HHS Public Access

Author manuscript

Gen Hosp Psychiatry. Author manuscript; available in PMC 2016 March 01.

Published in final edited form as:

Gen Hosp Psychiatry. 2015 ; 37(2): 139–143. doi:10.1016/j.genhosppsych.2014.11.007.

Collaborative care for pain results in both symptom improvement and sustained reduction of pain and depression

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Abstract

Objective—Traditional analytic approaches may oversimplify the mechanisms by which interventions effect change. Transition probability models can quantify both symptom improvement and sustained reduction in symptoms. We sought to quantify transition probabilities between higher and lower states for four outcome variables, and to compare two treatment arms with respect to these transitions.

Method—Secondary analysis of a year-long collaborative care intervention for chronic musculoskeletal pain in veterans. Forty-two clinicians were randomized to intervention or treatment as usual (TAU), with 401 patients nested within clinician. The outcome variables, pain intensity, pain interference, depression, and disability scores, were dichotomized (lower/higher). Probabilities of symptom improvement (transitioning from higher to lower) or sustained reduction (remaining lower) were compared between intervention and TAU groups at 0–3, 3–6 and 6–12 month intervals. General estimating equations quantified the effect of the intervention on transitions.

Results—In adjusted models, the intervention group showed about 1.5 times greater odds of both symptom improvement and sustained reduction compared to TAU, for all the outcomes except disability.

Conclusions—Despite no formal relapse prevention program, intervention patients were more likely than TAU patients to experience continued relief from depression and pain. Collaborative care interventions may provide benefits beyond just symptom reduction.

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Conflicts of Interest: None

Authors' Contributions: ST conceived of the research and conducted the main analyses; KC and SD developed and refined the methods, interpreted results and were awarded funding for the parent study; ST and KC prepared the manuscript.

Keywords

pain; collaborative; transition; remission; relapse

Introduction

Collaborative care interventions for depression have flourished in the last decade, demonstrating outcomes superior to usual care across a variety of treatment settings.[1] Collaborative or stepped care interventions for pain, or for both pain and depression, have similarly demonstrated improvements in pain-related disability and pain severity.[2–6] The average differences in outcomes between treatment and control groups in these studies have typically been ascertained by measuring changes between two time points, baseline and study completion. This provides an estimate of the overall effect of the intervention, but fails to account for how symptoms changed during treatment.

The success of an intervention relies on both reducing symptoms among those who have them, and ensuring that those without significant symptoms do not develop or resume having them. Changes between various degrees of symptoms are described as *transitions*. Studies of transitions in various outcomes such as mortality, exhaustion, and pain, have demonstrated that their balance influences population-level outcomes, and that measuring only average differences between groups at a single endpoint often fails to explain *how* the group differences developed.[7–10]

In the current study, we modeled and interpreted transitions between higher and lower symptom states among patients enrolled in a randomized controlled trial of collaborative care for chronic pain. We compared symptom improvement and sustained reduction for four of the study outcomes (pain intensity, pain interference, pain-related disability, and depression) between intervention and treatment as usual (TAU) patients during three transition intervals. Because the intervention concentrated its efforts on patients in higher symptom states rather than on formal relapse prevention, we hypothesized that patients in the intervention group would be more likely to transition from higher to lower symptom states (defined here as symptom improvement) than TAU patients. Because the intervention did not specifically target relapse prevention, we hypothesized that intervention patients would be no more likely to remain in lower symptom states when they reached them (defined here as sustained reduction), for each outcome.

Methods

Setting, Population, and Procedures

The Study of the Effectiveness of a Collaborative Approach to Pain (SEACAP) was a cluster-randomized trial of a collaborative care intervention for chronic musculoskeletal pain conducted at five primary care clinics of one Veterans Affairs Medical Center. Eligible patients had medical record documentation of musculoskeletal pain diagnosis, self-reported pain of at least 12 weeks duration prior to intake, scores of 4 or greater on both Chronic Pain Grade (CPG) Intensity and Interference scales, and scores of 6 or greater on the Roland-

Morris Disability Questionnaire (RMDQ). These scores represent moderate or greater levels of severity and disability.[11–14] Patients with documented diagnoses of fibromyalgia, chronic fatigue syndrome, somatization disorder, bipolar disorder, psychotic disorder, dementia, or terminal illness were excluded, as were those with active suicidal ideation. Full details of study procedures are discussed elsewhere.[5,15]

The study enrolled forty-two primary care clinicians, 20 of whom were randomized to the Assistance with Pain Management (APT) collaborative care intervention.[15] Collaborative care interventions apply a structured framework to educate and activate patients, track symptoms and treatment adherence, and make treatment recommendations. The primary APT team consisted of a full-time psychologist care manager and an internist, who spent up to one half day per week in the intervention.[15] Intervention primary care clinicians were invited to participate in two 90-minute workshops about the APT intervention, chronic pain treatment, and shared decision-making. Patients in the intervention received an initial phone call, written educational materials and a list of community resources, and an assessment visit with the care manager in order to survey pain-related behaviors and treatment barriers, identify psychiatric comorbidities, and develop individualized functional goals. Patients were invited to attend a four-session workshop that presented a brief activating approach to pain management, and provided additional educational materials that focused on self-management. After the initial assessment, every two months the care manager contacted patients by phone to administer screenings for pain, depression, and substance abuse, to assess achievement of goals, and to provide support. If participants showed clinically meaningful improvements or remission, a watchful waiting approach was taken until the next APT re-assessment point. If there was no or inadequate improvement, or in the event of recurrence of symptoms, the care manager worked with clinicians to adjust the treatment plan or arrange for specialist care. Participants in the usual care arm were not restricted from using any services related to pain or mental health; upon enrollment, a note was placed in their medical records indicating their participation in the study.

Measures and Data Collection

At baseline, three, six, and 12 months, research assistants who were blinded to group assignment contacted patients by phone or mail to administer assessments of pain, disability, depression, and other health outcomes. Research assessment results were not shared with the APT intervention team.

We analyzed four patient-level variables, dichotomizing each into higher and lower symptom states. The RMDQ is well-validated 24-item self-report measure that assesses functional limitations in patients with chronic pain.[12] Scores are sensitive to changes during treatment.[16] It was initially developed for back pain, but the questions were modified to refer to pain in general.[15] Patients indicate whether “today” their activities are limited by pain (e.g., “I get dressed more slowly than usual because of my pain”). Items are scored as yes=1 and no=0, and scores of 14 or greater define higher disability in patients with chronic musculoskeletal pain. [12,16] The Patient Health Questionnaire (PHQ-9) has been well validated as an outcome and severity measure for depression.[17] It encompasses nine items assessing depression symptoms over the past two weeks (e.g, “Little interest or pleasure

doing things"), each with four response options (0, none of the days-3, nearly every day); scores of 11 or greater indicate a higher degree of depression The Chronic Pain Grade (CPG) is a validated measure of current and prior 3-months pain intensity (3 items rated 0=no pain to 10=pain as bad as could be) and interference (4 items).[11] The items are transformed to a scale of 0 – 100. While the CPG has been found to be a valid instrument for assessing change in pain over time,[19] the cutoff between "high" and "low" pain has not been well established. We considered that >50 signified higher intensity or interference, and ≤ 50 represented lower intensity or interference. For a sensitivity analysis to ascertain the importance of cutoffs on transitions, we classified ≥ 50 as higher intensity or interference.

Sociodemographic measures were obtained by self-report. Here we included marital status (married, yes/no), education (beyond high school, yes/no), and race/ethnicity (white, black, and American Indian/Alaskan Native).

Analyses

Analyses were based on 12 transition intervals: 4 symptoms [pain intensity, pain interference, disability, and depression] by 3 periods [0–3 months, 3–6 months, and 6–12 months]. Intervals for which both the stating state and the ending state were measured prior to patient drop-out, death, or exclusion were included; pairwise deletion was used for intervals with missing data points. In order to avoid considering very small changes as transitions, minimally clinically important differences (MCIDs) were defined as ≥ 3 points change (out of 24 total) for the RMDQ, ≥ 3 points change (out of 27 total) for the PHQ-9, and ≥ 5 for each of the 100-point CPG scales. We chose these as minimums because they represented ten or more percent of the value at the transition threshold (e.g. 50 points on the CPG scales), and corresponded roughly to other MCIDs in research[20,21]. Differences less than these cutoffs that generated a transition between states were considered to have remained in the starting state.

We first compared at a bivariate level the fraction of TAU and APT patients who had either symptom improvement or sustained reduction. Next, to test the effect of intervention on transitions, we created logistic regression models. The first model estimated the odds of symptom improvement among those who started in higher symptom states. The second estimated the odds of sustained reduction, for those who started in a lower symptom state. Odds ratios (ORs) were calculated using generalized estimating equations to account for nesting of time within patients and patients within providers. Models were adjusted for years of age, sex, education, marital status, and race/ethnicity. Because we were interested in intervention effects rather than the predictors of transitions, we did not control for diagnoses or baseline values of the variables.

Because there is no consensus about cutoffs for higher pain intensity and pain interference on the 100-point CPG scales, and because a large number of participants rated their pain intensity or interference at a score of exactly 50, we constructed an alternate set of models using 50 or greater (instead of greater than 50) as an indicator of the higher state. We calculated the same transitions (symptom improvement and sustained reduction), and compared the average differences in outcomes between intervention and treatment as usual groups using the same regression models.

The dataset was transformed into a transition format using code written in Perl (ActiveState Perl). Analyses were conducted in Stata version 11.2 (StataCorp, College Station, Texas), PASW Version 19 (IBM Corporation, Armonk, NY), and Microsoft Excel.

Results

214 TAU participants and 187 intervention participants were enrolled and completed at least one follow-up. Baseline characteristics did not differ significantly between the groups (Table 1). During the course of the study, three TAU participants dropped out, two died, and 21 were excluded or had missing outcome data; eight APT patients dropped out, two died, and 18 were excluded or had missing outcome data. Two-thirds of participants had more than one musculoskeletal pain diagnosis, and the mean duration of pain was 14.8 years. Mean baseline scores were RMDQ = 14.7, PHQ-9 = 8.3, CPG-Intensity = 66.9, and CPG-Interference = 49.5. Within groups defined as higher or lower symptom states, there were no differences between APT and TAU groups in the mean starting values for any outcome measure (results not shown). For the three transition intervals, there were 1127 transitions with complete data.

Few of the measured changes in symptom severity across measurement intervals fell below the MCID cutpoints: 5.5% of the transitions for RMDQ, 4.5% for PHQ-9, 7.1% for CPG-Intensity and 2.5% for CPG-Interference involved moving from one symptom state to the other, but with a small degree of absolute change (as defined above). Differences in these rates of transition that were below the MCID cutpoint did not differ significantly between TAU and APT. There were also no significant differences between TAU and APT groups in the mean values of each variable in the lower and higher symptom states. Table 2 shows the probabilities of symptom improvement and sustained reduction by treatment group and interval. APT intervention patients showed a significantly greater probability of symptom improvement than TAU patients for six out of the 12 symptom-intervals measured, and a significantly greater probability of sustained reduction for four out of 12. The TAU group did not have a greater probability of either symptom improvement or sustained reduction at any of the transition intervals.

Table 3 presents results of GEE multivariate models of symptom improvement and sustained reduction. The intervention showed a significant or nearly significant effect compared to TAU on odds of symptom improvement depression (OR 1.74, 95% CI [1.07–2.81], p=0.023), pain intensity (OR 1.43, 95% CI [0.99–2.08], p=0.058), and pain interference (OR 1.48, 95% CI [1.03–2.13], p=0.036). Odds of sustained reduction were also higher for intervention patients for depression (OR 1.55, 95% CI [0.98–2.48], p=0.060), pain intensity (OR 1.89, 95% CI [1.04–3.44], p=0.037), and pain interference (OR 1.57, 95% CI [1.08–2.27], p=0.017). The odds ratios for the differences between the groups were not significant for RMDQ disability scores.

In the sensitivity analysis model which assumed that a score of 50 (rather than 51) out of 100 signified higher pain intensity or pain interference, the OR favoring the intervention for symptom improvement in pain intensity was 2.15 (95% CI [1.28–3.60], p=0.003), and for sustained reduction the OR was 1.47 (95% CI [0.67–3.22], p=0.339). For pain interference,

the OR favoring the intervention for symptom improvement was 1.49 (95% CI [1.05–2.12], p=0.023) and for sustained reduction was 1.51 (95% CI [1.05–2.17], p=0.025).

Discussion

Previous analyses of the SEACAP trial found that the intervention improved disability, depression, pain intensity, and pain interference at 12 months[5], but did not explicate the processes by which differences in outcomes between groups originated. It might be assumed that the entire effect was due to reducing symptoms, with no differences in the return of symptoms for those participants who, in either group, had experienced reductions. By investigating symptom state transitions, we found that a greater proportion of intervention patients experienced favorable transitions compared to TAU patients for both interference symptom improvement and sustained reduction for pain intensity, pain interference, and depression. Morevoer, odds ratio effect sizes favoring the APT intervention were of roughly similar size across measures. This suggests that the intervention had an effect through both symptom improvement and sustained reduction, each in a roughly equal degree.

The exception to this was symptom improvement and sustained reduction of pain-related disability as measured by RMDQ, where there was no significant different between the groups in adjusted models. This finding may reflect the different areas of focus and different time periods in the RMDQ and the CPQ. The RMDQ queries pain-related functional impairments “today,” while the CPG asks patients to rate overall pain-related interference for the prior 3 months. Retrospective ratings of pain may be biased by current pain as well as by psychosocial factors and perhaps health care utilization. The SEACAP sample showed a significant degree of long-standing pain-related disability: one-third of participants reported working in the 12 months prior to study start, two of three were currently receiving disability payments, and one in five reported having a disability application in progress.[5]

The intervention’s positive effect on sustained reduction was unexpected as the intervention did not involve a formal relapse prevention component. We had hypothesized that both intervention and TAU patients in a lower symptom state would revert to a higher state at the same rate, but our results suggested that APT intervention participants were more likely to remain in lower symptom states than TAU participants. This effect was not due to lower starting symptom scores in the lower group, which did not differ between groups (results not shown). The difference might be due to treatment adherence and self-help methods encouraged by the APT team, or simply that intervention patients were simply more activated. Persistence of a lower degree of symptoms is consequential for this population, given that patients here reported an average of almost 15 years of chronic pain, and many had multiple comorbidities in addition to depression, potentially making it more difficult to sustain functional gains.

Our analyses showed that there was a considerable amount of flux in symptoms across time intervals. In both groups, many of those who occupied a lower state were not “cured”, nor were those who had a higher degree of symptoms “stuck.” A main goal of pain treatment is to achieve a low symptom state, and it is important to remember that this goal can be

accomplished by either going from a higher to a lower state, or by remaining in a low state through prevention or relapse prevention.

The categorization of higher and lower pain is somewhat arbitrary, and the cutoffs could influence the balance of transitions in symptom improvement and sustained reduction. A sensitivity analysis which defined that 50 out of 100 was “higher” pain found similar overall effects to those when using 50 as “lower” pain, but suggested no significant effect on sustained reduction for pain intensity or interference. Other sensitivity analyses using higher cutpoints for the RMDQ and PHQ-9 produced slightly higher estimates of the intervention’s effect on both symptom improvement and sustained reduction. Subsequent research on transitions between pain states should account for the impact of various cutoffs, but our research did not suggest that the use of different cutoffs substantially changed the estimates of the intervention’s effect.

The bulk of the differences between the intervention and control groups occurred between months 0–3, when six of the ten significant differences in transitions were observed. Attention to this early effect, noted in a previous analysis of this data as an aggregate difference[5], could enhance intervention design and future research. For instance, understanding how patient traits interact with treatments to induce early response and remission could inform treatment models aimed at non-responders.

Our findings must be considered in light of several limitations. The study sample consisted of mostly male, older Veterans. There may have been meaningful changes between measurement points, or after the conclusion of the study that were not captured. Our examination of patient-level characteristics that might confound our analysis of symptom improvement or sustained reduction was limited to demographic variables, and there could be other differences between APT and TAU groups that influenced the transition probabilities. Table 1 suggested that the treatment groups were very similar, and in the multivariate models, age, sex, education, and ethnicity were not significant predictors of the main outcomes (results not shown). Future research might examine factors such as use of medication or healthcare patterns, which may influence the likelihood of transitions, with the goal of increasing the likelihood of positive transitions.

In 2011 the Agency for Healthcare Research and Quality (AHRQ) established a national agenda to determine “what works” in collaborative care interventions, including which approaches are most effective across settings, and which metrics are reliable.[22] A key part of this process involves ascertaining the manner by which subgroups of patients improve. One conclusion from our findings about the process of collaborative care is that interventions might achieve more robust outcomes by expending more effort to keep healthier individuals in a healthy state, that is, by attending to relapse prevention as well as to symptom reduction. For instance, the IMPACT collaborative care intervention for depression, which applied a relapse prevention plan for participants who achieved remission, showed reductions in risk of relapse one year after the active treatment ended.[23]

Although relapse prevention is a common element in interventions for depression and pain, there has been little systematic study of techniques to enhance it.. Whereas some factors

associated with risk of relapse for depression have been identified (e.g., limited medication adherence, limited self-efficacy, and childhood trauma[24]), little is known about how to plan interventions in order to maximize rates of sustained remission. Preliminary research on preventive interventions for depression has focused on reducing negative emotions[25,26], but these approaches have not been incorporated into collaborative care interventions. Exercise[27] and interactive voice response systems[25] have been investigated in small studies as ways to promote relapse prevention for pain. Quantifying time-specific transition rates and developing the understanding of the mechanisms of relapse prevention for patients with chronic pain or disability could help to maximize the benefits of collaborative care interventions and add value to new models of pain treatment.

Conclusion

In a collaborative care intervention for chronic pain, dynamic changes in pain intensity, pain interference, depression, and pain-related disability were observed over the year-long trial. APT intervention patients were more likely than treatment as usual patients to demonstrate symptom improvement and sustained reduction, despite a focus of the intervention on the former. Most of the favorable transitions occurred in the first three months. Quantifying differences between groups in time-specific rates of remission and relapse highlights ways in which interventions might effect more substantial changes, both through more deliberate emphasis on early non-responders and through prevention of symptom re-occurrence among those who do respond.

Acknowledgments

Funding: This research was supported by NIMH K23 MH093591 (Thielke) and Department of Veterans Affairs, Veterans Health Administration and Health Services Research and Development Service Projects PMI 03-195 and REA 06-174. The views expressed in this manuscript are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

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Table 1

Baseline participant characteristics of veterans enrolled in the Study of the Effectiveness of a Collaborative Approach to Pain by treatment group.

Characteristic	Treatment as Usual (n = 214)	Intervention (n = 187)
Age, years, mean (SD),	61.3 (12.3)	62.1 (11.2)
Male sex, n (%)	196 (92)	172 (92)
Race/ethnicity, n (%)		
White	189 (88)	168 (90)
Black	5 (2)	2 (1)
American Indian/Alaska Native	6 (3)	7 (4)
Married, n (%)	122 (57)	114 (61)
Education beyond high school, n (%)	164 (77)	137 (73)
Duration of pain, years, mean (SD)	14.9 (13.1)	14.7 (12.3)
RMDQ, mean (SD)	14.5 (4.4)	14.9 (4.4)
% in higher symptom state (≥14)	55.6%	51.9%
PHQ-9, mean (SD)	8.4 (6.0)	8.1 (5.7)
% in higher symptom state (≥11)	28.5%	26.2%
CPG Pain intensity, mean (SD)	66.3 (13.4)	67.8 (12.9)
% in higher symptom state (>50)	90.7%	94.0%
CPG Pain interference, mean (SD)	48.7 (24.6)	48.3 (24.4)
% in higher symptom state (>50)	52.8%	55.6%

No group differences were statistically significant

RMDQ: Roland-Morris Disability Questionnaire

PHQ-9: Patient Health Questionnaire for depression

CPG: Chronic Pain Grade

Table 2

Proportion of patients experiencing symptom improvement or sustained remission at three transition intervals and overall by treatment group among veterans with chronic musculoskeletal pain.

		Transition Interval							
	Group	**0–3 months**		**3–6 months**		**6–12 months**		**Across all transitions**	
RMDQ									
Symptom improvement	TAU	0.14	*	0.25		0.29		0.22	
	Intervention	0.27		0.25		0.29		0.27	
Sustained reduction	TAU	0.81		0.80		0.80		0.81	
	Intervention	0.81		0.85		0.83		0.81	
PHQ-9									
Symptom improvement	TAU	0.23	**	0.39	*	0.30	*	0.31	*
	Intervention	0.43		0.48		0.35		0.43	
Sustained reduction	TAU	0.78		0.93		0.87	*	0.85	*
	Intervention	0.83		0.94		0.95		0.91	
CPG Pain Intensity									
Symptom improvement	TAU	0.08	*	0.13		0.15		0.12	**
	Intervention	0.16		0.19		0.13		0.16	
Sustained reduction	TAU	0.50	**	0.68		0.61	**	0.60	**
	Intervention	0.70		0.67		0.79		0.73	
CPG Pain Interference									
Symptom improvement	TAU	0.32	*	0.31		0.31		0.31	*
	Intervention	0.44		0.39		0.39		0.41	
Sustained reduction	TAU	0.68	**	0.70		0.74		0.70	
	Intervention	0.83		0.75		0.77		0.78	

n = 1127 transition intervals.

Symptom improvement: move from higher to lower symptom state

Sustained reduction: remain in lower symptom state

TAU: Treatment as usual

RMDQ: Roland-Morris Disability Questionnaire; higher state ≥14

PHQ-9: Patient Health Questionnaire for depression; higher state ≥11

CPG: Chronic Pain Grade; higher state ≥50

* $p < 0.05$ for comparison between TAU and intervention

** $p < 0.01$ for comparison between TAU and intervention

Table 3

Odds of symptom improvement and sustained reduction across three times intervals among veterans with chronic musculoskeletal pain

	OR Favoring Intervention [95% CI]	p-value	n
RMDQ (disability)			
Symptom improvement	1.25 [0.83–1.89]	0.281	582
Sustained reduction	1.13 [0.67–1.89]	0.635	620
PHQ-9 (depression)			
Symptom improvement	1.74 [1.07–2.81]	0.023	341
Sustained reduction	1.55 [0.98–2.48]	0.060	861
CPG Pain Intensity			
Symptom improvement	1.43 [0.99–2.08]	0.058	967
Sustained reduction	1.89 [1.04–3.44]	0.037	228
CPG Pain Interference			
Symptom improvement	1.48 [1.03–2.13]	0.036	536
Sustained reduction	1.57 [1.08–2.27]	0.017	662

Models adjusted for age, sex, ethnicity, education with nesting of patients within clinician, and time (0–3, 3–6 and 6–12 months) within patient.

Symptom improvement: move from higher to lower symptom state

Sustained reduction: remain in lower symptom state

TAU: Treatment as usual

RMDQ: Roland-Morris Disability Questionnaire; higher state ≥14

PHQ-9: Patient Health Questionnaire for depression; higher state ≥11

CPG: Chronic Pain Grade; higher state ≥50