Psychosomatics 2016:57:47–56

Original Research Reports

Influence of Priming on Patient-Reported Outcome Measures: A Randomized Controlled Trial

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Background: *Patient-reported outcome measures (PROMs) are influenced by psychosocial factors, but it is unknown whether we can influence PROM scores by modifying the mindset of the patient.* **Purpose:** *We assessed whether priming affects scores on PROMs.* **Methods:** *In all, 168 patients with musculoskeletal illness participated in this double-blinded, randomized, controlled, parallel study between July 2014 and October 2014 in a level I trauma center. Inclusion criteria were patients aged 18 years or older with English fluency and literacy and the ability to provide informed consent. Priming was performed by means of the Pain Catastrophizing Scale (PCS). The patients were randomized (1:1:1) into 3 groups: intervention group I was negatively primed with the original PCS; intervention group II was positively primed with a positively phrased PCS group; and control group III was not primed. Assessments were performed using PROMs on the domain of physical function, depression, and pain. Bivariate and multivariable regression analyses were conducted.* **Results:** *The intervention and control groups were well balanced in demographic and condition-specific characteristics. The positive PCS was independently associated with higher PROM scores in the physical function domain (Patient-Reported Outcome Measurement Information System Upper Extremity Function: coefficient = 4.7, partial R^2 = 0.042; CI: 1.2–8.2; $p < 0.010$).* **Conclusions:** *Patients primed with a positively phrased version of the PCS reported less functional disability as compared with patients who were either negatively primed or not primed at all. This suggests that by influencing the mindset, PROMs can be influenced, resulting in better outcome if positively primed.* **Level of evidence:** *Level 1 therapeutic study. Trial registration: NCT02209259.*
(Psychosomatics 2016; 57:47–56)

INTRODUCTION

Patient-reported outcome measures (PROMs) quantify symptom intensity and magnitude of disability.[1] PROMs are increasingly used to assess quality and value in health care and may soon be tied to reimbursement.[2] The goal of the National Institutes of Health–sponsored Patient-Reported Outcome Measurement Information System (PROMIS) was to provide validated PROMs and normative data for all aspects of human illness and to reduce the burden on patients by using computerized adaptive testing based on item response theory. Most patients get to a full score after answering only 4 or 5 questions in approximately 15 seconds.[3]

Among patients with musculoskeletal illness PROMs are influenced by mindset and circumstances (e.g., stress, distress, and ineffective coping strategies) as much as or more than by objective impairment/

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pathophysiology (e.g., motion, union, arthrosis, and sensibility).[4,5] This raises the possibility that PROMs can be influenced by priming of the patient's mindset. Priming is the unconscious process of activating specific associations just before performing an action or task.[6,7] Priming is a form of implicit memory and priming experiments usually consists of 2 stages. In the first stage, the patient is presented with a stimulus, e.g. happy faces or negative words. In the second stage the patient is given reduced perceptual information about the stimulus, e.g., letters of the negative words or the originally presented happy face in a schematic form.[7] Priming is said to have occurred if the probability of baseline identification performance of the stimulus is increased in comparison with control patients.[7] Priming affects all aspects of human behavior.[6] For example, a speaker who has just heard a sentence in passive voice is more likely to use a passive construction. Priming apparently also has affective dimensions.[8–10] For instance, subjects primed with happy faces or action words were able to exercise significantly longer than a control group primed with unhappy faces and nonaction words.[10]

Priming is related to the broader concept of expectancy. The expectancy theory hypothesizes that individuals behave or act in a certain way because they are motivated to choose a specific behavior over other behaviors due to what they expect the result of that behavior would be. Positive expectancy means that the outcome is positively influenced and negative expectancy means that the outcome is negatively influenced.[11,12]

Although the observation that priming might influence PROMs introduces the possibility that providers being assessed based on PROMs can attempt to manipulate the scores, our interest is more in attempting to improve health by consistently using positive language and concepts in medical care. For instance, focusing on ineffective coping strategies using a negatively oriented questionnaire such as the Pain Catastrophizing Scale (PCS) might inadvertently reinforce them.

The PCS is often used to measure the ineffective coping strategy of catastrophic thinking (feeling protective and preparing for the worst) in response to pain.[13] The items in the PCS are negatively phrased, e.g., "When I'm in pain it's terrible and I think it's never going to get any better" or "When I am in pain I become afraid that the pain will get worse."[13] These negatively phrased items might prime patients to consider themselves in a negative light and score themselves lower on measure of symptoms and disability (PROMs).

The current study was conducted to assess whether priming affects scores on PROMs of physical function, symptoms of depression, or pain intensity in patients with musculoskeletal illness. The primary null hypothesis was that there is no difference in mean physical function PROM scores between patients who complete the original PCS, patients who complete a revised PCS in which the items are positively phrased (positive PCS), and patients who do not complete either PCS. Our secondary null hypotheses were that there is no difference in depression, pain, and among patients who complete the original PCS, patients who complete the positive PCS, and patients who do not complete the PCS.

MATERIAL AND METHODS

Study Design and Setting

An institutional review board approved this double-blinded, randomized, controlled, parallel-designed study, which was performed at the outpatient clinic of the Hand and Upper Extremity Service of a level 1 trauma center. The trial was registered on www.clinicaltrails.gov NCT02209259.

Participants

Between July 2014 and October 2014 new and follow-up patients presenting to the outpatient clinic of an orthopedic hand surgeon at the Hand and Upper Extremity Service of the Massachusetts General Hospital were invited to participate in this study. Inclusion criteria were patients aged 18 years or older with English fluency and literacy and the ability to provide informed consent. Pregnant women were excluded. Written informed consent of each patient was obtained after providing information about the subject of the study and risks and discomforts orally and in writing. Patients were not informed about the randomization.

Randomization

Patients were randomized (1:1:1) to 3 groups by computer-generated random numbers and using