OR 72; 3375809 results. 74. MEDLINE; 64 AND 73; 76 results.		
AMED	17. AMED; exp "DEPRESSION (EMOTION)"/ OR exp MAJOR DEPRESSION/; 0 results. 18. AMED; exp ANXIETY/; 868 results. 19. AMED; 17 AND 18; 0 results. 20. AMED; homeop*.ti,ab; 3456 results. 21. AMED; homoeop*.ti,ab; 2856 results. 22. AMED; alumina.ti,ab; 31 results. 23. AMED; (aluminium adj2 metallicum).ti,ab; 1 results. 24. AMED; (aluminium adj2 oxide).ti,ab; 0 results. 25. AMED; (nat* adj2 sulph*).ti,ab; 22 results. 26. AMED; "Arsenicum album".ti,ab; 51 results. 27. AMED; Ignatia.ti,ab; 28 results. 28. AMED; "Natrum muriaticum".ti,ab; 44 results. 29. AMED; sepia.ti,ab; 69 results.	15	

	30. AMED; "Baryta carb".ti,ab; 1 results. 31. AMED; 20 OR 21 OR 22 OR 29; 6269 results. 32. AMED; 19 AND 31; 0 results. 33. AMED; DEPRESSION/; 1098 results. 34. AMED; 18 OR 33; 1775 results. 35. AMED; depress*.ti,ab; 5898 results. 36. AMED; anxiety.ti,ab; 3267 results. 37. AMED; 34 OR 35 OR 36; 8014 results. 38. AMED; HOMEOPATHY/; 10324 results. 39. AMED; 31 OR 38; 12228 results. 40. AMED; 37 AND 39; 215 results. 41. AMED; CLINICAL TRIALS/; 1731 results. 48. AMED; (clinical adj3 study).ti,ab; 2043 results. 49. AMED; trial.ti,ab; 8118 results. 52. AMED; "randomised controlled trial".ti,ab; 560 results. 53. AMED; "randomised control trial".ti,ab; 23 results. 54. AMED; "randomized controlled trial".ti,ab; 2046 results. 55. AMED; "randomized control trial".ti,ab; 89 results. 56. AMED; 41 OR 48 OR 49 OR 52 OR 53 OR 54 OR 55; 10979 results. 57. AMED; 40 AND 56; 15 results.		
Summary	**NA**	**NA**	

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