Pre-trial Pilot Study of the Effect on Patient Reported Outcomes of the Egoscue Method as an Intervention for Spine Pain

Introduction: This white paper reports findings of a pre-trial pilot study conducted by The Clinical Excellence Research Center (CERC) at Stanford University to assess individualized postural therapy (IPT) as delivered by The Egoscue Method (TEM) for spine (back and neck) pain. This pilot study was conducted to inform the design of a subsequent randomized trial of TEM and a second unevaluated treatment innovation compared to conventional medical treatment. Research on the comparative value of treatment ionizations reflects CERC's mission to discover, demonstrate and help scale innovative, high-value approaches to patient care.

Objective: The pilot study's purpose was to generate initial estimates of TEM's impact on patient reported outcomes for pain severity, physical disability, and overall functioning.

Spine Pain: Spine pain is the second most common problem seen in primary care patients. The effectiveness of costly traditional clinical care compared to no treatment is negligible for many patients. Frequent use of imaging technologies, pain medications, and surgeries contribute to growing costs of care of this condition. In 2005, the national expenditure for back and neck pain (spine pain) approached $86 billion, a 60% increase over 1995.[1] Patients with spine pain in 2005 report worse physical and social function, mental health, and ability to work than patients did a decade prior.[1] Over the same time period, the prevalence of disability attributed to musculoskeletal pain— of which back pain contributed a large portion — rose from 20% to 25% in the US adult population. In brief, over the last few decades, the United States is spending more and experiencing worse outcomes for care of spine pain.

> **Spine Pain INtervention to Enhance Care quality And Reduce Expenditure (SPINE-CARE):** CERC is conducting a multicenter national pragmatic randomized clinical trial that compares two approaches to treating acute or acute on chronic spine pain to usual care. One of these approaches is The Egoscue Method. Each of the two experimental arms will be compared to usual care individually. The results of this study will be forthcoming.

The Egoscue Method: CERC's review of the research literature and interviews with experts in spine pain care indicated that exercise regimens based on postural therapy such as TEM can achieve improved patient outcomes without the expense and risks of imaging, prescription pain medications, referrals to orthopedic specialists, and surgeries.

The Egoscue Method is a nonmedical treatment in which a TEM-trained therapist evaluates a subject's posture to identify postural and alignment deviations. Based on these findings the therapist develops a personalized corrective exercise program for patients. Patients are instructed on how to perform the exercises correctly and given updated exercise regimens in successive visits. Patients are asked to perform recommended exercises daily. A standard course of TEM care for spine pain involves six to eight clinic visits.

Egoscue maintains an international network of clinics and trains their therapists through an internal program. Each clinic has a senior manager to monitor the clinic's therapists, and standard Egoscue tools and exercise props are used in its clinics. These factors support consistent IPT care approach across clinics and thereby its suitability for a national SPINE-CARE trial.

Pilot Methods:

Patient Survey: CERC compiled a patient survey by drawing on well-validated surveys measuring four key outcomes: level of pain; disability level related to spine pain; health status; and self-efficacy (Table 1). The survey also collected data on demographics, previous care received for spine pain, and patient confidence in their ability to manage subsequent episodes of spine pain (Appendix).

Table 1. Description of Surveys Used to Measure Key Outcomes

Domain	Source	Definition
Current rating of pain level[2]	10 Point Pain Scale	Measure of current pain level on a scale of 0-10 with 0 being no pain. Lower scores mean lower perceived pain level
Functioning status[3]	Oswestry Disability Index (ODI)	How pain impacted the patient's functionality was measured with the Oswestry Disability Index (ODI) and converted to scale of 100. Higher scores indicate the patient has more disability.
Scale health status[4]	EuroQol (EQ-5D)	Measure of health related quality of life that comprises of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Additionally, there is a vertical visual analogue scale that records the patient's self-rated health. Higher scores mean a higher health status level.
Self-efficacy	Arthritis Self-Efficacy Scale (ASES-8) *Adapted with permission from author (Kate Lorig) to spine pain*	Self-efficacy in managing spine pain was measured with ASES-8 measure. Higher scores meaning the patient has greater self-efficacy in managing his/her pain.

Patient Recruitment: Patients attending three Egoscue clinics in San Francisco, Phoenix, and San Diego were invited to participate in the study. Inclusion criteria included a chief complaint of spine pain, having had no more than one Egoscue visit for their current episode of spine pain, and being over 18 years of age. Patients meeting these criteria who agreed to participate in the study and signed an informed consent were given the baseline Egoscue patient survey. A second follow-up survey was administered eight weeks later. Both surveys were paper based and self-administered.

Study Population: Nineteen patients were enrolled in the study, with 11 women and 8 men. Patients had an average age of 54 and all but one was college educated. More than half of the patients had other comorbidities such as diabetes (5), lung disease (6), and kidney disease (4). They reported having either back (11) or both back and neck pain (7). Duration of the current episode ranged from several months (9) to more than five years (2).

A majority of the patients (15) experienced previous episodes of spine pain, ranging from one prior episode (3) to more than five (5). They had sought a number of different medical care services (an

average of 4) for previous episodes, the most common being over-the-counter medications (11), radiology (10), physical therapy (9), massage therapy (9), and chiropractor (8).

<u>Findings:</u>

Patients reported (as defined in Table 1) improvement on all four outcome measures: pain level, disability, health status and self-efficacy (See Table 2). The strongest positive change was reported in pain level where average scores moved from 7.3 to 4.3 on a scale from 0-10 with lower scores meaning lower perceived pain. This change equated to a 41% decrease in pain severity. In the measure of disability due to spine pain, patients' scores changed from 30.1 to 11.5 on the 100-point scale where higher scores mean more disability. This equated to a 62% improvement. On health status, patients showed meaningful improvement with an 18.8% increase in quality of life. For self-efficacy, scores indicated a 9.6% increase in ability to manage pain. Additionally, illustrative patient comments are listed in Table 3.

Table 2. Change in Measures of Pain, Health Status, and Self-Efficacy from Baseline to Follow-up

Measures of Pain, Health Status, and Self-Efficacy	Baseline Survey n=19	Follow-up Survey n=19	Change (FU – BL)	Meaningful Change Score(*Indicates Change Meets or Exceeds Meaningful Change)
Current rating of pain level,[a] average (range)	7.3 (3-10)	4.3 (1-10)	-2.9 (-7-1)	*Improvement of 2-3 points (lower scores mean lower perceived pain level)
Health status,[b] average (range)	0.685 (0.315-0.861)	0.846 (0.756-1.000)	0.161 (-0.012-0.561)	*Improvement of 0.040 (higher scores mean a higher health status level)
Oswestry Disability Index,[c] average (range)	30.1 (10-92)	11.5 (0-35)	-18.6 (-90-10)	*Improvement of 10 points (higher scores indicate the patient has more disability)
Minimal disability (0-20), # (%)	6 (32)	15 (79)	+9	
Moderate disability (21-40), # (%)	10 (53)	4 (21)	-6	
Severe disability (41-60), # (%)	2 (11)	0 (0)	-2	
Crippled (61-80), # (%)	0 (0)	0 (0)	0	
Bed-bound (81-100), # (%)	1 (5)	0 (0)	-1	
Self-efficacy,[d] average (range)	7.5 (3.1-10)	8.3 (3.6-10)	0.7 (-2.1-3.6)	N/A – No published meaningful change score (higher scores mean the patient has greater self-efficacy in managing his/her pain)

Notes:
a. Pain level was measured using a 10-point scale.
b. Health status was measured with the EQ-5D measure.
c. How pain impacted the patient's functionality was measured with the Oswestry Disability Index (ODI) and converted to a scale of 100.
d. Self-efficacy in managing spine pain was measured with ASES-8 measure.

Table 3. Selected Patient Testimonials

The treatment has made my pain reduce and helped realign my body.
Help me set positive goals and hope for change and improvement - choices & support if needed. Some of the exercises were very elementary, but that was a start.
Gave me exercises and knowledge in understanding what I need to do.
I feel that I now have the tools to cope with my back pain for acute and chronic episodes. Egoscue has been extremely helpful to me and I feel more confident that I can manage my pain without the use of medication and I feel that I am able to increase my level of activity and manage my pain.
Somewhat less pain in the leg due to Sciatica and more localized pain in the low back.
I have more movement and can recover from episodes more quickly.

The outcomes indicate stronger recovery rates on one subscale, the Oswestry Disability Index ODI), than those reported for other spine pain treatments. In two published studies using the same ODI scale measuring spine-pain disability, patients treated with oral steroids reported improvement of 37% at three-week follow-up and patients undergoing discectomies reported 36% to 38% improvement at three months.[5,6] By comparison, Egoscue patients reported notably greater ODI improvement of 62% at two months. A 10% decrease on the ODI is accepted as a clinically meaningful improvement.[7]

On another subscale, Egoscue outcomes were roughly similar to those reported in other studies. On our Current Rating of Pain Visual Analogue Scale (VAS), Egoscue patients reported a 39% decrease in pain. In a population being treated for sciatica with surgery or conservative care, the change on a similar VAS for back pain at two months was a decrease of 57% in the surgery group and 17% in the conservative treatment group[8] In another study, patients undergoing two types of discectomy reported decreases of 33% and of 47% on a VAS for back pain at three months.[6]

These comparisons are not exact because other studies offering short-term patient reported outcomes used different data collection time points and enrolled patient populations with differing types of spine pain complaints. We can, however, conclude that this group of Egoscue patients experienced improvement after two months of treatment that appears to exceed or approximate that reported by spine pain patients receiving traditional medical interventions.

Limitations:
There were two key limitations to this study. A sample size of 19 is too small to determine the generalizability of the measured effects. The study design is subject to patient selection bias, since the data gathered are based on the baseline and follow-up surveys of patients who self-selected to engage in the Egoscue Method.

Conclusions:

Overall, our pre-trial pilot study suggests that the Egoscue Method is effective in treating patients with spine pain measure by validated patient survey tools (see Figure 1). Most patients also reported that they would return to the Egoscue Method for further treatment or to their original Egoscue Method exercises to manage future episodes of spine pain.

Given the general lack of positive outcome for standard medical interventions in treating spine pain and the many negative complications reported for pharmaceutical and surgical interventions, it is also noteworthy that none of these patients reported complications. One explanation for the lack of complications may be that because of reduced pain and disability, our study patients avoided the use of opioids and other prescription pain medications with side effect risks.

This small pre-trial pilot study suggests that the Egoscue Method is efficacious. The now-unfolding multi-state SPINE –CARE trial will definitively examine the efficacy and cost of IPT compared to prevailing medical approaches.

Figure 1. Percentage Improvement in Patient Reported Outcomes from Egoscue Method Treatment
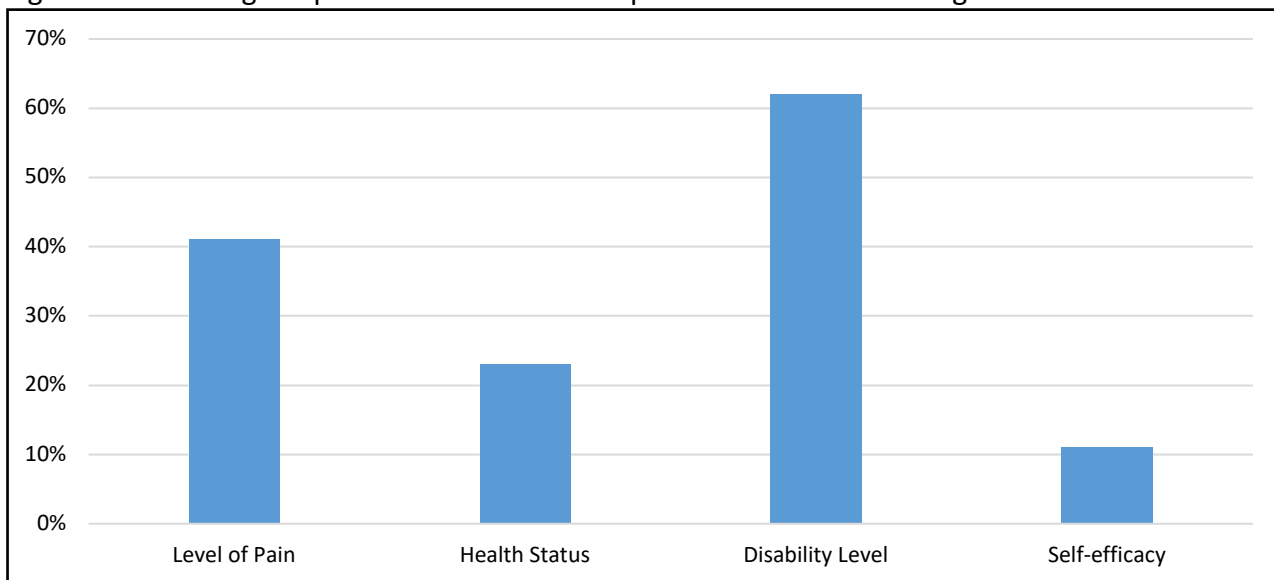
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4.   Luo N, Johnson J, Coons SJ. Using instrument-defined health state transitions to estimate minimally important differences for four preference-based health-related quality of life instruments. Med Care. 2010 Apr;48(4):365-71

5.   Goldberg, 2015.

6.   Gibson 2016.

7.   Fairbank JCT & Pynsent, PB (2000) The Oswestry Disability Index. Spine, 25(22):2940-2953. Davidson M & Keating J (2001) A comparison of five low back disability questionnaires: reliability and responsiveness. Physical Therapy 2002;82:8-24. The Oswestry Disability Index is a widely used tool that researchers and disability evaluators use to measure a patient's functional disability. The test is considered the 'gold standard' of back pain functional outcomes.

8.   Peul et al, 2007.

9.   Gibson, 2016.

Appendix: Additional Survey Data

Table A1: Demographics

Marital Status, # (%)	
Single	3 (16)
Married/partnered	15 (79)
Divorced	1 (5)
Widowed	0 (0)
Race/ethnicity, # (%)	
Caucasian	17 (89)
African American	1 (5)
Hispanic/Latino	1 (5)
Education status, # (%)	
Grade school or less	0 (0)
High school or technical school	1 (5)
College	10 (53)
Graduate or professional school	8 (42)
Employment Status, # (%)	
Full-time paid position	10 (53)
Part-time paid position	1 (5)
Not working, but looking	0 (0)
Not working, and not looking	2 (11)
Retired	5 (26)
Student	0 (0)
Student and working	1 (5)
Household income, # (%)	
Less than $20,000	0 (0)
$20,000 - $39,999	1 (5)
$40,000 - $59,999	3 (16)
$60,000 - $79,999	2 (11)
$80,000 - $99,999	0 (0)
$100,000+	10 (53)
Decline to answer	3 (16)

Note: Percentages may not add to 100 due to rounding.

Table A2. Current Spine Pain Characteristics

Current Spine Pain Characteristics	Completed Both Surveys n=19
Pain location, # (%)	
Neck	0 (0)
Back	11 (58)
Both neck and back	7 (37)
Other	1 (5)
Cause of pain, # (%)	
Unknown	8 (42)
Fall	2 (11)
Lifting something	1 (5)
Motor vehicle accident	1 (5)
Other	3 (16)
More than one above	4 (21)
Age in years of first pain episode, average (range)	33.9 (15-60)
Current duration of pain, # (%)	
1-3 months	9 (47)
4-6 months	4 (21)
1-2 years	1 (5)
3-5 years	2 (11)
> 5 years	2 (11)
Decline to answer	1 (5)

Note: Percentages may not add to 100 due to rounding.

Table A3. Health Characteristics

Note: three patients who responded to the baseline survey did not respond to the follow-up survey. Therefore, in the following tables we report descriptors for three categories of patients. Those who responded to both baseline and follow-up, the three who responded only to the baseline survey, and all 22 respondents.

Health Characteristics	Completed Both Surveys n=19	Completed Only Baseline survey n=S	All Respondents n=22
Most frequently reported health conditions[a], # (%)			
Arthritis, rheumatic diseases, musculoskeletal conditions	9 (50)[b]	1 (33)	10 (48)[c]
Endocrine disorders (including diabetes and thyroid disorders)	5 (28)[b]	1 (33)	6 (29)[c]
Lung disease, respiratory conditions (including allergies and asthma)	6 (33)[b]	0 (0)	6 (29)[c]
Eye disorders	8 (28)[b]	0 (0)	5 (24)[c]
Kidney disease, urinary conditions	4 (22)[b]	0 (0)	4 (19)[c]
Metabolic conditions (including high cholesterol)	3 (17)[2]	1 (33)	4 (19)[c]
Stomach, intestinal, gastrointestinal disease	3 (17)[b]	1 (33)	4 (19)[c]
Number of health conditions reported, average (range)	2.7 (0-9)[b]	2.0 (0-4)	2.6 (0-9)[c]
Current number of prescription medications, average (range)	1.3 (0-5)[b]	0.7 (0-2)	1.2 (0-5)[c]

Notes:
  a. Respondents could choose more than one option.
  b. n=18 since one person did not answer this question.
  c. n=21 since one person did not answer this question.

Table A4. Previous Spine Pain Treatment Characteristics

Previous Spine Pain Treatment Characteristics	Completed Both Surveys n=19	Completed Only Baseline Survey n=3	All Respondents n=22
Number of prior episodes of back or neck pain in past 5 years, # (%)			
None	4 (21)	0 (0)	4 (18)
1 prior episode	3 (16)	1 (33)	4 (18)
2 prior episodes	2 (11)	1 (33)	3 (14)
3 prior episodes	3 (16)	0 (0)	3 (14)
4 prior episodes	0 (0)	0 (0)	0 (0)
5 prior episodes	2 (11)	0 (0)	2 (9)
> 5 prior episodes	5 (26)	1 (33)	6 (27)
Number of medical care services used for prior episodes of back or neck pain, average (range)	3.9 (0-11)	6.0 (3-9)	4.2 (0-11)
Medical care services used for prior episodes of back or neck pain[b], # (%)			
Primary care provider	7 (37)	3 (100)	10 (45)
Radiology	10 (53)	2 (67)	12 (55)
Physical therapy	9 (47)	2 (67)	11 (50)
Egoscue	1 (5)	0 (0)	1 (5)
Prescription pain medications	5 (26)	1 (33)	6 (27)
Prescription muscle relaxants	4 (21)	2 (67)	6 (27)
Surgery	3 (16)	0 (0)	3 (14)
Acupuncture	4 (21)	1 (33)	5 (23)
Massage therapy	9 (47)	2 (67)	11 (50)
Chiropractor	8 (42)	1 (33)	9 (41)
Psychological counseling	0 (0)	0 (0)	0 (0)
Pain clinic	1 (5)	1 (33)	2 (9)
Over-the-counter medications	11 (58)	3 (100)	14 (64)
Other	3 (16)	0 (0)	3 (14)

Notes:
a. Percentages may not add to 100 due to rounding.
b. Respondents could choose more than one option.