Study Title: The Positive Piggy Bank - A Positive Activities Intervention for Improving Functional Status in Patients with Back Pain

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A. BACKGROUND

Chronic back pain is the leading cause of disability in Americans under 45 years old and data suggest that the problem is growing. One recent study showed that the prevalence in North Carolina alone had increased from 3.9% to 10.2% over a 14-year period.[1] Additionally, chronic back pain is associated with significant disability;[2] for example, the Global Burden of Disease Study reported that low back pain was among the top ten high burden diseases with an average number of disability-adjusted life years greater than HIV, tuberculosis, lung cancer, and chronic obstructive pulmonary disease.[3] Thus, improving pain management, which includes promoting and enabling patient self-management, is a public health priority.[4]

Epidural steroid injections are one of the most common interventions used to treat back pain; however, the role of ESI in the management of spine pain has been questioned of late.[5] While ESI often lead to a short-term analgesic response, evidence supportive of long-term relief is lacking and an estimated 25 to 45% of patients fail to achieve clinically meaningful improvement in pain.[6-10] Studies have shown that the salutary effects are particularly small for the treatment of axial low back pain[11] or spinal stenosis,[12,13] while the best indicator for success for ESI is radicular pain secondary to a herniated disc.[6] To boost the effectiveness of such an intervention, the addition of patient self-management strategies has been proposed.

Although there are strong data supporting pain self-management approaches for functional restoration in chronic back pain patients,[14-17] such interventions are greatly underutilized. Barriers to broader integration of highly effective behavioral self-management techniques include limited access to psychologists/social workers, difficulties integrating psychological practices into medical settings, and poor reimbursement. Plus, the stigma associated with mental health interventions decreases enthusiasm for adopting some of these approaches in medical populations.[18-20] More specifically, Bair and colleagues noted that self-management programs for chronic musculoskeletal pain are also hindered by lack of resources, physical limitations (i.e., demanding activities), and time constraints or other priorities.[21]

Although rarely used in chronic pain populations, positive activities interventions have been used successfully in many other clinical settings. Not only have positive activities interventions been found to be more appealing than standard interventions (e.g., medication, cognitive-behavioral therapy),[22,23] but two meta-analyses have shown that these interventions have been used to treat a range of healthy and clinical populations with a mean effect size for improving well-being ranging from 0.34 to 0.61 (Cohen's d).[24,25] Positive activities interventions are thought to function by increasing positive affect, which in turn, enables creativity, problem-solving, perspective-taking, and myriad other beneficial states.[26] Such states are conducive to better mood,[22,27] behavioral activation/increased physical activity,[28-31] healthier habits[30,32,33] and physiological changes (e.g., improved vagal tone, lower blood pressure, more adaptive immune responses).[28,34-37] Such changes reflect psychological and physiological resilience[38] – improved ability to "bend" under stress, but not "break."[39,40] Recent studies have successfully adapted positive activities interventions for use in a variety of clinical populations, including depressed adults,[22] suicidal inpatients,[41] schizophrenic outpatients,[42] individuals who are quitting smoking,[43] patients with cardiovascular disease,[44] those recently diagnosed with HIV,[45] adults with type 2 diabetes,[46] and individuals with mild to moderate bodily pain.[47] Positive activities may be particularly helpful for patients with chronic low back pain given that depression is a frequent comorbidity[48-50] and our pilot data show that they have very low levels of positive affect, as well. Finan and Garland posed that higher levels of positive affect attenuate both the perception of and the negative affective response to pain.[51]

***The Positive Piggy Bank*.** Our intervention is based on the principles of Positive Psychology and Positive Psychotherapy as developed by Seligman and Parks (Co-I).[22,52] Positive activity interventions target increasing positive affect and life satisfaction, while decreasing negative affect. These are the core factors in subjective well-being.[53-55] Changes in subjective well-being are thought to result in functional restoration and improved symptoms including depressive symptoms, sleep disturbances and pain.[24,25,45]

The structure and content of the Positive Piggy Bank intervention are based on the Broaden and Build Theory of positive emotions.[26] This theory proposes that in contrast to negative emotions which narrow our perceptions, positive emotions broaden awareness and encourage fresh, diverse, and exploratory thoughts and behaviors. This positive perspective broadens one's behavioral repertoire and helps build skills (e.g., more effective coping) and resources (e.g., increased social support). The Positive Piggy Bank is built on the

premise that engaging in a daily activity that promotes reviewing positive occurrences can help individuals become more aware of positive events (broadens perspective). Not only are individuals called upon to review positive events that took place that day, but they also can develop a habit of scanning the environment for positive events throughout the day in anticipation of noting them later. Moreover, new coping skills are learned (thinking about the good things in life) and social support is enhanced as positive emotions draw people in.

The intervention itself involves noting at least one positive event each day, writing it down on a slip of paper and then depositing this piece of paper in a piggy bank. This practice is to take place at the end of the day, every day over a circumscribed period of time. At the end of the "deposit period," in the case of this study after 30 days, the participant "closes the account" and makes a full withdrawal by taking all of the slips out of the piggy bank and reading each one. This intervention builds on eliciting other well-studied concepts such as positive daily reflection,[22,27,44,47] gratitude,[45,46,56,57] and savoring.[22,27,45-47,58]

Figure 1. Positive Piggy Bank Instructions.

The Positive Piggy Bank

Every evening think about the people, things or events that made you happy that day. You may make a list if you like. Pick one of these and spend a moment savoring it. What made it so special to you? Now, write down this moment on a "currency" slip. Use enough detail that you can immediately recall what happened later. Next, add the date, fold up your happy memory "currency," and drop it in the piggy bank. You will make these happy memory "deposits" in the same way every evening for the next 30 days.

At the end of 30 days, you will "close your account." This means that you will withdraw all of the "currency" from your piggy bank and read each and every one of the deposited happy memories. As you read them, try to recall details of the happy event and what made it so special to you at the time. Enjoy!

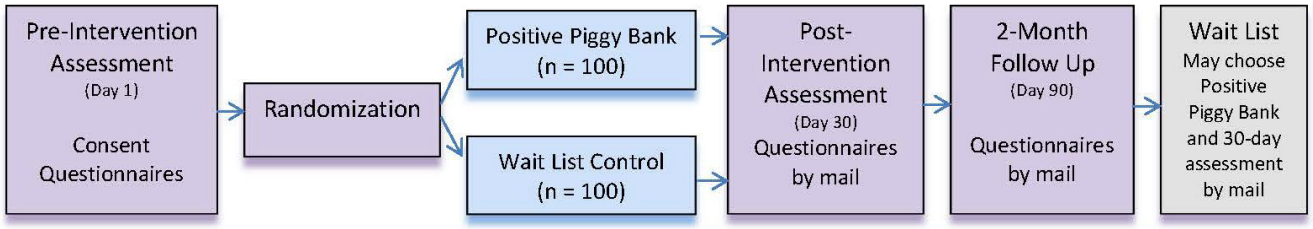
B. OBJECTIVE & HYPOTHESIS

The objective of this study is to assess the efficacy of a positive activities intervention, Positive Piggy Bank, for improving functional status in adults with back pain undergoing an epidural steroid injection. We hypothesize that participants in the intervention group will demonstrate a greater improvement in functional status compared to a wait list control group.

C. METHODS

Overview of the Study Procedures. We will conduct a randomized controlled trial of a 30-day positive activities intervention, Positive Piggy Bank, compared to a Wait-List control group (Figure 2). Prior to their scheduled appointment to undergo epidural steroid injection, all patients meeting study criteria will be contacted by research staff to be invited to participate in this study. Patients will be recruited from University of Michigan's Back and Pain Center as well as the Physical Medicine and Rehabilitation Clinic. Those interested will be asked to arrive 45 minutes before their regularly scheduled appointment. At that time they will learn more about the study and provide informed consent if they choose to participate. Participants will then complete the study questionnaires and be randomized 1:1 to the Positive Piggy Bank condition (n=100) or the Wait List control group (n = 100). All participants will receive the usual treatment provided at the Back & Pain Center at the University of Michigan, Department of Anesthesiology and Physical Medicine and Rehabilitation Clinic (e.g., maintenance of medication regimen, standard office visits). Post-intervention (Day 30) and 2 months after that (Day 90), participants will complete the same questionnaires by mail. The primary outcome will be improved functional status, while secondary outcomes will be symptomatic (i.e., pain, fatigue and sleep) and related to mood and well-being. After the study period, the patients in the Wait List control will be offered the Positive Piggy Bank intervention and will be asked to complete one more set of questionnaires at 30 days by mail.

Figure 2. Study Diagram



Participants – Inclusion Criteria
Subjects to be entered in this study will have a primary diagnosis of back pain and schedule to undergo an epidural steroid injection. Participants will be recruited from the Back & Pain Center and the Physical Medicine and Rehabilitation Clinic. In addition, participants must also meet the following criteria (verified by chart review when applicable): 1) ages 18 to 80; 2) able to read/understand English and give consent; 3) willing and able to comply with all aspects of study procedures; 4) if on antidepressants, medications stable for ≥4 weeks prior to study; 5) no plan to initiate a new non-pharmacological pain intervention during the 30-day study period (e.g., back surgery, physical therapy, cognitive-behavioral therapy [CBT]); and 6) if on pain medications, medications stable for ≥4 weeks prior to study and no plans to switch medications during the 30-day study period.

Participants – Exclusion Criteria
Participants may meet all criteria above, but will be excluded under the following additional conditions: 1) having a known psychotic disorder or the presence of another psychiatric condition (e.g., severe depression [HADS scores ≥15], suicidal ideation) or cognitive impairment (e.g., severe dyslexia, traumatic brain injury) limiting ability to give consent and/or participate fully in the study; 2) currently undergoing psychotherapeutic care at the Back & Pain Center because many of the concepts that are the focus of this study are already employed in that treatment; and 3) other factors that at the discretion of the investigators would adversely affect study participation. We will not exclude participants who undergo unanticipated changes in treatment, but will handle these data as described later.

Assessment Measures
Primary Outcome Measure: Functional Restoration: Oswestry Disability Questionnaire (ODI [version 2.1a]): The ODI consists of 10 items that query pain intensity and areas of disability (e.g., personal care, walking, sitting, standing, lifting, traveling).[59,60] Each item is scored 0 to 5 and scores from all ten items are totaled (range 0-50). The total is then divided by 50 and multiplied by 100 to produce a percentage score (range 0-100%). Low percentage scores suggest little or no disability, while high percentage scores indicate increased disability (e.g., disability: 0-20% minimal; *21-40% moderate*; 41-60% severe; 61-80% crippling; and 81-100% bed-bound). The ODI has good test-retest reliability[59] (e.g., one week, $r = 0.83$)[61] and acceptable internal consistency (Cronbach's alpha 0.87).[62] Face and content validity are also acceptable, including assessments using patient behavior as the comparator (sitting and walking tests).[59,62,63] The ODI is responsive to change[64-66] and is often superior to other commonly used measures including the SF-36.[66-69]

Secondary Outcome Measure: Pain – Brief Pain Inventory (BPI). The BPI will be used to assess pain severity (4 items). The BPI, validated for chronic, non-malignant forms of pain, asks patients to rate their current pain intensity, as well as their worst, least and average pain in the last week (0-10 numeric rating scale).

Secondary Outcome Measure: Fatigue - PROMIS Fatigue-Short Form 4a.[70,71] This measure consists of 4 items that assess the impact and experience of fatigue in the past week. It uses a 5-point Likert-like scale with response options that range from "Not at all" to "Very much." A raw score is calculated by summing scores across items then a conversion table is used to calculate T-scores with higher scores indicating greater fatigue.

Secondary Outcome Measure: Perceived Sleep Problems - PROMIS-Sleep Disturbance (*PROMIS-SD4a*).[70,71] To assess sleep disturbances the 4-item static form will be used. It uses a 5-point Likert-like scale with response options that range from "Very poor" to "Very good." A raw score is calculated by summing scores across items then a conversion table is used to calculate T-scores with higher scores indicating greater sleep

disturbance.

Secondary Outcome Measure: Depression and Anxiety. The well-validated 14-item *Hospital Anxiety and Depression Scale (HADS)* will be used to assess symptoms of both depression and anxiety.[72,73]

Secondary Outcome Measure: Subjective Happiness Scale. The subjective happiness scale is a 4-item validated measure of overall happiness. A 7-point Likert scale is used to create a total score. Higher scores indicate greater levels of happiness. Item 4 is reversed scored.[74]

Secondary Outcome Measure: Subjective Well-Being Scores: Theory and research suggest that subjective well-being has at least three components: positive affective appraisal, negative affective appraisal, and life satisfaction.[53,75] Composite scores for well-being will be calculated using scores obtained on the measures below. For each case, negative affect will be subtracted from positive affect and life satisfaction score will be added to that for a single global well-being score. Well-being scores derived in this manner have been shown to be sensitive to change and are the most commonly used outcome measure in positive activities interventions.[53]

Well-Being – Affect: Positive and Negative Affect Scale (PANAS). The PANAS consists of two mood scales with 10-items each rated on a 5-point scale for assessing positive (e.g., inspired, strong) and negative affect (e.g., guilty, scared).[76] Each scale has a range of 10-50 with higher scores indicating greater positive or negative affect. Both scales are internally consistent, uncorrelated, and stable over a 2-month time period; good convergent and discriminant validity have also been demonstrated.[76,77]

Well-Being – Life Satisfaction: Satisfaction with Life Scale (SWLS). The SWLS is a global measure of life satisfaction consisting of 5 items rated on a 7-point scale.[54] The SWLS is a reliable and valid measure of life satisfaction showing large correlations with reports by family/friends of the person's life satisfaction, number of memories of satisfying experiences and other similar scales.[54,55,75]

Secondary Outcome Measure - Fibromyalgia Survey Criteria: Close to half of low back pain patients we see also have widespread pain and these patients may be even more likely to respond to this intervention based on our previous work. The survey criteria assess the degree to which fibromyalgia-like symptoms are present using a continuous scale with a range 0-31.[78-80] These criteria have been found to be reliable and valid.[81-83]

Secondary Outcome Measure (Follow up only): Patient Global Assessment. Consistent with IMMPACT recommendations, the Patient Global Assessment of Change (PGIC) will be used as a secondary measure of response.[84] PGIC consists of a 7-point scale with response options ranging from “Very much improved” to “No different” to “Very much worse.”

Secondary Outcome Measure (Follow up only): Patient Satisfaction Numeric Rating Scale. An 11-point numeric scale will be used that instructs, “Please rate your overall satisfaction with the care you received at the Back & Pain Center.” The scale is anchored by 0 = “Extremely dissatisfied” to 10 “Extremely satisfied.”

Exploratory Outcome: Holmes-Rahe Life Stress Inventory (HRLSI) (Follow up only).[85] We will use this very brief and well-validated measure of psycho-social stress to evaluate the potential impact of remarkable events that could occur during the intervention period. Participants indicate what stressful events have taken place over the last month by endorsing a series of 42 items with an “X.” The measure takes about 2 minutes to complete.

Exploratory Outcome:30 Day Post Intervention Follow Up Questionnaire (Follow up only). We will use this brief questionnaire to assess if the patient plans to do the intervention on his or her own. This questionnaire will be included in the 30 day follow up packet. Patients who are randomized to the control group and chose to do the intervention after the initial study period will also be given this questionnaire after 30 days of positive noting.

Exploratory Outcome:90 Day Post Intervention Follow Up Questionnaire (Follow up only). We will use this brief questionnaire to assess if the patient continued to do the intervention on his or her own. This questionnaire will be included in the 90 day follow up packet.

Randomization. A random numbers generator will be used to create the randomization schedule. Participants will be assigned in equal numbers to one of the two groups.

Intervention Procedures – The Positive Piggy Bank. Patients randomized to this group will meet with a research assistant (RA) for an orientation session. The RA provides an overview of the intervention, explains the rationale for this treatment, and then gives the patients the instructions on a decorative card (text shown above in Figure 1), piggy bank, and currency slips (lined pieces of paper with a place for the date). Participants in this group will be instructed as detailed above in the Positive Piggy Bank instructions. At the end of the monitoring period, 30 days, they are to "close their account" by opening the piggy bank and reviewing all of the slips of paper.

Participants will be instructed to put their piggy bank in a highly visible place, such as the kitchen counter or dinner table. They will also be instructed to create a reminder system be it setting a reminder alarm in their cell phones or hanging sticky notes on the refrigerator or bathroom mirror. Further, patients will be informed that if they ever have a difficult time finding something that made them happy that particular day, that it is OK to note this on a currency slip and put that in the piggy bank. We will add, 'We all have bad days sometimes!" Study personnel will contact patients within 72 hours of beginning the study to answer questions and/or provide encouragement. Participants will also be contacted at 30 days to let patients know that they should read all of their currency slips in one sitting. They are also told that the intervention part of the study is over and are asked they complete the follow up questionnaires and return them by mail. Then, close to the 2-month assessment point, study personnel will call again to let the participant know that the questionnaires will be arriving by mail and encourage them to return them promptly. Calls will also be made as needed to remind patients to send back follow up questionnaires.

Wait List Control Group. The control group will serve to show the relative benefits of the Positive Piggy Bank intervention. Those in the control group who meet study criteria will also receive regular care after their epidural steroid injection (e.g., physician visits, medication maintenance, standard patient education). These patients will follow the same questionnaire follow up procedures as listed above including phone calls. The phone call at 72 hours will be to simply thank them for their participation in the study. At the end of the study period, approximately three months, Wait List control patients will also be offered the Positive Piggy Bank intervention along with the supportive phone calls. Should they choose to try the Positive Piggy Bank intervention, they will be required to return to the center to pick up supplies and receive instruction. They will also complete study questionnaires by mail at 30 days to assess intra-individual change.

Expectancy and Credibility. Since expectancy and credibility are considered key mechanisms in treatment outcomes,[86] these factors will be measured using the Credibility and Expectancy Questionnaire (CEQ) for patients assigned to the Positive Piggy Bank group. The CEQ is a six-item self-report measure consisting of questions such as, "At this point, how logical does the therapy offered to you seem?" and "How confident would you be in recommending this treatment to a friend who experiences similar problems?" The CEQ will be administered at the orientation meeting.[86,87]

Fidelity Checks. To assess the fidelity of the Positive Piggy Bank intervention, the slips of paper will be collected and counted. Patients are instructed to date the slips of paper and thus daily participation or non-participation can be logged by date. We will also ask patients if they continued to keep a Positive Piggy Bank on their own after the study ended or if they continued to reflect on the positive aspects of their day on a regular basis.

Post-Intervention Assessments and Patient Payment. Participants complete a packet of questionnaires by mail after the end of the intervention period (post-intervention assessment, Day 30) and two months after that (2-month follow up, Day 90). They will be contacted by phone to alert them to watch for the study packets (for both follow up periods). Participants will also be contacted to affirm that the study questionnaires have been completed. Participants will be asked to return follow up questionnaires within 10 days of the assessment date (i.e., within 10 days of Day 30 or Day 90) Participants will complete the same questionnaires as used pre-intervention plus the PGIC, HRLSI, and a questionnaire assessing changes in medications, new diagnoses, and other interventions, including changes in exercise. Changes in medications, new diagnoses, and other interventions, including changes in exercise reported will be crossed to the EMR. Those in the Positive Piggy Bank arm will also complete the CEQ to assess credibility of the intervention. The currency slips are to be mailed back to study personnel along with the questionnaires. The currency slips will be mailed back to

participants after they have been photocopied (sent with Day 90 follow up questionnaires). Participants will be sent a $20 check after the first appointment and another $20 check after sending their first set of questionnaires back by mail and a third $20 check for returning their questionnaires by mail at 2 months post-intervention. Participants in the control group will complete questionnaires at the same time points and receive the same compensation on the same schedule. Should control group participants choose to try the Positive Piggy Bank intervention, they will receive $20 for the return trip to pick up supplies and $20 for completing the 30-day follow up questionnaires. Any participant who completes the Positive Piggy Bank intervention will be able to keep his/her piggy bank (value < $15). Individuals who are screen failures will receive a $10 check for their time and effort.

Data Management. All questionnaires and raw scores will be reviewed by the study coordinator and data manager before data entry. Data will be entered separately by two study personnel and the two sets of data will be compared for accuracy. SPSS Data Entry software will be used since it has the built-in functions to automatically compare for potential errors and logic discrepancies. The data files will be backed-up weekly and the computer storing the research data is password protected to ensure safety and confidentiality.

Potential Participant Declines. A 'decline' is any potential participant that upon phone screen or being consented decides that she/he does not want to participate. Reason for declining and age, sex and race are collected and retained to later assess participation bias.

D. STATISTICAL DESIGN

Data will be analyzed by a qualified biostatistician who will remain blind to group assignment.

Outcomes: The *Primary Outcome* will be functional restoration as measure the ODI. The *Secondary Outcome measures* will be pain severity, fatigue, sleep, and subjective well-being.

Potential covariates: *Demographics* including Age, Sex, Race, and Education, as well as *medical history* including Medical and Psychiatric Co-morbidities (including other pain disorders [e.g., osteoarthritis]). Treatment changes will be carefully documented and controlled for including instances of minimally invasive procedures (e.g., epidural steroid injection), opioid use change (i.e., oral morphine equivalents), other medication changes (e.g., new antidepressant), physical therapy or new exercise regimen or major intervention (e.g., back surgery). Group differences between these possible covariates will be assessed using t-tests or chi-square tests as appropriate.

Between group differences in the primary and secondary outcomes at the immediate post-intervention time point will be assessed using t-tests or chi-square tests as appropriate. Although significant differences between the potential covariates are not expected, any covariates that do differ will be controlled for in linear or logistic regression models. As a secondary analysis, longitudinal changes across the 3 time points will be assessed with a series of multivariate longitudinal mixed models to explore the effect of the group by time interaction on the primary response variable (subjective well-being) and secondary response variables.

A modest fraction (up to 20%) of drop-outs and partially missing observations are expected in the study. Missing data will be handled by list-wise deletion. Failure to complete the positive activities intervention (Positive Piggy Bank) will also be handled with intent to treat (ITT) analyses.

Power analysis. Hypotheses tests will be two-sided with an alpha of .05. Independent t-tests were used for power assessments comparing mean between-subject differences between the groups (Piggy bank vs. control). A set of power analyses using the range of previously report effects sizes (.34 to .59) was conducted using GPower 3.1. As seen in Figure 3 (below), a sample size of 200 will result in 80% power to detect an effect size of .40 between two independent group means. If we assume a 20% drop out rate, we will have a sample of 160 which results in 80% power to detect an effect of .44.

Figure 3. Range of effect sizes plotted as a function of Power and Sample Size for differences between two independent samples

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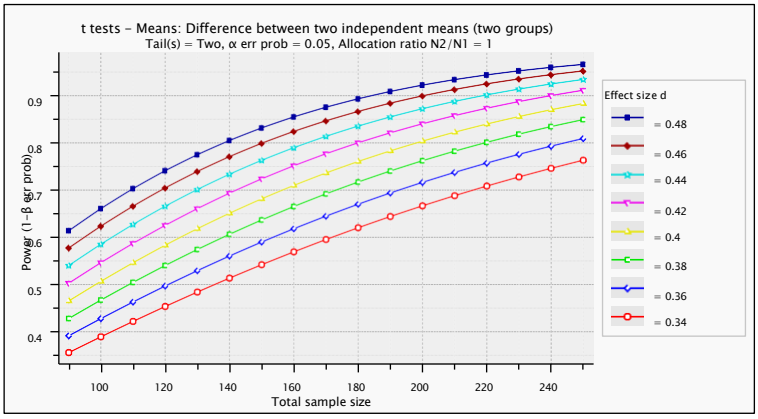

Reference List

1. Freburger JK, Holmes GM, Agans RP, et al. The rising prevalence of chronic low back pain. *Arch Intern Med.* Feb 9 2009;169(3):251-258.
2. Collaborators USBoD. The state of US health, 1990-2010: burden of diseases, injuries, and risk factors. *JAMA : the journal of the American Medical Association.* Aug 14 2013;310(6):591-608.
3. Murray CJ, Vos T, Lozano R, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet.* Dec 15 2012;380(9859):2197-2223.
4. Medicine Io. Relieving pain in America a blueprint for transforming prevention, care, education, and research. Washington, DC: National Academy of Sciences; 2011.
5. Choi HJ, Hahn S, Kim CH, et al. Epidural steroid injection therapy for low back pain: a meta-analysis. *International journal of technology assessment in health care.* Jul 2013;29(3):244-253.
6. Wilkinson IM, Cohen SP. Epidural steroid injections. *Curr Pain Headache Rep.* Feb 2012;16(1):50-59.
7. Pinto R, Maher CG, M.L. F, et al. Epidural corticoid injections in the management of sciatica. *Annals of internal medicine.* 2012;157:865-877.
8. Ghahreman A, Ferch R, Bogduk N. The efficacy of transforaminal injection of steroids for the treatment of lumbar radicular pain. *Pain medicine.* Aug 2010;11(8):1149-1168.
9. Iversen T, Solberg TK, Romner B, et al. Effect of caudal epidural steroid or saline injection in chronic lumbar radiculopathy: multicentre, blinded, randomised controlled trial. *BMJ.* 2011;343:d5278.
10. Sayegh FE, Kenanidis EI, Papavasiliou KA, Potoupnis ME, Kirkos JM, Kapetanos GA. Efficacy of steroid and nonsteroid caudal epidural injections for low back pain and sciatica: a prospective, randomized, double-blind clinical trial. *Spine.* Jun 15 2009;34(14):1441-1447.
11. Staal JB, de Bie RA, de Vet HC, Hildebrandt J, Nelemans P. Injection therapy for subacute and chronic low back pain: an updated Cochrane review. *Spine.* Jan 1 2009;34(1):49-59.
12. Lee JW, Park KW, Chung SK, et al. Cervical transforaminal epidural steroid injection for the management of cervical radiculopathy: a comparative study of particulate versus non-particulate steroids. *Skeletal radiology.* Nov 2009;38(11):1077-1082.
13. Ferrante FM, Wilson SP, Iacobo C, Orav EJ, Rocco AG, Lipson S. Clinical classification as a predictor of therapeutic outcome after cervical epidural steroid injection. *Spine.* May 1993;18(6):730-736.
14. Hoffman BM, Papas RK, Chatkoff DK, Kerns RD. Meta-analysis of psychological interventions for chronic low back pain. *Health Psychol.* Jan 2007;26(1):1-9.
15. Rossy LA, Buckelew SP, Dorr N, et al. A meta-analysis of fibromyalgia treatment interventions. *Ann Behav Med.* Spring 1999;21(2):180-191.
16. Glombiewski JA, Sawyer AT, Gutermann J, Koenig K, Rief W, Hofmann SG. Psychological treatments for fibromyalgia: a meta-analysis. *Pain.* Nov 2010;151(2):280-295.
17. Morley S, Eccleston C, Williams A. Systematic review and meta-analysis of randomized controlled trials of cognitive behaviour therapy and behaviour therapy for chronic pain in adults, excluding headache. *Pain.* Mar 1999;80(1-2):1-13.
18. Vogt DP. Mental Health-Related Beliefs as a Barrier to Service Use for Military Personnel and Veterans: A Review. *Psychiatric Services.* Feb 2011 2011;62(2):135-142.
19. Ben-Zeev D. Stigma of mental illness and service use in the military. *Journal of mental health (Abingdon, England).* 06 2012;21(3):264-273.
20. Mittal D DK, Blevins D, Curran G, Corrigan P, Sullivan G. . Stigma associated with PTSD: Perceptions of treatment seeking combat veterans. *Psychiatric Rehabilitation Journal.* 2013;36(2):86-92.

21. Bair MJ, Matthias MS, Nyland KA, et al. Barriers and facilitators to chronic pain self-management: a qualitative study of primary care patients with comorbid musculoskeletal pain and depression. *Pain medicine.* Oct 2009;10(7):1280-1290.

22. Seligman ME, Rashid T, Parks AC. Positive psychotherapy. *The American psychologist.* Nov 2006;61(8):774-788.

23. Parks AC, Szanto RK. Assessing the efficacy and effectiveness of a Positive Psychology based self-help book. *Terapia Psicologica.* 2013;31:141-149.

24. Sin NL, Lyubomirsky S. Enhancing well-being and alleviating depressive symptoms with positive psychology interventions: a practice-friendly meta-analysis. *Journal of clinical psychology.* May 2009;65(5):467-487.

25. Bolier L, Haverman M, Westerhof GJ, Riper H, Smit F, Bohlmeijer E. Positive psychology interventions: a meta-analysis of randomized controlled studies. *BMC Public Health.* 2013;13:119.

26. Fredrickson BL. The role of positive emotions in positive psychology. The broaden-and-build theory of positive emotions. *The American psychologist.* Mar 2001;56(3):218-226.

27. Seligman ME, Steen TA, Park N, Peterson C. Positive psychology progress: empirical validation of interventions. *The American psychologist.* Jul-Aug 2005;60(5):410-421.

28. White DK, Keysor JJ, Neogi T, et al. When it hurts, a positive attitude may help: association of positive affect with daily walking in knee osteoarthritis. Results from a multicenter longitudinal cohort study. *Arthritis Care Res (Hoboken).* Sep 2012;64(9):1312-1319.

29. Strine TW, Chapman DP, Balluz LS, Moriarty DG, Mokdad AH. The associations between life satisfaction and health-related quality of life, chronic illness, and health behaviors among U.S. community-dwelling adults. *Journal of community health.* Feb 2008;33(1):40-50.

30. Grant N, Wardle J, Steptoe A. The relationship between life satisfaction and health behavior: a cross-cultural analysis of young adults. *International journal of behavioral medicine.* 2009;16(3):259-268.

31. Baruth M, Lee DC, Sui X, et al. Emotional outlook on life predicts increases in physical activity among initially inactive men. *Health education & behavior : the official publication of the Society for Public Health Education.* Apr 2011;38(2):150-158.

32. Kelloniemi H, Ek E, Laitinen J. Optimism, dietary habits, body mass index and smoking among young Finnish adults. *Appetite.* Oct 2005;45(2):169-176.

33. Leventhal AM, Ramsey SE, Brown RA, LaChance HR, Kahler CW. Dimensions of depressive symptoms and smoking cessation. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco.* Mar 2008;10(3):507-517.

34. Ostir GV, Berges IM, Markides KS, Ottenbacher KJ. Hypertension in older adults and the role of positive emotions. *Psychosom Med.* Sep-Oct 2006;68(5):727-733.

35. Stone AA, Cox DS, Valdimarsdottir H, Jandorf L, Neale JM. Evidence that secretory IgA antibody is associated with daily mood. *Journal of personality and social psychology.* May 1987;52(5):988-993.

36. Steptoe A, Wardle J, Marmot M. Positive affect and health-related neuroendocrine, cardiovascular, and inflammatory processes. *Proc Natl Acad Sci U S A.* May 3 2005;102(18):6508-6512.

37. Kok BE, Coffey KA, Cohn MA, et al. How positive emotions build physical health: perceived positive social connections account for the upward spiral between positive emotions and vagal tone. *Psychol Sci.* Jul 1 2013;24(7):1123-1132.

38. Russo SJ, Murrough JW, Han MH, Charney DS, Nestler EJ. Neurobiology of resilience. *Nature neuroscience.* Nov 2012;15(11):1475-1484.

39. Karatsoreos IN, McEwen BS. Annual Research Review: The neurobiology and physiology of resilience and adaptation across the life course. *Journal of child psychology and psychiatry, and allied disciplines.* Apr 2013;54(4):337-347.

40. Karatsoreos IN, McEwen BS. Resilience and vulnerability: a neurobiological perspective. *F1000prime reports.* 2013;5:13.

41. Huffman JC, DuBois CM, Healy BC, et al. Feasibility and utility of positive psychology exercises for suicidal inpatients. *General hospital psychiatry.* Jan-Feb 2014;36(1):88-94.

42. Meyer PS, Johnson DP, Parks A, Iwanski C, Penn DL. Positive Living: A pilot study of group positive psychotherapy for people with schizophrenia. *Journal of Positive Psychology.* 2012;7:239-248.

43. Kahler CW, Spillane NS, Day A, et al. Positive Psychotherapy for Smoking Cessation: Treatment Development, Feasibility and Preliminary Results. *The journal of positive psychology.* Jan 1 2014;9(1):19-29.

44. Huffman JC, Mastromauro CA, Boehm JK, et al. Development of a positive psychology intervention for patients with acute cardiovascular disease. *Heart international.* Sep 29 2011;6(2):e14.

45. Moskowitz JT, Hult JR, Duncan LG, et al. A positive affect intervention for people experiencing health-related stress: development and non-randomized pilot test. *Journal of health psychology.* Jul 2012;17(5):676-692.

46. Cohn MA, Pietrucha ME, Saslo LR, Hult JR, Moskowitz JT. An online positve affect skills intervention reduces depression in adults with type 2 diabetes. *Journal of Positive Psychology.* In press.

47. Hausmann LR, Parks A, Youk AO, Kwoh CK. Reduction of bodily pain in response to an online positive activities intervention. *The journal of pain : official journal of the American Pain Society.* May 2014;15(5):560-567.

48. Gore M, Sadosky A, Stacey BR, Tai KS, Leslie D. The burden of chronic low back pain: clinical comorbidities, treatment patterns, and health care costs in usual care settings. *Spine.* May 15 2012;37(11):E668-677.

49. Von Korff M, Crane P, Lane M, et al. Chronic spinal pain and physical-mental comorbidity in the United States: results from the national comorbidity survey replication. *Pain.* Feb 2005;113(3):331-339.

50. Reme SE, Tangen T, Moe T, Eriksen HR. Prevalence of psychiatric disorders in sick listed chronic low back pain patients. *Eur J Pain.* Nov 2011;15(10):1075-1080.

51. Finan PH, Garland EL. The Role of Positive Affect in Pain and Its Treatment. *The Clinical journal of pain.* Apr 18 2014.

52. Parks A, Seligman MEP. 8-week group Positive Psychotherapy (PPT) manual. *Unpublished manual, available on request.* 2007.

53. Diener E. *Assessing Well-Being: The Collected Works of Ed Diener.* New York: Springer; 2009.

54. Diener E, Emmons RA, Larsen RJ, Griffin S. The Satisfaction With Life Scale. *Journal of personality assessment.* Feb 1985;49(1):71-75.

55. Pavot W, Diener E, Colvin CR, Sandvik E. Further validation of the Satisfaction with Life Scale: evidence for the cross-method convergence of well-being measures. *Journal of personality assessment.* Aug 1991;57(1):149-161.

56. Emmons RA, McCullough ME. Counting blessings versus burdens: an experimental investigation of gratitude and subjective well-being in daily life. *Journal of personality and social psychology.* Feb 2003;84(2):377-389.

57. Kashdan TB, Uswatte G, Julian T. Gratitude and hedonic and eudaimonic well-being in Vietnam war veterans. *Behaviour research and therapy.* Feb 2006;44(2):177-199.

58. Bryant FB. A four-factor model of perceived control: Avoiding, coping, obtaining, and savoring. *Journal of Personality.* 1989;57:773-797.

59. Fairbank JC, Pynsent PB. The Oswestry Disability Index. *Spine.* Nov 15 2000;25(22):2940-2952; discussion 2952.

60. Fairbank J. Revised Oswestry Disability questionnaire. *Spine.* Oct 1 2000;25(19):2552.

61. Gronblad M, Hupli M, Wennerstrand P, et al. Intercorrelation and test-retest reliability of the Pain Disability Index (PDI) and the Oswestry Disability Questionnaire (ODQ) and their correlation with pain intensity in low back pain patients. *The Clinical journal of pain.* Sep 1993;9(3):189-195.

62. Kopec JA, Esdaile JM, Abrahamowicz M, et al. The Quebec Back Pain Disability Scale: conceptualization and development. *J Clin Epidemiol.* Feb 1996;49(2):151-161.

63. Beurskens AJ, de Vet HC, Koke AJ. Responsiveness of functional status in low back pain: a comparison of different instruments. *Pain.* Apr 1996;65(1):71-76.

64. Fisher K, Johnston M. Validation of the Oswestry low back pain disability questionnaire, its sensitivity as a measure of change following treatment and its relationship with other aspects of the chronic pain experience. *Physiotherapy Theory and Practice.* 1997;13:67-80.

65. Niskanen RO. The Oswestry Low Back Pain Disability Questionnaire. a two-year follow-up of spine surgery patients. *Scandinavian journal of surgery : SJS : official organ for the Finnish Surgical Society and the Scandinavian Surgical Society.* 2002;91(2):208-211.

66. Walsh TL, Hanscom B, Lurie JD, Weinstein JN. Is a condition-specific instrument for patients with low back pain/leg symptoms really necessary? The responsiveness of the Oswestry Disability Index, MODEMS, and the SF-36. *Spine.* Mar 15 2003;28(6):607-615.

67. Taylor SJ, Taylor AE, Foy MA, Fogg AJ. Responsiveness of common outcome measures for patients with low back pain. *Spine.* Sep 1 1999;24(17):1805-1812.

68. Carreon LY, Berven SH, Djurasovic M, Bratcher KR, Glassman SD. The discriminative properties of the SF-6D compared with the SF-36 and ODI. *Spine.* Jan 1 2013;38(1):60-64.

69. Mannion AF, Junge A, Grob D, Dvorak J, Fairbank JC. Development of a German version of the Oswestry Disability Index. Part 2: sensitivity to change after spinal surgery. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society.* Jan 2006;15(1):66-73.

70. Cella D, Riley W, Stone A, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *J Clin Epidemiol.* Nov 2010;63(11):1179-1194.

71. Cella D, Yount S, Rothrock N, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS): progress of an NIH Roadmap cooperative group during its first two years. *Medical care.* 5/2007 2007;45(5 Suppl 1):S3-S11.

72. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand.* Jun 1983;67(6):361-370.

73. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. *Journal of psychosomatic research.* Feb 2002;52(2):69-77.

74. Lyubomirsky S, Lepper HS. A measure of subjective happiness: preliminary reliability and construct validation. *Social Indicators Research.* 1999(46):137-155.

75. Pavot W, Diener E. Review of the Satisfaction with Life Scale. *Psychol Assess.* 1993;5:164-172.

76. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. *Journal of personality and social psychology.* Jun 1988;54(6):1063-1070.

77. Crawford JR, Henry JD. The positive and negative affect schedule (PANAS): construct validity, measurement properties and normative data in a large non-clinical sample. *The British journal of clinical psychology / the British Psychological Society.* Sep 2004;43(Pt 3):245-265.

78. Wolfe F. Pain extent and diagnosis: development and validation of the regional pain scale in 12,799 patients with rheumatic disease. *The Journal of rheumatology.* Feb 2003;30(2):369-378.

79. Wolfe F, Michaud K. Predicting depression in rheumatoid arthritis: the signal importance of pain extent and fatigue, and comorbidity. *Arthritis and rheumatism.* May 15 2009;61(5):667-673.

80. Wolfe F. Fibromyalgianess. *Arthritis and rheumatism.* Jun 15 2009;61(6):715-716.

81. Hauser W, Jung E, Erbsloh-Moller B, et al. Validation of the Fibromyalgia Survey Questionnaire within a cross-sectional survey. *PloS one.* 2012;7(5):e37504.

82. Wolfe F, Clauw DJ, Fitzcharles MA, et al. The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. *Arthritis Care Res (Hoboken).* May 2010;62(5):600-610.

83. Wolfe F, Clauw DJ, Fitzcharles MA, et al. Fibromyalgia criteria and severity scales for clinical and epidemiological studies: a modification of the ACR Preliminary Diagnostic Criteria for Fibromyalgia. *The Journal of rheumatology.* Jun 2011;38(6):1113-1122.

84. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain.* Jan 2005;113(1-2):9-19.

85. Holmes TH, Rahe RH. The Social Readjustment Rating Scale. *Journal of psychosomatic research.* Aug 1967;11(2):213-218.

86. Borkovec TD, Nau SD. Credibility of analogue therapy rationales. *Journal of Behavior Therapy and Experimental Psychiatry.* 1972;3:257-260.

87. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. *Journal of Behavior Therapy and Experimental Psychiatry.* 2000;31:73-86.