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EVIDENCE-BASED PROTOCOLS:

Into the Home Healthcare Setting

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Abstract

Activity-limiting pain is common among older home care patients and pain management is complicated by the high prevalence of physical frailty and multimorbidity in the home care population. A comparative effectiveness study was undertaken at a large urban home care agency to examine an evidence-based pain self-management program delivered by physical therapists (PTs). This article focuses on PT training, methods implemented to reinforce content after training

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and to encourage uptake of the program with appropriate patients, and therapists' fidelity to the program. Seventeen physical therapy teams were included in the cluster randomized controlled trial, with 8 teams (155 PTs) assigned to a control and 9 teams (165 PTs) assigned to a treatment arm. Treatment therapists received interactive training over two sessions, with a follow-up session 6 months later. Additional support was provided via emails, e-learning materials including videos, and a therapist manual. Program fidelity was assessed by examining PT pain documentation in the agency's electronic health record. PT feedback on the program was obtained via semistructured surveys. There were no between-group differences in the number of PTs documenting program elements with the exception of instruction in the use of imagery, which was documented by a higher percentage of intervention therapists ($p = 0.002$). PTs felt comfortable teaching the program elements, but cited time as the biggest barrier to implementing the protocol. Possible explanations for study results suggesting limited adherence to the program protocol by intervention-group PTs include the top-down implementation strategy, competing organizational priorities, program complexity, competing patient priorities, and inadequate patient buy-in. Implications for the implementation of complex new programs in the home healthcare setting are discussed.

Pain is highly prevalent among older adults receiving home healthcare (Murtaugh et al., 2008; Maxwell et al., 2008), putting them at increased risk of developing limitations in activities of daily living and contributing to increased health service utilization (Soldato et al., 2007). There are multiple barriers to effective pain management in this population including patient resistance to pharmacologic management due to side effects and fears of addiction (Vallerand et al., 2004) and the presence of comorbid illnesses, which complicate pharmacologic management efforts (Maxwell et al., 2008). Despite high percentages of patients reporting treatment of pain by their home care providers, nationally in 2015 only 69.7% of home healthcare (HHC) patients who reported pain at baseline had a lower level of pain on discharge (data.medicare.gov). Therefore, improving pain management in home care is critically important.

Structured quality improvement (QI) efforts directed at addressing this problem are challenging in the decentralized HHC service delivery system. Effective implementation of complex evidence-based protocols often requires bringing staff into the office for training, reducing time spent on direct patient care. After training, the lack of regular in-person contact with coworkers and supervisors minimizes opportunities to review the newly learned program to troubleshoot problem areas. This article describes the implementation of an evidence-based pain self-management program designed to improve pain outcomes among older adult HHC patients. Undertaken as a comparative effectiveness study (Reid et al., under review), the pain management program required training a large cohort of physical therapists (PTs) in the new treatment protocol. Information is presented on the training process including supports developed to facilitate implementation of the program. The article then examines clinician fidelity to the protocol and implications for the roll-out of complex new clinical programs in HHC.

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Background

This work was conducted at the Visiting Nurse Service of New York (VNSNY), a large HHC agency providing services to patients in all boroughs of New York City and the surrounding counties of Nassau, Suffolk, and Westchester. In response to increasing literature on the impact of pain on disability (Patel et al., 2013; Soldato et al., 2007), the agency's rehabilitation services division was concerned with the degree to which pain limited patients' ability to increase their functional mobility and overall activity level. This led to collaboration with researchers on a strategy for improving the pain outcomes of geriatric patients receiving physical therapy.

A senior center-based program that combined cognitive-behavioral techniques with exercise therapy was adapted for use in the HHC setting (Beissner et al., 2012). The program was modified with input from practicing PTs for delivery in the home in the context of usual PT HHC services (Bach et al., 2013; Beissner et al., 2013). The resulting HHC protocol, referred to in our work as the cognitive-behavioral pain self-management (CBPSM) program, includes 10 elements designed to be delivered over five PT visits/sessions (Box 1). Patients were to be taught all program elements and could then choose the techniques they found to be most effective in mitigating their pain. A patient guide called "Take Charge of Your Pain" was developed using best practice standards for health literacy. The guide was designed for visual appeal with easy-to-read text, multiple illustrations, and color-coding by protocol element. Each section included an area for patient notes and there was a section of the guide where patients could document their personal goals and keep a record of daily activity. For easy reference, a one-page summary sheet was created for the therapist using the same color-coding and protocol materials order. These materials are available on request.

Many of the components of the CBPSM program (e.g., muscle relaxation, activity pacing) are familiar to PTs due to their application in other areas of practice. However, the use of these techniques by PTs for pain management is less common (Beissner et al., 2009), despite mounting evidence in support of this approach (Dowell et al., 2016; Keefe et al., 2005). Therefore, training HHC PTs in the use of the protocol techniques was essential prior to implementation of the program.

Methods

Funds were obtained from the Federal Agency for Healthcare Research and Quality to conduct a cluster randomized controlled trial to test the effectiveness of the CBPSM program plus usual PT care relative to usual PT care alone for patients with activity-limiting pain. Data for the analyses presented here were collected as part of this study. Research staff conducted a telephone screen of patients admitted to VNSNY with a referral for PT who reported activity-limiting pain with an intensity of 3 or higher on admission. Screening also included confirmation of English language use and pain at an intensity of 3 or greater on a 10-point scale. A brief cognitive screen was also included. Those who passed the screening and consented to the study completed an in-home interview by trained research staff. Of the 3,243 patients screened between October 2012 through May 2014, 588 (18%) met eligibility

and other study design requirements (e.g., enrollment of roughly equivalent numbers of patients in each of 3 race–ethnicity groups) and provided consent.

At the time of the study, rehabilitation services were provided by 17 geographically distinct treatment teams. These rehabilitation teams were randomized into an intervention (9 teams) or control (8 teams) group. The PTs on the intervention teams were informed they would undergo training on a QI initiative to improve pain outcomes, but were blinded to the study associated with the program. PTs on the control teams were not informed of the QI initiative or the associated study.

Training

PTs on intervention teams received two half-day educational sessions on the CBPSM program approximately 1 month apart, and a 45- to 60-minute booster session 6 months later. The educational sessions were standardized and two of the authors taught all sessions. The training sessions were delivered to each intervention team, with anywhere from 14 to 25 therapists attending a given training session. The training session format is shown in Box 2.

Support for the CBPSM protocol elements was provided through the agency's online learning system. A training manual for intervention group PTs summarized the rationale and literature supporting the CBPSM program, a reference list and sample scripts for teaching each program element. Online videos showed each element of the protocol being presented to an older adult by one of the authors. The videos demonstrated the therapist–patient interaction and referred to the related patient guide section. Only PTs randomized to the intervention arm received access to the protocol videos; access was open ended so videos could be serially viewed over time if desired. The CBPSM protocol was also reinforced through a monthly email sent to intervention therapists over a 14-month period. Each email focused on one program element or related topics and included resource links, references, and tips for managing pain. Intervention team therapists who did not attend the training, who transferred to a different team, or who left employment were excluded from data collection. PT assistants and their supervisors also were excluded because relatively few PT assistants were employed by the agency at the time of the study and the program was designed to be provided by a single PT.

Measures

Demographic information on the intervention and control group PTs who treated patients enrolled in the study were abstracted from the human resources database and deidentified prior to analysis by the study team. These data include age, gender, highest earned degree, and years of employment with the agency.

Program Fidelity

Clinician documentation at the HHC agency was entered into an electronic medical record (EMR) that contained a separate problem-based section entitled “Pain.” This area of the clinical visit note did not require a forced response; clinicians entered data based on assessment findings and interactions during each patient visit. Areas of documentation were cross-linked to most of the CBPSM protocol elements. The CBPSM protocol items

associated with the pain problem fields that were a close match were pain theory (Reason for Pain), Deep Breathing (Breathing exercises), Imagery (same), Pleasant Activity Scheduling (Activities to distract from pain), Managing Flare ups (Avoid Stressors), and Activity Pacing and Becoming More Active (Rest/Exercise Schedule). For the remainder of protocol items, there was no direct match. Intervention PTs were specifically trained in the use of the pain problem part of the EMR for documentation of the CBPSM program. Data were extracted from the EMR for these six items and collated by PT. No other portions of the EMR were examined.

The number of PTs documenting each program element was calculated for each group (i.e., intervention and control). Chi-squared tests were used to test for between-group differences in the percent of PTs documenting each element. Therapist feedback on the program was obtained via follow-up surveys. The initial phone survey had a very low response rate so an online survey was implemented. Twenty-four of the 153 intervention therapists still employed by VNSNY completed the online survey. Survey items included questions regarding the use of the program, perceived comfort in delivering each of the program elements, patient response to specific elements, and challenges encountered with implementation. Open-ended questions allowed therapists to provide narrative input. These statements were tabulated by question and two investigators independently reviewed the statements to identify themes.

Results

Study Sample Characteristics

Demographic characteristics of intervention and control therapists who treated patients enrolled in the study are shown in Table 1. The majority of PTs worked for the agency full time and had a bachelor's degree as their highest educational level. No significant differences in gender or employment status were found when comparing control and intervention PTs. Differences were seen in the highest educational degree obtained and years of experience. Control group PTs had higher educational degrees and fewer years of professional experience than the intervention group PTs.

Fidelity

Overall, documentation of the program elements in the EMR was relatively low for both intervention and control group PTs. There was no statistically significant difference between the two groups in the percent documenting that they taught patients the following elements: Reason for Pain (Pain Theory); Breathing Exercises (Deep Breathing); Activities to Distract from Pain (Pleasant Activity Scheduling); Rest/Exercise Schedule (Activity Pacing); and Avoid Stressors (Managing Flare ups) (Figure 1). However, significantly more intervention PTs documented the use of imagery than control team PTs ($p = .0024$).

Therapist Feedback

Data from the therapists' surveys showed that 80% of PTs were comfortable or very comfortable teaching the protocol elements. Representative statements in response to the open-ended questions are shown in Box 3. The most frequent feedback received was that the

PTs felt there was not enough time to complete the protocol while delivering the other therapy interventions required for each patient's plan of care. In response to items regarding how much additional time was required to implement the program, the majority of respondents indicated 15 to 20 additional minutes per visit. Other PT comments included the desire to select program elements rather than deliver the entire program, and concerns with patient receptivity to the program (Box 3).

Discussion

Prior work on the implementation of QI initiatives in the HHC setting have highlighted the difficulty in ensuring program uptake (Ryvicker et al., 2011; Ryvicker et al., 2008) resulting in substantial delay in integrating evidence-based practice into home care, a problem common to healthcare regardless of treatment setting (Morris et al., 2011). The low percentage of intervention group PTs documenting use of the CBPSM elements and the survey feedback suggest the program was not implemented as designed. PTs in other settings have been able to deliver cognitive-behavioral interventions with acceptable fidelity following extensive training and competency evaluation (Bryant et al., 2014; Johnson et al., 2007). The program implemented in our study was based upon cognitive and behavioral principles but took a self-management approach in order to simplify the protocol. Our own pilot work showed that HHC PTs could deliver the program with acceptable fidelity (Bach et al., 2013). PTs in the pilot study reported a high level of comfort teaching the program elements, with the exception of imagery, indicating the intervention therapists in the pilot study were likely competent in program delivery. It is disappointing, therefore, to find such low levels of adherence with the treatment protocol when it was rolled out on a larger scale. On the other hand, the lack of between-group differences in pain problem documentation (with the exception of imagery) may indicate the program elements are already being implemented as part of usual PT care for at least some patients who present with pain problems. Deep breathing, relaxation, avoiding stressors, and activity pacing are commonly used physical therapy interventions for patients with a variety of diagnoses, and educating patients to use these techniques to manage pain is a logical extension of this approach. With the available data, we have no way of determining the extent or quality of instruction in each of these areas. Although one could speculate that intervention PTs integrated the protocol but did not document the techniques used in the portion of the EMR examined in this study, the outcomes described above indicate limited up-take of the protocol by intervention PTs.

We provide possible explanations for the limited adherence to the study protocol and study limitations below.

1. **Top-down implementation.** Therapists were not given the option to select learning about the CBPSM program, but rather were informed in a team meeting that the program was developed as a QI initiative due to concerns with inadequate pain management at the agency. In the previous study (Beissner et al., 2013), we involved therapists from one treatment team in the adaptation of the program as a means of addressing potential concerns, consistent with diffusion theory (Rogers, 2003) but the decision to implement was not presented as an option. This top-down introduction of the program is common in QI initiatives.

Given that supervisors were not involved in any oversight of the CBPSM program and no ongoing supervisory reviews addressed the protocol, therapists may have perceived the protocol as a program that they could decide to use as appropriate or not.

2. **Competing organizational priorities.** The intervention therapists continued to receive team- and agency-wide communications regarding work and patient care issues. Some issues were prioritized as critical elements for compliance such as changes in Centers for Medicare and Medicaid Services required documentation, and these mandated changes may have conflicted with implementation of the CBPSM protocol.
3. **Complex program.** The protocol was designed to be delivered over five sessions with all elements addressed and then the patient could select the elements deemed most effective and preferred for continued use on an ongoing basis. Therapists were not aware that some patients were enrolled in a study and they were asked to use the program with all appropriate patients with activity-limiting pain. Therapists indicated that they would have preferred the option of selecting the elements most appropriate for the patient or wanted to “shorten” the protocol.
4. **Time demands.** Consistent with prior work on time demands in HHC (Liebel & Powers, 2015) and our prior work (Bach et al., 2013), therapists indicated that the time needed to implement this program was in conflict with other treatment demands. Physician referrals for PTs were based on the patient’s injury and/or illness and included other interventions unrelated to pain management. Through the online videos we demonstrated integration of these techniques with usual patient care in order to minimize the additional time demands of the program, but PTs still indicated that substantially more time was needed in each visit. Increasing session time limits productivity, and given payment systems this presents a disincentive for program implementation (Bao et al., 2014). Notably, the online videos and manuals developed to support program implementation required time to access and view. It is likely that this uncompensated time also served as a disincentive for integrating the program into practice.
5. **Inadequate patient buy-in.** PTs described limited patient engagement in the program as an important implementation barrier. These comments reflected several trends including patients’ preference for analgesic medication for pain control; their low expectations for pain improvement; concerns with prior pain treatment failure; and patients’ preference for hands-on PT care rather than education (e.g., pain theory, sleep tips). Therapists also indicated that younger patients seemed more receptive to self-management and were more motivated. This is consistent with our finding that study patients who had at least one CBPSM program technique documented in the pain problem were younger, on average, than those with no item documented (72.0 vs. 74.1 years, $p = 0.0125$).

Implications

Our findings have important implications for implementation of complex QI programs in home care. Based on our previous work (Bach et al., 2013; Beissner et al., 2013) and related literature (Ryvicker et al., 2011; Ryvicker et al., 2008), recommendations for future implementation initiatives include:

- Simplify if possible! Less complex programs are most likely to be implemented as planned.
- Note that variability in program delivery may impact the effectiveness of evidence-based interventions, but when possible allow program staff flexibility in delivery based on patient status.
- To increase program ownership, involve opinion leaders from treatment teams in the process of analyzing the problem and formulating solutions.
- Incentivizing the program through use of audits and feedback increases program uptake and integration of new programs into standard care (Shatpattananunt et al., 2015).
- Recruit an influential care provider to be a champion for the program, encouraging other team members to use the program.
- When appropriate, an interdisciplinary approach that involves the entire service delivery team may be helpful, as it allows peer support and reinforcement of the program.

Summary

The many operational demands of HHC, particularly scheduling, productivity, and coordinating diverse patient needs, are challenging when merged with the competing priorities of care efficiency, care outcomes, and QI activities. Despite best efforts, complex evidence-based programs may not be implemented as designed. Our experience implementing a pain self-management program indicates that the training and support of frontline workers provided to intervention groups PTs was insufficient to ensure program uptake. A comprehensive approach to program implementation should include early and ongoing audits for program uptake and fidelity and structured opportunities for clinician feedback.

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Box 1**Program Elements by Treatment Session**

Session	Program Element
1	Pain Theory; Becoming More Active
2	Relaxation; Deep Breathing
3	Imagery; Pleasant Activity Scheduling
4	Activity Pacing; Progressive Muscle Relaxation
5	Sleep Tips; Managing Flare-ups

Box 2**PT Training Sessions****Initial Training: Part I**

- *Introduction*
 - Pain prevalence and impact, including agency home care compare pain data
 - Traditional pain management approaches o Rationale and evidence base for cognitive–behavioral approach
 - Program development process
- *Program presentation*
 - Description, discussion, practice of each element
 - Role-plays of patient education for each program element
 - Strategies for integrating CBPSM into home program (sequencing with exercises)
- Integrating program into usual care
- *Documentation*
 - Demonstration in electronic medical record
- *Introduction to resources*
 - Online support materials for therapists
 - Patient handouts

Initial Training: Part II (one month after “Initial Training: Part I”)

- A. *Experience-sharing*
 - Solicited patient examples, challenges, and successes.
- B. *Program review*
 - Discussion of each program element, with practice.
- C. *Promoting program uptake*
 - Behavior change theory applied to troubleshooting program barriers
- D. Patient education tips
- E. *Review of resources*
 - Email
 - Learning Center therapist manual and videos

Booster Trainings (4–6 months after “Initial Training: Part I”)

- A.** Program overview
- B.** Experience-sharing and troubleshooting
- C.** Distribution of additional patient guides

Box 3**Sample Statements From PT Feedback Survey**

For what types of patients did the program work best?	What were the patient-level barriers to using program?	What was your (the therapist's) experience using the program?	What changes could help to improve the program?
Patients must be "cognitively intact," and "...actively believe that this will help them."	"Some patients don't have the attention span to go through the subject, especially if they are distracted by pain, or don't believe in the treatment approach to begin with."	"The main barriers to implementing the program were the time needed to do the techniques during a treatment session."	"Involve, educate other clinicians (OT, VN, SW) in the pain management program."
"Patients with chronic pain combined with high anxiety typically respond better to the pain program."	The "home environment [is] not conducive for the techniques (noise, other people in the house, animals barking)."	"I have found that the packet helps these patients stay focused on the steps that help regain control over their pain which lessens their anxiety."	"I would consider making the program more concise. It was something that was difficult to do at each visit and still have adequate time to do the rest of the visit. This was particularly true in the TKR patient who required more time."
The program works if the "patient is willing and open to trying something new."	"You can feel when they don't care for it. They will just say 'yes,' but never do it."	Concerning imagery, "patients' family member(s) had concerns about this technique."	"Simplify it; cut down on the reading material; separate techniques into smaller packets so PT can choose which they want to use."
"It works with my patients between 55–60 who are alert, oriented and cooperative...."	It was difficult "getting patients to read [the] entire booklet and document in it."

Figure 1.
PT documentation of pain strategies.

Table 1

Therapist Characteristics

Characteristic	Control <i>N</i> = 122	Intervention <i>N</i> = 116	<i>p</i> -value
Female Sex	63 (52%)	52 (45%)	0.27
Highest Degree			
Bachelors	72 (59%)	69 (60%)	0.01
Masters	21 (17%)	34 (29%)	
Doctorate	29 (24%)	13 (11%)	
Employment			
Part-time	18 (15%)	16 (14%)	0.43
Full-time	92 (75%)	82 (71%)	
Per diem	12 (10%)	18 (15%)	
Years of Experience			
0–3	38 (31%)	15 (13%)	0.003
4–9	34 (28%)	38 (33%)	
10 or more	49 (41%)	63 (54%)	