

Bibliographic Data	
Authors	Buhrman M, Syk M, et al
Title	Individualized Guided Internet-delivered Cognitive-Behavior Therapy for Chronic Pain Patients With Comorbid Depression and Anxiety: A Randomized Controlled Trial.
PMID	25380222
Citation	Clin J Pain. 2015 Jun;31(6);504-16.
Other information if relevant	

Methods	
Aim of study	To test an individualized cognitive behavioral treatment delivered through the internet for patients with chronic pain and emotional distress
Design	Randomized clinical trial

Reasons not to cite as evidence
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- High risk of bias arises from selective outcome reporting, shown as follows:
- The study was registered at clinical trials.gov
<https://clinicaltrials.gov/ct2/show/NCT01329861?term=NCT01329861&rank=1>
- The primary outcome in the protocol was the Coping Strategies Questionnaire (CSQ): specifically, the change from baseline in the catastrophizing subscale to two weeks post-treatment
- The CSQ did not show a significant difference between intervention groups, although the internet-based intervention group did have a significant improvement in the CSQ score
- In the published article, the CSQ is listed and reported as a secondary outcome rather than a primary outcome
- In the published article, the Montgomery-Asberg Depression Rating Scale (MADRS-S) is designated as a primary outcome, and did show a significant difference between groups
- However, in the registered protocol, the MADRS-S is not even listed as an outcome at all, neither primary nor secondary
- Thus, the primary outcome, which did not show a difference between groups, was demoted to the status of a secondary outcome, and an outcome which was not listed in the study protocol was reported as a primary outcome, probably because it did show a difference between groups
- Another outcome which had a significant difference favoring the treatment group, the Pain Disability Index (PDI), also is promoted to the status of a primary outcome, even though it is not even listed in the registered protocol
- The same is true of the Beck Anxiety Inventory (BAI)
- This study illustrates the importance of registering all clinical trials, whether of pharmacological or non-pharmacological interventions

Additional references or comments if relevant

- “Outcome sprawl,” meaning the reporting of a large number of outcomes spread out over a large number of column-inches, should be suspected as a sign of selective outcome reporting until proven otherwise, as evidenced by a registered protocol showing clearly that the outcomes reported in the study were specified in advance