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| **Critique author** | Linda Metzger |

| **Bibliographic Data** | |
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| Authors | Henschke N, Ostelo RWJG, van Tulder MW, Vlaeyen JWS. |
| Title | Behavioral treatment for chronic low-back pain |
| PMID | 20614428 |
| Citation | *Cochrane Database of Systematic Reviews* 2010, Issue 7. Art. No.: CD002014. |
| Other information if relevant | |

| **Methods** | |
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| Aim of study | To determine whether behavioral therapy is more effective than other treatments for non-specific chronic low back pain (CLBP), and to ascertain which type of behavioral therapy is most effective. |
| Design | Meta-analyses of randomized clinical trials |

| **PICOS** | |
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| Population from which participants are drawn | Adults between 18 and 65 years of age reporting non-specific CLBP that persisted for 12 weeks or more and was not associated with pathological entities. |
| Intervention being evaluated | Three main types of psychological behavioral treatments which include operant, cognitive and respondent treatments.<br>- Operant treatment involves the removal of positive reinforcement of pain behaviors and the promotion of healthy behaviors (e.g. exercise, work). Increased activity levels are promoted.<br>- Cognitive treatment aims to identify and modify harmful cognitions which patients may have regarding their pain and disability using techniques such as imagery and attention diversion.<br>- Respondent treatment aims to modify the physiological response to pain, through reduction of muscular tension (relaxation, biofeedback). Pain is viewed as both a cause and a result of muscular tension. |
| Comparison or control intervention | Placebo, no treatment, waiting list controls, other kinds of treatment, physiotherapy, or a different type of behavioral treatment |
| Outcomes | Overall improvement, back pain specific functional status, generic function, return-to-work, and pain intensity |

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| Study types | RCTs that evaluated one or more of the 3 types of psychological behavioral treatments |

| **Study selection** | |
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| Search date of literature review | February 2009 |
| Databases in literature search | Cochrane Back Review Group Trials Register, CENTRAL, MEDLINE, EMBASE, and PsycINFO |
| How authors assessed study quality (risk of bias and other considerations | Cochrane risk of bias tool using the 12 criteria recommended by the Cochrane Back Review Group. A low risk of bias was defined as studies fulfilling 6 or more of the 12 internal validity criteria. GRADE (Grades of Recommendation, Assessment, Development and Evaluation) profiles were used to evaluate the overall quality of the evidence and the strength of the recommendations. |
| Additional information if relevant | The clinical relevance of each included trial was also assessed. |

| **Results** | |
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| Number of studies screened | 21 RCTS were screened from the 2005 version of this Cochrane review, and 392 additional references were screened in this updated search. |
| Number of studies selected for analysis of results | 19 RCTS were selected from the 2005 Cochrane and 11 RCTs were added in this current Cochrane for a total of 30 studies with 3438 participants. Included studies were published between 1982 and 2008. |
| Whether authors elected to perform meta-analysis to pool study results statistically and type of meta-analysis done (fixed effect or random effects, heterogeneity, etc) | If studies were clinically homogeneous regarding study population, types of treatment, outcomes and measurement instruments, a fixed effect or a random effects meta-analysis was performed. In total, 54comparisons were made, each containing 2 to 5 studies where results were pooled and a meta-analysis was performed. Heterogeneity was high in some comparisons with $I^2$ values ranging between 0% and 91%. Standard mean differences (SMDs) or mean differences (MD) and 95% confidence intervals (CIs) were calculated for each analysis. |
| Quality of studies as assessed by authors | Fourteen studies (47%) had a low risk of bias, meeting 6 or more of the criteria. Only 9 studies (30%) used a clearly described and adequate randomization procedure in combination with an adequate concealment of treatment allocation. Most studies were free of selective reporting (28 studies; 93%). Fifteen studies (50%) had an acceptable drop-out rate, and 11 studies (37%) reported acceptable compliance. For most comparisons (39 out of 54), there was only low or very low quality evidence to support the results. |

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| Effect sizes reported for primary outcomes (mean differences, standardized mean differences, response ratios, etc) | There was moderate quality evidence to support 15 of the comparisons.<br>- **There was moderate quality evidence from 3 studies (153 participants) that showed that operant therapy was significantly more effective for short-term pain relief than waiting list control (SMD -0.43, 95% CI -0.75 to -0.11).** |
| Effect sizes reported for additional outcomes (mean differences, standardized mean differences, response ratios, etc) | - There was moderate quality evidence from 2 studies (93 participants) that there is little or no difference between cognitive therapy and operant therapy for pain relief over a short (SMD 0.41, -0.63 to 1.45) to intermediate term follow-up (SMD 0.35, -0.64 to 1.35).<br>- There was moderate quality evidence from 3 studies (139-161 participants) that there is little or no difference between operant therapy or combined behavioral therapy for pain relief over a short (SMD -0.15, -0.46 to 0.16), intermediate (SMD -0.23, -0.57 to 0.11), and long-term follow-up (SMD -0.31, -0.65 to 0.03).<br>- **There is moderate quality evidence (two RCTs; N = 330) that behavioral treatment is more effective than usual care for pain relief in the short-term (MD -5.18; 95%CI -9.79 to -0.57),** but there is little or no difference between the groups for pain relief in the intermediate-term (MD -4.29, 95% CI -9.28 to 0.69).<br>- There is moderate quality evidence (two RCTs; N = 330) that there is no significant difference between behavioral treatment and usual care for improved back-specific functional status in both the short (SMD -0.20, 95% CI -0.41 to 0.02) to intermediate-term (SMD -0.12, 95% CI -0.34 to 0.10).<br>- There is moderate quality evidence (two RCTs; N = 137) that there is no significant difference between behavioral treatment and a group exercise program for pain relief in the intermediate (MD 1.18, 95% CI -3.16 to 5.53) to long-term (MD 0.14, 95% CI -4.40 to 4.67).<br>- There is moderate quality evidence (two RCTs; N = 137) that there is no significant difference between behavioral treatment and a group exercise program for symptoms of depression in the intermediate (SMD 0.02, 95% CI -0.32 to 0.35) to long-term (SMD 0.07, 95% CI -0.27 to 0.41).<br>- There is moderate quality evidence (two RCTs; N = 405) that the addition of behavioral treatment to an inpatient multidisciplinary program is no more effective than the multidisciplinary program alone for pain intensity in the short-term (SMD -0.14, 95% CI -0.34 to 0.05). |

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| Additional information if relevant –summary of results | - Behavioral treatment has very small positive effects on pain when compared to a waiting list control or usual care in the short-term.<br>- There was moderate quality evidence that showed that operant therapy was significantly more effective for short-term pain relief than waiting list control.<br>- There is moderate quality evidence that behavioral treatment is more effective than usual care for pain relief in the short-term. |

| **Authors' Conclusions** | |
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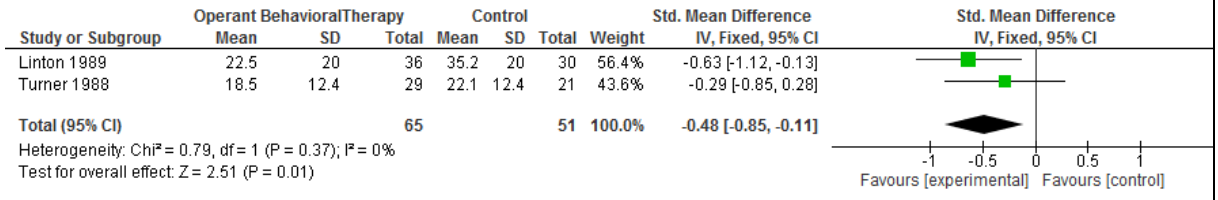
| Key conclusions of study authors | - For patients with CLBP, there is moderate quality evidence that in the short-term, operant therapy is more effective than waiting list control, and behavioral therapy is more effective than usual care for pain relief, but no specific type of behavioral therapy is more effective than another.<br>- In the intermediate to long-term, there is little or no difference between behavioral therapy and group exercises for pain relief or depressive symptoms.<br>- While the evidence from the current review shows a promising effect on pain relief in favor of behavioral therapy, it is important to consider how the interventions are applied in practice and the clinical importance of the effect size before it is recommended as part of CLBP management.<br>- Whether clinicians should refer chronic low-back pain patients to behavioral treatments or to other active conservative treatments cannot be concluded from this review.<br>- Because many of the included trials did not measure pain and functional ability with a VAS or the RMDQ, which both have defined clinically significant effect sizes, there was usually insufficient information to determine if the size of the effect was clinically significant for other outcomes. While these outcomes are recommended for use in most CLBP trials, further research is needed to expand the definition of a clinically significant effect size, especially when measured with other commonly used behavioral treatment outcome measures.<br>- It is still unknown what type of patients benefit most from what type of behavioral treatment.<br>- Further research is likely to have an important impact on our confidence in the estimates of effect and may change the estimates.<br>- More fundamental or basic research is warranted to identify which psychological factors have the strongest influence on a patient's experience of LBP and which of these factors can be utilized as appropriate outcome measures.<br>- In future trials, we advocate the use of valid and reliable outcome measures in the low-back pain field and also a move to determine the most reliable and valid outcome measures in the behavioral domain.<br>- Also in future studies, behavioral treatment should be compared to other active treatments for CLBP, and a cost-effectiveness analysis should be included. |
| Additional information if relevant | |

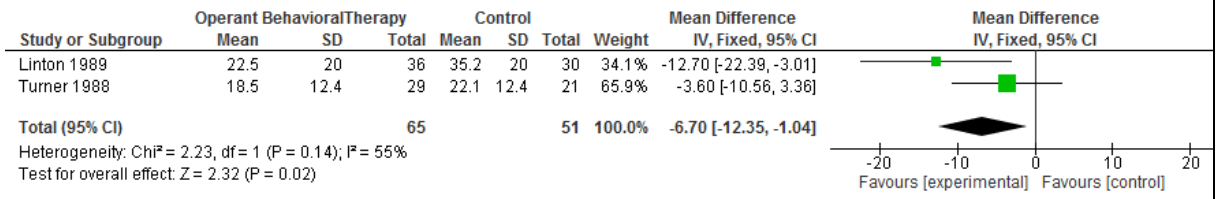
**Comments by DOWC staff**

- This review found that operant therapy was significantly more effective for short-term pain relief than waiting list control. This effect size (SMD -0.43) would be considered small. The authors cited this as moderate quality evidence, but of the 3 RCTs pooled in this meta-analysis, two had a low risk of bias (Linton 1989, Turner 1988) and one RCT had a high risk of bias (Turner 1990). The Turner 1990 RCT would be considered a low quality study by DOWC standards. By pooling only the 2 moderate quality studies by DOWC standards, the effect size is similar, but remains small (SMD -0.48; 95% CI -0.85 to -0.11). Even though this small effect size found for operant therapy was statistically significant, it is not clinically important alone in the treatment of chronic pain. By pooling the 2 moderate quality studies, the group mean difference is only 6.7 points on a 100 point pain scale (MD -6.70; 95% CI -12.35 to -1.04). The minimal clinically important difference (MCID) for pain is generally considered to be between 15 to17 points on a VAS scale. This statistically significant result did not meet the MCID. Even the confidence intervals do not encompass the MCID of 15 points which further indicates that this small effect is not clinically important. Since few if any chronic pain treatments have specific large effects that meet the threshold for clinically relevant benefits, this does not necessarily mean that there are no effective treatments for chronic pain. It appears that operant therapy or any intervention in isolation will not be sufficient to adequately reduce chronic pain. This might mean instead that the threshold for clinical relevance is too high for any individual treatment alone, and that a multidisciplinary approach to chronic pain management, with a focus on combining several non-pharmacological therapies is necessary. Operant therapy could still be considered clinically important in addition to other chronic pain treatments.

Operant Therapy vs Wait List Control for Short-Term Pain Relief-Standard Mean Difference




Operant Therapy vs Wait List Control for Short-Term Pain Relief-Mean Difference




- This review also found that behavioral treatment was more effective than usual care for pain relief in the short-term (MD -5.18; 95% CI -9.79 to -0.57). Both of the 2 RCTs pooled in this meta-analysis had a high risk of bias and would be considered low quality studies by DOWC standards. Evidence cannot be obtained from only low quality studies, even if a small statistically significant difference with a clinically unimportant benefit was found
- From the results of the meta-analyses, it can be seen that behavioral treatment for CLBP generally results in small effect sizes. However, as behavioral treatment can be considered inherently harmless, small benefits could be considered useful if they prove to be cost-effective.

**Comments by DOWC staff**

- The included trials were small in size, did not provide long-term outcomes, and suffered from poor reporting of a number of methodological quality items. None of the comparisons made in this systematic review provided high quality evidence, either for or against behavioral treatment. For most of the comparisons made in this review, there was only low or very low quality evidence to support the results. Moderate quality evidence was found for a small number of comparisons. Due to the low quality studies included in this review, only good evidence, not strong, can be derived from this review.
- This review contained too many small comparisons where each meta-analysis contained only 2 to 3 mostly small studies. Smaller studies usually show larger effect sizes, and in this review many of the small studies had the largest effect sizes along with wide confidence intervals resulting in nonsignificant results. If larger studies had been included in the pooled analyses, perhaps more conclusive results would have been found.
- The risk of bias of the trials included in this review was generally high. Considering the nature of behavioral therapy, blinding of patients and care providers was virtually impossible. Many of the other criteria used to assess risk of bias were not reported, especially details about the randomization procedure and concealment, compliance, and tracking of co-interventions.
- When homogeneity was present among trials, the authors did not describe or address. Homogeneity is equated with similar characteristics among studies, and if heterogeneity was high, an explanation or subgroup analysis should have been performed to help uncover which characteristics contributed to the heterogeneity. The variation in outcome measures among trials could be a potential contributor causing a high degree of heterogeneity.
- The previous version of this review (Ostelo 2005) used a “levels of evidence” approach in grading the quality of the evidence. This update applied the GRADE approach, which considers limitations in the design of trials as well as factors such as inconsistency, imprecision, and indirectness leading to a more stringent grading of the quality of the evidence. This may be one reason why it appears that more of the included studies in this update were of lower quality compared to the previous version, and why this update provided fewer results of moderate quality evidence.
- The variation in outcome measures hampered the comparability between studies in this review. Future studies need to determine the appropriate behavioral outcomes to use that are the best predictors of disability.
- As occurs with other Cochrane reviews, the meta-analyses in this review considered behavioral treatment as stand-alone therapies for the treatment of chronic pain, and not as a component in a multidisciplinary approach to chronic pain management.

| **Assessment by DOWC staff** | |
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| Overall assessment as suitability of evidence for the guideline<br>☒ High quality<br>☐ Adequate<br>☐ Inadequate | High quality Cochrane meta-analysis supporting good evidence that in the short-term, operant therapy in isolation shows small effects of little clinical importance in reducing pain compared to waiting list controls, but no specific type of behavioral therapy is more effective than another in the treatment of patients with chronic pain. |
| If inadequate, main reasons for recommending that the article not be cited as evidence | Note: Cochrane and DOWC do not always have the same evidence standards. Moderate quality in a Cochrane does not always meet DOWC evidence criteria, especially when Cochrane includes low quality studies in their moderate quality evidence. |

| **Additional references if relevant** |
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| - Ostelo RWJG, van Tulder MW, Vlaeyen JWS, and et al. Behavioral treatment for chronic low-back pain. *Cochrane Database of Systematic Reviews* 2005, Issue 1. [Art. No.: CD002014. |