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Bibliographic Data	
Authors	Kroenke K, Krebs EE, Wu J, and et al.
Title	Telecare Collaborative Management of Chronic Pain in Primary Care - A randomized clinical trial
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Other information if relevant	trial registration with clinicaltrials.gov NCT00926588

Methods	
Aim of study	To determine the effectiveness of a telephone-delivered collaborative care management intervention for primary care patients compared with usual care for the management of chronic musculoskeletal pain.
Design	Single-blind randomized clinical trial

Participants	
Population from which participants are drawn	Recruited from 5 primary care clinics in the Roudebush Veterans Administration (VA) Medical Center in Indianapolis.
Setting (location and type of facility)	The intervention took place at 5 primary care VA clinics in Indianapolis and in participants' homes.
Age	Adults between18 and 65 years, mean age 55.1years
Sex	43 females, 207 males
Total number of participants for whom outcome data were reported	The number of participants assessed was 250 at baseline, 248(123 intervention, 125 control) at 1 month, 244 (122 and 122) at 3 months, 245 (120 and 125) at 6 months, and 238 (116 and 122) at 12 months.
Inclusion criteria	1. Ages 18 to 65 years 2. Musculoskeletal pain, either regional (joints, limbs, back, neck) or more generalized (fibromyalgia or chronic widespread pain). 3. moderately severe pain, Brief Pain Inventory (BPI) intensity item score of 5 or higher for either "average" or "worst" pain in the past week 4. persistent pain of ≥3 months despite trying at least 1 analgesic medication
Exclusion criteria	Individuals who had a pending pain-related disability claim, schizophrenia, bipolar disorder, moderately severe cognitive impairment, active suicidal ideation, current illicit drug use, or a terminal illness.
Other information if relevant	Baseline pain did not differ between groups. The baseline means (SD) on the BPI for the intervention group was 5.31 (1.81) and the usual care control group was 5.12(1.80).

Intervention Groups

Group 1	
Group name	Telephone-delivered collaborative care management intervention
Number in group	124

Description of intervention	This active intervention included 2 major components: 1) automated home-based symptom monitoring and 2) optimized telephone-based analgesic management by a nurse care manager and physician pain specialist in collaboration with the primary care physician to decide on treatment changes. The automated symptom monitoring (ASM) was conducted either by interactive voice recorded telephone calls or by Internet, depending on patient preferences. Reports from ASM were scheduled weekly for the first month, every other week for months 2 and 3, and monthly for months 4 through 12. Nurse contacts were scheduled as initial, at 1 and 3 months, when requested by the patient, and other times as determined by ASM responses. A stepped care analgesic optimization algorithm was used which included the 6 major categories of analgesics.
Duration of treatment period	12 months
Co-interventions if reported	
Additional information if relevant	Patients in the intervention group had a mean of 12.7 nurse telephone contacts and a mean of 13.5 ASM contacts during the 12-month period.

Group 2	
Group name	Usual care-control group
Number in group	126
Description of intervention	Patients continued to receive care for their chronic musculoskeletal pain from their primary care physician. There was no attempt by study personnel to influence clinical management.
Duration of treatment period	12 months
Co-interventions if reported	More chiropractic and massage therapy used than in the intervention group.
Additional information if relevant	Treatment groups did not differ in use of health care services, including outpatient visits, emergency department visits, and hospitalizations, during the 12-month trial.

Primary outcome	
Outcome name and criteria for definition	The Brief Pain Inventory (BPI) is an 11-item scale that measures self-reported pain severity and interference. It consists of 4 pain severity items and 7 pain interference items. Each item is scored from 0 (no pain) to 10 (worse pain imaginable). The primary outcome was the mean between-group difference in BPI total score (pain and interference) during the 12-month trial. The primary end time point was the 12-month post-intervention follow-up. The MCID is a 1 point change.
Time points measured and/or reported	Assessments were conducted at baseline and at 1, 3, 6, and 12 months by a research assistant blinded to study group assignment.

Differences between groups	Patients in the intervention group had significantly greater improvement in their BPI total score during the 12-month trial and between-group differences at 12 months were also significant for BPI total. Compared with usual care, the intervention group had a 1.02-point lower (95% CI, −1.58 to −0.47) BPI score at 12 months (3.57 vs 4.59). This more than 1-point improvement between groups in BPI total score is clinically important and represents a moderate treatment effect size of 0.57. These results showed statistically and clinically significant differences between groups in pain reduction with participants in the intervention group having greater reduction of pain at 12 months (P< 0.001).
Additional information if relevant	There were no statistically significant differences between the 2 groups in baseline demographics or outcome measures. Follow-up rates were excellent, with outcome assessments completed by 99% of participants at 1 month, by 98% at 3 and 6 months, and by 95% at 12 months. The estimated time spent per patient in the intervention group during the 12 months was 3 to 4 hours by the study nurse and 1 hour by the study physician.

Secondary outcomes	
Outcome name and criteria for definition	Secondary pain outcomes included between-group comparisons of the (1) difference in response rates (with individual response defined as a 30% or greater decrease in BPI total from baseline to 12 months); (2) mean BPI interference and BPI severity scale scores at 12 months; and (3) patient retrospective assessment of change in pain from baseline to 6 months (using a 7-point global rating of change item). Several demographic and secondary psychological, health-related quality-of-life, and disability outcomes.
Time points measured	Assessments were conducted at baseline and at 1, 3, 6, and 12 months by a research assistant blinded to study group assignment.

Differences between groups	(1) Patients in the intervention group were nearly twice as likely to report at least a 30% improvement from their baseline pain score by12 months (51.7% vs 27.1%; relative risk [RR], 1.91 [95% CI, 1.4 to 2.7]). (2) Patients in the intervention group had significantly greater improvement in their BPI severity and interference pain scores. Between-group differences at 12 months were also significant for BPI interference and BPI severity (P< 0.001). The -1.00 point improvement in BPI pain severity score and the -1.05 point improvement in BPI pain interference score between groups at 12 months are also clinically important differences favoring the intervention group. (3) Patients in the intervention group were also significantly more likely to report global pain improvement (55.8% vs 31.2%; RR, 1.8[95% CI, 1.3 to 2.4]) and only half as likely to report worsening pain (19.2% vs 36.0%; RR, 0.5 [95% CI, 0.3 to 0.8]) by 6 months. Patients in the intervention group reported greater improvement in depression, anxiety, somatization, sleep, social functioning, and physical component summary scores, only depression reached the significance threshold for secondary outcomes of $P < .001$. During the 12-month trial, patients in the intervention group received a greater number of analgesics for more months and at a higher mean dose than the usual care group. Treatment groups did not differ in their opioid use at baseline, during the trial, or at the end of the trial.
Additional information if relevant	At 12 months, 95% of patients in the intervention group rated the nurse calls as “very or moderately helpful,” 92% rated ASM as “easy,” and 76% rated ASM as “very or moderately helpful.” Of the 166 patients in the overall sample who were not taking opioids at the start of the trial, opioids were initiated in only 6 patients (3.6%).

Conclusions	
Key conclusions of study authors	- This study showed that the collaborative telecare management intervention for primary care patients produced clinically meaningful improvements in pain, with a moderate treatment effect size (0.57), and a greater rate of improvement (56% vs 31%) accompanied by greater patient satisfaction with pain treatment. - These results show that using a stepped care algorithm-guided optimization of nonopioid medications for pain along with monitoring can be efficiently delivered through a predominantly telephone and Internet-based approach to improve chronic musculoskeletal pain in primary care patients. - This study revealed that although one-third of patients were taking opioid therapy at baseline, few patients in either group were started on opioids or had escalations in their opioid dose. - Patients in the usual care group were more likely to experience worsening of pain by 6 months compared with those in the intervention group (36% vs 19%). - The results of this study support that the intervention was effective, even though most trial participants reported pain that had been present for many years, that involved multiple sites, and that had been unsuccessfully treated with numerous analgesics. - Combining this approach of optimizing pain medications with one or more other evidence-based treatments might produce even greater pain improvement in some patients. - Monitoring the response of pain to treatment when adjusting medications maximizes the tailoring of therapy to the individual patient with pain.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	Randomized assignment was conducted by the project coordinator to ensure that the 2 research assistants responsible for outcome assessments were blinded to treatment group assignment.
Allocation concealment *(selection bias)*	Low	Assignment to treatment group was determined by a computer-generated randomization list.
Blinding of participants and personnel *(performance bias)*	High	Patients were aware of which group they were in, and it was not possible to blind them. Nurses and physicians providing the care were not blinded to the intervention The lack of blinding does not prejudice the conclusions.
Blinding of outcome assessment *(detection bias)*	Low	All outcome assessments were conducted by research assistants blinded to intervention assignment.

Incomplete outcome data *(attrition bias)*	Low	Participant follow-up was excellent with few drop-outs. Results of all outcomes were reported.
Selective outcome reporting? *(reporting bias)*	Low	The trial was registered with clinicaltrials.gov NCT00926588
Other bias		

Sponsorship if reported		
Study funding sources if reported	This work was supported by a Department of Veterans Affairs (VA) Health Services Research and Development Merit Review award to Dr Kroenke and a VA Career Development Award to Dr Krebs.	
Possible conflicts of interest for study authors	None declared. The Department of Veterans Affairs had no role in the design and conduct of the Study.	
Notes:		

Comments by DOWC staff

- At 12 months post-intervention, patients in the intervention group had significantly greater improvement in their BPI total pain, severity and interference pain scores. Between-group differences were statistically significant and these improvements were small, but clinically meaningful.

- Statistically significant differences between groups in all pain scores were not evident at 1, 3, and 6 month follow-ups, even though less pain was observed in the intervention group at these time points. It was not until the 12 month follow-up that the differences were statistically significant for all pain scores.

- Statistically significant differences in analgesic medication use (doses and duration) during and at the end of the trial existed between the intervention group and the usual care group (P <.001). At the end of the study, the mean maximum dose for all analgesics was 24.6% in the intervention group and 12.6% in the usual care group, even though the baseline maximum dose was essentially equal in both groups (15.4% and 15.6%). This represents a maximum dose of analgesics that is twice as large in the intervention group as in the usual care group. The number of analgesic months for the intervention group was 10.0 and for the usual care group 5.1 months. Analgesic months is the sum of the number of months taking each discrete analgesic during the12-month trial. So the intervention group consumed twice the dose of analgesics for twice as long as the usual care group. Granted opioid use remained essentially unchanged throughout the trial in both groups. Regrettably, the study's optimization of nonopioid analgesic medications needed to accomplish greater pain reduction resulted in a significantly increased analgesic dosage and over a longer period of time. One must question whether the intervention was effective because of the components of the program (added attention, symptom monitoring, care management) or because of increased analgesic use. If the usual care group had similarly increased their analgesic use without receiving intervention program components, would their pain reduction be similar to the intervention group? If all patients need is more pain medication to reduce their pain, then is a telephone-delivered collaborative care management intervention really necessary?

- The results did not detail which major categories of analgesics were consumed by both groups. If the increased consumption of analgesics by the intervention group consisted of safer medications, then perhaps the effectiveness of the intervention could be justified.

- The improvement in pain with minimal opioid initiation or dose escalation is important, given increasing concerns about the consequences of long-term opioid use. However, the results would have been more impressive if opioid dose reduction had shown similar improvements in pain. Even though the goals of the study were not to wean or replace opioids with safer analgesics, optimizing analgesic medications should have included an opioid reduction component as part of the intervention. The results of the study would be more meaningful with opioid reductions. Now there is no evidence that this intervention decreases opioid use.

- The authors failed to address adverse effects and differences between groups, other than hospitalizations and emergency room visits.

- Limitations of the study included no functional outcome, however the BPI includes a component on interference of pain with activities that acts as a pseudo functional outcome.

- Strengths of the study included an active control group, adequate randomization, a designated primary follow-up endpoint, clinical trial registration, and long-term follow-up at 12 months.

- The low rate of drop-outs in both groups is indicative of well tolerated interventions.

Comments by DOWC staff

- Because the control group was usual care rather than an attention control, the non-specific effects of attention received in the intervention group could have contributed to the effectiveness of the intervention. If an attention control had been used as the control group, the effect size observed for improvement in pain in the intervention group may have been smaller.

- Since participants were only veterans recruited from a single Veterans center, the generalizability to the general population may be decreased. While this intervention appears to be successful for this study population tested, further studies are needed to investigate those with higher or lower levels of pain and disability, as well as in other cultural and occupational groups, in order to determine the generalizability of the findings.

- Since the study participants had at least moderate to severe pain and many had pain for years, the results may provide a conservative estimate of intervention effectiveness in patients with less severe pain or with pain of more recent origin.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☐ High quality ☒ Adequate ☐ Inadequate	This study is adequate for some evidence that the telephone-delivered collaborative care management intervention for primary care patients produced clinically meaningful improvements in pain at 12-month follow-up compared with usual care by increasing nonopioid analgesic medications and without changing opioid usage for the management of chronic musculoskeletal pain.
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant