Critique author	**Ed Whitney**

Bibliographic Data	
Authors	Bair MJ, Ang D, et al
Title	Evaluation of Stepped Care for Chronic Pain (ESCAPE) in Veterans of the Iraq and Afghanistan Conflicts: A Randomized Clinical Trial.
PMID	25751701
Citation	JAMA Intern Med. 2015 May;175(5);682-9.
Other information if relevant	

Methods	
Aim of study	To determine whether a stepped-care intervention is more effective than usual care, as hypothesized, in reducing pain-related disability, pain interference, and pain severity
Design	Randomized clinical trial

Participants	
Population from which participants are drawn	Recently discharged veterans from Iraq and Afghanistan being seen at a postdeployment clinic and 5 general medical clinics in a single VA medical center
Setting (location and type of facility)	VA medical center in Indianapolis
Age	36.7
Sex	213 men, 28 women
Total number of participants for whom outcome data were reported	241

Inclusion criteria	Deployment to Iraq or Afghanistan while on active duty, with self-reported chronic pain (over 3 month duration) of neck, back, shoulder, hip, or knee, which was at least moderately disabling with at least 7 points on the 24 point Roland-Morris disability scale (RMDS) at the initial visit
Exclusion criteria	Severe medical conditions which could prevent study participation, active psychosis, schizophrenia, current alcohol or substance abuse, active suicidal ideation, prior or pending back surgery, and pregnancy
Other information if relevant	

Intervention Groups

Group 1	
Group name	Stepped care intervention
Number in group	121
Description of intervention	- Care was organized into two steps which were executed in sequence: step 1 being optimization of pharmacological treatment for 12 weeks, and step 2 being a cognitive behavioral treatment (CBT) for 12 weeks - Step 1 was delivered by 2 nurse case managers (NCMs) who first obtained a history of previous pain treatments and assessed whether appropriate dosing and scheduling of these treatments had been done; if not, adjustments were made wherein dosing and scheduling were optimized - The NCMs followed an algorithm for analgesic administration into 8 categories, including NSAIDS, topicals, gabapentinoids, tricyclics, tramadol, short acting opioids, and long acting opioids - During step 1, the NCMs also instructed patients in the natural history of pain and also in self-management techniques, encouraging patients to minimize bed rest, returning to activities, stretching and strengthening exercises, and walking - Step 1 also involved assessing depressive symptoms at each phone contact, referring the patient to mental health practitioners when indicated - During step 2, a CBT program was implemented, consisting of 6 individual 45 minute sessions delivered by phone - CBT involved discussion of thoughts and feelings about pain, identification of barriers to reducing functional limitations, and identification of maladaptive thoughts which were replaced with more adaptive cognitions

Duration of treatment period	24 weeks
Co-interventions if reported	
Additional information if relevant	

Group 2	
Group name	Usual care
Number in group	120
Description of intervention	- Educational handouts on musculoskeletal pain were provided, and patients were followed up by their treating physician for all medical care - This care included clinic visits, continuation of medication, specialty referrals, and use of pharmacological and nonpharmacological care
Duration of treatment period	24 weeks
Co-interventions if reported	
Additional information if relevant	

Primary outcome	
Outcome name and criteria for definition	- Change in pain related disability as scored by the 24 point RMDS, where a minimal clinically significant difference was considered to be 2 to 3 points, and a 30% improvement is also considered clinically important - Pain interference as assessed by the Brief Pain Inventory (BPI) taken from 7 items which indicate the degree of interference with sleep, mood, work, physical activity, social activity, enjoyment of life, and relations with others; the composite score was on a scale of 1 to 10, and a 1 to 2 point change was considered clinically important - Pain severity on a scale of 0 to 100, without specification of clinically important cut points

Time points measured and/or reported	3, 6, and 9 months after randomization
Differences between groups	- On the RMDS, the stepped care group experienced a mean 3.7 point improvement and the usual care had a 1.7 point improvement, with an adjusted group difference of 1.9 points in favor of stepped care - The mean change in the BPI pain interference scale was 1.7 points for stepped care and 0.9 points for usual care, for a group difference of 0.8 points in favor of stepped care - The pain severity score decreased by an average of 11.1points for stepped care and 4.5 points for usual care, for a 6.6 point difference in favor of stepped care
Additional information if relevant	- Analgesic use was also assessed and compared between groups - At the end of step 1 (3 months), patients in the stepped care group received more agents in each analgesic class relative to what they had been taking at baseline - At the end of the study (9 months), the stepped care patients were using more topical agents than the usual care group, and the usual care group was using more tricyclics than the stepped care group

Secondary outcomes	
Outcome name and criteria for definition	Although the change in RMDS was the primary outcome, the BPI pain interference and pain intensity scores were also grouped as primary outcomes
Time points measured	
Differences between groups	
Additional information if relevant	Although group comparison assessments were done at 3 and 6 months, the data for these interim comparisons are presented in graphical form without numerical or tabular displays of data It appears that stepped care outperformed usual care at the 3 and 6 month intervals, but the differences are difficult to quantify

Conclusions	
Key conclusions of study authors	- Stepped care which combines analgesics, self-management techniques, and CBT is more beneficial than usual care in terms of pain-related disability, pain interference, and pain severity

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	
Allocation concealment *(selection bias)*	Low	
Blinding of participants and personnel *(performance bias)*	Low	
Blinding of outcome assessment *(detection bias)*	Low	
Incomplete outcome data *(attrition bias)*	Low	
Selective outcome reporting? *(reporting bias)*	Low	
Other bias	Low	

Sponsorship if reported		

Study funding sources if reported	VA Rehabilitation Research and Development Grant	
Possible conflicts of interest for study authors	Two authors receive honoraria from Eli Lilly for work done in other settings	
Notes:		

Comments by DOWC staff

- The design and execution are of generally high quality with good control of bias at each step
- The outcomes emphasize disability and pain interference over pain severity, which is a rare but very commendable ranking of outcomes in terms of clinical importance
- The specific contribution of CBT in step 2 is difficult to separate from the effects of optimizing pharmacologic management in step 1, since the effects of CBT would begin to be manifested between the three month and the six month followups, where the group effects are displayed graphically rather than numerically
- The use of the term "biweekly" is regrettable, since it can mean twice per week and can also mean every other week; the latter usage applies to this article
- A 30% reduction in RMDS disability was considered as a clinically important, and the authors report a relative "risk" of 1.52 in favor of stepped care; however, the actual numbers of patients who met this criterion in each group is not apparent
- The study protocol, published as a supplement to the main study, indicates that step 2 targeted veterans who had persistent pain and high disability at 12 weeks; however, the flow diagram does not shed light on whether a significant number of participants met this criterion at 12 weeks; it is clear that only a few withdrawals took place at the end of step 1, and it seems likely that CBT was offered to all participants at the end of step 1, regardless of whether or not they continued to have high disability at 12 weeks
- Opioid use did not appreciably decline for stepped care; at baseline, 42 patients (34.6%) were taking opioids, and at 9 months, 37 were taking opioids (30.6%) (data in a supplement separate from the main study)
- For usual care, 44.2% took opioids at baseline and 35.8% took opioids at 9 months
- From the same data supplement, it appears that gabapentin, but not pregabalin, was included in the analgesics administered during the study

Assessment by DOWC staff	

Overall assessment as suitability of evidence for the guideline ☒ High quality ☐ Adequate ☐ Inadequate	There is good evidence that a stepped care program is more effective than usual care in veterans with chronic musculoskeletal pain. The stepped care program consisted of 12 weeks during which nurse case managers took a medication use history and adjusted medication dosage and scheduling through telephone contacts with patients every other week, followed by a 12 week step in which cognitive behavioral treatment was administered by 45 minute individual sessions by telephone every other week. Disability and pain interference with daily activity with stepped care were both superior to usual care in which patients were given printed handouts and were followed for all care by their primary treating physicians
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant
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