Cover Page

Title

Expanding access to Pain Coping Skills Training (PCST): A professional certificate program to enable Advanced Practice Registered Nurses (APRNs) to fill the gap

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Abstract

Millions of Americans suffer from persistent chronic pain despite medical intervention. It is estimated that 2-40% of U.S. adults have chronic pain, with a median of 15% (i.e. >34M). Recent projections indicate the growing gap between the need for medical services and availability of health providers, especially in primary care. One proposed solution is to increase service delivery by Advanced Practice Registered Nurses (APRNs) for management of chronic illness. The history and philosophical core of the profession of nursing prioritizes patient education and self-management. This proposal is designed to leverage both the nursing profession's expertise in patient education and their increased care of patients with chronic pain by training APRNs in Pain Coping Skills Training (PCST). PCST is an efficacious, brief intervention, based on cognitive-behavioral principals for managing chronic pain. We recently completed the first randomized, controlled clinical trial that demonstrated the effectiveness of APRNs providing PCST to patients with chronic pain. This has set the stage for dramatically increasing patient access to PCST to improve clinical outcomes. We propose to create a national training/certificate program in PCST for APRNs and to evaluate the effectiveness of this training in community practice. Outcomes will include APRN increase in knowledge in PCST principles, confidence, and competence in delivery. Subsequent APRN delivery of PCST to patients in their practices will be assessed on a weekly basis along with patient characteristics that factor into the clinical decision to deliver PCST to those patients. Patient outcomes will be assessed pre- and post-receipt of PCST treatment.

Overall Goal & Objectives

Millions of Americans suffer from persistent chronic pain despite medical intervention. It is currently estimated that 2-40% of U.S. adults have chronic pain, with a median of 15% (i.e. >34M).[1] Recent projections point to the growing gap between the need for medical services and availability of health providers, especially in primary care.[2] One proposed solution is to increase service delivery by Advanced Practice Registered Nurses (APRNs) in primary care and pain clinics for management of chronic illness.[3] The history and philosophical core of the profession of nursing prioritizes patient education and self-management. This proposal is designed to leverage both the nursing profession's expertise in patient education and their increased care of patients with chronic pain by training APRNs in Pain Coping Skills Training (PCST). **PCST is an efficacious, brief intervention, based on cognitive-behavioral principals for managing chronic pain**.[4] We recently completed the first randomized, controlled clinical trial (RCT) that demonstrated the effectiveness of APRNs providing PCST to patients with chronic pain.[5] This has set the stage for dramatically increasing patient access to PCST to improve clinical outcomes above and beyond what conventional medical care can provide. **We propose to create a national certificate program in PCST for APRNs and to evaluate the effectiveness of this training in community practice using a longitudinal protocol, which will align with the goal of Pfizer to improve chronic pain outcomes.**

Key Objectives

1: Parlay recent evidence that APRNs can improve outcomes of patients with chronic pain by introducing PCST during clinical encounters. APRNs working in primary care and pain centers in the United States will receive training in how to provide PCST.
2: Quantitatively evaluate the effectiveness of APRN training on (1) knowledge of PCST skills, (2) confidence to deliver the skills, (3) competence in delivering the skills, (4) clinical decision making re: delivery of skills to their patients.
3. Quantitatively determine the effectiveness of PCST training of APRNs for the (1) reduction of symptom burden, (2) improvement in global health, and (3) satisfaction with medical care for patients with chronic pain.
4: Demonstrate the feasibility and utility of clinical assessment of patient reported outcomes (PROs) in community practice using the NIH PROMIS measures (http://www.nihpromis.org) through the NIH Assessment Center (www.assessmentcenter.net).
5: Demonstrate the feasibility and utility of innovative educational technologies to deliver a blended approach to training in pain management and to enhance patient learning.
6: Use the success of this project as the foundation for broadly disseminating training opportunities through establishing a PCST train-the-trainer program at Stony Brook's School of Nursing along with an ongoing certificate program.

Technical Approach

Assessment of Need for the Project

Recently, we conducted a survey of APRNs (*N*=35) attending a regional Nurse Practitioner

Association meeting (Long Island, New York). Respondents worked in a variety of health settings and had practiced as an APRN on average for 7.4 years (range 1-29 years). Most had a specialty in adult health (69%) or family medicine (14%) and practiced in community/private practices (29%), hospitals or hospital outpatient clinics (27%), or a community health center (15%). Following a brief, written description of PCST, the survey asked, "How valuable do you think PCST would be for your patients with chronic musculoskeletal pain?" The average rating was 9.0 on a 0-10 scale (range 7-10). Another question, "How interested would you be in taking a course to acquire skills to deliver coping skills training to your patients with chronic musculoskeletal pain?" yielded an average rating of 8.1 (range 3-10) with 86% giving a rating of ≥ 7. The survey arguably demonstrated the very high level of perceived value of PCST and the degree of interest by APRNs to learn how to more effectively treat their patients with chronic pain. In light of recent national developments in pharmacological management of moderate to severe pain, non-pharmaceutical, self-management patient skills to improve their pain experience and functioning is clearly needed.[6,7] Consistent with this, we have also received many requests for this training as knowledge of our RCT spread in New York and through national professional pain and nursing organization presentations.

Primary Audience

As such, our project will invite APRNs in the United States, and their patients with chronic pain, using the Stony Brook University School of Nursing (SON) alumni distribution list, the American Society for Pain Management Nurses, and the Nurse Practitioner Association of New York State to nationally recruit 40 APRNs and 200 of their chronic pain patients. Demonstration of the effectiveness of the training and APRN evaluation of its utility for patient care will form the basis for establishing an ongoing PCST training program that will dramatically increase patient access to this form of treatment.

Project Design and Methods

Our team is the first group (and to our knowledge the only group to-date) to train and evaluate the effectiveness of APRNs delivering PCST, a treatment originally developed and provided by health psychologists. The trial report of our work has just been published in the journal *Pain*.[5] We conducted a pragmatic, multi-site, randomized, controlled clinical effectiveness trial for osteoarthritis patients with chronic pain of the knee or hip (*N*=256). Adult health APRNs provided PCST in patients' doctors' offices; the control group received usual care. A 12-month post-treatment endpoint analysis indicated significantly greater improvement for the PCST group for pain intensity, physical functioning, psychological distress, use of pain coping strategies, self-efficacy, fatigue, satisfaction with health, and reduced use of pain medication. **The results of our published trial demonstrate the effectiveness of APRN delivery of PCST for chronic pain.** This proposal is a very exciting and logical next step **to improve patient access to PCST by developing a training opportunity for APRNs to deliver this treatment**. Our plan is to conduct a demonstration project that will provide the foundation for national dissemination of PCST training for APRNs. Based upon lessons learned in the clinical trial, we will enhance the original PCST treatment manual to include behavior change motivational interviewing and approaches for integrating PCST with pharmaceutical treatments to improve clinical utility. **This project assumes the efficacy of PCST and will focus on a**

detailed evaluation of a 2½ day APRN training program to learn PCST. Primary outcomes will focus on key components of adult learning that will demonstrate the effectiveness of the nurse-training program. These will include empirical assessment of (1) pre- to post-training changes in knowledge of the Gate Control Theory of chronic pain and the specific skill components of PCST, (2) change in confidence to deliver PCST to patients, (3) competency ratings of nurse delivery of PCST skills by trained simulated patients, and (4) weekly tracking of nurse delivery of PCST in their clinical practice, and the factors influencing their clinical decision to deliver PCST to a particular patient. Secondary outcomes will include pre- to post- ratings of pain-related symptoms by patients receiving PCST treatment from their nurses.

Institutional Review Boards and Informed Consent

Nurses and their patients will be participants in this project and the outcomes evaluation. Therefore, the protocol will be reviewed by University of Southern California and Stony Brook University Institutional Review Boards of Human Subjects Research. Participating nurses and their patients will engage in an informed consent process prior to any data collection. Research staff are fully trained and certified to conduct research with human subjects.

Recruitment of Advanced Practice Nurses

APRNs (*N*=40) will be recruited for this demonstration project through the Stony Brook University School of Nursing alumni distribution list (*N*=170/yr APRNs), the American Society for Pain Management Nurses (*N*=1450), and the Nurse Practitioner Association of New York State (*N*=2,700). To be eligible for training enrollment, the participant must: (1) be licensed as an APRN and have practiced for ≥ 3 years, and (2) provide a letter of support from the medical facility supervisor for the APRN to implement PCST with patients.

Training and Certificate in PCST for APRNs

There are several considerations for developing and implementing a high quality PCST health behavior change program for nurse practitioners.[8,9] These include a curriculum and method of evaluation that address desired acquisition knowledge, skills, and behaviors relative to PCST.

Based on these guidelines, we propose a demonstration certificate program consisting of a two and a half day on-site didactic and experiential training and competency assessment. Training will include didactic instruction in the cognitive-behavioral model of pain underlying PCST and the overarching concepts of patient empowerment through skilled self-management. The principles of motivational interviewing, an effective strategy for engaging patients in cognitive and emotional reasons for improved self-management, will be taught. The didactic component will be presented with underlying theory and review of each of the pain coping skills making up PCST. A knowledge-based written examination developed for this program will address theoretical concepts delivered in the workshop and supplemental learning material provided in the LMS. The examination will be delivered electronically via the LMS system following the format currently utilized in Stony Brook University School of Nursing curriculum delivery. The Stony Brook School of Nursing is accredited by the Commission on Collegiate Nursing Education inclusive of the LMS curriculum delivery model.

The goal of this project is to give nurses the theoretical and, importantly, the practical skills and confidence to implement PCST with their patients. Therefore, experiential training with behavioral rehearsals is a core component of the program. Behavioral rehearsal in the delivery of each of the four selected PCST skills will be conducted using a highly detailed treatment manual. (A recent meta-analysis of factors associated with strongest patient outcomes for cognitive-behavioral treatment of pain is the use of a treatment manual.[10])

As a demonstration project, it will be essential to objectively assess nurse competencies in PCST delivery at the end of the training workshop. A culminating assessment of workshop skill acquisition will be a competency assessment in our Clinical Skills Center at Stony Brook University Medical Center (http://www.hsc.stonybrook.edu/centers/csc) by a professional standardized patient. Activity pacing is one of the PCST skills that was rated as highly relevant and helpful by patients in our clinical trial. Delivery of this skill will be used in the competency assessment because it incorporates foundational core competencies inherent in PCST. These include general aspects of patient-provider communication, patient-specific problem identification, addressing motivation, patient engagement, and development of patient-specific action plans. Nurses will demonstrate PCST skills utilizing standardized patients in a simulation with video feedback. They will also receive didactic and supplementary materials that will be available on the Stony Brook University School of Nursing electronic Learning Management System (LMS). This innovative LMS had been used to successfully deliver curriculum to both undergraduate and graduate nursing students since 1994. This LMS has the capacity to deliver didactic material, video links, and electronic exams among other features. Dr. Bruckenthal has developed and taught both distance-education and blended-delivery education utilizing this system for over 20 years.

The final component of the training program will be two 30-minute phone calls with our master trainers over the 2-3 months following training. This will be an opportunity for the trained APRNs to problem solve challenges with delivery to patients, successes, and planning for future delivery to patients.

APRN's who complete all phases of the training will receive a certificate from the Stony Brook School of Nursing attesting to successful completion of PCST training.

Detailed Outline of training workshop

PCST teaches patients cognitive and behavioral skills to manage pain and enhance their perception of control over pain. In addition, Motivational Interviewing (MI) and Brief Action Planning (BAP) will be included in the training. MI is a collaborative, person-centered form of communication to elicit and strengthen motivation for change.[11] BAP is an efficient, evidence-based, highly structured, stepped care, self-management support technique that is grounded in the principles of MI and can be used in any health care population. Action planning and self-efficacy are the foundational constructs of BAP. The BAP framework assists patients to create specific, behavioral action plans toward health goals, while building self-efficacy to enact the goals outlined in the action plan.[12] BAP can easily be incorporated within the context of a 20-minute office visit, and it can be conducted in 3-5 minutes. Woven throughout the sessions is reinforcement of the idea that the patient does not have to be a passive victim of pain, but

through changes in behavior, thoughts, and affect can exert a meaningful effect, thus increasing their self-efficacy. The importance of incorporating these skills, as part of a total treatment plan including current pharmacological treatment, will be stressed. Together, these skills can improve outcomes for patients by building self-efficacy for pain management.

The adjacent table provides a detailed overview of the 2½ day workshop content. APRN's will be provided with a training manual with sections for each didactic topic. Session 1 begins with a review of the rationale for PCST, including the gate control theory of pain[13,14] that describes how the brain influences blocking of pain signals through behavior, thought, and affect. These concepts help the patient to understand the basis for PCST and how active use of the coping skills will reduce their pain experience. The four most important pain coping skills will be taught: progressive muscle relaxation, mini relaxation practices, altering activity and rest patterns, and pleasant imagery. Patient debriefing from our previous trial found that these four skills were those most often selected by patients for ongoing pain self management.[5] Patient homework assignments are an integral component of PCST. Therefore, in addition to the treatment manual, a toolkit will be provided via the SBU SON electronic LMS educational link that will support nurses' delivery of PCST in their clinics. The toolkit will include additional materials for each pain coping skill, logs to prescribe and record patient home practice of the skill, and handouts for patients.

Day 1		
Time	**Activity**	**Hours for CE**
8:45-9:00	Welcome and introductions	
9:00-10:30	Overview Health Behavior Change Theory Skills as part of integrated plan of care	1.5
10:30-10:45	Break	
10:45-12:00	PCST rationale; Introduction to progressive muscle relaxation	1.25
12:00-1:00	Lunch on your own	
1:00-2:15	Progressive muscle relaxation ; Relaxation mini-practice skill	1.25
2:15-2:30	Break	
2:30-3:45	Activity-rest cycle skill	1.25
3:45-4:15	Debriefing and wrap up	
Day 2		
8:45-9:00	Welcome	
9:00-10:30	Concepts of Motivational Interviewing	1.5
10:30-10:45	Break	
10:45-12:00	Brief Action Planning	1.25
12:00-1:00	Lunch on your own	
1:00-2:15	Pleasant Imagery	1.25
2:15-2:30	Break	
2:30-3:45	Application to real world settings	1.25
3:45-4:15	Debriefing and wrap up	
Day 3		
9:00 -10:00	SIM or role play practice	1.0
10:00-11:00	SIM or role play practice	1.0
11:00-12:00	Debriefing Next steps/workshop evaluation	1.0
12:00	Departure	Total=14.25

During the training, following didactic presentations, the nurses will practice delivery of the coping skills using behavioral rehearsal with their classmates and master trainers. This approach was found to be very effective when training nurses for our clinical trial. They will work directly from the treatment manual that emphasizes the importance of fidelity of

treatment delivery to maximize clinical effectiveness. Behavioral rehearsal provides the opportunity to gain mastery of the material, comfort with the verbal delivery and communication with the patient, and to receive feedback on delivery from peers and trainers.

The training will conclude with two follow-up supervision telephone calls in the 3 months after training. The purpose of these calls is to troubleshoot challenges in skill delivery and patient uptake, while providing feedback and coaching.

Evaluation Design

Outcomes Assessment

Our team is highly experienced in conducting clinical outcome studies and has internationally recognized expertise in measurement of patient reported outcomes (PROs). The primary goal of this project is to provide and evaluate nurse training in the evidence-based treatment, PCST. We are not evaluating the efficacy of PCST, since that is well established in the research literature. Rather, we will follow the model outlined by the CDC for program evaluation in public health using the logic model or impact pathway to specify the crucial features of the training necessary for effective clinical implementation.[15] Outcome assessment will use process analysis to evaluate the effectiveness of training.[16] The effectiveness of this APRN training project to train nurses to close the gap in patient access to Pain Coping Skills Training will be empirically evaluated in several ways.

Primary Nurse Outcomes

1. Announcement of the training workshops will be posted on multiple national APRN professional sites as well as through emails to distribution lists and newsletters. Rate of response to the announcement will be tabulated as an objective indicator of APRN interest in the training. Rate of full completion of training by nurses to certification will also be tabulated.
2. Traditional nursing curriculum may include some components of PCST, such as progressive muscle relaxation training. However, most of the didactic material presented in the PCST training will be new. The first step in creating professional capacity for providing PCST to chronic pain patients is to acquire the knowledge of underlying theory and practical implementation of skills to manage pain and its life consequences to improve wellbeing. APRNs in the training program will complete two assessments of knowledge of theory and practice in four pain skills, motivational interviewing, and brief action planning. A pre-training assessment will be compared with a post-training assessment to objectively measure increase in knowledge.
3. A second necessary condition for incorporating a new treatment into one's clinical repertoire is confidence to implement effectively. We will empirically evaluate the change in confidence to deliver PCST in clinical practice. Likert scale ratings of confidence to deliver each skill will be collected pre and post training. Changes in summed ratings will be compared.
4. A third condition for achieving change in patients' pain experience is the ability of the nurse to competently deliver the PCST treatment to patients. Competency will be evaluated in the Clinical Skills Center (CSC) at Stony Brook University Medical Center. It is a state-of-the-art training center that is used as a resource for specialized training of physicians and other

healthcare professionals. In the CSC, our nurses will interact with standardized patients who will have been trained specifically for this protocol. The nurses will deliver one of the PCST skills, activity-rest cycle, to the patient. At the conclusion, a series of ratings will be completed by the standardized patient to assess competency of delivery. The competency rating tool is below. The total score range is 12-60. "Satisfactory" competence will be set at scores ≥ 32; lower competence = ≤ 31; high competence ≥ 48.

Nurse PCST Competency Rating Form **APRN:** **Sim. Patient Rater: _____**	
	Fidelity of Skill Delivery Rate each item below on a 1 - 5 scale as follows: **1** = Poor **2** = Fair **3** = Satisfactory **4** = Very Good **5** = Excellent
	Reviews agenda/goals for this pain coping skill
	Describes over-activity cycle and consequences of overdoing
	Discusses activity-rest cycling and its benefits
	Guides patient in developing personal activity-rest cycle plan
	Assigns home practice
	Develops a patient specific BAP to complete homework
	General Ratings of Nurse Performance
	Establishes/maintains rapport
	Stays on schedule with the protocol or makes appropriate adjustments when needed
	Adapts PCST protocol to patient's situation and current challenges
	Encourages patient's active involvement in the training session
	Demonstrates good interpersonal skills (warmth, concern, confidence, genuineness)
	Demonstrates professionalism and clinical judgment (e.g. boundaries, role)
	TOTAL= SUM OF ITEM SCORES

5. The final training outcome is rate of actual implementation of PCST in clinical practice. This will be systematically assessed on a weekly basis for three months following the nurses' training. Nurses will log into the NIH Assessment Center (www.nihpromis.org) each week and record the number of patients to whom they delivered a PCST skill during their clinical practice.
6. In addition, patient characteristics entering into the nurses' clinical decision making to implement delivery of PCST for a particular patient will be collected. The following check list will be completed on the Assessment Center each week for each patient:

Pt	Clinical Decisions to deliver PCST to each pt.
1	*Check all that apply.* □ Insufficient response to medications □ Severity of pain □ Degree of functional disability □ Pt interested in non-pharma interventions □ Inadequate patient coping skills □ Other: - _____

7. Qualitative analysis will be conducted at the endpoint of the project to assess the participating nurses' evaluation of the training. Interviews will be conducted with a randomly selected set of 10 APRNs to capture more detailed feedback and suggestions. These data will be used to generate a report of "lessons learned" and recommendations for future training programs.

Secondary Patient Outcomes

This program creates the opportunity not only to assess nurse acquisition of skills to deliver PCST, but also to assess their patients' response receiving PCST skills and impact on their illness experience. While this project does not afford the substantial resources necessary to conduct a randomized, controlled trial, important patient outcomes can be collected to assess impact on patients in a real world setting.[17,18] Nurses will invite each patient who will receive PCST treatment to be contacted by the research team to be enrolled in the study.

A questionnaire assessment will be conducted pre- and 3 months after nurse delivery of a PCST skill. Additional skills may or may not have been delivered during this time interval. Patients will be guided to the NIH Assessment Center (*www.nihpromis.org*) to complete the assessment. Patients without Internet access will be mailed the questionnaire. The following assessments will be included:

1. Global impression of change due to nurse delivery of PCST skill (post only)
2. NIH PROMIS (*www.nihpromis.org*) measures[19] of:
   - Global Health
   - Pain intensity
   - Pain Interference
   - Physical Functioning
   - Fatigue
   - Psychosocial Illness Impact
3. Rating of satisfaction with care due to nurse delivery of PCST
4. Rating of utility of PCST skill(s) delivered by nurse for their pain management

Confidentiality of Data and Security of Datasets

Personal identifiers (e.g., participant's name, address, telephone number) will be kept in a separate, locked location in the research offices apart from health-related information and data generated in the study. All data will be coded with a numerical identifier. Only the research staff will have access to information to link personal identifiers with health data. All data will be treated as confidential research data using HIPAA guidelines.

Expectations of Program Outcomes

Nurse Outcomes	
Nurse interest in training program	Full recruitment of 40 APRNs
Knowledge of PCST, Motivational Interviewing, Brief Action Planning	Pre: 20%; Post: ≥ 75%
Confidence to deliver PCST	Pre: 10%; Post: ≥ 70%
Patient Simulation testing for competence	Low: 20%; Satisf: 55%; Hi: 25%
Nurse delivery of PCST skill to patient	Pre: 0; Post: 3/week
Satisfaction with training program	80% ≥ 6 (7 pt. scale)
Patient Outcomes	
Global impression of change	50% "improved"
PROMIS symptom scores	Pre- to post effect size= ≥ .20
Satisfaction with care following PCST skill delivery	75% ≥ 6 (7 pt. scale)
Perceived utility of PCST skill(s) for managing pain	75% ≥ 6 (7 pt. scale)

Outcomes Data Analysis

Primary nurse outcomes

The statistical analyses will determine whether the nurses' outcomes meet *a priori* specified expectations on each of the outcome criteria (competence, satisfaction, knowledge, confidence). For post-training competence outcomes, we will observe the proportion of nurses achieving at least "satisfactory" competence in delivering the PCST treatment. The hypothesis that this proportion exceeds zero is of little interest. Rather, the statistical analysis will examine whether the rate of nurses achieving satisfactory competence can be expected to be at least 75% in the population. This will be determined using a one-sample binomial test comparing the observed proportion against a null-proportion of .75. Post-training ratings of satisfaction with the program will be dichotomized using a pre-specified cutoff (≥6 on a 7-point scale); a one-sample binomial test will determine whether the rate of nurses meeting this cutoff exceeds 80%.

Data for knowledge and confidence outcomes will be collected at pre- and post-training using continuous measures. The distributions of these measures will be inspected at each time

point to evaluate whether they deviate from normality assumptions. Paired samples t-tests (for approximately normal distributions) or Wilcoxon's signed rank tests (for severely skewed distributions) will be used to examine the statistical significance of changes in knowledge and confidence outcomes from pre- to post-training. Effect sizes will be estimated as the standardized change in outcomes, with bias correction for small to moderate sample sizes using the gamma function.[20] In addition, we will determine the proportion of nurses for whom knowledge and confidence outcomes meet acceptable levels from a pragmatic standpoint. To accomplish this, the outcomes will be dichotomized based on pre-determined cutoffs for "minimally sufficient" knowledge and confidence. McNemar's test for paired nominal data will be used to determine whether the rates of nurses meeting these cutoffs differ at pre- and post-training. One-sample binomial tests will determine whether the rates of nurses meeting the cutoffs exceed 75% (for knowledge) and 70% (for confidence outcomes).

Other nurse outcomes involving the rates of training completion, rates of patients to whom the intervention was delivered, and clinical decisions for intervention delivery will be summarized descriptively with means (standard deviations) and frequency distributions.

We estimated the statistical power that a sample of 40 nurses would provide for detecting that the true proportion of nurses who meet a given criterion (of competence, satisfaction, knowledge, confidence) in the population exceeds a given target value. Our goal is to have a reasonably narrow confidence interval (CI) surrounding the observed proportion of sampled nurses who meet the criterion. The lower and upper bounds of the 90% CI indicate the range in the true population proportion (with 5% uncertainty in each the lower and upper bound) for the different possible proportions observed in our sample. We are most interested in the lower bound of the CI, which indicates the lower margin of the proportion of nurses in the population that are likely to meet the criterion at a one-tailed alpha of.05. The width of the confidence interval varies with the magnitude of the proportion observed in the sample, becoming narrower as the proportion increases.

Table: Upper and lower bound of 90% confidence interval of observed proportions (n = 40)

Observed	**.70**	**.75**	**.80**	**.85**	**.90**
Lower bound	.58	.64	.70	.76	.82
Upper bound	.82	.86	.90	.94	.97

Secondary patient outcomes

Data for patient outcomes will be collected in a clustered design, where multiple patients are "nested" within the same APRN. Individuals belonging to the same cluster are likely to resemble one another because of common environment (e.g., clinic) and common APRNs, and ignoring this non-independence of observations can seriously inflate Type 1 error rates.[21] Cluster-robust standard errors will be used in the analysis of patient outcomes as they explicitly account for the nested data structure and for potentially unbalanced data due to variation in

the number of patients per APRN.[22] One-sample binomial tests with robust standard errors will determine whether patient outcomes meet the program expectations for global impression of change (50% patients with ratings of "improved" or better), satisfaction with care (75% ≥6 on a 7-point scale) and perceived utility of PCST skills (75% ≥6 on a 7-point scale). Paired samples t-tests with cluster-robust standard errors will be used to examine pre- to-post PCST changes in PROMIS symptom scores.

In our recent randomized controlled trial, we calculated effect sizes (ES) for 6- and 12-month follow-up treatment effects. We found long-term gains at a magnitude of ES = .21 for the pain composite variable. The power calculations for the proposed study were therefore conducted so as to assure 80% power for the detection of change in PROMIS symptom (pain interference) scores with an ES as small as 0.20. This effect size (ES = 0.20) is considered small as per Cohen's conventions,[23] and probably approaches the smallest effect that could be considered clinically significant. The statistical power in a clustered design depends on factors that are not known a priori, importantly, the intraclass correlation (ICC) of outcomes due to the nesting of patients in NPs. ICCs for self-reported health outcomes in primary care settings have been found to range from very small (<0.001) up to a level of 0.05.[24,25] Accordingly, we conservatively estimate that 5% of the variance will be between APRNs. In addition, the correlation between baseline and post-trial outcome measurements is unknown, but presumed to be approximately 0.65 based on analyses of correlations between baseline and follow-up in our previous randomized controlled trial.[5,26] This correlation is used to calculate the expected standard deviation of the change scores. To power the test to 80%, a sample size of 34 NPs (170 patients) with complete data is necessary to detect an ES of .20 at a statistical significance level of .05 (two-tailed). In order to allow for a 15% dropout rate, 40 NPs (200 patients) will be enrolled. Whatever data are available for the additional 30 patient subjects will increase the power of the analyses above 80%.

Dissemination of Project Outcomes

The potentially successful results of this project will set the stage for establishing a national certificate for APRNs to widely increase chronic pain patients' access to PCST. Dissemination will be through a subsequent national train-the-trainer program at Stony Brook School of Nursing, publications in major medical journals, and presentations at national and regional meetings and conferences. Our team has a strong record of top-tier publications and presentations at national and international conferences.

Detailed Workplan and Deliverables Schedule

During the first seven months of the project, we will design the PCST training, obtain IRB approval, design the recruitment materials for the NPs, advertise and recruit them, and enroll both APRNs and patients. During the next five months of the project, we will continue to advertise and recruit, train our first cohort of 20 APRNs, and establish a baseline PRO assessment for patients. By the end of the project's first year, we will have trained our first cohort, will begin to offer phone support as described above, and will begin to gather weekly outcomes for NPs who are putting their new skills into practice. During the first half of the second year, we will continue to recruit NPs and hold a second training session. Once the

training session is complete, as before, we will offer phone support and gather data weekly on outcomes for participants, and some patients will complete a patient post-PRO assessment. During the final year of the program, we will gather weekly APRN outcomes, obtain the final set of patient outcomes, and complete our final data analysis and report. The schedule for completion and costs associated with each deliverable are summarized in the table below.

Project Timeline

Project Tasks	**Months:** across 2.5 Years				
	1-7 (7 mos)	8-12 (5 mos)	1-6	7-12	1-6
Design PCST training					
Obtain IRB approval					
Design NP recruitment					
Advertise/recruit NPs					
Enroll APRNs and pts					
Pt Baseline PRO assess					
Training group #1					
Training session #2					
Phone Support					
Weekly NP outcomes					
Pt post PRO assess					
Data analysis & report					
Budget for task items (directs only)	$73,211	$52,294	$61,378	$61,378	$41,365

Requested Total Budget: $350,000

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Organizational Details

Project Leadership

Dr. Joan Broderick, a clinical health psychologist, was the Principal Investigator of the NIH/NIAMS-funded project "Coping Skills Training For Arthritis: An Effectiveness Trial", a $3.2M multi-site RCT that investigated the effectiveness of APRN delivery of PCST for chronic pain and from which this proposal emanates. The results were recently published in *Pain* and documented improved clinical outcomes across several important domains in chronic pain patients. This work was conducted with Co-Investigator, Dr. Patricia Bruckenthal, Chair of Graduate Studies in Advanced Practice Nursing and professor in the School of Nursing (SON) at Stony Brook University. Several months ago, Dr. Broderick took the position of Associate Director of the Center for Self-Report Science (CSS) and Senior Behavioral Scientist at the Center for Economic & Social Research at the University of Southern California. Dr. Broderick, PI of 1 of 12 NIH-funded Patient Reported Outcomes Measurement Information System (PROMIS) study sites, has published numerous papers on issues related to the accuracy of patient reported outcomes (PROs) in clinical populations (e.g., [19,27-29]). Given this expertise and experience running several clinical trials, Dr. Broderick is capable and poised to successfully lead this project from concept development, study design, implementation, data capture and analysis through to final report and analysis. Broadly speaking, the research aspects of the project will be centered at USC, and the nurse training aspects at Stony Brook University. Dr. Broderick's team has extensive experience collecting clinical outcomes from multiple sites remotely.

Dr. Bruckenthal has practiced as a nurse clinician in pain management for over 18 years. She completed a research post-doctoral fellowship at the Applied Behavioral Medicine Research Institute in the Stony Brook Medicine Department of Psychiatry under the mentorship of Dr. Broderick. She has been very active in regional and national nursing organizations, including as President of the American Society for Pain Management Nurses, and member of the Ethics Committee and former member of the Analgesic Regulatory Affairs Committee for the American Pain Society. As well, she served on the Medical Society of the State of New York Task Force, "Pain Management Education for Physicians." She has also published articles in pain assessment and clinical education and treatment (e.g., [30-32]).

Dr. Schneider, a social psychologist and biostatistician, has worked with Dr. Broderick for over 5 years. As a co-investigator on the clinical trial and PROMIS grants, he has made important contributions, especially in highly sophisticated data analysis and manuscript preparations. Dr. Schneider will oversee data management and will conduct the analysis of outcomes in this project.

University of Southern California Facilities

The Center for Self-Report Science

The Center for Self-Report Science was established in 2014 with the goal of improving our understanding about how people answer questions and using that knowledge to develop methods and techniques that provide accurate and reliable assessments of self-reports. Center

faculty are involved in methods that allow collection of self-reports in natural environments at fairly high frequency, using sophisticated computer and remote methods. The Center provides consultation for the design and analysis of clinical trials and other research, including methods consistent with current FDA guidance for self-report.

The Center for Economic and Social Research

The goal of The Center for Economic and Social Research (CESR) is to conduct a wide range of research projects in the social sciences and economics across areas of research that include: the economics of education, financial decision-making, health, health disparities and socio-economic status, aging populations, work disability and subjective well-being.

The Statistical Consultation and Research Center

The Statistical Consultation and Research Center (SCRC) is an Organized Research Unit at the University of Southern California that integrates statistical, epidemiological and computing resources and offers them to professionals conducting clinical, biomedical and translational research. The SCRC consists of a team of statisticians, epidemiologists, database developers, programmers, project coordinators and data managers that provides an optimal structure to assist both the public and private sectors in carrying out clinical and prevention trials, observational and retrospective studies, cross-sectional and longitudinal surveys and translational research. Members of the SCRC are co- investigators on a range of studies in atherosclerosis, cancer, diabetes, neuroscience, ophthalmology, stroke rehabilitation interventions, lifestyle redesign interventions and alternative medicine.

The Southern California Clinical and Translational Science Institute

The Southern California Clinical and Translational Science Institute (SC CTSI) offers biostatistics and bioinformatics support to promote efficient and accurate data collection and analysis, and to help researchers avoid translational research pitfalls. Services include:

- Study/experimental design
- Data management through REDCap
- Statistical analysis

Stony Brook SON Facilities

Stony Brook University SON also will provide institutional support for this project in the form of physical space, and administrative and technological support for nurse training. The SON is an international leader in local and global learning for Advanced Practice Nursing. Dr. Bruckenthal is director of the program that utilizes innovative electronic learning management systems.

The Clinical Skills Simulation Center

The Clinical Skills Simulation Center at Stony Brook Medical Center is a state-of-the-art training center that is used as a resource for specialized training of health care professionals. Participants evaluate and diagnose patients through teaching modules that incorporate the use of actor patients and computerized mannequins that simulate disease. The center provides opportunities for hands on training in a safe environment. Select features of the center

include; 6,000 square feet, 10 fully equipped exam rooms with computer stations, audio/visual monitoring for each exam room, a comprehensive system used for simultaneous monitoring, testing, and assessment, digital A/V management, centralized data capture, and a computer server system that stores 2-3 years of videotaped student/patient encounters with up to 4 terabytes of storage.

School of Nursing – Technical Environment for Learning Success:

The School's extremely successful Distance Education (DE) program for advanced practice nursing is based on a *computer mediated design* using the Lotus Domino/Notes platform. Our custom written application enables our students to access their curriculum, collaborate with fellow students on projects, communicate with faculty, submit assignments, take electronic quizzes and exams, and submit evaluations for the faculty, courses, and the program.

The computing environment that supports the School of Nursing's DE programs is web based. Our Web server translates our custom Lotus Domino/Notes applications and databases into HTML on demand, giving learners access to School of Nursing courses from a Web browser. The server component of this environment consists of 5 Windows based servers. These servers are physically located in the School of nursing and are dedicated to supporting the School's DE programs.

School of Nursing (including Health Sciences Classrooms)

The SON's physical space, approximately 24,000 sq. feet, is located in the Health Sciences Center and has access to high quality classroom, laboratory, technology, and conference and office space to ensure a highly effective learning environment. The SON (internally) has 2 classrooms and has access (externally) to 6 lecture halls, 6 seminar rooms and an additional 22 classrooms. Wireless Internet service is available throughout the building and five lecture halls provide electrical service at each seat to support uninterrupted laptop computer use. These facilities contain multi media equipment that includes data projectors, voice amplification, Internet access and VCR/DVD players. Audiovisual staff is readily available to assist and advise regarding facilities and equipment. Campus wide resources include but are not limited to: Career Services Center, Writing Center, Health Science Library, Melville Library, Student Health Services, Disability Student Services, Computing Services, and Student Affairs (Main Campus).

Recently, the SON added computer projection equipment, Blu-ray DVD players, ceiling mounted speakers, and projection screens to its classrooms and conference rooms. A videoconference center and new faculty computers with high definition webcams and personal videoconference software to facilitate audio/video communication with students, faculty and clinical preceptors and for faculty/staff development were added.

G

USC University of Southern California

DEPARTMENT OF CONTRACTS AND GRANTS

Ocotober 13th, 2014

Sponsor: Pfizer

Proposal entitled: "Expanding access to Pain Coping Skills Training (PCST): A professional certificate program to enable Advanced Practice Registered Nurses (APRNs) to fill the gap"

PI: Joan Broderick
Time Period: 12/01/2014-05/31/2017
Total Cost: $350,000

We are pleased to forward the subject proposal, which has been approved by the department of Contracts and Grants on behalf of the University of Southern California (USC), for your review and consideration. Should an award be made, acceptance will be based on mutually agreeable terms.

If you have any questions or require further information that is administrative in nature, please contact me at burelli@usc.edu or by phone at (213)740-6064. Please address all technical inquiries to our Principal Investigator.

Nicole Burelli
Senior Contract and Grant Officer

Enclosure: Proposal

Cc: PI/file

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SUNY RF
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The State University of New York

Stony Brook University

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W5510 Frank Melville Jr. Library
State University of New York
Stony Brook, New York 11794-3362

Telephone: 631-632-4402/9949
Fax: 631-632-6963

www.stonybrook.edu/research

October 10, 2014

Michael Beltran
Principal C&G Subcontract Officer (ISI&ICT)
University of Southern California
Department of Contracts and Grants
3720 S. Flower Street
Los Angeles, CA 90089-0701

Dear Mr. Beltran:

The enclosed proposal is being submitted for your consideration by The Research Foundation for The State University of New York at Stony Brook University for inclusion in your larger grant proposal to Pfizer Corporation.

Stony Brook University is a U.S. institution of higher education that conducts fundamental research in basic and applied science and engineering. This research is widely and openly published and made available to the scientific and academic community. Stony Brook University does not undertake classified work or research requiring national security controls. Based on State University of New York policy and federal laws prohibiting discrimination based on nationality, country of origin, ethnicity, gender, race, or religion, Stony Brook University cannot accept any conditions of award which would restrict any members of the research group, including faculty, students and staff, from the ability to participate fully in all of the intellectually significant portions of the project.

Project Director:	Dr. Patricia Bruckenthal
Project Title:	Expanding Access to Pain Coping Skills Training
Period of Support:	12/1/14 through 5/31/17
Funding Level:	$92,545

In the event action on the request is favorable, The Research Foundation for The State University of New York will enter into an appropriate inter-institutional agreement with your organization. The Foundation will serve as fiscal administrator of the award and depository for all funds in support of such award. Award notices or contracts resulting from this submission should be sent to my attention at:

The Research Foundation for The State University of New York
Office of Sponsored Programs
W5510 Frank Melville Jr. Library
Stony Brook University
Stony Brook, New York 11794-3362

By signing this letter of intent, Foundation certifies that it has a written and enforced conflict of interest policy that is consistent with the provisions of 42 CFR Part 50, Subpart F "Responsibility of Applicants for Promoting Objectivity in Research" and 45 CFR Part 94 "Responsible Prospective Contractors." Foundation also certifies that, to the best of its knowledge: (1) all financial disclosures have been made related to the activities that may be funded by a resulting agreement and required by its conflict of interest policy; and (2) all identified conflicts of interest have or will have been satisfactorily managed, reduced, or eliminated in accordance with Foundation's conflict of interest policy prior to the expenditure of any funds under any resulting agreement and within a timely manner sufficient to enable timely financial conflict of interest reporting.

Any questions or negotiations regarding this submission should be directed to me at 631.632.9029 or at the email below.

Sincerely,

Deborah Chalmers

Deborah Chalmers
Contracts Administrator
deborah.chalmers@stonybrook.edu